Ministry of Agriculture,
Livestock and Food Supply





Legislation Manual

NATIONAL ANIMAL HEALTH PROGRAMS IN BRAZIL



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BRASÍLIA, DF

Ministry of Agriculture, Livestock, and Food Supply
Animal and Plant Health and Inspection Secretariat
Animal Health Department

Legislation Manual

NATIONAL ANIMAL HEALTH PROGRAMS IN BRAZIL

TECHNICAL MANUAL

MAPA's Mission:

"To promote the sustainable development and the competitiveness of agribusiness to the benefit of Brazilian society."

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Foreword

The Ministry of Agriculture, Livestock, and Food Supply has successfully endeavored to have animal health care addressed in a coordinated manner by the different government levels. To this end it has sponsored a series of legislative pieces on the preparation of animal health programs. The series consists of administrative rules and normative and services instructions that regulate the programs, so as to ensure comprehensive attention to animal health. These rules and norms have been drawn with wide participation of representatives of professional institutions and of users involved with the issue.

As the major tool for carrying out initiatives in the field of Animal Health, the National Agricultural and Livestock Health and Inspection Policy seeks to establish guidelines and define institutional responsibilities for creating the conditions for the protection of the national herd, as well as preventing harm to public health. This Manual puts together the major legislative pieces that govern this process, issued between 1934 and 2008. The full text of each edition of the Manual is available in digital format on MAPA's web site. It will be continuously updated as new legislation is enacted.

We trust that this Manual will be used by Brazil's Official Agricultural and Livestock Health and Inspection Services as a valuable source of information and knowledge.

Jamil Gomes de Souza

Director, Animal Health Department

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PART I

Background

LAWS AND DECREES

LAW No. 9712 OF NOVEMBER 20, 1998

Published in the Federal Official Gazette of 23 November 1998, Section 1, Page 1

Modifies Law No. 8171 of January 17, 1991, by adding to it provisions on agriculture and livestock health and inspection.

THE PRESIDENT OF THE REPUBLIC

The NATIONAL CONGRESS has decreed and I have sanctioned the following Law:

Art. 1. Chapter VII of Law No. 8171 of January 17, 1991, enters into force with the following articles:

"Art. 27-A. The objective of agriculture and livestock health and inspection is to ensure:

I – The health of plant populations;

II – The health of animal herds;

III – The suitability of inputs and services for agriculture and livestock use;

IV – The identity and hygienic, sanitary, and technological safety of final agricultural and livestock products destined for consumers.

Paragraph 1. To ensure the achievement of the aforementioned objectives, the Government will carry out the following activities on a continuing basis:

I – Plant health surveillance and health and inspection;

II – Animal health surveillance and heath and inspection;

III – Inspection and classification of plant products, their byproducts, subproducts, and residues of economic value;

IV – Inspection and classification of animal products, their byproducts, subproducts, and residues of economic value; and

V – Inspection of inputs and services used in agricultural and livestock activities.

Paragraph 2. The activities listed in the preceding paragraph are organized so as to ensure compliance with current legislation on agriculture and livestock health and inspection and with international commitments undertaken by the Brazilian Government."

"Art. 28-A. To promote health, animal and plant health surveillance and heath and inspection actions shall be organized, under the coordination of the different government levels, pursuant to their competence, into a Agriculture and Livestock Health Care Unified System , coordinated in turn, as regards public health, with the Unified Health System established under Law No. 8080 of September 19, 1990, with the participation of:

I – Official services and institutions;

II – Rural producers and workers, their associations, and technicians that assist them;

III – Oversight bodies of professional categories directly connected with agriculture and livestock health and inspection;

IV – Management of funds set up by the private sector to complement government actions in the field of agriculture and livestock health.

Paragraph 1. The municipal area shall be considered the basic geographical unit for the organization and operation of the agriculture and livestock health official services.

Paragraph 2. The Local Organ of the Agri-

culture and Livestock Health Care Unified System shall provide comprehensive health care within its jurisdiction, with the participation of the organized community, particularly as regards the following activities:

I – Establishment of a property register;

II – Inventory of animal and plant populations;

III – Animal and plant movement control;

IV – Establishment of a register of active health professionals;

V – Establishment of a register of businesses selling products for agronomic and veterinary use;

VI – Establishment of a register of disease diagnostic laboratories;

VII – Inventory of diagnosed diseases;

VIII – Launching of disease control campaigns;

IX – Education and Health surveillance;

X – Participation in disease and pest eradication projects.

Paragraph 3. The following activities shall be incumbent upon the Agriculture and Livestock Health Care Unified System 's Intermediate Organs:

I – Surveillance of the interstate movement of plants and animals;

II – Coordination of disease and pest control and eradication campaigns;

III – Maintenance of nosographic reports;

IV – Coordination of epidemiologic actions;

V – Coordination of sanitary education actions;

VI – Oversight of the diagnostic network and of accredited health professionals.

Paragraph 4. The following activities shall be incumbent upon the Agriculture and Livestock Health Care Unified System 's Central and Superior Organ:

I – Surveillance of ports, airports, and international border checkpoints;

II – Establishment of norms pertaining to disease and pest control and eradication campaigns;

III - Approval of diagnostic methods and products of veterinary and agronomic use;

IV – Maintenance of the epidemiologic information system;

V – Evaluation of actions carried out by local and Intermediate Organs of the Agriculture and Livestock Health Care Unified System ;

VI – Representing the country at international forums dealing with Agriculture and Livestock Health and Inspection;

VII – Undertaking epidemiologic studies and supporting the development of the Agriculture and Livestock Health Care Unified System ;

VIII – Technical cooperation provided to other Agriculture and Livestock Health Care Unified System Organs;

IX – Improvement of the Agriculture and Livestock Health Care Unified System ;

X – Coordination of the Agriculture and Livestock Health Care Unified System ;

XI – Maintenance of the Agriculture and Livestock Health and Inspection Code.

Paragraph 5. Management of funds set up by the private sector to complement government actions in the area of Agriculture and Livestock Health and Inspection shall form part of the Agriculture and Livestock Health Care Unified System.

Paragraph 6. Strategies and policies aimed at promoting health and surveillance shall be ecosystemic and decentralized according to types of health problem so as to ensure pest- and disease-free areas, pursuant to international agreements and treaties of which Brazil is a signatory.

Paragraph 7. Whenever epidemiologically recommended, the eradication of diseases and pests shall have priority under the pest- and disease-free areas strategy."

"Art. 29-A. Industrial and health inspection of plant and animal products and of agricultural and livestock inputs shall be managed so that inspection procedures and organization shall be universal and equitably applied to all inspected establishments.

Paragraph 1. Inspection may follow the hazard analysis and critical control points method.

Paragraph 2. As part of the Agriculture and Livestock Health Care Unified System , a Brazilian plant product inspection system and a Brazilian animal product inspection system shall

be established, as well as specific inspection systems for agricultural and livestock inputs."

Art. 2. The Executive shall regulate this Law within ninety days of its publication.

Art. 3. This Law shall enter into force on the date of its publication.

Brasília, the twentieth day of November of the year 1998, the 177th of Independence and the 110th of the proclamation of the Republic.

FERNANDO HENRIQUE CARDOSO
FRANCISCO SÉRGIO TURRA

LAW No. 569 OF DECEMBER 21, 1948

Published in the Federal Official Gazette of December 23, 1948, Section 1, Page 18256

Establishes animal health and inspection measures and makes other provisions.

THE PRESIDENT OF THE REPUBLIC, make known that the NATIONAL CONGRESS has decreed and I have sanctioned the following Law:

Art. 1. Whenever the sanitary slaughter of diseased animals or the destruction of rural items or facilities is determined to safeguard public health, their owner shall be entitled to a cash indemnity established by prior assessment.

Sole Paragraph. Should the assessment determine that a part of the rural items or facilities is fit for use, a proportionate amount shall be deducted from the indemnity.

Art. 2. Animals affected by any of the zoonoses specified under Art. 63 of the Animal Health and Inspection Service Regulations approved by Decree No. 24548 of July 3, 1934 shall be sanitary slaughtered.

Sole Paragraph. No indemnity shall be due in case of rabies, pseudorabies, or any other disease considered incurable and lethal.

Art. 3. The indemnity due for a sanitary slaughtered animal shall be paid on the following basis:

(a) a fourth of the animal's value, in case of tuberculosis;

(b) half of the animal's value, in other cases;

(c) the full value of the animal if the necropsy or another procedure fails to confirm the clinic diagnostic.

Art. 4. The indemnity due for rural items or premises shall be equal to the total amount established by the assessment.

Art. 5. The assessment shall be done by a commission consisting of Federal Government representatives, who must be veterinary professionals, a State Government representative, and a representative of the Rural Associations established under Decree-law no. 7449 of April 9, 1945, who may be replaced in regions where such associations do not exist by a ruralist of known technical capacity, appointed by the interested party.

Sole Paragraph. The report may be appealed within thirty days to the Minister of Agriculture by:

(a) the Federal Government representative, if he deems the indemnity excessive or unacceptable;

(b) the owner of the animal or rural items or premises if the indemnity is denied or considered insufficient by the assessment commission.

Art. 6. The indemnity shall be paid by the Federal Government under a specific budget appropriation, additional credit for the same purpose, or budget appropriation for expenditures with prophylaxis and combating epizooties.

Sole Paragraph. Should there be an agreement between the Federal Government and a Sate with the contribution of another entity for the execution of public animal health and inspection services, one third of the indemnity shall be paid by the State and the remaining two thirds shall be paid by the Federal Government;

Art. 7. The right to enter an indemnity claim shall expire ninety days as of the date of the animal's death or item's destruction.

Art. 8. The Executive shall issue within sixty days the requisite regulations for this Law's enforcement.

Art. 9. This Law shall enter into force ninety days as of its publication; all provisions to the contrary are hereby revoked.

Rio de Janeiro, the twenty-first of December of the year 1948, the 127th of Independence and the 60th of the proclamation of the Republic.

EURICO G. DUTRA
Daniel Carvalho
Corrêa Castro

DECREE No. 5741 OF MARCH 30, 2006

Published in the Federal Official Gazette of March 31, 2006, Section 1, Page 82

Regulates Articles 27-A, 28-A, and 29-A of Law No. 8171 of January 17, 1991, establishes the Agriculture and Livestock Health Care Unified System, and makes other provisions.

THE PRESIDENT OF THE REPUBLIC, by virtue of the powers vested in him under Art. 84, IV and VI, a of the Constitution, having in view the provisions of Arts. 27-A, 28-A, and 29-A of Law no. 8171 of 17 January 1991,

DECREES:

Art. 1. The Regulation of Arts. 27-A, 28-A, and 29-A of Law no. 8171 of January 17, 1991 is hereby regulated pursuant to the Annex hereto.

Art. 2. It is incumbent upon the Minister of Agriculture, Livestock, and Food Supply to issue the complementary acts and norms called for under the Regulations hereby approved. (NR)

Art. 3. This Decree enters into force on the date of its publication.

Brasília, the thirtieth of March of the year 2006; the 185th of Independence and the 118th of the proclamation of the Republic.

LUIZ INÁCIO LULA DA SILVA
Roberto Rodrigues
Miguel Soldatelli Rosseto

ANNEX

REGULATION OF ARTS. 27-A, 28-A, AND 29-A OF LAW No. 8171 OF JANUARY 17, 1991

CHAPTER I

PRELIMINARY DISPOSITIONS

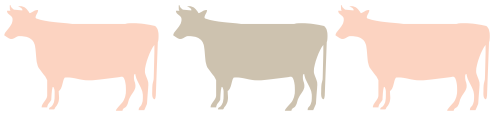
Art. 1. The Agriculture and Livestock Health Care Unified System is hereby established pursuant to these Regulations.

Paragraph 1. Participants in the Agriculture and Livestock Health Care Unified System shall be as follows:

I – Official services and institutions;

II – Rural producers and workers, their associations, and technicians that assist them;

III – Oversight bodies of professional catego-



ries directly connected with agriculture and livestock health; and

IV – Management of funds set up by the private sector to complement government actions in the field of agriculture and livestock health.

Paragraph 2. The Agriculture and Livestock Health Care Unified System operates in accordance with the principles and definitions of agriculture and livestock Health, including the control of activities pertaining to health, oversight, inspection, education, and to the surveillance of animals, plants, and animal and plant inputs and products.

Paragraph 3. The Agriculture and Livestock Health Care Unified System shall carry out the following activities on a continuing basis:

I – surveillance and plant health and inspection;

II – surveillance and animal health and inspection;

III – inspection and classification of plant products, byproducts, subproducts, and residues of economic value;

IV – Inspection and classification of animal products, their byproducts, subproducts, and residues of economic value; and

V – Inspection of inputs and services used in agricultural and livestock activities.

Paragraph 4. The Agriculture and Livestock Health Care Unified System shall be coordinated with the Unified Health System in matters pertaining to public health.

Section I

Principles and General Obligations

Art. 2. The norms and procedures of the Agriculture and Livestock Health Care Unified System conform to the principles to be observed in connection with agriculture and livestock health, especially with those pertaining to the duties incumbent upon producers, manufacturers, and competent authorities, including agriculture and livestock health's structural and operational requirements.

Paragraph 1. The objective of the Agriculture and Livestock Health Care Unified System's general and specific norms is to ensure the protection of animal and plant health the suitability of inputs and services for agricultural and livestock use; and the identification and hygienic, sanitary, and technological safety of final agricultural and livestock products destined for consumers.

Paragraph 2. The Agriculture and Livestock Health Care Unified System operates in and integrated form to guarantee agriculture and livestock health an safety, from the primary production location to the placement of the final product on the internal or on the export market.

Paragraph 3. Rural producers, industrialists, and input suppliers, distributors, cooperatives and associations, industrialists and agroindustrialists, wholesalers and retailers, importers and exporters, entrepreneurs and any other agribusiness operators along the production chain are responsible for ensuring that the health and quality of animal and plant products and the agricultural and livestock inputs will not be compromised.

Paragraph 4. Undertaking official controls pursuant to these Regulations does not exempt participants in the production chain from the legal and principal obligation to ensure the health of animals and of plants, the safety and quality of animal and plant products, as well as agricultural and livestock inputs; neither does it prevent the performance of new controls nor exempts participants from civil or penal liability for failure to comply with their obligations.

Paragraph 5. Rural producers and other participants in production chains shall cooperate with the competent authorities to ensure the effectiveness of official controls and improve agriculture and livestock healthiness.

Paragraph 6. Health control procedures shall include traceability of animal and plant products, agricultural and livestock inputs and their ingredients, and raw materials throughout the production chain.

Paragraph 7. Complementary agriculture and livestock health and inspection norms stemming from these Regulations shall be based on scientific knowledge.

Paragraph 8. Importation and exportation of animals and plants, animal and plant products, agricultural and livestock inputs and their ingredients, as well as of raw materials shall

abide by these Regulations' provisions.

Art. 3. The municipality's area shall be the basic geographical area of the Agriculture and Livestock Health Care Unified System's structure and of the operation of official agriculture and livestock health services.

Art. 4. These regulations shall apply to the production, processing, and distribution stages and to the official agriculture and livestock services, without prejudice to specific requirements to ensure agriculture and livestock health and the quality, origin, and identity of agricultural and livestock products and inputs.

Art. 5. Production chain participants shall provide the following information to the competent authority in the form required by the latter:

I – Name and characteristics of establishments under their controls which are devoted to any of the production, processing, and distribution stages, and of agriculture and livestock services;

II – Current data about their establishments, including notification of any significant change in their activities, or their closing; and

III – Occurrence of changes in health and phytosanitary conditions in their establishments, production units, or properties.

Art. 6. These Regulations establish norms aimed at participants in the Agriculture and Livestock Health Care Unified System as well as norms pertaining to the undertaking of official controls to verify compliance with agriculture and livestock health legislation and the quality of agricultural and livestock products and inputs, taking the following into consideration:

I – Guarantee of animal health and plant healthiness;

II – Guarantee of the healthiness, quality, and safety of animal and plant products along the production chain, starting with primary production;

III – Maintenance of the cold chain, especially for frozen or perishable animal and plant products that cannot be safely stored at room temperature;

IV – Overall application of the procedures based on the Hazard Analysis and Critical Control Points-HACCP and on risk analysis;

V – Observance of microbiologic criteria;

VI – Guarantee that imported animals, plants, agricultural and livestock inputs and animal and plant products meet the same health and quality criteria required in Brazil or equivalent criteria;

VII – Prevention, elimination, or reduction of hazards to acceptable levels;

VIII –Compliance with zoosanitary and phytosanitary norms;

IX – Compliance with official sampling and analysis methods; and

X – Compliance with any other requirements established by the agriculture and livestock health legislation.

Paragraph 1. The official sampling and analysis methods to be used as reference shall be established under a specific norm.

Paragraph 2. While official sampling or analysis methods are still pending, participants may use other methods that are scientifically validated according to internationally accepted norms or protocols.

Art. 7. The Ministry of Agriculture, Livestock, and Food Supply shall establish specific norms pertaining to agriculture and livestock health and inspection for:

I – Rural primary production for self-consumption and the domestic preparation, handling, or storage of agricultural and livestock products for family consumption;

II – Sale or bulk or retail supplying of small quantities of primary production products directly to the end-consumer by family farmers or their equivalent; and

III – Agroprocessing done on a family farming rural property or its equivalent.

Sole Paragraph. The application of specific norms referred to in this article's heading is subject to the minimum risk of circulation and dissemination of regulated pests and diseases.

Art. 8. These regulations do not exempt participants in the production chain from compliance with any specific disposition pertaining to other federal, state, and municipal official controls unrelated to agriculture and livestock health and inspection.

Sole Paragraph. Federal official controls referred to in the preceding include provisions per-

taining to hygiene and sanitary control under the Unified Health System (SUS).

CHAPTER II

AGRICULTURE AND LIVESTOCK HEALTH CARE UNIFIED SYSTEM

Section I
Organs

Art. 9. Agriculture and Livestock Health Care Unified System activities shall be carried out by a Central and Superior Organ and by Intermediary and Local Organs.

Paragraph 1. It shall be incumbent on the Central and Superior Organ to carry out activities that are incumbent exclusively on the Federal Government pertaining to policy, strategy, norms, regulation, coordination, oversight, audit, verification, or inspection, including operational activities if required by national or regional interest.

Paragraph 2. It shall be incumbent on the Intermediary Unit to carry out activities pertaining to strategy, norms, regulation, coordination, and operation of interest to the Federal Government as well as activities exclusive to the State in their respective jurisdictions, pursuant to pertinent federal, state, and Federal District regulations.

Paragraph 3. It shall be incumbent on the Local Organs to carry out actions of interest to the Federal Government, the States, or the Municipalities pursuant to pertinent federal, state , or municipal legislation.

Paragraph 4. It shall be incumbent on participants in the Agriculture and Livestock Health Care Unified System to see to full compliance with current specific legislation that regulates agriculture and livestock health and inspection activities, obligations, and commitments undertaken under international agreements.

Paragraph 5. Control activities carried out by the competent authorities of the three Organs are considered direct Government activities.

Paragraph. 6. It shall be incumbent on the competent authorities of the three Organs to ensure the following:

I – The effectiveness and adequateness of official controls throughout the production chains;

II – The hiring, through competitive examination, of personnel to perform official controls;

III – The absence of any conflict of interest on the part of the personnel that undertake

IV – Existence of or access to laboratories with sufficient capacity to perform tests, staffed with qualified, experienced personnel in sufficient number to perform official controls efficiently and effectively;

V – The availability, adequateness, and proper maintenance of facilities and equipment to ensure that the staff will be able to undertake official controls with assurance and effectiveness;

VI – The assurance of the requisite legal powers to undertake official controls and to adopt measures contemplated hereunder; and

VII – The existence of emergency and contingent plans, and staff prepared for executing such plans.

Paragraph 7. The competent authorities of the three Organs shall guarantee the impartiality, quality, and consistence of official controls.

Art. 10. The authorities in the three Organs shall ensure that official controls are regularly undertaken, consistently with existing or potential agriculture and livestock health risks and as frequently as is appropriate for achieving these Regulations' objective, particularly in connection with the following:

I – Identified or associated risks;

II – Background of those responsible for production or processing;

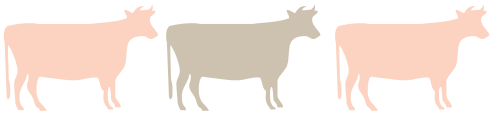
III – Reliability of self-controls; and

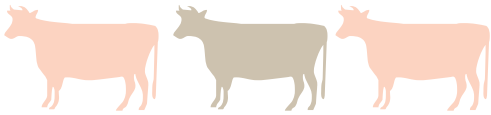
IV – Signs of noncompliance with these Regulations or with specific legislation.

Art. 11. At the competent authority's discretion, official controls may be undertaken at any stage of production, processing, storage, transportation, and distribution, and shall cover the internal market as well as exports and imports.

Paragraph 1. The competent authorities of each Organ shall verify compliance with the legislation through non-discriminatory controls;

Paragraph 2. To establish official controls, the competent authorities of each Organ shall request from producers documents and additional information on their products.





Paragraph 3. Should any case of noncompliance be detected during the undertaking of an official control at the destination point or during storage or transportation, the competent authorities of each Organ shall adopt the appropriate measures.

Paragraph 4. Audits, inspections, and controls shall be done without prior notice, except in specific cases, when prior notification of the person responsible for the establishment or services shall be obligatory.

Art. 12. Any adaptation, formulation, or modification of the agriculture and livestock health and inspection norms shall conform to these Regulations so as to ensure the continuous improvement of the Agriculture and Livestock Health Care Unified System.

Section II

The Central and Superior Organ

Art. 13. The Central and Superior Organ's activities shall be carried out by the Ministry of Agriculture, Livestock, and Food Supply and its collegiate bodies set up by and subject to the National Agricultural Policy Council pursuant to Art. 5 of Law No. 8171 of January 17, 1991.

Paragraph 1. It shall be incumbent upon the National Agricultural Policy Council to ensure that the collegiate bodies are set up with the participation of representatives from the government and civil society and to guarantee their democratic functioning, while harmonizing the interests of the Federal Government and of all system participants, as well as approving the bylaws of the collegiate bodies.

Paragraph 2. The Ministry of Agriculture, Livestock, and Food Supply as the Central and Superior Organ shall establish the collegiate bodies within a maximum of ninety days as of the setting-up of the National Agricultural Policy Council.

Paragraph 3. The Ministry of Agriculture, Livestock, and Food Supply's decentralized units – the Federal Agriculture, Livestock, and Supply Superintendences and the National Agriculture and Livestock Laboratories – shall form part of the Central and Superior Organ.

Paragraph 4. As the Central and Superior Organ, the Ministry of Agriculture, Livestock, and Food Supply shall set up Executive Committees by the deadline established in Paragraph 2 above to support agriculture and livestock health and inspection management, which is incumbent upon the Central and Superior Organ.

Art. 14. The following shall be incumbent upon the Agriculture and Livestock Health Care Unified System's Central and Superior Organ:

I –Agriculture and livestock surveillance of ports, airports, and international border checkpoints, and special customs posts;

II – Establishment of norms pertaining to plant pest and animal disease control and eradication campaigns;

III – Approval of diagnostic methods and of products for veterinary and agronomic uses;

IV – Maintenance of the epidemiologic data system;

V – Regulation, regularization, introduction, implementation, coordination, and evaluation of activities pertaining to sanitary education in agriculture and livestock health and inspection at the three Organs of the Unified System;

VI – Auditing, oversight, evaluation, and coordination of activities carried out by Intermediary and Local Organs;

VII – Representing Brazil at international forums that deal with agriculture and livestock health and inspection;

VIII – Undertaking epidemiologic studies and studies in support of the development of the Agriculture and Livestock Health Care Unified System;

IX – Improvement of the Agriculture and Livestock Health Care Unified System.

X- Technical cooperation with the other Organs of the Agriculture and Livestock Health Care Unified System;

XI – Maintenance of agriculture and livestock health and inspection norms; and

XII – Execution and operationalization of certification and of agriculture and livestock surveillance in areas under its jurisdiction.

Art. 15. As the Agriculture and Livestock Health Care Unified System's Central and Superior Organ, the Ministry of Agriculture, Livestock, and Food Supply is responsible for:

I – Establishing the sanitary and phytosanitary regulations for the importation and exportation of animals and plants and of parts, products,

and subproducts thereof, organic matter, biologic organisms, and other items that are regulated because of the risk associated with the introduction and dissemination of pests and diseases;

II – Organizing, conducting, preparing, and homologating pest and disease risk analysis pertaining to the importation and exportation of products and raw materials;

III – Promoting the accreditation of cooperating centers;

IV – Participating in the development of international standards pertaining to sanitary and phytosanitary requirements and to pest and disease risk analysis;

V – Managing, compiling, and processing pest and disease associated risk information; and

VI – Promoting training activities in connection with issues related to risks associated with pests and diseases.

Art. 16. As the Agriculture and Livestock Health Care Unified System's Central and Superior Organ, the Ministry of Agriculture, Livestock, and Food Supply shall establish the operating norms, specifying the Agriculture and Livestock Health Care Unified System's activities within its competence.

Art. 17. The States and the Municipalities shall provide the information requested by the Ministry of Agriculture, Livestock, and Food Supply as the Central and Superior Organ.

Art. 18. To put into operation and control the Agriculture and Livestock Health Care Unified System, the Ministry of Agriculture, Livestock, and Food Supply as its Central and Superior Organ, shall:

I – Organize and define relations among authorities of the Agriculture and Livestock Health Care Unified System;

II – Establish the objectives and goals to be achieved;

III – Define staff functions, responsibilities, and duties;

IV – Establish sampling procedures, methods and techniques of control and interpretation of results, and related decisions;

V – Develop programs for the follow-up of official controls and agriculture and livestock surveillance;

VI – Support mutual assistance whenever official controls require the intervention of more than one of the Intermediate Organs;

VII – Cooperate with other services or departments that may have responsibilities in this field;

VIII – Verify the conformity of sampling methods, analysis methods, and detection tests; and

IX – Develop or promote other activities and generate information needed for the effective functioning of official controls.

Section III

Intermediate Organs

Art. 19. The Intermediate Organs' activities shall be carried out in each State by the agency that has the mandate or attribution for carrying out agriculture and livestock Health and Inspection activities.

Paragraph 1. The Intermediate Organs' activities may be carried out by institutions defined by the State or Federal District governments; such institutions may represent:

I – Geographical regions;

II – Groups of States, individual States, or the Federal District;

III – Production poles; or

IV – A specific geographical region.

Paragraph 2. The Intermediate Organs shall appoint the competent authorities to be responsible for the achievement of the objectives and for the fiscal controls contemplated hereunder.

Paragraph 3. Should an Intermediary Organ delegate the competence for undertaking official controls to an authority or to authorities of another Intermediate Unit, or to an institution, the delegating Organ shall ensure the efficient and effective coordination of all activities involved.

Art. 20. The following activities shall be incumbent upon the Intermediate Organs:

I – Agriculture and livestock surveillance of interstate movement of animals and plants;

II – Coordination and execution of programs and campaigns on the control and eradication of plant pests and animal diseases;

III – Maintenance of nosographic reports;

IV – Coordination and execution of epidemiologic actions;

V – Coordination and execution of programs,

projects, and activities of sanitary education in their area of operation; and

VI – Control of the diagnostic network and of accredited health professionals.

Art. 21. Each Intermediary Organ shall adopt the requisite measures to ensure that control procedures are followed in an equivalent manner in all Municipalities and Local Organs.

Paragraph 1. The competent authority in each State shall verify compliance with the legislation through nondiscriminatory controls.

Paragraph 2. Should any case of noncompliance be detected during the undertaking of an official control at the destination point or during storage or transportation, the competent authorities of each Organ shall adopt the appropriate measures.

Art. 22. The Intermediate Organs shall coordinate and compile data on agricultural and livestock health activities in their areas of operation.

Section IV
Local Organs

Art. 23. Local Organ activities shall be carried out by the local agriculture and livestock health unit, which shall be connected to the Intermediate Organ, as defined by the Ministry of Agriculture, Livestock, and Food Supply as the Central and Superior Organ, and may encompass one or more than one basic geographical unit and Municipality, including microregions, microterritories, Municipalities associations, Municipalities consortiums, or other Municipalities' associative forms.

Paragraph 1. Each Local Organ shall, within its jurisdiction, pay full attention to agriculture and livestock health, with the participation of organized society, through the following activities:

I – Establishment of a property register;

II - Inventory of animal and plant populations;

III – Animal and plant movement control;

IV – Register of active health professionals;

V – Execution of sanitary education programs, projects, and activities pertaining to agriculture and livestock health and inspection in its area of operation;

VI – Establishment of a register of businesses selling products for agronomic and veterinary use;

VII – Establishment of a register of disease diagnostic laboratories;

VIII – Inventory of diagnosed diseases and pests;

IX – Launching of disease and pest control campaigns;

X – Sanitary surveillance education;

XI – Participation in disease and pest eradication projects; and

XII – Implementation of disease and pest eradication programs.

Paragraph 2. Local Organs shall appoint the competent authorities to be responsible for the achievement of the objectives and for the official controls contemplated hereunder.

Art. 24. A Local Organ may have more than one post to assist rural producers and the community in connection with agriculture and livestock health and inspection.

Art. 25. Local Organs shall be responsible, through their offices to assist the community and the agriculture and livestock health care posts, for notifying events pertaining to agriculture and livestock health and inspection.

CHAPTER III

PROCEDURES AT THE DIFFERENT ORGANS OF THE AGRICULTURE AND LIVESTOCK HEALTH CARE UNIFIED SYSTEM

Section I
Eradication and Control of Pests and Diseases

Art. 26. Strategies and policies aimed at promoting health and surveillance shall be ecosystemic and decentralized according to types of health problem so as to ensure pest- and disease-free areas, pursuant to international agreements and treaties of which Brazil is a signatory.

Paragraph 1. Whenever epidemiologically recommended, the eradication of diseases and pests shall have priority under the pest- and disease-free areas strategy.

Paragraph 2. Should eradication prove unfeasible, prevention, control, and sanitary and

phytosanitary programs should be adopted with a view to contain the disease or pest so as to ensure the recognition of the area as a low prevalence area or for the purpose of establishing a risk mitigation system.

Art. 27. For all relevant cases, a contingency or emergency plan shall be adopted, consistently with the role of each system's Organ.

Art. 28. National or regional prevention, control, and eradication campaigns must be consistent with the objective of ensuring the recognition of the status of the area, district, zone, or locality as free of or with low prevalence of pest or disease.

Art. 29. The Ministry of Agriculture, Livestock, and Food Supply as the Central and Superior Organ shall establish and keep current the sanitary and phytosanitary requirements pertaining to the national and international movement of animals and plants and of parts, products, and subproducts thereof, as well as residues of economic value, biologic organisms, and other regulated products and items susceptible of serving as pest or disease substratum, culture medium, vector, or dissemination vehicle.

Art. 30. The Intermediary and Local Organs shall introduce a warnings and communication system for notification of direct or indirect risks to animal and plant health and for the exchange of information that may facilitate prompt and proper risk assessment and management by the members of the Agriculture and Livestock Health Care Unified System.

Art. 31. The Ministry of Agriculture, Livestock, and Food Supply as the Central and Superior Organ shall establish mechanisms to permit the participation of consortiums of public and private entities, institutes and funds in the implementation of common sanitary or phytosanitary policies, so as to ensure in turn greater participation of microregions in the regional, national, and international markets.

Art. 32. The Agriculture and Livestock Health Care Unified System's three Organs shall establish mechanisms for the mobilization, coordination, and organization of local communities with a view to the formulation, implementation, and evaluation of sanitary and phytosanitary policies.

Art. 33. The Ministry of Agriculture, Livestock, and Food Supply as the Central and Superior Organ shall prepare contingency, control, and emergency plans to address diseases and pests of significant impact, and set up National Sanitary and Phytosanitary Emergency Groups.

Paragraph 1. Contingency, control, and emergency plans to address diseases and pests of significant impact shall be preventively prepared and shall be a priority for all three Organs.

Paragraph 2. The Ministry of Agriculture, Livestock, and Food Supply as the Central and Superior Organ shall coordinate the National Sanitary and Phytosanitary Emergency Groups and define the norms for their makeup and functioning as well as for their qualification and training programs, hierarchy, and specific attributions.

Paragraph 3. The National Sanitary and Phytosanitary Emergency Groups shall be preferentially set up by type of sanitary or phytosanitary problem.

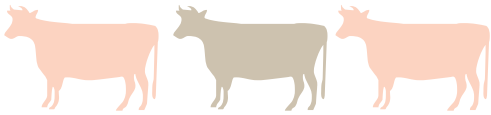
Paragraph 4. For the functioning of the National Sanitary and Phytosanitary Emergency Groups, the Ministry of Agriculture, Livestock, and Food Supply as the Central and Superior Organ shall ensure that they will have a minimum of personnel, ongoing training, and mobility conditions so that they can carry out control actions in case of sanitary or phytosanitary emergencies.

Paragraph 5. The National Sanitary and Phytosanitary Emergency Groups may be assisted by specialized technical teams as defined by the Ministry of Agriculture, Livestock, and Food Supply as the Central and Superior Organ.

Art. 34. The Intermediate Organs shall set up and coordinate State or Regional Sanitary and Phytosanitary Emergency Groups.

Sole Paragraph. To function, the State or Regional Sanitary and Phytosanitary Emergency Groups must be recognized by the Ministry of Agriculture, Livestock, and Food Supply as the Central and Superior Organ.

Art. 35. The National, State, or Regional Sanitary and Phytosanitary Emergency Groups shall act as operative bodies and assist the competent authorities in their activities, with the support of the Ministry of Agriculture, Livestock, and Food Supply, and operate as a task force.



Paragraph 1. The National, State, or Regional Sanitary and Phytosanitary Emergency Groups shall begin their field operations with the declaration of a sanitary or phytosanitary state of alert or emergency as prescribed by the Ministry of Agriculture, Livestock, and Food Supply as the Central and Superior Organ.

Paragraph 2. The National, State, or Regional Sanitary and Phytosanitary Emergency Groups shall remain permanently prepared and on call, independently from the declaration of emergencies; and shall undertake the recommended preventive and corrective measures to contain sanitary or phytosanitary events.

Art. 36. The National, State, or Regional Sanitary and Phytosanitary Emergency Groups' training and qualification shall be coordinated by the Ministry of Agriculture, Livestock, and Food Supply as the Central and Superior Organ, in accordance with the contingency, control, and emergency plans.

Section II

Animal Health

Art. 37. The Agriculture and Livestock Health Care Unified System shall maintain an animal health promotion service charged also with the prevention, control, and eradication of diseases susceptible of harming animal productivity, the economy, and agriculture and livestock healthiness, and shall carry out the following activities consistently with the attributions of each Organ of the System and with current legislation:

I –Risk evaluation and control of the movement of animals, their products, subproducts, and residues and of any other products or goods likely to serve as disease substratum, culture medium, vector, or vehicle;

II – Establishment of policies, norms, and guidelines for disease prevention, control, and eradication programs for the purpose of establishing a free or controlled area;

III – Programming, coordination, and execution of zoosanitary surveillance actions, with particular attention to the definition of sanitary requirements pertaining to the movement of animals and of animal products, subproducts, and byproducts;

IV – Preparation of contingency, control, and emergency plans pertaining to diseases of significant impact, defining the administrative authorities that will intervene, their respective powers and responsibilities, as well as the channels and procedures for the exchange of information among the different interveners;

V – Planning, coordination, and implementation of the zoosanitary information system and pertinent databank to facilitate the coordination of activities, the exchange of information, and the preparation and execution of common projects;

VI – Planning, coordination, and undertaking of epidemiologic studies of diseases of interest to animal health;

VII – Undertaking of studies and analyses of zoosanitary data and pertinent epidemiologic research to support planning, evaluation, and control activities related to sanitary programs and to strategies for the formulation of the national animal health policy;

VIII – Programming, coordination, and execution of the inspection of the movement of animals, veterinary products, animal reproduction materials, animal feed products, animal products, subproducts, and byproducts, as well as enforcing the sanitary requirements pertaining to imports and exports;

IX – Planning, coordination, and execution of actions related to animal quarantine and pertinent quarantine facilities;

X – Planning, coordination, and execution of actions related to expositions, fairs, auctions, and other animal conglomerations;

XI – Establishment of control procedures, including audits, for all Agriculture and Livestock Health Care Unified System Organs, to help animal health management, oversight of activities, and planning review;

XII – Designation and qualification, in conjunction with the international agriculture and livestock surveillance system, of specific points for the entry into the Brazilian territory of imported animals and products requiring prior notification, taking into account the associated risk, access to control and storage facilities, appropriate quarantine facilities, and the existence of a support laboratory;

XIII – Coordination with the network of accredited, official, and authorized laboratories that carry out activities related to animal health, with a view to enhancing the quality and uniformity of results; and

XIV – Coordination of the zoosanitary warning system for the notification of risks to animal health and for information to facilitate prompt and proper risk management actions.

Sole Paragraph. The importation of animals, their products, byproducts, subproducts, and residues of economic value, animal reproduction material, and animal organs, tissues, and cells must abide by the principles defined through risk analysis and the procedures prescribed the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ.

Section III

Plant Health

Art. 38. The Agriculture and Livestock Health Care Unified System shall maintain a plant health promotion service charged also with the prevention, control, and eradication of pests capable of harming plant productivity, the economy, and agriculture and livestock healthiness, and shall carry out the following activities consistently with the attributions of each Organ of the System and with current legislation:

I –Risk evaluation and control of the movement of plants, their products, subproducts, and residues, organic material and biologic organisms, inputs, and of any other products or goods likely to serve as pest substratum, culture medium, vector, or vehicle;

II – Establishment of policies, norms, and guidelines for pest prevention, control, and eradication programs for the purpose of establishing a free area or controlled area;

III – Programming, coordination, and execution of phytosanitary surveillance actions, with particular attention to the definition of sanitary requirements pertaining to the movement of plants and of plant products, subproducts, and byproducts, residues, organic material, biologic organisms, and any products, inputs and goods susceptible of serving as culture medium, vector, or vehicle of pests;

IV – Preparation of contingency, control, and emergency plans pertaining to pests of great impact, defining the administrative authorities that will intervene, their respective powers and responsibilities, as well as the channels and procedures for the exchange of information among the different interveners;

V – Planning, coordination, and implementation of the phytosanitary information system and related databank to facilitate the coordination of activities, the exchange of information, and the preparation and execution of common projects;

VI – Establishment of phytosanitary requirements for authorizing the importation and exportation of plants, their products and subproducts, and of any other items subject to regulation, for commercial, scientific, cultural, or diplomatic purposes;

VII – Undertaking of studies and analyses of phytosanitary data and pertinent phytosanitary research to support planning, evaluation, and control activities related to phytosanitary programs and to strategies for the formulation of the national plant health policy;

VIII – Programming, coordination, and execution of the inspection of the movement of plants, organic products, plant propagation reproduction materials, biologic organisms and any other products, inputs, or goods susceptible of serving as pest substratum, culture medium, vector, or vehicle, as well as enforcing the phytosanitary requirements pertaining to imports and exports;

IX – Planning, coordination, and execution of actions related to plant quarantine and pertinent quarantine facilities;

X – Establishment of control procedures, including audits, for all Agriculture and Livestock Health Care Unified System Organs, to help plant health management, oversight of activities, and planning review;

XI – Designation and qualification, in conjunction with the international agriculture and livestock surveillance system, of specific points for the entry into the Brazilian territory of imported plants and products requiring prior notification, taking into account the associated risk,

access to control and storage facilities, appropriate quarantine facilities, and the existence of a support laboratory;

XII – Coordination with the network of accredited, official, and authorized laboratories that carry out activities related to plant health, with a view to enhancing the quality and uniformity of analysis results;

XIII – Regulation of the criteria and guidelines for the provision of phytosanitary and quarantine services by accredited enterprises, collaborating centers, and quarantine stations, pursuant to the pertinent legislation;

XIV – Coordination of the phytosanitary warnings system for the notification of risks to plant health and for information to facilitate prompt and proper risk management actions.

Sole Paragraph. The importation of plants, their products, byproducts, subproducts, and residues of economic value, and of organic, biologic, and plant propagation material, must abide by the principles defined through risk analysis and procedures prescribed the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ.

Section IV

Sanitary Education

Art. 39. Sanitary education is a strategic activity and an agriculture and livestock health and inspection tool under the Agriculture and Livestock Health Care Unified System for ensuring the involvement of the participants in the agricultural and livestock production chain and of society in general, for the achievement of the objectives hereunder.

Paragraph 1. For the purposes of these Regulations, sanitary education in agriculture and livestock health and inspection is understood as the active, ongoing process of utilization of means, methods, and techniques capable of educating the target public and of developing a critical consciousness.

Paragraph 2. The Agriculture and Livestock Health Care Unified System's Three Organs shall have an appropriate structure for sanitary education actions in regard to agriculture and livestock health and inspection.

Paragraph 3. The Three Organs may support sanitary education activities carried out by public and private services, institutions, and organizations.

Art. 40. The Ministry of Agriculture, Livestock, and Food Supply as the Central and Superior Organ shall continuously develop plans, programs, and actions aimed at sanitary education in agriculture and livestock health and inspection, in coordination with the other Organs and with the Brazilian Agriculture and Livestock Products and Inputs Inspection Systems.

Paragraph 1. The Ministry of Agriculture, Livestock, and Food Supply as the Central and Superior Organ shall establish, regulate, coordinate, and periodically evaluate a National Program for Sanitary Education in Agriculture and Livestock Health and Inspection.

Paragraph 2. The National Program shall abide by the following guidelines, among others:

I – Promotion of the understanding and enforcement of the agriculture and livestock health and inspection legislation;

II – Promotion of sanitary education courses;

III – Training of multipliers;

IV – Promotion of the exchange of experiences; and

V – Utilization of the means of communication as an information and educational instrument.

Art. 41. The Ministry of Agriculture, Livestock, and Food Supply as the Central and Superior Organ shall support actions geared to sanitary education in agriculture and livestock health and inspection carried out by public and private segments of the agricultural and livestock production chain and by society in general, as well as by teaching and research institutions, provided such actions are consistent with the National Program for Sanitary Education in Agriculture and Livestock Health and Inspection.

Section V

Laboratory Management

Art. 42. The competent authorities of each Organ of the Agriculture and Livestock Health Care Unified System shall designate the accredited laboratories for the analysis of official control samples, as prescribed by the Ministry of Agricul-

ture, Livestock, and Food Supply as the Central and Superior Organ.

Paragraph 1. The National Agriculture and Livestock Laboratories are the Ministry of Agriculture, Livestock, and Food Supply's official laboratories.

Paragraph 2. The National Agriculture and Livestock Laboratories and accredited public and private laboratories make up the Agriculture and Livestock Health Care Unified System's National Network of Agriculture and Livestock Laboratories, which is coordinated by the Ministry of Agriculture, Livestock, and Food Supply as the Central and Superior Organ.

Paragraph 3. The National Agriculture and Livestock Laboratories shall be organized into a network, on a hierarchic and regional basis, and their structure shall be grounded on the following:

I – The level of complexity of their laboratory facilities;

II – The epidemiologic, sanitary, demographic, and geographic criteria whereby their territorial base is defined; and

III – The activities carried out in their respective jurisdictions.

Paragraph 4. The accreditation of laboratories shall be according to the demand for analyses and tests, and groups of analyses or specific specimens, pursuant to the criteria defined by the Ministry of Agriculture, Livestock, and Food Supply as the Central and Superior Organ.

Paragraph 5. The competent authority at the Agriculture and Livestock Health Care Unified System's Three Organs that is responsible for accrediting laboratories may at any time cancel their accreditation, should they fail to abide by the terms of the accreditation system.

Paragraph 6. A laboratory, whether public or private, accredited by one of Agriculture and Livestock Health Care Unified System's Three Organs may be designated as a reference laboratory in one or more than one area, provided it meets the pertinent requirements.

Paragraph 7. In designating a laboratory as a reference laboratory in one or more than one area to operate within its jurisdiction, an Intermediate Organ shall follow a documented procedure to verify compliance with the criteria established by said Organ with a view to formally recognize and accept said laboratory's analysis competence.

Paragraph 8. The Intermediate and Local Organs may enter into technical cooperation agreements with reference laboratories in other States.

Art. 43. In the lack of a laboratory with the appropriate biosecurity level or with prior authorization from the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ, the manipulation of any high-risk pathogenic organism is hereby prohibited.

Section VI

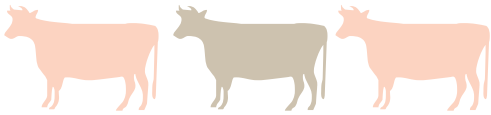
Movement of Animals, Plants and of other Agricultural and Livestock Items

Art. 44. The inspection of the domestic and international movement, by whatever means, of animals and plants, their products and subproducts or any other of their byproducts, as well as of agricultural equipment and implements shall be obligatory for the evaluation of their sanitary and phytosanitary conditions and verification of their mandatory transit documentation.

Paragraph 1. Inspection and sanitary agriculture and livestock control of domestic and international movement of animals, plants, and inputs – including animal feed –, and of animal and plant products, as well as of agricultural equipment and implements, as required hereunder, shall follow uniform procedures at all Agriculture and Livestock Health Care Unified System's Organs.

Paragraph 2. The authorities responsible for domestic and international transport by air, international and coastal navigation, railways, waterways, and highways shall ensure the access of sanitary agriculture and livestock inspection teams to passenger departure and arrival areas and to cargo loading and unloading facilities.

Paragraph 3. The Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ shall establish the requisite norms for and coordinate the control of domestic and international movement, by whatever means, of animals and plants, their products and subprod-



ucts, or any other of their byproducts.

Paragraph 4. The Agriculture and Livestock Health Care Unified System's Intermediate Organs shall undertake the agriculture and livestock control of interstate movement, pursuant to the norms established by the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ.

Paragraph 5. The Agriculture and Livestock Health Care Unified System's Intermediate Organs shall regulated and coordinate the agriculture and livestock inspection of interstate and intra-municipality movement pursuant to the norms established by the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ.

Paragraph 6. The Agriculture and Livestock Health Care Unified System's Local Organs shall undertake the agriculture and livestock inspection in their area of operation.

Paragraph 7. The Agriculture and Livestock Health Care Unified System's Local Organs shall regulate and coordinate the movement within their municipality, pursuant to norms established by the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ.

Art. 45. Inspection of the domestic and international movement shall include, among other measures, the requirement of an official agriculture and livestock health document issued by the pertinent service, stating their origin, destination, and purpose, in addition to compliance with other legal requirements.

Section VII

Interstate Animal and Plant Movement Surveillance

Art. 46. The technical criteria for the classification and grading of the risks of dissemination and establishment of regulated pests and diseases by States or geographical regions, which will guide interstate movement inspection, shall be defined by the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ, based on the following:

I – Specific epidemiologic characteristics of the pests and diseases in question;

II – History of occurrences pest or disease foci;

III – History of noncompliance in movement inspection;

IV – Definition of the geographic area included in the program, to which the risk classification or grading applies;

V – Evaluation of the zoosanitary or phytosanitary conditions in geographic areas and their borders to be classified or graded;

VI – Structure, implementation, and performance of pest and disease prevention, eradication, and control programs;

VII – Organization of the agriculture and livestock surveillance system;

VIII – Conditions and effectiveness of animal and plant movement inspection; and

IX – Degree of coordination of institutional support structures, including the laboratory network.

Art. 47. The planning of the actions and the application of sanitary and phytosanitary measures pertaining to each disease or pest, and the definition of the norms applicable to the control of the movement of plants, animals, their products, or of any other products or goods shall be based on the classification or grading risk established by the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ.

Art. 48. At its discretion, the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ shall identify the movement routes and the specific entry and exit points of plants, animals, basic products, and other regulated items susceptible of acting as vectors or vehicles for the dissemination or dispersion of a given pest or disease.

Paragraph 1. The Intermediate Organs shall install stationary or mobile interstate or interregional sanitary and phytosanitary inspection checkpoints for movement inspection, including, among other measures, intercepting mechanisms and the exclusion of and diseases and pests, and the destruction of apprehended material, in close cooperation with other agencies as necessary.

Paragraph 2. In case of identification of pests, diseases, or of vectors or vehicles of pests or diseases with a high dissemination potential, the infested material shall be im-

mediately sent to destruction or eliminated pursuant to a specific norm.

Paragraph 3. The Organs responsible for movement control in their coverage area shall identify the location and facilities destined for oversight, inspection, disinfection, disinfestation, sacrifice and destruction, or elimination of apprehended material, and shall notify the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ accordingly.

Art. 49. As they undertake animal and plant movement control, the competent Intermediate and Local Organs authorities shall verify compliance with the obligations established hereunder and in other pertinent normative acts.

Paragraph 1. The competent Intermediate Organ authority shall plan its work and that of the Local Organs on the basis of multiyear plans established in accordance with these Regulations and of the risk classification and grading.

Paragraph 2. Controls shall cover all aspects contemplated by the sanitary legislation pertaining to animals, plants, and inputs – including animal feed –, as well as animal and plant products.

Paragraph 3. Controls shall be undertaken on all movement routes of plants, animals, their products and any other products, goods, agricultural equipment and implements likely to act as pest or disease vectors or dissemination vehicles.

Paragraph 4. Civil servants at Intermediate Organs, meeting the requirements under Paragraph 6 of Art. 9 hereunder, shall be competent authorities to inspect the movement of plants, animals, their products or any other products or goods, or agricultural equipment or implements likely to act as pest or disease vectors or dissemination vehicles as they move between States.

Art. 50. Official agriculture and livestock sanitary controls shall include, at the competent authority's discretion, documental, origin, and physical control, pursuant to the pertinent norm set by the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ.

Paragraph 1. The frequency and nature of controls shall be set forth in specific norms issued by the Three Organs.

Paragraph 2. The frequency of physical controls shall depend on the following:

I – Risks associated with animals, plants, inputs – including animal feed –, as well as animal and plant products;

II – Antecedents pertaining to compliance with requirements applicable to the product in question; and

III – Producers' control of animals, plants, inputs – including animal feed –, as well as animal and plant products.

Paragraph 3. Samples taken for inspection of agriculture and livestock movement shall be handled in such a way as to preserve their validity for analysis.

Art. 51. The Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ shall establish and publicize a list of agricultural and livestock products that present risks associated with pests and diseases and that require control and prior movement notification between the origin and the destination Organs.

Sole Paragraph. The Organs responsible for managing agriculture and livestock sanitary roadblocks shall provide minimum conditions for the carrying out of agriculture and livestock surveillance connected with interstate, intermunicipal, and intra-municipality movements.

Art. 52. Should there be signs of nonconformity with the legislation or doubts as to the identity or destination of products, cargo, or shipment, or as to the consistency of the products, cargo, or shipment with the certified guarantees, the competent authority at the agriculture and livestock sanitary checkpoints may hold the shipment or lot until such signs or doubts are cleared away.

Paragraph 1. The competent authority shall officially hold the transported animals, plants, inputs – including animal feed –, as well as animal and plant products that do not meet the legal requirements.

Paragraph 2. The competent authority shall officially notify those responsible for the cargo of the detected nonconformity, which may be appealed in the manner established under a specific norm.

Paragraph 3. At its discretion, the competent authority shall adopt the following measures:

I – It shall order that the animals, plants, inputs – including animal feed –, as well as animal and plant products be subjected to special treatment or to quarantine, or returned, sanitary slaughtered, or

sent to sacrifice and destruction; or

II – It shall destine the animals, plants, inputs – including animal feed –, as well as animal and plant products for purposes other than their original purpose, depending on their associated risk.

Paragraph 4. In the case of agricultural equipment and implements capable of disseminating diseases and pests, the competent authority shall condition their clearance to their disinfection or disinfestation.

Paragraph 5. Should nonconformities be detected, the competent authority shall notify the other Organs involved and provide the information required under specific norms issued by the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ.

Paragraph 6. The competent authority shall ensure that special treatment or quarantine be applied in accordance with the conditions established hereunder and with the applicable specific norms.

Paragraph 7. The maximum period for which cargoes or lots may be held for agriculture and livestock sanitary control shall be fifteen days.

Paragraph 8. The maximum period referred to in the preceding Paragraph 7 may be extended at the competent authority's discretion in cases specified under specific norms.

Paragraph 9. If at the expiration of the fifteen-day deadline the shipment has not been reshipped, save for justified delay, the shipment shall be returned, sanitary slaughtered, or sent to sacrifice and destruction.

Art. 53. The competent authority shall apprise the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ of its decisions, preferably through the official electronic system.

Art. 54. Those responsible for contracting carrier services and the carrier of animals, plants, inputs – including animal feed –, as well as animal and plant products, and agricultural equipment and implements shall bear the expenses incurred as a result of the competent authorities' decisions.

Section VIII

International Agricultural Goods and Livestock Movement Surveillance

Art. 55. Agriculture and livestock sanitary surveillance activities pertaining to imported animals, plants, inputs – including animal feed –, as well as animal and plant products, and packaging and wood crates going through customs or exported by Brazil are under the sole responsibility of the Ministry of Agriculture, Livestock, and Food Supply.

Paragraph 1. The Ministry of Agriculture, Livestock, and Food Supply shall coordinate and carry out the activities called for under the international agriculture and livestock surveillance system.

Paragraph 2. The Ministry of Agriculture, Livestock, and Food Supply shall set up a managing committee for the international agriculture and livestock surveillance system at international airports, regular ports, border checkpoints, and special customs, which will serve as consultative bodies to the competent authorities.

Paragraph 3. The Federal Agriculture and Livestock Inspectors are the competent authorities to undertake the agriculture and livestock sanitary inspection of imports, exports, as well as of customs procedures pertaining to the movement of animals, plants, inputs – including animal feed –, and animal and plant products.

Paragraph 4. The general norms regarding international agriculture and livestock surveillance contemplated hereunder and in specific legislation shall apply to official control of imported and exported animals, plants, inputs – including animal feed –, as well as animal and plant products.

Paragraph 5. Official controls shall encompass all aspects of agriculture and livestock sanitary legislation pertaining to animals, plants, inputs – including animal feed –, as well as animal and plant products.

Paragraph 6. Official controls shall be undertaken on sites designated by the Ministry of Agriculture, Livestock, and Food Supply, including points of entry and exit of goods on national territory, entrepots, and production facilities, whether subject to customs clearance or destined for free zones, special entrepots, special reexportation units, or other points on the chain of production and distribution, including reshipment.

Art. 56. The Ministry of Agriculture, Livestock, and Food Supply as Central and Superior

Organ shall define the primary agriculture and livestock health and inspection zones and establish import and export corridors for animals, plants, inputs – including animal feed –, as well as animal and plant products on the basis of risk analysis, sanitary requirements and controls, zoosanitary and phytosanitary status, geographic location, and availability of infrastructure and human resources.

Art. 57. Agriculture and livestock sanitary controls pertaining to the exportation or importation of animals, plants, inputs – including animal feed –, as well as animal and plant products shall include, at the competent authority's discretion, documental, identity, and physical control pursuant to the pertinent norm established by the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ.

Paragraph 1. The frequency and nature of such controls shall be defined by the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ, and shall depend on the following:

I – The risks associated with the animals, plants, inputs – including animal feed –, as well as animal and plant products;

II – The controls undertaken by producers or importers; and

III – The guarantees issued by the exporting country's competent authorities.

Paragraph 2. Samples must be handled in such a way as to preserve their validity for analysis.

Paragraph 3. For organizing the official controls pertaining to international agriculture and livestock surveillance, the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ may require that importers or those responsible for the importation of animals, plants, inputs – including animal feed –, as well as animal and plant products provide prior notification of such imports' nature and arrival, pursuant to a specific norm.

Art. 58. Those responsible for the administration of customs facilities shall ensure basic and proper conditions for the carrying out of international agriculture and livestock surveillance activities and for the operation of the points of entry and exit on the national territory at ports, airports, special customs, border checkpoints, and other qualified points or bonded warehouses as defined by the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ.

Art. 59. Should there be signs of nonconformity with the legislation or any doubts as to the identity, quality, or destination of products, cargo, or shipment, or as to the consistency of the imports with the certified guarantees, the competent authority at the international agriculture and livestock surveillance units may hold the shipment or lot until such signs or doubts are cleared away.

Paragraph 1. The competent authority shall officially notify those responsible for the cargo of the nonconformity detected, which may be subject to appeal, pursuant to the established norm.

Paragraph 2. The competent authority may, at its discretion and in accordance with the pertinent legislation:

I – Order the animals, plants, inputs – including animal feed –, as well as animal and plant products to be sanitary sacrificed or destroyed, subjected to special or quarantine treatment, returned, or reexported;

II – Order the animals, plants, inputs – including animal feed –, as well as animal and plant products to be destined for other than the original purpose, depending on their associated risk; and

III – Notify the other customs services of its denial decision and provide information on the final destination of the imports in question, in case of detected nonconformity or of denial of authorization for the entry of said animals, plants, inputs – including animal feed –, as well as animal and plant products.

Paragraph 3. At the competent authority's discretion and in accordance with the pertinent legislation, the measures referred to in Paragraph 2, I above, shall be as follows:

I – Treatment or processing so that the animals, plants, inputs – including animal feed –, as well as animal and plant products are made to conform with the requirements of national legislation or with the requirements of a reshipping exporter country, including decontamination, as the case may be, but exclusive of dilution; and

II – Processing, through any other appropriate manner, for purposes other than the original purpose, except for animal or human consumption, provided such processing is allowed under the pertinent legislation.

Paragraph 4. The competent authority shall ensure that the special or quarantine treatment is dispensed at official or accredited establishments and in conformity with the conditions specified hereunder and with approved specific norms.

Paragraph 5. The Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ's competent authority shall permit reexportation, provided that:

I – The new destination has been approved by the party responsible for the cargo; and

II – The destination country has been informed in advance of the motives and circumstances that prevented the entry of the animals, plants, inputs – including animal feed –, as well as animal and plant products in question into Brazil.

Paragraph 6. The maximum period for which cargoes or lots may be held for agriculture and livestock sanitary control shall be fifteen days.

Paragraph 7. The maximum period referred to in the preceding Paragraph 6 may be extended at the competent authority's discretion in cases specified under specific norms.

Paragraph 8. If at the expiration of the fifteen-day deadline the shipment has not been reshipped, save for justified delay, the shipment shall be destroyed.

Paragraph 9. The competent authorities of the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ shall notify the customs services of its decisions, preferably through the computerized system.

Paragraph 10. The Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ shall take the requisite measures to prevent the introduction of the rejected or refused cargo into the national territory, as provided for under the legislation.

Paragraph 11. Those responsible for the importation of animals, plants, inputs – including animal feed –, as well as animal and plant products shall bear the expenses incurred as a result of the competent authorities' decisions.

Art. 60. The Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ's competent agriculture and livestock surveillance authorities and the other customs, public, and private services shall work in close cooperation in the organization of the official controls referred to hereunder.

Paragraph 1. The customs services shall not permit the introduction into or the handling in primary zones, free zones, or special customs of shipments of animals, plants, inputs – including animal feed –, as well as animal and plant products without approval of the Ministry of Agriculture, Livestock, and Food Supply's competent international agriculture and livestock surveillance authority.

Paragraph 2. The Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ's competent authority shall, through the documentation stipulated under specific, pertinent norms, inform the customs services and the importers whether the lots may or may not be introduced into the national territory.

Paragraph 3. The Ministry of Agriculture, Livestock, and Food Supply's competent authority shall, through the documentation stipulated under specific, pertinent norms, inform the customs services and the importers whether the goods may or may not be admitted into the national territory before the sample analysis' results have been obtained, unless the imports' traceability is guaranteed.

Art. 61. In conformity with these Regulations, necessary measures shall be taken to ensure the uniform execution of the official controls pertaining to the introduction of animals, plants, inputs – including animal feed –, as well as animal and plant products.

Section IX
Certifications

Art. 62. It is incumbent upon the Three Organs of the Agriculture and Livestock Health Care Unified System and to the Brazilian Systems of Agricultural and Livestock Product

and Input Inspection, within their respective areas of competence, to introduce, monitor, and manage the procedures for sanitary, phytosanitary, identity, and quality certification to guarantee the origin, quality, and identity of certified products and endow the traceability process with credibility.

Paragraph 1.The control processes shall ensure the conditions for identifying and ascertaining the supplier of the certified material at the products' origin and destination. Said products shall be identified by codes that permit their traceability along the entire production chain as prescribed by a specific norm.

Paragraph 2. Under the law, it is incumbent upon the Federal Agriculture and Livestock Inspectors to issue the official agriculture and livestock certificates required by international trade.

Art. 63. The Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ shall establish and coordinate databanks pertaining to certification.

Sole Paragraph. The sanitary and phytosanitary requirements for intermunicipal, interstate, and international movement of animals, plants, and their products or subproducts, as well as of other products that might serve as substratum, culture medium, vector, or vehicle of regulated diseases or pests shall be defined by specific information norms pertaining to certification.

Art. 64. A national register of qualified technical personnel entitled to issue certificates of sanitary origin, phytosanitary origin, identity, and quality, as well plant movement permits and animal Movement Permits defined by the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ and the pertinent legislation shall be established.

Art. 65. Without prejudice to the general requirements adopted for agriculture and livestock health and to Brazilian and international norms, the certification process shall take the following into account:

I – The certificate forms prescribed under current norms;

II – The sanitary and phytosanitary requirements and certification's legal underpinning;

III – The qualification of those charged with certification;

IV – The guarantees and the reliability of certification, including electronic certification;

V – The procedures for issuing, following-up, monitoring, canceling, correcting, and replacing certificates; and

VI – The documents that must accompany the lot, shipment, or cargo after the official controls.

Art. 66. Whenever certification is required, the following must be ensured:

I – That there is relation and guaranteed traceability between the certificate and the shipment, lot, item, or cargo;

II – That the information contained in the certificate is true and accurate; and

III – That the specific requirements pertaining to certification have been met.

Section X

Registers and Records

Art. 67. The Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ shall, in the form established by it, promote the databanks' coordination and management, interconnecting the Agriculture and Livestock Health Care Unified System's Three Organs for the maintenance of a unified record and register based on uniform identification.

Art. 68. The Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ shall define the procedures pertaining to the register of establishments and organizations.

Paragraph 1. The obligatory register shall be established by the official services in the area of competence of the Agriculture and Livestock Health Care Unified System in the manner defined by the Agriculture and Livestock Health Care Unified System.

Paragraph 2. The register shall contain individual identification in the Agriculture and Livestock Health Care Unified System, which will identify the interested parties in all procedures of their interest.

Paragraph 3. In case there are other official registers established for other purposes, the information and the database they contain shall be

preferentially used to complement the Agriculture and Livestock Health Care Unified System's unified register and data for the purposes hereunder.

Paragraph 4. The competent authorities of the Agriculture and Livestock Health Care Unified System's Three Organs shall keep current the register of establishments and producers of animals, plants, and agricultural and livestock inputs – including animal feed –, whether they are individuals or legal entities, enterprises, services providers, or organizations.

Art. 69. The Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ shall define the procedures to be followed for the registration of establishments, organizations, or products in accordance with these Regulations.

Paragraph 1. The granting of registration with the Agriculture and Livestock Health Care Unified System shall require official inspection and auditing to verify whether legal provisions and the requirements hereunder have been met.

Paragraph 2. The register shall be used solely for the purpose for which it has been established; its transfer to or utilization by other units or establishments is hereby prohibited.

Paragraph 3. A registered establishment is obligated to purchase only material that is in conformity with the requirements of current legislation.

Paragraph 4. A registered establishment is obligated to cooperate and to grant qualified persons free access to their premises for inspection, auditing, sample collection, and verification of documents.

Section XI

Accreditation of Providers of Technical and Operating Services

Art. 70. The Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ shall define the procedures to be followed for accreditation of enterprises or organizations interested in providing technical or operating services in accordance with current legislation.

Paragraph 1. Whenever it receives an accreditation request, the competent authority shall visit the premises and issue an inspection report and other pertinent reports in the prescribed form.

Paragraph 2. The competent authority shall accredit a services provider if requirements under the agricultural and livestock requirements and other legal requirements have been met.

Paragraph 3. It is incumbent upon the competent authority to establish whether a services provider meets the requirements pertaining to procedures, personnel, infrastructure, equipment, technical know-how, as well as other legal requirements as established hereunder and under specific sanitary and phytosanitary legislation.

Art. 71. The competent authority shall, at its discretion and in the form prescribed by the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ, audit and inspect the services provider's activities.

Paragraph 1. In case any deficiency or nonconformity is detected, the competent authority shall take the corrective measures prescribed under a specific norm and may at is discretion suspend the provision of accredited services until said deficiency or nonconformity is corrected by a specified deadline.

Paragraph 2. Should deficiencies and nonconformity persist after the expiration of the deadline referred to in the preceding Paragraph 1, procedures for disaccreditation of the enterprise or organization shall be started, while the right of Health and Inspection shall be assured, without prejudice to the application of the penalties established under the pertinent legislation.

Paragraph 3. In case of relapse into nonconformity or deficiency or of nonconformity and deficiency deemed serious under a specific norm, the competent authority shall suspend accreditation forthright and start disaccreditation procedures.

Art. 72. The competent authorities shall maintain current registers of accredited services providers, preferably on an electronic medium, and make said registers available to all Agriculture and Livestock Health Care Unified System Organs and to the general public as may be appropriate.

Art. 73. The following shall be incumbent upon services providers:

I – To meet the criteria, guidelines, parameters, and specifications pertaining to services, materials and products, physical plant, equipment components, and modes of applying treat-

ment and procedures, as well to safety measures under specific norms;

II – Whenever requested to do so, to make available to the Three Organs the accreditation supporting documents, a list of products and equipment utilized, and a history of activities carried out and services provided, for the purpose of agriculture and livestock sanitary inspection;

III – To grant the competent authority access to the facilities, so that the competent authority may visit them and issue an inspection report and other pertinent reports as prescribed by the regulations, whenever accreditation is applied for, or at any time;

IV – To inform the pertinent Organ of any change in the information submitted for accreditation, for analysis with a view to approval and authorization;

V – To keep for at least five years the records and information on procedures and services rendered and provided; and

VI – To guarantee supervision by a technical staff member pursuant to current agriculture and livestock sanitary legislation.

Art. 74. Under a specific norm, the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ shall define accreditation procedures, services whose accreditation shall be obligatorily homologated, and specific homologation rules, in accordance with the pertinent legislation.

Section XII

Qualification and Recognition of Professionals

Art. 75. Agriculture and Livestock Health Care Unified System's Three Organs may qualify professionals to render services and issue documents pursuant to current legislation in the manner defined by the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ.

Paragraph 1. It shall be incumbent upon the Three Organs to promote and inspect the activities carried out by professionals.

Paragraph 2. In special cases, the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ shall permit qualified private professionals to issue documents and render services, in accordance with other specific legislation.

Section XIII

Compliance with International Commitments

Art. 76. The Agriculture and Livestock Health Care Unified System's Three Organs shall be responsible for compliance with commitments and obligations under international agreements signed by Brazil in connection with agriculture and livestock health activities.

Paragraph 1. The Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ shall coordinate and follow the implementation of decisions of interest to the national agriculture and livestock sector issued by international organizations or stemming from agreements with foreign governments.

Paragraph 2. Without prejudice to its rights and obligations at international forums, the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ shall:

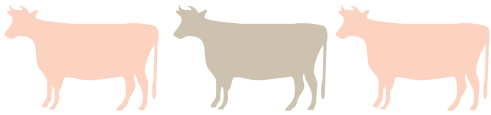
I – Contribute to the consistent formulation of international technical norms pertaining to agricultural and livestock products and animal feeds, as well as of sanitary and phytosanitary norms;

II – Promote the coordination of the work on norms proposed by international organizations in connection with agriculture and livestock Health and Inspection, whenever justified;

III – Contribute, whenever relevant and appropriate, to the preparation of agreements regarding the recognizing of the equivalence of specific measures related to animal and plant products and to animal feed;

IV – Pay special attention to the specific development, financial, and commercial needs of the States so as to ensure that international norms will not raise obstacles to their exports; and

V – Promote consistency between international technical norms and the legislation on agriculture and livestock health care, while at the same time ensuring that the level of protection will not be reduced.



Section XIV

Personnel Training

Art. 77. Agriculture and Livestock Health Care Unified System's Three Organs shall be responsible for the training of their professional staff.

Paragraph 1. Training activities shall be utilized to develop a harmonious approach to official controls at Agriculture and Livestock Health Care Unified System's Three Organs.

Paragraph 2. The qualification and training program shall address the following topics among others:

I – National and international legislation on agriculture and livestock health;

II – Control methods and techniques, such as audit systems conceived by operators, for complying with agriculture and livestock health legislation;

III – Methods and techniques of production and marketing of inputs, including animal feed, as well as animal and plant products;

IV – Pedagogical and communications means, methods, and techniques for the work of sanitary educators with participants of the production chain and with society in general; and

V – Other specific issues of the competence of each Organ, to be defined by the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ.

Paragraph 3. Training activities may be open to participants from other countries.

Art. 78. The Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ shall propose the training policy in consultation with the Intermediate and Local Organs.

Art. 79. The competent authorities of the Agriculture and Livestock Health Care Unified System's Three Organs shall ensure that their official control personnel shall:

I – Have the professional training required for agriculture and livestock health activities;

II – Receive, in their respective area of work, appropriate training and mandates to discharge the functions of their competence, with independence and impartiality;

III – Keep abreast of developments in their area of competence and, if necessary, receive further training; and

IV – Be able to work in cooperation with a multidisciplinary team.

CHAPTER IV

METHODOLOGY AND SPECIAL PROCEDURES

Section I

Risk Analysis

Art. 80. Risk analysis is the basic method used in defining procedures pertaining to agriculture and livestock health care.

Paragraph 1. Risk analyses shall use the references and internationally harmonized concepts approved under agreements signed by Brazil.

Paragraph 2. To achieve the overall objective of ensuring a high level of animal and plant health protection and the safety of animal and plant products, sanitary and phytosanitary measures shall be based on risk analysis, unless this is inappropriate under the circumstances or in view of the measure's nature.

Paragraph 3. Risk analyses shall take into consideration the available scientific information, the pertinent production processes and methods, the pertinent testing, sampling, and inspection methods, the prevalence of specific pests or diseases, the existence of areas and localities free of pests or diseases, the environmental and ecologic conditions, and the quarantine regimes.

Paragraph 4. The choice of a measure to be applied to achieve the adequate level of sanitary and phytosanitary protection should consider the potential damage to animal and plant health, the economic losses resulting from the introduction, establishment, and dissemination of a given pest or disease, the costs of control and eradication on the affected territory, and the cost/benefit of alternative approaches to limiting risks.

Art. 81. The competent authorities of the Agriculture and Livestock Health Care Unified System's Three Organs shall establish procedures for the identification of risks in the areas of their competence.

Art. 82. Whenever an authority suspects that there is a sanitary or phytosanitary risk, it shall

request additional information from the other Agriculture and Livestock Health Care Unified System's Organs, which shall promptly provide all pertinent information in their possession.

Art. 83. The necessary corrective measures to determine the adequate level of sanitary and phytosanitary protection for a locality, Municipality, region, or State in connection with an identified risk shall be consistent with the objective of reducing to a minimum the negative effects on the Agriculture and Livestock Health Care Unified System and on trade among the involved localities and areas.

Paragraph 1. Should scientific evidence be insufficient for risk analysis, protection sanitary and phytosanitary measures may be provisionally adopted at the authority's discretion on the basis of available information, including information originating in reference international organizations, as well as of sanitary and phytosanitary measures adopted by other countries.

Paragraph 2. Risk analyses shall be necessary for the authorization of the importation of animals, plants, and products thereof whenever this is warranted by the sanitary and phytosanitary conditions in the country or origin or of its neighbor countries, or in case of noncompliance with the established sanitary or phytosanitary standards.

Paragraph 3. The Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ shall analyze the Brazilian regions, formulate diagnostics, and propose lines of action based on risk analysis studies, as a strategy for developing local, regional, or national agribusiness.

Section II

Hazard Analysis and Critical Control Points (HACCP)

Art. 84. Producers of animals, plants, agricultural and livestock inputs – including animal feed –, and animal and plant products shall abide by the Hazard Analysis and Critical Control Point principles pursuant to specific norms.

Paragraph 1. In accordance with specific norms, a producer of animals, plants, agricultural and livestock inputs shall:

I – Provide the competent authority with proof of compliance with established requirements in the requisite form, taking into consideration the size and nature of his operation;

II – Make sure that all documents describing the processes followed are kept current; and

III – Keep any other documents and records for the period determined by the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ.

Paragraph 2. Special conditions shall be devised for small producers of animals and plants, requiring the use of processes mentioned in the guidelines for the application of HACCP principles or principles of equivalent systems.

Paragraph 3. Conditions should specify the period during which small producers must keep documents and records.

Paragraph 4. Actions, programs, and projects implemented with the objective of valorizing control activities related to the HACCP system shall be recognized under the Agriculture and Livestock Health Care Unified System pursuant to specific acts issued by the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ.

CHAPTER V

AGRICULTURE AND LIVESTOCK HEALTH AND INSPECTION COMPLEMENTARY NORMS

Section I

Commitment toward Consumers and Producers

Art. 85. The national and State complementary agriculture and livestock Health and Inspection norms are drafted according to the guidelines hereunder and seek to protect the interests of consumers, agricultural and livestock production, and producers in connection with raw materials' quality, inputs, fraud, product alteration, and practices susceptible of leading consumers into error, keeping in view the guarantee of animal and plant healthiness and the safety of animal and plant products.

Sole Paragraph. The complementary norms referred to in the preceding shall define and stress the producer's responsibility for placing safe products and services on the market, controlling production, and observing the critical control points of every approved process.

Section II

Drafting of Complementary Norms of Good Practices

Art. 86. The Agriculture and Livestock Health Care Unified System's Three Organs shall draft complementary norms of good practices for agriculture and livestock health, including operating hygiene standard procedures to permit the application of pest and disease risk analysis principles and of hazard analysis and critical control points consistently with these Regulations.

Paragraph 1. The National Agricultural Policy Council shall approve the national and state complementary norms and determine their periodical review.

Paragraph 2. Said review's purpose is to ensure that the complementary norms continue to be objectively applied and to incorporate scientific and technologic advances.

Paragraph 3. The national complementary norms' titles and references shall be published and publicized throughout the national territory.

Paragraph 4. The national complementary norms of good practices shall be drafted for each production chain and with the participation of producers and other agents on the chain, and shall take into consideration pertinent complementary norms of good practices of reference international organizations.

Art. 87. The Intermediate Organs may, at their discretion and keeping in view specific interests, draft their own complementary norms of good practices, which shall be submitted to the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ and to other Intermediate Organs for their information.

CHAPTER VI

OPERATIONALIZATION AND CONTROL

Section I

Laboratory Control

Art. 88. Analysis methods should meet the following criteria:

I – Accuracy;

II – Applicability (matrix and concentration spectrum);

III – Detection limit;

IV – Determination limit;

V – Precision;

VI – Recovery;

VII – Selectivity;

VIII – Sensitivity;

IX – Linearity;

X – Measurements uncertainty; and

XI – Other criteria that may be chosen as needed.

Paragraph 1. The results indicating the accuracy referred to in item I above should be obtained through trial of groups of products conducted in accordance with nationally or internationally recognized protocols and, if performance criteria have been established for the analysis methods, accuracy should be based on conformity tests.

Paragraph 2. Results of trial of groups of products shall be published or made available without restriction.

Paragraph 3. Analysis methods uniformly applied to several groups of products shall be preferable to methods applicable only to specific products.

Paragraph 4. Special norms and guidelines aimed at harmonization shall be established for situations in which:

I – The analysis methods can be validated solely at accredited or reference laboratories; and

II – The performance criteria for the analysis methods are abased on conformity tests.

Art. 89. Analysis methods adapted to these Regulations shall be conceived pursuant to specifications and to nationally and internationally recommended analysis methods.

Section II

Sampling

Art. 90. Sampling and analysis methods used for official controls should comply with applicable Brazilian norms.

Paragraph 1. The analysis methods should be validated in laboratories in accordance with national norms or with internationally recommended protocols.

Paragraph 2. In the absence of internationally recognized national norm or protocol, the

Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ shall approve norms or instructions defining appropriate methods for achieving the intended objective.

Paragraph 3. The analysis methods should have the characteristics defined hereunder.

Art. 91. The competent authorities of the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ shall regulate counterproof procedures and establish appropriate procedures to ensure the right of producers of animals, plants, inputs – including animal feed – and animal and plant products, whose products are subjected to sampling and analysis, to seek the opinion of another accredited expert as prescribed, without prejudice to the competent authorities' obligation to take prompt measures in emergencies.

Sole Paragraph. Counterproof procedures and second opinions do not apply in case of risks associated with animals, plants, and perishable agricultural and livestock products.

Art. 92. Samples should be properly collected, handled, conditioned, identified, and transported so as to ensure their validity for analysis.

Section III

Agriculture and Livestock Health Care Unified System's Controls

Art. 93. The Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ shall perform general and specific audits in the Intermediate and Local Organs to assess the conformity of their controls and activities with national multi-year control plans.

Paragraph 1. The Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ may designate Intermediate and Local Organ experts, if necessary, to perform or support general and specific audits at the other Intermediate and Local Organs.

Paragraph 2. General and specific audits shall be performed in coordination with and with the cooperation of the competent authorities of the Intermediate and Local Organs.

Paragraph 3. General audits shall be regularly performed in accordance with the multi-year control plans.

Paragraph 4. Before general audits, , current information on the sanitary agriculture and livestock controls may be requested at the discretion of the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ.

Art. 94. General audits shall be complemented with specific audits and specific inspections in one or more than one specified area.

Paragraph 1. Specific audits and inspections have the following purposes:

I – To assess the implementation of the national multi-year control plan and the enforcement of legislation pertaining to animals, plants, inputs – including animal feed – and animal and plant products, and may include, as the case may be, on-site inspection of official services and facilities associated with the production chain subjected to the audit.

II – To assess the Intermediate and Local Organs' operation conditions and their work organization;

III – To identify, evaluate, and propose contingency or emergency plans geared to relevant, critical, or recurring problems at the Intermediate and Local Organs; and

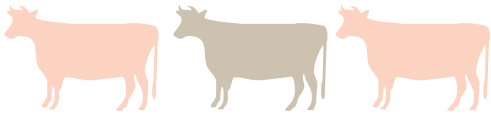
IV – To investigate emergency situations, emerging problems, resolution of contingency plans, or improvements at Intermediate and Local Organs.

Paragraph 2. The Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ shall prepare a report on the results of audits in which it participates.

Paragraph 3. The reports should include, as the case may be, recommendations to the Intermediate and Local Organs aimed at enhancing compliance with the agriculture and livestock health and inspection legislation.

Paragraph 4. The Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ shall submit to the Intermediate and Local Organ's competent authority the draft report, and the competent authority shall submit its opinion and comments within thirty days.

Paragraph 5. The Intermediate and Local Organ's opinion and comments shall be included in the final report, provided they are submitted by the deadline established in the preceding Paragraph.



Paragraph 6. The reports shall be publicized as determined by the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ.

Art. 95. The Intermediate and Local Organs shall:

I – Participate in general and specific audits performed by the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ;

II – Perform their own general and specific audits;

III – Adopt corrective measures pursuant to the recommendations stemming from the audits;

IV – Provide all the requisite assistance and all the documentation and any other kind of technical support requested by the Ministry of Agriculture, Livestock, and Food Supply as Central and Highest Organ; and

V – Grant the auditors of the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ access to all the facilities or parts thereof as well as to all requested information, including information systems, which may be relevant for the audit.

Art. 96. The Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ shall at any time assess the sanitary or phytosanitary conditions or the consistency between the legislation and the sanitary agriculture and livestock systems adopted by the Intermediate and Local Organs as pertains the federal agriculture and livestock healt and inspection legislation.

Section IV

Imports and Exports Control

Art. 97. Importers of animals, plants, inputs – including animal feed – and animal and plant products susceptible of presenting the risk of introduction and dissemination of diseases or pests are obligated to meet the requirements hereunder and comply with the norms established by the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ.

Art. 98. The Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ shall, on the basis of risk analysis, establish and keep current a list of pests and diseases, animals, plants, inputs – including animal feed – and animal and plant products that will be subjected to official controls at the points of entry into the national territory, at the authorities' discretion.

Art. 99. The competent authorities of the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ shall undertake official controls to verify conformity with the legislation pertaining to importation and exportation, as specified hereunder.

Art. 100. The Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ shall define, under specific norms and by country, special controls prior to the exportation to Brazil of animals, plants, inputs – including animal feed – and animal and plant products to ensure that the requirements and other conditions hereunder are met.

Paragraph 1. Approval shall be granted regarding animals, plants, inputs – including animal feed – and animal and plant products from countries that have a sanitary agreement with Brazil; approval may be granted to one or more than one product.

Paragraph 2. Should approval be granted pursuant to the preceding Paragraph, the control of the importation of animals, plants, inputs – including animal feed – and animal and plant products will be simplified and expedited in accordance with the associated risk and the specific rules established by the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ.

Paragraph 3. Controls prior to exportation undertaken at the country of origin may be efficient, at the competent authority's discretion, the undertaking of further official controls may be requested to confirm the healthiness and quality of the imported animals, plants, inputs – including animal feed – and animal and plant products.

Paragraph 4. The approval referred to in Paragraph 1 above shall be granted, provided that:

I – The audits or official procedures undertaken on the basis of specifications defined by the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ prove that the animals, plants, inputs – including animal

feed – and animal and plant products exported to Brazil meet the requirements hereunder or equivalent requirements; and

II – The controls undertaken at the country of origin prior to shipment are deemed sufficiently efficient and effective to replace or reduce the documental, identity, and physical control contemplated hereunder.

Paragraph 5. The approval shall identify the competent authority in the country of origin under whose responsibility the controls prior to exportation are undertaken.

Paragraph 6. The competent authority or control organ specified in the approval of the exporter country shall be responsible for contacts with the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ.

Paragraph 7. The competent authority or control organ in the exporting country shall ensure the official certification of the controlled shipment before the latter's entry into the national territory.

Paragraph 8. The approval shall specify the certificate forms.

Paragraph 9. Should the official control of imports subject to the aforementioned procedure detect any noncompliance with these Regulations, the authorities of the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ shall broaden inspections and controls, pursuant to the noncompliance's seriousness, and undertake new risk analysis, and shall immediately notify the exporting countries in accordance with the pertinent agriculture and livestock sanitary agreements.

Paragraph 10. Should the noncompliance referred to in Paragraph 9 above persist or should the noncompliance jeopardize the objectives hereunder, including agriculture and livestock health, the application of the simplified or fast control regime shall be immediately suspended.

Art. 101. In addition to the legal requirements of the importing countries, the requirements of these Regulations and of the current sanitary and phytosanitary legislation must be met in connection with the exportation or reexportation of animals, plants, inputs – including animal feed – and animal and plant products.

Art. 102. The Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ shall establish specific norms for the undertaking of importation control pertaining to the following:

I – Animals and plants without commercial value, whenever international transportation means are used;

II – Exemptions or specific conditions applicable to certain processing, industrialization, and immediate exportation procedures;

III – Animal and plant products for supplying crew and passengers of international means of transportation;

IV – Inputs, including animal feed, and animal and plant products ordered by mail, telephone, or the internet, and delivered to the consumer;

V – Animal feed and animal and plant products carried by crew and passengers of international means of transportation;

VI – Shipments from Brazil that are being returned by importing countries; and

VI I- Documents that must accompany shipments, whenever samples are collected.

Art. 103. The Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ may at any time evaluate the sanitary condition or the equivalence of the legislation and of the agriculture and livestock sanitary systems of exporter and importer countries with the Brazilian agriculture and livestock health and inspection legislation.

Paragraph 1. The Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ may at its discretion designate experts or specialists for the specific tasks referred to in this article's heading.

Paragraph 2. Evaluations should address the following items, among others:

I – The consistency and coherence of the exporter country's agriculture and livestock health and inspection legislation;

II – The organization and functioning of the exporter country's official services, and competent authorities and their attributions and autonomy;

III – The personnel's and team's qualification for the performance of the official controls;

IV – The infrastructure in place, including diagnostic laboratories and facilities;

V – The existence and functioning of control procedures;

VI – The situation of animal health, zoonoses, and sanitary and phytosanitary control, and procedures for the notification of animal and plant disease outbreaks or events; and

VII – The guarantees the exporter countries can offer of compliance with the national requirements, or of sanitary equivalence.

Paragraph 3. The frequency of evaluation of the agriculture and livestock sanitary conditions in the countries that export to Brazil shall be determined on the basis of the following:

I – Risk analysis of the exported products;

II – Brazilian legal dispositions;

III – Volume and nature of imports from the country in question;

IV – Results of previous evaluations done by the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ;

V – Results of importation controls;

VI – Information received from other organs;

VII – Information received from internationally recognized sources, such as the World Health Organization, the Codex Alimentarius, the International Plant Protection Convention, and the World Organization for Animal Health;

VIII – Detection of diseases and pests in the exporting country;

IX – Identification of risks associated with animals, plants, and perishable agricultural and livestock products; and

X – Need to investigate emergency situations in the exporter country.

Art. 104. Should risk analysis identify risks associated with animals, plants, and perishable agricultural and livestock products, the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ will immediately take the emergency measures contemplated hereunder or under the provisions of current legislation on the protection of agriculture and livestock health.

Art. 105. The Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ shall issue a report on the results of each evaluation undertaken, including pertinent recommendations.

Art. 106. The Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ may request from exporting countries information on the organization and management of their agriculture and livestock sanitary control systems.

Paragraph 1. Said information shall be checked against the exporting country's control results.

Paragraph 2. Should the exporting country fail to provide said information or should the information provided prove incorrect, Brazil will unilaterally and immediately demand the full application of importation controls, without any concessions.

Paragraph 3. The Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ shall determine the form whereby information should be collected, compiled, organized, and presented as well as the transition measures meant to give exporter countries time to prepare said information.

Art. 107. The equivalence agreements recognize that measures applied in the exporting country provide guarantees equivalent to those applied in Brazil.

Paragraph 1. For equivalence determination, the following items shall be evaluated:

I – Nature and content of the certificates that must accompany products;

II – Specific requirements applicable to exports to Brazil; and

III – Audit results.

Paragraph 2. The Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ shall prepare and keep current a list of regions or establishments whose exports to Brazil will not be permitted, taking into consideration the equivalence system.

Paragraph 3. The recognition of equivalence shall be revoked immediately and unilaterally whenever any of the established conditions is not met.

Art. 108. The Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ is hereby authorized to carry out joint ini-

tiatives and support neighbor countries in connection with the healthiness of animals, plants, inputs – including animal feed – and animal and plant products so as to develop the requisite institutional capability to meet the conditions referred to hereunder.

CHAPTER VII

COOPERATION AND ASSISTANCE

Art. 109. At the request of the competent authorities of the Local Organs and in collaboration with them, the Intermediate Organs shall extend cooperation and assistance to the Local Organs.

Art. 110. At the request of the competent authorities of the Intermediate Organs and in collaboration with them, the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ shall extend cooperation and assistance to Intermediate Organs.

Sole Paragraph. Cooperation and assistance extended by the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ shall encompass particularly the following:

I – Clarifications pertaining to national agriculture and livestock health and inspection;

II – Information and data available at the national level that might be useful for the control of Intermediate and Local Organs in ensuring the universality, harmonization, equity, and effectiveness of the agriculture and livestock health controls and actions; and

III – Operating support required for controls under the responsibility of the Intermediate and Local Organs under the Agriculture and Livestock Health Care Unified System.

Art. 111. The Intermediate Organ shall adopt emergency and temporary assistance measures in case of a Local Organ's noncompliance with obligations under the agriculture and livestock sanitary legislation and hereunder, susceptible of compromising the objectives of the Agriculture and Livestock Health Care Unified System.

Art. 112. The Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ shall adopt emergency and temporary assistance measures in case of and Intermediate Organ's noncompliance with obligations under the agriculture and livestock sanitary legislation and hereunder, susceptible of compromising the objectives of the Agriculture and Livestock Health Care Unified System.

Paragraph 1. Should the competent authority of the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ identify any noncompliance, it shall adopt measures to ensure that the Intermediate of Local Organ in question may solve the situation.

Paragraph 2. In deciding in favor of assistance in view of the Intermediate Organs' operating or temporary incapacity to comply with the provisions of the preceding Paragraph 1, the competent authority of the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ shall take into consideration the noncompliance's antecedents and nature.

Paragraph 3. The assistance action referred to in this article's heading may include one or more than one of the following measures:

I – Adoption of sanitary procedures or any other measures deemed necessary to ensure the safety of animals, plants, inputs – including animal feed – and animal and plant products, as well as of norms pertaining to animal health;

II – Restriction or prohibition of placement of products on the market;

III – Monitoring of products and, if necessary, determination that they be recalled, withdrawn, or sent to destruction;

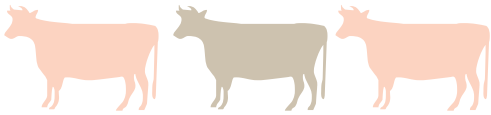
IV – Authorization for the use of inputs – including animal feed – and animal and plant products for a purpose different from their original purpose;

V – Suspension of operations or outright closing of part of production activities or of enterprises;

VI – Suspension or cancellation of accreditation; and

VII – Any other measures deemed appropriate by the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ's competent authority.

Paragraph 4. The burden of the actions referred to under Paragraph 3 above shall be born by the producers of animals, plants, inputs –



including animal feed – and animal and plant products, appeal being possible as prescribed by the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ.

Art. 113. Penalties for infractions related to agriculture and livestock health shall be imposed as prescribed under specific federal, state, and municipal legislation.

Art. 114. All Agriculture and Livestock Health Care Unified System procedures must be documented.

Art. 115. In case of noncompliance with agriculture and livestock health norms on the part of producers of animals, plants, inputs – including animal feed – and animal and plant products, producers at fault shall be formally notified by the competent authority.

Section I
Crisis Control

Art. 116. The Agriculture and Livestock Health Care Unified System shall have a Crisis Management Procedures Manual and Special Groups for Agriculture and Livestock Health Action, which shall abide by specific norms issued by the Ministry of Agriculture, Livestock, and Food Supply.

Art. 117. For the implementation of the guidelines contained in the Crisis Management Procedures Manual, the Agriculture and Livestock Health Care Unified System's Three Organs shall proactively prepare contingency and emergency plans defining readily applicable measures whenever there is a risk to agriculture and livestock health, whether directly or through the environment.

Paragraph 1. The contingency and emergency plans shall specify the administrative authorities that must intervene, their respective powers and attributions, and the channels and procedures for the exchange of information among the different interveners.

Paragraph 2. The Intermediate Organs shall, within their areas of competence, review and adapt the contingency and emergency plans to their specific conditions.

Art. 118. The Intermediate Organs shall, within their areas of competence and by request or at their own initiative, assist each other whenever the results of official controls show the need for the adoption of emergency measures in more than one Intermediate Organ.

Sole Paragraph. Mutual assistance among Intermediate Organs may include, as the case may be, participation in local controls undertaken by a competent authority from other Intermediate Organs.

Art. 119. Should a Three Organs' competent authority have knowledge of a case of noncompliance and such case is likely to have implications for the Agriculture and Livestock Health Care Unified System and for another Intermediate Organ, it shall promptly convey such information to the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ and to other Intermediate Organs, without any need for a prior request.

Paragraph 1. The Organs receiving such information shall start investigations and shall inform the Organ that provided the information of the investigations' results and, as the case may be, of the measures adopted, particularly the application of the assistance received without prior request.

Paragraph 2. Should the competent authorities of the Organs involved have reason to suspect that these measures are inadequate, they should seek together ways and means of addressing the noncompliance.

Paragraph 3. The Intermediate Organs shall inform the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ if they fail to reach a consensus on adequate measures or if the noncompliance may affect the Agriculture and Livestock Health Care Unified System as a whole.

Paragraph 4. Should it be concluded that the noncompliance may affect the agriculture and livestock health in the region or in the entire country, the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ shall provide assistance without prior request to the area identified.

Art. 120. The Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ shall suspend the application of sanitary

and phytosanitary measures among Organs of the Agriculture and Livestock Health Care Unified System, which are unwarranted or contrary to the agriculture and livestock health legislation, and shall adopt pertinent measures.

CHAPTER VIII

PLANNING

Art. 121. The Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ shall establish Agriculture and Livestock Health, strategic, and executive multi-year plans, in coordination with the Agriculture and Livestock Health Care Unified System's Three Organs. These plans shall:

I – Be prepared every five years with the participation of the social segments and governments involved, and be subjected to yearly review;

II – Serve as reference for the preparation of the Federal Government's Multi-year Plan, and similar state , and municipal plans and their respective plans of action; and

III – Be organized and executed in function of hazards identified and related to animals, plants, inputs – including animal feed – and animal and plant products.

Paragraph 1. The Agriculture and Livestock Health Multiyear Plans shall establish the goals, objectives, and responsibilities for each Organ, as well as the requisite resources, including financial counterparts and financing sources.

Paragraph 2. The Ministry of Agriculture, Livestock, and Food Supply shall define how resources are to be applied, all in accordance with the pertinent legislation.

Paragraph 3. The Three Organs shall assume responsibility for the application of resources and for full compliance with the jointly established Agriculture and Livestock Health Multi-year Plans.

Art. 122. The Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ shall establish the timetable for the preparation and updating of the Federal Government's Multiyear Plan.

Paragraph 1. The Agriculture and Livestock Health Multiyear Plan should contain general information on the following:

I – The plan's strategic objectives and how they reflect on the setting of priorities and allocation of resources;

II – Category or classification of the risks associated with the activities;

III – Designated competent authorities and their respective attributions in their different spheres of action, and the resources available to them;

IV – Organization and management of official controls, including official controls at the different establishments;

V – Control systems applied and coordination among competent authorities responsible for official controls;

VI – Possible delegation of tasks;

VII – Methods for ensuring the observance of operating criteria;

VIII – Training of the personnel in charge of official controls;

IX – Documented procedures;

X – Preparation and implementation of contingency and emergency plans in case of diseases and pests of significant impact, and other risks;

XI – Organization of mutual cooperation and assistance;

XII – Institutional coordination mechanisms; and

XIII – Collegiate bodies and cooperation and assistance systems, such as rural extension.

Paragraph 2. The Agriculture and Livestock Health Multi-year Plans may be altered as they are being executed.

Paragraph 3. Alterations shall take the following into consideration:

I – Emergence of new diseases or pests of significant impact or of other risks;

II – New legislation and adjustments defined by the Central and Superior Organ;

III – Significant adjustments in the structure, management, or functioning of the competent authorities;

IV – Results of fiscal controls undertaken under the Agriculture and Livestock Health Care Unified System;

V – Scientific discoveries;

VI – Suggestions from technical consultant services rendered by the Three Organs or from international technical missions; and

VII – Results of audits performed by the Central and Superior Organ.

Paragraph 4. The Agriculture and Livestock Health Multi-year Plans shall observe the following:

I – Consistent, global, and integrated approach to legislation;

II – Priorities set in view of the risks;

III – Criteria for grading and classifying the risks of activities;

IV – Control and correction procedures;

V – International, multilateral, or bilateral commitments pertaining to agriculture and livestock health;

VI – Indicators in the stages of the production chain that will provide information on compliance with the agriculture and livestock sanitary legislation;

VII – Good practices systems at all stages of the production chains;

VIII – Traceability control systems;

IX – Performance evaluation systems and results of control actions, including performance indicators;

X – Norms and recommendations of reference international organizations;

XI – Auditing criteria; and

XII – Structure of annual reports and information they should contain.

Art. 123. A year after the beginning of the implementation of the Agriculture and Livestock Health Multi-year Plans and every year thereafter, progress reports shall be prepared on the work done by the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ, indicating the following:

I – Changes proposed or introduced in the Agriculture and Livestock Health Multiyear Plans;

II – Results of controls and audits performed the previous year, as provided under the Agriculture and Livestock Health Multiyear Plans;

III – Type and number of cases of noncompliance identified and geographic location of major events, preferably with the use of electronic maps; and

IV – Recommendations for improving the execution of the activities called for under the Agriculture and Livestock Health Multiyear Plans.

Art. 124. The report shall be submitted to the National Agricultural Policy Council, which will forward it with its recommendations to the Ministry of Agriculture, Livestock, and Food Supply, which in turn will publicize it to the general public.

CHAPTER IX

RESOURCES AND FINANCING

Art. 125. It is incumbent upon the Three Organs to guarantee the necessary resources for Agriculture and Livestock Health Care Unified System's activities in their respective jurisdictions, in accordance with the pertinent legislation.

Paragraph 1. The Agriculture and Livestock Health Care Unified System Organs may levy fees or charges, pursuant to their respective legislation, to defray the costs incurred during official controls; duplication of charges for services rendered is hereby forbidden.

Paragraph 2. Should different official controls be undertaken simultaneously at a given establishment, the competent authority should consider them as a single activity and levy only one charge for them.

Paragraph 3. A receipt must be obligatorily issued, pursuant to regulations, each time charges are collected.

Art. 126. Based on their own legislation, the Agriculture and Livestock Health Care Unified System Organs may set differentiated fees for services rendered or establish exemptions in specific cases.

Art. 127. The Agriculture and Livestock Health Care Unified System Organs shall publicize their schedule of rates applicable to their services or activities.

Art. 128. The Agriculture and Livestock Health Care Unified System Organs may charge for expenses incurred with additional controls, should any noncompliance detected entail official controls or corrective measures that exceed the competent authority's regular activities, in accordance with the pertinent legislation.

Sole Paragraph. Activities that exceed regular activities include corrective measures and other additional controls to determine the problem's seriousness and its solution.

Art. 129. The Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ may suspend the transfer of resources to the Intermediate and Local Organs in the following cases:

I – Noncompliance with these Regulations and other specific agriculture and livestock health norms;

II – Failure to carry out the activities and achieve the goals envisaged under the Multi-year Agriculture and Livestock Health Plans and in specific projects, should justifications alleged by the pertinent Intermediate and Local Organs authority be deemed unwarranted;

III – Lack of proof of the corresponding counterproof;

IV – Irregular application of financial resources transferred;

V – Lack of proof of the regular feeding and feedback of epidemiologic information systems; and

VI – Lack of timely compliance with formal requests for information.

Sole Paragraph. After analyzing justifications alleged by Intermediate and Local Organs that have led to the suspension of resources transfer, the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ may, on the basis of reasoned technical opinion, resume the transfer of financial resources, extend assistance without prior request, maintain the suspension of resources transfer, or withdraw recognition of the defaulting Organ.

CHAPTER X

INSPECTION OF AGRICULTURAL AND LIVESTOCK PRODUCTS AND INPUTS

Art. 130. As part of the Agriculture and Livestock Health Care Unified System and for the purpose of inspecting and controlling animal and plant products and agricultural and livestock inputs, the Brazilian Systems of Inspection of Agricultural and Livestock Products and Inputs are hereby established, as follows:

I – Brazilian Plant Products Inspection System;

II – Brazilian Animal Products Inspection System; and

III – Brazilian Agricultural and Livestock Inputs Inspection System.

Paragraph 1. The Brazilian Agricultural and Livestock Products and Inputs Inspection Systems shall carry out the following activities:

I – Auditing, inspection, control, certification, and classification of plant products, their byproducts, subproducts, and residues of economic value;

II - Auditing, inspection, control, certification, and classification of animal products, their byproducts, subproducts, and residues of economic value;

III – Auditing, inspection, control, and certification of inputs and services used in agricultural and livestock activities.

Paragraph 2. The activities of the Brazilian Agricultural and Livestock Products and Inputs Inspection Systems shall be carried out in accordance with current agriculture and livestock health and inspection and with the international commitments undertaken by Brazil.

Paragraph 3. Auditing, inspecting, and controlling shall be done without advance notice, except in specific cases when advance notice must be given the person in charge of production.

Paragraph 4. Auditing, inspecting, and controlling shall be done at any stage of production, processing, storage, or distribution.

Paragraph 5. Auditing, inspecting, and controlling as envisaged under the preceding Paragraph 4 shall not be required in connection with foodstuffs, beverages, and water for human consumption under the responsibility of the sanitary surveillance organs that form part of the Unified Health System (SUS).

Paragraph 6. For inspections, hazard analysis and critical control points method may be used, at the competent authority's discretion.

Paragraph 7. Audits, inspections, and controls shall encompass all animal and plant products and agricultural and livestock inputs,

imported or domestically produced, whether destined for exportation or not.

Paragraph 8. At the competent authorities' discretion, inspections may be done on a continuous basis at industrial or agro-industrial plants.

Art. 131. The Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ shall coordinate the Brazilian Agricultural and Livestock Products and Inputs Inspection Systems.

Paragraph 1. The States may join the Brazilian Agricultural and Livestock Products and Inputs Inspection Systems.

Paragraph 2. The Municipalities may also join the Brazilian Animal Products Inspection Systems and the Brazilian Plant Products Inspection System.

Paragraph 3. The Ministry of Agriculture, Livestock, and Food Supply shall, within ninety days of the publication of these Regulations, establish the requirements and procedures for joining the Brazilian Agricultural and Livestock Products and Inputs Inspection Systems.

Paragraph 4. To join the Brazilian Agricultural and Livestock Products and Inputs Inspection Systems, the States must adapt their inspection and control processes and procedures.

Art. 132. The States, the Federal District, and the Municipalities that have not joined or that have decided not to join the Brazilian Agricultural and Livestock Products and Inputs Inspection Systems shall have their inspection and control of animal and plant products and of agricultural and livestock inputs recognized solely within their own jurisdictions.

Paragraph. 1. Subject to a formal request, the Federal Government may provide technical cooperation to the States, just as the States may cooperate with the Municipalities.

Paragraph 2. The Ministry of Agriculture, Livestock, and Food Supply shall perform yearly audits in the inspection services of the States, Territories, and Municipalities.

Paragraph 3. The States shall perform yearly audits in the Municipalities under their jurisdiction.

Art. 133. By joining the Brazilian Agricultural and Livestock Products and Inputs Inspection Systems, the Ministry of Agriculture, Livestock, and Food Supply, the States and the Municipalities shall ensure the following:

I – That inspections and controls will be effective and appropriate at all stages of the production chains;

II – That the technical and support personnel in charge of inspections and controls will be hired solely through public competitive exams;

III – That the technical and support personnel in charge of inspections and controls will have no conflict of interest;

IV – That there will be official or accredited laboratories or access to such laboratories with adequate capacity to perform tests, and staffed with qualified, experienced personnel in sufficient number to perform the official controls efficiently and efficaciously;

V – That there will be adequate, well-maintained facilities and equipment to ensure that the personnel will be able to do inspections and controls safely and effectively;

VI – That there will be assurance of the requisite legal powers to undertake inspections and controls and that the measures contemplated hereunder will be adopted;

VII – That controls and sanitary education activities will be assured;

VIII – That no industrial establishment or entrepot will be able to function in the country without prior registration with the competent organ charged with oversight of its activity;

IX – That clandestine activities will be effectively combated; and

X – That rural and industrial producers and input suppliers, distributors, cooperatives, associations, industrialists and agribusiness entrepreneurs, wholesalers and retailers, importers and exporters, and other entrepreneurs and operators along the production chain will be subjected to inspections or controls performed pursuant to the regulations hereunder and will support the competent authority in the fulfillment of its mission.

Sole Paragraph. By joining the Brazilian Agricultural and Livestock Products and Inputs Inspection Systems, the States and Municipalities undertake the commitment to abide by the fed-

eral legislation or to have equivalent regulations, approved pursuant to the provisions hereunder and to specific norms pertaining to the inspection of animal and plant products, as well as of agricultural and livestock inputs.

Art. 134. The Brazilian Agricultural and Livestock Products and Inputs Inspection Systems shall be responsible for ensuring that the procedures and organization of the inspection of animal and plant products, as well as of agricultural and livestock inputs will use universal methods equitably applied in all inspected establishments.

Art. 135. Audits and technical evaluations shall be geared to the organization, structuring, and proper systematization of inspections and controls in the country and to the improvement of the Brazilian Agricultural and Livestock Products and Inputs Inspection Systems, and shall be performed according to the following procedures:

I – The States inspection services shall be evaluated by the Ministry of Agriculture, Livestock, and Food Supply; and

II – The Municipal inspection services shall be evaluated by the States according to their geographical areas of operation.

Paragraph 1. The Ministry of Agriculture, Livestock, and Food Supply shall provide guidance to the State, and Municipal inspection services as regards compliance with the legal provisions hereunder.

Paragraph 2. Any corrective measures adopted shall be communicated to the organizations representative of society, region, or affected sectors.

Art. 136. Activities under the Brazilian Agricultural and Livestock Products and Inputs Inspection Systems that are incumbent on the States , and Municipalities shall be carried out by public institutions duly recognized by the Ministry of Agriculture, Livestock, and Food Supply.

Art. 137. The States and Municipalities shall designate civil servants as members of teams that will act as the authorities responsible for the inspections and controls contemplated hereunder.

Art. 138. The States and Municipal competent authority may delegate competences pertaining to inspection and control to one or more than one public institution.

Art. 139. The competent authorities of the Brazilian Agricultural and Livestock Products and Inputs Inspection Systems shall ensure the impartiality, quality, and consistency of official controls.

Art. 140. Whenever official control functions are delegated to different public institutions, the delegating competent authority shall ensure the coordination and cooperation among said institutions.

Art. 141. Mechanisms shall be established for the interaction between the Brazilian Agricultural and Livestock Products and Inputs Inspection Systems and teaching and research institutions with a view to the ongoing training, qualification, and education of the professionals involved.

Section 1
Animal Products Inspection and Control

Art. 142. The hygiene and sanitary, technological, and industrial inspection of animal products is incumbent upon the Federal Government, the States and the Municipalities.

Paragraph 1. All animal products, whether they are edible or not, with or without the addition of plant products, must be inspected from both an industrial and a sanitary standpoint.

Paragraph 2. Inspection of animals is done both ante- and post-mortem and encompasses the receiving, handling, processing, preparation, conservation, conditioning, packaging, storage, labeling, transportation, and consumption of any products, subproducts, and residues of economic value, with or without the addition of plant products, whether or not they are destined for human consumption.

Art. 143. No industrial establishment or entrepot dealing with animal products may operate in the country without being registered with the competent organ to ensure the inspection of its activity.

Section II
Inspection of Plant Products and Control

Art. 144. The hygiene and sanitary, technological, and industrial inspection of animal products is incumbent upon the Federal Government, the States and the Municipalities.

Art. 145. The Brazilian Plant Product Inspection System's purpose is to ensure the identity, quality, conformity, fitness, and hygiene and sanitary as well as technological safety of animal products, subproducts, byproducts, and residues of economic value through the inspection, control, and classification of products, systems, or production chain, as the case may be.

Section III

Inspection of Agricultural and Livestock Inputs

Art. 146. The hygiene and sanitary, technological, and industrial inspection of animal products is incumbent upon the Federal Government, the States and the Municipalities.

Art. 147. The Brazilian Agricultural Inputs Inspection and Control System and the Brazilian Livestock Inputs Inspection and Control System are hereby established and shall be structured and organized under the coordination of the Ministry of Agriculture, Livestock, and Food Supply. The two systems shall be responsible for the activities pertaining to the inspection and control of agricultural and livestock inputs.

Art. 148. The purpose of the Brazilian Agricultural Inputs Inspection and Control System and the Brazilian Livestock Inputs Inspection and Control System is to ensure the identity, quality, conformity, fitness, and hygiene and sanitary as well as technological safety of animal products, subproducts, byproducts, and residues of economic value through the inspection, control, and classification of products, systems, or production chain, as the case may be.

Section IV

Equivalence of Services

Art. 149. The Ministry of Agriculture, Livestock, and Food Supply, the States and the Municipalities shall adopt the requisite measures to ensure that the inspection and control of animal and plant products and inputs are done in a uniform, harmonious, and equivalent manner in all States and Municipalities.

Art. 150. The Ministry of Agriculture, Livestock, and Food Supply shall ensure that inspections and controls follow the norms and criteria preestablished by the Brazilian Agricultural and Livestock Products and Inputs Inspection Systems.

Art. 151. The State and Municipal inspection services shall apply to the Ministry of Agriculture, Livestock, and Food Supply for verification and recognition of their equivalence for engaging in interstate trade, in conformity with the procedures for joining the Brazilian Agricultural and Livestock Products and Inputs Inspection Systems.

Sole Paragraph. After the requisite documentation is reviewed and approved, documental and operational audits in the State or Municipal inspection services shall be done by the competent authorities of the Ministry of Agriculture, Livestock, and Food Supply for their adherence to the System.

Art. 152. The State and Municipal services joining the Brazilian Agricultural and Livestock Products and Inputs Inspection Systems shall be recognized as equivalent for the carrying out of their activities, provided they follow the federal norms and regulations and meet the requirements established by the Agriculture and Livestock Health Care Unified System and by the Ministry of Agriculture, Livestock, and Food Supply, and preserve their original administrative features.

Paragraph 1. The States and Municipalities shall ensure that all products, whether or not they are destined for the local, regional, or national market, are inspected and controlled with the same rigor.

Paragraph 2. The competent authorities at the destination must check compliance with the legislation on animal and plant products through nondiscriminatory controls.

Paragraph 3. The States and Municipalities may request specific technical information from the official services that have authorized the delivery of goods from other States or other Municipalities.

Paragraph 4. The States and Municipalities that approve establishments located on their territory pursuant to their respective legislation must inform the Ministry of Agriculture, Livestock, and Food Supply and the other States and Municipalities accordingly.

Art. 153. The requirements for recognition of the equivalence and qualification of inspection services under the Brazilian Agricultural and Livestock Products and Inputs Inspection Systems are as follows:

I – Formal application, in conformity with the requirements and criteria established by the Ministry of Agriculture, Livestock, and Food Supply;

II – Submission of an inspection and control work plan; and

III – Proof of the existence of a structure and staff consistent with their functions.

Sole Paragraph. The application for recognition of the inspection services of States and Municipalities shall be reviewed by the Ministry of Agriculture, Livestock, and Food Supply, which will undertake technical and administrative audits.

Art. 154. Public inspection services under the Brazilian Agricultural and Livestock Products and Inputs Inspection Systems shall be disqualified in the following cases:

I – Noncompliance with the norms or with the approved activities and goals called for under the work plan, which might compromise the objectives of the Agriculture and Livestock Health Care Unified System;

II – Failure to feed the information system and to keep it current; and

III – Failure to comply in a timely manner with formal requests of information.

Art. 155. To achieve the objectives of the Brazilian Agricultural and Livestock Products and Inputs Inspection Systems, the Ministry of Agriculture, Livestock, and Food Supply shall develop, on an ongoing basis, the planning and the management programs pertaining to programs, actions, audits, and other activities necessary for the inspection of animals, plants, and inputs.

CHAPTER XI

FINAL DISPOSITIONS

Art. 156. The competent authorities of the Agriculture and Livestock Health Care Unified System's Three Organs and of public services connected with the Brazilian Agricultural and Livestock Products and Inputs Inspection Systems shall ensure that their activities are carried out with transparence; to this end, they shall grant the public access to relevant information in their possession, particularly as regards control activities.

Sole Paragraph. Agriculture and Livestock Health Care Unified System's Three Organs and the authorities in charge of public services connected with the Brazilian Agricultural and Livestock Products and Inputs Inspection Systems shall have available mechanisms for preventing that confidential information to which they gain access as they undertake official controls, which, by its nature, is covered by professional confidentiality.

Art. 157. The Ministry of Agriculture, Livestock, and Food Supply is hereby authorized, in conformity with the legislation and within its area of competence, to enter into agreements with public entities to ensure complementary support for field actions pertaining to agriculture and livestock health and inspection.

DECREE No. 27.932, OF MARCH 28, 1950

Published in the Official Federal Gazette of march, 30, 1950, Section 1, Page 4873

Approves regulations on the implementation of animal health and inspection mesures.

The President, by the powers invested in him on article 87, paragraph I of the Constitution, and in view of the disposition on article 8 of Law nº 569, of December 21, 1948, hereby declares:

Art. 1. The regulation that accompanies this is approved and signed by the Secretary of States

for Agricultural Matters, in reference to the measures for animal health and inspection mesures referred to Law nº 569, of December 21, 1948.

Art. 2. This Decree shall take effect on the date of the publication, being revoked any contrary dispositions.

Rio de Janeiro, March 28, 1950, 129th of the Independence and the 62nd of the Republic.

EURICO G. DUTRA
CARLOS DE SOUSA DUARTE

REGULATION CONCERNING THE APPLICATION OF MEASURES FOR SANITARY ANIMAL HEALTH AND INSPECTION, AS STATED IN LAW No. 569, OF DECEMBER 21, 1948.

Art. 1. The slaughter of animals contaminated with any zoonosis specified in the following article and the destruction of objects and rural constructions, as public health interest or protection and rural constructions, are hereby authorized by Director of the Animal Health and Inspection Department (D.D.S.A), National Animal Production Department (N.P.A.), the Secretary of Agriculture, by proposition of the Regional Chief of Inspection, in the same Division, and whose jurisdiction the application of the referenced measures applies.

Paragraph I. The compliance with the provisions in this article shall be carried out in the least amount of time possible, after the evaluations mentioned in articles 5 and 6.

Paragraph 2. If the reason for the slaughter of animals justifies immediate attention and is out of the Federal District, the authorization might be given by the Regional Chief Inspector, and later ratified by the Director of Animal Health and Inspection Division.

Art. 2. Animals are subject to slaughter if contaminated by diseases such as glanders, rabies, pseudorabies, tuberculosis, pullorum disease, classical swine fever and any other infectious diseases not officially recognized as existing in the Country, as well as any others that came in contact, direct or indirect, with sick animals, being considered suspected of contamination and could pose a threat of dissemination of the disease as determined by the health authority.

Art. 3. When the slaughter is authorized, pursuant to article 1 of this Regulation, the Regional Chief Inspector of Animal Health Protection shall issue order designating the Evaluation Committee as per the art. 5 of Law 569, of December 21, 1948, and stating the name of the representative from the Federal Government who will be in charge of the Committee Presidency.

Paragraph I. If there is a Rural Association in the region, he/she shall be named the president who can delegate to another trusted member the right to represent him/her on the Evaluation Committee.

Paragraph II. In the event that there is no Rural Association in the region, a farmer of renowned ability, chosen by the interested party, shall be nominated to replace the representative of that entity.

Paragraph III. When the measures stated by art 1 shall be taken in the Capital, the provisions in this article, in the scope of the Regional Chief Inspector, will be taken by the Director of Animal Health and Inspection Division.

Art. 4. When a ruling is made pursuant to the previous article, the authority who draws it up will communicate his/her decision to the state body and to the proper Rural Association, or the latter and the interested party, according to what is stated in paragraph II of the previous article, who will be responsible for taking the necessary measures to have their representative present at the location where the animals will be sanitary slaughtered or objects or rural constructions destroyed.

Art. 5. The assessment of the animals to be sanitary slaughtered will be made based on its value in face of racial characteristics, age, gender, economic purpose and other elements, per the committee's judgment.

Sole paragraph. In the case of things or rural buildings, the assessment will be made based

on the estimated expenses that, determined by the Committee, will be necessary to rebuild or acquire the objects.

Art. 6. The assessment of the animal must be done immediately after its slaughter and necropsy, performed before the Evaluation Committee, in order to confirm the diagnoses.

Paragraph 1. After the necropsy, samples will be collected for further tests at the DNPA laboratory, in case there are questions regarding the diagnostics.

Paragraph 2. As determined by the Evaluation Committee, in case there is conditional use of the animal, the slaughter shall be done at the nearest slaughterhouse, and the Regional Inspector shall be responsible for taking measures to avoid any possibility of dissemination of the disease.

Art. 7. The disposal of bodies, objects and buildings shall be made by deep burial or fire, depending on the case.

Art. 8. The value given by the Evaluation Committee to the sanitary slaughtered animals and objects and buildings destroyed, pursuant to art. 5 and paragraph shall be the basis to calculate the indemnification referred by article 1 of Law 569, of December 21, 1948, per the following items:

I – the indemnification amount shall correspond to the total assessed value:

a) when it is not by the necropsy or later tests;

b) when it is referred to objects or rural buildings, with confirmed diagnoses.

II – if diagnosed with tuberculosis, the indemnification amount shall be a fourth of the assessed value.

III – the indemnification amount shall correspond to half of the assessed value for all other cases, with exceptions stated in paragraph II of this article.

Paragraph 1. When there is conditional use; the indemnification amount will be the difference between what is determined per this article and the amount received from the use, with valid proof, except in the case of breeders with racial characteristics of zootechnical value, in which case there will be no discount.

Paragraph 2. There will be no indemnification when the zoonosis causing the slaughter are rabies, pseudorabies or any other considered incurable or lethal.

Art. 9. After the arbitration of the indemnification, the Evaluation Committee will issue an evaluation report, with three copies, of which the first will be given, as notice, to the interested party, the second will be sent to the DDSA, to be attached to the indemnification process which will be initiated by request of the interested party, pursuant to article 10, and the third will be filed with the respective Regional Inspector or the DDSA, in case it occurs in the Capital.

Paragraph 1. The assessment report mentioned in this article, in addition to other details, as determined by the Committee shall contain:

a) declaration of slaughter of the animal or animals and the destruction of objects or rural buildings;

b) owner's name, nationality, residence and profession;

c) species, breed, approximate age, mark and other characteristics of the animal or animals sanitary slaughtered;

d) nature of the objects and description of the buildings destroyed;

e) assessed value of the animal or animals and the objects or buildings, pursuant to art. 5;

f) necropsy report referred in art. 6;

g) test result referred in paragraphs 1 to 6 if it is the case;

h) assessment amount, calculated according to item in art. 8.

Paragraph 2. There can be recourse to the Evaluation Proceeding, within thirty days, to the Minister of Agriculture, through the Regional Chief, and it should be filed:

a) by a representative of the Federal Government, when it is thought that the evaluation is excessive or the indemnification is not applicable;

b) by the owner of the animal, objects or rural premises, when the indemnification is denied or the evaluation is considered insufficient.

Paragraph 3. The established period in the previous paragraph will begin as of the date of filing, if the recourse is filed by the Federal Government representative, or as of the date the notification is received, if the recourse is filed by the interested raiser.

Art. 10. The interested raiser will have 90 (ninety) days to request the rightful indemnification to the Minister of Agriculture, through the Regional Chief Inspector in the States or the Director of the D.D.S.A., in the capital, who will forward the request with the process that contains the elements for the indemnification arbitration and indicate the funds to cover the expenses, according to art. 6 and its paragraph, of Law nº 569/48.

Sole paragraph – The deadline referred by this article will started as of the date that the animal is slaughtered or object is destroyed; however, the resolution for the request will depend on the previous recourse decision, if it is the case.

Art. 11. The indemnification payment processing will be considered urgent and shall be made in the least amount of time possible.

DECREE No. 24.548 OF JULY 3, 1934

Approves the Animal Health and Inspection Service's Internal Regulations.

Exercising the powers conferred upon him by art. 1st of Decree No. 19,398, dated November 11, 1930, the Head of the Provisional Government of the Republic of the United States of Brazil, decrees:

Art. 1. The regulations herein issued are approved and are to be implemented in the country by the Service of Animal Health and Inspection.

Art. 2. All provisions to the contrary are hereby revoked.

Rio de Janeiro, July 3, 1934, 113th Year of Independence and the 46th of the Republic.

GETÚLIO VARGAS
Juarez do Nascimento Fernandes Távora

REGULATIONS OF THE SERVICE OF ANIMAL HEALTH AND INSPECTION

CHAPTER I

PRELIMINARY PROVISIONS

Art. 1. The Service of Animal Health and Inspection shall implement the prophylactic measures specified in these regulations, in such a way as to protect the country from the invasion of exotic zoonoses and to combat the infectious-contagious and parasitic diseases extant in the territory of the nation.

Art. 2. As a means of defending the national herds, a definitive prohibition is imposed on the entry into the national territory of any animal that has been attacked or which is under suspicion of having been attacked by any diseases, that may be either directly or indirectly transmissible, even when such animals are in an apparently healthy state, while the same prohibition is applicable to animals bearing external and internal parasites which, if disseminated, could constitute a threat to the national herds.

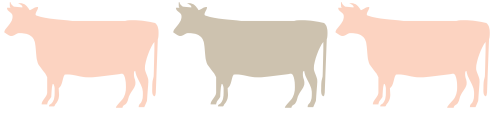
Art. 3. Also prohibited from entering the national territory are animal products or remains, forages or any other material that may be presumed to bear etiological agents of contagious diseases.

Art. 4. The following conditions are essential for entry into the country of animals of foreign origin:

a) presentation of a health certificate of origin, signed by a government veterinarian;

b) presentation, according to each case, of an official certificate of the intradermal tuberculin test, mallein test, serum agglutination test for diagnostic of brucellosis and pullorum disease.

Sole Paragraph. The health certificates



of origin shall only be valid:

a) when they are duly recognized by Brazilian consular authority of the country of origin of the animals;

b) when they attest to the good health of the animals on the day of shipment;

c) when they declare that no infectious-contagious diseases were epidemic in the place of origin, in the forty day period prior to shipment;

Art. 5. Animals originating from countries where trypanosomosis, rinderpest, contagious bovine pleuropneumonia and other exotic contagious diseases exist in epidemic proportions, in and enzootic state will only be permitted to enter the country with the prior authorization of the Director of the Service of Animal Health and Inspection, who shall determine the conditions under which this import operation will be permitted.

Art. 6. The importers should notify the port and border inspection officials of the time of arrival of the animals, at least 24 hours before such time. In cases involving exports, the notification should be given at least 10 days before the departure of the animals, so that they can be submitted to the biological tests referred to in article 4th.

Art. 7. The health certificate of origin shall remain in the possession of the employee responsible for the inspection of the animals, who shall grant a animal movement permit, if the animals be found to possess good health conditions.

Art. 8. In order to avoid the propagation of diseases within the national territory, a health certificate must be supplied for the interstate transit of animals, by sea, river or land transportation, while such a certificate must also be provided for animals to be slaughtered for the supply of the international market.

Sole Paragraph. Infractors of this article shall be subject to a fine of Cr$ 50.00 per animal, and double this amount in cases of repetition.

Art. 9. In the case of interstate transport of breeder animals, by sea, aside from the health certificate of origin, the certificate of the intradermal tuberculin test, mallein test and serum agglutination test for diagnostic of brucellosis should also be presented, depending on the case.

Sole Paragraph. Whenever it is deemed convenient, the Service of Animal Health and Inspection shall demand a serum agglutination test for *S. pullorum* and vaccination against rabies of the dogs.

Art. 10. The Ministry of Agriculture shall take those measures deemed necessary to ensure that the proper federal, state and municipal authorities obey and ensure obedience of the present regulations.

CHAPTER II

PORT AND BORDER INSPECTION

Art. 11. The import and export of animals will only be permitted through the ports and borders that have been duly equipped by the service of Animal Health and Inspection.

Art. 12. Based on the recommendations of the board of the Service of Animal Health and Inspection, the Minister of Agriculture will designate the border posts through which animals may be imported and exported.

Art. 13. In order to fulfill the terms of article 11, Veterinarian Quarantine Centers will be created at the ports of São Salvador, Santos, Rio Grande, while that of Rio de Janeiro will be maintained, and the border posts designated according to the terms of the previous article will be duly equipped.

Sole Paragraph. The Quarantine Centers referred to in this article will be installed as soon as budgetary resources so permit.

Art. 14. Imports and exports of animals are also subject to the following conditions:

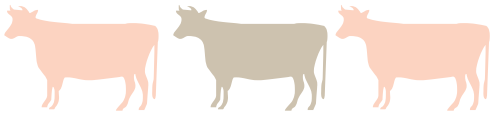
I - that the animals involved be recognized as clinically healthy;

II - that such animals register no positive reactions to the government biological tests, no symptoms of any disease, during the observation period to which they shall be subjected.

Art. 15. Aside from the documents demanded in article 4th, chapter I and its subdivisions, at the moment of the health inspection of imported animals, the respective owner or his representative should present the following information to the proper authority:

a) residence of the owner;

b) destination and objective of the import operation;



c) the number of days spent in travel;

d) if any death occurred among the animals during travel.

Sole Paragraph. The inspection referred to in this article should be carried out in full daylight and requested at least 24 hours beforehand.

Art. 16. Without the health certificate or license issued by the veterinary authority responsible for the inspection, the imported animals, together with forages, boxes and any utensiles that may accompany the animals, will not be permitted to leave the means of transportation utilized in shipment.

Sole Paragraph. The Ministry of Agriculture shall take those measures deemed necessary to ensure that the port authorities obey and see to the obedience of this article.

Art. 17. In exceptional cases, at the discretion of the general director of the DNPA, an animal may be permitted to enter the country without the health certificate of origin, with the condition that such an animal be apparently healthy at the time of unloading, and that it be considered free of disease, after being submitted to observation quarantine and those tests and biological examinations considered necessary.

Art. 18. Should the presence of rinderpest be found, all of the ruminants included in the shipment will be immediately sanitary slaughtered and all prophylactic measures considered necessary will be taken, and the owner of such animals shall have no right to indemnity of any kind whatsoever.

Art. 19. Should the diagnosis show the presence of tuberculosis, paratuberculosis, contagious bovine pleuropneumonia, trypanosomosis, anthrax, blackleg, rabies, pseudorabies, pernicious anemia, brucellosis, glanders, sheep, goat and pig pox, typhus, classical swine fever, contagious caprine pleuropneumonia, malignant catarrhal fever, avian influenza, fowl typhoid and pullorum disease, only those animals that have been attacked will be sanitary slaughtered and the prophylactic measures deemed necessary in each case will be taken, and the owner of such animals shall have no right to indemnity of any kind whatsoever.

Sole Paragraph. The expenses consequent upon the prophylactic measures taken, according to the terms of this article, shall be the responsibility of the owners of the animals.

Art. 20. The sanitary slaughter of the animals as determined in articles 18 and 19 will take place in the presence of the responsible employees of the Service of Animal Health and Inspection and a descriptive statement of this act will be elaborated and signed by the two highest ranking employees present, by the owner or consignee of the animals and by two witnesses.

Sole Paragraph. At the time of sanitary slaughter, the owner or his representative shall have the right to request an autopsy of the animals.

Art. 21. When the autopsy and other examinations of the sanitary slaughtered animal do not show the lesions or pathognomonic characteristics of the diseases cited in articles 18 and 19, the owner shall have the right to payment of indemnity in cash at a value corresponding to the full value of the animal and of the objects that accompanied the animal and which were destroyed.

Art. 22. In the case of imports through the port of Rio de Janeiro, the request for autopsy, as referred to in article 21, should be presented to the director of the Service of Animal Health and Inspection, while in the case of the other ports and border posts cited in article 13, chapter II, such a request should be presented to the head inspectors or inspectors.

Art. 23. When, due to the negligence of the responsible, employee, the requested autopsy is not carried out within 24 hours of the moment in which the animal was sanitary slaughtered, the right of the petitioner to the indemnity cited in article 21 shall be recognized, and the aforementioned employee shall be responsible for the payment of such indemnity.

Art. 24. Should the diagnosis be confirmed by the necropsy, the consequent expenses shall be the responsibility of the interested party that requested the necropsy.

Art. 25. The expenses cited in the previous article shall be paid according to the rates determined by the Ministry of Agriculture, in the form of federal revenue stamps, which shall be rendered useless on the necropsy reports.

Art. 26. In the case specified in article 21, the federal government shall be responsible for the consequent expenses.

Art. 27. When the interested party does not agree with the result of the necropsy, he may request the immediate carrying out of a new examination and, in this case, he may designate a professional of his confidence to verify the results. If the two professionals do not arrive at an agreement, they shall gather authenticated matter for examination at a DNPA laboratory, which shall then resolve the doubt.

Sole Paragraph. In no case shall the remains of the necropsied cadaver fail to be cremated on the same day in which the autopsy was carried out.

Art. 28. In the case specified in article 26, the general director of the National Department of Animal Production shall designate a three member commission, in which the owner or his representative shall participate, to arbitrate the value of the indemnity, while voluntary appeal to the Minister shall be permitted.

Art. 29. The import and export of animals through border posts for purposes of slaughter shall be permitted, independently of the biological tests referred to in line II of article 14, chapter II, with the condition that the animals be in an apparently good state of health, free of ectoparasites and originate from areas in which infectious-contagious diseases are not epidemic.

Sole Paragraph. In this case, notification of the arrival or departure of such animals should be presented at least 24 hours beforehand, so that the respective inspection may be carried out and the respective health certificate issued or received.

Art. 30. The signatures of the director of the Service of Animal Health and Inspection and of the employees authorized to sign certificates for the international export of animals shall be sent, in the quantities demanded by the respective consulates, to the representatives of the governments of those countries that import animals from Brazil.

CHAPTER III

MOVEMENT OF ANIMALS WITHIN THE COUNTRY

Art. 31. Those companies licensed to operate in the river transportation of cattle along the borders of the states should construct a trough for the control of ticks, as well as corrals for the resting of the animals, with resistant flooring to avoid the possibility of the animals becoming mired in mud.

Paragraph 1. The animals transported by river in the barges that are specifically used for this purpose, shall be subject to obligatory health inspection by the Service of Animal Health and Inspection.

Paragraph 2. As soon as the animals have been unloaded, the barges shall be washed and disinfected with products approved by the Board of the Service of Animal Health and Inspection, and the expenses shall be the responsibility of the respective owners.

Art. 32. When transported by railroad, field animals that are destined for slaughter may not be kept on board for periods of more than 72 hours.

Sole Paragraph. The railroad companies should install rest fields for the animals, which should remain in these fields for at least 24 hours when travel time exceeds the period specified in this article.

Art. 33. In the case of breeding animals that can be fed during the trips, there is no necessity of observing the period specified in article 32.

Art. 34. The interstate transit of animals shipped in a standing position may only be done through the points previously determined by the Service of Animal Health and Inspection, on the basis of an agreement with the state authorities.

Paragraph 1. At the points determined by the Service of Animal Health and Inspection, all cattle must be examined on the normal transit roads and a animal movement permit should be issued when they are found to be free of infectious-contagious diseases.

Paragraph 2. Infractors shall be subject to a fine of from Cr$ 50.00 to Cr$ 100.00 per animal, and this amount shall be doubled in the case of repetition.

Art. 35. Animals transported by railroad and destined to the cold storage facilities of slaughter houses involved in international exports shall be inspected in the corrals and loading chutes or on the farms themselves, by employees of the Service of Animal Health and Inspection or by employees of the states, when this task has been entrusted

to them by the Ministry of Agriculture.

Art. 36. Animals destined to other states for slaughter, breeding or fattening shall be examined in the corrals or loading chutes by an employee of the Service of Animal Health and Inspection who shall issue the respective health certificate or by employees of the states, according to the terms of the previous article.

Paragraph 1. At loading points that do not have a specifically designated employee, the Service of Animal Health and Inspection shall see to it that the inspection takes place at another locality indicated beforehand in special instructions, before the trains transporting the animals cross the border of the neighboring state.

Paragraph 2. Trains transporting animals infected by foot-and-mouth disease or other diseases, when the dissemination of such diseases could constitute a threat to the herds of the region, shall be impeded from continuing and shall be reconducted to their points of departure, while all expenses shall be the responsibility of the owners.

Paragraph 3. With the exception of special cases, determined at the discretion of the director of the Service of Animal Health and Inspection, the complaints presented by the owners of animals that have been impeded from being shipped shall only be considered when the animals are once more at their point of departure or when they have been reconducted to the same.

Art. 37. The railroad companies that transport animals are obligated to construct freight cars considered suitable to the different species.

Art. 38. The railroad companies, navigation companies or any other companies involved in the transportation of animals are obligated to clean and disinfect their livestock cars, vehicles, vessels and boxes, as well as the sites of loading or unloading, corrals, loading chutes and all other facilities and localities that have been occupied by the animals.

Art. 39. The demands determined in article 38 are subject to the direct inspection of the Service of Animal Health and Inspection.

Paragraph 1. The vehicles should be washed and disinfected within a maximum period of 24 hours after unloading.

Paragraph 2. When suitable installations exist, the cars or any other vehicles that have transported animals to cold storage plants and slaughter facilities should be cleaned and disinfected immediately after unloading.

Paragraph 3. Infractors shall be subject to a fine of from Cr$ 500.000 to Cr$ 1,000.00, such amount being doubled in the case of repetition.

Art. 40. The methods of cleaning and disinfecting to be utilized and the disinfecting substances to be adopted shall be determined in instructions to be approved by the Minister.

Art. 41. In cases of epizootic outbreaks, the Service of Animal Health and Inspection may, on the basis of instructions approved by the Minister, take measures aimed at making those specific in these regulations more severe.

Art. 42. The facilities for disinfecting the railroad cattle cars shall be constructed at the expense of the companies themselves, which shall also be responsible for the costs of the cleaning and disinfecting material and for the payment of the personnel demanded for this Service.

Sole Paragraph.To cover these expenses, the companies shall charge the rates specified in law.

Art. 43. The construction projects and budgets of the disinfection facilities shall be organized by the transportation companies, on the basis of plans supplied by the Board of the Service of Animal Health and Inspection, and should include specifications as to the channelling of water, energy, light, drainage of residues and details of the construction.

Art. 44. The disinfection facilities will be installed at the posts indicated by the Board of the Service of Animal Health and Inspection, while the choice of the localities should be based on the points that are indicated naturally by the traffic, the sidings of slaughter facilities, cattle fairs and expositions.

Art. 45. After being cleaned and disinfected, the vehicles, livestock cars or other facilities may only be withdrawn from the disinfection centers and utilized, after inspection on the part of an employee of the Service of Animal Health and Inspection, who shall place a tag on the unit containing the word “disinfected”, together with the date and his signature.

Art. 46. In the case of death during trans-

portation, the cadaver should be immediately necropsied at the site of unloading, in order to establish the cause of death and the recommended health measures that should be applied.

Art. 47. Infractorts of the health measures determined in the previous article will be subject to a fine of from Cr$ 300.00 to Cr$ 1,000.00, such amount being doubled in the case of repetition.

Art. 48. The interested parties may take advantage of the residual product of the cleaning of the livestock cars for purposes of fertilization, with the condition that measures be taken on the basis of a process approved by the Service of Animal Health and Inspection to make this product harmless.

Art. 49. For the purposes of the provisions of article 42 and in relation to the railroads pertaining to the federal government, the Ministry of Agriculture shall come to an agreement with the Ministry of Transportation in order to transfer to the latter, on the basis of an assessment, the present disinfection centers located in Santa Cruz, Barrra do Piraí and Carlos de Campos, on the "Estrada de Ferro Central do Brasil".

CHAPER IV

IMPORTS AND EXPORTS OF PRODUCTS OF ANIMAL ORIGIN

Art. 50. The import of products of animal origin is prohibited, when such products are not accompanied by a health certificate supplied by the proper authority of the country of origin.

Art. 51. Such certificates will only be valid:

a) when the models and forms are approved by the Ministry Of Agriculture;

b) when they are recognized by Brazilian consular authorities;

c) when the inspection regulations of the products of animal origin of the countries of origin are approved by the Brazilian health authorities;

d) when the products originate in inspected establishments.

Art. 52. The certificates that accompany the imported products destined for human consumption shall be recognized by the employees of the Service of Animal Health and Inspection for the purposes of the provisions of the previous article and transmitted to the health authorities of the DNSP, which shall be responsible for inspecting such products at the consumer centers.

Art. 53. In cases involving hides, furs, wool, horns, hair, etc. for industrial purposes, such products shall only be unloaded when the respective certificates contain a declaration that they originate in areas free of outbreaks of anthrax, foot-and-mouth disease and rinderpest.

Art. 54. Edible products of animal origin elaborated within the country shall only have free transit through the ports and border posts when they originate in inspected establishments and are accompanied by certificates of hygiene, supplied by the Inspection Service of Products of Animal Origin.

Pararaph 1. The certificates referred to in this article shall be valid for a maximum period of one month and shall be controlled by the competent employees of the Service of Animal Health and Inspection.

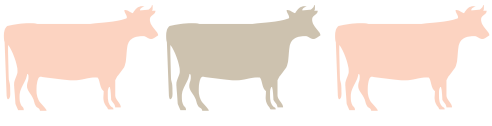
Pararaph 2. Infractors shall be subject to a fine of from Cr$ 500.00 to Cr$ 1,000.00, such amount being doubled in the case of repetition, while clearance of the products shall be denied to them.

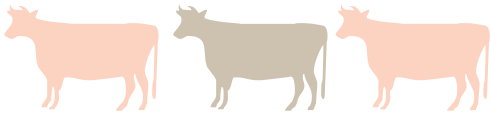
Art. 55. Once it has been verified during unloading that the products originated in establishments registered and inspected by the SIPOA, the certificates accompanying such products will be recognized and transmitted to the health authorities of the DNSP or of the states, for the purposes of the provisions of article 52.

Art. 56. When products originating in factories in the interior of the country are not loaded in a single shipment or are destined to diverse ports, the employees of the Service of Animal Health and Inspection may make multiple use of the certificates accompanying such products, utilizing the same models of the SIPOA, indicating the name and headquarters of the factory and the name of the employees who signed the certificate of origin.

Sole Paragraph. The certificates of origin should be filed for purposes of control.

Art. 57. Products of animal origin for industrial purposes that originate in establishments that are not registered in the SIPOA, such as leathers, wools and hides of wild animals, shall





only have free transit when they originate in areas where there are no current outbreaks of foot-and-mouth disease, in the case of untreated leathers, or anthrax, in any case whatsoever, is they are accompanied by the certificate issued by the Service of Animal Health and Inspection.

Pararaph 1. When such products are destined to international commerce, the certificate that will permit the shipment of the same will only be provided after disinfection through the use of a process approved by the SDSA.

Pararaph 2 - Such certificates will be provided in the same model used by the SIPOA.

CHAPTER V

INSPECTION OF MARKETS AND FAIRS OF LIVE CATTLE

Art. 58. Live cattle fairs and markets may only operate when they are inspected by the SDSA and are duly equipped, making it possible for the Service to carry out its responsibilities of health control.

Sole Paragraph. The facilities that obey the model approved by the Board of the SDSA shall include a sufficient number of corrals, with resistant flooring to avoid the possibility of the cattle becoming mired, administrative installations, with an office for the employee responsible for the health inspection of the animals, a corral for the isolation of diseased animals, a trough for the control of ticks and facilities equipped with an necropsy room and crematorium.

Art. 59. When cases of infectious-contagious disease are found in the animal on exposition, the fair will be closed and, in the case of anthrax or blackleg, all of the animals pertaining to the group in which the disease was found will be vaccinated free of charge, while the interested parties shall be responsible only for the cost of the vaccine.

Art. 60. The animals form other states that participate in the cattle fairs should be accompanied by health certificates supplied by employees of the SDSA, a technical employee of another service subordinated to the DNPA and duly authorized for this purpose, or state employees, in keeping with the terms of the provisions of article 35.

Sole Paragraph. When the animals originate in the same state or in areas where there are no outbreaks of infectious-contagious disease, the animals will be examined in a locality near the fairs before entry into the respective areas of the fairs will be permitted.

CHAPTER VI

INFECTIOUS DISEASES PROPHYLAXIS

Art. 61. The diseases specified below are subject to the application of the measures of animal health and Inspection determined in these regulations:

Rinderpest - in ruminants;

Foot-and-mouth disease - in ruminants and pigs;

Rabies and pseudorabies - in mammals;

Tuberculosis - in cattle, pigs and fowl;

Anthrax - in ruminants, pigs and equines;

Blackleg and Contagious bovine pleuropneumonia - in cattle;

Brucellosis - in ruminants, pigs and equines;

Salmonellosis - in cattle, pigs and fowls;

Pasteurellosis - and mammals and fowl;

Trypanosomosis - in mammals;

Piroplasmosis - in ruminants, equines and canines;

Anaplasmosis - in cattle;

Glanders - in equines, asses and mules;

Enzootic Encephalitis - in equines;

Classical swine fever - in pigs;

Granular vaginitis and malignant catarrhal fever - in bovine;

Coccidiosis - in mammals and fowl;

Psittacosis, avian spirochaetosis, diphtheria and avian influenza - in fowl;

Scabies - in ruminants, equines, pigs, fowl and small domestic animals;

Sole Paragraph. At the proposal of the director of the SDSA based on the results of scientific studies and investigations of any origin, this list of diseases may be altered by the Minister or Agriculture.

Art. 62. Measures equivalent to those mentioned above shall be taken respect to any animals of any species that may be bearers of the

virus of the diseases cited in the previous article, even though such animals may be not susceptible to those diseases.

Art. 63. In the interests of animal health and Inspection or public health, the sanitary slaughter of all animals infected by the following zoonoses is obligatory: glanders, rabies and pseudorabies, tuberculosis, pullorum disease, classical swine fever.

Sole Paragraph. In the case of rinderpest, contagious bovine pleuropneumonia, paratuberculosis or any other infectious-contagious disease that is not officially recognized as existent in the country, it will be obligatory to sanitary slaughter both the animals that have been infected and those others that may be necessary to defend the nation's herds.

Art. 64. The animals that have been infected by or are suspected of bearing the diseases listed in the paraghaph of the previous article shall, when the sanitary slaughter of the same has been requested, will be sanitary slaughtered before two witnesses of good repute within a maximum period of 24 hours after the owner or the one responsible for such animals has received the order of sanitary slaughter, issued by the director of the SDSA or by one the head inspectors of the Regional Inspection offices of the same Service.

Pararaph 1. When the employee of the Service of Animal Health and Inspection finds difficulty in carrying out the measures described in this article, he shall request the material support needed to fulfill his duties from the federal authorities.

Pararaph 2. Those owners who hinder the carrying out of the terms of the present article shall be subject to fines of from Cr$ 200.00 to Cr$ 1,000.00, such amounts being doubled in the case of repetition.

Art. 65. Animals that have been infected or are suspected of bearing contagious diseases and which, in the interests of science, are maintained in quarantine centers and teaching establishments or scientific institutions are not subject to the measures specified in articles 2nd and 3rd.

Art. 66. If the owner of an animal scheduled for sanitary slaughter contests the diagnosis, it is permitted to proceed according to the terms of the paraghaph of article 20.

Sole Paragraph. While the clarifying test are being carried out, the animal shall be maintained in rigorous quarantine and the property or locality shall be interdicted, without prejudice to the other prophylactic measures that may be recommended in each case, while the owner shall be responsible for all expenses involved.

Art. 67. The competent municipal, state and federal authorities and the veterinary doctors shall indicate to the employees of the SDSA those establishments where an animal has been infected or is suspected of bearing one of the diseases specified in article 61 or whether there have been violations of the measures of quarantine isolation or interdiction, as defined in these regulations, or violations of any orders issued for the purpose of avoiding the contagion of such diseases.

Art. 68. Should a transmissible diseases occur in one of the normally utilized means of transportation, at the first point of health inspection, the vehicle shall be submitted to the most efficient possible disinfection, after the animals have been unloaded.

Art. 69. At the discretion of the responsible veterinary authority or his representative, all animals that are to take part in expositions or fairs may be detained for observation, isolation or disinfecting at ports, borders, loading facilities, roads, etc.

Art. 70. In order to avoid the propagation of piroplasmosis and anaplasmosis, the federal government shall, on the basis of agreements to be made with the local government and when financial conditions so permit, set off the areas infested with tics and those free of tics and shall construct troughs for the control of tick infection in the most suitable points.

Art. 71. Measures of a special character involving the prophylaxis of each contagious disease will be determined in instructions approved by the Minister of Agriculture.

Art. 72. Notification shall be presented by the employees of the Service of Animal Health and Inspection to the proper authorities with respect to the diseases of fish, feather fowl of hunt and furred animals of hunt, as determined in the regulations of the Service of Hunting and Fishing.

CHAPTER VII

VETERINARY ASSISTANCE

Art. 73. In order to make the efforts against infectious-contagious diseases more efficient, a service of health advertising, dissemination and education will be organized and will involve the free distribution of pamphlets, leaflets, brochures, posters or monographs, as well as conferences to be proffered by its technical staff.

Art. 74. Acting through its technical staff, the Service of Animal Health and Inspection will provide free cooperation to breeders in the rendering of veterinary assistance to their herds.

Pararaph 1. The veterinary assistance referred to in this article will consist of the vaccination and revaccination of the herds, identification, prophylaxis and treatment of contagious, infectious-contagious, and internal and external parasitic diseases.

Pararaph 2. the vaccines and other biological products utilized in the vaccination and treatment of the herds shall be acquired by the livestock farmers, while application on the part of the employees of the SDSA will be entirely free of charge.

Pararaph 3. The transportation of the employees by railroad to the point nearest the farms of the interested party will also be free of charge, while transportation will be provided by the interested parties to such employees from the aforementioned points to their respective farms.

Art. 75. Requests presented by farmers for verification of diseases in animals must be attended following the order in which such requests enter the Service of Animal Health and Inspection.

Sole Paragraph. At the discretion of the director and the head inspectors, preference will be given to those cases which, by their nature, demand immediate measures.

CHAPTER VIII

THE NATIONAL COUNCIL OF ANIMAL HEALTH AND INSPECTION

Art. 76. The National Council of Animal Health and Inspection is hereby instituted within the Ministry of Agriculture and has the following objectives:

a) to study and propose to the Minister both complementary measures of animal health and inspection and those specified in these regulations, as well as others which may be deemed necessary;

b) to express its opinion on cases that have been omitted and on interpretations regarding the carrying out of these regulations;

c) to judge, at the level of appeal, the penalties that are applied for infractions against these regulations.

Art. 77. The National Council of Animal Health and Inspection shall be composed of both permanent and consulting members.

Pararaph 1. The following shall be permanent members:

The Minister of Agriculture;

The General Director of the National Department of Animal Production;

The Director of the Service of Animal Health and Inspection;

The Director of the Service of Inspection of Products of Animal Origin;

The Director of the Institute of Animal Biology.

Pararaph 2. the consulting members shall be the other directors, the presidents of the nation's rural associations, assistant heads and the employees of the technical divisions of the Ministry of Agriculture, who shall take part in the meetings when they are called upon by the Minister or by the acting president.

Pararaph 3. An employee designated by the Minister will act as secretary of the National Council of Animal Health and Inspection.

Art. 78. The National Council of Animal Health and Inspection shall meet at a previously determined time, day and locality, under the presidency of the Minister or, in his absence, of the general director of the DNPA who, when unable to attend, shall be substituted by the Director of the Service of Animal Health and Inspection.

Art. 79. All of the decisions of the National Council of Animal Health and Inspection shall be taken by majority vote of the members present.

Art. 80. The Council shall meet and delib-

erate with a majority of its members. However, when the subject at hand is not considered urgent, a copy of the minutes may be sent to those absent, so that they too can express an opinion on the matters discussed.

Sole Paragraph. The decisions of the National Council of Animal Health and Inspection will be published in the Federal Official Gazette.

Art. 81. whether the decisions are taken according to the terms of articles 79 or 80, the employees responsible for their execution shall be notified by the director member of the Council to whom they are hierarchically subordinate.

CHAPTER IX

GENERAL PROVISIONS

Art. 82. the technical functions involved in animal health and inspection and included in these regulations shall be exercised by the Service of Animal Health and Inspection, in all parts of the territory of the Republic.

Paragraph 1. In the carrying out of these regulations, the Service of Animal Health and Inspection shall further strict collaboration with the other services of the DNPA.

Art. 83. By means of the presentation of their professional identity cards, the employees responsible for the carrying out of these regulations will have free access to rural properties, official breeding establishments, storage areas, warehouses, railroad stations, airports, ships whether they are docked or not, customs facilities or any other place where there may exist animals or animal remains to be inspected.

Sole Paragraph. The employees cited herein may request the assistance of the public power for those measures which may become necessary in the implementation of these regulations.

Art. 84. Should it become necessary to carry out a task of an experimental nature or to acquire knowledge with respect to the work being performed at other establishments, the director of the SDSA is hereby authorized to request the collaboration of the heads of these establishments.

Art. 85. In the case of tasks performed outside the normal working schedule, at the express request of private parties the employees involved shall receive bonuses previously defined in directives issued by the Minister of Agriculture.

Art. 86. The cases omitted from these regulations or which demand posterior instructions shall be settled by means of directives issued by the Minister of Agriculture, after the opinion of the National Council of Animal Health and Inspection has been duly heard.

Art. 87. The present regulations shall go into effect on the date of their publication.

Juarez do Nascimento Fernandes Távora
Rio de Janeiro, July 3, 1934

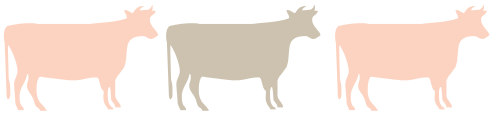
(Published in the Federal Official Gazette, 07.14.34)

COMPLEMENTARY LEGISLATION

DECREE-LAW No. 818 OF SEPTEMBER 5, 1969

Published in the Federal Official Gazette of September 8, 1969, Section I, Page 7569

Provides on the acceptance, by the Ministry of Agriculture, for purposes related to Animal Health and Inspection, of certificates issued by veterinary doctors not connected with Civil Service, and makes other provisions.



DECREE-LAW No. 8911 OF JANUARY 24, 1946

Published in the Federal Official Gazette of January 30, 1946, Section I, Page 1511

Provides for the execution of cleaning and disinfection services in means of transportation used in the movement of live animals, and makes other provisions.

ADMINISTRATIVE RULING No. 24 OF NOVEMBER 28, 1977

Published in the Federal Official Gazette of December 16, 1977, Section I, Page 17314

Regulates the accreditation of veterinary doctors not connected with Civil Service.

ADMINISTRATIVE RULING No. 9 OF JANUARY 8, 1970

Published in the Federal Official Gazette of January 13, 1970, Section I, Page 250

Approves the norms pertaining to the acceptance, by the Ministry of Agriculture, of zoo-sanitary certificates issued by veterinary doctors not connected with Civil Service.

ANIMAL AND PLANT HEALTH AND INSPECTION SECRETARIAT

ADMINISTRATIVE RULING No. 45 OF MARCH 22, 2007

Published in the Federal Official Gazette of March 23, 2007, Section I, Page 6

Approves the Animal and Plant Health and Inspection Secretariat's Internal Regulations, as hereto annexed.

THE MINISTER OF AGRICULTURE, LIVESTOCK, AND FOOD SUPPLY, by virtue of the powers vested in him by Art. 4 of Decree No. 5351 of January 21, 2005 and having in view Procedure No. 21000.008272/2005-41, decides as follows:

Art. 1. To approve the Animal and Plant Health and Inspection Secretariat's Internal Regulations, in the form of the Annex hereto.

Art. 2. This ADMINISTRATIVE RULING shall enter into force on the date of its publication.

Art. 3. ADMINISTRATIVE RULING no. 574 of December 8, 1998 is hereby revoked.

LUÍS CARLOS GUEDES PINTO

PART II

Animal Health and Inspection Programs

NATIONAL PROGRAM FOR THE ERADICATION AND PREVENTION OF FOOT-AND-MOUTH DISEASE

LAW No. 11515 OF AUGUST 28, 2007

Published in the Official Gazette of August 28, 2007, Section 1, Page 1

Modifies provisions of Law No. 569 of December 21, 1948, which establishes animal health and Inspection measures

THE PRESIDENT OF THE REPUBLIC. Know all men that the National Congress has decreed and I have sanctioned the following Law:

Art. 1. Arts. 6 and 7 of Law 569 of December 21, 1948 shall now enter into force with the following modifications, while Art. 6's Sole Paragraph shall now become Paragraph 1 of Art. 6:

"Art. 6 .....

Paragraph 1. .....

Paragraph 2. If, under the provisions of the preceding Paragraph 1, animals are sanitary slaughtered on properties situated on a 150-km wide strip along borders, known as a border strip, and if said animals are sanitary slaughtered owing to the application of sanitary measures for combating or eradicating foot-and-mouth disease, full indemnity shall be paid by the Federal Government.

Art. 7. The right to claim the indemnity expires 180 days as of the date of an animal's sanitary slaughter or of an item's destruction."

Art. 2. This Law shall enter into force on the date of its publication.

Brasília, August 28, 2007, the 186th year of Independence and the 199th of the Republic.

LUIS INÁCIO LULA DA SILVA
Reinhold Stephanes
Paulo Bernardo Silva

ADMINISTRATIVE RULING No. 4 OF JANUARY 21, 2000

Published in the Official Gazette of February 25, 2000, Section 1, Page 12

Modifies Annex I of Administrative Ruling No. 50 of May 19, 1997

THE MINISTRY OF AGRICULTURE, LIVESTOCK, AND FOOD SUPPLY'S SECRETARY FOR AGRICULTURE AND LIVESTOCK HEALTH AND INSPECTION, by virtue of the powers vested in him under Art. 83, IV of this Office's Internal Regulations approved under Ministerial Administrative Ruling No. 574 of December 8, 1998, hereby resolves as follows:

Art. 1. To modify Annex I to Art. 5 of Administrative Ruling No. 50 of May 19, 1996, which shall enter into force as follows:

ANNEX I

FOOT-AND-MOUTH DISEASE RISK LEVEL CLASSIFICATION

RISK LEVEL	BR-D NEGLIGIBLE RISK	BR-1 MINIMAL RISK	BR-2 LOW RISK	BR-3 MEDIUM RISK	BR-4 HIGH RISK	BR-N UNKNOWN RISK
Prevention / Eradication / Control Program	Prevention	Prevention / Eradication	Eradication	Eradication	Limited Control	None
Program Coverage	Total	Total	Total	Total	Total or partial	None
Neighboring areas' status	BR-D or BR-1	BR-1, BR-2	BR-2 or BR-3*	BR-3 or BR-4	NR-N	-
Veterinary Care System	Good	Good	Good	Good	Fair or deficient	None or deficient
Surveillance System	Good	Good	Good	Good	Fair or deficient	None or deficient
Occurrence of clinical cases	None for over five years	None for over three years	None for one to two years	Low or none	High or unknown	Unknown
Vaccination coverage	None	> 90%	> 90%	= or > 80%	< 80%	Very low
Viral activity	None	None	None	Yes	Yes	Unknown
Virus handling biosecurity	Yes	Yes	Yes	No	No	No
Entry prohibition / restriction	Yes	Yes	Yes	Yes	None	None
Control of the entry of animals	Yes	Yes	Yes	Fair	Deficient	None
Community participation	Good	Good	Good	Good	Fair or none	None

* Natural Barrier to or Prohibition/Restriction of the entry of animals and products.

Art. 2. This Administrative Ruling shall enter into force on the date of its publication.

LUIZ CARLOS DE OLIVEIRA

ADMINISTRATIVE RULING No. 50 OF MAY 19, 1997

Published in the Official Gazette of May 23, 1997, Section 1, Page 10760

Modified by Administrative Ruling No. 4 of January 21, 2000

Approves the technical criteria for the classification of foot-and-mouth disease risk levels in the States.

THE SECRETARY FOR AGRICULTURE AND LIVESTOCK HEALTH AND INSPECTION, by virtue of the powers vested in him under Art. 83 of this Office's Internal Regulations approved under Ministerial Administrative Ruling Nº. 319 of May 6, 1996,

Whereas there is a need to introduce appropriate mechanisms for the planning of actions under the National Program for the Eradication of Foot-and-Mouth Disease (PNEFA) in the States so as to maintain or improve their sanitary status so far achieved;

Whereas risk analysis pursuant to the principles established under the WTO Agreement on the Application of Sanitary and Phytosanitary Measures and the International Zoosanitary Code of the World Organization for Animal Health (OIE) is the most appropriate method for defining zoosanitary norms for the trade in animals and animal products;

Whereas the strategies for the regionalization of the actions planned for FMD's eradication are consistent with the technical criteria for zoning and regionalization under the International Zoosanitary Code;

Whereas there is a need to establish zoosanitary norms and procedures pertaining to the movement of live animals and animal products susceptible of being vehicles of the FMD virus among the States,

RESOLVES:

Art. 1. To approve technical criteria for classifying the levels of FMD risk in States pursuant to the following risk indicators or factors:

(a) Program phase: prevention, eradication, or control;

(b) Geographical area covered by PNEFA;

(c) Sanitary status of neighboring areas;

(d) Veterinary health system;

(e) Sanitary surveillance system;

(f) Occurrence of FMD clinical cases;

(g) Vaccination coverage;

(h) Absence/presence of viral activity;

(i) Biosecurity pertaining to virus manipulation;

(j) Prohibition/restriction of the entry of animals;

(k) Control of the entry of animals and animal products; and

(l) Level of community participation.

Art. 2. To establish the following six risk categories: BR-D, or negligible risk; BR-1, or minimal risk; BR-2, or low risk; BR-3, or medium risk; BR-4, or high risk; and BR-N, or unknown or unclassified risk, negligible risk being the lowest risk of FMD transmission, while the other levels show a gradually increasing risk.

Art. 3. The evaluation of each state and their classification according to their risk level will be done by this Secretariat's Animal Health and Inspection Department and should indicate the quality and the technical and operating capacity of their veterinary services, as well as their sanitary status regarding foot-and-mouth disease.

Sole Paragraph. Classification shall be dynamic and may change as the risk situation changes owing to the disease's occurrence or to a change in any of the risk factors pointed out above.

Art. 4. The planning of sanitary actions aimed at foot-and-mouth disease's eradication and the establishment of norms pertaining to the interstate movement of foot-and-mouth susceptible animals and their products and subproducts, as well as the procedures to be adopted for reducing the risk of dissemination of the foot-and-mouth disease virus throughout the states must be based on the risk classification done by the Animal Health and Inspection Department.

Art. 5. To approve the following Tables hereto annexed:

Annex I – FMD risk classification;

Annex II – Criteria for Classification of the Veterinary Health Care System; and

Annex III – Criteria for Classification of the Sanitary Surveillance System.

Art. 6. This Administrative Ruling shall enter into force on the day of its publication.

ENIO ANTONIO MARQUES PEREIRA

ANNEX I

CLASSIFICATION OF FOOT-AND-MOUTH DISEASE RISK LEVELS

Modified by Administrative Ruling No. 4 of January 21, 2000

ANNEX II

CRITERIA FOR CLASSIFICATION OF THE VETERINARY HEALTH CARE SYSTEM

HUMAN RESOURCES	No. of Veterinary Doctors No. of Technical Assistants No. of Administrative Assistants Other categories
HUMAN RESOURCES POLICY	Working status Job and salary structure Training Motivation
STRUCTURE	No. of Regional Offices No. of Local Offices No. of vehicles
VEHICLES	Average age Condition
COMMUNITY PARTICIPATION	No. of state Associations No. of local Associations
FINANCIAL RESOURCES	Sufficient amount Timeliness
LEGISLATION	Current
MATERIALS AND EQUIPMENT	To address outbreak Office
MOBILIZATION CAPACITY IN EMERGENCIES	Prompt attention Swift mobilization of human, physical, and financial resources
SANITARY EDUCATION	—

ANNEX III

CLASSIFICATION CRITERIA FOR THE SANITARY SURVEILLANCE SYSTEM

REGISTER OF ESTABLISHMENTS	% of registered establishments
CONTROL OF THE ENTRY OF ANIMALS	No. of fixed checkpoints No. of mobile checkpoints No. of entry highways
CONTROL OF INTERNAL MOVEMENT	No. of mobile checkpoints No. of Animal Movement Movement Permits issued
VACCINATION INSPECTION	% of inspected properties No. of infraction bookings
COMMUNITY PARTICIPATION	% of notifications by owners No. of local Associations
VACCINE SALES INSPECTION	No. of inspected selling establishments No. of vaccine doses sold
MATERIAL COLLECTION	% of collection
COMMUNICATION	Telephone Fax Computers Radio
INSPECTION OF EXPOSITIONS, FAIRS, AUCTIONS, AND OTHER ANIMAL AGGLOMERATIONS	Presence of veterinary services Inspection and control actions Cleaning and disinfection
ATTENTION TO OUTBREAKS	Intervened Interdiction Traceability Disinfection Perifocal vaccination Sanitary slaughter

NORMATIVE INSTRUCTION No. 63 OF DECEMBER 17, 2008

Published in the Official Gazette of December 18, 2008, Section 1, Page 48

Approves the Guidelines for the Implementation of the Veterinary Surveillance System in the Foot-and-Mouth Disease High Surveillance Zones (ZAVs) established along the borders between the State of Mato Grosso do Sul and the Republics of Paraguay and Bolivia, pursuant to the Annex hereto.

THE MINISTER OF AGRICULTURE, LIVESTOCK, AND FOOD SUPPLY, by virtue of the powers vested in him under Art. 87, Sole Paragraph, II of the Constitution, having in view the provisions of Decree No. 5741 of March 30, 2006; the Regulations of the Animal Health and Inspection Service, approved by Decree No. 24548 of July 3, 1934; Normative Instruction No. 44 of October 2, 2007; and Proceeding No. 21000.010691/2008-95,

RESOLVES:

Art. 1. To approve the Guidelines for the Implementation of the Veterinary Surveillance System in the Foot-and-Mouth Disease High Surveillance Zones (ZAVs) established along the border between the State of Mato Grosso do Sul and the Republics of Paraguay and Bolivia, pursuant to the Annex hereto.

Paragraph 1. The aforementioned ZAVs encompass a strip of land approximately 15-km wide belonging to the Municipalities of Porto Murtinho, Caracol, Bela Vista, Antônio João, Ponta Porã, Aral Moreira, Coronel Sapucaia, Paranhos, Sete Quedas, Japorã, Mundo Novo, Corumbá, and Ladário in the State of Mato Grosso do Sul.

Paragraph 2. The ZAVs' boundaries shall be set on the basis of the geographical boundaries of rural properties situated in an approximately 15-km wide strip beginning at the border and consisting preferentially of natural barriers or, in the absence of such, of specific elements that facilitate the identification of their boundaries and permit better control of livestock undertakings and veterinary surveillance actions.

Paragraph 3. It is incumbent on the state veterinary service to define the ZAVs' geographical boundaries and to execute the veterinary surveillance actions defined in the technical manuals issued by the Animal and Plant Health and Inspection Secretariat through the Animal Health Department, and with the specific guidelines hereunder.

Paragraph 4. Rural properties, producers, and livestock establishments located in the ZAVs, which have foot-and-mouth susceptible animals shall be specifically identified in the state veterinary service's register and information system, which must be kept current and made available when required for animal health actions and by Official Veterinary Services of the other states, as well as of the Republics of Paraguay and Bolivia.

Paragraph 5.The individual identification system referred to in the preceding Paragraph 4 is mandatory and shall be introduced and controlled by the state veterinary service, which, on the basis of technical evaluation, may employ other existing systems, provided there is no prejudice to the sanitary controls and procedures adopted in the ZAVs.

Paragraph 6. Rural properties encompassed by ZAVs and near their geographical boundaries should be fully included in them.

Art. 2. To authorize the Animal and Plant Health and Inspection Secretariat to issue complementary norms consistently with the unfolding of the work in the High Surveillance Zones established along the border between the state of Mato Grosso do Sul and the Republics of Paraguay and Bolivia.

Art. 3. This Normative Instruction shall enter into force on the date of its publication.

Art. 4. SDA Normative Instructions No. 6 of February 2008 and No. 19 of April 14, 2008 are hereby revoked.

REINHOLD STEPHANES

GUIDELINES FOR THE IMPLEMENTATION OF THE VETERINARY SURVEILLANCE SYSTEM IN THE FOOT-AND-MOUTH DISEASE HIGH SURVEILLANCE ZONES (ZAVs) ESTABLISHED ALONG THE BORDER BETWEEN THE STATE OF MATO GROSSO DO SUL AND THE REPUBLICS OF PARAGUAY AND BOLIVIA

Art. 1. Veterinary surveillance actions carried out in the Foot-and-Mouth Disease High Surveillance Zones (ZAVs) shall follow MAPA's general guidelines, including the specific actions called for hereunder.

Art. 2. The state veterinary service shall maintain a structure consistent with veterinary surveillance actions, having in view the establishment and maintenance of the following items in the ZAVs:

I – A local veterinary unit in each municipality;

II – A permanent staff of at least two veterinary doctors per local veterinary unit;

III – Fixed inspection checkpoints at entry locations;

IV – Mobile inspection teams;

V – Cartographic maps, both printed and in electronic form, showing the boundaries and the identification of all rural properties located in the ZAVs; these maps should be available at all offices serving the community; and

VI – Adequate communications and displacement structure.

Paragraph 1. The fixed inspection checkpoints shall be established at the following locations:

I – Amambai Municipality, Route MS 289, Latitude 23.1983, Longitude 55.2939;

II – Amambai Municipality, Route MS 485, Latitude 23.1030, Longitude55.2643;

III – Antônio João Municipality, Route MS 384, Latitude 22.1133, Longitude 56.1664;

IV – Antônio João Municipality, Route MS 384, Latitude 22.2784, Longitude 55.8439;

V – Aral Moreira Municipality, Route 386, Latitude 22.8165, Longitude 55.3624;

VI – Bela Vista Municipality, Highway BR 060, Latitude 22.0294, Longitude 56.5156;

VII – Bonito Municipality, Route MS 382, Latitude 21.0627, Longitude 56.7319;

VIII – Caracol Municipality, Highway BR 384, Latitude 21.9997, Longitude 57.0176;

IX – Japorã Municipality, Route MS 386, Latitude 23.7566, Longitude 54.5882;

X – Tacuru Municipality, Route MS 295, Latitude 23.6584, Longitude 54.9095;

XI – Mundo Novo Municipality, Highway BR 163, Latitude 24.0048, Longitude 54.3121;

XII - Eldorado Municipality, Highway BR 163, Latitude 23.7922, Longitude 54.2821;

XIII – Paranhos Municipality, Route MS 295, Latitude 23.7413, Longitude 55.2526;

XIV – Paranhos Municipality, Route MS 165, Latitude 23.6489, Longitude 55.3909;

XV – Ponta Porã Municipality, Route MS 164, Latitude 21.977 [sic], Longitude 55.5453;

XVI – Ponta Porã Municipality, Route MS 386, Latitude 22.6889; Longitude 55.6076;

XVII – Ponta Porã Municipality, Highway BR 463, Latitude 22.3658, Longitude 55.3356;

XVIII – Porto Murtinho Municipality, Highway BR 267, Latitude 21.7465, Longitude 57.5611;

XIX – Jardim Municipality, Highway BR 267, Latitude 21.5521, Longitude 56.6048;

XX – Sete Quedas Municipality, Route MS 160, Latitude 23.9609, Longitude 55.0038;

XXI – Tacuru Municipality, Route MS 160, Latitude 23.8020, Longitude 55.0369;

XXII – Corumbá Municipality, Jacadigo Road, Latitude 19.0994, Longitude 57.8134;

XXIII – Corumbá Municipality, Assentamento Urucum Entrance, Latitude 19.1633, Longitude 57.6356; and

XXIV – Corumbá Municipality, Forte Coimbra, Latitude 19.3218, Longitude 57.5876.

Paragraph 2. Any modification to the above list of fixed checkpoints shall be permitted only under approval by the Animal and Plant Health and Inspection Secretariat, subject to technical opinion handed down by the state veterinary service.

Art. 3. The state veterinary service shall establish and keep current the following in the ZAVs, without prejudice to other norms and guidelines under the National Program for the Eradication and Prevention of Foot-and-Mouth Disease (PNEFA):

I – A georeferenced register of all rural properties with animals susceptible to FMD;

II – Long-standing individual identification, specific to the state veterinary service, to be applied to all cattle, buffalo and small ruminant specimens; and

III – An official system of inspection and monitoring of foot-and-mouth disease vaccination.

Paragraph 1. At the ZAVs, a specific veterinary monitoring and surveillance system should be introduced pursuant to PNEFA's guidelines.

Paragraph 2. Registers pertaining to rural properties, rural producers, livestock establishments, individual animal identification, and movement of animals should be maintained at the state veterinary service's local veterinary units for consultation and checking on the occasion of inspections and audits.

Paragraph 3. The systematic vaccination of cattle and buffalo should take into consideration the general guidelines established under Normative Instruction No. 44 of October 2, 2007, and be carried out consistently with the Official Veterinary Service of the neighboring countries involved, under approval of the Animal and Plant Health and Inspection Secretariat.

Paragraph 4. In the region along the border between Corumbá and the Republics of Paraguay and Bolivia, in the stretches situated between the lat 19º15'00.22" S and long 57º53'09.26 W geographical markers and the Porto Murtinho Municipality boundary, and between the seat of the Corumbá Municipality and the Mato Grosso do Sul state line there will be no need to establish ZAVs in view of predominant geographical conditions, low animal concentration, and scarcity of roads. However, rural properties located in the area circumscribed by this Art. should be subjected to specific surveillance by the state veterinary service, including the monitoring of FMD vaccination.

Art. 4. The movement of and trade in animals and animal products under FMD risk from ZAVs shall be subject to the same requirements applicable to regions of origin classified as BR-3 (medium risk) for FMD or classified under a similar risk category that may be adopted by MAPA, pursuant to Chapters VI and VII of Normative Instruction No. 44 of October 2, 2007, according to the destination's sanitary status.

Paragraph 1. Beef ageing and boning and the procedures for inactivating the foot-and-mouth disease shall be waived if the beef comes from an establishment that has a Federal Inspection Service unit; however, this requirement stands if the destination is a foot-and-mouth disease free zone without vaccination.

Paragraph 2. The serologic tests required for the movement of animals may, at the Agriculture and Livestock Office's discretion, be replaced by other surveillance procedures capable of ensuring the protection of the sanitary status of the animals' destination.

Paragraph 3. Irrespective of the destination of the animals and animal products, transport vehicles must have their cargo officially sealed and must follow the routes established by the state veterinary service, which must obligatorily include passage through one of the fixed checkpoints referred to under Art. 2 hereunder.

Paragraph 4. The Animal Movement Permits(GTAs) issued for the movement of cattle, buffalo, or small ruminants leaving a ZAV must be accompanied by a list of the individual animals transported.

Paragraph 5. The period of quarantine at the origin shall be waived in the case of cattle destined for immediate slaughter, and reduced to fifteen days on establishments that have no record of the entry of animals susceptible to FMD in the 30 days prior to their movement.

Art. 5. Susceptible animals may enter ZAVs only under prior authorization of the state veterinary service, and must be promptly entered into the register and individual identification system adopted in the destination zone.

Sole Paragraph. Under this Article's provisions, entry may be permitted only if the routes established by the state veterinary service are followed, including the obligatory passage through one of the fixed checkpoints referred to in Art. 2 above.

ADMINISTRATIVE RULING No. 53 OF NOVEMBER 23, 2007

Published in the Official Gazette of November 26, 2007, Section 1, Page 16
Republished on November 27, 2007

Recognizes and confirms the sanitary status of the States in regard to the foot-and-mouth disease.

THE MINISTER OF AGRICULTURE, LIVESTOCK, AND FOOD SUPPLY, by virtue of the powers vested in him under the provisions of Art. 2 of Decree No. 5741 of March 30, 2006, having in view the provisions of Art. 71 of the Animal Health and Inspection Service Regulations approved under Decree No. 24548 of July 3, 1934 and pursuant to Proceeding No. 21000.010424/2007-37, hereby resolves as follows:

Art. 1. To recognize and confirm the sanitary status of the States in regard to the foot-and-mouth disease, pursuant to the Annex hereto.

Art. 2. The occasional occurrence of one or more than one case of foot-and-mouth disease in any of the areas considered to be free of the disease shall imply the temporary suspension of the current status.

Paragraph 1. Suspension may apply to only part of the free area if the outbreak is circumscribed and if it is possible to establish a contention zone on which to concentrate all the cases so as to reduce the disease's impact to a minimum.

Paragraph 2. The previous sanitary status shall be restored once the recommended sanitary measures have been applied within the minimum deadline established for each case.

Art. 3. This Administrative Ruling shall enter into force on the date of its publication.

REINHOLD STEPHANES

BRAZIL'S SANITARY STATUS IN REGARD TO THE FOOT-AND-MOUTH DISEASE
2007

Sanitary Status	States	Last foot-and-mouth disease occurrence record	Observations	Recognition Acts
Free of foot-and-mouth disease without vaccination	Santa Catarina	December 1993	The entire territory	MAPA Administrative Ruling 153/2000
Free of foot-and-mouth disease with vaccination	Acre	June 1999	The entire territory	MAPA Administrative Ruling No. 14/2005
	Amazonas	September 2004	Municipalities of Boca do Acre and Guajará	MAPA Administrative Ruling No. 14/2005
	Bahia	May 1997	The entire territory*	MAPA Administrative Ruling No. 14/2005
	Federal District	May 1993	The entire territory	MAPA Administrative Ruling No. 618/1999
	Espírito Santo	April 1996	The entire territory	MAPA Administrative Ruling No. 14/2005
	Goiás	August 1995	The entire territory	MAPA Administrative Ruling No. 618/1999
	Mato Grosso	January 1996	The entire territory	MAPA Administrative Ruling No. 618/1999
	Mato Grosso do Sul	April 2006	The entire territory	MAPA Administrative Ruling No. 39/2007
	Minas Gerais	May 1996	The entire territory	MAPA Administrative Ruling No. 618/1999
	Pará	June 2004	Center-South Region. Municipalities listed under Administrative Ruling No. 43/2006	MAPA Administrative Ruling No. 43/2006
	Paraná	February 2006	The entire territory	MAPA Administrative Ruling A No. 61/2006
	Rio de Janeiro	March 1997	The entire territory	MAPA Administrative Ruling No. 14/2005
	Rio Grande do Sul	May 2001	The entire territory	MAPA Administrative Ruling No. 14/2005
	Rondônia	February 1999	The entire territory*	MAPA Administrative Ruling No. 543/2002
	São Paulo	March 1996	The entire territory	MAPA Administrative Ruling No. 618/1999
	Sergipe	September 1995	The entire territory	MAPA Administrative Ruling No. 14/2005
	Tocantins	May 1997	The entire territory*	MAPA Administrative Ruling No. 14/2005
States that do not present the conditions required for inclusion in one of the two categories above	Alagoas	September 1999	The entire territory	Without recognition
	Amapá	October 1999	The entire territory	Without recognition
	Amazonas	September 2004	Except for the Municipalities of Boca do Acre and Guajará	Without recognition
	Ceará	April 1997	The entire territory	Without recognition
	Maranhão	August 2001	The entire territory	Without recognition
	Pará	June 2004	Northern Region. Municipalities not listed under IN SDA Nº. 25/200725/2007	Without recognition
	Paraíba	October 2000	The entire territory	Without recognition
	Pernambuco	February 1998	The entire territory	Without recognition
	Piauí	February 1997	The entire territory	Without recognition
	Rio Grande do Norte	August 2000	The entire territory	Without recognition
	Roraima	June 2001	The entire territory	Without recognition

* Except for buffer zone

NORMATIVE INSTRUCTION No. 44 OF OCTOBER 2, 2007

Published in the Official Gazette of October 3, 2007 Section 1, Page 2

Approves the general guidelines for Foot-and-Mouth Eradication and Prevention, pursuant to Annexes I, II, III, and IV hereto, to be followed throughout the National Territory, with a view to the implementation of the National Program for the Eradication and Prevention of Foot-and-Mouth Disease (PNEFA), as established by the Agriculture and Livestock Health Care Unified System.

THE MINISTER OF AGRICULTURE, LIVESTOCK, AND FOOD SUPPLY, by virtue of the powers vested in him under Art. 2 of Decree No. 5741 of March 30, 2006, having in view the provisions of said Decree and of Arts. 10 and 71 of the Regulations of the Animal Health and Inspection Service, approved by Decree No. 24548 of July 3, 1934; and Proceeding No. 21000.0045/2007-81

RESOLVES:

Art. 1. To approve the general guidelines for Foot-and-Mouth Eradication and Prevention, pursuant to Annexes I, II, III, and IV hereto, to be observed throughout the National Territory, with a view to the implementation of the National Program for the Eradication and Prevention of Foot-and-Mouth Disease (PNEFA), as established by the Agriculture and Livestock Health Care Unified System.

Art. 2. This Normative Instruction shall enter into force on the date of its publication.

Art. 3. SDA Administrative Ruling No. 11 of November 3, 1983; Ministerial Ruling No. 121 of March 29, 1993; SDA Administrative Ruling No. 185 of December 1, 1993; Administrative Ruling No. 162, I a, b, c, d, and e of October 18, 1994; Administrative Ruling No. 82 of June 28, 1996; SDA Normative Instruction No. 11 of March 13, 2001; SDA Normative Instruction No. 47 of September 26, 2001; SDA Normative Instruction No. 5 of January 17, 2003; Administrative Ruling No. 40 of July 14, 2003; and SDA Normative Instruction No. 82 of November 20, 2003 are hereby revoked.

REINHOLD STEPHANES

ANNEX I

GENERAL GUIDELINES ON THE ERADICATION AND PREVENTION OF FOOT-AND-MOUTH DISEASE

CHAPTER I

DEFINITIONS

Art. 1. The National Program for the Eradication of Foot-and-Mouth Disease (PNEFA) uses the technical and scientific definitions established by international organizations and institutions of which Brazil is a signatory, and especially those established by the World Organization for Animal Health (OIE).

Sole Paragraph. For the purposes of this Normative Instruction, the following definitions apply:

I – Susceptible animals: cattle, buffalo, sheep, goats, pigs, wild ruminants, and other animals in which infection has been scientifically proven;

II – Sanitary protection area: geographical area established around FMD outbreak under the strategy for containment and elimination of the infectious agent. The definition of the geographical boundaries is incumbent on the Official Veterinary Service, which should take into account the disease's epidemiological characteristics, the predominant livestock production systems, and the existing communication structure and road system

as well as natural barriers capable of preventing the disease's dissemination. Such an area shall be established by a specific act that must specify the sanitary actions to be carried out. A sanitary protection area should encompass the following:

a) A perifocal area: an area immediately adjacent to the FMD outbreak, covering at least the rural properties adjacent to the outbreak in question. For its delimitation, a three-kilometer radius may be drawn taking as starting point the geographical limits of the confirmed outbreak;

b) A surveillance area: an area immediately adjacent to the perifocal area. For its delimitation, rural properties situated within a seven-kilometer radius from the boundaries of the perifocal area may be considered; and

c) A buffer area: an area immediately adjacent to the surveillance area and whose limits are the outermost boundaries of the surveillance area. In support of its delimitation, rural properties located within a radius of up to fifteen kilometer from the boundaries of the surveillance area.

III – Infectious vesicular diseases: a set of transmissible diseases characterized mainly by fever and limping and excessive salivation syndrome caused by vesicles or vesicular lesions in the mouth, muzzle, or feet, which may also occur in the udder region. This category includes foot-and-mouth disease, vesicular stomatitis and other diseases that may be confused with them and that may present ulcerating or erosive lesions as they progress;

IV – Veterinary emergency: a condition caused by outbreak of diseases with an epidemic potential to entail serious sanitary, social, and economic consequences, which may compromise domestic and international trade, food security, or public health, and which require immediate control or elimination actions, so as to reestablish the previous sanitary status as soon as possible and at the best cost/benefit ratio;

V – Pathogenic material: material posing FMD risk, collected from confirmed cases of infectious vesicular disease or from any FMD susceptible animal in the infected zone, including the following:

a) Samples of foot-and-mouth disease virus;

b) Samples of blood serum, total blood, or any infectious matter;

c) Excreta, tissue, organ, or any other material that can be sent to a specialized laboratory for diagnostic.

VI – In natura offal: organs and viscera of susceptible animals, not subjected to any physical or chemical treatment;

VII – Contingency Plan: document setting forth the principles, strategies, procedures, and responsibilities pertaining to a veterinary emergency, geared to training and to organizing, guiding, facilitating, expediting, and standardizing the requisite actions for rapid response aimed at controlling and eliminating the disease;

VIII – Action Plan: a part of the Contingency Plan that establishes specific procedures for the investigation of suspected cases of vesicular disease and for addressing foot-and-mouth disease outbreak;

IX – Sanitary slaughter: elimination of all animals that, in the judgment of the Official Veterinary Service that pose a risk of spreading or maintaining the biologic agent, followed by destruction of the carcasses by incineration, burial or any other process that ensures the elimination of the infectious agent and stops the infection's propagation, followed in turn by cleaning and disinfection;

X – Official Veterinary Service: government animal health and inspection agency;

XI – Veterinary emergency system: a set of resources, structures, and procedures whose objective is to develop the capacity for rapid detection of and prompt response to the occurrence of diseases, and for their control and eradication. It includes the preparation of contingency and action plans.

XII – Types of cases covered by the investigation of vesicular diseases:

a) Suspected case of vesicular disease: notification by third parties to the Official Veterinary Service, indicating the possibility of one or more than one animal with clinical signs consistent with infectious vesicular disease;

b) Confirmed case of vesicular disease: certification by the Official Veterinary Service of the existence of animals showing clinical signs consistent with infectious vesicular diseases

and requiring the prompt adoption of biosecurity measures and steps toward laboratory diagnostic;

c) Dismissed case of vesicular disease: any suspected case of vesicular disease that has been investigated by the Official Veterinary Service, which has determined that the clinical signs are not consistent with infectious vesicular disease; and

d) Case or outbreak of FMD: occurrence at some epidemiologic unit of at least on case that meets one or more than one of the following criteria:

1. Isolation and identification of the foot-and-mouth disease virus in samples from susceptible animals showing or not clinical signs of the disease or in samples of products from these animals;

2. Detection of the specific FMD virus antigen in samples from confirmed cases of vesicular disease or from animals that may have had direct or indirect contact with the causing agent;

3. Existence of an epidemiologic link to another FMD outbreak and occurrence of at least one of the following conditions:

Occurrence of one or more than one confirmed case of vesicular disease;

Detection of antibodies against nonstructural or noncapsidial proteins of the FMD virus in animals not vaccinated against this disease;

Detection of antibodies against nonstructural or noncapsidial proteins of the foot-and-mouth disease virus, and the suspicion of infection cannot be dismissed by epidemiologic investigation;

e) Dismissed case of FMD: any confirmed case or outbreak of vesicular disease that does not meet the confirmation criteria for FMD;

XIII – Epidemiologic unit: a group of animals with similar probability of exposure to the FMD virus. Depending on the epidemiologic relations established and on the size of the involved rural properties, an epidemiologic unit may consist of one rural property, a group of rural properties (e.g. rural settlements or small villages), part of a rural property, or any other kind of establishment with a concentration of animals susceptible to the disease (e.g., on exposition grounds or in auction facilities). The determination of an epidemiologic unit is incumbent on the Official Veterinary Service, which should base its determination on technical analyses and field assessment. If more than one rural property is involved, consideration should be given to geographic continuity.

XIV – Epidemiologic link: expression used to establish the possibility of transmission of the infectious agent between confirmed cases of diseased animals and susceptible animals, whether or not these are located on the same livestock establishment. It may be established through the movement of animals, geographic proximity allowing contact between diseased and susceptible animals, or the presence of other elements capable of serving as carriers for the infectious agent. Characterization of the epidemiologic link is incumbent on the Official Veterinary Service, and should be based on technical analyses and field assessments;

XV – Zone: a concept introduced by the OIE and adopted in PNEFA's strategies to mean a clearly circumscribed part of a country with an animal subpopulation in a particular health condition for a specific animal disease. As regards foot-and-mouth disease, OIE's Sanitary Terrestrial Animal Health Code recognizes the following four zones:

a) Free zone, with or without vaccination, refers to a geographical space that has been certified by the Ministry of Agriculture, Livestock, and Food Supply (MAPA) as meeting the following conditions: no occurrence of outbreak and viral circulation under an established timeframe; existence of an adequate animal health surveillance system; existence of a consistent legal framework; and existence of an adequate Official Veterinary Service structure;

b) Buffer zone, a geographical space established to protect the health condition of a free zone herds vis-à-vis animals and animal products and subproducts from another country or from a zone with a different sanitary status, through the adoption of measures based on the disease's epidemiologic characteristics, so as to prevent the introduction of the pathogenic agent. These measures may include vaccination, control of the movement of animals, and enhanced surveillance of the disease;

c) Infected zone, a country's geographical space that lack the requisite conditions to be recognized as a free zone with or without vaccination; and

d) Containment zone, a geographical space established around infected or supposedly infected livestock establishments, whose extent is determined on the basis of epidemiologic factors and investigation results, where control measures are taken to prevent the infection from spreading.

CHAPTER II

PNEFA'S FUNDAMENTS AND STRATEGIES

Art. 2. PNEFA's objectives are the eradication of the FMD from the entire National Territory and the preservation of this sanitary status through the introduction and implementation of a sanitary surveillance system underpinned by the Official Veterinary Service's structures and by community participation. These objectives have been incorporated into the Hemispheric Plan for the Eradication of Foot-and-Mouth Disease, which seeks to eliminate the disease in all of South America.

Art. 3. PNEFA's execution is based on scientific criteria and on international guidelines on combating the disease, and relies on the sharing of responsibilities between the public and the private sectors. Its strategies encompass the following:

I – General and common measures, such as:

a) maintenance and strengthening of the Official Veterinary Services' structures;

b) register of livestock sector's establishments;

c) adoption of acts to support PNEFA's operating measures, including corrective actions;

d) establishment of Official Veterinary Service supervision and auditing systems;

e) modernization of the epidemiologic information system;

f) strengthening of laboratory diagnostic structures;

g) strengthening of human resources training programs;

h) control of the movement of animals and of products and subproducts thereof;

i) implementation of sanitary education and public relations programs;

j) organization and consolidation of community participation through the establishment and maintenance of state and local animal health commissions;

k) maintenance of an adequate supply of foot-and-mouth disease vaccines produced under MAPA's control;

l) control of FMD vaccine's marketing and application procedures; and

m) introduction and maintenance of a veterinary emergency system with capacity for immediate notification and prompt response vis-à-vis suspected and conformed cases of vesicular disease.

II – Priority measures in free zones:

a) Strengthening of the prevention system, including the introduction of ongoing clinical and scientific analyses to identify vulnerabilities and guide surveillance and inspection activities;

b) Introduction of normative and technical procedures pertaining to the sanitary slaughter of animals and the destruction of animal products under FMD risk, whose entry was irregular or without proof of origin;

c) Adoption of procedures for monitoring the health condition of susceptible herds;

d) Establishment and maintenance of private or public financial funds to support the veterinary emergency system; and

e) Implementation, in free zones with vaccination, of strategies and a timetable for suspension of the obligation of vaccination against FMD.

III. Priority measures in infected zones:

a) Strengthening of the animal health surveillance system, taking into consideration the introduction of Official Veterinary Services;

b) Performance of analyses and technical evaluations for epidemiologic characterization and assessment of the agricultural and livestock productive conditions of the involved regions and for defining viral agent eradication strategies; and

c) Reinforcement of the participation by other public and private sectors.

CHAPTER III

ADDRESSING SUSPECTED VESICULAR DISEASE CASES AND FOOT-AND-MOUTH DISEASE OUTBREAKS

Art. 4. The notification of infectious vesicular diseases is compulsory. All veterinary doctors, rural producers, animal carriers, and professionals working in official or private veterinary laboratories and at veterinary teaching or research institutions who have knowledge of suspected cases of vesicular diseases are under the obligation of reporting the fact to the Official Veterinary Service within 24 hours from the moment they acquired knowledge of the suspected cases.

Paragraph 1. Should the notification's author own or be in charge of the livestock establishment with suspected cases of vesicular disease, he should hold the movement of animals and of animal products and subproducts, pending authorization from the Official Veterinary Service.

Paragraph 2. Suspected cases must be notified in person or by any available means of communication, the right to anonymity being safeguarded.

Paragraph 3. All notifications of suspected cases of vesicular disease must be entered into the records by the Official Veterinary Service, which must act on them within 12 hours from their submission, pursuant to the action plan adopted by the Official Veterinary Service.

Paragraph 4. Noncompliance with the provisions of this Article's heading shall be duly investigated by the Official Veterinary Service, which shall bring charges against the infringer before the Public Attorney's Office, if appropriate.

Paragraph 5. Should the infringer be a veterinary doctor, in addition to following the procedure referred to in the preceding Paragraph 4, the Official Veterinary Service shall lodge formal charges before the Regional Council of Veterinary Medicine;

Paragraph 6. The Official Veterinary Service in the States is responsible for waging educational, awareness-raising campaigns informing the community and preparing it for prompt notification of suspected cases of vesicular disease.

Art. 5. The development and maintenance of FMD epidemiologic surveillance involves the following actions:

I – Maintenance of an appropriate administrative structure for veterinary emergency cases, as part of the contingency plan;

II – Immediate notification of suspected cases of vesicular disease and prompt response to confirmed cases;

III – Drafting of an action plan for attention to and epidemiologic investigation of confirmed cases of vesicular disease and FMD outbreaks;

IV – Offering of training and doing simulations for the action plan's execution;

V – Development of adequate operating capacity, with emphasis on diagnostic laboratories;

VI – Drafting of acts and disciplining procedures with a view to the participation of other government and private sectors in prompt response; and

VII – Development of the capacity for applying all the requisite resources to contain the disease's spread, including personnel, equipment, financial resources, and government measures to mitigate the attendant economic and social impact.

Paragraph 1. MAPA is responsible for coordinating the introduction and management of the veterinary emergency system.

Paragraph 2. It shall be incumbent on the Official Veterinary Service to adopt all the recommendations under the action plan on vesicular diseases.

Art. 6. The recording and communication of suspected and confirmed cases of vesicular disease should meticulously follow the communication system established and coordinated by MAPA.

Art. 7. The confirmation of a case of vesicular disease entails the prompt adoption of sanitary measures to identify and contain the causing agent. In such case, the epidemiologic investigation should be carried further to determine the origin and extent of the health problem. Immediate actions include the following:

I – The entry into the records and communication of the occurrence to the higher authorities by the filled-out pertinent form and through the communication channels defined by MAPA;

II – Definition and interdiction of the epide-

miologic unit with confirmed cases of vesicular disease;

III – Collection of material for laboratory diagnostic, accompanied by clinical and epidemiologic evaluation;

IV – An initial epidemiologic investigation, taking into account the analysis of the movement of susceptible animals; and

V – Temporary suspension of the movement of risk animals and products from rural establishments adjacent to or having an epidemiologic link to the epidemiologic unit where cases of vesicular disease have been confirmed.

Art. 8. Interdiction, as provided for in the preceding Art. 7, involves the following:

I - Entering the interdiction into the records and informing accordingly the rural producers, or their proxies, who own livestock establishments in the epidemiologic unit at stake, and giving them orientation about the requisite biosecurity measures to be adopted; and

II – Prohibition of the exit of animals, whether or not susceptible to the disease, and of any other products or materials likely to carry the viral agent, as well as prohibition of the entry and exit of unauthorized vehicles or persons.

Paragraph 1. If it is not possible to store milk at the epidemiologic unit, the Official Veterinary Service shall decide in favor of the on-site destruction of milk and provide orientation accordingly, or authorize its transportation under official control by an appropriate means of transportation to the nearest location, where procedures will be undertaken to ensure the destruction of the viral agent.

Paragraph 2. The prohibitions hereunder may be replaced by biosecurity measures defined by the Official Veterinary Service, provided the zoosanitary measures to prevent the spread of the viral agent are adopted.

Paragraph 3. For the purposes of investigation of suspected cases of vesicular diseases, control of outbreaks, monitoring, or surveys for assessing viral circulation, or of any other activity of importance for the disease's eradication, the Official Veterinary Service may temporarily suspend foot-and-mouth disease vaccination and the movement of animals of the livestock establishment involved or of regions considered at sanitary risk.

Art. 9. When there is no confirmation of a outbreak of FMD or of another disease, whether exotic or eradicated in the country, the interdiction referred to in the preceding Arts. 7 and 8 may be suspended, provided this is done according to the technical recommendations for each case.

Art. 10. The confirmation of a foot-and-mouth disease outbreak shall entail the declaration of a veterinary emergency in accordance with the contingency and action plans.

Paragraph 1. MAPA shall define and coordinate the actions to be undertaken, taking into account the sanitary status of the region involved, the assessment of the risk of dissemination of the viral agent, the evaluation of the region's vulnerability and receptivity, and the local veterinary service's response capacity, as well as the possible economic and social consequences. Actions may include sanitary slaughter, emergency vaccination, and interdiction measures.

Paragraph 2. Pending the definition and delimitation of the sanitary protection areas around the confirmed foot-and-mouth disease outbreak, MAPA shall determine the interdiction of a larger security area, which may encompass municipalities, states, or some other geographic division and which may be necessary to prevent the infectious agent from spreading to other regions of the country.

Art. 11. The confirmation of vesicular disease by the veterinary inspection service at slaughterhouses during ante- and post-mortem inspections must be promptly reported to the Official Veterinary Service of the involved state, as the case may be.

Paragraph 1. Irrespective of the scope of the veterinary inspection service at the slaughterhouse, the sanitary measures and technical procedures established by MAPA must be applied.

Paragraph 2. The sale of meat, products, and subproducts obtained from slaughtering shall be suspended until the Official Veterinary Service makes a decision on their destination.

Art. 12. Should an infectious vesicular disease be confirmed on the premises of expositions, fairs, auctions, and other animal agglomerations, the provisions under Arts. 7 and 8 hereunder must be complied with, as applicable.

CHAPTER IV

RECOGNITION AND MAINTENANCE OF FOOT-AND-MOUTH DISEASE FREE ZONES

Art. 13. The recognition and maintenance of FMD free zones in the country and the restoring of sanitary status after reintroduction of the viral agent follow OIE's guidelines.

Paragraph 1. Conduction of the process of recognition of a foot-and-mouth disease free zone with or without vaccination is incumbent on MAPA and has the following stages:

I – Assessment, through supervision and audits by MAPA, of compliance with the requisite technical and structural conditions;

II – National declaration, issued by MAPA, of recognition of the area involved as a foot-and-mouth disease free zone, with or without vaccination, based on MAPA's favorable opinion; and

III – Submission of the Brazil's technically supported application to the OIE, requesting the international recognition of a foot-and-mouth disease free zone with or without vaccination.

Paragraph 2. To be classified as a foot-and-mouth disease free zone or as a buffer zone, a state, or part thereof must fall at least into category BR-3 (medium risk) regarding foot-and-mouth disease or into another risk category similar to another eventually adopted by MAPA.

Art. 14. The maintenance of the sanitary status in FMD free zones requires the ongoing carrying out of epidemiologic surveillance activities encompassing the following elements, without prejudice of other MAPA norms and procedures:

I – Control at interstate, port, airport, special customs, duty-free shop, landing strip, highway, and colis posteaux entry checkpoints, including passenger baggage inspection;

II – Permission for the entry of animals, products, and subproducts presenting FMD risk only after evaluation by the Official Veterinary Service;

III – Prohibition of holding and manipulating whole FMD virus, except at institutions with an adequate biosecurity level and officially approved by MAPA;

IV – Prohibition of keeping animals at dump yards or on sanitary landfills, and of removing food leftovers from them for feeding animals;

V – Prohibition of the use, for feeding pigs, of food leftovers from any origin, except if subjected to thermal treatment to ensure the inactivation of the FMD virus;

VI – Identification and monitoring of likely points of entry of animals, products, and subproducts in noncompliance with this Normative Instruction.

VII – Specific identification in the Official Veterinary Service's register of establishments that pose greater risk of introduction of the FMD virus;

VIII – Specific identification of rural producers that own livestock establishments in other states, or foreign countries;

IX – Intensification of epidemiologic surveillance of livestock establishments, with priority attention to the establishments referred to in the preceding VII and VIII items; and

X – Establishment and maintenance of mobile inspection teams.

Paragraph 1. All animals susceptible to FMD, their products and subproducts, and any materials, substances, or any other veterinary product likely to carry the viral agent that enter free zones with or without vaccination in noncompliance with this Normative Instruction shall be sent to sanitary slaughter or to sacrifice and destruction.

Paragraph 2. At the Official Veterinary Service's discretion, the products and subproducts derived from sanitary slaughter or the seizure referred to under the preceding Paragraph 1 may be destined for consumption, provided public health and animal health are safeguarded.

Paragraph 3. Leftovers of food transported or consumed on air, sea, river, or land travel shall be destroyed under Official Veterinary Service supervision by a method and at a location previously approved by MAPA.

CHAPTER V

VACCINATION AGAINST FOOT-AND-MOUTH DISEASE

Art. 15. Only foot-and-mouth disease vaccines registered with and controlled by MAPA may be sold and used in the country.

Paragraph 1. Registration shall be accorded solely to inactivated vaccines approved by the Official Veterinary Service.

Paragraph 2. The virus strains to be used in vaccines shall be defined by the Official Veterinary Service, based on assessment of the prevailing epidemiologic situation.

Paragraph 3. At the Official Veterinary Service's discretion, vaccines with specific characteristics to be used in risk areas and risk situations may be produced.

Art. 16. It shall be incumbent on the Official Veterinary Service to inspect and control all phases of production, marketing, distribution, transport, and use of the foot-and-mouth disease vaccine as well as its discarding.

Paragraph 1. Distributors or sellers must abide by the determinations of the Official Veterinary Service regarding the conservation, sale, and control of foot-and-mouth disease vaccines.

Paragraph 2. Foot-and-mouth disease vaccines may leave a selling establishment solely under conditions that permit the maintenance of their temperature during transportation to a rural property.

Art. 17. The strategies for vaccination against FMD shall be defined by the Official Veterinary Service in accordance with the epidemiologic status of each state, zone or other geographical areas, consistently with the following:

I – The periods and the duration of the systematic vaccination stages shall be defined by MAPA, based on a technical proposal of the Official Veterinary Service in the states, drafted after evaluation of the region's predominant geographic and agricultural and livestock characteristics;

II – The systematic, mandatory vaccination in areas defined by MAPA shall be done on cattle and buffalo of all ages. The vaccination of goats, sheep, pigs, and other susceptible species is prohibited, save in special situations, with MAPA's approval.

III – The following strategies of systematic, mandatory vaccination of cattle and buffalo are recognized:

a) Semestral vaccination of all animals in 30-day stages;

b) Semestral vaccination of animals up to 24 months of age, and annual vaccination of animals over 24 months of age, including or not booster vaccination of animals up to 12 months of age, in 30-day stages. This strategy shall be adopted in states where the rural properties register has been consolidated and where semestral vaccination has been done for at least two consecutive years and overall vaccination indicators exceed 80 percent;

c) Annual vaccination of all animals in 45-60-day stages in regions where geographic characteristics permit the management of livestock establishments only during a limited period of the year; and

d) Other vaccination strategies may be adopted after MAPA's appreciation.

IV – Once the vaccination stages have been defined, the Official Veterinary Services of the States will regulate and publicize the established procedures for their respective jurisdiction;

V – Any postponement or anticipation of vaccination stages must be approved by MAPA, on the basis of a request supported by a technical opinion issued by the interested Official Veterinary Service.

Paragraph 1. Foot-and-mouth disease vaccination is incumbent on rural producers, who must provide proof of purchase of vaccines in a quantity consistent with their livestock establishment, and report their application according to the prescribed timetable and pursuant to procedures defined by the Official Veterinary Service.

Paragraph 2. The Official Veterinary Services of the States may accompany foot-and-mouth disease vaccination at any livestock establishment located within their jurisdiction and may also assume the task of purchasing or of applying the vaccine in risk areas or in other livestock establishments deemed of strategic importance.

Paragraph 3. The vaccination stages in place until the date of publication of this Normative Instruction shall remain in force, and any modification thereof must be approved by MAPA.

Paragraph 4. At MAPA's discretion, and as an exceptional measure, vaccination other than in the prescribed stages may be authorized.

Paragraph 5. The Official Veterinary Service

of the States shall prepare and submit to MAPA a report on foot-and-mouth disease vaccination activities, in accordance with MAPA's guidelines, within 30 days of the stage's end.

Paragraph 6. The Official Veterinary Service, under MAPA's coordination, shall undertake epidemiologic studies with a view to stopping systematic foot-and-mouth disease vaccination.

Art. 18. It shall be incumbent on the Official Veterinary Service of the States to inspect the sale, distribution, and application of the vaccine against foot-and-mouth disease; inspection may be done through random sampling consistently with parameters defined by MAPA.

Paragraph 1. In foot-and-mouth disease free zones, dairy establishments may receive fresh milk solely from livestock establishments whose producers can show proof that vaccination has been done.

Paragraph 2. In areas where vaccination is mandatory, dairy establishments may receive fresh milk from livestock establishments whose producer can provide proof that vaccination has been done.

CHAPTER VI

CONTROL AND INSPECTION OF THE MOVEMENT OF ANIMALS SUSCEPTIBLE TO FOOT-AND-MOUTH DISEASE

Section I

General considerations

Art. 19. Any movement of foot-and-mouth susceptible animals requires an Animal Movement Permit (GTA) and other documents established by the Official Veterinary Service according to current norms.

Paragraph 1. The Animal Movement Permit for the movement of cattle, buffalo, sheep, and goats may be issued solely by the Official Veterinary Service.

Paragraph 2. Any cargo of foot-and-mouth susceptible animals that is in noncompliance with the provisions hereunder shall be seized and destined for sanitary slaughter or for other purpose determined by the Official Veterinary Service of the involved state, as the case may be, after assessment of the attendant risks, and the infringer shall be subjected to the sanctions and penalties called for under the legislation of said state.

Paragraph 3. Any cargo of foot-and-mouth susceptible animals that has been sealed by the Official Veterinary Service at the origin according to the provisions hereunder may be unsealed only under Official Veterinary Service supervision.

Paragraph 4. If the travel time exceeds 12 hours on the road, an intermediate stop must be designated beforehand, where the animals may rest and be fed. In this case, the cargo seal may be broken and the cargo must be sealed again under the supervision of the Official Veterinary Service on site, and the number of the new seal must be entered into the Animal Movement Permit.

Art. 20. The issuance of the Animal Movement Permit for the movement of cattle and buffalo from a state, as the case may be, or from a region where foot-and-mouth disease vaccination is mandatory must take into account the following requirements, without prejudice to other norms in force:

I – Compliance with the following timetable as of the date of the last vaccination:

a) Fifteen days for animals that have been vaccinated once;

b) Seven days for animals that have been vaccinated twice;

c) Any time after the third vaccination.

II – During the stages of foot-and-mouth disease vaccination, the animals may be moved only after having received the vaccine corresponding to the scheduled stage, in accordance with the timetable referred to in the preceding item I, save when they are destined for immediate slaughter;

III – During the vaccination stage and up to 60 days after it ends, animals destined for immediate slaughter are exempted from the mandatory foot-and-mouth disease vaccination;

IV – Animals over three months of age cannot be moved without proof that they have been vaccinated at least once against foot-and-mouth disease;

V – Animals from regions where the foot-and-mouth disease vaccination strategy described under Art. 17, III c hereunder is applied, which are

destined for participation in expositions, fairs, auctions, and other animal conglomerations in regions where foot-and-mouth disease vaccination is mandatory must be accompanied by proof that they have received at least two vaccinations against the disease, the last of which must have been applied no more than six months prior to the event.

VI – At the discretion of the Official Veterinary Service, which will take into consideration the foot-and-mouth disease epidemiologic status of the region in question, the participation of foot-and-mouth susceptible animals in expositions, fairs, auctions and other animal conglomerations may be temporarily suspended at localities posing a risk of spreading the disease, or subjected to complementary sanitary norms, which may include booster vaccination against foot-and-mouth disease;

VII – The holding of expositions, fairs, auctions, and other animal conglomerations in regions whose geographic characteristics permit the management of livestock establishments only during a limited period of the year must be subjected to specific norms established by the Official Veterinary Service of the states, as the case may be, after MAPA's approval.

Art. 21. The entry of foot-and-mouth susceptible animals into free zones, buffer zones, or states, which have been classified at least under the BR-3 category (medium risk) for foot-and-mouth disease or under any similar category eventually adopted by MAPA is subject to compliance with the specific sanitary requirements referred to in Sections II-IV hereunder, in accordance with the following procedures:

I – The party interested in the entry of animals into the regions in question must submit an application to the Official Veterinary Service of the destination state, in accordance with the model form shown in Annex II hereto;

II – The Official Veterinary Service at the animals' destination, after verifying the appropriateness of the request in light of current norms, shall notify the Official Veterinary Service at the origin accordingly, requesting it to check the information submitted and to consider the feasibility of the execution of the requisite zoosanitary procedures at the origin;

III – The Official Veterinary Service at the animals' origin shall notify the Official Veterinary Service at the destination of the result of the evaluation and the beginning of the requisite zoosanitary procedures;

IV – After compliance with the established zoosanitary requirements, the Official Veterinary Service at the animals' origin shall notify the Official Veterinary Service at the destination accordingly, so that the latter may issue the authorization for the entry of the animals into the region in question, in accordance with the model form shown in Annex III hereto; and

V – With the authorization issued by the Official Veterinary Service of the animals' destination state in hand, the Official Veterinary Service at the origin may authorize the issuance of the requisite Animal Movement Permit, which must be accompanied by a zoosanitary certificate, in accordance with the model form shown in Annex IV hereto, which in turn must accompany the animals in question during the entire travel period. Copies of the aforementioned documents must be forwarded to the Official Veterinary Service at the destination.

Paragraph 1. The coordination of the procedures referred to hereunder is incumbent on MAPA's Federal Agriculture Superintendence in the states, as the case may be, which should have the support and participation of the respective Official Veterinary Services.

Paragraph 2. The documents described in the preceding must be issued according to the forms shown in Annexes II-IV hereto and should bear, if applicable, the logo of the state or Federal District's Official Veterinary Service.

Paragraph 3. The entry of foot-and-mouth susceptible animals into free zones, buffer zones, or states, which have been classified at least under the BR-3 category (medium risk) for foot-and-mouth disease or under any similar category eventually adopted by MAPA should be restricted to specific routes defined by MAPA, based on reasoned proposals from the Official Veterinary Service of the involved states.

Art. 22. If, among the zoosanitary procedures

described in Sections II-IV hereunder, the isolation of animals is required, this can be done on the establishment of origin, provided the animals remain together and separated from the other foot-and-mouth disease susceptible animals on the establishment, during the entire evaluation period.

Art. 23. The movement of foot-and-mouth disease susceptible animals involving passage through regions with different zoosanitary status must be defined by MAPA, and the following procedures may be followed:

I – Authorization by MAPA after assessment of the sanitary risks involved;

II – Establishment of the flow of documents and information, including the entry request, the zoosanitary certificate, and the movement permit issued by the Official Veterinary Service of the involved state;

III – Technical procedures may include: sealing of the cargo on transport vehicles; definition of the transport route; specification of fixed inspection checkpoints for the entry of animals; and cleaning and disinfection of the transport vehicles.

Art. 24. The state Official Veterinary Services should maintain at the local veterinary units a register of animal carriers, whether these are legal or natural persons.

Sole Paragraph. Depending on the epidemiologic situation, the Official Veterinary Service may require that vehicles that transport foot-and-mouth susceptible animals be washed and disinfected after the animals are unloaded or as they pass through the fixed inspection checkpoints, as well as prohibiting the use of straw, wood shavings, or any other organic matter on the floor of transport vehicles.

Section II

Entry of animals into foot-and-mouth disease free zone without vaccination

Art. 25. The entry of animals vaccinated against foot-and-mouth disease into free zones without vaccination is prohibited.

Art. 26. The entry of foot-and-mouth susceptible animals into free zones without vaccination shall be authorized for:

I – Animals born or that have remained for at least 12 months immediately after their entry in another foot-and-mouth disease free zone without vaccination, which are transported in sealed vehicles, while the other procedures referred to under Art. 25 above shall be waived;

II – Sheep, goats, pigs, and other foot-and-mouth susceptible animals from a foot-and-mouth disease free zone with vaccination, provided the following conditions are met:

a) Unvaccinated animals against foot-and-mouth disease, born or that have remained immediately after their entry for a minimum of 12 months in a foot-and-mouth disease free zone with vaccination, and from rural establishments registered with the Official Veterinary Service;

b) Animals transported on freight vehicles with their cargo sealed by the Official Veterinary Service of the original state;

c) Animals destined for immediate slaughter, which must be sent directly to establishments with official veterinary inspection service, while the procedures referred to under Art. 21 above shall be waived; and

d) For purposes other than slaughtering, the entry may be authorized pursuant to the provisions of Art. 21 hereunder, consistently with the following zoosanitary procedures:

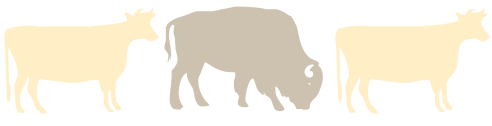
1. The animals must receive an individual, permanent, or long-lasting identification and remain isolated for a period of at least 30 days prior to shipment in a location approved by and under the supervision of the Official Veterinary Service of the original state;

2. Performance of diagnostic tests for foot-and-mouth disease, as defined by MAPA, on samples collected after at least fourteen days from the quarantine's start;

3. Proof of negative results of the diagnostic tests performed; and

4. The animals must remain confined at destination, under the supervision of the Official Veterinary Service for a period of at least 14 days. During the evaluation period, the exit of any other foot-and-mouth susceptible animals from the destination establishment shall be forbidden, save for immediate slaughter.

Paragraph 1. If the diagnostic tests referred to under Item II, d, 2 above yield at least one positive result, the entire group of animals shall be



barred from entering the free zone without vaccination, and the following actions shall be carried out at the original state, to clarify the positive reaction to the diagnostic tests done, during which time the establishment shall remain interdicted pending the investigation's final result:

I – Epidemiologic investigation on the rural establishment of origin, taking into consideration the clinical evaluation of susceptible animals;

II – Positive sheep and goats shall be submitted to the collection of samples of the esophageal-pharyngeal liquid for viral research or to other diagnostic procedures defined by MAPA;

III – In case of positive reaction in pigs, serologic tests must be extended to other animals on the livestock establishment, as defined by the Official Veterinary Service, based on epidemiological signs in each case, or other diagnostic procedures defined by MAPA must be followed; and

IV – MAPA should be informed of the epidemiologic investigation under way and may determine other actions to be carried out in each case.

Paragraph 2. In the case of pigs from GRSC farms (Certified Pig Reproducer Farm), the diagnostic tests referred to under this Article are waived.

Section III

Entry of animals into foot-and-mouth disease free zone with vaccination

Art. 27. Permission for the entry of foot-and-mouth susceptible animals into a free zone with vaccination shall be subject to compliance with the following zoosanitary requirements:

I – Animals from foot-and-mouth disease free zones without vaccination:

a) Sheep, goats, pigs, and other susceptible animals, with the exception of cattle and buffalo, are exempted from additional requirements pertaining to foot-and-mouth disease;

b) Cattle and buffalo, with the exception of those destined for immediate slaughter and other animals MAPA may authorize, must be promptly vaccinated against foot-and-mouth disease in the destination state; and

c) As regards cattle and buffalo that are not destined for slaughter, the Official Veterinary Service of the state, of origin must send advance notification of the movement of said animals to the Official Veterinary Service of the destination state, as the case may be.

II – Susceptible animals from a buffer zone or from a state or part thereof classified as BR-3 (medium risk) for foot-and-mouth disease or into another, similar risk category eventually adopted by MAPA:

a) The animals should proceed directly from the aforementioned region where they have remained for at least 12 months prior to the issuance of the authorization, or since their birth, in the case of animals under 12 months of age; or from a livestock establishment where foot-and-mouth disease has not been officially recorded in the 12 months preceding the date of shipment, provided no case of foot-and-mouth disease has been recorded within a 25-km radius from said establishment in the six months prior to shipment. The animals must not show any clinical signs of the disease on the day of shipment;

b) The animals must be kept in isolation for at least 30 days prior to shipment in an officially approved location, under Official Veterinary Service supervision, and must be subjected to the laboratory tests determined by MAPA for foot-and-mouth disease. Diagnostic samples must be collected at least fourteen days after quarantine has started, and must be analyzed at laboratories of the Agriculture and Livestock Health Care Unified System's Agriculture and Livestock Laboratories Network. At MAPA's discretion, laboratory tests may be waived if the animals are destined for immediate slaughter.

c) If the animals are not destined for slaughter and if laboratory tests identify at least one positive animal, the entire group of animals must be barred from the foot-and-mouth disease free zone with vaccination. For the purposes of slaughter, should laboratory tests be required, only animals that test positive will be denied entry into the free zone, while the others may be taken directly to the slaughterhouse; and

d) At the destination, the animals must be kept in isolation for no less than fourteen days in an officially approved location and under official veterinary supervision.

Paragraph 1. Pigs from GRSC farms must conform only to the provisions under item II, a

and b of this Article; diagnostic tests will not be required.

Paragraph 2. Should diagnostic tests referred to in item II above yield at least one positive result, an investigation should be done at the establishment of origin, in accordance with the provisions of Art. 26, Paragraph 1 hereunder.

Paragraph 3. Cattle, buffalo, goats, and sheep up to six months of age, whether or not accompanied by their mothers, are exempted from the aforementioned laboratory tests; they should be individually identified and put on the list shown in the pertinent form.

Paragraph 4. If there are foot-and-mouth susceptible animals in the establishment approved for isolation at the destination, said animals cannot be moved during the isolation period, unless they are taken directly to slaughter.

Paragraph 5. In exceptional cases pertaining to slaughter capacity and available means at the origin, MAPA may authorize the entry of pigs destined for immediate slaughter irrespective of the foot-and-mouth disease risk classification at the origin, provided the animals meet the following zoosanitary requirements:

I – They come from establishments registered with and supervised by the Official Veterinary Service;

II – They have remained at the establishment of origin since birth;

III – They have been quarantined at the origin under official veterinary supervision and subjected to diagnostic tests for foot-and-mouth disease as determined by MAPA; and

IV – They are to be sent directly to slaughterhouses under official inspection, except for those qualified for international markets that have specific requirements as to the animals' origin.

Section IV

Movement of animals involving buffer zones, infected zones, and other areas as regards the foot-and-mouth disease risk classification

Art. 28. In the case of foot-and-mouth susceptible animals meant for entry into a buffer zone and into states, or into regions classified at least under the BR-3 category (medium risk) for foot-and-mouth disease or under a similar risk category that may be eventually adopted, which are not recognized as foot-and-mouth disease free zones, should said animals come from states that have a lower risk classification, they must meet the requirements under Art. 27, II hereunder, except for the diagnostic tests requirement.

Art. 29. In case of temporary suspension of the recognition as foot-and-mouth disease free zones because of the disease's occurrence, the movement of foot-and-mouth susceptible animals and of risk products and subproducts from the involved states, or parts thereof, including protection zones and containment zones, must be subjected to specific procedures determined by MAPA after evaluation of each case.

Art. 30. The movement of pigs involving GRSC farms or a similar classification eventually adopted by MAPA and not covered hereunder, irrespective of the foot-and-mouth disease risk classification at the origin, may be authorized by MAPA after evaluation supported by technical opinion issued by the Official Veterinary Service of the state of origin.

Art. 31. The movement of animals through an infected zone, to which the provisions of Art. 28 above do not apply, should meet the following requirements, irrespective of the purpose envisaged:

I – The animals must come from a livestock establishment where no foot-and-mouth disease outbreak has been detected in the previous 60 days, provided no foot-and-mouth disease case has occurred in its proximity within a 25-km radius in the previous 30 days;

II – In the case of cattle and buffalo from regions where foot-and-mouth disease vaccination is mandatory, the Official Veterinary Service must provide proof that vaccination has been done pursuant to the guidelines established under Chapter V hereunder;

III – Cattle and buffalo from a foot-and-mouth disease free zone without vaccination must be vaccinated upon arrival and revaccinated after they have been under the control of the Official Veterinary Service for 30 days, should foot-and-mouth disease vaccination be mandatory at the destination region.

CHAPTER VII

CONTROL AND INSPECTION OF THE MOVEMENT OF PRODUCTS AND SUBPRODUCTS FROM ANIMALS SUSCEPTIBLE TO FOOT-AND-MOUTH DISEASE

Art. 32. To be marketed, any animal product or subproduct must be accompanied by a sanitary certificate as determined by the Official Veterinary Service.

Art. 33. Animal products from a foot-and-mouth disease free zone without vaccination and from an establishment forming part of the Brazilian Animal Products Inspection System may be freely moved throughout the national territory.

Art. 34. The entry of the products and subproducts listed below from anywhere on the national territory into a foot-and-mouth disease free zone without vaccination shall be permitted, without prejudice of other legal instruments in force:

I – Meat and viscera destined for human consumption, subjected to sufficient thermal treatment to inactivate the foot-and-mouth disease virus;

II – Hides and skins, tanned or in any industrialization stage;

III – Pasteurized milk, or long life milk subjected to ultra high temperature treatment (UHT);

IV – Hooves, horns, hair, and mane subjected to treatment capable of inactivating the foot-and-mouth disease virus, dried and properly packaged;

V – Industrial animal feed;

VI – Tallow (melted grease) and meat and bone meal;

VII – Gelatin and hydrolyzed collagen from bovine and swine skin; and

VIII – Other products and byproducts of foot-and-mouth susceptible animals, subjected to sufficient treatment to inactivate the viral agent, and other products and subproducts not specified hereunder, subject to MAPA's decision and authorization after specific risk evaluation.

Art. 35. The entry of the products listed below into a foot-and-mouth disease free zone without vaccination shall be permitted, provided their origin and specific zoosanitary procedures are taken into consideration:

I – Products from a foot-and-mouth disease free zone with vaccination:

(a) Boned or unboned fresh meat of cattle or buffalo that have remained in a foot-and-mouth disease free zone with vaccination for the preceding 12 months or since birth. The meat must be from animals that have not shown clinical signs of infectious vesicular disease at the time of shipment for slaughtering or during the ante-mortem examination, and regarding which the post-mortem has not detected any lesions suggestive of foot-and-mouth disease, and that have been slaughtered at a slaughterhouse with official veterinary inspection and forming part of the Brazilian Animal Products Inspection System;

b) Boned or unboned fresh meat and fresh viscera of sheep, goats, pigs, and other susceptible animals that have remained since birth or for the preceding 12 months in a foot-and-mouth disease free zone with vaccination, slaughtered at slaughterhouses with official veterinary inspection and forming part of the Brazilian Animal Products Inspection System;

c) Fresh milk transported under refrigeration in appropriate sealed tank trucks from establishments with official veterinary inspection and forming part of the Brazilian Animal Products Inspection System, for immediate processing; and

d) Raw hides and skins from slaughterhouses with official veterinary inspection or that have been subjected to treatment in sea salt brine containing 2 percent of sodium carbonate for at least seven days.

II – Products from a buffer zone or from a state, classified at least under the BR-3 category (medium risk) pertaining to foot-and-mouth disease or under another, similar category eventually adopted by MAPA:

a) Deboned beef:

1. From animals that have remained in a specified region of origin for 12 months prior to

the issuance of the authorization, or since birth, in the case of animals under one year of age, which have not shown any signs of infectious vesicular disease at the time of being shipped for slaughter;

2. From slaughterhouses with official veterinary inspection and forming part of the Brazilian Animal Products Inspection System; and

3. Subjected before deboning to a sanitary ageing temperature over 2º C for at least 24 hours after slaughtering, provided the pH content does not exceed 6 at the center of the longissimus dorsi muscle;

b) Fresh meat of goat, sheep, pigs, and other susceptible animals from slaughterhouses with official veterinary inspection and forming part of the Brazilian Animal Products Inspection System and destined for another establishment with official veterinary inspection and forming part of the Brazilian Animal Products Inspection System, where it will be subjected to treatment sufficient for inactivating the foot-and-mouth disease virus;

c) Fresh milk transported under refrigeration in appropriated sealed tank trucks from an establishment with official veterinary inspection and forming part of the Brazilian Animal Products Inspection System and destined for industries with official veterinary inspection and forming part of the Brazilian Animal Products Inspection System, for immediate processing;

d) Raw hides and skins subjected to treatment in sea salt brine with a 2 percent sodium carbonate content for at least 28 days;

Sole Paragraph. Products must be transported in vehicles with the cargo sealed by the Official Veterinary Service of the state of origin or subjected to another type of control authorized by the Official Veterinary Service, and must enter the foot-and-mouth disease free zone through entry points previously established and approved by MAPA.

Art. 36. The entry of the products listed below into a foot-and-mouth disease free zone with vaccination from a buffer zone or from a state or parts thereof, classified at least under the BR-3 category (medium risk) for foot-and-mouth disease or under another, similar category eventually adopted:

I – Deboned beef:

a) From animals that have remained for at least three months prior to slaughter in the specified region of origin, where no occurrence of foot-and-mouth disease has been recorded in the preceding 60 days, provided also that no case of foot-and-mouth disease has occurred in the preceding 30 days within a 25-km radius around the establishment. In addition, the animals have not shown any sign of infectious vesicular disease at the time of being shipped for slaughter;

b) From slaughterhouses with official veterinary inspection and forming part of the Brazilian Animal Products Inspection System; and

c) Subjected, prior to deboning, to sanitary ageing at a temperature above 2º C for at least 24 hours after slaughtering, provided the pH content does not exceed 6 at the center of the longissimus dorsi muscle.

II – Fresh meat of goat, sheep, pigs, and other susceptible animals that meet the same requirements as for fresh beef, except for the deboning and ageing requirement;

III – Fresh viscera from a slaughterhouse with official veterinary inspection and forming part of the Brazilian Animal Products Inspection System, destined for processing for optotherapeutic purposes or for the production of animal feed at MAPA-approved establishments;

IV – Fresh milk transported under refrigeration in appropriated sealed tank trucks from an establishment with official veterinary inspection and forming part of the Brazilian Animal Products Inspection System and destined for industries with official veterinary inspection and forming part of the Brazilian Animal Products Inspection System; and

V – Raw hides and skins subjected before shipment to treatment in sea salt brine with 2 percent of sodium carbonate for at least 14 days.

Sole Paragraph. Products must be transported in vehicles with the cargo sealed by the Official Veterinary Service of the state of origin or subjected to another type of control authorized by the Official Veterinary Service, and must enter the foot-and-mouth disease free zone through entry points previously established and approved by MAPA.

Art. 37. The entry of raw skins and hides into a foot-and-mouth disease free zone with vaccination shall be permitted if they come from states classified as being of high or unknown risk for foot-and-mouth disease or under another similar category eventually adopted, provided they are subjected to treatment in sea salt brine with a 2-percent sodium carbonate content for at least 28 days.

Art. 38. The entry of semen, embryos, or ovocytes of foot-and-mouth disease susceptible animals into a foot-and-mouth disease free zone shall be permitted, provided they have been obtained and processed pursuant to international technical norms at a center registered with the Official Veterinary Service located in a state, classified at least as being of medium risk for foot-and-mouth disease or under another, similar category eventually adopted by MAPA, provided they meet the requirements specified under Art. 27, II, a and b hereunder and are accompanied by a zoosanitary certificate.

Art. 39. The entry of meat and meat products and fresh viscera into a foot-and-mouth disease free zone with or without vaccination shall be permitted, provided they are properly packaged and conditioned and are destined for exportation through ports, airports, border posts, and other warehouse premises at these locations, from any state, as long as they come from establishments licensed by MAPA for exportation, and are accompanied by the pertinent sanitary documentation.

Sole Paragraph. The transport vehicle must be sealed at the origin and the seal may be broken only at the destination by the Official Veterinary Service.

Art. 40. The entry of pathogenic material for any purpose into a foot-and-mouth disease free zone with or without vaccination is prohibited, unless it has been previously authorized by MAPA.

Art. 41. The entry, into a foot-and-mouth disease free zone with or without vaccination, of products and subproducts of foot-and-mouth susceptible animals, which have not been specified hereunder, including material of scientific interest and for industrial use shall require prior MAPA authorization.

CHAPTER VIII

INTERNATIONAL MOVEMENT OF FOOT-AND-MOUTH SUSCEPTIBLE ANIMALS AND PRODUCTS AND SUBPRODUCTS THEREOF

Art. 42. The importation of foot-and-mouth susceptible animals and of products and subproducts thereof shall be prohibited if they come from countries, regions, or zones not on OIE's List of Foot-and-Mouth Disease Free Countries, save for the exceptions hereunder.

Art. 43. The importation of fresh deboned meat from bovine carcasses shall be permitted if:

I –It has been taken from animals that have remained in the exporting country for two years prior to slaughter or since birth in areas where official control measures have been introduced and are in force;

II – It has been taken from animals from an establishment where no foot-and-mouth disease outbreak has occurred in the 60 preceding days, provided also that no foot-and-mouth disease case has been detected in the surrounding area, within a 25-km radius, in the 30 preceding days;

III - It has been taken from animals slaughtered in slaughterhouses qualified for exporting to Brazil;

IV – It has been taken from carcasses from which the main lymph nodes have been removed; and

V – It has, before deboning, been subjected to sanitary ageing at a temperature above 2º C for at least 24 hours after slaughtering, and the pH at the center of the longissimus dorsi muscle in each half of the carcass does not exceed 6.

Art. 44. The importation of products containing beef as raw material shall be permitted, provided the provisions under Art. 43 hereunder are observed.

Art. 45. The importation of products containing beef, offal, and viscera as raw material shall be permitted, as long as they have been subjected to procedures for inactivation of the foot-and-mouth disease virus, pursuant to OIE recommendations.

Art. 46. The importation of bovine semen and embryos shall be permitted, provided the provisions under Art. 43, I-II hereunder are complied with and the following conditions are met:

I – They have been collected at artificial insemination centers or other establishments registered with or approved by the Official Veterinary Service of the exporting country and meet both the general and the specific conditions recommended by OIE;

II – They have been collected, processed, and stored pursuant to OIE guidelines, in the case of semen, and to the International Embryo Transfer Society's guidelines, in the case of embryos; and

III – The exporting country's Official Veterinary Service certifies compliance with the Brazilian zoosanitary requirements applicable to the goods in question.

Art. 47. The importation of straw and fodder from countries, regions, or zones on OIE's List of Foot-and-Mouth Disease Free Countries, or from establishments where in the 30 days preceding collection no foot-and-mouth disease outbreak has occurred and in whose surroundings within a 3-km radius no outbreak has been detected either, provided such products have been subjected to one of the following treatments:

I – Water steam in an environment closed for at least 10 minutes at a temperature of at least 80º C; or

II –Phormol steam (phormaldehyde gas) produced from a 35-40 percent solution in an environment closed for at least 8 hours at a temperature of at least 19º C.

Art. 48. The importation of other animal products shall be permitted, provided they are subjected to the OIE-recommended procedures for inactivation of the foot-and-mouth disease virus,

Art. 49. The zoosanitary certificates accompanying the goods referred to hereunder must contain the specific guarantees defined for each case.

Art. 50. The importation conditions hereunder shall apply without prejudice of other sanitary requirements in force.

CHAPTER IX

FINAL DISPOSITIONS

Art. 51. Omissive cases and doubts pertaining to this Act's execution shall be resolved by MAPA.

ANNEX II

(Model)

APPLICATION FOR THE ENTRY OF FOOT-AND-MOUTH DISEASE SUSCEPTIBLE ANIMALS INTO A FOOT-AND-MOUTH DISEASE FREE ZONE, BUFFER ZONE, OR MEDIUM RISK ZONE

( ) WITHOUT VACCINATION ( ) WITH VACCINATION ( ) BUFFER ZONE OR MEDIUM RISK ZONE

As we are interested in bringing foot-and-mouth susceptible animals into the region indicated above, we hereby request authorization in accordance with the provisions of the Ministry of Agriculture, Livestock, and Food Supply's _____ No. _____/07, and to that end we submit the following information:

1. Information about the animals' origin and characterization

Origin:

State ☐ Municipality: _____

Establishment's name: _____

Name of the person responsible for the animals at the origin: _____

Address for contact _____

_____

Phone: _____ FAX _____ E-mail _____

Information about the animals:

Species: _____ Purpose: _____ Quantity: _____

Additional information on the animals (if necessary) _____

_____

_____

2. Information about the destination

State ☐ Municipality: _____

Establishment's name: _____

Name of the Person responsible for the animals at the destination: _____

Phone: _____ FAX _____ E-mail _____

Means of transportation ☐ ☐ Land ☐ Air ☐ Sea Other: _____

Point of entry: _____

_____

Place and date

_____

Applicant's name and signature

ANNEX III

(Model)

AUTHORIZATION FOR THE ENTRY OF FOOT-AND-MOUTH DISEASE SUSCEPTIBLE ANIMALS INTO A FOOT-AND-MOUTH DISEASE FREE ZONE, BUFFER ZONE, OR MEDIUM RISK ZONE

( ) WITHOUT VACCINATION ( ) WITH VACCINATION ( ) BUFFER ZONE OR MEDIUM RISK ZONE

No. _____/ _____

I HEREBY AUTHORIZE the entry of the animals identified bellow in accordance with the provisions of the Ministry of Agriculture, Livestock, and Food Supply's _____ No. _____/07, subject to compliance with the following:

I. The animals must be moved to the destination establishment identified hereunder, under the supervision of the designated Official Veterinary Service for the purposes of:

( ) confinement, observation for at least ____ days;

( ) performance of the requisite laboratory tests;

II. This authorization shall be valid solely for entry at the specified entry point specified hereunder;

III. This authorization may be cancelled at any time if any change occurs in the sanitary status of the livestock establishment of origin or of the state of origin, at the discretion of the Animal and Plant Health and Inspection Secretariat's Animal Health Department.

Information about the destination's confinement site:

State ☐ Municipality: _____

Establishment's name: _____

Name of the Person responsible for the animals at the destination: _____

Phone: _____ FAX _____ E-mail: _____

Means of transportation: ☐ Land ☐ Air ☐ Sea ☐ Other: _____

Point of entry: _____

Information about the animals:

Species: _____ Purpose: _____ Quantity: _____

Additional information about the animals (please attach a list with individual identification) _____

_____

_____

Origin:

State ☐ Municipality: _____

Establishment's name: _____

Name of person responsible for the animals at the origin: _____

_____

Place and date of issuance

_____

Seal and signature of authorizer

1st copy: Receiver 2nd copy: State of origin 3rd copy: Point of entry 4th copy: Authorizer

ANNEX IV

(Model)

ZOOSANITARY CERTIFICATE OF ORIGIN FOR THE ENTRY OF FOOT-AND-MOUTH SUSCEPTIBLE ANIMALS INTO A BUFFER ZONE OR MEDIUM RISK ZONE

( ) WITHOUT VACCINATION ( ) WITH VACCINATION ( ) BUFFER ZONE OR MEDIUM RISK ZONE

ADDITION TO THE ANIMAL MOVEMENT PERMIT (GTA) No. ____/_____

SPECIES INVOLVED: ☐ Bovine ☐ Bubaline ☐ Goat ☐ Sheep ☐ Pig ☐ Other _____

I hereby certify, for the purposes of entry into a foot-and-mouth disease free zone, a buffer zone or medium risk zone, pursuant to Ministry of Agriculture, Livestock, and Food Supply's Normative Instruction No. _____/07, that the animals identified below meet the following conditions:

( ) 1. They have been born and reared on the establishment of origin, where they have spent the last _____ months prior to shipment.

( ) 2. They meet the conditions stipulated under Arts. _____ of Ministry of Agriculture, Livestock, and Food Supply's Normative Instruction No. _____/07.

( ) 3. In the state of origin where the establishment of origin is located, the vaccination of cattle and buffalo is regularly practiced and officially controlled.

( ) 4. In the state the Official Veterinary Service is structurally organized and meets the requisite legal provisions for inspecting the movement of animals, exercising epidemiologic and sanitary surveillance, and imposing the interdiction of the disease's outbreaks, as well as enforcing other animal health and Inspection measures.

( ) 5. They have been kept in confinement for 30 days prior to shipment, in an officially approved environment and under official veterinary supervision, and have not shown any clinical sign of transmissible disease when subjected to the officially approved foot-and-mouth disease tests.

( ) 6. The pigs have been born and reared at an establishment officially certified as CERTIFIED PIG REPRODUCERS FARM pursuant to the zoosanitary norms in force.

( ) 7. Animals' identification:

No.	Identification	Breed	Gender	Age (months)
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				

No.	Identification	Breed	Gender	Age (months)
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				

Continuation in attached sheet? ( ) Yes ( ) No

Obs.: _____

_____

Identification and signature of the veterinary doctor at the state Official Veterinary Service

_____	_____
Seal	Signature

COMPLEMENTARY LEGISLATION

ADMINISTRATIVE RULING No. 17 OF JANUARY 12, 2007

Published in the Official Gazette No. 12, Section 2, page 4, Wednesday, January 17, 2007

Establishes the Biosecurity Commission on the Foot-and-mouth Disease Virus under the Animal and Plant Health and Inspection Secretariat - SDA.

ADMINISTRATIVE RULING No. 43 OF FEBRUARY 10, 2006

Published in the Official Gazette of February 13, 2006, Section 1, Page 2

Declares the State of Paraná's Center-South region, which consists of the municipalities and parts of the municipalities listed in the Annex, as free of foot-and-mouth disease with vaccination.

ADMINISTRATIVE RULING No. 9 OF JANUARY 15, 2004

Published in the Official Gazette of January 19, 2004, Section 1, Page 12

Declares the State of Acre, the Municipalities of Guajará and Boca do Acre in the State of Amazonas, and the Municipalities located in the Center-South region of the State of Pará free of foot-and-mouth disease with vaccination.

ADMINISTRATIVE RULING No. 543 OF OCTOBER 22, 2002

Published in the Official Gazette of October 23, 2002, Section 1, Page 3

Declares the State of Rondônia free of foot-and-mouth disease with vaccination.

ADMINISTRATIVE RULING No. 582-A OF DECEMBER 28, 2000

Published in the Official Gazette of January 12, 2001, Section 1, Page 52

Establishes a Buffer Zone in the States of Tocantins and Bahia, consisting of the municipalities listed under Annex I, to separate the foot-and-mouth disease free zone with vaccination from the other States considered as infected.

ADMINISTRATIVE RULING No. 153 OF APRIL 27, 2000

Published in the Official Gazette of April 28, 2000, Section 1, Page 78

Declares the zone consisting of the States of Rio Grande do Sul and Santa Catarina as a foot-and-mouth disease free zone without vaccination.

ADMINISTRATIVE RULING No. 713 OF NOVEMBER 12, 1995

Published in the Official Gazette of November 7, 1995, Section 1, Page 17760

Approves Norms for the Production, Control, and Use of Vaccines against Foot-and-Mouth Disease, and revokes Administrative Ruling No. 533 of October 22, 1993

ADMINISTRATIVE RULING No. 194 OF NOVEMBER 29, 1994

Published in the Official Gazette of December 09, 1994, Section 1, Page 8968

Establishes the Coordination Commission of Livestock Circuits, as listed hereunder, to harmonize and coordinate the actions of public and private agencies involved in foot-and-mouth disease control and eradication.

ADMINISTRATIVE RULING No. 177 OF OCTOBER 27, 1994

Published in the Official Gazette of November 10, 1994, Section 1, Page 16875

Biologic Security Norms on the Manipulation of the Foot-and-Mouth Disease Virus.

ADMINISTRATIVE RULING No. 768 OF DECEMBER 13, 1993

Published in the Official Gazette of December 15, 1993, Section 1, Page 19371

Order the Animal and Plant Health and Inspection Secretariat, through the Animal Health and Inspection Department, to undertake the monthly publication of lab results in the media by the 10th day of the month following the performance of the qualitative tests of foot-and-mouth disease vaccines.

ADMINISTRATIVE RULING No. 16 OF JANUARY 26, 1989

Published in the Official Gazette of January 30, 1989, Section 1, Page 1641

Prohibits on the entire National Territory the researching, production, marketing, and use of foot-and-mouth disease vaccine made from modified live virus.

NORMATIVE INSTRUCTION No. 25 OF JUNE 28, 2007

Published in the Official Gazette of July 2, 2007, Section 1, Page 2

Includes the State of Para's center-south region consisting of the listed municipalities and parts of municipalities in the internationally recognized foot-and-mouth disease free zone with vaccination.

NORMATIVE INSTRUCTION No. 61 OF NOVEMBER 6, 2006

Published in the Official Gazette No. 214 of November 8, 2006, Section 1, Page 67

Lifts the restrictions imposed under SDA Normative Instruction No. 9 of March 15, 2006.

NORMATIVE INSTRUCTION No. 51 OF SEPTEMBER 21, 2006

Published in the Official Gazette of September 25, 2006, Section 1, Page 2

Lifts the restrictions imposed under SDA Normative Instruction No. 9 of March 15, 2006 on the areas under sanitary risk related to outbreaks detected in the Municipalities of Bela Vista do Paraíso, Grandes Rios, Maringá, and São Sebastião da Amoreira, identified in Art. 1, II of the aforementioned Normative Instruction.

NORMATIVE INSTRUCTION No. 14 OF JULY 6, 2005

Published in the Official Gazette No. 129 of Thursday, July 7, 2005, Section 1, Page 2

Includes the State of Acre and the Municipalities of Boca do Acre and Guajará, State of Amazonas, in the zone free of foot-and-mouth disease with vaccination, consisting of the States of Bahia, Espírito Santo, Goiás, Mato Grosso, Mato Grosso do Sul, Minas Gerais, Paraná, Rio de Janeiro, Rio Grande do Sul, Santa Catarina, São Paulo, Sergipe, Tocantins, and the Federal District.

NORMATIVE INSTRUCTION SDA No. 61 OF AUGUST 18, 2003

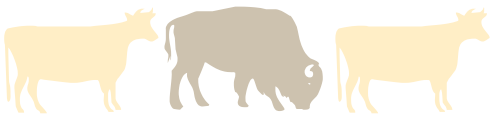
Published in the Official Gazette No. 164 of Tuesday, August 26, 2003, Section 1, Pages 6-8 as amended by Normative Instruction No. 25 of June 28, 2007.

Establishes the procedures hereunder as a condition for the entry of animals susceptible to foot-and-mouth disease, as well as their products and subproducts into the State of Pará in connection with the interstate movement of animals, without prejudice of other sanitary norms in force.

NORMATIVE INSTRUCTION No. 7 OF JUNE 11, 2003

Published in the Official Gazette No. 112 of Thursday, June 12, 2003, Section 1

Includes the State of Rondônia in the zone free of foot-and-mouth disease with vaccination, consisting of the States of Bahia, Espírito Santo, Goiás, Mato Grosso, Mato Grosso do Sul, Minas Gerais, Paraná, Rio de Janeiro, Rio Grande do Sul, Santa Catarina, São Paulo, Sergipe, Tocantins, and the Federal District.



NORMATIVE INSTRUCTION No. 11 OF MAY 9, 2001

Published in the Official Gazette No. 90 of Thursday, May 10, 2001, Section 1

Orders the immediate vaccination of all the bovine and bubaline herds in the State of Rio Grande do Sul.

NORMATIVE INSTRUCTION No. 6 OF JULY 13, 2000

Published in the Official Gazette of July 14, 2000, Section 1, Page 95

Establishes a Buffer Zone in the States of Bahia and Tocantins, separating the possible foot-and-mouth disease free zone with vaccination from the other States considered as infected.

NORMATIVE INSTRUCTION No. 229 OF DECEMBER 7, 1998

Published in the Official Gazette No. 1 of Monday, January 4, 1999, Section 1

Authorizes the use of a Guarantee Seal on foot-and-mouth disease vaccine ampoules, and makes other provisions.

NATIONAL PROGRAM FOR THE CONTROL AND ERADICATION OF ANIMAL BRUCELLOSIS AND TUBERCULOSIS

ADMINISTRATIVE RULING No. 11 OF JANUARY 26, 2004

Published in the Official Gazette of January 29, 2004, Section 1, Page 3

Exempts the State of Santa Catarina from the compulsory vaccination of cattle and buffalo females against brucellosis

THE DIRECTOR OF THE ANIMAL HEALTH AND INSPECTION DEPARTMENT OF THE MINISTRY OF AGRICULTURE, LIVESTOCK, AND FOOD SUPPLY'S ANIMAL AND PLANT HEALTH AND INSPECTION SECRETARIAT, by virtue of the powers vested in him under Art. 84, VIII of the Secretariat's Internal Regulations approved by Ministerial Administrative Ruling no.574 of December 8, 1998, and under Art. 13 of SDA Normative Instruction No. 6 of January 8, 2004,

WHEREAS the soroepidemiologic investigation of bovine brucellosis undertaken by the State of Santa Catarina's sanitary authorities has

detected low prevalence of properties and animals infected with the disease;

WHEREAS, given the low prevalence detected, vaccination will not yield beneficial effects, and in view of the possibility that the use of vaccine prepared with B19 sample may interfere with the results of diagnostic tests, a procedure systematically used in areas in the process of eradicating the disease, and in light of Proceeding No. 21000.013020/2003-71,

RESOLVES:

Art. 1. To exempt the State of Santa Catarina from the compulsory vaccination of cattle and buffalo females against brucellosis.

Art. 2. The actions to be carried out in areas in the process of eradicating the disease shall be defined under a specific act issued by the Animal Health and Inspection Department-DDA.

Art. 3. This Administrative Ruling shall enter into force on the date of its publication.

JOÃO CRISOSTOMO MAUD CAVALLÉRO

NORMATIVE INSTRUCTION SDA No. 33 OF AUGUST 24, 2007

Published in the Official Gazette of August 28, 2007, Section 1, Page 6

Establishes the conditions for the vaccination of cattle females against brucellosis with a RB51 sample vaccine.

THE MINISTRY OF AGRICULTURE, LIVESTOCK HEALTH AND FOOD SUPPLY'S AGRICULTURE AND LIVESTOCK AND INSPECTION SECRETARY, by virtue of the powers vested in him under Arts. 9 and 42, Annex I of Decree No. 5351 of January 21, 2005, having in view the provisions under Decree No. 24548 of July 3, 1934; SDA Normative Instruction No. 6, of January 8, 2004; and Proceeding No. 21000.004860/2005-13,

RESOLVES:

Art. 1. To set forth the conditions for the vaccination of cattle females against brucellosis with a RB51 sample vaccine.

Art. 2. The vaccination of female cattle with a RB51 sample vaccine shall be recommended in the following cases:

I – Females aged over eight months that have not been vaccinated with B19 sample between three and eight months of age; or

II – Adult females that do not react to diagnostic tests on rearing establishments with brucellosis outbreak.

Art. 3. The vaccination referred to in the preceding Art. shall be performed under the responsibility of a veterinary doctor registered with the Official Veterinary Service of the state as the case may be.

Art. 4. The use of a RB51 sample vaccine against brucellosis on male cattle of any age, on females aged up to eight months, and on pregnant females is hereby prohibited.

Art. 5. The marketing of the RB51 sample vaccine against brucellosis may be done solely by duly registered and authorized commercial establishments and shall be subject to the official service's inspection.

Paragraph 1. Acquisition of the vaccine shall be permitted solely against a pertinent prescription, pursuant to the form shown in Annex I hereto, issued by a veterinary doctor registered with the official and Inspection service of the pertinent state.

Paragraph 2. The veterinary doctor's prescription shall be kept by the commercial establishment and shall include the veterinary doctor's full name and signature, his registration number with the Veterinary Medicine Council (CRMV), his registration number with the official and Inspection service, as the case may be, the number of doses to be purchased, and the place and date.

Art. 6. The commercial establishment shall apprise the official service of the purchase, sale, and stock of the RB51 sample vaccine, as prescribed under Annex II hereto.

Art. 7. The veterinary doctor responsible for the vaccination shall issue a vaccination cer-

tificate in three copies, of which the first shall be kept by the owner, the second by the local unit of the official service of the state as the case may be, and the third by the issuer, as prescribed under Annex III or Annex IV hereunder, as the case may be.

Art. 8. This Normative Instruction shall enter into force on the date of its publication.

INÁCIO AFONSO KROETZ

ANNEX I

PRESCRIPTION FOR THE PURCHASE OF RB51 SAMPLE VACCINES

Veterinary doctor's name: _____

No. of registration with the state's official service: _____

No. of registration with the Veterinary Medicine Council (CRMV): _____

Address: _____

Phone: _____

Vaccine: RB51 sample

Quantity of doses _____ (_____).

_____

Place and date

_____

Veterinary doctor's signature and seal

ANNEX II

REPORT ON THE MARKETING OF RB51 SAMPLE VACCINE AGAINST BRUCELLOSIS

Commercial establishment:

Address and telephone: Municipality: State:

Period covered:

PURCHASE:

Date	Laboratory	Lot	No. vials	No. doses	Expiration

SALE:

Veterinarian's name and registration nº.	Laboratory	Lot	No. vials	No. doses	Expiration

CURRENT STOCK:

Date	Laboratory	Lot	No. vials	No. doses	Expiration

OBSERVATIONS:

Place and date:

Name and signature of the person in charge:

ANNEX III

CERTIFICATE OF VACCINATION AGAINST BRUCELLOSIS RB51 SAMPLE VACCINE

I hereby certify that _____ (_____) females were vaccinated against brucellosis on _____'s property known as _____, registered with the official state service under No._____ and located in the Municipality of _____, in the state of _____.

The vaccine used was the RB51 sample vaccine produced by the _____ laboratory, lot No. _____, manufactured on _____, and valid until _____.

Place and date of vaccination

_____

Veterinary Doctor

CRMV Registration No._____ and No. of registration

with the state official health and inspection service _____

ANNEX IV

CERTIFICATE OF VACCINATION AGAINST BRUCELLOSIS RB51 SAMPLE VACCINE

(Form to be used in connection with the vaccination of individually identified females under an appropriate system prescribed by MAPA)

OWNER: _____

PROPERTY'S NAME: _____

No. OF REGISTRATION WITH THE OFFICIAL AND INSPECTION SERVICE: _____

MUNICIPALITY: _____ STATE.: _____

I hereby certify for the pertinent purposes that the females listed below have been vaccinated against brucellosis with the RB51 sample vaccine, lot nº. _____ manufactured by the _____ laboratory on _____ and with expiration date _____.

(Females listed by number, name, age, and breed)

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____

_____

Place and date of vaccination

_____

Veterinary Doctor

CRMV Registration nº. _____ and nº. of registration

with the state official and Inspection service _____

NORMATIVE INSTRUCTION No. 41 OF NOVEMBER 24, 2006

Published in the Official Gazette of November 28, 2006, Section 1, Page 86

Approves "Specific Criteria for Accreditation and Monitoring of Bovine and Bubaline Brucellosis Diagnostic Laboratories."

THE MINISTER OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY, by virtue of the powers vested in him under Art. 2 of Decree No. 5741 of March 30, 2006 and Proceeding 21000.004434/2006-52,

Resolves:

Art. 1. To approve "Specific Criteria for Accreditation and Monitoring of Bovine and Bubaline Brucellosis Diagnostic Laboratories" pursuant to Annexes I-X hereto.

Art. 2. This Normative Instruction shall enter into force on the date of its publication.

LUÍS CARLOS GUEDES PINTO

ANNEX I

SPECIFIC CRITERIA FOR THE ACCREDITATION AND MONITORING OF BOVINE AND BUBALINE BRUCELLOSIS DIAGNOSTIC LABORATORIES

The accreditation and monitoring of bovine and bubaline brucellosis diagnostic laboratories shall be based on this Normative Instruction as well as on SDA Normative Instruction No. 51 of June 27, 2003; SDA Normative Instruction No. 6 of January 8, 2004; and any acts that may eventually replace them.

1. OBJECTIVES:

1.1. To standardize the procedures adopted by bovine and bubaline brucellosis diagnostic laboratories; and

1.2. To accredit laboratories provided with a quality guarantee system, in support of animal health and Inspection actions determined by the Ministry of Agriculture, Livestock, and Food Supply-MAPA.

2. APPLICATION

2.1. This Normative Instruction applies to public and private laboratories interested in joining the Agriculture and Livestock Health Care Unified System's National Network of Agriculture and Livestock Laboratories in connection with bovine and bubaline brucellosis diagnostic, provided they have a veterinary doctor responsible for the technical area as well as a quality control system.

3. DEFINITIONS

3.1. For the purposes hereunder, the follow definitions shall apply:

3.1.1. Official Health and Inspection Service: service under the Central and Superior Organ and the Intermediate and Local Organs charged with the promotion of animal health and the prevention, control, and eradication of diseases that may harm animal productivity, the economy, and agriculture and livestock health.

3.1.2. Official veterinary doctor: government Health and Inspection service veterinary doctor.

3.13. Accredited veterinary doctor: a private sector professional qualified before one of the Agriculture and Livestock Health Care Unified System's three Organs to carry out specific animal health and Inspection actions as determined by the Ministry of Agriculture, Livestock, and Food Supply as Central and Superior Organ.

3.1.4. Owner: any legal or natural person that owns one or more than one cattle and buffalo.

3.1.5. Herd: a group of animals reared under the same management conditions at the same rearing establishment.

3.1.6. Brucellosis: zoonosis caused by Brucella spp, which causes infertility and miscarriage in late pregnancy, and affects mainly the bovine and bubaline species.

3.1.7. Accredited laboratory: a public or private laboratory that has been subjected to Agriculture and Livestock Health Care Unified System's accreditation process and been officially recognized as competent for performing official analysis in accordance with the accreditation's scope and the laboratory's quality system.

3.1.8. Senior professional: a veterinary doctor in charge of an accredited laboratory that has been subjected to evaluation and approved by the competent authority of one of the Agriculture and Livestock Health Care Unified System's Organs and who has responsibility for the laboratory's technical activities.

3.1.9. Reference laboratory: an official laboratory of the National Network of Agriculture and Livestock Laboratories designated by MAPA as a reference laboratory for the diagnostic of brucellosis in light of the Program's scope.

3.1.10. Retesting: a test performed on a new sample collected from the same animal(s) under the conditions established under the PNCEBT.

3.1.11. Monitoring: procedures adopted by the accreditation organ to ascertain that the accredited laboratory continues to be in compliance with the accreditation requirements.

4. MATERIAL

4.1. Antigen:

4.1.1. Only antigens (Ag) registered with MAPA's competent organ and whose lots have been tested and approved may be used, provided their validity limits is respected.

4.1.2. Antigens must be transported and maintained at a temperature between +2º C (two centigrade degrees) and +8º C (eight centigrade degrees) and protected from direct sunlight.

4.1.3. Accredited laboratories must acquire their antigens from the official health and inspection service of their respective state.

5. SAMPLES

5.1. Samples to be tested:

5.1.1.1. Blood serum – a minimum of 2 ml, frozen or cooled to a temperature no higher than +8º C (eight centigrade degrees); and

5.1.1.2. Milk cooled to a temperature between +2º C and +8º C (two and eight degrees centigrade).

6. RECEIVING

6.1. Samples must be properly identified, maintained at a temperature of up to +8º C (eight degrees centigrade), and accompanied by a sample forwarding form (Annex V), filled-out and signed by the accredited veterinary doctor, with his professional identification, or by the official animal health and Inspection service; and

6.1.1. In case the requesting veterinary doctor himself is not the carrier of the collected material, he should designate a proxy pursuant to the form shown in Annex VI.

6.2. Serums showing excessive hemolysis, impurities, or signs of bacterial contamination should be discarded.

6.3. Samples should be properly recorded in an official log established pursuant to the form shown in Annex IX.

6.4. Blood received must be centrifuged and the resulting serum must be subjected to the treatment referred to under the preceding items.

6.5. Samples to be tested must be kept under refrigeration until the analysis is performed, or frozen if the analysis is done 48 (forty-eight) hours after samples are received.

7. METHOD

7.1. The tests indicated for the diagnostic of bovine and bubaline brucellosis are as follows:

7.1.1. Buffered Brucella antigen test (BBAT), as described in Annex II;

7.1.2. 2-Mercaptoethanol (2-ME), as described in Annex III;

7.1.3. Milk ring test, as described in Annex IV; and

7.2. Modification or addition of any analytical method must be previously approved by MAPA's competent organ.

8. LABORATORY

8.1. The laboratory must have the appropriate premises, equipment, and operating flow for

the performance of brucellosis diagnostic tests, and one or more than one technical professional duly approved by MAPA.

9. FACILITIES

9.1. All laboratory facilities must be located on the same site.

9.1.1. Office: an area reserved for receiving and entering samples into the records, issuing results, and file-keeping.

9.1.2. Analysis room: area reserved for sample processing. Must be provided with sufficient and appropriate power outlets and water supply and drainage points for tests; waterproof counter, walls, and floor for easy washing and disinfection; and air conditioning.

9.1.3. Washing and sterilization: area reserved for washing the materials used in diagnostic tests and for autoclaving samples and their discardable residues. Must be provided with sufficient and appropriate power outlets and water supply and drainage points, tanks, or sinks. Counters, walls, and floors must be waterproof and resistant to washing and disinfection.

10. EQUIPMENT AND MATERIALS

10.1. A laboratory must have the following equipment and materials, as a minimum:

10.1.1. Office:

- file with lock; and
- typewriter or personal computer.

10.1.2. Analysis room:

- plate shaker (optional);
- cuvette with disinfectant solution;
- light box with indirect lighting for reading results;
- pipetting device, preferentially automatic, or provided with a rubber bulb;
- grid-patterned glass plates, with 4 cm x 4 cm squares;
- micropipette for volumes ranging from 10 µL to 100 µL;
- pointers for volumes ranging from 10 µL to 100 µL;
- laboratory glass vessels;
- refrigerator and freezer to – 20º C (minus twenty degrees centigrade) or two-door refrigerator;
- centrifuge with a minimum capacity of 1500 RPM (rotations per minute);
- pH meter;
- hot air oven or water bath at 37º C (thirty-seven degrees centigrade);
- gas exhaustion cabinet;
- minute timer or alarm clock;
- plain or five-point stirrers; and
- tube racks.

10.1.3. Washing and sterilization:

- autoclave;
- cuvette with disinfectant solution; and
- water distiller or deionizer.

10.1.4. Reactants:

- specific antigens for each test;
- control serum and milk, both positive and negative;
- 0.85 percent saline-0.5 percent phenicate solution;
- 0.85 percent saline solution;
- 2-mercaptoethanol; and
- distilled water.

11. BIOSAFETY

11.1. The laboratory must follow the recommended biosafety norms and procedures pertaining to the performance of brucellosis serologic diagnostic tests.

11.2. Before being discarded, samples and residues must be autoclaved at +121º C (hundred twenty-one degrees centigrade) for at least 30 (thirty) minutes under one-pound pressure.

11.3. Environmental, Sanitary, and Labor Security Norms must also be followed in connection with lab operations.

12. RETEST

12.1. Samples destined for retest must be accompanied by a request signed by an official or accredited veterinary doctor pursuant to the form shown in Annex VII;

12.2. In retesting, only the 2-ME test shall be performed.

13. RESULTS AND REPORTS

13.1. Results should be issued in three copies: the first to be kept by the accredited veterinary doctor that has requested the exam; the second to be forwarded to the state animal health and Inspection department; and the third to be kept in the laboratory file.

13.2. Results should be issued on the pertinent forms pursuant to the form shown in Annex

X and in accordance with the established flow;

13.2.1. POSITIVE or INCONCLUSIVE results: must be immediately and compulsorily reported to the SFA Agriculture and Livestock Sanitary Health and Inspection Service (SEDESA) and to the accredited veterinary doctor that has requested the test.

13.2.2. NEGATIVE result: must be reported to the veterinary doctor that has requested the test.

13.3. Reports on operating activities shall be issued in three copies – the first to be sent to MAPA's laboratory unit in charge of accrediting brucellosis laboratories; the second to be sent to the official and Inspection service that has provided the antigen; and the third to be kept in the laboratory's file.

13.4. Reports should be issued on a monthly basis according to the model form in Annex VIII and to the prescribed schedule, as follows:

13.4.1. To be sent by the fifth of the subsequent month to MAPA's laboratory unit in charge of accrediting brucellosis laboratories and to the local official health and inspection service from which the antigens were acquired.

13.4.2. By the 10th of the subsequent month in states where antigens are distributed by the state animal health service, which shall forward the report to the state's SFA/SEDESA.

13.5. Only the Senior Professional in charge may sign the results form and the monthly reports.

14. SENIOR PROFESSIONAL IN CHARGE

14.1. For the purposes of a laboratory's accreditation, its senior professional in charge shall be subjected to a capacity evaluation at an official laboratory or through the remote follow-up of an assay at the laboratory in question, by auditors designated by the competent authority of one of the Agriculture and Livestock Health Care Unified System's Organs. The decision should be sent to the laboratory that has provided the material, within five business days after receipt of the test, in a sealed envelope with a POSTAL RETURN RECEIPT SLIP (AR).

14.2. For monitoring purposes, distance exams may be done and the result may be sent to the laboratory that has provided the material, within five business days after the test's receipt, in a sealed envelope with a POSTAL RETURN RECEIPT SLIP (AR).

14.3. The Senior Professional may have only one laboratory unit under his charge.

15. GENERAL DISPOSITIONS

15.1. Omissive cases hereunder shall be solved by MAPA.

ANNEX II

BUFFERED BRUCELLA ANTIGEN TEST (BBAT)

MATERIALS REQUIRED

- antigen for the BBAT ;
- Bang pipette or 30 µL pipetting device or of adjustable volume;
- pointers;
- plates with delimited 15 mm squares;
- plastic, glass, or metal stirrers;
- light box with indirect lighting for reading;
- positive control serum;
- negative control serum;
- plate shaker (optional); and
- minute timer or alarm clock.

PRECAUTIONS DURING TEST PERFORMANCE

1. The antigen suspension stock must be kept between 4º C and 8º C when not in use;

2. If the antigen is to be used for a small number of tests, it should be divided into portions, and only the amount to be used each day should be taken out of the refrigerator, so as to prevent loss of sensitivity owing to repeated cooling down and warming up.

3. The desirable temperature for test performance should be around 22º C + 4º C; temperatures considerably lower or higher than these should be avoided.

4. Plates, stirrers, and pipettes should be cleaned in running water right after use. They should be immersed in a neutral detergent

solution for two hours, or preferentially overnight. Thereafter they should be washed in running water, then in distilled water, and be dried in an oven or at room temperature.

5. Hemolysed serums should be discarded as they may yield false positive results.

6. Parallel testing of positive and negative control samples should be done in connection with all tests.

METHOD:

1. Serums and antigens should be kept in equilibrium at 22º C + 4º C for at last 30 minutes. If serums are frozen, the equilibrium period at room temperature must be longer. Serums should be homogenized before test is performed.

2. Test forms identifying the location of each serum should be filled out.

3. During utilization of a 30 µL pipetting device or of a Bang pipette equipped with a rubber bulb, or another pipetting device to prevent the use of the mouth, 30 µL of serum (or serum measured from the 0.04 to the 0.01 mark on the Bang pipette) should be dispensed on each area of the plate; this amount should be deposited on the glass plate by touching the pipette's tip on the plate at a 45º angle.

4. Lightly agitate the antigen and place 30 µL of it next to the serum, without mixing.

5. Using a simple or multiple mixer, mix the serum and the antigen by making circular movements until a circle of approximately 2 cm in diameter is obtained.

6. Agitate the plate with oscillating movements at a rate of approximately 30 (thirty) movements per minute so as to allow the antigen mixture to slowly flow into each circle. The plate must be agitated continuously for four minutes.

7. Place the plate in the reading box with indirect lighting and read.

8. Write down the results.

9. Ignore any agglutinating reactions that may occur after the four minutes.

INTERPRETATION OF RESULTS

Presence of granules – REACTIVE

Absence of granules – NON-REACTIVE

ANNEX III

2-MERCAPTOETHANOL (2-ME) TEST

MATERIALS:

antigen for slow tube seroagglutination (SAT);
2 Mercaptoethanol (2-ME);
0.85-percent saline solution;
0.5-percent saline-phenicate solution;
Serum samples to be tested;
high-titer positive control serum;
medium-titer positive control serum;
low-titer positive control serum;
negative control serum;
10 mm x 75 mm or 10 mm x 100 mm tubes;
tube rack;
Bang pipettes or adjustable volume micropipetting devices;
1 ml automatic dispenser;
2 ml automatic dispenser;
10 ml pipettes;
light box with indirect lighting for reading results;
hot air oven at 37º C; and
glass vessels for diluting reactants.

PRECAUTIONS DURING TEST PERFORMANCE

1. The antigen for the series of tubes should be diluted with 2-ME in an 0.85-percent saline solution without the addition of phenol;

2. It is recommended that the antigen dilution be done 12 (twelve) hours before use;

3. Diluted antigens should be kept under refrigeration (+4º C - +8º C) and may be used for up to one week;

4. 2-ME should be kept in tightly-closed amber-colored vessels under refrigeration;

5. 2-ME is toxic for humans and should be

kept in a gas exhaustion cabinet;

6. For each day of work at least on selected serum should be included, especially one with a high anti-Brucella IgM antibodies content and that does not contain IGg detectable through the 2-ME test, as well as other serum that is reactive under SAT and 2-ME;

7. Each test should also include antigen control tubes with positive-tested serums of known titer, and negative serum; and

8. The 2-ME test is incubated and read together with SAT. Occasionally, the 1:25 dilution tube may seem somewhat opaque in the 2-ME test, even though the following tubes are clear. This should not be considered as a negative result of the test.

METHOD

1. Dilute the antigen for SAT in tubes 100 (one hundred) times in a 0.85 percent saline solution containing 0.5 percent phenol. Final concentration: 0.045 percent;

2. Dilute the antigen for the 2-ME test in tubes 50 (fifty) times in a 0.85-percent saline solution without addition of phenol. Final concentration: 0.090 percent;

3. Prepare the 0.1M 2-ME solution, mixing 7.8 ml of 2-ME into a 992.20 ml of a 0.85-percent saline solution without phenol, or in proportionately smaller volumes;

4. Place two rows of four tubes in a tube rack for each test;

5. Identify the first tube of each row with the number of the serum to be tested;

6. The first row corresponds to the four dilutions of the SAT serum and should be marked with the letter "T". The second row to be subjected to the 2-ME test should be marked with the letter "M";

7. With a Bang pipette provided with a rubber bulb or some other pipetting device to avoid the use of the mouth, transfer the serum until it reaches a slightly higher mark. Clean the pipette's tip with absorbent paper; Keeping the pipette in a vertical position against the wall of the tube containing the sample, let the serum trickle in until the bottom of the piston stroke inside the pipette is level with its highest mark;

8. With the pipette at the bottom of the first tube of the first row, let 0.08 ml of serum flow out. Deposit 0.04 ml into the second tube, 0.02 ml into the third, and 0.01 into the fourth;

9. Repeat the procedure to deposit the same serum amounts into the tubes of the second row (the 2-ME series);

10. Repeat the procedure for all serum samples in a similar way, pipetting serum into every properly identified rows of tubes;

11. Identify the positive control serums of known agglutinating activity;

12. Include the negative control serum into the 2-ME test;

13. With the 2 ml automatic dispenser, or with a 10 ml-pipette, add to each of the four tubes of the T row 2 ml of the antigen diluted at 1:100 (0.045 percent of cells) in a saline-phenicate solution;

14. With the 2 ml automatic dispenser (adjusted to 1 ml), or a 10 ml-pipette, add 1 ml of 0.1 M 2-ME solution (diluted in a solution without phenol) to each tube of the M row;

15. Mix well by shaking the rack;

16. Let racks with samples rest for 30 (thirty) minutes at room temperature;

17. After 30 (thirty) minutes, using the automatic pipetting device or another 10 ml pipette, add to each tube in row M 1 ml of the antigen diluted at 1:50 (0.09 percent of cells) in a saline solution (without phenol);

18. Mix well by agitating the rack;

19. Incubate at 37º C (thirty-seven degrees centigrade) for 48 hours + three hours;

20. Test reading is done under indirect lighting against a dark, opaque background, as bright light shines through the tubes. Other sources of light should be dimmed. Interpretation is based on the cloudiness in the tubes and the firmness of granules after a slight agitation of the tubes (antigen agglutination);

21. Write down the results. If there is interest in determining a serum's final titer, the serial dilutions method may be employed.

INTERPRETATION OF RESULTS

The extent of agglutination in each of the different solutions should be classified as: complete (+), incomplete (I), or negative (-):

Complete reaction: the serum-antigen mixture is clear, and a slight agitation does not break down the granules;

Incomplete reaction: the serum-antigen mixture is partially clear, and a slight agitation does not break down the granules;

Negative reaction: the serum-antigen mixture is opaque or cloudy, and a slight agitation does not show any granules.

Interpretation of the test results is based on tables 1 and 2 below:

TABLE 1: Interpretation of the 2-ME test of females aged 24 months or over and vaccinated between three and eight months of age

2-ME SAT	NR	25 I	25	50 I	50	100 I	100	200 I	200
NR	-								
25 I	-	-							
25	-	-	+						
50 I	-	-	+	+					
50	-	-	+	+	+				
100 I	-	-	+	+	+	+			
100	Inc	Inc	+	+	+	+	+		
200 I	Inc	Inc	+	+	+	+	+	+	
200	Inc	Inc	+	+	+	+	+	+	+

+: positive

- : negative

SAT = Slow Agglutination Test

2-ME = 2-Mercaptoethanol Test

NR = nonreactive

I = incomplete reaction

Inc = inconclusive reaction

☐ – Combination that should not occur

TABLE 2: Interpretation of the 2-ME test of unvaccinated females and males over 8 (eight) months of age.

2-ME SAT	NR	25 I	25	50 I	50	100 I	100	200 I	200
NR	-								
25 I	-	-							
25	-	-	+						
50 I	-	-	+	+					
50	Inc	Inc	+	+	+				
100 I	Inc	Inc	+	+	+	+			
100	Inc	Inc	+	+	+	+	+		
200 I	Inc	Inc	+	+	+	+	+	+	
200	Inc	Inc	+	+	+	+	+	+	+

+: positive

- : negative

SAT = Slow Agglutination Test

2-ME = 2-Mercaptoethanol Test

NR = nonreactive

I = incomplete reaction

Inc = inconclusive reaction

☐ – Combination that should not occur

ANNEX IV

MILK RING TEST (MRT)

MATERIALS:

antigen for the Milk Ring Test;
milk samples to be tested;
10 mm x 75 mm or 10 mm x 100 mm tubes
tube rack
1 ml pipettes
30 µl pipetting device; and
Hot air oven or steam bath at 37º C (thirty-seven degrees centigrade).

PRECAUTIONS DURING TEST PERFORMANCE

1. Milk samples should be kept between +2º C and +8º C for at least 24 (twenty-four) hours before the MRT.

2. Excessive agitation of milk samples breaks down fat globules, which interferes with the formation of the cream layer on the milk surface.

3. Heating the milk above 45º C (forty-five degrees centigrade) reduces the quantity of anti-Brucella antibodies in the sample.

4. Freezing or pasteurizing the sample may yield false-negative results; such samples should not be used in the MRT.

5. Acid milk, recently collected milk, milk containing colostrum, cow milk from the drying-up period and from cows with mamitis may yield false-positive results.

6. The herd's size may influence test results when the milk is collected in milk cans. In this case, the quantity of milk to be used in the test should be increased according to the following table:

Nº of animals	Milk volume (in ml)
Up to 150	1
151 – 450	2
451 – 700	3
Over 700	Divided into smaller batches

7. Parallel testing of positive and negative control samples should be done in connection with all tests.

METHOD

1. Keep milk samples and the antigen at a temperature of 22º C (twenty two degrees centigrade) + 4º C (four degrees centigrade) for at least 60 (sixty) minutes;

2. Mix milk samples well;

3. Deposit 1 ml of milk into 10 mm x 1000 mm tubes. The milk column should be at least 2 cm (two centimeters) high.

Observation: Depending on the herd's size, the amount of milk to be used in the test (for the same antigen amount – 30 µl) should be increased to 2 ml or 3 ml (two or three ml) as recommended under item 6

PRECAUTIONS DURING TEST PERFORMANCE;

4. Add 30 µl of antigen to the milk;

5. Put lid on the tube and mix the contents by inverting the tube several times;

6. Let it rest for one minute and check if mixture is homogenous. No antigen should be clinging to the wall of the tube;

7. Incubate for one hour at 37º C (thirty-seven degrees centigrade);

8. Proceed with the reading;

9. Write down the results.

INTERPRETATION OF RESULTS:

A blue cream ring and white or bluish milk column: REACTIVE

A white cream ring and blue milk column: NONREACTIVE

ANNEX V

MODEL FORM FOR FORWARDING SAMPLES FOR BRUCELLOSIS DIAGNOSTIC

Space reserved for laboratory use.

Sample condition at reception: ( ) Frozen ( ) Chilled Date: ___/___/___

( ) Satisfactory ( ) Unsatisfactory Received by:

I – REQUESTER'S INFORMATION

1. Name: _____
2. CRMV No.: _____ Qualification Document _____
3. Address: _____

_____ District: _____

Municipality: _____ State: _____ Postal Code: _____

4. Telephone: _____ Fax: _____
5. E-mail: _____
6. Carrier: ( ) Yes ( ) No

II – CARRIER'S INFORMATION (IF OTHER THAN THE REQUESTER)

1. Name: _____
2. CRMV No.: _____ Qualification Document: _____
3. Address: _____

_____ District: _____

Municipality: _____ State: _____ Postal Code: _____

4. Telephone: _____ Fax: _____
5. E-mail: _____

III – SAMPLE INFORMATION

1. Collection data: ___/___/___
2. Reason for test: _____
3. Number of animals from which sample was collected * _____
4. Animal's origin: _____

Property: _____

Owner: _____

Municipality: _____

Location: _____

5. Species: _____ Breed: _____
6. Gender: _____ Age: _____
7. Vaccinated animal:: ( ) Yes ( ) No. ( ) Don't know Date: ___/___/___
8. Abortion on the Property: ( ) Yes ( ) No. ( ) Don't know
9. Serologic tests : ( ) Yes When: ___/___/___ Which ones: _____
10. Serologic test results: _____
11. History: _____

* In case samples are destined for MRT.

ANNEX VI

MODEL OF FORM FOR DESIGNATING A CARRIER

DESIGNATION OF A CARRIER

I, _____ , a Veterinary Doctor, CRMV Registration
(full name)

No._____ . in the state of_____ , bearer of Qualification No. _____ ,
(UF) (habilitação)

hereby designate _____
(nome completo)

Bearer of I.D. No. _____ , as carrier of _____ sample(s) of blood / milk by

me collected and identified pursuant to Requests No._____

Place and date: _____ , _____/_____/_____

_____

Veterinary Doctor

Signature and seal

ANNEX VII

MODEL OF FORM FOR RETESTING REQUEST

RETESTING REQUEST

To the SFA Chief / State
(Please specify)

I, _____, a Veterinary Doctor, CRMV Registration No. _____ in the
(Full name)

state of _____, bearer of Qualification No. _____, hereby request the start of procedures for

the retesting of the samples registered under No. _____ of the series No. _____ , at the Laboratory

_____, located in the city of _____
(Laboratory's name)

JUSTIFICATION: _____

_____

_____

(signature: Veterinary doctor / interested party)

Date

of _____, bearer of Qualification No. _____, hereby ____/_____/_____

ANNEX VIII

REPORT ON BRUCELLOSIS DIAGNOSTIC OPERATING ACTIVITIES

MONTH / YEAR _____

Laboratory: _____	Veterinarian in charge: _____
Accreditation Administrative Ruling No.: _____	CRMV Registration No. _____

Brucellosis Antigen	Lab:	Lot (s):	Validity:	Doses purchased	Used:	Losses:	Stock

TESTS PERFORMED

Owner/Property	Municipality/ State	Test type*	No. of animals tested	No. of negatives	No. of positives

*1 - BBAT

2 – 2-ME

3 - MRT

ANNEX IX

MODEL OF LOG FOR THE RECORDING OF SAMPLES FOR BRUCELLOSIS DIAGNOSTIC

DATE	REGISTRATION No.	REQUEST SERIAL No.	ANIMAL'S NAME OR No.	MUNICIPALITY	OWNER	PROPERTY	TYPE OF EXAM	RESULT	DATE	OBS

ANNEX X

MODEL OF CERTIFICATE OF THE PERFORMANCE OF BRUCELLOSIS TEST

Accreditation Administrative Ruling No.	Lab identification:

Owner:		Property:	
Municipality:		State:	
No. brucellosis tests	Species:	Collection date: ___/___/___	Test date: ___/___/___
Antigen:	Laboratory:	Lot:	Manufacturing date:
Collected by Vet. Dr.	CRMV	Qualification No.	
Reason for testing:			

No.	Identidication	Gender	Age	Breed	Test Diagnostic			Vaccination	Vaccination date	Interpretation
					BBAT	SAT	2-ME			
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										
11										
12										
13										
14										
15										
16										
17										
18										
19										
20										

NORMATIVE INSTRUCTION No. 30 OF JUNE 7, 2006

Published in the Official Gazette of June 16, 2006, Section 1, Page 5

Establishes norms for the qualification of private sector veterinary doctors for carrying out the activities contemplated under the Technical Regulations of the National Program for the Control and Eradication of Animal Brucellosis and Tuberculosis-PNCEBT, as regards performing brucellosis and tuberculosis diagnostic tests, forwarding samples to accredited laboratories, and participating in the certification of raising establishments free of or monitored for bovine and bubaline brucellosis and tuberculosis.

THE MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY'S AGRICULTURE AND LIVESTOCK HEALTH AND INSPECTION SECRETARY, by virtue of the powers vested in him under Art. 42 of Annex I to Decree No. 5351 of January 21, 2005, having in view the provisions under Art. 2 of Ministerial Normative Instruction No. 2 of January 10, 2001, and

Having in view Chapter X of the Technical Regulations of the National Program on the Control and Eradication of Animal Brucellosis and Tuberculosis-PNCEBT approved under SDA Normative Instruction No. 6 of January 8, 2004, and Proceeding No. 21000.004861/2005-50,

RESOLVES:

Art. 1. To establish norms for the qualification of veterinarian doctors from the private sector for carrying out activities contemplated under the Technical Regulations of the National Program on the Control and Eradication of Animal Brucellosis and Tuberculosis-PNCEBT, in connection with the performance of brucellosis and tuberculosis diagnostic tests, to the forwarding of samples to accredited laboratories, and to participation in the process for the certification of livestock establishments free of bovine and bubaline brucellosis and tuberculosis or monitored in regard to these diseases, pursuant to the Annexes hereto.

Sole Paragraph. The qualification of veterinary doctors from the official animal health and inspection service is hereby prohibited.

Art. 2. The interested veterinary doctor should apply for qualification to the local unit of the animal health and Inspection service of the State(s) where he intends to work, by filling out the forms shown in Annexes I and II. The State service will evaluate whether the applicant meets the established requirements and submit the proceeding to the State's Federal Agriculture Superintendence, which will issue the qualification decision.

Art. 3. The qualification shall be valid in the State(s) for which the veterinary doctor has been qualified.

Art. 4. To be qualified, the veterinary doctor must meet the following requirements:

I – Be registered with the Regional Veterinary Medicine Council (CRMV) of the State(s) where he will work;

II – Submit to the Local Unit of the animal health and Inspection service of the State(s) where he intends to work a registered certificate of having successfully concluded the "Training Course on Methods of Animal Brucellosis and Tuberculosis Diagnostic and Control and on Notions of Transmissible Spongiform Encephalopathy" accredited by the Animal Health Department, or a certificate of participation in a "Seminar on Standardization of Courses on Methods of Animal Brucellosis and Tuberculosis Diagnostic and Control," issued by the Animal Health Department; and

III – Have at his disposal the appropriate infrastructure and materials for the performance of brucellosis and tuberculosis diagnostic tests, in accordance with the following:

a) 1. For the performance of the brucellosis test, veterinary doctors must also have the following items available: climatized environment (controlled temperature at 22º C ± 4º C), a

water supply point; refrigerator with freezer, or refrigerator and freezer; automatic or adjustable 30 µl pipetting device; indirect lighting; chronometer; agglutination glass plate; blood collection material; irons to brand positive reactive animals; and certificate forms;

2. For the performance of the milk ring test: 10 mm x 75 mm or 10 mm x 100 mm tubes; tube rack; 1 ml pipettes; oven or bain-marie at 37 º C (thirty-seven degrees centigrade);

b) For tuberculosis diagnostic: at least two multi-dose syringes for applying tuberculin on cattle set for 0.1 ml and equipped with appropriate needles for intradermal inoculation; specific caliper for bovine tuberculin testing graduated on a scale of tenths of millimeters; tricotomy device; iron for branding positive reactive animals; certificate forms;

c) At the official animal health and Inspection service's discretion, the requirement pertaining to the facilities and equipment listed in (a)1 and (a)2 above may be waived, except for the items for blood collection and for branding positive reactive animals, provided the veterinary doctor states that he will forward the brucellosis diagnostic samples solely to accredited [private] laboratories or accredited official laboratories. In this case, the veterinary doctor is barred from acquiring antigens and from performing diagnostic tests for brucellosis and becomes responsible for issuing this test's performance certificate (Annex III), to which must be attached the test results issued by the accredited laboratory in question;

d) At the official animal health and Inspection service's discretion, up to five veterinary doctors that work in formal societies or cooperatives may be accepted for qualification, provided they share facilities and equipment listed under items (a) and (a)1 for brucellosis diagnostic; and

e) At the official animal health and Inspection service's discretion, up to five veterinary doctors that work in formal societies or cooperatives may be accepted for qualification, provided they share syringes and calipers for tuberculosis diagnostic, as described under item (b) above.

Art. 5. For the purposes of issuing a prescription for the acquisition of vaccines against brucellosis and of assuming technical responsibility for vaccination, a veterinary doctor must be registered with the respective State's official animal health and inspection service, pursuant to PNCEBT Technical Regulations.

Art. 6. An accredited veterinary doctor shall:

I – Comply with the PNCEBT Technical Regulations and other complementary norms established by the Animal Health and Inspection Department and by the official animal health and inspection service of the State for which he has been qualified;

II – Provide information related to the Program and submit one copy of the brucellosis and tuberculosis tests' performance (Annex III) to the Local Unit of the Municipality's official animal health and Inspection service where the establishment serviced is located, on a monthly basis, by the fifth day of the following month;

III – Submit a monthly report by the fifth day of the following month on the use of antigens and tuberculin to the official animal health and inspection service of the jurisdiction where these items were acquired (Annex IV);

IV – Record all tuberculosis test results on the appropriate form (Annex V), which may be requested by the official animal health and inspection service at any time;

V – To brand positive animals with the letter "P" pursuant to PNCEBT Technical Regulations and take steps toward the correct elimination of such animals;

VI – Notify positive results within one business day to the Local Unit of the Municipality's official animal health and inspection service where the livestock establishment is located; and

VII – To respond to calls from the official service.

Art. 7. The State's official animal health and inspection service may, under its own legislation, establish the sanctions applicable to accredited veterinary doctors that fail to comply with items I, II, III, IV, V, VI, and VII of the preceding Art. 6.

Art. 8. The dispensing of antigens and tuberculin to veterinary doctors in noncompliance with the provisions of Art. 6 hereunder is hereby automatically suspended, pending regularization of their situation.

Art. 9. At the official animal health and in-

spection service's discretion, the collection of two blood samples may be officially overseen, one of which shall be destined for an accredited official laboratory; inoculation and the reading of tuberculosis test results may also be officially overseen. To this end, the health and inspection body may require prior notice of the date of the accredited veterinary doctors' visits to the properties.

Art. 10. Qualification may be cancelled as follows:

I – At the State's official animal health and inspection service or the State's Federal Agricultural Superintendence in case of noncompliance with PNCEBT Technical Regulations and other sanitary norms enacted by the Ministry of Agriculture, Livestock, and Food Supply, or by the State's official animal health and inspection service. In such a case, the veterinary doctor may apply again for qualification only one year after cancellation. At the official service's discretion, new qualification may me granted or denied, depending primarily on the type of noncompliance; and

II –The veterinary doctor may apply again at any time, pursuant to the procedures hereunder.

Art. 11. This Normative Instruction shall enter into force on the date of its publication.

Art. 12. SDA Normative Instructions No. 10 of January 15, 2004 and No. 55 of August 4, 2004 are hereby revoked.

GABRIEL ALVES MACIEL

ANNEX I

To the Federal Agricultural Superintendent in the State of _____

I, _____, a veterinary doctor, bearer of _____ CRMV. No. _____ and of Taxpayer ID No. _____, residing at _____ _____, Municipality of _____, State of _____, e-mail _____ , without any link to the official animal health and inspection, legally active in my profession in this Sate, hereby apply, pursuant to SDA Normative Instruction No. _____, of _____, 200_____, for qualification to perform brucellosis and tuberculosis diagnostic tests, forward samples to accredited laboratories, and participate in the process of certification of properties free of bovine and bubaline brucellosis and tuberculosis and in the monitoring said diseases in this State. Attachments: proof of registration with this State's Regional Veterinary Medicine Council; copy of conclusion of the Training Course on Methods of Animal Brucellosis and Tuberculosis Diagnostic and Control and on Notions of Transmissible Spongiform Encephalopathy," or a certificate of participation in a "Seminar on Standardization of Courses on Methods of Animal Brucellosis and Tuberculosis Diagnostic and Control; and declaration that I am not subject to any ethical or disciplinary proceedings. All listed documents have been duly signed.

Respectfully submitted.

_____, _____, 200_____.

Signed: _____

ANNEX II

DECLARATION

I, _____, a veterinary doctor, bearer of _____ CRMV No. _____, hereby declare, for the purposes of qualification before the Federal Agricultural Superintendence of the State of _____, that I am not being subjected to any ethical or disciplinary proceeding. I further declare that I shall perform brucellosis diagnostic tests at the following address(es): _____ and forward the brucellosis diagnostic samples to an accredited laboratory, thereby being barred from acquiring antigens for the performance of brucellosis tests.

_____, _____ 200_____.

_____

signed

ANNEX III

CERTIFICATE OF PERFORMANCE OF BRUCELLOSIS AND TUBERCULOSIS TESTS

Owner:	Property:	State Registration:
Municipality:	State:	Certificate No.:
Total No. of animals:	Raising system:	Animal breed:

Motive for testing: Movement-Agglomeration- Certificate of Free Property – Certificate of Monitored Property-Other

Number of brucellosis tests::	Sampling date:	Test date:
Number of tuberculosis tests:	Inoculation date:	Reading date:

Buffered Brucella antigen test:	Laboratory:	Lot:	Manufacturing date:
Bovine PPD:	Laboratory:	Lot:	Manufacturing Date:
Avian PPD:	Laboratory:	Lot:	Manufacturing Date:

Animal's number	Gender	Age	Breed	Brucellosis result			Tuberculosis result			Reactants' destination
				BBAT	2-ME	CF	SCT 1	CITT 1	PCT 3	
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										
11										
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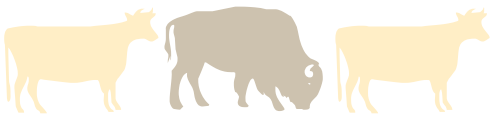


ANNEX IV

REPORT ON THE USE OF ANTIGENS AND TUBERCULIN FOR BRUCELLOSIS AND TUBERCULOSIS DIAGNOSTIC BY ACCREDITED VETERINARY DOCTORS MONTH / YEAR _____

Veterinary doctor: _____ CRMV: _____ Qualification: _____

Signature: _____

Brucellosis antigen	Lab:	Lot(s)	Expiration date:	Doses acquired:	Used:	Lost:	In stock:
Tuberculine PPD	Avian Lab:	Lot(s)	Expiration date:	Doses acquired:	Used:	Lost:	In stock:
	Bovine Lab:	Lot(s))	Expiration date:	Doses acquired:	Used:	Lost:	In stock:

BRUCELLOSIS TESTS

Owner / Property	Municipality/ State	No. of animals tested		No. negative		No. positive		No. positives sent to:	
		M	F	M	F	M	F	Complementary test(s)	Sanitary slaughter/ sacrifice and destruction

TUBERCULOSIS TESTS

Owner / Property	Municipality/ State	No. of animals tested		No. negative		No. positive		No. inconclusive		No. positives sent to:	
		M	F	M	F	M	F	M	F	Complementary test(s)	Sanitary slaughter/ sacrifice and destruction

OBS: Slots not filled-out should be crossed out.

ANNEX V

TUBERCULINE TESTED ANIMALS' CONTROL SHEET

Owner: _____ Property: _____

Municipality: _____ State: _____ Certificate No.: _____

Veterinary Doctor: _____ CRMV No.: _____

Qualification: _____

Date of tuberculin inoculation: _____

Animal No.	Aviary Tuberculin (mm)			Bovine Tuberculin (mm)			AB-AA (mm)	Test result
	A0	A72h	AA(A72-A0)	B0	B72H	AB (B72-B0)		
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								
16								
17								
18								
19								
20								

Observations: _____

Place and date: _____

_____

signature and seal

NORMATIVE INSTRUCTION No. 6 OF JANUARY 8, 2004

Published on the Union Official Journal of January 12, 2004, Section 1, Page 6 Amended by Normative Instruction 59 of August 24,2004

Approves the Technical Regulations of the the National Program for the Control and Eradication of Animal Brucellosis and Tuberculosis.

THE SECRETARY OF ANIMAL AND PLANT HEALTH AND INSPECTION OF THE MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY, exercising the powers conferred upon him by Article 15, subsection II of Decree 4629 of March 21st, 2003, in view of the provisions contained in the Animal Health and Inspection Service regulations approved by Decree 24,548 of July 3rd, 1934,

Accounting the need to standardize and guarantee the quality of the instruments and actions of prophylaxis, diagnosis and sanitation of herds, and of active sanitary surveillance pertaining to the labors against brucellosis and tuberculosis,

Accounting the need to define the role of public animal health and inspection bodies in the fight against these diseases and the integration of such bodies with cattle breeders, teaching or research institutions, private sector veterinarians and laboratories outside the Ministry of Agriculture, Livestock and Food Supply network, and the contents of Proceedings 21000.012771/2003-71, resolves to:

Art. 1. Approve the Technical Regulations pertaining to the National Program for the Control and Eradication of Animal Brucellosis and Tuberculosis.

Art. 2. Subdelegate to the Director of the Animal Health and Inspection Department the competence, as appropriate, to issue legal acts supplementary to this Regulation.

Art. 3. This Normative Instruction shall enter into force on the date of its publication.

Art. 4. Normative Instruction SDA 2 of January 10th, 2001 is hereby revoked.

MAÇAO TADANO

APPENDIX

TECHNICAL REGULATIONS PERTAINING TO THE NATIONAL PROGRAM FOR THE CONTROL AND ERADICATION OF ANIMAL BRUCELLOSIS AND TUBERCULOSIS

CHAPTER I

DEFINITIONS

Art. 1. For the purposes of this Regulation, the following definitions shall be considered:

I - brucellosis: a zoonosis caused by microorganism *Brucella abortus*, which is characterized by infertility and abortion by the end of pregnancy, and affects mainly the bovine and bubaline species;

II - tuberculosis: a chronic zoonosis caused by microorganism *Mycobacterium bovis*, which causes granulomatous lesions, and affects mainly the bovine and bubaline species;

III – official health service: animal health service on the federal, state or municipal level;

IV – local official health service unit: state official animal health service office coordinated by an official veterinarian, and responsible for surveillance and veterinary care actions in one or more municipal areas;

V – official inspection service: animal products inspection service on the federal, state and municipal levels;

VI - sanitary slaughter: slaughter of animals

that reacted to brucellosis or tuberculosis diagnostic tests, carried out in an establishment under official inspection service, in accordance with the pertinent legislation;

VII - sacrifice and destruction: elimination of animals that reacted to tests to diagnose brucellosis or tuberculosis, carried out within the rearing establishment itself, following the criteria defined by the Animal Health and Inspection Department;

VIII – rearing establishment: a place where cattle and buffalo are reared under ordinary handling conditions;

IX – rearing establishment undergoing certification: a rearing establishment that is complying with the sanitation procedures provided for in this Regulation, with the purpose of obtaining a brucellosis- and tuberculosis-free certificate;

X – brucellosis-free rearing establishment: a rearing establishment that has obtained a brucellosis-free certificate after concluding sanitation procedures against the disease, and that keeps a diagnosis routine as provided for in this Regulation;

XI – tuberculosis-free rearing establishment: a rearing establishment that has obtained a tuberculosis-free certificate after concluding sanitation procedures against the disease, and that keeps a diagnosis routine as provided for in this Regulation;

XII – rearing establishment monitored for brucellosis and tuberculosis: a farm that keeps a diagnosis routine for females aged 24 (twenty-four) months and over, as well as for bulls, as provided for in this Regulation;

XIII – accredited laboratory: a laboratory accredited by the Animal Health and Inspection Department by delegation of competence to perform laboratorial diagnosis for brucellosis or tuberculosis;

XIV – official accredited laboratory: a laboratory in a federal, state or municipal institution that has been accredited by the Animal Health and Inspection Department to perform laboratorial diagnosis for brucellosis or tuberculosis;

XV – reference laboratory: a laboratory that is part of the Ministry of Agriculture, Livestock and Food Supply network;

XVI – registered veterinarian: a private sector veterinarian who is registered with the state official defence service to carry out vaccination against brucellosis and other activities provided for in the National Program for the Control and Eradication of Brucellosis and Animal Tuberculosis;

XVII – accredited veterinarian: a private sector veterinarian who has been approved in the Training Course on Methods to Diagnose and Control Brucellosis and Tuberculosis, recognized by the Animal Health and Inspection Department, therefore being able to carry out certain activities as provided for in the National Program for the Control and Eradication of Animal Brucellosis and Tuberculosis, under supervision of the state and the federal official health service;

XVIII – official veterinarian: a veterinarian working at official health service;

XIX - owner: anyone who is a possessor, trustee, or in any capacity keeps cattle or buffalo under their control or guard;

XX - herd: group of animals reared under ordinary handling conditions, at the same rearing establishment;

XXI – general herd animals: animals not registered with any bodies recognized by the Ministry of Agriculture, Livestock and Food Supply;

XXII – registered animals: animals which have zootechnical value and are registered with bodies recognized by the Ministry of Agriculture, Livestock and Food Supply;

XXIII – routine test: the first diagnosis test for brucellosis and tuberculosis, usually involving large numbers of animals with unknown sanitary conditions for these diseases, with the objective of identifying any animals suspected of carrying an infection, or of obtaining a conclusive diagnosis;

XXIV – confirmation test(s): one or more tests used to obtain a conclusive diagnosis for animals that had previously reacted to routine tests;

XXV – herd test: one or more diagnosis tests performed on an entire herd, except for any animals that may not be submitted to any diagnosis tests for brucellosis or tuberculosis, in accordance with this Regulation;

XXVI - prevalence: total number of infected animals at a certain moment, divided by the total number of animals at risk of acquiring the infection, at the same moment;

XXVII - incidence: number of new cases of infected animals in a certain population, during a specified period of time;

XXVIII – diagnosis sensitivity: capacity of a diagnosis test to classify infected animals as positive for a disease.

XXIX – diagnosis specificity: capacity of a diagnosis test to classify non-infected animals as negative for a disease.

CHAPTER II

OBJECTIVES OF THE PROGRAM AND OPERATIONS STRATEGY

Art. 2. The National Program for the Control and Eradication of Brucellosis and Animal Tuberculosis has the following specific objectives:

I – to lower the prevalence and incidence of brucellosis and tuberculosis;

II – to certify a large number of rearing establishments where the control and eradication of these diseases are carried out with rigor and efficiency, with the aim of increasing the offer of products posing a low risk to public health.

Art. 3. The operational strategy of the National Program for the Control and Eradication of Brucellosis and Animal Tuberculosis is based on the adoption of compulsory animal health and inspection procedures, which are supplemented by voluntary adhesion measures aiming at protecting public health and developing the bases for future actions for the eradication of the diseases. With consideration to the epidemiology of brucellosis and tuberculosis, the Program's sanitary measures are applied especially to cattle and buffalo populations, and we highlight the following:

I – mandatory vaccination against brucellosis for females between three and eight months of age, aimed at lowering the prevalence and incidence of the disease;

II – control of the interstate transit of animals for reproduction and participation of bulls and females in exhibitions, fairs, auctions and other agglomerations of animals, with the objective of avoiding the dissemination of brucellosis and tuberculosis;

III – voluntary certification of brucellosis- and tuberculosis-free rearing establishments, where rigorous sanitation and active sanitary surveillance measures are applied, which will contribute to fight the diseases and improve the sanitary standards of animal products, especially milk and derivatives, and to add value to livestock products;

IV – voluntary certification of rearing establishments monitored for brucellosis and tuberculosis, with the same objectives defined in the above numeral, however using risk management procedures adapted to the handling conditions and to the size of the beef herds.

Art. 4. The official health service will qualify private sector veterinarians and accredit laboratories outside the Ministry of Agriculture, Livestock and Food Supply network to carry out the activities provided for in this Program, and it will be necessary to train all professionals involved and to standardize the actions developed by them.

Paragraph 1. For the qualification of veterinarians, specific training courses on diagnosis and control methods for brucellosis and tuberculosis offered by teaching or veterinary medicine research institutions shall be recognized and standardized.

Paragraph 2. The Animal Health and Inspection Department shall accredit private and official laboratories to secure adequate diagnosis capacity for the needs of this Program.

Art. 5. The efficiency of sanitary actions depends on the quality and standardization of the diagnosis methods and prophylactic tools used. This Program contemplates and standardizes techniques available in the country and made reference to by the World Organization for Animal Health - OIE, and that guarantee the adequate diagnosis sensitivity and specificity. The possibility of introducing new diagnosis tests and vaccines is expected, so that scientific and technological progress may be followed.

Art. 6. The credibility of the measures proposed in this Program is directly associated with the monitoring and inspection actions of the official health and inspection service, carried out in collaboration with the official inspection

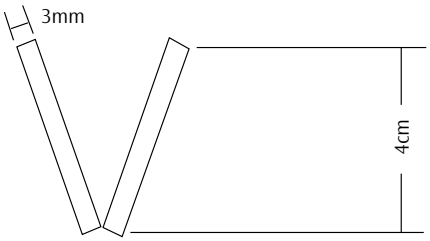
service. The official health and inspection service will certify the quality and efficiency of the sanitary measures, by acting at critical points of the Program.

CHAPTER III

VACCINATION AGAINST BRUCELLOSIS

Art. 7. Vaccination of all cattle and buffalo females in the age group from three to eight months is mandatory.

Paragraph 1. The hot-branding of vaccinated females is mandatory, with a letter V on the left side of the face, according to the following picture, followed by the last digits of the vaccination year.



Paragraph 2. Any females designated for Genealogical Registration are excluded from the provisions of Paragraph 1 above, when properly identified, as well as any females identified individually by a system approved by the Ministry of Agriculture, Livestock and Food Supply.

Art. 8. Vaccination will take place under the technical responsibility of a registered veterinarian, using a single dose of live, freeze-dried vaccine, prepared with sample 19 of *Brucella abortus* (B19).

Sole Paragraph. In regions where there are no registered veterinarians or where they do not fully cater to Program demand, the official health service may take upon itself the technical responsibility for the vaccination or even carry out the vaccination.

Art. 9. The registration of veterinarians shall be free of charge.

Art. 10. Use of the B19 vaccine in males at any age and in females aged over 8 (eight) months is hereby forbidden.

Art. 11. Proof of vaccination of female calves at the local official health service unit, at least once every semester, is mandatory.

Sole Paragraph. Proof of vaccination will take the form of a certificate issued by a registered veterinarian, according to the standards and using a model document to be defined by the Animal Health and Inspection Department.

Art. 12. Vaccination of females over eight months old may be authorized using immunogens that do not interfere with the diagnosis tests, under the conditions defined by the Animal Health and Inspection Department.

Art. 13. The Director of the Animal Health Department may change vaccination strategies and regulations based on the evolution of the epidemiological situation in the states or part of them.

CHAPTER IV

PRODUCTION, CONTROL AND TRADING OF VACCINES AGAINST BRUCELLOSIS

Art. 14. Production and control of all batches of freeze-dried vaccine shall obey Animal Health and Inspection Department standards.

Art. 15. Trading of the vaccine shall require a prescription issued by a registered veterinarian, which will be retained by the commercial establishment and will remain at the disposal of official health service inspectors.

Sole Paragraph. The establishment responsible for trading the vaccine is hereby under obligation to communicate the purchase, sale and stocking of the vaccine, to the local official state defence service unit, using a model document established by the Animal Health and Inspection Department.

Art. 16. The annual demand of vaccines in each state must be notified by the state official health and inspection service to the federal official defence service in the state, up to November of the previous year.

CHAPTER V

PRODUCTION, CONTROL AND DISTRIBUTION OF ANTIGENS FOR THE DIAGNOSIS OF BRUCELLOSIS

Art. 17. The antigens to be used in serological tests for the diagnosis of brucellosis shall be the buffered acidified antigen, the slow serum agglutination antigen and the milk ring test antigen, produced and controlled according to the standards approved by the Animal Health and Inspection Department.

Sole Paragraph. Other antigens may be used for the diagnosis of brucellosis after the approval of and under the conditions defined by the Animal Health and Inspection Department.

Art. 18. The distribution of antigens shall be controlled by the official health service, and they shall be supplied only to accredited veterinarians, accredited laboratories, accredited official laboratories and teaching and research institutions.

Paragraph 1. The accredited veterinarian responsible for obtaining the antigen shall supply the official health service with an official usage report, under the conditions to be defined by the Animal Health Department.

Paragraph 2. From the date of publication of this Regulation until July 31, 2005 (changed by Normative Instruction No. 59 of august 24, 2004) registered veterinarians shall be authorized to obtain antigen for serological diagnosis of brucellosis, all conditions established by the Animal Health Department respected.

CHAPTER VI

INDIRECT DIAGNOSIS OF BRUCELLOSIS

Art. 19. The performance of indirect diagnosis tests for brucellosis must obey this Regulation and follow the supplementary recommendations given by the Animal Health and Inspection Department.

Art. 20. The serological diagnosis tests for brucellosis will be performed on:

I – females aged 24 months or up, vaccinated at between three and eight months of age;

II – non-vaccinated females and males over eight months old.

Paragraph 1. Any females submitted to serological diagnosis tests for brucellosis within a 15 day period before giving birth to within a 15 day period after giving birth must be retested within 30 to 60 days after giving birth.

Paragraph 2. Castrated animals are hereby excluded from serological diagnosis tests for brucellosis.

Art. 21. The Buffered Brucella antigen test (BBAT) test will be used as a routine test, according to the following conditions and criteria:

I – it must be performed by a accredited veterinarian, accredited laboratory, accredited official laboratories or, up to July 31, 2005 (changed by Normative Instruction No.59 of august 24, 2004), by a registered veterinarian;

II – the presence of any agglutination will classify the animal as reacting to the test;

III – non-reacting animals are considered negative for the disease;

IV – reacting animals may be submitted to a confirmation test or be sent for sanitary slaughter or sacrifice and destruction, at the accredited veterinarian's discretion, as provided for in Chapter IX.

Art. 22. The 2-Mercaptoethanol (2-ME) test will be used as a confirmation test for animals reacting to the BBAT test, according to the following conditions and criteria:

I – to be performed by an accredited laboratory or an accredited official laboratory;

II – the interpretation of the test will obey Tables 1 and 2:

Table 1. Interpretation of 2-ME test for females aged 24 months and up, vaccinated at between three and eight months of age.

Slow seroagglutination test (UI/ml)	2-ME Test (UI/ml)	Interpretation
≤ 50	< 25	Negative
≥ 100	< 25	Inconclusive
≥ 25	≥ 25	Positive

UI - (International Unit)

Table 2. Interpretation of 2-ME test for non-vaccinated females and males aged over eight months old.

Slow seroagglutination test (UI/ml)	2-ME Test (UI/ml)	Interpretation
≤ 25	< 25	Negative
≥ 50	< 25	Inconclusive
≥ 25	≥ 25	Positive

UI - (International Unit)

III – according to the accredited veterinarian's decision, animals reacting inconclusively can be:

a) subjected to the complement fixation test; or

b) retested after an interval of 30 to 60 days, using the 2-ME test, and classified as reacting positive if upon being retested they present a positive result or second inconclusive result; or

c) sent for sanitary slaughter or sacrifice and destruction, according to the provisions of Chapter IX.

Art. 23. The Complement Fixation Test will be used as a confirmation test, to be performed and interpreted according to recommendations by the Animal Health and Inspection Department, and it must be:

I – performed by an accredited official laboratory;

II – used for the international animal movement;

III – used as a test for animals reacting to the BBAT test or for animals who had an inconclusive result to the 2ME test.

Art. 24. The Milk Ring Test (MRT) may be used by the official health service or by a accredited veterinarian to monitor rearing establishments certified as brucellosis-free or for other purposes according to criteria laid down by the official health service.

Paragraph 1. The test result is considered positive when the intensity of the ring color is equal to or superior to that of the milk column.

Paragraph 2. The test result is considered negative when the intensity of the ring color is inferior to that of the milk column.

Paragraph 3. In cases of positive results, the animals in the rearing establishment must be tested individually for brucellosis.

Art. 25. Other diagnosis tests for brucellosis can be used to supplement or substitute the tests specified in Articles 21, 22, 23 and 24, after the approval of and under the conditions established by the Animal Health and Inspection Department.

CHAPTER VII

PRODUCTION, CONTROL AND DISTRIBUTION OF TUBERCULIN

Art. 26. Only bovine and avian PPD (Purified Protein Derived) tuberculin produced and controlled in accordance with Animal Health and

Inspection Department standards shall be used.

Art. 27. Controlling the distribution of tuberculin will fall under the responsibility of the official health service, which will supply it only to accredited veterinarians and teaching and research institutions.

Paragraph 1. The accredited veterinarian in charge of obtaining tuberculin must supply the official health service with a usage report, under the conditions to be defined by the Animal Health and Inspection Department.

Paragraph 2. From the date of publication of this Regulation until July 31, 2005 (changed by Normative Instruction No. 59 of august 24, 2004), registered veterinarians shall be authorized to obtain tuberculin, all conditions established by the Animal Health and Inspection Department respected.

CHAPTER VIII

INDIRECT DIAGNOSIS OF TUBERCULOSIS

Art. 28. Indirect diagnosis of tuberculosis shall be obtained via tuberculin delayed hipersensitivity tests to be performed on cattle and buffalo aged six weeks and up by a accredited veterinarian or until July 31, 2005 (changed by Normative Instruction No. 59 of august 24, 2004), by a registered veterinarian.

Sole Paragraph. Females submitted to a diagnosis test for tuberculosis within a period of 15 days before giving birth until a period of 15 days after giving birth must be retested within 60 to 90 days after giving birth. A minimum interval of 60 days between tests must be obeyed.

Art. 29. The use of proper tuberculinization material is mandatory, according to the decision of the Animal Health and Inspection Department.

Art. 30. The Single Cervical Test (SCT) is the recommended routine test, and the following conditions and criteria must be observed:

I – it should be performed via an intradermal inoculation of 0.1 ml of bovine PPD tuberculin to the cervical region or the scapular region of cattle, to be administered on the same side of all animals in the rearing establishment;

II – the inoculation spot will be market by the removal of local hair, and skin fold thickness shall be measured with skin fold calipers prior to inoculation;

III – after 72 hours ± 6 hours of the inoculation, a new measurement of the skin fold where the bovine PPD tuberculin was inoculated shall be made;

IV – the increase in thickness of the skin fold (ΔB) shall be calculated by subtracting the measure of the skin fold on the day the bovine PPD tuberculin was inoculated from the measure of the skin fold at 72 hours ± 6 hours after inoculation;

V – the results for cattle will be interpreted according to Table 3:

Table 3 – **Interpretation of cervical test on cattle.**

Reactions				
ΔB (mm)	Sensitivity	Consistency	Other changes	Interpretation
0 to 1,9	—	—	—	negative
2,0 to 3,9	little pain	hardened	delimited	inconclusive
2,0 to 3,9	much pain	soft	exudation, necrosis	positive
4,0	—	—	—	positive

VI – animals reacting inconclusively or be considered positive to the test may be submitted to a confirmation test after an interval between 60 and 90 days, at the accredited veterinarian's discretion, and be sent for sanitary slaughter or sacrifice and destruction, according to the provisions of Chapter IX;

Art. 31. The caudal fold test (CFT) may be used as a routine test exclusively at beef farms and according to the following conditions and criteria:

I – intradermal inoculation of 0.1ml dose of bovine PPD tuberculin to be administered six to ten centimeters from the tail base, where hairy and non-hairy skin join, on the same side of the caudal fold of all animals of the rearing establishment;

II – reading and interpretation of the results shall take place 72 hours ± 6 hours after inoculation of the tuberculin, when the inoculated fold shall be compared with the opposite fold by visual evaluation and palpation;

III – any increase in thickness of the inoculated fold will classify the animal as reacting;

IV – reacting animals may be submitted to confirmation tests after an interval of 60 to 90 days, or be sent for sanitary slaughter or sacrifice and destruction at the registered veterinarian's discretion according to the provisions of Chapter IX.

Art. 32. The comparative intradermal tuberculin test (CITT) is the confirmation test performed on animals reacting to the routine tests described in Articles 30 and 31. It is also recommended as a routine test for rearing establishments where there is occurrence of unspecific reactions, establishments certified as free, and for buffalo farms, with the purpose of securing good diagnosis specificity, to be used under the following conditions and criteria:(changed by Normative Instruction No. 59 of august 24, 2004)

I – intradermal inoculation of 0.1 ml dose of avian and bovine PPD tuberculin in the cervical region or the scapular region, with a distance of 15 to 20 cm between both inoculations, the avian PPD to be inoculated in the cranium and the bovine PPD in the tail, making sure the inoculation is performed on the same side of all animals in the farm;

II – the inoculation sites are to be marked by local hair removal, and the skin fold thickness shall be measured with a skin fold caliper before inoculation;

III – after 72 hours ± 6 hours of the inoculation, a new measurement of the skin fold will be made at the inoculation site of the avian and bovine PPD tuberculin;

IV – the increase in thickness of the skin fold will be calculated by subtracting the measure of the skin fold at 72 hours ± 6 hours after inoculation from the measure of the skin fold on the day the inoculation of avian PPD tuberculin (ΔA) and bovine PPD tuberculin (ΔB) took place. The difference in skin fold increase caused by the inoculation of bovine PPD tuberculin (ΔB) and the avian PPD tuberculin (ΔA) will be calculated by subtracting ΔA from ΔB.

V – the results of the comparative test in cattle shall be interpreted according to Table 4:

Table 4. Interpretation of comparative intradermal tuberculin test on cattle.

△ B – △ A (mm)	Interpretation	
△ B < 2,0	—	negative
△ B < △ A	< 0	negative
△ B ≥ △ A	0,0 to 1,9	negative
△ B > △ A	2,0 to 3,9	inconclusive
△ B > △ A	≥ 4,0	positive

VI –animals reacting inconclusively may be subjected to a second comparative intradermal tuberculin test within a minimum interval of 60 days between the tests or be considered positive and sent for sanitary slaughter or sacrifice and destruction at the accredited veterinarian's discretion, according to the provisions in Chapter IX;

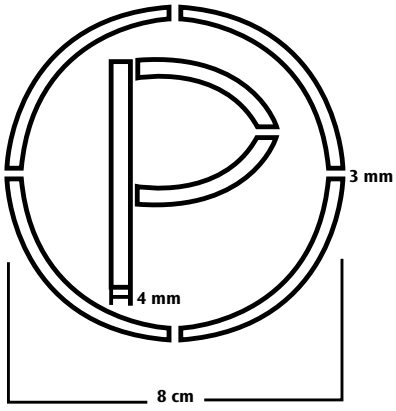
VII – any animals showing two consecutive inconclusive results shall be classified as reacting positive;

Art. 33. Other diagnosis tests for tuberculosis may be used to supplement or substitute the tests specified on Articles 30, 31 and 32, after approval and under the conditions established by the Animal Health and Inspection Department.

CHAPTER IX

ANIMALS WHITH POSITIVE REACTION TO THE DIAGNOSIS TESTS FOR BRUCELLOSIS OR TUBERCULOSIS

Art. 34. Animals whith positive reaction to the diagnosis test for brucellosis or tuberculosis shall be hot-branded with iron on the right side of the face with a "P" contained in a circle eight centimeters in diameter, according to the following figure.



Art. 35. Animals reacting positive shall be isolated from the herd and sent to sanitary slaughter within a maximum period of 30 (thirty) days following the diagnosis, at an establishment under official inspection service and nominated by the federal or state official health service.

Paragraph 1. Animals reacting positive must be immediately removed from dairy production.

Paragraph 2. The official inspection service of the establishment where the sanitary slaughter is to take place shall be notified of the arrival of the animals at least 12 hours in advance, so that the measures provided for in the relevant legislation may be put to effect.

Paragraph 3. Animals reacting positive must be accompanied by an Animal Movement Permit (GTA) upon arrival at the sanitary slaughter establishment. The document must inform their positive condition, according to the provisions of the pertinent legislation

Art. 36. If the sanitary slaughter at an establishment under official inspection service nominated by the federal and state official health service is not possible, the animals shall be sacrificed and destructed at their rearing establishment, under the direct inspection of the local official health service unit, all procedures established by the Animal Health and Inspection Department respected.

Art. 37. The exit of animals reacting positive and of inconclusive reacting animals from the rearing establishment is hereby forbidden, except when they are proven to be headed for sanitary slaughter at an establishment under official inspection service, nominated by the federal or state official health service.

CHAPTER X

CERTIFICATION AND CAPACITY BUILDING OF VETERINARIANS

Art. 38. The Federal Agriculture Agencies, together with the state animal health and isnpection services shall certify private sector veterinarians for the performance of diagnosis tests and for work in the certification process of farms in their state.

Art. 39. The accredited veterinarian must:

I – be regularly registered with the Veterinary Medicine Council of their state;

II – have been approved in a Training Course on Methods to Diagnose and Control Brucellosis and Tuberculosis recognized by the Animal Health Department;

III – comply with this Regulation and other supplementary standards established by the Animal Health and Inspection Department;

IV – have adequate infrastructure and material for the performance of diagnosis tests for brucellosis and tuberculosis, as determined by the Animal Health Department;

V – supply information and submit activity reports in relation with the National Program for the Control and Eradication of Animal Brucellosis and Tuberculosis, to the local official health service unit, with a frequency and using the model documents established by the Animal Health and Inspection Department.

Art. 40. Certification will be suspended by the Federal Agriculture Agency in case of non-compliance with this Regulation or with other standards established in any sanitary legislation by the Ministry of Agriculture, Livestock and Food Supply.

Art. 41. Official veterinarians must be attend and pass the Training Course on Methods to Diagnose and Control Brucellosis and Tuberculosis, recognized by the Animal Health and Inspection Department.

CHAPTER XI

RECOGNITION OF TRAINING COURSES FOR THE CERTIFICATION AND CAPACITY BUILDING OF VETERINARIANS

Art. 42. Teaching or veterinary medicine research institutions interested in offering Training Course on Methods to Diagnose and Control Brucellosis and Tuberculosis with the objective of training and allowing the certification of veterinarians who wish to participate in the National Program for the Control and Eradication of Brucellosis and Animal Tuberculosis must fulfill all requirements defined by the Animal Health and Inspection Department.

Art. 43. Each Training Course on Methods to Diagnose and Control Brucellosis and Tuberculosis will last at least 40 hours, and the number of participants may not exceed 20.

Art. 44. Any theoretical-practical subjects taught on the Training Course on Methods to Diagnose and Control Brucellosis and Tuberculosis must be in compliance with this Regulation and other supplementary standards as established by the Animal Health and Inspection Department.

Art. 45. Approval in the Training Course on Methods to Diagnose and Control Brucellosis and Tuberculosis is conditioned to passing the theoretical-practical assessment.

Art. 46. The Animal Health and Inspection Department will hold workshops concerning the National Program for the Control and Eradication of Animal Brucellosis and Tuberculosis with the objective of certifying teaching veterinarians for the Training Course on Methods to Diagnose and Control Brucellosis and Tuberculosis and standardize procedures.

CHAPTER XII

ACCREDITATION OF LABORATORIES FOR THE DIAGNOSIS OF BRUCELLOSIS AND TUBERCULOSIS

Art. 47. The Animal Health and Inspection Department will accredit private laboratories, to which it will delegate activities for the diagnosis of brucellosis or tuberculosis, and it will be their role to determine which diagnosis tests are to be performed in these laboratories and what requirements are to be fulfilled in order to obtain the accreditation.

Art. 48. The Animal Health and Inspection Department will accredit official laboratories, to which it will delegate activities for the diagnosis of brucellosis or tuberculosis, and it will be their role to determine which diagnosis tests are to be performed in these laboratories and what requirements are to be fulfilled in order to obtain the accreditation.

CHAPTER XIII

REFERENCE LABORATORIES

Art. 49. The Animal Health and Inspection Department shall appoint reference laboratories

for brucellosis and tuberculosis, and these shall:

I – be responsible for the production of reference brucellosis antigens and tuberculin, or tuberculin for use in programs or in exceptional situations that may be of interest to the Animal Health and Inspection Department;

II – perform direct and indirect diagnosis techniques for brucellosis and tuberculosis in situations to be defined by the Animal Health and Inspection Department;

III – carry out the official control of batches of brucellosis antigens and tuberculin produced in the country;

IV – control the quality of the commercial vaccines against brucellosis;

V – isolate and perform the epidemiologic characterization of field samples in situations to be defined by the Animal Health and Inspection Department;

VI – perform and collaborate in research work and evaluate new diagnosis methods and new vaccines.

Art. 50. The reference laboratories must supply standard samples for the production of antigens, allergens and immunogens.

CHAPTER XIV

GENERAL PROVISIONS FOR CERTIFIED REARING ESTABLISHMENTS, OR ESTABLISHMENTS UNDERGOING CERTIFICATION, FOR THE CONDITION OF BRUCELLOSIS- AND TUBERCULOSIS-FREE

Art. 51. The brucellosis- or tuberculosis-free certificate shall be issued by the Federal Agriculture Agency.

Art. 52. Certification as brucellosis- and tuberculosis-free rearing establishment is adhered to voluntarily, and it must be formally request from the local official health service unit where the rearing establishment is registered.

Art. 53. All rearing establishments certified as or undergoing certification as free from brucellosis and tuberculosis are hereby obliged to:

I – comply with measures to control and eradicate brucellosis and tuberculosis as provided for in this Regulation;

II – operate under the technical supervision of an accredited veterinarian;

III – use an individual animal identification system as indicated by the Ministry of Agriculture, Livestock and Food Supply or, if not indicated by the Ministry, to adopt their own animal identification system, as long as it is approved by the official health service;

IV – bear the costs of activities to control and eradicate brucellosis and tuberculosis.

Art. 54. The entrance of animals in rearing establishments certified as or undergoing certification as free from brucellosis and tuberculosis is conditioned to:

I – their being from a brucellosis-free rearing establishment or the performance of 2 (two) diagnosis tests for brucellosis, complying with the following requirements:

a) both tests must have negative results;

b) the first test must be performed within a 30 (thirty) day period prior to loading and the second test within a 30 (thirty) day period following their entrance in the rearing establishment of destination, with an interval of at least 30 days between tests, and the animals must be kept isolated from the moment they enter the rearing establishment until their second negative result;

c) if it is not possible to keep the animals isolated in the rearing establishment of destination, both tests may be performed during the 60 day period prior to loading, with an interval of 30 to 60 days between tests;

d) the tests will be performed by an accredited veterinarian, an accredited laboratory or accredited official laboratory;

e) females up to 24 months of age and vaccinated at between three and eight months of age may only enter the rearing establishment if they are from brucellosis-free rearing establishments.

II – their being from a tuberculosis-free rearing establishment or the performance of two diagnosis tests for tuberculosis, complying with the following requirements:

a) both tests must have negative results;

b) the first test must be performed within a 30 (thirty) day period prior to loading and the

second test up to 90 days following their entry in the rearing establishment of destination, with an interval of at least 60 days between tests, and the animals must be kept isolated from the moment they enter the establishment until the second negative result;

c) if it is not possible to keep the animals isolated in the rearing establishment of destination, both tests may be performed during the 90 days that precede their loading, with an interval of at least 60 days between tests;

d) the tests will be performed by a accredited veterinarian.

Art. 55. The official veterinarian may collect biological material to test for brucellosis or tuberculosis, and oversee or perform diagnosis tests for tuberculosis at any moment and without burden to the owner, with the objective of verifying and validating the sanitary condition of the certified rearing establishment, or establishment undergoing certification.

CHAPTER XV

SANITATION FOR CERTIFICATION AS BRUCELLOSIS-FREE REARING ESTABLISHMENT

Art. 56. Any rearing establishments undergoing sanitation in order to obtain a brucellosis-free certificate must comply with the following measures:

I – to perform herd tests for the diagnosis of brucellosis leaving an interval of 30 to 90 days between tests until a negative result is obtained, including the sanitary slaughter or sacrifice and destruction of animals reacting positive as per the provisions of Chapter IX;

II – the sanitation period ends when 3 (three) consecutive negative herd test results are obtained, with an interval of 90 to 120 days between the first and second tests and of 180 to 240 days between the second and third tests;

III – animals reacting inconclusively to the brucellosis tests must be isolated from the herd and retested 30 to 60 days after the previous test;

IV – blood sampling for the third herd test, as specified in numeral II, must be overseen by a state official health service veterinarian, and the tests must be performed at an accredited official laboratory. The accredited veterinarian is responsible for informing the local official health service unit of the blood sampling date with at least 15 days in advance.

CHAPTER XVI

CERTIFICATION AS BRUCELLOSIS-FREE REARING E STABLISHMENT

Art. 57. The certificate for brucellosis-free rearing establishment shall be issued by the Federal Agriculture Agency, on condition that the following requirements are complied with:

I – all females between three and eight months of age must be vaccinated against brucellosis with the B19 vaccine;

II – all animals specified in Article 20 must be submitted to diagnosis tests for brucellosis;

III – three consecutive negative herd tests must be obtained, and performed with an interval of 90 to 120 days between the first and the second tests, and 180 to 240 days between the second and third tests.

Art. 58. The certificate for brucellosis-free rearing establishment is valid for 12 (twelve) months.

Art. 59. Renewal of the certificate for brucellosis-free rearing establishment must be requested every year at the local official health service unit, with negative results in the brucellosis diagnosis test performed on all animals specified on Article 20;;

Art. 60. The accredited veterinarian must inform the local official health service unit of the date for blood sampling for the performance of the tests mentioned on Article 59 at least 15 days in advance.

Art. 61. Renewal of the certificate can be extended for a maximum of 90 days if there is need to perform a further diagnosis test for brucellosis on animals showing an inconclusive result in the annual retesting.

Art. 62. The detection of one or more ani-

mals reacting positive to a test performed by an accredited veterinarian or official veterinarian or after confirmation of clinical suspicions will result in the temporary suspension of the certificate for brucellosis-free rearing establishment. Returning to the free condition will require 2 (two) negative herd tests performed with an interval of 30 to 90 days between them, the first performed 30 to 90 days after the sanitary slaughter or sacrifice and destruction of the last animal that reacted positive.

Sole Paragraph. The blood sampling intended for the second herd test to return to the free condition must be overseen by a state official health and inspection service veterinarian and the tests must be performed at an accredited official laboratory. The accredited veterinarian must inform the local official health an inspection service unit of the blood sampling date at least 15 days in advance.

CHAPTER XVII

SANITATION FOR CERTIFICATION AS TUBERCULOSIS-FREE REARING ESTABLISHMENT

Art. 63. Any rearing establishments undergoing sanitation to obtain a tuberculosis-free certificate must comply with the following measures:

I – to perform herd tests for tuberculosis on the animals specified in Article 28, leaving an interval of 90 to 120 days between tests, until one negative herd test is obtained. Any animals reacting positive must be sent to sanitary slaughter or sacrifice and destruction, according to the provisions of Chapter IX;

II – the sanitation period ends when three consecutive negative herd tests are obtained, with an interval of 90 to 120 days between the first and second tests and of 180 to 240 days between the second and third tests;

III – animals showing inconclusive reactions to the diagnosis test for tuberculosis must be isolated from the herd and retested 60 to 90 days after the previous test;

IV – performance of the third herd test specified in numeral II must be overseen by the state official health service veterinarian. The accredited veterinarian is responsible for informing the local official health and inspection service unit of the date of the test at least 15 days in advance.

CHAPTER XVIII

CERTIFICATION AS TUBERCULOSIS-FREE REARING ESTABLISHMENTS

Art. 64. The certificate for tuberculosis-free rearing establishment will be issued by the Federal Agriculture Agency, on condition that three consecutive negative herd tests are obtained, performed within an interval of 90 to 120 days between the first and second tests and of 180 to 240 days between the second and third tests.

Art. 65. The certificate for tuberculosis-free rearing establishment is valid for 12 (twelve) months.

Art. 66. Renewal of the certificate for tuberculosis-free rearing establishment must be requested every year at the local official health and inspection service unit, with negative results in the tuberculosis diagnosis test performed on all animals aged six weeks and up..

Art. 67. The accredited veterinarian must inform the local official health service unit of the date when the tests mentioned on ARTICLE 66 are to be performed at least 15 days in advance.

Art. 68. Renewal of the certificate can be extended for a maximum of 90 days if there is need to perform a further diagnosis test for tuberculosis on animals showing an inconclusive result in the annual retesting.

Art. 69. The detection of one or more animals reacting positive to the test performed by an accredited veterinarian or an official veterinarian, or following confirmation of clinical suspicions, will result in the temporary suspension of the certificate for tuberculosis-free rearing establishment. In order to return to the free condition, it will be necessary to obtain two negative herd tests performed at an interval of 90 to 120 days. The first test is to be performed 90 to 120 days after the sanitary slaughter or sacrifice and destruction of the last positive reacting animal.

Sole Paragraph. The second herd test performed in order to return to a free condition must be overseen by a state official health and inspection service veterinarian. The accredited veterinarian must inform the local official health service unit of the date when the test is to be performed at least 15 days in advance.

Art. 70. The detection of suggestive lesions of tuberculosis during the *postmortem* sanitary inspection of animals from tuberculosis-free rearing establishments implies on sending samples of the suspicious lesions to the laboratory indicated by the Animal Health and Inspection Department. If infection by *Mycobacterium bovis* is confirmed, all animals aged six weeks and up must be submitted to the tuberculosis test, and animals reacting positive shall be sent to sanitary slaughter or sacrifice and destruction as per the provisions of Article 69.

CHAPTER XIX

CERTIFICATION OF REARING ESTABLISHMENT MONITORED FOR BRUCELLOSIS AND TUBERCULOSIS

Art. 71. The certification of rearing establishment monitored for brucellosis and tuberculosis shall be issued by the Federal Agriculture Agency.

Art. 72. The certification of rearing establishment monitored for brucellosis and tuberculosis must be adhered to voluntarily, and is restricted to beef farms. It must be formally requested from the local official health and inspection service unit with which the rearing establishment is registered.

Art. 73. The rearing establishment monitored for brucellosis and tuberculosis is hereby under obligation to:

I – comply with measures to control and eradicate brucellosis and tuberculosis, as provided for in this Regulation;

II – operate under the technical supervision of an accredited veterinarian;

III – use an individual identification system for females aged 24 months and up, as well as bulls, as indicated by the Ministry of Agriculture, Livestock and Food Supply or, if there is no indication by the Ministry, to use their own animal identification system as long as it is approved by the official health and inspection service;

IV – vaccinate all females between three and eight months of age against brucellosis, using the B19 vaccine;

V – submit females aged 24 months and up, as well as bull, to tests for the diagnosis of brucellosis and tuberculosis, to which any animals reacting positive shall be sent to sanitary slaughter or sacrifice and destruction, according to the provisions of Chapter IX;

VI – bear the costs of activities to control brucellosis and tuberculosis.

Art. 74. The first diagnosis test for brucellosis and tuberculosis performed in the monitored rearing establishment will be performed by sampling, according to Table 5. The animals will be selected at random:

Table 5. **Sampling table for the initial test in a monitored rearing establishment, according to the number of females aged 24 months and up, and of bulls in the establishment.**

Existing animals	Number to be tested (*)
≤ 350	255
351 – 500	300
501 – 750	350
751 – 1500	400
1501 – 5000	440
> 5000	460

(*) Sampling parameters: (1) probability of detecting one or more reacting animals (degree of reliability) = 99%; (2) minimum expected percentage of reacting animals in herd = 1%.>

Art. 75. After the first test by sampling as specified on Article 74, the rearing establishment must keep a diagnosis routine, including periodic retesting also by sampling, under the following conditions:

I – the diagnosis tests for brucellosis must be performed at an interval of 10 to 12 months;

II – the diagnosis tests for tuberculosis must be performed at an interval of 10 to 12 months, until two consecutive negative results are obtained for all animals tested, and the tests will then be performed at an interval of 18 to 24 months;

III – periodic retesting will be performed according to Table 6:

Table 6. Sampling table for periodic retesting in a monitored rearing establishment, according to the number of females aged 24 months and up, and of bulls in the establishment.

Existing animals	Number to be tested (*)
≤ 350	200
351 – 500	225
501 – 750	250
751 – 1500	270
1501 – 5000	290
> 5000	300

(*) Sampling parameters: (1) probability of detecting of one or more reacting animals (degree of reliability) = 95%; (2) minimum expected percentage of reacting animals in herd = 1%.

Art. 76. In case of one or more animals whith positive reaction to the brucellosis tests during the sampling specified on Articles 74 and 75; to another test performed under the responsibility of a certified or official veterinarian; or following confirmation of clinical suspicions, all females aged 24 months and up, as well as all bulls not included in the initial sampling, will have to be tested for the disease.

Art. 77. In case of one or more animals whith positive reaction to the tuberculosis tests during the sampling specified on Articles 74 and 75; to another test performed by a certified or official veterinarian; or following confirmation of clinical suspicions, all females aged 24 months and up, as well as all bulls not included in the initial sampling, will have to be tested for the disease.

Art. 78. The certification as rearing establishments monitored for brucellosis and tuberculosis is valid for 12 months and will be issued after 100% of negative samples are obtained in a test. If there are any positive animals, the certificate may only be issued after examination of all females older than 24 months of age, as well as bulls not included in the initial sampling, including the sacrifice and destruction / sanitary slaughter of all positives.

Art. 79. Renewal of the certificate for rearing establishments monitored for brucellosis and tuberculosis shall be requested every year from the local official health and inspection service unit, for which negative result must be presented for any diagnosis tests performed, and conditioned to the sanitary slaughter or sacrifice and destruction of all animals reacting positive for brucellosis and/or tuberculosis, according to the provisions of Chapter IX.

Sole Paragraph. Renewal of the certificate can be extended for a maximum of 90 days if necessary to perform new diagnosis test for brucellosis or tuberculosis on animals presenting inconclusive results in the annual retesting. An extension for the same period may be authorized if necessary in order to procede the sanitary slaughter or sacrifice and destruction of animals whith positive reactions.

Art. 80. The accredited veterinarian must inform the local official health and inspection

service unit of the date when the tests mentioned in Article 79 will be performed at least 15 days in advance.

Art. 81. The detection of suggestive lesions of tuberculosis during the postmortem sanitary inspection of animals from rearing establishments monitored for brucellosis and tuberculosis implies in sending samples of the suspicious lesions to the laboratory indicated by the Animal Health and Inspection Department and, if an infection by *Mycobacterium bovis* is confirmed, all females aged 24 months and up, as well as all bulls, must be subjected to diagnosis tests for tuberculosis. Any animals reacting positive shall be sent to sanitary slaughter or sacrifice and destruction, according to the provisions of Chapter IX.

Art. 82. The entrance of females aged 24 months and up, as well as of bulls in rearing establishments monitored for brucellosis and tuberculosis is conditioned to:

I – their being from a brucellosis-free rearing establishment or from a rearing establishment monitored for brucellosis and tuberculosis, or after undergoing two diagnosis tests for brucellosis, complying with the following requirements:

a) both tests must have a negative result;

b) the first test must be performed within a 30 day period prior to loading, and the second test within 30 days after entering the rearing establishment of destination, with a minimum interval of 30 days between tests, and the animals must be kept isolated from entering the establishment until the second negative result;

c) the tests will be performed by a accredited veterinarian, accredited laboratory or accredited official laboratory.

II – their being from a tuberculosis-free rearing establishment or from a rearing establishment monitored for brucellosis and tuberculosis, or after undergoing two diagnosis tests for tuberculosis, complying with the following requirements:

a) both tests must have a negative result;

b) the first test must be performed within a 30 day period prior to loading, and the second test within 90 days of entering the rearing establishment of destination, with a minimum interval of 60 days between tests, and the animals must be kept isolated from the moment they enter the establishment until the second negative result;

c) the tests shall be performed by an accredited veterinarian

Art. 83. The official veterinarian may at any moment and without burden to the owner, collect biologic material for brucellosis or tuberculosis tests, and oversee or perform diagnosis tests for tuberculosis with the objective of verifying and validating the sanitary condition of the rearing establishment monitored for brucellosis and tuberculosis.

CHAPTER XX

CONTROL OF BOVINE AND BUFFALO MOVEMENT

Art. 84. For the purposes of interstate movement of male and female cattle and buffalo for reproduction, the presentation of negative results to brucellosis and tuberculosis tests is mandatory, and the following must be obeyed:

I – issuing the Animal Movement Permit (GTA) is conditioned to the presentation of negative certificates for brucellosis and tuberculosis, issued by a accredited veterinarian or, until July 31, 2005 (changed by Normative Instruction No. 59 of august 24, 2004), by a registered veterinarian. The certificates must be attached to the copy of the GTA travelling with the animals;

II – the diagnosis tests must have been performed by an accredited veterinarian, an accredited laboratory, an accredited official laboratory or, until July 31, 2005 (changed by Normative Instruction No. 59 of august 24, 2004), by a registered veterinarian;

III – negative certificates for brucellosis and tuberculosis shall be valid for 60 (sixty) days, counted from the date the blood samples were collected for the brucellosis test, and the date the tuberculosis test was performed;

IV – diagnosis tests for brucellosis are mandatory for the animals specified on Article 20, except for animals from rearing establishment certified as brucellosis-free, or from rearing establishment monitored for

brucellosis and tuberculosis;

V – diagnosis tests for tuberculosis are mandatory for animals aged six weeks and up, except for animals from a rearing establishment certified as tuberculosis-free, or from a rearing establishment monitored for brucellosis and tuberculosis.

Sole Paragraph. Starting on a date to be determined by the Animal Health and Inspection Department, the interstate movement of cattle and buffalo for reproduction will only be allowed for animals from rearing establishments certified as brucellosis- and tuberculosis-free, or from rearing establishments monitored for brucellosis and tuberculosis.

Art. 85. Issuing the GTA for the movement of cattle and buffalo for any purpose is conditioned to proof of vaccination against brucellosis in the rearing establishment of origin, according to the provisions of Chapter III.

Art. 86. The international movement of animals, semen and embryos is ruled by the standards provided for in the International Animal Health Code of the World Organization for Animal Health (OIE), or according to standards specified in international agreements.

CHAPTER XXI

PARTICIPATION IN EXHIBITIONS, FAIRS, AUCTIONS AND OTHER ANIMAL AGGLOMERATIONS

Art. 87. Issuing an Animal Movement Permit (GTA) for cattle and buffalo for participation in exhibitions, fairs, auctions and other animal agglomerations is conditioned to the observance of the following requirements:

I – for brucellosis:

a) certificate bearing a negative result to a diagnosis test for brucellosis performed within a 60 day period before the beginning of the event, for animals over eight months of age, issued by a accredited veterinarian or, until July 31, 2005 (changed by Normative Instruction No. 59 of august 24, 2004), by a registered veterinarian;

b) animals being sent for sanitary slaughter, females up to 24 months of age – as long as they have been vaccinated between three and eight months of age –, castrated animals and animals from brucellosis-free rearing establishments are hereby excluded from the tests;

c) proof of vaccination against brucellosis in the rearing establishment of origin.

II – for tuberculosis:

a) certificate bearing a negative result to the diagnosis test for tuberculosis, performed within a 60 day period before the beginning of the event, for animals aged six weeks and up, issued by a accredited veterinarian or, until July 31, 2005 (changed by Normative Instruction No. 59 of august 24, 2004), by a registered veterinarian;

b) animals being sent for sanitary slaughter and animals from tuberculosis-free establishments are hereby excluded from the provisions of the item above.

Art. 88. Animals headed for participation at auctions are exempt from presenting negative certificates, except when deemed necessary by the state official service.

Art. 89. Starting on a date to be determined by the Animal Health and Inspection Department, the issuing of GTA for the participation of cattle and buffalos in exhibitions, fairs and at registered animal auctions is conditioned to their being from brucellosis- and tuberculosis-free rearing establishment.

CHAPTER XXII

ROLE OF THE OFFICIAL INSPECTION SERVICE

Art. 90. The official inspection service takes part in the National Program for the Control and Eradication of Animal Brucellosis and Tuberculosis in collaboration with the official health and inspection service with the purpose of improving the efficiency of the sanitary surveillance and monitoring actions of this Program.

Art. 91. The following duties are specific to the official inspection service:

I – to perform the sanitary slaughter of animals identified as positive for brucellosis or tuberculosis;

II – to comply with hygienic-sanitary procedures and to judge and give destination to the carcasses and viscera, according to the provisions of the pertinent legislation;

III – to communicate the official health and inspection service of any suggestive findings of tuberculosis on carcasses and viscera at slaughter.

SERVICE INSTRUCTION DDA No. 6 OF MARCH 27, 2003

Establishes criteria for recognition of Training Courses on Animal Brucellosis and Tuberculosis Diagnostic and Control Methods and on Notions of Transmissible Spongiform Encephalopathies (TSEs) for accreditation of veterinary doctors under the National Program on the Control and Eradication of Animal Brucellosis and Tuberculosis-PNCEBT.

The Ministry of Agriculture, Livestock, and Food Supply's Animal Health and Inspection Department, by virtue of the powers vested in it under Art. 18 of Ministerial Ruling No. 574 of December 8, 1998:

Whereas the Technical Regulations of the National Program for the Control and Eradication of Animal Brucellosis and Tuberculosis have been approved under SDA Normative Instruction No. 2 of January 10, 2001;

Whereas there is a need to standardize the criteria for accreditation of training courses on methods of animal brucellosis and tuberculosis diagnostic and control for the accreditation of veterinary doctors as well as the need to enhance surveillance of transmissible spongiform encephalopathies (TSEs),

RESOLVES:

1. Training courses on methods of diagnostic and control of animal brucellosis and tuberculosis and on notions of TSEs aimed at veterinary doctors shall be offered by educational institutions accredited by the Ministry of Education (MEC), or by veterinary medicine research institutions.

2. Any educational or veterinary medicine research institution interested in offering the aforementioned course must submit an application by filling out the form shown in Annex I hereto to the Animal Health Service of the Federal Agricultural Superintendence in the respective state, as well as meeting the following requirements:

I. Have on its staff at least two veterinary doctors qualified by the Ministry of Agriculture, Livestock, and Food Supply, who have a record of 100-percent attendance at a seminar on the PNCEBT;

II. Have on its staff or hire a veterinary doctor with experience in pathology, duly qualified by the Ministry of Agriculture, Livestock, and Food Supply, who has a record of 100-percent attendance at a seminar on notions of TSEs;

III. Have equipment and facilities for the teaching of theoretical classes sufficient to accommodate up to twenty students per course;

IV. Have equipment and laboratory facilities as described in Annex II hereto;

V. Ensure conditions to allow each participating veterinary doctor to test at least twenty serums for brucellosis – ten with positive and ten with negative results; and

VI. Have available for each course at least twenty bovines in good physical and sanitary condition.

Of these animals, eight must be sensitized by the inoculation of 10 mg of *Mycobacterium bovis*, AN5 sample, and two by the inoculation of 10 mg of *Mycobacterium avium*, D4 sample. The remaining ten should not be sensitized

ADMINISTRATIVE RULING DDA No. 73 OF DECEMBER 4, 2003

Published in the Official Gazette of December 8, 2003 Section 2, Page 4

Establishes the structure of the Consultative Scientific Committee on Animal Brucellosis (*B. abortus*) and Tuberculosis (*M. bovis*)-CCBT under the National Program for the Control and Eradication of Animal Brucellosis and Tuberculosis (PNCEBT), and specifies the area ascribed to each of its members.

ADMINISTRATIVE RULING No. 10 OF MARCH 7, 2003

Published in the Official Gazette of March 11, 2003 Section 1, Page 8

Establishes the Consultative Scientific Committee on Animal Brucellosis (*B. abortus*) and Tuberculosis (*M. bovis*)-CCBT.

ADMINISTRATIVE RULING No. 64 OF MARCH 18, 2003

Published in the Official Gazette of March 23, 2003 Section 1, 4198

Approves the Instructions annexed to this Administrative Ruling, regarding the Tuberculin Norms of Production, Control and Application.

NORMATIVE INSTRUCTION No. 59 OF AUGUST 24, 2004

Published in the Official Gazette of August 28, 2004 Section 1, Page 9
Modifies Normative Instruction No. 6 of January 8, 2004

Extends from July 31, 2004 to July 31, 2005 the deadline set under Art. 18, paragraph 2, Art. 21, item I; Art. 27, paragraph. 2; Art. 28; Art. 84, II and II; and Art. 87, I, a and II, a, respectively under Chapters V, VI, VI, VII, VIII, XX and XXI of the Technical Regulations of the National Program for the Control and Eradication of Animal Brucellosis and Tuberculosis, approved under SDA Normative Instruction No. 6 of January 8, 2004.

NORMATIVE INSTRUCTION No. 15 OF FEBRUARY 19, 2004

Published in the Official Gazette of February 25, 2004 Section 1, Page 2

Approves the Technical Regulations for the quality control and production of vaccines against brucellosis, and antigens for brucellosis diagnosis.

SERVICE INSTRUCTION SDA No. 19 OF JUNE 28, 2002

Provides for the distribution of antigens and tuberculin for the diagnostic of brucellosis and tuberculosis.

SERVICE INSTRUCTION DDA No. 21 OF DECEMBER 7, 2001

Provides for the marketing and use of the brucellosis vaccine.

NATIONAL HERBIVORE RABIES CONTROL PROGRAM

ADMINISTRATIVE RULING SDA No. 168 of September 27, 2005

Published in the Official Gazette of September 29, 2005 Section 1, Page 9

Approves the Technical Manual for the Herbivorous Rabies Control – 2005 Edition.

THE MINISTRY OF AGRICULTURE, LIVESTOCK, AND FOOD SUPPLY'S ANIMAL AND PLANT HEALTH AND INSPECTION SECRETARY, by virtue of the powers vested in him under Art. 42 of Annex I to Decree No. 5351 of January 21, 2005, having in view the provisions under Normative Instruction No. 5 of March 1, 2002 and Proceeding No. 21000.004608/2005-04,

RESOLVES:

Art. 1. To approve the hereto annexed TECHNICAL MANUAL ON HERBIVOROUS RABIES CONTROL, 2005 Edition, prepared by this Office's Animal Health and Inspection Department for the use of public agents in actions under the National. Program on Herbivorous Rabies Control throughout the National Territory.

Art. 2. To determine the publication and wide publicizing of the Manual through the Ministry of Agriculture, Livestock, and Food Supply's website.

Art. 3. This Administrative Ruling shall enter into force on the day of its publication.

GABRIEL ALVES MACIEL

NORMATIVE INSTRUCTION No. 5 OF MARCH 1, 2002

Published in the Official Gazette of March 04, 2002 Section 1, Page3

Approves the Technical Norms for the Control of Rabies in Domestic Herbivores

THE STATE MINISTER OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY, exercising the powers conferred upon him by art. 87, sole paragraph of the Constitution, taking into account the provisions of art. 86, of the Statute of the Animal Health and Inspection Department, approved by Decree no. 24 548, July 3, 1934, and which is reported in the Process no 21000.009298/2001-82, decides:

Art. 1. To approve the Technical Norms for the control of rabies in domestic herbivorous animals, according to the Annex of this Normative Instruction.

Art. 2. Item "b" of art. 3 of Administrative Ruling No. 516 of December 9, 1997, will be in effect with the following wording:

b) the incorporation of bovine spongiform encephalopathy, scrapie and other diseases with neurological progressive symptomology to the surveillance system of rabies in domestic herbivorous animals in the manner to be established in an act of the Ministry of Agriculture, Livestock and Food Supply.

Art. 3. This Normative Instruction will be in effect as of the day of its publication.

Art. 4. The Administrative Ruling no. 126 of March 18, 1976 is hereby revoked.

MARCUS VINICIUS PRATINI DE MORAES

ANNEX

TECHNICAL NORMS FOR THE CONTROL OF RABIES IN DOMESTIC HERBIVOROUS ANIMALS

CHAPTER I

PRELIMINARY PROVISIONS

Art. 1. For the purpose of these Rules, an owner shall be he who is holder, depositary or in any way keeps animals susceptible to rabies.

Art. 2. The owner shall promptly warn the Official Veterinary Service of any incident or suspicion of rabies, as well as the presence of animals attacked by hematophagous bats or the existence of shelters of such species.

Art. 3. The Official Veterinary Service should take the necessary steps to assist the animals and collect material for rabies and other differential encephalitis diagnosis.

Art. 4. The officials working in laboratory or in disease control activities must be protected through preventive immunization, according to policy recommended by the World Health Organization.

CHAPTER II

PROGRAM OBJECTIVE AND OPERATION STRATEGY

Art. 5. The National Program for the Rabies Control in Herbivorous Animals is meant to lower the prevalence of the disease in domestic herbivorous population.

Art. 6. Program operation strategy is based on the vaccination of domestic herbivorous animals, control of sources of rabies infection and other animal health and inspection procedures to protect public health and develop of bases of future actions to control this disease.

CHAPTER III

VACCINATION

Art. 7. For prophilaxis of rabies in herbivorous animals, an inactive vaccine will be used, in a two (2) ml doses, will be administered by the owner, through subcutaneous or intramuscular application.

Art. 8. In areas with rabies events, the vaccination will be systematically adopted for cattle and equidae at or above three (3) months of age, under the supervision of the veterinary.

Paragraph 1. Vaccination of cattle and equidae under three (3) months of age and other species can be done at veterinary's discretion.

Paragraph 2. Animals being vaccinated for the first time should be revaccinated after thirty (30) days.

Art. 9. The anti-rabies vaccine certificate will be issued by the veterinary, and will be valid through the protection period of the vaccine applied.

Sole paragraph. In order to complement vaccination confirmation, animal owners may be asked for:

I - receipt of vaccine acquisition, which should include departure number, validity and producing laboratory;

II - vaccination date notation, number of vaccinated animals by species and their respective identification.

Art. 10. The duration of the vaccine immunity for herbivorous animals, for revaccination purposes, will be twelve (12) months at most.

CHAPTER IV

VACCINE PRODUCTION, CONTROL AND SALE

Art. 11. Production and control of all vaccine allotments will comply with all rules of the Animal Health and Inspection Department, where all the vaccines should be previously licensed.

Art. 12. Solely vaccine with expiration date greater or equal to one (1) year will be approved.

Art. 13. From production to its use, anti-rabies vaccine should be stocked at two to eight centigrade degrees.

Art. 14. Whenever required by the Veterinary Official Service, the institution responsible for selling the vaccine is obliged to communicate the purchase, selling and supply of vaccine.

Art. 15. Whenever needed, the anti-rabies vaccines produced in Brazil or imported will be collected for fiscal inspection wherever they are to assess their effectiveness.

CHAPTER V

CONTROL OF SOURCES OF RABIES INFECTION

Art. 16. Teams working in rabies outbreaks should carry out inquiries to determine the presence of other species other than bats that could function as sources of rabies infection.

Art. 17. The chosen method to control the sources of rabies infection will depend on the animal species, on the topography of the area and on possible legal restrictions.

Art. 18. Until studies are accomplished regarding other products, the method to control hematophagous bats will be based on the use of anticoagulant substances.

Art. 19. The application of anticoagulant substances in hematophagous bats should be carried out under the supervision of the veterinary.

Art. 20. The application of anticoagulant substances around recent lesions by hematophagous bats in herbivorous animals should be done by the producer, under the orientation of the veterinary.

Art. 21. Anticoagulant substances and "nylon" nets used to control hematophagous bats are program exclusive-use materials.

Art. 22. In refuges, the use of other methods to control hematophagous bats is recommended, provided the places are easy to access and present good working conditions, at veterinary's discretion.

Art. 23. The refuges of hematophagous bats, especially those of the species *Desmodus rotundus,* notified to the Official Veterinary Service, should be registered and revised periodically, in order to maintain the control of the existing bat population in the refuges.

Art. 24. When rabies occur in wild carnivorous, an epidemiological survey should be carried out, in order to verify the origin of the case and, if there is an outbreak reaching one or more species, the control of that population will be promoted, through systematic captures, to determine viral activity and the extension of the outbreak.

CHAPTER VI

OTHER MEASURES OF EPIDEMIOLOGICAL SURVEILLANCE

Art. 25. In the epidemiological surveillance of the disease, an information system will be established, which will include the obligatory notification of cases and continuous information.

Art. 26. Permanent diagnosis of the epidemiological situation will be made, as well as the analysis of the conditioning factors, and rabies magnitude, distribution and propagation.

Art. 27. All areas where the disease has been confirmed in the past two (2) years will be considered rabies occurrence areas.

Art. 28. Control zone or area shall be considered all areas where rabies control reached satisfactory levels, with the cattle and equidae properly vaccinated and transmitter population reduced.

Art. 29. Immediate operation area shall be all areas where an endemic state of rabies is found, as well as where there are requests for prompt intervention.

Art. 30. Focal and perifocal vaccinations will include all existing properties in the infected area, covering a radius of up to twelve (12) km; the combat of transmitters shall proceed likewise.

Art. 31. The surveillance of transmitters should be constantly maintained through the verification of bite coefficient and their population dynamics.

CHAPTER VII

MATERIAL COLLECTION AND LABORATORY EXAMS

Art. 32. The collection of material of animals suspicious of suffering from rabies will be guided and done by a veterinary or an assistant with appropriate training and properly immunized.

Art. 33. Samples of the central nervous system of the animal suspicious of having rabies should be collected after its death, or when the animal is sanitary slaughtered in the early phase of the disease (paralytic phase).

Art. 34. Samples of the central nervous system of the suspicious animal should be sent to the laboratory, as well as ten percent (10%) of the captured hematophagous bats.

Art. 35. The exams of the collected material will be processed through the direct immunofluorescence technique and biological proof (inoculation in mice or cells), or other technique recommended by the World Health Organization, in a private or official laboratory, accredited by the Ministry of the Agriculture, Livestock and Food Supply – MAPA.

CHAPTER VIII

SANITARY EDUCATION AND PROMOTION

Art. 36. All available means and information, political, ecclesiastical and education representatives should be used for sanitary education and promotion in order to reach as many breeders and other members of the rural community as possible.

Art. 37. The organization of all different social actors of the community in Municipal or Intermunicipal Animal Sanity Councils, integrated with a State Animal Sanity Council, is fundamental to effectively solve the problem of rabies in domestic herbivorous animals.

CHAPTER IX

GENERAL PROVISIONS

Art. 38. Technical and auxiliary personnel in charge of controlling rabies must be provided continuous specialized training on vaccine control, epidemiology, statistics, planning and management of sanitary campaigns, laboratory diagnosis, bioecology and control of hematophagous bats, handling of non-he-

matophagous bats and sanitary education.

Art. 39. The rabies combat activities will have a national character and all states should create specific laws based on current Norms.

Art. 40. Laboratories that produce vaccines will have one-hundred eighty (180) days, after the publication of this Normative Instruction, to make all necessary changes in order to fully comply with it.

Art. 41. Incorporate the surveillance of bovine spongiform encephalopathy, scrapie and other diseases that present nervous symptomology of progressive character to the surveillance system of rabies in domestic herbivorous animals.

Art. 42. The Animal and Plant Health an Inspection Secretariat - SDA, of the Ministry of Agriculture, Livestock and Food Supply, will create complementary instructions on the matter and solve the cases omitted.

COMPLEMENTARY LEGISLATION

ADMINISTRATIVE RULING No. 34 OF MAY 28, 2004

Published in the Official Gazette of June 1, 2004 Section 2, Page 4

Establishes the makeup of the Consultative Scientific Committee on Herbivorous Rabies-CCR.

ADMINISTRATIVE RULING SDA No. 8 OF JANUARY 31, 2003

Published in the Official Gazette of February 3, 2003 Section 1, Page 5

Sets up the Consultative Scientific Committee on Rabies-CCR.

NORMATIVE INSTRUCTION SDA No. 69 OF DECEMBER 13, 2002

Published in the Official Gazette of December 16, 2002 Section 1, Page 29

Determines the use of a seal of guarantee (holographic) on all vials of vaccine against herbivorous rabies in lots approved and released by the Ministry of Agriculture, Livestock, and Food Supply for marketing, so as to ensure conformity with the norms on control of the production and marketing of vaccines against herbivorous rabies.

NATIONAL PROGRAM FOR THE PREVENTION AND CONTROL OF TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES

ADMINISTRATIVE RULING No. 516 OF DECEMBER 9, 1997

Published in the Official Gazette of December 1, 1997 Section 1, Page 29476

Modified by the Normative Instruction No. 5 of March 1, 2002
Declares Brazil free of bovine spongiform encephalopathy pursuant to Art. 3.2.13.2 of the International zoosanitary Code.

THE MINISTER OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY, using the assignments given by the Article 87, Sole Paragraph, part II, of the Constitution of the Republic, considering what has been determined on Article 71 of the Animal Sanitary Health an Inspection Service Regulation, approved by the Decree number 24.548, of July 3, 1934, considering the decision of the 65th General Meeting of the World Organization for Animal Health - OIE, which altered chapter 3.2.13 - Bovine Spongiform Encephalopathy, of the International Animal Health Code, resolves to:

Art. 1. Declare Brazil free from Bovine Spongiform Encephalopathy, according to what article 3.2.13.2 of the International Animal Health Code established.

Art. 2. Include Bovine Spongiform Encephalopathy and scrapie in the list of diseases subject to animal sanitary health measures reported on article 61 of the Animal Sanitary Health Service Regulation, approved by Decree number 24.548, July 3, 1934.

Sole Paragraph - Bovine spongiform encephalopathy and scrapie are diseases of compulsory notification and their occurrences or suspicions shall be immediately reported to the jurisdiction's animal sanitary health and inspection authority.

Art. 3. Determine the application, from January 1 , 1998, of the recommendations for prevention of bovine spongiform encephalopathy and other animal transmissible spongiform encephalopathies, reported on article 3.2.13.1 of the International Animal Health Code, especially:

a) the identification of potential danger of disease introduction through risk analysis that include the importation of alive animals, products and byproducts of animal origin;

b) the annexation of bovine spongiform encephalopathy, scrapie and other progressive nervous signs diseases in the domestic herbivore rabies surveillance system, being established by an Act of the Ministry of Agriculture, Livestock and Food Supply.

c) the prohibition of using any source of ruminant protein in the feeding of the same, except for dairy proteins.

Art. 4. Delegate the competence to the Animal and Plant Health and Inspection Secretariat of lowering the necessary complementary regulations to the implementation of what has been disposed in this Administrative Ruling.

Art. 5. The entry in Brazil of animals and products and byproducts of animal origin from third part countries is conditioned to proof of following the surveillance measures of transmissible spongiform encephalopathies and that are recommended on Chapter 3.2.13 of the International Animal Health Code.

Art. 6. This Administrative Ruling will be in force with effect from the date of its publication.

MARCUS VINICIUS PRATINI DE MORAES

NORMATIVE INSTRUCTION No. 49 of September 15, 2008

Published in the Official Gazette of September 16, 2008 Section 1, Page8

Establishes the following categories of risk for Bovine Spongiform Encephalopathy – BSE: Category I – countries with negligible risk of BSE; Category II – countries with controlled risk of BSE; Category III – countries with an undetermined or unclassified risk of BSE.

THE MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY , through the jurisdiction conferred to it by Article 87(2) of the Constitution, taking into consideration that contained in Decree No.5,741 of March 30, 2006; in Article 71 of Decree No. 24,548 of July 3, 1934; in Articles 1 and 2 of Law No. 6,198 of December 26, 1974 and Process No. 21000.001378/2008-66 resolves:

Art. 1. To establish the following categories of risk for Bovine Spongiform Encephalopathy (BSE): Category I – countries with negligible risk of BSE; Category II – countries with controlled risk of BSE; Category III – countries with an undetermined or unclassified risk of BSE.

Sole Paragraph. The classification of countries in this article will follow the World Organisation for Animal Health (OIE) own classification based on the sanitary situations of member countries with respect to BSE.

Art. 2. All countries which have been notified indigenous cases of BSE or are classified as category III are considered as BSE risk for sanitary slaughter reasons.

Art. 3. To prohibit the importation of ruminants, their products and subproducts irrespective of purpose; of products intended for veterinary use containing ingredients of ruminant origin; and of products and ingredients of animal origin destined for the alimentation of animals in cases where the animal originates or come from countries classified in Category III.

Art. 4. To subject to the compliance of sanitary requisites established by Animal and Plant Health and Inspection Secretariat (SDA), the importation of ruminants, their products and subproducts irrespective of purpose; of products intended for veterinary use containing principle ingredients of ruminant origin; and of products and ingredients of animal origin destined for animal feeding in cases where the animal originates or come from countries in Categories I or II.

Art. 5. To exclude from prohibitions mentioned in Articles 3 and 4 of this Normative Instruction, in compliance with sanitary requisites stipulated by MAPA, the following products: milk and dairy products; semen and embryos from cattle reared conforming to guidelines set out by the International Embryo Transfer Society; deproteinised animal fats and their derivatives (with insoluble impurities corresponding to a maximum of 0.15% of the weight); leathers and skins; and gelatine and collagen processed in accordance with the OIE's Terrestrial Animal Health Code.

Sole Paragraph. Following review and consideration in accordance with SDA criteria, other products and inputs may be included in the list outlined by this Article.

Art. 6. To approve the "Decision matrix for the importation of animals, products and subproducts of animal origin, taking into consideration the risk for Bovine Spongiform Encephalopathy (BSE)" as detailed in this Normative Instruction.

Sole Paragraph. This decision matrix should be used to analyse the importation of animals, their products and subproducts of animal origin.

Art. 7. The complementary acts necessary for the application of this Normative Instruction will be elaborated and published by the Animal and Plant Health and Inspection Secretariat (SDA).

Art. 8. Doubts and omissions will be resolved by MAPA.

Art. 9. This Normative Instruction will enter in vigour 60 (sixty) days after the date of its publication.

Art. 10. Ministerial Normative Instruction No. 7 of March 17, 2004 is hereby revoked.

REINHOLD STEPHANES

ANNEX

Decision Matrix to be used in considering the risk for Bovine Spongirm Encephalopathy (BSE) for the importation of animals, animal products and subproducts of animal origin

Risk Product	Risk Country		
	I	II	III
I	R	R	P
II	A	R	P
III	A	A	R

References:

• Decision:

- P: Importation prohibited.
- R: Importation subject to restriction and control of product integrity in accordance with sanitary exigencies stipulated by MAPA.
- A: Importation authorised in accordance with sanitary exigencies stipulated by MAPA.

• Country Risk:

- Category I: Countries at negligible risk of BSE.
- Category II: Countries with controlled risk of BSE.
- Category III: Countries with an undetermined or unknown risk of BSE.

• Product Risk:

The categories of product risk were stipulated based upon available scientific information and the World Organisation for Animal Health (OIE) Terrestrial Animal Health Code.

In order to grade a product's risk of BSE, consider Category I as highest risk, Category II as iintermidiate risk and Category III as least risk:

Category I:

- Live ruminants;
- Products and subproducts of ruminants, including those used in animal feed, with the exception of those composed exclusively of products listed in Category III;
- Products intended for veterinary use containing principle ingredients of ruminant origin with the exception of those products listed in Category III;
- Readymade animal feeds composed of products and ingredients derived from ruminants, with the exception of those composed exclusively products listed in Category III.

Category II:

- Products and byproducts of non-ruminant origin destined for animal feeding, with the exception of those composed exclusively of products listed in Category III.
- Readymade animal feeds composed of products and ingredients of animal origin, except those derived from ruminants.
- Principle ingredients derived from ruminants for use in laboratories;
- Material containing principle ingredients derived from ruminants for use in scientific and technological research with diverse use *in vitro*;
- Residues of the rearing or slaughter of pigs and birds.

Category III

- Products included in Article 5 of this Normative Instruction.
- Kits for diagnostic tests *in vitro* developed with principle ingredients derived from ruminants;
- Material containing principle ingredients derived from ruminants for use in scientific and technological research with exclusive *in vitro* use.

NORMATIVE INSTRUCTION No. 15 OF APRIL 2, 2008

Published in the Official Gazette of April 4, 2008 Section 1, Page 2

Approves the Procedures for Action in Suspected Cases of Scrapie.

THE MINISTER OF AGRICULTURE, LIVESTOCK, AND FOOD SUPPLY, by virtue of the powers vested in him under Art. 87, sole para., II of the Constitution, and having in view Decree No. 5741 of March 30, 2006; Decree No. 24548 of July 3, 1934; Administrative Ruling No 516 of December 9, 1997; and Proceeding No. 21000.014191/2006-61,

RESOLVES:

Art. 1. To approve the Procedures for Action in Suspected Cases of Scrapie, the Disclaimer, and the Epidemiologic Investigation Questionnaire – Annexes I, II, and III hereto, respectively.

Art. 2. This Normative Instruction shall enter into force on the day of its publication.

REINHOLD STEPHANES

ANNEX I

PROCEDURES FOR ACTION IN SUSPECTED CASES OF SCRAPIE

CHAPTER I

OBJECTIVES AND GENERAL DISPOSITIONS

Art. 1. Establishment of Procedures for Action in Suspected Case of Scrapie in sheep and goats

Art. 2. Scrapie is a fatal, transmissible neurodegenerative disease that affects sheep and goats and that falls into the group of transmissible spongiform encephalopathies-TSEs.

Art. 3. Scrapie is subject to mandatory notification; suspected cases or occurrence must be promptly reported to the animal health and inspection authorities at any level (Central and Superior, Intermediate, and Local Organs).

Art. 4. Sheep and goats aged more than 12 (twelve) months are suspected if they show one or more than one of the following nervous clinical signs that persist for more than 15 (fifteen) days: changed behavior, locomotion, or posture.

Sole Paragraph. A suspect case of scrapie is the one that persists after clinical, epidemiological, and differential investigation of other diseases, such as scabies and other ectoparasites, cenurosis, rabies, pseudorabies, ovine progressive pneumonia (Maedi-visna), encephalic listeriosis, polioencephalomalacia, preeclampsia, photosensitivity, hypomagnesaemia, and intoxication by chemical substances or plants, among others.

Art. 5. Scrapie is diagnosed in sheep and goats if they test positive in immunohistochemical test of samples of nervous or lymphoid tissue or under other diagnostic techniques and methodologies approved by the Ministry of Agriculture, Livestock, and Food Supply-MAPA.

Sole Paragraph. Samples collected for scrapie diagnostic should be sent to the TSE diagnostic laboratories of the Agriculture and Livestock Health Care Unified System's National Network of Agricultural and Livestock Laboratories, accompanied by the Standard Form for Requesting Neurological Syndrome Analysis referred to in SDA Administrative Ruling No. 168, of September 27, 2005.

Art. 6. Owners or holders of sheep and goats that are suspected of, at high risk for, or that have been exposed to scrapie are responsible for their custody and must sign the Disclaimer shown in Annex II of this Normative Instruction

Art. 7. A commission to evaluate the animals that are the object of indemnification shall be appointed by the Ministry of Agriculture, Livestock, and Food Supply's Federal Superintendence in the respective State, pursuant to Law 569 of December d21, 1948.

Sole Paragraph. No indemnification shall be granted for animals slaughetered and destroyed that may be the object of laboratory confirmation of scrapie cases.

CHAPTER II

ACTION IN CASES OF CLINICAL SUSPICION OF SCRAPIE

Art. 8. In case of clinical suspicion of scrapie, the following measures shall be adopted by the Agriculture and Livestock Health Care Unified System's Intermediate or Local Organs:

I – Visit to the establishment and substantiation of the suspicion based on the clinical and epidemiological investigation of the flock/herd; and

II – In case of a suspect case, the following actions should be undertaken:

a) Interdiction of the establishment, which consists in the prohibition of the entry and exit of sheep and goats, as well as of products, byproducts, and materials likely to be a scrapie transmission or spreading means.

b) Application of the Epidemiologic Investigation Questionnaire, pursuant to Annex III, of this Normative Instruction; and

c) Collection of samples from suspected animals and notification of the Agriculture and Livestock Health Care Unified System's Central and Superior Organ responsible for the State where the suspicion occurs, by using the first care form specified by the Animal Health Department-DSA/SDA/MAPA.

1. In the case of a live suspected animal, samples should be collected from the third eyelid or another lymphoid tissue as necessary; and

2. In the case of a dead suspected animal or in case the owner chooses to procede the sacrifice and destruction of the diseased animal, samples should be collected from nervous tissue, including the brain stem; lymphoid tissue, including the third eyelid; and other tissues deemed necessary during necropsy.

Art. 9. Suspected animals submitted to the lymphoid tissue test should remain under observation – and in isolation, in the case of females – until the conclusion of lab results.

Art. 10. If laboratory results of tests done solely on lymphoid tissue are negative, the suspected animals should remain under observation – and in isolation, in the case of females – for another 15 (fifteen) days.

Paragraph 1. If there is no abatement of clinical signs at the expiration of the aforementioned deadline, suspected animals should be evaluated by the Evaluation Commission and sent to sanitary slaughter and destruction for the collection of nervous tissue samples.

Paragraph 2. If clinical signs show abatement at the expiration of the aforementioned deadline, the establishment's interdiction should be promptly lifted and the suspicion case closed pursuant to a complementary care form specified by the Animal Health Department-DSA/SDA/MAPA.

Art. 11. If laboratory tests on nervous tissue samples are negative, the establishment's interdiction should be promptly lifted, and the suspicion case closed pursuant to the complementary care form.

Art. 12. In case technical conditions are lacking for the collection of samples from a dead suspected animal, appropriate, auditable records about the care provided should be kept by the competent Agriculture and Livestock Health Care Unified System's Organ, and at the latter's discretion the establishment's interdiction may be lifted and the establishment may be placed under routine surveillance.

Art. 13. The identification of the animals referred to under Arts. 9 and 10 above shall be incumbent on their owner or holder.

Sole Paragraph. The individual identification device shall be proposed by the Agriculture and Livestock Health Care Unified System's Intermediate Organ and approved by the competent Federal Agricultural Superintendence-SFA.

Art. 14. Dead suspected animals or animals sent to sanitary slaughter and destruction should be destroyed under the supervision of the Agriculture and Livestock Health Care Unified System's competent Organ.

CHAPTER III

ACTION IN THE OCCURRENCE OF SCRAPIE

Art. 15. Positive laboratory results shall characterize an establishment as a Outbreak Property and the following measures shall be adopted by the Agriculture and Livestock Health Care Unified System's Intermediate or Local Organs:

I – Interdiction of the establishment;

II – Application of the Epidemiologic Investigation Questionnaire shown in Annex III hereto;

III – Notification of the occurrence to the Agriculture and Livestock Health Care Unified System's Central and Superior Organ by the State where the occurrence has taken place;

IV – If positive animals are alive, they should be sent to sanitary slaughter and destruction :

a) The sanitary slaughter and destruction consists in the elimination of the animals, followed by destruction of the carcasses by incineration, burial, or any other procedure approved by MAPA, under the supervision of the Agriculture and Livestock Health Care Unified System's competent Organ at the raising establishment or at another establishment designated by said Organ.

V – Individual identification and isolation of high-risk animals, which are as follows:

The grandmother, mother, and sisters and female descendants of a female tested positive for scrapie; the grandmother, mother, and sisters of a male tested positive for scrapie; and other animals at the discretion of the Agriculture and Livestock Health Care Unified System's competent Organ;

VI – Evaluation by the Evaluation Commission, sanitary slaughter and destruction, and collection of samples from high-risk animals;

VII – Individual identification and isolation, at the discretion of the Agriculture and Livestock Health Care Unified System's competent Organ, of exposed animals, i.e., all those that have had contact with matter expelled at birth, during parturition, or miscarriage of any animal tested positive for scrapie, pursuant to the establishment's reproduction management;

VIII – Collection of lymphoid tissue samples from exposed animals aged over 12 (twelve) months;

Paragraph 1. At the owner's or holder's request and at the discretion of Agriculture and Livestock Health Care Unified System's competent Organ, exposed animals under 12 (twelve) months of age may be kept at the establishment until they reach the age of 12 months, when they should be subjected to the procedure referred to in the preceding Item VIII.

Paragraph 2. Exposed animals tested positive in the lymphoid tissue exam shall be subjected to the procedures described under item IV above.

Paragraph 3. Exposed animals tested negative in the lymphoid tissue exam shall be subjected to surveillance by Agriculture and Livestock Health Care Unified System's competent Organ.

Paragraph 4. The individual identification of animals referred to under items V and VI above shall be incumbent on their owner or holder with an identification device proposed by the Agriculture and Livestock Health Care Unified System's competent Organ and approved by the competent Federal Agricultural Superintendence.

Art. 16. During interdiction, the exit of animals destined for sanitary slaughter shall be permitted, provided said animals are not being subjected to epidemiologic investiga-

tion as being positive, high-risk, or exposed.

Sole Paragraph. The aforementioned sanitary slaughter shall be carried out at an inspected establishment duly registered with the competent municipal, state, or federal entity; carcasses may be used, while specific risk materials (brain, spinal cord, eyes tonsils, spleen, and intestines from the duodenum to the rectum) should be removed and destroyed.

Art. 17. Upon completion of the actions referred to under Art. 15 above and at the discretion of Agriculture and Livestock Health Care Unified System's competent Organ, the establishment's interdiction may be lifted and the outbreak reported closed pursuant to the complementary care form.

CHAPTER IV

EXPOSED ESTABLISHMENTS

Art. 18. Exposed establishments are those that have high-risk or exposed animals and that, should there be laboratory confirmation of scrapie, will be considered Outbreak Establishments.

Paragraph 1. Exposed establishments shall be interdicted and subjected to the Epidemiologic Investigation Questionnaire pursuant to Annex III hereto;.

Paragraph 2. High-risk or exposed animals found on exposed establishments shall be submitted to the procedures referred to under Art. 15, V-IX.

ANNEX II

DISCLAIMER

I hereby testify that I have under my responsibility sheep or goats considered as suspect, positive, or high-risk for scrapie. To prevent the disease from spreading, I commit myself not to sell said animals or transfer their ownership, and to notify the Agriculture and Livestock Health Care Unified System's competent Organ of any change in their condition, such as:

- Disease;

- Death;

- Escape;

- Raiding or stealing.

I further testify that I am aware that full or partial noncompliance with the terms hereof shall entail sanctions under the legislation in force.

Owner: _____ I.D. No.: _____

Establishment: _____ Telephone (___) _____

Municipality: _____ State: _____

Number of animals: _____(_____).

Animals' identification:

Species	Individual identification (*)	Name	Gender	Date of birth	Breed

(*) Approved by the Agriculture and Livestock Health Care Unified System's competent Organ.

Place and date

Owner's signature

ANNEX III

EPIDEMIOLOGIC INVESTIGATION QUESTIONNAIRE

1. ESTABLISHMENT'S IDENTIFICATION		
1. Name of owner or person in charge:		
2. Name of establishment:		
3. Geographic coordinates:		
4. Name of primary/secondary shelter, if any:		
5. Address:		
6. Municipality:	7. State:	
8. Mailing address:		
9. Municipality:	10. State:	11. Postal Code (CEP):
12. Telephone Nos.:		
13. E-mail:		

2. ESTABLISHMENT'S MANAGEMENT DATA				
14. Species:	☐ goats		☐ sheep	
15. Breed(s):				
16. Purpose:	☐ Subsistence		☐ Commercial	
	☐ Meat ☐ Milk ☐ Meat and milk ☐ Cow calf ☐ Rearing ☐ Fattening		☐ Meat ☐ Milk ☐ Meat and milk ☐ Cow calf ☐ Rearing ☐ Fattening	
17. Number of animals:	F < 1 year:	M < 1 year:	F < 1 year:	M < 1 year:
	F > 1 year:	M > 1 year:	F > 1 year:	M > 1 year:
	Total F:	Total M:	Total F:	Total M:
18. Area (hectares):				
19. Beginning of breeding operation:				
20. Origin of first animals	☐ national:_____(State) ☐ imported: _____(country) ☐ national:_____(State) ☐ imported: _____(country)			

21. Reproductive management of exposed species:

a. Parturition stage: ☐ No ☐ Yes - Duration: ——— days – Period of the year: _____

b. Parturition location: ☐ Field ☐ Birthing corral ☐ Other:_____

c. Duration of stay in parturition location: Pre-parturition:—— days – Post-parturition: —— days

d. Placenta's destination: ☐ None ☐ Burial ☐ Incineration ☐ Other: _____

3. IDENTIFICATION OF AFFECTED ANIMAL	
22. Species: ☐ goat ☐ sheep	**23.** Breed:
24. Gender: ☐ M ☐ F	**25.** Date of birth or age:
26. Registration No.:	**27.** Tattoo/Earring:

4. DISEASE'S HISTORY	
28. Date of first clinical signs:	**29.** Date of death:

30. Clinical signs:

☐ Self-mutilation ☐ Blindness ☐ Recumbency ☐ Motor incoordination

☐ Sideways head movement ☐ Behavioral change ☐ Vacant stare

☐ Wool or hair loss ☐ Marked weight loss ☐ Scratching

☐ Teeth grinding ☐ Nibbling reflex ☐ Slight tremor

31. Description of clinical signs, if necessary:

32. Veterinarian doctor responsible for clinical diagnostic:

Name:

CRMV No.:

5. TRACING OF AFFECTED ANIMALS

33. Born at the establishment? ☐ Yes ☐ No (indicate establishment, municipality, and State of origin):

34. Individual identification and list of high-risk kin animals on the establishment:

35. Individual identification and list of high-risk kin animals moved to other establishments and their destination:

36. Identification of exposed animals on the property:

37. Identification and destination of exposed animals moved to other properties:

Place and date:

Official veterinary doctor's identification and signature:

NORMATIVE INSTRUCTION No. 8 OF MARCH 25, 2004

Published in the Official Gazette of March 26, 2004 Section 1, Page 5

Forbids in the whole national territory the production, commercialization and use of products destined to the feeding of ruminants that contain in their composition proteins and fat of animal origin.

THE MINISTER OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY, using the assignments given by the Article 87, Sole Paragraph, part II, of the Constitution, considering what has been determined on Article 71 of the Animal Sanitary Health Service Regulation, approved by the Decree number 24,548 of July 3, 1934, on articles 1 and 2 of Law number 21000.008269/2003-65, and considering the epidemiology of Bovine Spongiform Encephalopathy – BSE and the necessity of maintaining the sanitary situation of Brazil related to this disease, resolves:

Art. 1. To forbid in the whole national territory the production, commercialization and use of products destined to ruminants feeding that contain in their composition proteins and fat of animal origin.

Sole Paragraph. This prohibition shall include the poultry litter, residues of pig rearing, as well as any other product that contains proteins and fat of animal origin.

Art. 2. The production, commercialization and use of products, destined to ruminants, used by veterinarians that contain in their formulation input from ruminants, is forbidden.

Art. 3. Milk and dairy products, calcinated bone meal (without proteins and fat), and gelatin and collagen prepared exclusively from leather and skin are excluded from the prohibition treated in the articles before.

Sole Paragraph. According to the Animal and Plant Health and Inspection Secretariat, based on risk analysis, other products and input shall be excluded.

Art. 4. Labels and tags of products destined to non-ruminants feeding that contain any source of protein and fat of animal origin, except for those mentioned on Article 3 of this Regulation, shall contain on the main panel and pointed out the following expression: "USE FORBIDDEN IN RUMINANT FEEDING".

Art. 5. Products destined to ruminant feeding are subjected to analysis examination to identify the ingredients used as protein source.

Art. 6. The Animal and Plant Health and Inspection Secretariat and Secretariat for Rural Support and Co-operative Activities, in their respective areas of competence, will dispatch complementary instructions for the cases that need more regulation or for the default cases.

Art. 7. This Normative Regulation will be in force with effect from the date of its publication.

ROBERTO RODRIGUES

(*) republished, due an inaccuracy compared to the original, in the Official Gazette of March 26, 2004, section 1, page 4.

NORMATIVE INSTRUCTION NUMBER No. 7 OF MARCH 17, 2004

Published in the Official Gazette of March 18, 2004 Section 1, Page 3
Prohibits the importation of ruminants, their products and by-products intended to any means, and veterinary products that contain input from ruminants, when coming from countries that have registered domestic cases of BSE, or any other country considered as risk for the disease by the Animal and Plant Health and Inspection Secretariat

THE MINISTER OF AGRICULTURE, LIVESTOCK AND SUPPLY, using the assignments given by the Article 87, Sole Paragraph, part II, of the Constitution, considering what has been determined on Article 71 of the Animal Sanitary Health Service Regulation, approved by the Decree number 24,548 of July 3, 1934, on articles 1 and 2 of Law number 6198, OF December 26th, 1974, and what says the process 21000.008269/2003-65, and considering the necessity of preventing the entrance of the agent of Bovine Spongiform Encephalopathy – BSE in the country resolves:

Art. 1. To prohibit the importation of ruminants, their products and by-products intended to any means, and veterinary products that contain input from ruminants, when coming from countries that have registered domestic cases of BSE, or any other country considered as risk for the disease by the Animal and Plant Health and Inspection Secretariat.

Art. 2. It's also forbiden to import any products and ingredients of animal origin, when intended for ruminant feeding, and coming from the same countries refered in the previous article.

Art. 3. this prohibition exempts the following products: milk and dairy products, semen and embryos, protein-free tallow (maximum level of insoluble impurities of 0.15% in weight) and derivatives made from this tallow, dicalcium phosphate (with no trace of protein or fat), hides and skins, gelatine and collagen prepared exclusively from hides and skins.

Sole Paragraph. The Animal and Plant Health and Inspection Secretariat can, based on risk analysis, exempt other products and inputs.

Art. 4. The Animal and Plant Health and Inspection Secretariat shall enact complementary instructions when necessary.

Art. 5. This Normative Instruction will be in force with effect from the date of its publication.

Art. 6. This Normative Instruction revokes the Normative Instruction number 15, of July 17, of 2001.

ROBERTO RODRIGUES

NORMATIVE INSTRUCTION No. 18 OF DECEMBER 15, 2003

Published in the Official Gazette of December 24, 2003 Section 1, Page 21

Forbids the slaughtering of cattle and buffalo imported form countries where autochthonous cases of BSE have occurred or countries considered at risk of such disease

THE MINISTER OF STATE OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY, making use of the prerogative conferred upon him by the art. 87, sole paragraph, clause II, of the Constitution, bearing in mind what is determined by the Regulation of Animal Sanitary Health and Inspection, approved by means of the Decree number 24,548, of July 3, 1934, and considering the non-occurrence of Bovine Spongiform Encefalophathy – BSE in Brazil, a condition that must be maintained and preserved, for the benefit of the national livestock patrimony, and what is determined by the Process number

21000.010302/2003 - 17, hereby resolves:

Art. 1. To forbid the slaughtering of cattle and buffalo imported form countries where autochthonous cases of BSE have occurred or countries considered as risk of such disease.

Art. 2. To forbid the commercialization and transfer to other cattle raising establishments of the cattle or buffalo cited in the former article, without a previous authorization from the official animal sanitary and inspection service.

Art. 3. If animals such as mentioned in art. 1 die, they can only be buried or destroyed after communication with the official animal sanitary health and inspection service and previous authorization has been obtained from them. It will carry out the technical procedures recommended in the annexes to this Normative Instruction.

Art. 4. All imported cattle or buffalo, whose country of origin has registered the occurrence of one or more autochthonous cases of BSE, or is considered as risk, once it has lost the attributes that justify its objective, should be sacrificed and destroyed with the monitoring of the official animal sanitary health and inspection service.

Art. 5. Indemnification by the Federal Government for the owner will be applicable in cases of cattle or buffalo imported before the publication of this Normative Instruction, slaughtered according to the terms of art. 4.

Sole paragraph. After the publication of this Normative Instruction, no indemnification will be applicable when the country of origin of the imported cattle or buffalo presents an autochthonous case of BSE or is considered as a risk for such disease.

Art. 6. To approve the technical procedures to be adopted, at the time of instructing the process of sanitary slaughter or sanitary slaughter and indemnification of cattle or buffalo imported from a country considered as a risk of BSE, as listed in the Annex I of this normative instruction.

Art. 7. The Animal Health and Inspection Department – DDA, of the Animal and Plant Health and Inspection Secretariat – SDA, will be responsible for implementing the procedures approved by this Document.

Art. 8. The total or partial non-observance of this Normative Instruction will subject the offender to the sanctions established in the Brazilian Criminal Code.

Art. 9. This Normative Instruction goes into effect on the date of its publication.

Art. 10. The Normative instruction number 08, of February 13, 2001 and the Service instruction DDA number 01, of January 7, 2002 are hereby revoked.

ROBERTO RODRIGUES

ANNEX I

TECHNICAL PROCEDURES FOR THE SANITARY SLAUGHTER AND INDEMNIFICATION OR SANITARY SLAUGHTER OF CATTLE OR BUFFALO IMPORTED FROM COUNTRIES CONSIDERED AS A RISK OF BOVINE SPONGIFORM ENCEFALOPATHY (BSE)

The process of sanitary slaughter or indemnification of cattle or buffalo imported from a country considered to have a risk of BSE, will follow the technical procedures below:

I - the owner of the cattle or buffalo imported from a country where the occurrence of BSE has been registered or considered to have a risk of this infirmity, should communicate, in writing, to the Official Veterinary Service of the state where the animal is, his desire to eliminate him (annex II) to begin the process of elimination and, when pertinent, of posterior indemnification, attaching a copy of the document proving the property of the respective animal;

II - the cattle or buffalo to be sanitary slaughterd, for which an indemnification may be received, should be previously evaluated by a state commission constituted for that end

a) this commission will be instituted through a Decree from the Federal Agriculture Commis-

sioner in the state and comprised of veterinary doctors or animal health technicians from the executive agency for the activities of animal sanitary and inspection service of the state and of representatives designated by the association of raisers or the state's agriculture federation.

b) the objective of the commission will be to inspect, asses and procede the sanitary slaughter of the animal(s) and, in accordance with the average price of the arroba (one arroba corresponds to 15 kg) in the region, define the amount to be paid for the animal(s) sanitary slaughterd.

c) the commission should attach to the process a document that proves the means through which the quotation of the arroba was obtained.

d) the commission will issue a Sanitary slaughter Assessment Record (annex III) (Auto de Avaliação de Sacrifício). The owner must agree with the amount to be paid.

III - when an indemnification is not applicable, only the Sanitary slaughter Record (annex V) should be issued, which will be signed by two employees of the state's Animal Sanitary and Inspection Service. One of them should be a veterinary doctor.

IV - whether or no indemnification is applicable, the state's official service will coordinate the sanitary slaughter, incineration and burial of the animal, as well as the packaging and sending of the collected brain stem to the laboratory indicated by the DDA for diagnosis of BSE;

V - the head of the Animal Heath Service or Section – SSA, will confirm the regularity of all the actions in the records, through a circumstantiated technical note.

VI - if indemnification is applicable, the Federal Commissioner of Agriculture of the state, after analyzing the process and receiving the report from the local Juridical Consultancy, or the State's Juridical Consultancy Center, will forward the process to the Animal Health Department, in Brasilia, to request the necessary funds.

VII - The SDA should, after analyzing the conclusive report or the process written by the DDA, forward it to MAPA's Juridical Consultancy, for its opinion.

VIII - Once the process is concluded, whether or not indemnification is applicable, and once all the formal procedure has been completed, the process should be filed at the DFA, after including the information in the National Databank of the Brazilian System for Identification and Certification of Cattle and Buffalo – SISBOV (Sistema Brasileiro de Identificação e Certificação de Bovinos e Bubalinos), also for audit purposes.

ANNEX II

REQUEST FOR ELIMINATING ANIMALS

To Mr. _____

I,_____, of _____ nationality, _____, marital statues _____, profession _____, resident at_____, Municipality _____, state _____, holder of the CPF number _____ and the do RG number _____, respectfully request the elimination of _____(number) cattle or buffalo imported from countries considered at risk for Bovine Spongiform Encephalopathy (BSE), by the Ministry of Agriculture, Livestock and Food Supply, discriminated below, of which I am the owner. It (They) is (are) at the property named _____, at the municipality _____, state _____, I am based on the art. 4º of the Normative Instruction number 18, of December 15, 2003.

Individual Identification Code (SISBOV)	Species	Gender	Breed	Country of Origin

_____, _____ , _____

_____

Signature of the owner of his legal representative

ANNEX III

SANITARY SLAUGHTER ASSESMENT RECORD NUMBER _____/ STATE
(when indemnification is applicable)

On the _____of the month of _____ of _____ , the Assessment and Sanitary slaughter Commission, designated through the decree number _____, of _____ _____, _____, of the Federal Commissioner of Agriculture of the state of _____, carried out the assessment for sanitary slaughter of _____ (number) cattle imported from countries considered at risk for Bovine Spongiform Encephalopathy (BSE) by the Ministry of Agriculture, Livestock and Food Supply, as established in the item II of the annex I of the Normative Instruction number 18, of december 15, 2003,
They exist in the property defined below:

LOCATION AND IDENTIFICATION OF THE PROPERTY / OWNER:

Name of Property:
Location:
Municipality: ZIP CODE: State:
Code of the Property at SISBOV:

Name of Owner:
CPF: Nationality: Profession:
Address of Owner:
Municipality: State: ZIP CODE:

ANIMAL(S) FOR WHICH INDEMNIFICATION WILL BE PAID:

Individual identification code (SISBOV)	Species	Gender	Breed	Country of Origin	Total of Arrobas	Value per Arroba (R$)	Total Value (R$)
GENERAL TOTAL							

MEMBERS OF THE COMMISSION	
Name / Organization	Signature:
Name / Organization	Signature:
Name / Organization	Signature:

ANNEX IV

DECLARATION OF THE OWNER

_____ (owner) _____ (nationality)_____ (marital status)_____ (profession), _____ (number of the RG), _____ (number of the CPF) and _____ (address), declares to be in full agreement with the Assessment Record number _____/____ (state) of ___/___/__ referring to _____(number) animal (s) imported from countries considered to be at risk of Bovine Spongiform Encephalopathy (BSE) by the Ministry of Agriculture, Livestock and Food Supply, in his property, carried out by the Assessment Commission designated by means of the Decree number_____ of the Federal Commissioner of Agriculture of the state of _____.
The amount was calculated at R$ _____ (_____ _____).

_____

Date and Place

_____

Signature of the owner or legal representative

ANNEX V

SANITARY SLAUGHTER RECORD
(indemnification is not applicable)

On the _____ day of the month of _____ of the year _____ , the persons signed below, in fulfillment of item III of the Annex I of the Normative Instruction No. 18 of december 15, 2003, proceeded to the sacrifice and destruction of the animal(s) described below.

LOCATION AND IDENTIFICATION OF THE PROPERTY/ OWNER:

Name of Property: Location: Municipality: ZIP CODE: Unit of the Federation: Property code at SISBOV:

Name of Owner: CPF: Nationality: Profession: Address of owner: Municipality: Unit of the Federation: ZIP CODE:

SPECIES TO BE SANITARY SLAUGHTERD: BOVINE / BUBALINE

GENDER	Animal's individual identification code (SISBOV)	NUMBER OF ANIMALS
MALE		
FEMALE		
TOTAL NUMBER OF ANIMALS SANITARY SLAUGHTERD	( ) _____	

PERSONS RESPONSIBLE FOR THE SACRIFICE AND DESCTRUCTION:

Name /RG / Institution	Signature:
Name /RG / Institution	Signature:

WITNESSES:

Name /RG / Institution	Signature:
Name /RG / Institution	Signature:

NORMATIVE INSTRUCTION SDA No. 18 OF FEBRUARY 15, 2002

Published in the Official Gazette of february 18, 2002 Section 1, Page 1

Approves the Norms that shall be adopted, aiming to increment the epidemiological surveillance for detection of Transmissible Spongiform Encephalopathies – TSE in ruminants

THE SECRETARY OF AGRICULTURE AND LIVESTOCK HEALTH AND INSPECTION OF THE MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY, using the assignments give to him by article 83, part IV, of the Department Statute, approved by the Ministerial Administrative Ruling number 574, of December 8, 1998, the article 4, of the Administrative Ruling number 516, of December 9, 1997, considering what has been determined by the Animal Sanitary Health and Inspection Regulation, approved by Decree number 24.548, of July 3, 1934, and what is registered in process number 21000.000439/2002-82, resolves:

Art. 1. Approve the Norms that shall be adopted, aiming to increment the epidemiological surveillance for detection of Transmissible Spongiform Encephalopathies – TSE in ruminants.

Art. 2. The Animal Health Department, hearsay the Department of Inspection of Animal Origin Products, shall define the necessary procedures and rules for the implementation of a surveillance system approved by this Normative Regulation.

Art. 3. This Normative Regulation will be in force with effecto on the date of its publication.

LUIZ CARLOS DE OLIVEIRA

ANNEX

TECHNICAL NORMS OF THE EPIDEMIOLOGICAL SURVEILLANCE SYSTEM FOR DETECTION OF TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES IN RUMINANTS - TSE

Art. 1. An active surveillance system shall be implemented on slaughtered cattle with official inspection, through collection of material for laboratory tests, according to what follows:

I – the sample definition shall be established by the Animal Health Department, hearsay the Department of Inspection of Animal Origin Products.

II – the active surveillance system for TSE detection in cattle shall be performed in animals with more than 30 (thirty) months, and are of dairy exploration or intensive or semi-intensive systems of beef cattle, as well as of all cattle or sheep/goats destined to casualty slaughtering.

III – in the sheep/goats case, the collection of material shall be performed in animals with more than 12 (twelve) months.

IV – the above-mentioned animals will have their brain stem collected by the official inspection service at the time of slaughtering.

Art. 2. The Animal Health Services of the Federal Agriculture Stations of the states included in this statute surveillance system, shall arrange the shipment of material collected at the slaughertherhouse to DDA authorized laboratories, for the carrying out of laboratorial exams.

Art. 3. Field epidemiological surveillance measures shall be intensified through collection of material in the following cases:

I – Cattle or sheep/goats with clinical signs of sub acute nervous disturbance or behavioral alterations, with clinical evolution of 15 or more days;

II – Recumbent cattle or sheep/goats, with no determined cause;

III – Cattle or sheep/goats with chronic wasting diseases.

Art. 4. Surveillance shall be maintained in all cattle or sheep/goats with clinical signs of nervous disturbance, according to the Administrative Ruling number 516, of December 9, 1997.

Sole Paragraph. Every laboratory that diagnoses rabies shall obligatorily send the samples of encephalic material from investigated animals that are older than 24 (twenty-four) months, for cattle, and 12 months for sheep and goats, that are negative for rabies, to one of the authorized laboratories by the Ministry of Agriculture, Livestock and Supply laboratories, for the carrying out of BSE diagnosis.

Art. 5. The surveillance of every bovine imported from countries that had BSE autochthonal cases shall be done according to the Miniterial Administrative Ruling number 08, of February 15, 2001.

COMPLEMENTARY LEGISLATION

ADMINISTRATIVE RULING No. 14 OF MARCH 15, 2002

Published in the Official Gazette of March 18, 2002, Section 1, Page 36

Establishes the Consultative Scientific Committee on Transmissible Spongiform Encephalopathies-TSEs, whose attributions shall include the following: to provide the Animal Health Department-DDA with technical and scientific inputs; to issue technical opinions; to draft proposals aimed at improving the system for prevention and control of transmissible encephalopathies-TSEs in the country; and to propose norms on TSEs surveillance and prophylaxis.

NORMATIVE INSTRUCTION No. 17 OF APRIL 7, 2008

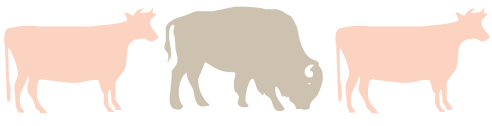
Published in the Official Gazette of April 8, 2008, Section 1, Page 21

Prohibits the manufacturing on the national territory, at the same plant, of products destined for ruminants and non-ruminants feeding, except at establishments that meet the specific requirements.

NORMATIVE INSTRUCTION No. 34 OF MAY 28, 2008

Published in the Official Gazette of May 29, 2008, Section 1, Page 13

Approves the Technical Regulations for Hygiene, Sanitary, and Technological Inspection of the Processing of Animal Residues, and the Form for the Transport of Animal Residues.



NORMATIVE INSTRUCTION No. 17 OF JULY 13, 2006

Published in the Official Gazette of July 14, 2006, Section 1, Page 23

Establishes the Operational Norm for the Cattle and Buffalo Production Chain's Traceability System (SISBOV) and determines the procedures for the authorization of the importation of Cattle and Buffalo.

NORMATIVE INSTRUCTION No. 18 OF FEBRUARY 27, 2004

Published in the Official Gazette of March 23, 2004, Section 1, Page 3

Establishes norms on quality requirements for the accreditation and monitoring of laboratories by MAPA to permit them to perform diagnostics of Transmissible Spongiform Encephalopathies-TSEs in ruminants, through the use of immunohistochemical analysis.

NORMATIVE INSTRUCTION No. 15 OF FEBRUARY 15, 2002

Published in the Official Gazette of March 5, 2002, Section 1, Page 5

Approves the Norms for the accreditation and monitoring of laboratories to perform diagnostic of Transmissible Spongiform Encephalopathies-TSEs in ruminants.

NORMATIVE INSTRUCTION No. 6 OF FEBRUARY 26, 1999

Published in the Official Gazette of March 2, 1999, Section 1, Page 61

Establishes the sanitary situation evaluation form hereto annexed for all countries where there have been occurrences of Transmissible Spongiform Encephalopathies, with which Brazil maintains trade in animals and in animal parts and byproducts.

JOINT DDA/DIPOA SERVICE INSTRUCTION No. 2 OF AUGUST 15, 2003

Determines that all slaughter/packing houses, slaughterhouses, and small- and medium-size-animal slaughterhouses with federal inspection service-SIF that slaughter cattle and/or sheep/goats must participate in the surveillance of transmissible spongiform encephalopathies-TSEs in animals of these species, which are destined for emergency slaughter.

DOI/DIPOA SERVICE INSTRUCTION No. 2 OF AUGUST 12, 2003

Provides for procedures and norms for the operationalization of the epidemiologic surveillance system for the detection of Transmissible Spongiform Encephalopathies-TSEs in ruminants.

DOI/DIPOA SERVICE INSTRUCTION No. 1 OF MARCH 7, 2002

Procedures and norms for the operationalization of the epidemiologic surveillance system for the detection of Transmissible Spongiform Encephalopathies-TSEs in ruminants.

INTERNAL NORM DSA No. 2 OF AUGUST 23, 2005

Establishes procedures for tracing, monitoring, and identifying imported bovines.

INTERNAL NORM DSA No. 1 OF MAY 17, 2005

Determines the adoption of an active surveillance system for detecting animal protein in ruminant animal feed at animal-raising establishments. The additional procedures and instructions for the collection of the requisite samples are set forth in the "Manual on the Collection of Samples of Ruminant Animal Feed for Detection of Animal Protein."

NATIONAL AVIAN HEALTH PROGRAM

ADMINISTRATIVE RULING No 147 OF JUNE 14, 2006

Published in the Official Gazette of June 16, 2006 Section 1, Page 3

Establishes a Consultative Technical Committee to help draft technical proposals pertaining to Avian Influenza and Newcastle Disease.

THE MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY'S DEPUTY AGRICULTURE AND LIVESTOCK HEALTH AND INSPECTION, by virtue of the powers conferred on him under Art. 42 of Annex I to Decree No. 5351 of January 21, 2005 and in view of Proceeding No. 21.000.004416/2006-71,

RESOLVES:

Art. 1. To establish a Consultative Technical Committee to help draft technical proposals pertaining to Avian Influenza and Newcastle Disease.

Art. 2. The aforementioned Committee's membership shall consist of the following representatives:

I – Brazilian Poultry Farming Union-UBA:

a) Alberto Back; and

b) Nelva Grando;

II – Rio Grande do Sul Federal University-UFRGS:

a) Carlos Tadeu Pippi Salle

III – Campinas State University-UNICAMP:

a) Clarice Arns;

IV – São Paulo University-USP

a) Edison Luis Durigon; and

b) Leonardo José Richtzenhain;

V – São Paulo State University-UNESP:

a) Hélio José Montassier;

VI – Brazilian Environmental Institute-IBAMA:

a) João Luiz Xavier do Nascimento;

VII – National Center for Swine and Poultry Research-Brazilian Agricultural and Livestock Research Enterprise-CNPSA/EMBRAPA:

a) Liana Brentano;

VIII – Santa Maria Federal University-UFSM:

a) Luiz Fernando Sangoi;

IX – Vale do Rio dos Sinos University-UNISINOS:

a) Martin Sander;

X – Uberlândia Federal University-UFU:

a) Paulo Lourenço da Silva;

XI – Pernambuco Federal Rural University-UFRPE:

a) Severino Mendes de Azevedo Júnior.

Art. 3. The Committee shall be chaired by the Director of the Animal Health Department.

Art. 4. The Committee's Chairman may call upon technical personnel from either the private or the public sector, as needed, for additional advisory services.

Art. 5. This Administrative Ruling shall enter into force on the day of its publication.

NELMON OLIVEIRA DA COSTA

ADMINISTRATIVE RULING No. 542 OF NOVEMBER 16, 1998

Published in the Official Gazette of November 17, 1998 Section 1, Page 89

Provides for Hygiene and Sanitary Norms for Qualification of Poultry Farming and Poultry Hatchery for Trade within MERCOSUR.

THE MINISTER OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY, by virtue of the powers vested in him under Art. 87, Sole paragraph, II of the Federal Constitution and pursuant to Administrative Ruling No. 116 of February 29, 1996; having in view the Asunción Treaty; the Ouro Preto Protocol; Decision No. 6/96 of the Common Market Council; Resolution no. 91/93 of the Common Market Group; and Recommendation no. 12/95 of Working Subgroup-VIII on Agriculture; and considering that the objective of the Common Market Group's decision is to facilitate trade in one-day old chicks and embryo eggs,

RESOLVES:

Art. 1. To adopt the "HYGIENE AND SANITARY NORMS FOR QUALIFICATION OF POULTRY FARMING AND POULTRY HATCHERY FOR TRADE WITHIN MERCOSUR" hereto annexed, which have been approved under Common Market Group-GMC Resolution No. 10/96.

Art. 2. This Administrative Ruling shall enter into force on the day of its publication.

FRANCISCO SÉRGIO TURRA

HYGIENE AND SANITARY NORMS FOR QUALIFICATION OF POULTRY FARMING AND POULTRY HATCHERY FOR TRADE WITHIN MERCOSUR

CHAPTER I

PRELIMINARY DISPOSITIONS

Art. 1. The application of the norms herein shall be incumbent on the Official Veterinary Services of the MERCOSUR States-Parties.

Art. 2. The approved norms shall be applied at poultry establishments engaged in the regional MERCOSUR trade of day-old birds and hatching eggs for incubation.

Art. 3. Poultry Farming Establishments engaged in the regional trade in day-old birds and hatching eggs for incubation must be registered with and qualified by the official services and shall operate under the responsibility of an accredited veterinary doctor.

Art. 4. For the purposes of registration and qualification, poultry farming establishments shall be classified into two categories:

a) Parent, grandparent, and great-grandparent breeding nuclei; and

b) Hatchery.

CHAPTER II

BREEDING ESTABLISHMENTS

Art. 5. For the purposes hereunder a breeding nucleus is understood as a nucleus consisting of one or more than one lot of parents, grandparent or great-grandparent of the same age, housed in different sheds under the same management.

Art. 6. The parents, grandparents, and great-grandparents breeding nucleus should meet the following requirements:

a) Be located on a geographically adequate site to facilitate hygiene and sanitary control;

b) Be protected by security fences with only one entry point;

c) Have one access gate for strict control of the movement of vehicles and people, as well as vehicle wheel disinfection points, and vehicle cleaning and disinfection equipment;

d) Poultry sheds must be wooden so that all interior surfaces are smooth and washable to allow proper cleaning and disinfection; and

e) Poultry sheds and egg storage facilities must be insect-free and not accessible to wild fowl and other wild or domestic animals.

Art. 7. Breeding nucleus must be free of the following:

a) Pullorum disease and Fowl typhoid (*Salmonella pullorum* and *Salmonella gallinarum*); and

b) Avian mycoplasmosis (*Mycoplasma gallisepticum* and *M. synoviae* in hens, and *M. meleagridis*, *M. synoviae*, and *M. gallisepticum* in turkeys);

Art. 8. Poultry farming establishments must be subject to a permanent epidemiologic surveillance system, i.e., must be controlled by an official service.

Art. 9. While establishments have been under permanent epidemiologic surveillance, no case of the following diseases was detected:

a) Duck Virus Hepatitis;

b) Chicken Infection Anemia;

c) Swollen head syndrome by pneumovirus;

d) *Salmonella enteritidis*; and

e) *Salmonella typhimurium*.

Art. 10. Criteria for determining that an establishment is free of Pullorum disease and Fowl typhoid as well as mycoplasmosis shall be approved by MERCOSUR's Health Committee, and shall include the following:

a) Types of laboratory diagnostic tests;

b) Antigens to be utilized;

c) Frequency and scope of laboratory diagnostic tests; and

d) Qualified or accredited laboratories.

Art. 11. Poultry must be vaccinated against infectious diseases according to a scheme adopted by each establishment in conformity with its epidemiologic status and the epidemiologic

situation of the region where it is located. The vaccines to be used must be approved and controlled by the official services.

CHAPTER III

HATCHERY.

Art. 12. Hatchery shall accept solely hatching eggs from establishments qualified for the production of day-old birds of a single species.

Art. 13. Incubation facilities must be properly built so as to facilitate hygiene and sanitary control and must have biosecurity systems pertaining to the transit of people, vehicles, and equipment, as well as to the protection of eggs and chicks to ensure the sanitary quality required hereunder.

CHAPTER IV

HYGIENE AND TRANSPORT OF HATCHING EGGS

Art. 14. Hatching eggs must be collected at regular intervals at least four times a day into clean, disinfected containers.

Art. 15. After collection, the clean eggs must be fumigated or disinfected as soon as possible according to the techniques recommended in Annex 4.2.4 of the International Epizooties Organization's International Zoosanitary Code (OIE, Ed. 1992) accepted by the Committee.

Art. 16. Eggs must be transported to the national or regional hatchery in new, clean, previously fumigated or properly disinfected containers. Transport vehicles must be also clean.

CHAPTER V

HYGIENE AND HANDLING OF EGGS AND DAY-OLD BIRDS

Art. 17. Personnel in charge of handling eggs in the hatcheries, sexing, and handling of day-old birds must follow the general personal hygiene guidelines, and put on clean clothing and shoes before beginning their work.

Art. 18. Day-old birds must be vaccinated against the Marek's disease before being shipped, with vaccines made from Specific Pathogen Free-SPF eggs and officially approved by the exporting country.

Art. 19. Day-old birds must be shipped from the incubation establishment to the destination by personnel wearing clean, disinfected protection closing. Transport vehicles must be clean and disinfected prior to any shipment of day-old birds.

CHAPTER VI

GENERAL DISPOSITIONS

Art. 20. Breeding and Hatchery establishments must keep a thorough zoosanitary record (mortality, disease diagnostics, treatments, vaccination, and monitoring) pertaining to each lot of birds and hatching eggs, to be shown to the veterinary authorities upon request.

Art. 21. The types of laboratory tests to be performed for diagnosing the diseases referred to hereunder shall be agreed with the Committee.

Art. 22. Day-old bird and hatching eggs exports should be accompanied since their origin by a MERCOSUR Member Countries' Common Zoosanitary Certificate issued by an accredited veterinary doctor and endorsed by an official veterinary doctor of the country of origin, pursuant to the form shown in the Annex hereto.

Art. 23. Day-old bird and hatching eggs exports shall be suspended in case of noncompliance with the conditions hereunder or of detection of any transmissible disease at the breeding or Hatchery, or in the region where they are located, susceptible of placing the sanitary situation of the importing country at risk.

Art. 24. The Official Veterinary Services shall make periodical inspection visits to the breeding and Hatchery registered and qualified for regional trade.

Art. 25. For this norm's certification a detailed Manual of Procedures for Qualification of Poultry Farming Establishments (Breeding and Incubation) for Regional Trade, should be issued.

Art. 26. Breeding nuclei reserved for parents, grandparents or great-parents must be located in Newcastle Disease Free Areas. For the purposes of this article, Newcastle Disease Free Areas are characterized as follows:

a) a legally defined geographical territory extending for less than 10 km around the establishment;

b) no case or evidence of the disease has been detected on said territory for a period of at least six months and on which vaccination is used as a control method. Or at least 21 (twenty one) days have elapsed since declaration of the last case of the disease and the method of sanitary slaughter has been employed, without vaccination, as a control measure; and

c) said territory must be subject to a permanent epidemiologic surveillance system that takes into account the following:

- a register of all poultry establishments located within a circumscribed area;
- a monitoring procedure and serologic surveys pursuant to a statistical design; and
- an information and analysis system in place.

EXPORTING COUNTRY .....
MINISTRY: .....
SERVICE : .....
COMMON ZOOSANITARY CERTIFICATE FOR DAY-OLD BIRDS AND HATCHING EGGS EXPORTS
CERTIFICATE No.: .....
DATE ISSUED : .....
EXPIRATION DATE : ..... (Valid for ten days)
I – IDENTIFICATION:
( ) DAY-OLD BIRDS ( ) HATCHING EGGS
Species.....
Trademark / Breed:.....
Classification : ( ) grandparents ( ) parents ( ) Commercial ( ) great-grandparents
Lineage : ( ) broiler ( ) laying
Quantity : male line male .....
female line male .....
male line female .....
female line female .....
commercial broiler .....
laying .....
TOTAL: .....
II – ORIGIN:
Exporter's name and address .....
Establishment of origin's name and address :.....
.....
Place of shipment : .....
Means of transportation:.....
Airline and Flight No. :.....
Registration No. .....
III – DESTINATION
Destination country .....
Importer's name and address.....
.....
.....

Destination establishment's name and address .....
.....
Point of entry in the country :.....
.....
IV- OBSERVATIONS:
V – SANITARY INFORMATION:
The undersigned official veterinarian CERTIFIES that:
1. The ..... day-old birds and ..... hatching eggs originate in the ..... breeding nucleus and in the ..... incubation establishment, which are qualified, regularly inspected by the veterinary services and have not had in the last six months any clinical manifestation of the Newcastle or Gumboro Diseases, Avian Infectious Bronchitis, Avian Infectious Laryngotracheitis, Fowl Cholera, or any other transmissible disease subject to mandatory notification.
2. Permanent epidemiologic surveillance has not detected the presence of Inclusion Body Hepatitis, Avian Infectious Anemia, Swollen Head Syndrome by Pneumovirus, *Salmonella enteritidis*, or *Salmonella typhimurium*.
3. The aforementioned items originate in breeding nuclei and Hatchery free of:
(a) Pullorum disease and Fowl typhoid (***S. pullorum and S. gallinarum***);
(b) Avian mycoplasmosis (*M. gallisepticum* and ***M. synoviae*** in hens, ***M. meleagridis***, ***M. sinoviae***, and ***M. gallisepticum*** in turkeys).
4. The day-old birds have been vaccinated against Marek's disease on ....., with a type ..... vaccine from the ..... laboratory, included in lot no. .....
5. The day-old birds were inspected on the shipment date and showed no clinical signs of disease.
6. The eggs and birds were packaged in clean containers provided with clean separators.
7. The country if free of Avian Influenza (Avian Pest) and the zone is free of Newcastle Disease.

Place and date: .....
Accredited veterinarian's name and registration nº.: .....
.....
Official stamp: .....
Official veterinarian's name and registration nº.: .....
.....

ADMINISTRATIVE RULING No. 115 OF OCTOBER 4, 1995

Published in the Official Gazette of October 10, 1995, Section 1, Page 15817

Defines the attributions of the National Avian Health Policy-PNSA's Scientific Committee

THE ANIMAL AND PLANT HEALTH AND INSPECTION SECRETARY, by virtue of the powers vested in him under Art. 78, VII of this Office's Internal Regulations approved under Ministerial Ruling No. 212 of August 21, 1992, and Art. 2 of Ministerial Ruling No. 193 of September 19, 1994, having in view the norms and attributions of the National Avian Health Program's Consultative Committee established under SDA Administrative Ruling No. 114 of October 4, 1995,

RESOLVES:

Art. 1. It shall be incumbent on the Committee to provide technical and scientific advisory services to the Ministry of Agriculture, Food Supply, and Agrarian Reform-MAARA in relation to the conduction of the National Avian Health Policy; evaluation of the performance of the public and private sectors; confirmation and control of outbreaks of Newcastle disease, Avian Influenza, and other diseases that affect state and international trade as well as public health; work methodology in laboratories and in animal health and inspection; decisions regarding intervention and sanitary measures; and evaluation and analysis of other issues as determined by the Animal and Plant Health and Inspection Secretary.

Art. 2. This Administrative Ruling shall enter into effect on the day of its publication. All dispositions to the contrary are hereby revoked.

ÊNIO ANTÔNIO MARQUES PEREIRA

ADMINISTRATIVE RULING No. 193 OF SEPTEMBER 19, 1994

Published in the Official Gazette of September 22, 1994 Section 1, Page 14309

Institutes the National Avian Health Program, in the sphere of the Animal and Plant Health and Inspection Secretariat – SDA and creates the Advisory Committee for the Avian Health Program

The Minister of Agriculture, Food Supply, and Agrarian Reform, using the powers invested in him under Art. 87 of the Constitution, in consideration of:

The importance of avicultural production for the country's economy:

The technological progress obtained by the private sector, ranking Brazil as the second country in the international market of poultry meat;

The structure of public and private veterinary services that support the sector in the field, laboratory and inspection areas;

The current sanitary status of aviculture, which enable the implementation of combat/eradication strategies for the main avian diseases;

The possibility and convenience of establishing co-management programs for public and private institutions, resolves:

Art. 1. To institute the National Avian Health Program, in the sphere of the Animal and Plant Health and Inspection Secretariat – SDA, involving the Animal Health and Inspection Department – DDA, and the Department of Inspection of Products of Animal Origin – DIPOA.

Art. 2. To delegate authority to the Animal and Plant Health and Inspection Secretary to is-

sue norms for the control/eradication of the main avian diseases, as well as for establishing priority areas and strategies.

Art. 3. To create the Advisory Committee for the Avian Health Program, delegating authority to the Animal and Plant Health and Inspection Secretary to define which entities will be represented in it.

Sole paragraph. The Board will be presided over by the Titular of the Animal and Plant Health and Inspection Secretariat (SDA) and have the Director of SDA's Animal Health and Inspection Department as secretary.

Art. 4. This Administrative Ruling comes into force on the date of its publication, and all provisions to the contrary are revoked.

SYNVAL GUAZZELLI

ADMINISTRATIVE RULING No. 70, OF MARCH 3, 1994

Published in the Official Gazette of March 03, 1994 Section 1, Page 3168

Regulates the enforcement of notification of suspected Newcastle Disease.

The Minister of Agriculture, Food Supply, and Agrarian Reform, using the powers invested in him under Art. 87, I, of the Constitution, and sole paragraph of Art. 61 of the Animal Sanitary Health and Inspection Service Regulation, approved by Decree No. 24.548, of July 3, 1934, resolves:

Art. 1. To alter the list of sanitary diseases set forth by Art. 61 of the Animal Sanitary Health and Inspection Service Regulation, approved by Decree No. 24.548, of July 3, 1934, to include avian Newcastle Disease.

Art. 2. Veterinarians and all owners, depositaries, or individuals who maintain birds of any species under their guard or custody, who are informed of the occurrence or suspect the occurrence of Newcastle Disease, are under the obligation to immediately notify the state or federal animal sanitary health and inspection service of the jurisdiction about the fact, suspending all transit of birds existing in the infected, or supposedly infected establishment, as well as of products of the birds and of sundry materials that may have had contact with them, until the relevant sanitary authority decides on which measures should be adopted.

Art. 3. This Administrative Ruling comes into force on the date of its publication.

SYNVAL GUAZZELLI

NORMATIVE INSTRUCTION No. 56 OF DECEMBER 4, 2007

Published in the Official Gazette of December 06, 2007 Section 1, Page 11

Establishes Procedures for the Registration, Inspection and Control of Comercial and Poultry Breeding Establishments

THE MINISTER OF STATE OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY, exercising the powers conferred upon him by Article 2, Decree No. 5741 of 30th March, 2006, considering the provisions of the Animal Health Defence Service Regulations approved by Decree No. 24548 of July 3, 1934 and the provisions of Proceedings No. 21000.008132/2005-72 and No.

21000.008133/2005-17, resolves:

Art. 1. To establish PROCEDURES FOR THE REGISTRATION, INSPECTION AND CONTROL OF COMMERCIAL AND POULTRY BREEDING ESTABLISHMENTS, in the form of its attachments.

Art. 2. Normative Instruction MAPA No. 4 of December 30, 1998 is hereby revoked.

Art. 3. This Normative Instruction shall come into force on the date of its publication.

REINHOLD STEPHANES

ATTACHMENT I

PROCEDURES FOR THE REGISTRATION, INSPECTION AND CONTROL OF COMMERCIAL AND POULTRY BREEDING ESTABLISHMENTS

CHAPTER I

GENERAL PROVISIONS

Art. 1. The present Normative Instruction defines procedures for the registration, inspection and sanitary control of Commercial and Poultry Breeding Establishments, with the exception of the breeding of ratites.

Art. 2. For the purposes of registration and inspection, poultry breeding establishments shall be classified according to their purpose, according to the species being breed – chicken, teal, duck and turkey, in the following categories:

I - PURE LINE ESTABLISHMENTS: farm or nucleus where there is genetic selection of primary breeders, importer, exporter and producer of hatching eggs for production of great-grandparents;

II - GREAT-GRANDPARENT BREEDING ESTABLISHMENT: great-grandparent farm or nucleus, importer, exporter and producer of hatching eggs for production of grandparents;

III – GRANDPARENT BREEDING ESTABLISHMENT: grandparent farm, importer, exporter and producer of hatching eggs for the production of parents;

IV – PARENT BREEDING ESTABLISHMENT: parent farm or nucleus, importer, exporter and producer of hatching eggss for the production of commercial broilers or egg-laying hens;

V – PARENT RAISING ESTABLISHMENT: day-old parent raising farm or nucleus producer of commercial broilers and egg-laying hens;

VI – RAISING ESTABLISHMENT: raising farm or nucleus for day-old birds for commercial egg-laying up to 20 weeks old;

VII – HATCHERY ESTABLISHMENTS FOR PURE LINE FARMS: importer, exporter and producer establishment of day-old birds for grandparent production;

VIII – HATCHERY ESTABLISHMENTS FOR GREAT-GRANDPARENT BREEDING FARMS: importers, exporters and producers of day old birds for the production of grandparents;

IX – HATCHERY ESTABLISHMENTS FOR GRANDPARENT BREEDING FARMS: importing, exporting and producing establishment of day old birds for the production of parents;

X – HATCHERY ESTABLISHMENTS FOR PARENT BREEDING FARMS: importing, exporting and producing establishment of day old birds, broilers and commercial egg-laying hens;

XI – ESTABLISHMENT PRODUCER OF SPF – SPECIFIC PATHOGEN FREE POULTRY AND EGGS;

XII – ESTABLISHMENT PRODUCER OF EGGS CONTROLLED FOR THE PRODUCTION OF INACTIVATED VACCINES.

Art. 3. For the purposes of registration and inspection, COMMERCIAL POULTRY ESTABLISHMENTS shall be classified as to their purposes in three categories:

I - COMMERCIAL BROILER ESTABLISHMENTS: Establishments exploiting commercial poultry for the production of chicken (Gallus gallus domesticus) and turkey (Meleagris gallopavo) for slaughter.

II - COMMERCIAL EGG-LAYING ESTABLISHMENTS: Establishments exploiting commercial poultry for the production of chicken eggs (Gallus gallus domesticus) for consumption.

III - BREEDING ESTABLISHMENTS FOR OTHER POULTRY NOT CONTEMPLATED IN THE PREVIOUS DEFINITIONS, EXCEPTION MADE TO RATITES:

Establishments exploiting other production fowl, considered exotic or not, exception made to ratites and their hatcheries, not contemplated in the poultry meat and egg production system.

Art. 4. Commercial and Poultry Breeding Establishments may be epidemiologically formed by:

I - NUCLEUS: physical poultry production unit composed by one or more sheds housing a group of birds of the same species and age. The nuclei must have a common production management and must be isolated from other poultry production activities by using natural or artificial physical barriers;

II - FARM: physical poultry production unit housing a group of birds of the same species. The farms must be subjected to a common production management and must be isolated from other poultry production activities by natural or artificial physical barriers, composed by one or more production nuclei.

Art. 5. A pre-existing poultry establishment is a poultry farm that had been physically installed before the date of publication of this Normative Instruction.

Art. 6. The poultry and the genetic material housed in the Poultry Establishments described in this Nornative Instruction must come from registered establishments subjected to sanitary monitoring by the Ministry of Agriculture, Livestock and Food Supply.

CHAPTER II

REGISTRATION OF POULTRY ESTABLISHMENTS

Art. 7. The poultry breeding establishments described in Article 2. of this Normative Instruction shall be registered with the Ministry of Agriculture, Livestock and Supply - MAPA.

Sole Paragraph. Poultry breeding establishments pre-existing the date of publication of this Normative Instruction must adapt to the registration procedures with the Ministry of Agriculture, Livestock and Food Supply, within a maximum of 1 (one) year.

Art. 8. The state animal health and inspection bodies in states participating in the National Avian Health Program must register the Commercial Poultry Establishments described in Article 3 of this Normative Instruction.

Sole Paragraph. Pre-existing Commercial Poultry Establishments must adapt to the registration procedures with the state animal health defence bodies within a maximum of 2 (two) years.

Art. 9. In order to register, the poultry establishments must be registered with the local veterinary attention unit of the state animal health and inspection service in the form of the ATTACHMENT II to this Normative Instruction and its owners must present the following documents to the body responsible for the registration:

I – Request to the registration body, in the form of ATTACHMENT III or IIIA of this Normative Instruction, depending on the case;

II – Legal Entity legal existence data:

a) copy of the CNPJ (National Register of Corporate Taxpayers) card;

b) copy of registration at the State Commercial Registry or of the company's Articles of Association, together with any changes made;

c) copy of the leasing agreement or partnership agreement registered at the registry office, if any.

III – Individual legal existence data:

a) copy of the CPF (Individual Taxpayer Registration) card;

b) copy of registration with INCRA (National Institute of Colonisation and Agrarian Reform) or copy of the property's inscription with the Federal Revenue;

c) copy of the inscription declaration of rural producer;

d) copy of the leasing contract or partnership deed registered in the registry office, if any.

IV – Note of technical responsibility of the Veterinarian carrying out the hygiene-sanitary control of the poultry establishment, following the model of the Regional Veterinary Medicine Council;

V – Plant showing the property's location,

signed by a professionally qualified technician, indicating all premises, roads, watercourses, bordering properties and respective activities in a scale compatible with the size of the property, or an aerial survey; In the case of Commercial Poultry Establishments, the sketch or aerial survey will be required, showing all installations, watercourses and bordering properties;

VI – Floor plan of the installations in a scale compatible with the visualisation of the infrastructure installed;

VI – Licence issued by a municipal, state or federal environment inspection body, approving the area where the establishment is to be built;

VII – List of hygiene-sanitary and biosecurity measures to be adopted by the poultry establishment and of the technological processes, including a detailed description of the following:

a) adopted management;

b) location and isolation of premises;

c) natural barriers;

d) physical barriers;

e) access control and transit flow;

f) care with feed and water;

g) poultry health programme;

h) contingency plan;

i) personnel qualification plan;

j) environment management plan; and

l) descriptive plan of the traceability of hatching eggs and the destination of non-hatching eggs, required only of hatcheries, producers of SPF poultry and eggs, and producers of controlled eggs for the production of inactivated vaccines.

VIII – document proving the microbiological, physical and chemical quality of the drinking water, according to sanitary surveillance standards, or a certificate of use of water from public water supply services.

Paragraph 1. For the registration of poultry breeding establishments, the documents listed in items I to VIII of this article should be presented together with a Physical and Sanitary Inspection Expert Report issued by an Agricultural and Livestock Federal Inspector (FFA) with the approval of the Agricultural and Livestock Health and Inspection Service and the Agricultural and Livestock Inspection Service (SEFAG) of the Federal Superintendence of Agriculture at the federation unit where the establishment is located, in the form of ATTACHMENT IV of this Normative Instruction.

Paragraph 2. For the registration of Commercial Poultry Establishments, the documents listed in items I to VIII should be presented together with a Physical and Sanitary Inspection Expert Report issued by the Official Veterinarian of the Local Veterinary Attention Unit, in the form of ATTACHMENT IVA of this Normative Instruction.

Paragraph 3. After issuing the poultry establishment's registration certificate in the form of Attachment V of this Normative Instruction, the document should be made available for inspection at the establishment.

Paragraph 4. The Commercial and Poultry Breeding Establishments should communicate any changes to the technical expert in charge to the body issuing the registration within a maximum of 30 (thirty) days, and present the corresponding documentation of the successor.

Paragraph 5. Any change of address, company name or improvements to the company's physical structure, as well as the alienation or lease of the Establishment must be obligatorily updated at the registration body by:

I – presenting a request o update the registration status;

II – presenting a copy of the new articles of association of the poultry establishment or the leasing contract; and

III – inspection of the physical area and hygiene-sanitary control carried out by the body responsible for the registration.

CHAPTER III

INSPECTION

Art. 10. The Poultry establishments covered by this Normative Instruction must be located in an area not subject to adverse conditions that may interfere in the health and well-being of the birds and the quality of the product, respecting the following minimal distances between the poultry establishment and other locations at sanitary risk:

I - 3 Km (three kilometres) between a breeding poultry establishment and abattoirs of any

purpose, feed mills, other poultry breeding or commercial establishments;

II – internal limits of the poultry establishment producer of SPF eggs and birds, and producer of controlled eggs for the production of inactivated vaccines:

a) 500 m (five hundred metres) between different age nuclei, between raising and production sheds, and between the nucleus and the vicinal road, state or federal highway;

b) 200 m (two hundred metres) between the nuclei and the peripheral limits of the property;

III. internal limits of other poultry breeding establishments:

a) 200 m (two hundred metres) between the nuclei and the peripheral limits of the property;

b) 300 m (three hundred metres) between the nuclei.

Paragraph 1. The establishment's accredited laboratory, if it exists, must be located outside the fence isolating the production nuclei.

Paragraph 2. Changes to the minimum distances mentioned in this article may be accepted by SEFAG/SEDESA-Federal Superintendence of Agriculture in the case of pre-existing establishments and based on risk assessment for poultry health, as a result of the adoption of new technologies, the existence of natural barriers (reforestation, natural forests, topography) or artificial barriers (brick walls), and the use of management techniques and differentiated biosecurity measures that make the introduction and the dissemination of disease agents difficult.

Art. 11. Poultry breeding establishments should be built in such a manner that their interior shed surfaces can be cleaned and disinfected, that their have a masonry floor, that their sheds are provided with protection against the external environment, including the installation of screens with a mesh not over 2 cm (two centimetres), to guard against the entrance of birds, domestic animals and wild animals.

Paragraph 1. Poultry breeding establishments should have an isolation fence of at least 1.5 m (one and a half metres) tall surrounding the shed or the nucleus, standing at 10 m (ten metres) from it, keeping the transit and presence of animals from other species outside its perimeter.

Paragraph 2. Poultry breeding establishments using sheds closed with a screen mesh over 2 cm (two centimetres) shall have 5 (five) years to change their screens to a mesh not over 2 cm (two centimetres). During this period, other biosecurity and management measures provided for in this Normative Instruction must be adopted.

Art. 12. SPF Poultry and Egg Producing Establishments should have masonry sheds, including their walls, so as to allow their cleaning and disinfection, and these should be fitted with an absolute air filtering system maintaining a constant positive pressure.

Art. 13. Controlled Egg Producing Establishments for the Production of Inactivated Vaccines should have curtains to enable the air to flow in one direction, and a system that assures that the air enters the premises from one source only, through the installation of devices that allow the monitoring of air quality.

Art. 14. The Commercial Poultry Establishments facilities should be built with materials that allow their cleaning and disinfection and they should be provided with protection against the outside environment, including the installation of screens with a mesh measuring not over 2 cm (two centimetres), to guard against the entrance of birds, domestic animals and wild animals.

Paragraph 1. Commercial broiler establishments and commercial egg-laying establishments should have an isolating fence at least 1.5 m (one and a half metres) tall surrounding the shed or nucleus, standing at least 5 m (five metres) away from the building, so as to prevent the transit and presence of animals from other species within its perimeter.

Paragraph 2. Commercial egg producing establishments, as well as adopting measures to prevent the presence of birds with unknown sanitary status, flies and rodents around and inside the shed, should avoid wasting feed, adopt measures to ease the quick desiccation of faeces, avoiding the accumulation of insects and their larvae, and to avoid humidity in birds faeces by controlling leakages from waterers and other water sources.

Paragraph 3. Pre-existing Commercial Poultry Establishments shall be given a 5-year period

from the date this Normative Instruction is published to install screens with a mesh not over 2 cm (two centimetres) over the shed's external open niches.

Paragraph 4. Establishments breeding other production birds and ornamental birds should be provided with screens with a mesh not over 2 cm (two centimetres) to avoid the entrance of birds, domestic and wild animals. Open air breeding facilities should have the upper part of the paddocks fitted with screens.

Paragraph 5. Ornamental bird establishments already using sheds closed with screens with a mesh over 2 cm (two centimetres) shall be given a period of 5 (five) years to replace them with meshes not over 2 cm (two centimetres).

Paragraph 6. The transit or presence of animals of other species inside production and ornamental bird breeding establishments is not permitted.

Art. 15. The premises of SPF Egg and Bird Producing Establishments shall be divided at least into the following areas:

I – dressing rooms, lavatories and toilets;

II - office;

III - depot;

IV - chick area;

V - production area:

VI - hatchery area;

VII - supplies area;

VIII - egg fumigation chamber;

IX - fumigation chamber for supplies entering the farm;

X - boxes and trays depot; and

XI - egg classification and storage room.

Art. 16. The premises of Controlled Egg Production Establishments for the Production of Inactivated Vaccines shall be divided at least into:

I - dressing rooms, lavatories and toilets;

II - office;

III - depot;

IV - egg fumigation chamber;

V - fumigation chamber for supplies entering the farm;

VI - boxes and trays depot; and

VII - egg classification and storage room.

Art. 17. Apart from the production area, the premises of poultry breeding establishments shall be divided at least into:

I - dressing rooms, lavatories and toilets at nuclei entrances;

II - office;

III - egg storage room;

IV - supplies room;

V - fumigation chamber for supplies and equipment; and

VI - vehicle cleaning and disinfection area.

Art. 18. The internal area of the hatchery shall be divided into book-keeping and technical areas, physically separated, both with individual ventilation and unidirectional air flow. The work area shall be provided with a single access for people, equipment and supplies.

Sole Paragraph. The technical premises of the hatchery shall be divided at least into:

I - egg reception room;

II - egg disinfection chamber;

III - egg storage room;

IV - hatchery room;

V - hatching room;

VI - room with areas for selection, sexing, vaccination, packing and stocking of chicks;

VII - chick dispatch room;

VIII – vaccine manipulation room;

IX - equipment washing and disinfection room;

X - dressing rooms, lavatories and toilets;

XI - refectory;

XII - office;

XIII - boxes depot; and

XIV - machines and generators room.

Art. 19. All animal feed and water introduced in the SPF Eggs and Poultry Production Establishment shall receive treatments to eliminate the possibility of entrance of pathogens through sterilisation mechanisms with the use of autoclave for feed and filter for water; the same is valid for any other material introduced in the premises, which shall be subjected to treatment allowing to eliminate contamination by pathogen agents.

Art. 20. Any visits to commercial and poultry breeding establishments by persons strange to the production process shall be preceded by the same procedures to which the establishment's personnel is subjected, such as showering and change of clothes and shoes at the entrance of

the establishment and at each nucleus.

Sole Paragraph. The visitor and the official veterinarian shall sign a term of responsibility where they affirm not to have had any contact with any type of bird for a minimum period of 7 days for SPF Egg and Poultry Establishments and Controlled Egg Establishments for the Production of Inactivated Vaccines, 3 days for Pure Line Establishments, Great-grandparent and Grandparent Establishments and 1 day for Parent Establishments, prior to entering the establishment or each nucleus.

Art. 21. Commercial and Poultry Breeding Establishments shall adopt the following actions:

I – to control and register the movement of vehicles and the access of persons to the establishment, including the placement of warning signs to avoid the entrance of persons strange to the production process;

II – to be protected by security fences and by different ways of access for vehicles and persons, contemplating an entrance for cleaned and disinfected material to be used in the production, and another for the removal of discarded material and further production waste;

III – to establish procedures for the disinfection of vehicles at the poultry establishment entrance and exit;

IV – the poultry establishment personnel is to wear clean clothes and shoes;

V – to adopt adequate procedures for the destination of wastewater and production waste (dead birds, discarded eggs, manure and packages), according to the environmental legislation in force;

VI – to prepare and execute a cleaning and disinfection programme to be carried out in the sheds after the exit of each lot of birds;

VII – to keep registers of the pest control programme so as to keep the sheds and feed or egg storage rooms free from insects and rodents, wild animals or domestic pets;

VIII – to carry out physical, chemical and bacteriological analyses of the water according to the norms established in CONAMA Resolution No. 357 of March 17, 2005, except for the count of thermotolerant coliforms, which shall follow the norm established by the Ministry of Health Administrative Ruling No. 518 of March 25, 2004 within the following periods:

a) Annual physical and chemical analysis and bacteriological analysis every three months for establishments producing SPF eggs and birds and eggs controlled for the production of inactive vaccines.

b) Annual physical and chemical analysis and bacteriological analysis every semester for further poultry breeding establishments.

c) Annual physical. chemical and bacteriological analysis for commercial bird establishments.

IX – to keep for a period not under 2 (two) years at the disposal of the official service, the registers of:

a) bird movement activities (copies of the Animal Movement Permits);

b) sanitary actions carried out;

c) vaccination protocols and medicines used; and

d) visit dates and recommendations by the Technical Person in Charge and by the official veterinarian.

X – Should any sanitary problems be identified, the poultry litter shall be subjected to a fermenting process for at least 10 days before its removal from the shed or another method approved by the Animal Health Department that assures the inactivation of disease agents. Commercial broiler establishments shall assure that poultry litter shall be re-used only if there is no sanitary problem detected that may represent any potential risk to the next lot to be housed, to the national poultry flock and to public health, according to the clinical inspection by the establishment's technical person in charge or by the official veterinarian or even during the slaughter of the lot by the Animal Origin Products Inspection Service.

Art. 22. At Commercial and Poultry Breeding Establishments, there will be sanitary monitoring for Newcastle disease, avian influenza, Salmonellosis, Mycoplasmosis, and the use of veterinarian drugs and environmental contaminants, according to the respective specific procedures.

Paragraph 1. Other diseases may be included in the monitoring system at the discretion of the Ministry of Agriculture, Livestock and Food Supply.

Paragraph 2. The sanitary monitoring programmes shall vary in consideration to the differing purposes of the establishments, according to the classification described in Articles 3 and 4 of this attachment.

Paragraph 3. The official service veterinarian is responsible for the inspection and supervision of sanitary monitoring activities, by making inspection visits and through documentation follow up.

Paragraph 4. The veterinarian in charge shall be responsible for the execution of hygiene-sanitary controls of Commercial and Poultry Breeding Establishment flocks.

Paragraph 5. Commercial and Poultry Breeding Establishments shall keep a register of sanitary monitoring procedures for each bird lot or hatchable egg lot, with reference to the diseases contemplated in the National Poultry Health Plan.

Paragraph 6. These tests shall be obligatorily carried out at laboratories belonging to the national network of agricultural and livestock laboratories of the Agriculture and Livestock Health Care Unified System.

Paragraph 7. Commercial and Poultry Breeding Establishments shall establish procedures to assure the traceability of animals and hatchable eggs.

Art. 23. The lots of SPF egg producing birds shall be free of the pathogenic agents and specific antibodies for the following microorganisms:

I - Avian Adenovirus (Groups I, II and III);

II - Chicken Infection Anemia;

III - *Haemophilus paragallinarum (Avibacterium paragallinarum);*

IV - *Mycoplasma gallisepticum and M. synoviae;*

V - Avian Paramyxovirus (types II and III);

VI - Avian pneumovirus;

VII - Avian reovirus;

VIII - *Salmonella pullorum, S. gallinarum, S. enteritidis*

IX - *Salmonella* sp.;

X - Avipoxvirus;

XI - Coronavirus infectious bronchitis virus;

XII - Marek's Disease Virus;

XIII - Newcastle Disease Virus;

XIV - Gumboro Disease Virus;

XV - Avian Encephalomyelitis Virus;

XVI - Avian Influenza Virus;

XVII - Avian Infectious Laryngotracheitis Virus;

XVIII - Avian Leukosis Virus; and

XIX - Reticuloendotheliosis Virus.

Paragraph 1. Lots of birds producing SPF eggs shall be monitored according to the specifications in the following table:

AGENT	TEST	INTERVAL LOT /%	ABBREVIATIONS
Avian Adenovirus group I – Serotypes 1-12	AGID; VN	(4) (5)	Tests and abbreviations – AGID - Agar gel immunodifusion test VN – Virus Neutralisation HI - Hemagglutination Inhibition ELISA - Enzyme Linked Immunosorbent Assay CO - Clinical observation PAT - Plate Agglutination Test AI – Agent isolation DVE – Duck virus enteritis EDS - Egg Drop Syndrome
Avian Adenovirus group II (HEV)	AGID	(4)	
Avian Adenovirus group III (EDS-76)	HI; AGID	(4) (5)	
Avian Encephalomyelitis Virus	ELISA; AGID; VN	(4) (5)	
Avian Reovirus	AGID; VN; ELISA	(4) (5)	
Coronavirus infectious bronchitis virus	AGID; ELISA	(2) (5)	
Gumboro Disease Virus	ELISA; AGID; VN	(2) (5)	
Newcastle Disease Virus	HI; ELISA	(2) (5)	
Avian Influenza Virus (type A)	AGID	(2) (5)	
Avian Leukosis Virus A, B	VN; ELISA	(4)	
Lymphoid Leukosis Virus A, B, C, D and J	ELISA	(2)	
Marek's Disease Virus – Serotypes 1, 2 and 3	AGID	(2) (5)	Frequency and percentage of birds tested (1) At the beginning of egg-laying – 100% of the lot; (2) Upon the first sampling - 10% of the lot and in following months: - 5% of the lot; (3) Up to 5 days old – Observation of Mortality – submission for serological test; (4) Monthly – 60 birds; (5) Weekly – 40 birds.
Reticuloendotheliosis Virus	ELISA; AGID	(2) (5)	
Avipoxvirus	AGID; CO	(4)	
Avian Infectious Laryngotracheitis Virus	ELISA; AGID	(4)	
Mycoplasma synoviae	PAT; HI; AI	(2) (5)	
Mycoplasma gallisepticum	PAT; HI; AI	(2) (5)	
Avian pneumovirus	ELISA; VN	(2)	
Avian paramyxovirus – Types II and III	HI	(2) (4)	
Salmonella Pullorum / S. Gallinarum	PAT; AI	(1); (3) (4)	
Salmonella Enteritidis	PAT; ELISA ; AI	(3); (4)	
Salmonella sp.	AI	(3); (4)	
Haemophilus paragallinarum (*Avibacterium paragallinarum*)	CO	-	
Chicken Anaemia Virus	ELISA; VN	(1); (2)	

Paragraph 2. The tests shall be carried out at the national network of agricultural and livestock laboratories of the Agriculture and Livestock Health Care Unified System, and their registries shall be kept stored and available to inspection for a minimum period of 3 years.

Paragraph 3. The supply of SPF eggs for trading and incubation shall be suspended during the positive diagnosis period for the diseases mentioned in this article.

Paragraph 4. Other diseases may be included in the monitoring system at the discretion of the Ministry of Agriculture, Livestock and Food Supply.

Art. 24. With regard to the sanitary control of controlled egg producing birds for the production of inactivated vaccines, the following standard shall be obeyed:

I – Chicken lots must be clear of pathogenic agents and antibodies specified for the following microorganisms:

a) Avian Adenovirus group III (EDS 76), when not vaccinated;

b) *Mycoplasma gallisepticum, M.synoviae;*

c) *Salmonella gallinarum, S. pullorum, S. enteritidis and S. typhimurium.*

d) Avian Influenza Virus;

e) Avian Infectious Laryngotracheitis Virus;

f) Avian Leukosis Virus; and

g) Reticuloendotheliosis Virus.

II – Lots of birds producers of Anseriformes eggs controlled for the production of inactivated vaccines must be clear of the following pathogenic agents and antibodies:

a) Avian Adenovirus group III (EDS 76) – vaccination not allowed;

b) *Mycoplasma gallisepticum, M.synoviae;*

c) *Salmonella gallinarum, S. pullorum, S. enteritidis and S. typhimurium.*

d) Newcastle Disease Virus;

e) Duck Enteritis Virus;

f) Duck Hepatitis Virus; e

g) Avian Influenza Virus.

III – Lots of controlled layers for the production of inactivated vaccines must be clear from clinical manifestations of infections caused by the following agents:

a) Avian Anemia Virus;

b) *Haemophilus paragallinarum (Avibacterium paragallinarum);*

c) Avian pneumovirus;

d) Avian Reovirus;

e) Avipoxvirus;

f) Avian Infectious Bronchitis Virus;

g) Marek's Disease Virus;

h) Newcastle Disease Virus;

i) Gumboro Disease Virus; and

j) Avian Encephalomyelitis Virus.

IV – Lots producing Anseriformes eggs controlled for the production of inactivated vaccines must be clear of clinical manifestations of infections caused by the pathogenic agents specified in this Article's caput as well as the following:

a) Duck Enteritis Virus;

b) Duck Hepatitis Virus; and

c) Eastern Equine Encephalomyelitis Virus.

V – Lots of birds producing eggs controlled for the production of inactivated vaccines shall be monitored every 30 (thirty) days. The diagnosis tests specified in the following table must be carried out on at least 30 (thirty) birds:

AGENT	TEST(*)	TESTS AND ABBREVIATIONS
Avian Adenovirus group III (EDS-76)	AGID; HI	AGID - Agar gel immunediffusion test HI - Hemagglutionation Inhibition ELISA - Enzyme Linked Immunosorbent Assay PAT - Plate Agglutination Test AI– Agent isolation AI* - agent isolation from cloacae swab EDS - Egg Drop Syndrome *Mycoplasma gallisepticum; Mycoplasma synoviae; Salmonella enteritidis; Salmonella typhimurium; Salmonella pullorum and Salmonella gallinarum*, shall follow the same model required for the control of reproducing birds, but at 30 days intervals in between each monitoring.
Avian Influenza Virus	AGID; ELISA	
Mycoplasma synoviae	PAT; HI; AI	
Mycoplasma gallisepticum	PAT; HI; AI	
Salmonella Pullorum/S. Gallinarum	PAT; AI	
Salmonella Enteritidis	PAT; ELISA; AI	
Salmonella Typhimurium	AI	
Salmonella sp.	AI*	
Avian Infectious Laryngotracheitis Virus	ELISA; AGID	
Avian Leukosis Virus A, B	VN; ELISA	
Reticuloendotheliosis Virus	ELISA; AGID	

Paragraph 1. The supply of controlled eggs for the production of inactivated vaccines shall be suspended during the period of clinical manifestation of the diseases mentioned in this article.

Paragraph 2. The tests shall be carried out by laboratories that are part of the national network of agricultural and livestock laboratories of the Unified Agriculture and Livestock Health Care Unified System, and their registers shall be kept stored and available for inspection for a minimum period of 3 (three) years.

Paragraph 3. The production of antigens

in controlled Anseriformes eggs must always be made in isolation and the eggs may not be sent to hatchery together with other controlled or SPF eggs within the production laboratory.

Paragraph 4. Every imported avian vaccine produced in isolation or combination in controlled eggs shall have their importation suspended upon the occurrence of an exotic avian disease in Brazil or a disease listed by the OIE until the country is considered free of such disease by the Brazilian Official Veterinary Service.

Paragraph 5. Every imported avian vaccine produced in isolation or combination in controlled eggs shall be accompanied by an expert report contemplating the tests required by the Ministry of Agriculture, Livestock and Food Supply.

Paragraph 6. Other diseases may be included in the monitoring system at the discretion of the Ministry of Agriculture, Livestock and Food Supply.

Art. 25. At poultry breeding establishments, the eggs must be collected at frequent intervals in cleaned and disinfected recipients.

Paragraph 1. After being collected, clean eggs must be disinfected as soon as possible, stored at a specific location and kept at a temperature between 13 and 25º C and a relative air humidity between 70 and 85%.

Paragraph 2. Dirty, broken or cracked eggs must be collected at separate recipients and may not be destined for incubation.

Paragraph 3. The eggs must be dispatched directly from the farm's stock room to the hatchery.

Paragraph 4. The eggs must be transported in appropriate closed vehicles: on trays, trolleys and boxes kept in good state of conservation and disinfected prior to each shipment. The boxes and trays, if made of carton, must be first use.

Paragraph 5. Day old birds must be dispatched directly from the hatchery to the place of destination.

Paragraph 6. The transporting vehicle must be cleaned and disinfected prior to each shipment.

Art. 26. The interstate transit of birds, including those destined for slaughter, as well as manure and poultry litter, shall comply with the regulations provided for in this article.

Paragraph 1. As well as following the procedures established by the Ministry of Agriculture, Livestock and Food Supply, all poultry establishments in international trade must follow the requirements of the importing countries.

Paragraph 2. In order to issue the Animal Movement Permit for birds, the qualified veterinarian must also be the technical person in charge for the establishment of origin.

Art. 27. The vaccination of breeding and commercial poultry flocks may only be carried out with a vaccine duly registered with the Ministry of Agriculture, Livestock and Food Supply.

Paragraph 1. The vaccination programme shall be specific per region and productive segment.

Paragraph 2. Breeding birds – with the exception of SPF birds – commercial layers and ornamental birds shall be systematically vaccinated against Newcastle disease.

Paragraph 3. Broiler establishments vaccinating against Newcastle disease and other officially controlled diseases shall obligatorily inform the activity to the state animal health and inspection service.

Paragraph 4. In case of an exotic disease, systematic vaccination shall not be allowed.

Paragraph 5. At Breeding Hatchery Establishments there shall be obligatory vaccination against Marek's disease before the dispatch of day-old birds.

CHAPTER IV

FINAL PROVISIONS

Art. 28. Poultry establishments shall allow the official veterinarian to access the documents and premises, all biosecurity procedures observed.

Art. 29. The veterinarians qualified to issue Animal Movement Permits from registered poultry establishments, who observe birds displaying sudden and quantitatively increased signs outside normal production standards, such as the decrease in egg production, in water or feed consumption, and increased mortality rate occurring within a 72-hour period shall communicate the fact immediately and officially to the animal health and inspection service of the federation unit.

ATTACHMENT II

POULTRY ESTABLISHMENTS REGISTRATION FORM

1. Establishment General Information

Taxpayer's No. (TAXPAYER'S No. (CNPJ/CPF)):	State Registration No. Or Producer Registration	
Incra No.:	Individual (1)	Legal Entity (2)
Company Name:		
Brand or Trade Name:		

2. Establishment Location

Address – street name:		
District:	Location:	
Municipal Area:	Postal Code:	Federation Unit:

3. Mail Address

Address - street name:		
District:	Location:	
Municipal Area:	Postal Code:	Federation Unit:
Telephone:	Fax:	Post Box:
E-mail:		

4. Establishment's Area of Performance

Area:	Activity:	Classification:	Additional Characteristic:
	Activity:	Classification:	Additional Characteristic:
	Activity:	Classification:	Additional Characteristic:

5. Cooperative / Integrator (in case the activity is integrated or cooperate)

Taxpayer's No. (CNPJ/CPF):		
Company Name:		
Trade Name:		
Address - street name:		
Municipal Area:	Federation Unit:	Registration Date: ____/____/____

6. Technical Person in Charge

Name:			
Profession: VETERINARY DOCTOR			
Taxpayer No. (CPF):	Abbreviation: CRMV	Region (Federation Unit):	Registration No.:
Type of responsibility: 1		Type of Technician: (1 – title holder / 2 – substitute)	

7. Type of Property

	Owned		Leased (if leased, please fill below)
Name of owner:		Taxpayer's No. (CPF/CNPJ):	
Address:			

8. Location / Premises **DATUM: South American 69 (SAD69)**

GPS Coordinates (*decimal format*)	S:	W:
Property Area: (ha)	Area used for poultry breeding: (ha)	
No. of Nuclei:	No. of Sheds / Paddocks:	
Constructed Area:	Housing Capacity:	
No. of persons involved with the activity:		

9. Person Responsible for the Information

Name:	
Title:	Identity Document:

10. Declaration

I do so declare that all the information given in this form is true and any change to such information shall be communicated immediately to the animal health and inspection body.

Place and date:

_____

Signature

11. Person Responsible for the Registration

To be filled by the employee responsible for the local veterinary attention unit

Name:	Body:
Title:	Employee No:

Filling of item 4 of Registration Form

Area of Interest:

Animal Multiplication Material (breeding)

Commercial Birds

Activity:

Independent Producer

Integrated Producer

Cooperate Producer

Classification:

Breeding Birds

Pure Line Farm

Great-grandparent Farm

Grandparent Farm

Parent Farm

SPF controlled egg Farm

Pure Line Hatchery

Great-grandparent Hatchery

Grandparent Hatchery

Parent Hatchery

Ostrich Hatchery

Ostrich Farm - Breeding

Ostrich Farm – Breeding and Fattening

Ostrich Farm - Fattening

Ostrich Farm – Complete Cycle

Ostrich Farm – Partial Cycle

Parent Raising Farm up to 20 weeks old

Chick Raising Farm from day-old to 20 weeks old
Commercial Birds:
Broiler Farm
Egg Farm
Other production bird and ornamental bird Farm
Additional Characteristics (species):
Breeding Birds
Chicken – meat poultry
Chicken – egg-laying
Duck – meat poultry
Duck - egg-laying
Turkey – meat poultry
Turkey - egg-laying
Teals – meat poultry
Teals - egg-laying
Commercial Birds
Chicken
Turkey
Duck
Teal
Quail
Helmeted Guinea fowl
Ostrich
Rhea
Others (please specify)

ATTACHMENT III

POULTRY ESTABLISHMENT REGISTRATION FORM

To the Federal Superintendence of Agriculture of the State of _____
_____
_____, (Legal Entity or Individual) Taxpayer's No. (CNPJ/CPF)_____, located at _____ (Full address) _____, GPS Coordinates (decimal format SAD 69) S: _____; W: _____, District _____, Municipal Area _____ State _____ Postal Code _____,Telephone_____, fax _____, Post Box No._____,e-mail_____. Requests its registration with the Federal Superintendence of Agriculture as _____
_____

In accordance with Normative Instruction of the Ministry of Agriculture, Livestock and Food Supply establishing the PROCEDURES FOR THE REGISTRATION, INSPECTION AND CONTROL OF POULTRY BREEDING ESTABLISHMENTS, all documents required by the legislation in force are attached to the present document.

RESPECTFULLY SUBMITTED,

_____, _____ _____, _____.

_____

(signature of the owner or legal representative)

ATTACHMENT IIIA

POULTRY ESTABLISHMENT REGISTRATION REQUEST

To the Animal Health and Inspection Body of the State of _____.

_____,

(Legal Entity or Individual) Taxpayer's No. (CNPJ/CPF) _____,

located at _____

(Full address) _____

_____

GPS Coordinates (decimal format SAD 69) S: _____; W: _____, District _____, Municipal Area _____ State _____

Postal Code _____, Telephone_____, fax _____,

Post Box No._____,e-mail_____. requests its registration with this Animal Health and Inspection Body as _____

_____ In accordance with Normative Instruction of the Ministry of Agriculture, Livestock and Food Supply establishing the PROCEDURES FOR THE REGISTRATION, INSPECTION AND CONTROL OF POULTRY BREEDING ESTABLISHMENTS, all documents required by the legislation in force.

RESPECTFULLY SUBMITTED,

_____, _____, _____.

_____

(signature of the owner or legal representative)

ATTACHMENT IV

PHYSICAL AND HEALTH INSPECTION TECHNICAL REPORT - MINIMAL GUIDE

OWNER:
ESTABLISHMENT:
LOCATION:
TYPE OF EXPLOITATION:
REGISTRATION PROCESS NO.:
The establishment has been inspected according to the provisions of the Ministry of Agriculture, Livestock and Food Supply Normative Instruction establishing the PROCEDURES FOR THE REGISTRATION, INSPECTION AND CONTROL OF POULTRY BREEDING ESTABLISHMENTS.

Sequence	Item	Present	Regular	Absent
	Documents			
1	Legal Existence Documents			
2	Technical Person in Charge (contract + Veterinarian Medicine Council card)			
3	Situation Plant or Aerial Survey			
	Floor plan			
4	Environmental Body Protocol or Surety			
5	Specifications List			
	Structure:			
6	Regulated Distances			
7	Materials Used (cleaning and disinfection)			
	Internal premises required			
8	Screen (except SPF, Pure Line and Great-grandparent)			
9	Isolation fence with single access			
10	Movement Control Registration (vehicles and persons)			
11	Disinfection of Vehicles			
12	Pest Control			
13	Microbiological Analysis of Water			
14	Management Registration			

Is apt / inapt to obtain registration with this Federal Superintendence of Agriculture, Livestock and Food Supply of the State of_____.
Notes_____
_____

_____ Signature and stamp FFA – SEDESA Signature and stamp FFA – SEFAG	_____ Signature and stamp Head of SEDESA of the Federal Superintendence of Agriculture-XX Signature and stamp Head of SEFAG of the Federal Superintendence of Agriculture-XX

THIS INSPECTION TECHNICAL REPORT IS VALID FOR ONE YEAR, CONDITIONED TO THE MAINTENANCE OF THE SANITARY STATUS OF THE NUCLEI OR POULTRY ESTABLISHMENT.

ATTACHMENT IV-A

PHYSICAL AND HEALTH INSPECTION TECHNICAL REPORT - MINIMAL GUIDE

OWNER:
ESTABLISHMENT:
LOCATION:
TYPE OF EXPLOITATION:
REGISTRATION PROCESS No.:
The establishment has been inspected according to the provisions of the Ministry of Agriculture, Livestock and Food Supply Normative Instruction establishing the PROCEDURES FOR THE REGISTRATION, INSPECTION AND CONTROL OF POULTRY BREEDING ESTABLISHMENTS.

Sequence	Item	Present	Regular	Absent
	Documents			
1	Legal Existence Documents			
2	Technical Person in Charge (contract + Veterinarian Medicine Council card)			
3	Sketch or Aerial Survey			
4	Environmental Body Protocol or Surety			
5	Specifications List			
	Structure			
6	Regulated Distances			
7	Materials Used (cleaning and disinfection)			
8	Screen			
9	Good Production Practices			
10	Isolation fence with single access			
11	Movement Control Registration (vehicles and persons)			
12	Disinfection of Vehicles			
13	Pest Control			
14	Microbiological Analysis of Water			
15	Management Registration			

Is apt / inapt to obtain registration with this **Federal Superintendence of Agriculture, Livestock and Supply of the State of**_____.
Notes_____
_____ .

_____ Signature and stamp Official responsible for the inspection	_____ Signature and stamp VETERINARY DOCTOR Head of the State Animal Health Service

THIS INSPECTION TECHNICAL REPORT IS VALID FOR ONE YEAR, CONDITIONED TO THE MAINTENANCE OF THE SANITARY STATUS OF THE NUCLEI OR POULTRY ESTABLISHMENT.

ATTACHMENT V

POULTRY ESTABLISHMENT REGISTRATION CERTIFICATE

Classification _____

Proceeding No. _____Registration No. _____

_____ We hereby certify that, in accordance with the Normative Instruction of Ministry of Agriculture, Livestock and Food Supply, establishing the PROCEDURES FOR THE REGISTRATION, INSPECTION AND CONTROL OF COMMERCIAL AND POULTRY BREEDING ESTABLISHMENTS, the poultry establishment:_____

Owner / Company_____ Taxpayer No. (CPF / CGC) _____ Located at _____

GPS Coordinates - S: _____; W: _____, Municipal Area _____ State _____ Is registered for the production of _____

Valid until _____ / _____ / _____.

_____, _____ _____ , _____.

_____

Person Responsible for Issuing the Registration

BODY ISSUING THE REGISTRATION

NORMATIVE INSTRUCTION No. 17 OF APRIL 7, 2006.

Published in the Official Gazette of April 10, 2006 Section 1, Page 06

Approves within the scope of the National Avian Health Program, the National Plan for the Prevention of Avian Influenza and Control and Prevention of Newcastle Disease

THE SECRETARY OF ANIMAL AND PLANT HEALTH AND INSPECTION OF THE MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY, in accordance with the duties and responsibilities assigned thereto by Articles 9 and 42, Annex I, Decree No. 5,351 of January 21, 2005, and in compliance with the provisions of Ministerial Administrative Ruling No. 193 of September 19, 1994, as well as the contents of the Judicial Proceeding No. 21000.001074/2006-37, hereby resolves:

Art. 1. To approve, within the scope of the National Avian Health Program, the National Plan for the Prevention of Avian Influenza and Control and Prevention of Newcastle Disease all over the national territory, as provided for in the Annex to this Normative Instruction.

Art. 2. This Normative Instruction shall enter into force on the date of publication thereof.

GABRIEL ALVES MACIEL

ANNEX

NATIONAL PLAN FOR THE PREVENTION OF AVIAN INFLUENZA AND CONTROL AND PREVENTION OF NEWCASTLE DISEASE

Art. 1. The National Plan for the Prevention of Avian Influenza and Control and Prevention of Newcastle Disease is a strategy feasible of being adopted in all Units of the Federation (UF) to promote actions focused on animal sanitary health and inspection, with a view to strengthening the veterinary care system and implementing the National Avian Health Program (PNSA) all over the national territory.

Art. 2. Acceptance of the rules provided for in the plan by the UFs is voluntary. The criteria described herein will serve to review the local veterinary care systems and consequently to rank the UFs by sanitary status in relation to Avian Influenza and Newcastle Disease.

Art. 3. For the purpose of implementing the National Plan for the Prevention of Avian Influenza and Control and Prevention of Newcastle Disease and making it operational and based on geopolitical criteria, Brazil will be divided into regions.

Paragraph 1. The Animal Health Department (DSA) will carry out periodic audits according to the criteria set forth in complementary rules, in those UFs that have joined the plan, so as to confirm the implementation of the rules provided for in the National Plan for the Prevention of Avian Influenza and Control and Prevention of Newcastle Disease and the suitability of animal sanitary health and inspection services.

Paragraph 2. The UFs may join the plan separately by forming regional blocs of UFs or by demarcating internal areas in their territories, as long as they are capable of providing equivalent guaranties that the animal sanitary health and inspection system will be operational in the proposed area.

Art. 4. The DSA will continually review and regulate the PNSA manuals as regards both routine and sanitary emergency activities related to Avian Influenza and Newcastle Disease and adjustment of the rules to different poultry sectors such as breeding, slaughter, commercial egg-laying, ratite, ornamental and non-commercial aviculture.

Art. 5. The following sectors will take part in the National Plan for the Prevention of Avian Influenza and Control and Prevention of Newcastle Disease:

I – Animal and Plant Health and Inspection Secretariat:

a) Animal Health Department - DSA;

b) Department of Inspection of Animal Origin Products - DIPOA;

c) Department of Surveillance of Livestock Inputs - DFIP;

c) General Coordination of Laboratory Support - CGAL;

d) Coordination of the International Agriculture and Livestock Surveillance System - VIGIAGRO;

II – Federal Agriculture Superintendencies - SFA;

III – State Agriculture Secretariats and Animal Sanitary Health and Inspection Agencies thereof; and

IV – The private sector.

Paragraph 1. the DSA shall:

I –Coordinate actions aimed at determining the epidemiological situation in the region with regard to Avian Influenza and Newcastle Disease in Brazil, by performing annual epidemiological inquiries;

II – Maintain updated the legal framework of actions to combat Avian Influenza and Newcastle Disease as well as the PNSA action manuals relating to operational procedures and field and sanitary emergency activities;

III – Define the parameters of sanitary status and efficiency levels equivalence in the execution of activities pertaining to animal sanitary health and inspection services, related to the National Plan for the Prevention of Avian Influenza and Control and Prevention of Newcastle Disease;

IV – Provide sample educational material with a view to promoting uniform actions as provided for in the PNSA, in the national territory and at all levels of execution;

V – Publish specific interstate movement rules for the different types of aviculture activities, aimed

at meeting the requirements for implementing the National Plan for the Prevention of Avian Influenza and Control and Prevention of Newcastle Disease;

VI – Permanently update the sanitary requirements regarding the importing and exporting of live birds, genetic material, poultry products and byproducts, with a view to complying with the rules provided for in the National Plan for the Prevention of Avian Influenza and Control and Prevention of Newcastle Disease;

VII – Introduce changes into biosafety and hygienic-sanitary measures for the prevention of Avian Influenza and Newcastle Disease in domestic bird breeding establishments;

VIII – Maintain updated the national register of veterinarians accredited for issuing the Animal Movement Permit (GTA) for birds;

IX – Establish sanitary rules for participation in agriculture and livestock events.

Paragraph 2. the DIPOA shall:

I – Immediately notify the DSA of the incidence of mortality rates above 10% in batches of slaughter birds occurred within less than seventy two (72) hours and recorded in the sanitary report as provided for in Administrative Ruling SDA No. 210 of November 10, 1998, Annex IV;

II - Immediately notify the DSA of the identification of signs typical of Avian Influenza or Newcastle Disease, during the ante-mortem inspection of the batch;

III – Participate in the active surveillance for Avian Influenza and Newcastle Disease by collecting biological samples in slaughterhouses during inspection of the birds.

Paragraph 3. the DFIP shall:

I – Keep control of vaccines by UF, with respect to the amount produced or imported by a laboratory and the amount used;

II – Evaluate the vaccines and drugs available and record them at the DAS's request.

Paragraph 4. The CGAL shall:

I – Ensure the supply of laboratory diagnosis as requested by the DSA, so as to contribute to the annual epidemiological monitoring of bird flocks as well as of the active and passive surveillance processes for Avian Influenza and Newcastle Disease;

II – Develop, in the laboratory network of LANAGRO, quick and affirmative diagnoses for Avian Influenza and Newcastle Disease, by modernizing the equipment used and training the technical staff responsible for performing the tests, with a view to carrying out annual serological monitoring as requested by the DSA.

Paragraph 5. VIGIAGRO shall:

I – Coordinate the inspection, in all Agriculture and Livestock Surveillance Units at the points of entry into the country, of imports of: live birds and edible and inedible products and byproducts thereof; eggs and edible and inedible products and byproducts thereof; hatching eggs and bird semen, or any other material for the animal breeding of birds; biological poultry products;

II – Ensure that the above mentioned products, when originating in or in transit through countries considered as risk zones by the DAS, will be subject to previous importing and interception authorization and prohibition of entry or destruction;

III – Ensure the inspection of solid waste from air, sea and land transportation vehicles, by requiring that such waste be treated in primary areas through methods of proven scientific efficacy and prohibiting the entry into the national territory of materials that are potential carriers of diseases;

IV – Ensure inspection of hand luggage and/or checked-in luggage in international passenger landing terminals at international airports, frontier posts, sea and river ports, by confiscating and destroying agricultural and livestock products that are not accompanied with the appropriate import authorization or certification;

V – Promote the enhancement of sanitary education campaigns aimed at international in-transit passengers.

Paragraph 6 . The SFA shall:

I – Ensure, at state level, adoption of the routine and emergency measures provided for in the legislation in force and in the Contingency Manual in case of suspicion of Avian Influenza or Newcastle Disease;

II – Accredit veterinarians to issue GTA for the interstate movement of birds;

III – Keep an updated register of veterinarians accredited to issue GTA;

IV – Carry out educational actions pursuant to

the rules and other sources designated by the DSA;

V – Participate in the State Poultry Health Committee and in the actions of the Groups on Sanitary Emergency in State Poultry Health;

VI – Update the georeferenced register, in electronic format, of all poultry breeding establishments and producers of specific pathogen-free (SPF) or controlled eggs.

Paragraph 7. State Animal Sanitary Health and Inspection Agencies in the UFs joining the plan shall:

I – Ensure operation of the veterinary care and sanitary surveillance in poultry health system, so as to enable implementation of the PNSA;

II – Adjust specific state legislation to poultry health by making sure that it is in tune with the federal legislation and taking into account sanitary emergency actions;

III – Carry out educational actions pursuant to the rules and other sources designated by the DSA;

IV – Develop and promote permanent training for Sanitary Emergency Groups, pursuant to the DSA regulation;

V – Participate in the State Poultry Health Committee as well as in the actions of the Sate Groups on Sanitary Emergency in Poultry Health;

VI – Update the georeferenced register, in electronic format, of all commercial poultry establishments and migratory winter sites for migratory birds. The following should also be located and identified by georeferencing: zoos, slaughterhouses and carcass processing plants and commercial establishments selling live birds.

Paragraph 8. The private sector shall:

I – Immediately notify the Official Service of any suspect case of Avian Influenza or Newcastle Disease and take the actions required for the full investigation of the situation;

II – Foster the development of private state funds recognized by the Ministry of Agriculture, Livestock and Food Supply (MAPA), for the purpose of carrying out emergency actions in case of Avian Influenza or Newcastle Disease foci in commercial or non-commercial flocks, including the possibility of awarding compensation;

III – Promote continued education programs for veterinarians, technical staff and producers of poultry, as provided for in the PNSA manuals;

IV – Participate in the State Poultry Health Committee and in the actions of the State Groups on Sanitary Emergency in Poultry Health;

V – Take the minimum biosecurity actions defined by the PNSA in commercial poultry establishments.

Art. 6 . The states that join the National Plan for the Prevention of Avian Influenza and Control and Prevention of Newcastle Disease should establish, by legal act, the State Poultry Health Committee, comprised of representatives of the SFA, the State Animal Sanitary Health and Inspection Committee, private entities representing the poultry sector, and the scientific community, with a view to proposing actions to the DSA, based on each state's reality.

Art. 7. The DSA shall organize, on an annual basis as a minimum, an active surveillance study on Avian Influenza and Newcastle Disease.

Paragraph 1. The study shall cover the UFs with a continuously updated georeferenced register in electronic format in the DSA's Poultry Health Coordination Unit (CSA).

Paragraph 2. The sampled population will include: commercial slaughter fowls; commercial laying fowls; non-commercial domestic fowls; and migratory birds.

Art. 8. The DSA shall certify establishments that are free of Avian Influenza and Newcastle Disease.

Sole Paragraph. The certification referred to in the heading of this Article shall cover poultry breeding establishments and producers of SPF or controlled eggs.

Art. 9. The CGAL shall be responsible for accrediting public laboratories for the serological diagnosis of Avian Influenza and Newcastle Disease in each of the UFs that has the conditions required for executing the plan, providing passive surveillance and establishment certification programs.

Art. 10. The SFAs shall provide the DSA with the list of veterinarians accredited to issue GTAs and the list of establishments certified in the PNSA sanitary programs.

Paragraph 1. The CSA shall publish the list of veterinarians accredited to issue GTAs and the list of establishments certified in the PNSA sanitary programs, to be posted on the MAPA website and updated on a monthly basis.

Paragraph 2. The SFAs shall submit to the CSA, up to the 5th working day of each month, the changes introduced into the lists referred to in paragraph 1 of this Article.

Art. 11. Interstate transit for different types of exploitation of live birds, genetic material, edible and inedible products and byproducts shall comply with the following rules:

Paragraph 1. The interstate transit of fowl and hatching eggs described in items I, II, III, IV, V, VI, VII, VIII and IX of this paragraph shall be authorized, provided that the specimens originate in establishments certified as free of Mycoplasma and Salmonella, according to Normative Instruction SDA No. 44, of August 23, 2001, and Normative Instruction SDA No. 78, of November 3, 2003, and in the case ratite, Joint Normative Instruction SDA/SARC No. 02, of February 21, 2003.

I – genetic selection farms of primary breeding flocks (pure lines), importers, exporters, producers of hatching eggs and day-old birds for the production of "great-grandmother" hens;

II – farms that import and export great-grandmother hens, produce hatching eggs and day-old birds for the production of breeding grandmother hens;

III – farms that import and export grandmother hens, produce hatching eggs and day-old birds for the production of parent breeders;

IV – farms that import and export parent breeders, produce hatching eggs and day-old birds for the production of commercial fowl, parent breeders up to 24-week old and other purposes;

V – establishments that produce commercial laying hens (90-day old);

VI - establishments that exploit other bird species, whether ornamental or not, intended for the commercial production of meat, eggs or feathers, such as turkey, quail, Guinea fowl, ostrich, Brazilian ostrich, emus;

VII – commercial breeding of ostrich and Brazilian ostrich, with the production of hatching eggs and young no more than 90-day old;

VIII – clear eggs (hatchery eggs) intended for industrial use;

IX – establishments controlled or free of specific pathogens.

Paragraph 2 . The GTA or the Sanitary Inspection Certificate (CIS) shall be issued by the official veterinarian or the veterinarian accredited by MAPA, technically responsible for the establishment of origin of the birds and hatching eggs, as regards the items described in § 1 of this Article.

Paragraph 3. Starting on the date to be defined by the DSA, the interstate transit of birds and hatching eggs as referred to in items I, II, III, IV, V, VI, VII, VIII and IX, § 1 of this Article, will only be permitted if the establishment of origin of the material is certified as free of Avian Influenza and Newcastle Disease.

Paragraph 4. Starting on the date to be defined by the DSA, the CIS for the interstate transit of clear eggs as referred to in item VIII, § 1 of this Article, will only be permitted if the establishment of origin of the material is certified as free of Avian Influenza and Newcastle Disease.

Paragraph 5. The interstate transit of slaughter fowl shall be accompanied with the GTA issued by an official veterinarian or a veterinarian accredited by MAPA, technically responsible for the establishment of origin of the birds.

Paragraph 6. The interstate transit of spent fowl from breeding farms and of spent fowl from farms producing eggs for consumption shall be accompanied with the GTA issued by an official veterinarian. These birds shall be sent to slaughter plants under federal inspection. Issuing of the GTA shall be linked to the proof of receipt, by the SIF, of previously sent spent fowl batches.

Paragraph 7 . Those UFs that join the National Plan for the Prevention of Avian Influenza and Control and Prevention of Newcastle Disease and demonstrate operational capacity to fulfill all of the PNSA rules may, as a preventive measure against the possible entry and dissemination of Avian Influenza and Newcastle Disease agents in their flocks, prohibit the interstate transit of slaughter fowl, spent fowl from breeding farms and spent fowl from consumption egg farms intended for slaughter, and shall comply with the following:

I – for the interdiction of the interstate transit of slaughter fowl, spent fowl from breeding farms, and spent fowl from consumption egg farms intended for slaughter, the UF shall submit beforehand to the approval of the DSA, the operational and inspection plan relating to this activity;

II – transit restriction shall only be valid to those UFs with a differentiated sanitary status or differentiated levels of efficiency in the execution of activities related to animal sanitary health and inspection services, as provided for in Art. 5, § 1, item III of this Normative Instruction.

Paragraph 8 . The interstate transit of manure and aviary bed, as well as of waste from hatcheries and slaughterhouses, regardless of the purpose, is hereby prohibited. This restriction excludes materials that have been submitted to treatment approved by the SDA, capable of ensuring the elimination of disease-causing agents.

I – The interstate transit of these materials shall be accompanied with a CIS specifying the treatment to which the material has been submitted, issued by the Veterinarian Accredited by the SFA.

Paragraph 9. Where official surveillance programs identify the presence of the high pathogenicity form of the Avian Influenza virus or of Newcastle Disease, the following interstate transit control measures shall be immediately adopted and remain in force until completion of the outbreak sanitation activities provided for in the Contingency Manual for Avian Influenza and Newcastle Disease:

I – day-old birds and eggs originating in the establishments described in items I, II, III, IV and IX, § 1 of this Article shall be accompanied with a GTA issued by an official or accredited veterinarian, following the performance of serological tests representative of the batch, that prove negative for Avian Influenza and whose parameters shall be defined by the DSA. The results of the serological tests shall be valid for thirty (30) days;

II – fowl and eggs originating in the establishments described in items V, VI, VII and VIII shall be accompanied with a GTA issued by an official or accredited veterinarian, following the performance of serological tests representative of the batch, that prove negative for Avian Influenza and whose parameters shall be defined by the DSA. The results of the serological tests shall be valid for seven (7) days.

III – clear eggs originating in the hatcheries described in item VIII shall be accompanied with a CIS issued by an official or accredited veterinarian, following the performance of serological tests representative of the batch, that prove negative for Avian Influenza and whose parameters shall be defined by the DSA. The results of the serological tests shall be valid for seven (7) days.

A**rt. 12**. The participation of birds, including ratite, in agriculture and livestock events such as fairs, exhibits, auctions and other animal concentrations shall be authorized only when the birds originate in establishments certified as free of Mycoplasma and Salmonella, as provided for in SDA No. 44, of August 23, 2001, and Normative Instruction SDA No. 78, of November 3, 2003, and in the case ratite, Joint Normative Instruction SDA/SARC No. 02, of February 21, 2003.

Paragraph 1. The participation of passerine ornamental birds, whether alien to the domestic fauna or not, in agriculture and livestock events, shall only be permitted when the birds are accompanied with a GTA issued by an official veterinarian and by a sanitary inspection certificate issued by a veterinarian, without prejudice to other legal requirements.

Paragraph 2. Starting on a date to be defined by the DSA, the participation of birds, including ratite, in agriculture and livestock events shall only be authorized for those birds originating in breeding establishments certified as free of Avian Influenza and Newcastle Disease.

Paragraph 3. Until the date to be defined by the DSA, the participation in agriculture and livestock events of birds originating in establishments not certified as free of Avian Influenza and Newcastle Disease, shall only be permitted upon submission of individual tests performed in an official laboratory, that prove negative for Newcastle Disease and valid for thirty (30) days.

Art. 13. State Animal Sanitary Health and Inspection Agencies shall submit to the SFA by the 10th day of the following month, the avian transit report for information, evaluation, consolidation and further submission to the CSA/DSA.

Art. 14. Twelve (12) months after the date of publication of this Normative Instruction, the sale of live domestic birds by commercial establishments shall only be permitted when the conditions set forth in the paragraphs below have been met.

Paragraph 1. The commercial establishments should be registered with the state animal

sanitary health and inspection agency.

Paragraph 2. The birds sold shall originate in establishments certified by the PNSA and be accompanied with a GTA issued by the official or accredited veterinarian technically responsible for the establishment of origin.

Paragraph 3. With respect to control of the official service, a record containing information on the origin and destination of the birds as well as the sanitary measures carried out during lodging and mortality shall be kept at the establishment and made available for inspection whenever so requested. Furthermore, the establishment shall keep a descriptive memorial of the biosafety actions taken during lodging of the animals, including disposal of remains and carcasses.

Art. 15. The Coordination Unit of Veterinary Products of the Department of Surveillance of Livestock Inputs (CPV/DFIP) shall control and supervise the distribution of vaccines against Avian Influenza and Newcastle Disease, as regards the amount of vaccines produced and imported and the amount distributed by UF.

Sole paragraph. The map showing the distribution of registered vaccines shall be delivered by producing and importing companies, on a quarterly basis, to the CPV/DFIP, which will be responsible for forwarding it to the DSA.

Art. 16. The sanitary report referred to in Administrative Ruling DAS No. 210 of April 10, 1998, Annex IV, shall be delivered to the Federal Inspection Service (SIF) 24 hours before the birds are scheduled to be slaughtered, and contain the following information:

- data on the establishment of origin of the birds;

- initial and final number of birds lodged per house;

- diseases detected in the batch during lodging;

- type of treatment to which the batch has been submitted, with specification of the therapeutic agent used and length of treatment, including the use of vaccine against Newcastle Disease;

- date and time when food was suspended; and

- signature of the veterinarian responsible for the establishment.

Paragraph 1. When the analysis of the Sanitary Report indicates a mortality rate equal to or higher than 10% during lodging of the birds in the establishment of origin, the SIF Federal Agriculture and Livestock Inspector (a veterinarian) shall collect serum, cloacal and tracheal swab in up to 1% of the birds in the batch for further forwarding to the Official Laboratory, and notify the SIPAG which, in turn, shall inform the SEDESA.

Paragraph 2. When the analysis of the Sanitary Report indicates a mortality rate above 10% within a period of less than seventy two (72) hours from lodging of the birds in the establishment of origin to issuing of the sanitary report, or where such mortality rate is equal to or higher than 1% during transportation of the birds from the farm to the slaughterhouse, or the report shows suggestive clinical signs of Avian Influenza or Newcastle Disease in the bird batch, the Animal and Plant Health and Inspection Service (SIPAG) and the Agriculture and Livestock Health and Inspection Service (SEDESA) shall be immediately notified.

NORMATIVE INSTRUCTION No.78 OF NOVEMBER 3, 2003

Published in the Official Gazette of April 10, 2006 Section 1, Page 06

Approves the Technical Rules for the Control and Certification of Poultry holdings and Nucleis, such as, free of *Salmonella gallinarum* and of *Salmonella pullorum*, and free or controlled for *Salmonella enteritidis* and *Salmonella typhimurium*

THE SECRETARY OF ANIMAL AND PLANT HEALTH AND INSPECTION, OF THE MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY, by the powers invested in him in article 15, clause

II, of Decree No.4.629, of March 21, 2003, in view of what is disposed by Ministerial Act No.193, of September 19, 1994, which creates the National Avian Health Program (PNSA), and what is stated from Process No.21000.009818/2003-19, decides:

Art. 1. To approve the Technical Rules for the Control and Certification of Aviary Establishments and Nucleis, such as, free of *Salmonella gallinarum* and of *Salmonella pullorum*, and free or controlled for *Salmonella enteritidis* and *Salmonella typhimurium*, attached.

Art. 2. This Normative Instruction will be in effect on the date of its publication.

Art. 3. Is hereby repealed Normative Instruction No.03, of January 9, 2002.

MAÇAO TADANO

ANNEX

TECHNICAL RULES FOR THE CONTROL AND CERTIFICATION OF POULTRY HOLDINGS AND NUCLEIS, SUCH AS FREE OF *SALMONELLA GALLINARUM* AND OF *SALMONELLA PULLORUM*, AND FREE OR CONTROLLED FOR *SALMONELLA ENTERITIDIS* AND *SALMONELLA TYPHIMURIUM*.

CHAPTER I

INTRODUCTION

1. These rules define the measures of monitoring salmonellosis in aviary businesses permanently and eventually controlled (except commercial position, poultry for slaughter and ratites), that perform the commerce or transference, domestic and international, of their products, intended for breeding and for the production of poultry and hatching eggs, having to perform monitoring of their flocks, obeying the directions of the National Avian Health Program (PNSA).

2. To proceed to the domestic and international market, and with transference, in the national ambit, of derived products, the aviary center or business must be certified as free of *Salmonella gallinarum* and *Salmonella pullorum*, and free or controlled for *Salmonella enteritidis* and *Salmonella typhimurium*.

3. The establishments of pure breeding businesses, great grandparents and grandparents, must be free of all four salmonellas.

4. The establishments of parent breeders must be free of *Salmonella gallinarum* and *Salmonella pullorum*, and free, and/or controlled for *Salmonella enteritidis* and *Salmonella typhimurium*.

5. The importing businesses or purchasers of genetic material of pure breeds, great grandparents and grandparents, must present the guarantee or certification as to free of the constant salmonellas in these rules.

CHAPTER II

DEFINITIONS

1. For the purpose of these rules, it is understood:

1.1. Batch: group of poultry for the same purpose, origin and age, lodged in one or many barns.

1.2. Boxes: are physical divisions inside a barn.

1.3. Barn: is the aviary production unit, characterized as the unit of a center, which lodges a group of breeders, poultry for slaughter or commercial laying hens, of the same age (with exeption of pure breeds, genetically selected), and of the same breed.

1.4. Commercial poultry: generation of poultry meant for slaughter and/or egg production for consumption.

1.5. Center of breeding: is the unit with an area adequately isolated, of comun handling, constituted of one or more barns.

1.6. Poultry holding: is the location where

poultry is kept for any purpose, which may be constituted of one or more centers.

1.6.1. Poultry holding permanently controlled: they are the farms, genetically selected, of primary breeders (pure breeds), great grandparent farms, grandparent farms, parent breeder farms, farms of breeding stock free of specific pathogens (SPF), and the hatcheries of these premises.

1.6.2. Poultry holding controlled eventually: they are the poultry holding producing commercial eggs, poultry for slaughter, exploring other wild birds, or ornamental, and/or exotic, and the hatcheries of these premises.

1.7. Official service: is the Federal, State, and Municipal Animal Health and Inspection Service.

1.8. Official laboratories: are the laboratories of the Ministry of Agriculture, Livestock and Food Supply (MAPA).

1.9. Accredited laboratories: are the laboratories of other federal, state, municipal, or private institutions, that have been approved and recognized by the MAPA, to perform laboratory diagnosis of disease agents referred by these rules.

1.10. Federal Inspector or Official Veterinarian: is the veterinarian of the Federal Animal Health and Inspection Service.

1.11. Official Veterinarian: is the federal inspector or the veterinarian of the official service.

1.12. Official Veterinarian for certification: is the federal inspector or official veterinarian of the Animal Health and Inspection Service.

1.13. Official Accredited Veterinarian: is the official, state, municipal, private, or an independent professional veterinarian, whom received delegation of competence of the federal official service to issue the Animal Movement Permit (GTA).

1.14. Responsible Technician: is the veterinarian responsible for the hygienic-health control at the flocks of Poultry holdings.

1.15. Monitoring of flocks: is the laboratory health and analysis follow up, by means of serological tests and other by other means, on other biological material or not, and epidemiological analysis of the health conditions of poultry lodged in an poultry holding.

1.16. MAPA: Ministry of Agriculture, Livestock and Food Supply.

1.17. SDA: Animal and Plant Health and Inspection Secretariat.

1.18. DDA: Animal Health and Inspection Department.

1.19. CLA: Animal Laboratory Coordinating Unit.

1.20. PNSA: National Avian Health Program, Program established at the SDA/DDA.

1.21. DIPOA: Department of Inspection of Animal Origin Products.

1.22. DFA: Federal Agricultural Delegacy.

1.23. SSA: Animal Health Service.

1.24. SIF: Federal Inspection Service.

1.25. RST: Rapid serum agglutination test.

1.26. CPV: Veterinary Product Coordination.

1.27. CPS: Surveillance and Health Program Coordination.

CHAPTER III

FROM THE REQUIREMENTS TO BE FULFILLED BY THE POULTRY HOLDING

1. To attend to the PNSA, the poultry holding of permanent and eventual controls must:

1.1. Be properly registered and qualified at the DFA of the State where they are located;

1.2. Be under surveillance and control of the Animal Health Service of the DFA, and/or of the Department executioner of State Health and Inspection where the poultry holding is located;

1.3. Be watched by a technical responsible veterinarian that is registered at the DFA of the State in which the establishment is located.

2. The poultry holding of Permanent Control will not be able to use:

2.1. Any vaccines for salmonellosis at establishment permanently controlled, except as foreseen in Chapter IV;

2.2. Any vaccine prepared with oily adjuvant during the four weeks prior to the tests;

2.3. Any drug scientifically proven to interfere in the results of serological tests, and/or interfere with the isolation of the salmonella in a period of three weeks prior to the tests;

2.4. At the parent hatchery premises, in exceptional cases evaluated by the DDA, undergoing medicated treatment for *S. enteritidis* and *S. typhimurium*, under the surveillance of the MAPA, the evaluation will be provided according to Chapter VIII in these rules.

3. Only controlled antigen and serum vaccines, approved by the MAPA, can be used, observing the expiration date.

4. Laboratory test will only be able to be used when properly approved by the PNSA.

5. The poultry holding must forward to the DFA of the State of its jurisdiction, a monthly calendar contemplating the schedules of birth, importation and dates of routine samples provided by the technician in charge, to give the Official Service the opportunity to adjust the dates of official collection of samples, as well as to inspect and supervise the referred establishment.

CHAPTER IV

THE USE OF THE VACCINE FOR *SALMONELLA ENTERITIDIS*

1. At parent hatchery premises, it will only be allowed to use inactive vaccines for *S. enteritidis;*

2. The technician in charge for the parent hatchery establishment must communicate the usage of the vaccine to the MAPA, specifying the location of the property, number of poultry that received vaccination, the vaccine program and its data (commercial name, batch, starting number);

3. The manufacturer/importer of the vaccine, must every three months communicate to the MAPA, the list of users, and the number of doses of the vaccine, which item 1 of this chapter regards to;

4. Autogenous vaccines are authorized as long as it is used in the terms of the relevant legislation;

5. It is herby prohibited the usage of any vaccine for salmonellas at grandparent hatchery premises, at great grandparent hatchery establishment and at farms genetically selected from the primary breeding stock (pure breeds).

6. Every three months the DDA by means of the CPS and the CPV, will confront the information gathered by the technicians responsible for the properties described in item 2 of this chapter, with the report issued by the manufacturer/importer, referred in item 3 of this chapter.

CHAPTER V

THE CERTIFICATION OF AVIARY CENTERS AND PREMISES

1. Certification of aviary centers and premises:

1.1. Free of *Salmonella gallinarum* (Fowl Typhoid), and *Salmonella pullorum* (Pullorum disease);

1.2. Free or Controlled for *Salmonella enteritidis* and *Salmonella typhimurium*;

1.3. Free or Controlled for *S. enteritidis* and *S. typhimurium*, and have received the vaccine for *S. enteritidis*;

CHAPTER VI

LABORATORY TESTS

1. The tests used for monitoring and laboratory test in the different stages of the process are:

1.1. Rapid serum agglutination test – Pullorum disease Test (with blood or serum total);

1.2. Tube agglutination test (TAT) or Micro-agglutination test;

1.3. Bacteriologic Diagnosis.

2. The implementation and interpretation of laboratory tests mentioned in the previous item must follow the rules established in legal acts, rules and specific technical regulations of the MAPA.

3. The laboratory exams will only be accepted when performed at official laboratories, and/or accredited by the MAPA for this matter, identifying the antigen, the starting number, and the amount used.

4. The Rapid serum agglutination test with blood total is considered a field test that is performed or supervised by the federal inspector, or by a veterinarian technician, responsible for the poultry holding by the MAPA.

5. Other laboratory exams may be used as long as they are previously approved by the DDA/SDA.

CHAPTER VII

SAMPLES COLLECTION AND FORWARDING TO THE LABORATORY FOR TESTS

1. The samples are collected for official monitoring, which will only be accepted when performed by a federal inspector, or by an official veterinarian, or by a professional from the poultry holding under official supervision.

2. To receive certification, the samples forwarded to the MAPA, by the veterinarian, responsible technician, and/or of the random sampling performed by the official service, will be analyzed by the SSA/DFA of the State.

3. All material forwarded for laboratory examining must be officially sealed along with the standard DDA/SDA sampling form, filled out correctly and signed by the responsible technician at the MAPA, and/or by the federal inspector, or by the official veterinarian.

4. The official sampling must be performed randomly among the barns in the same center for, serological tests, biological tests on SPF poultry, or on embryonated eggs, or bacteriological tests.

5. With intensions of monitoring the health condition and also certification management, besides regular sampling at pure breed premises, great grandparent and granparent hatchers, the monitoring must be performed directly by the federal inspector, or official veterinarian, providing random double sampling, at least once a year, and forwarded to a accredited or an official laboratory for analysis.

6. DFA's criteria as to the Animal Health Service, and/or of the State Secretariat of Agriculture, of the sate in which the poultry holding is located, at any time and in the presence of the federal inspector, or of an official veterinarian, random double samplings may be collected to be submitted for laboratory exams, respecting the criterions and rules of biosafety, at official or MAPA accredited laboratories for this matter.

7. The official monitored material for this matter could be sent to any MAPA accredited laboratory chosen by the federal inspector, or by the official veterinarian in charge of samplings.

8. The cost for official sample collections to be tested at a MAPA accredited laboratory plus shipping, will be the company's responsibility.

9. Random samplings performed by the official service may or not meet companies' schedules, of which a federal inspector, or an official veterinarian are responsible for, and also responsible for securing the material, being of responsibility of the company to provide the necessary means and materials for this operation.

10. The same criterions used for parent breeders will be applied for ornamental and wild poultry.

CHAPTER VIII

PERFORMING LABORATORY TESTS

1. The system of laboratory exams for *S. gallinarum, S. pullorum, S.enteritidis* and *S. typhimurium* will include:

1.1. On breeding stock or hatching eggs, and commercial production for restocking imported aviary flocks:

1.1.1. The sample collection will be performed on arrival, and the laboratory tests performed according to the specific rules for poultry and hatching egg importation and exportation, intended for breeding and commercial production, and for restocking aviary flocks.

1.1.2. The poultry produced from pure breeds, and great grandparent hatcheries born in Brazil, will follow the same procedure mentioned in item 1.1.1 of this chapter, having its first sampling performed in the Hatchery at the moment of birth, and sent to the official laboratory by the Animal Health Service of the DFA in the State where it is located.

1.2. Health monitoring of aviary flocks.

1.2.1. 01 (one) to 05 (five) day old poultry:

1.2.1.1. Bacteriological diagnosis of the dead poultry, identifying its genetic properties, maximum of 50 birds, and tray swabs (1 "pool" from each barn), and of paper (or shavings), from the crates.

1.2.2. 12 week old breeding stocks:

1.2.2.1. Bacteriologic Diagnosis. Must be

performed in at least one of the following samples provided below, depending on the feasibility and possibility of collecting the material:

a "pool" of fifty cloacal swabs, using one for every two birds, with a total of one hundred birds per center;

or a "pool" of one hundred samples of fresh feces per center;

or a "pool" of two drag swabs per barn in the center.

1.2.2.2. Rapid Serum Agglutination Test (RST)

in one hundred samples per centers. When as a reagent, it must be supplemented with Tube Agglutination Test, or Micro-agglutination test.

1.2.3. Breeding stock poultry in the beginning of production:

1.2.3.1. Pure breeds, great grandparent and grandparent hatchers.

1.2.3.1.1. SAR on 100% of the poultry. When as reagents, they must be supplemented with Slow Seroagglutination in Tubes, or Microagglutination.

1.2.3.1.2. Bacteriologic Diagnosis. use the same criterion described in item 1.2.2.1. of this chapter.

1.2.3.2. Parent hatcheries that were not vaccinated.

1.2.3.2.1. RST of five hundred samples per center. When as a reagent, it must be supplemented with Tube Agglutination Test, or Microagglutination test.

1.2.3.2.2. Bacteriologic Diagnosis. use the same criterion described in item 1.2.2.1. of this chapter.

Parent breeders that were vaccinated.

1.2.3.3.1. In the first batch of chicks born from the center vaccinated, 200 samples of meconium will be taken from four "pools" of 50 birds. Besides that, 150 non-born-beaked eggs, in ten "pools" of 15 eggs, for the accomplishment of the bacteriological exams, in "pool" of yolk, "pool" of liver, spleen and pouch (bursa of Fabricius), and "pool" of caecum.

1.2.3.3.2. For centers exclusively intended to the commercialization of hatching eggs, the control must be provided by means of bacteriological exams, which must be done on the 27 week of age, as per samples described in item 1.2.2.1. Organs should also be collected (liver, spleen, ovary and cecal tonsil) of at least 60 birds distributed accordingly within the center's aviaries. It ill be collected in "pool", separating bowels from cecal tonsils, and gathering samples 10 birds per "pool".

1.2.3.4. The samples mentioned in items 1.2.3.2., and 1.2.3.3., must be taken by the Veterinarian, technician in charge for the establishment, and sent to the Accredited Laboratory along with the Official Sample Collection Term of the PNSA, the sample collection of the material, and the fulfillment of the test in item 1.2.3.1., must be accompanied by the Veterinarian, technician in charge for the establishment that must register all the results of the test on the batch's history file.

1.2.4. Periodic control every three months.

1.2.4.1. Poultry holding permanently controlled:

1.2.4.1.1. Bacteriologic Diagnosis. use the same criterion described in item 1.2.2.1. of this chapter.

1.2.4.1.2. Bacteriologic Diagnosis in 1 "pool" of twenty beaked eggs, and in fifty milliliters of meconium, (collected in the Hatchery) in reference to the center being shown.

1.2.4.1.3. RST in one hundred samples per center. hen reagent, it must be supplemented with Slow Agglutination in Tubes, or Microagglutination, except on poultry vaccinated for *S. enteritidis*.

Note:

a) the repetitions are provided every three months, until the batch is clean, allowing a variation of up to two weeks, in a way to adapt the blood collection to other handling practices.

1.2.4.2. Establishment with eventual controls for wild and/or ornamental birds (periodic control every 03 (three) months):

1.2.4.2.1. Bacteriologic Diagnosis. use the same criterion described in item 1.2.2.1. of this chapter.

1.2.4.2.2. Bacteriologic Diagnosis in 1 "pool" of up to twenty beaked eggs, and in up to fifty milliliters of meconium (collected in the Hatchery).

1.2.4.2.3. RST of up to one hundred samples, or 100% on smaller populations, except for small poultry. When as a reagent, it must be supple-

mented with Tube Agglutination Test, or Micro-agglutination test. Sampling will be calculated with statistical basis, case by case.

2. If detected the presence of serologically reagent poultry in non vaccinated batches, in the Tube Agglutination Test, or Micro-agglutination test, the following procedures should be followed:

2.1. At establishment of permanent control:

2.1.1. Isolation and Identification of the reagent poultry, sanitary slaughter, and later sending the poultry collected and stored under refrigeration, for bacteriological diagnosis, obeying the following criterions:

2.1.1.1. If less than four birds, forward individual samples;

2.1.1.2. If more than four birds, forward "pools" of five samples of up to twenty birds.

2.2. At establishment of eventual control of wild and/or ornamental poultry:

2.2.1. Small and medium poultry: collect cloacal swab and feces of all reagent poultry, in individual samples.

CHAPTER IX

INTERPRETATION OF RESULTS AND APPLICATION OF SECURITY AND HEALTH CONTROL MEASURES

1. On poultry or hatching eggs of imported breeders, and pure breed poultry, great grandparent and grandparent hatchers born in Brazil:

1.1. If the official samples test positive for *Salmonella gallinarum, Salmonella pullorum, Salmonella enteritidis* and *Salmonella typhimurium* – sacrifice and destruction/sanitary slaughter of the center, and elimination of all the eggs, incubating or not, from the infected centers.

2. Parent Breeders:

2.1. If official sample tests positive for *Salmonella gallinarum, Salmonella pullorum*, there will be sacrifice and destruction/sanitary slaughter at the center, and elimination of all eggs, incubating or not, originated from there.

2.2. If official samples test positive for *Salmonella enteritidis* and *Salmonella typhimurium*, the virus-free certification will be cancelled, and the aviary center or establishment will be considered controlled, as long as it meets the following criterions:

2.2.1. Suspension of egg incubation until results test negative, and adoption of the following rules for the poultry of the outbreak:

2.2.1.1. Medicate the center with specific antibiotic therapy for enterobacterium;

2.2.1.2. Laboratory Diagnostic procedures, according to Chapters VI and VIII, being that the first test must be performed five days after ending the antibiotic therapy. In case of testing positive, the antibiotic therapy is repeated along with the initial test plan, until results test negative. After receiving the first negative result, it is allowed to resume incubation. Diagnostic procedures performed every three months until sending the poultry to be slaughtered;

2.2.1.3. Since they are pathogenic to man, its products cannot be commercialized for human consumption, must be saved if authorized by the DDA and DIPOA, and if industrialized at establishment with the SIF.

2.2.1.4. The negative result on two consecutive tests, will allow the center's certification or of the Poultry holdings, as being controlled for *Salmonella enteritidis* and *Salmonella typhimurium*, free to commercialize one day-old birds, or hatching eggs exclusively in nation territory.

2.2.1.5. The establishment considered as controlled must reinforce biosafety measures.

3. Wild and ornamental poultry for commercial production: will adopt the same criterions used for parent breeders.

4. If there are many death occurrences even after all demands were obeyed, the poultry holding must inform the official service, that will determine the sending of the material of about thirty dead, or agonizing poultry, to an official or MAPA accredited laboratory with the objective of isolating *S. pullorum, S. gallinarum, S. enteritidis, S. typhimurium*. After diagnosis is confirmed, the poultry from the center will be sanitary slaughtered, and an epidemiological investigation will be performed in search of the source.

CHAPTER X

FORWARDING THE RESULTS

1. The laboratory test results must be issued on a standard MAPA form, and communications according to the flowchart established:

1.1. Negative result: send FAX or use other means for the immediate communication to the Requesting Official Veterinarian, and to the Poultry holdings.

1.2. Positive result: send FAX or other type of immediate documentation to the DDA and to the Animal Health Service/SSA/DFA, where the establishment is located.

CHAPTER XI

CERTIFICATION OF THE PREMISES

1. When the results of these laboratory exams referred in Chapters VIII and IX of these rules, test negative for the center or Poultry holdings, the Official Service will proceed with the aviary center or premises' certification as free of *Salmonella gallinarum* and *Salmonella pullorum* and free or controlled for *Salmonella enteritidis* and *Salmonella typhimurium*.

2. The poultry holding being certified as a free or controlled center will only be authorized to commercialize poultry or hatching eggs.

3. The poultry holding that receive the infection free or controlled certificate, will be be able to proceed with the commercialization of poultry and/or hatching eggs of all the centers.

4. The DFA will issue a Health Certificate according to MAPA's standard model, for the centers or establishment free or controlled for the agents treated in this rule, after performing at least three tests.

5. The certificate will be valid for one year and obligated to the health maintenance situation of the aviary center or of the premises.

6. If the flock's health situation is altered, the certificate will be revoked, with the option of reinstating the certificate after the evaluation of the SSA/DFA, and/or of the State Secretariat of Agriculture of the state in which the poultry holding is located.

CHAPTER XII

GENERAL DISPOSITIONS

1. The serological laboratory exams are always selected, with the possibility of occuring nonspecific crossed reactions. Therefore, only the identification of the agent is considered exclusive for the confirmation of the four salmonella serotypes referred in this rule.

2. It is mandatory to send all isolated salmonellas to the official laboratory, and of reference to aviary salmonella, to be investigated under the epidemiological/microbiological aspects.

3. The commercialization of hatching eggs from outbreaks with *S. enteritidis and S. typhimurium*, cannot be used for human consumption, saved if authorized by the DDA and the DIPOA, according to the specific rules of the SIF.

4. The incubation of eggs from parent breeders controlled for *Salmonella enteritidis* and *S. typhimurium* must be done on separate machines from the icubators used for the eggs of infection free centers.

5. When slaughtering occurs at centers that tested positive for the reagents mentioned in this rule, they should be performed at the slaughterhouses with the SIF, according to the DIPOA rules, or under the orientation of the SIF/DIPOA.

6. The Animal Health Service of the DFA of the State in which the poultry holding is located, and the State Departments of Agriculture, are the responsible and competent offices for defining appropriate measures for handling issues of nature, health, observing as established in the Animal Health Regulation and in the PNSA, of the Department of Livestock Protection.

7. The omissive cases and the questions created in the application of this rule, and in complementary acts will be voided by the DDA.

NORMATIVE INSTRUCTION No. 11 OF SEPTEMBER 1, 2003.

Published in the Official Gazette of September 5, 2003 Section 1, Page 03

Declares the industrial avian flocks of the states of Santa Catarina, Rio Grande do Sul, Paraná, São Paulo, Minas Gerais, Goiás, Mato Grosso do Sul, Mato Grosso, and the Federal District free from Newcastle disease

THE STATE MINISTER OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY, using the powers invested in him under art. 87, sole paragraph, item II of the Constitution, in consideration of what is provided for by the Regulation of Animal Sanitary Health and Inspection, approved by Decree No. 24.548 of July 3, 1934,

Considering the sanitary status of the industrial avian flock of the states of Santa Catarina, Rio Grande do Sul, Paraná, São Paulo, Minas Gerais, Goiás, Mato Grosso do Sul, Mato Grosso, and the Federal District, where there has been no occurrence of Newcastle disease for over five (5) years;

Considering the results obtained in seroepidemiological survey for assessment of the viral activity for Newcastle disease in industrial avian flocks in susceptible animals, finished in July 2003, and what is reported in Process No. 21000.008236/2003-15, resolves:

Art. 1. To declare the industrial avian flocks of the states of Santa Catarina, Rio Grande do Sul, Paraná, São Paulo, Minas Gerais, Goiás, Mato Grosso do Sul, Mato Grosso, and the Federal District, free from Newcastle disease.

Art. 2. To delegate authority to the Director of the Animal Health Department to issue complementary norms needed for the execution of this Normative Instruction.

Art. 3. This Normative Instruction comes into force on the date of publication thereof.

ROBERTO RODRIGUES

JOINT NORMATIVE INSTRUCTION No. 2 OF FEBRUARY 21, 2003

Published in the Official Gazette of February 25, 2003

Provides for the approval of technical regulations for registration, inspection, and sanitary control of ratite incubation, breeding, and housing establishments.

THE SECRETARIES OF ANIMAL AND PLANT HEALTH AND INSPECTION AND OF RURAL SUPPORT AND COOPERATIVISM OF THE MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY, by virtue of the powers vested in them under Art. 83, IV of SDA's Internal Regulations approved under Ministerial Administrative Ruling No.574 of December 8, 1998 and Art. 11, III, d; Art. 17, II, a of Decree No. 3527 of June 28, 2000; having in view the provisions of Decree 24548 of July 3, 1934; Ministerial Administrative Ruling No. 193 of September 19, 1994; and Ministerial Normative Instruction no 4 of December 30, 1998, as well as Proceeding no. 21000.002092/2002-11,

RESOLVES:

Art. 1. To approve the technical regulations for registration, inspection, and sanitary control of ratite incubation, breeding, and housing establishments, complementary to Ministerial Normative Instruction No. 4 of December 30, 1998.

Art. 2. This Joint Normative Instruction shall be implemented by the Animal and Plant Health

and Inspection and the Rural Support and Cooperativism Secretaries.

Art. 3. This Joint Normative Instruction shall enter into force on the day of its publication.

MAÇAO TADANO
Animal and Plant Health and Inspection Secretary

MANOEL VALDEMIRO FRANCALINO DA ROCHA
Rural Support and Cooperativism Secretary

ANNEX

TECHNICAL REGULATIONS FOR REGISTRATION, INSPECTION, AND SANITARY CONTROL OF RATITE INCUBATION, BREEDING, AND HOUSING

CHAPTER 1

RANGE OF APPLICATION

These Technical Regulations apply, as appropriate, to the registration, inspection, and sanitary control of establishments dedicated to ratite breeding, raising, rearing, fattening, housing, and incubation, destined for breeding and commercial production of products and subproducts of ratites (ostriches and rheas), classified according to their purpose.

CHAPTER II

CLASSIFICATION OF ESTABLISHMENTS

1. For the purposes hereof, commercial establishments dealing with ratites shall be classified as follows:

1.1 Hatchery
1.2 Breeding
1.3 Raising and Rearing
1.4 Fattening
1.5 Full cycle
1.6 Partial cycle

CHAPTER II

DEFINITIONS

1. For the purposes hereof, the following definitions apply:

1.1. Official Service: Animal Health Service at the federal, sate, and municipal level, and the service for inspection and development of animal production nationwide;

1.2. Official Laboratories: Laboratories on MAPA's chain of laboratories;

1.3. Accredited Laboratories: Laboratories from other federal, state, municipal, o private institutions that have been qualified and recognized by MAPA for the performance or laboratory diagnostic of the agents of diseases referred to hereunder;

1.4. Federal Agricultural and Livestock Inspectors: Ministry of Agriculture, Livestock, and Food Supply inspectors trained in veterinary medicine, entrusted with inspection and supervision related to Animal Health and Inspection. They have the same attributions as veterinarians and zootechnicians charged with the inspection and supervision of animal production.

1.5. Official veterinarian for sanitary certification: Federal Agricultural and Livestock Inspector trained in veterinary medicine or veterinarian of the Official Animal Health and Inspection Service;

1.6. Official Veterinary Control: Official service familiar with the establishments where animals are kept, and with the owner's or the person in charge's identity, which can enforce appropriate zoosanitary control measures as needed;

1.7. Accredited veterinarian: Official state and municipal veterinarian, either private or a liberal professional, that has been delegated by the Official Federal Service's competence for issu-

ing Animal Movement Permit (GTA);

1.8. Technician in charge: veterinarian in charge of the hygiene and sanitary control of ratite flocks at rearing establishments, registered with the Federal Agriculture Enforcement Unit-DFA in whose jurisdiction the establishments are located;

1.9. Sanitary Certificate: sanitary inspection certificate describing the animal health and/or public health requirements, pursuant to current legislation;

1.10. Animal Movement Permit-GTA: mandatory document required by MAPA for the transportation of animals, including ratites and fertile ratite eggs for any movement and purpose thereof;

1.11. Transportation License: document issued by IBAMA authorizing the transportation of wild animals between raising, breeding, and fattening establishments, and flock movement;

1.12. Wild animals: all animals belonging to native, migratory, and any other water or land species, whose life cycle has fully or partially occurred within the Brazilian territory or in waters under Brazilian jurisdiction;

1.13. Exotic animals: all animals whose geographic distribution does not include the Brazilian territory, and species introduced by man, including domestic animals gone wild. Some species introduced out of the Brazilian territory or of waters under Brazilian jurisdiction which may have entered the Brazilian territory are also considered to be exotic;

1.14. Domestic animals: all animals that, through traditional, systematized management and/or zootechnical processes, have become domestic and now display biologic and behavioral characteristics in close dependence from man, and which may have a variable phenotype different from their wild species;

1.15. Production animals: all wild, exotic, and domestic animals destined for breeding and for the production of products and subproducts;

1.16. Ratites: Flightless running birds without a keeled sternum (ostrich –Struthius camellus and emu, Rhea americana);

1.17. Raising establishments: establishments destined for genetic selection and breeding, which produce hatching eggss and/or chicks;

1.18. Hatchery establishments: establishments destined for the incubation of hatching eggss for the production of ratites;

1.19. Rearing establishments: establishments destined for the production of reproducing parent breeders and ratites for slaughter;

1.20. Fattening establishments: establishments destined for commercial production of mature ratites for slaughter;

1.21. Full-cycle establishments: establishments engaged in all the aforementioned stages.

1.22. Partial-cycle establishments: establishments engaged in one or more than one stage of the production cycle;

1.23. Commercial rhea raising establishments: establishments registered with IBAMA to foster the management of wild ratites (rheas) under captivity for their economic exploitation or for trial;

1.24. Commercial ostrich raising establishments: establishments registered with MAPA for commercial exploitation or trial;

1.25. Conservationist raising establishments: establishments registered with IBAMA to foster the management of wild ratites (rheas) under captivity to help environmental agencies in their projects or programs aimed at restoring the species to nature;

1.26. Scientific raising establishments: establishments registered with IBAMA to foster the management of wild ratites (rheas) under captivity for supporting basic or applied scientific research geared to the species studied or to public or animal health;

1.27. Zoological Garden: any collection of living wild animals kept under captivity or in partial freedom and exposed to public visitation;

1.28. Discardable ratites: ratites with inadequate zootechnical or sanitary characteristics for breeding;

1.29. Day-old ratites: birds up to seven days after hatching, that have not taken any food or drunk any water;

1.30. Flock monitoring: sanitary follow-up and laboratorial analysis performed at an official or MAPA-accredited laboratory through serologic tests and other tests in other materials, biologic or not; and epidemiologic analysis of the health conditions of ratites housed in establishments;

and proper interpretation of results;

1.31. Registration: registration by MAPA through the DFAs and by IBAMA through its executive offices at the ratite raising, rearing, fattening, and hatchery, for which specific documents and prior inspection by the official service are required;

1.32. Register: an identification record kept by the official service; it is required for the registration of an establishment or rural property that houses ratites; a copy should be kept at the DFA and/or Agricultural Office's local veterinary unit or executing agency, for the purposes of sanitary monitoring;

1.33. Biosecurity: encompasses sanitary measures, including measures pertaining to cleaning and disinfection; control of the movement of people, animals, and vehicles; discarding; and security control of the facilities of establishments destined for incubation and raising of ratites. These measures aim at ensuring the housed ratites' sanitary status and their health, thereby reducing the risk of introduction and dissemination of diseases;

1.34. Hatching eggs: fertilized eggs, appropriate for incubation;

1.35. Infertile eggs: eggs that have not been fertilized;

1.36. Commerce: the system of purchase, sale, barter, exchange, transfer, loan, or donation of ratites;

1.37. GPS: instrument that determines the geographical location of a property by satellite;

1.38. CNPJ: National Register of Legal Entities;

1.39. CPF: National Identification of Natural Persons;

1.40. MAPA: Ministry of Agriculture, Livestock and Food Supply

1.41. SDA: Animal and Plant Health and Inspection Secretariat;

1.42.DDA: Animal Health Department;

1.43.CPV: Veterinary Products Coordination Office;

1.44. CPS: Sanitary Surveillance and Programs Coordination Office;

1.45. CLA: Animal Laboratories Coordination Office:

1.46. PNSA: National Avian Health Program, under the SDA/DDA;

1.47. DIPOA: Department of Inspection of Animal Origin Products;

1.48. DFA: Federal Agricultural Enforcement Unit;

1.49. SSA: Animal Health Service

1.50. SFFA: Animal Production Development and Oversight Service;

1.51. SIF: Federal Inspection Service

1.52. SARC: Rural Support and Cooperativism Office;

1.53. DFPA: Animal Production Development and Oversight Department;

1.54. IBAMA: Brazilian Institute for the Environment and Renewable Natural Resources;

1.55. INCRA: National Settlement and Agrarian Reform Institute;

1.56. CFMV: National Veterinary Medicine Council;

1.57. CRMV: Regional Veterinary Medicine Council;

1.58. Breeders Association: association of ratite breeders of national prominence;

1.59. CC/PNSA: National Avian Health Program's Consultative Committee;

1.60. COESA: State Avian Health Committee; and

1.61. CITES: Convention on International Trade in Endangered Species of Wild Fauna and Flora.

CHAPTER IV

REGISTER AND REGISTRATION OF RATITE ESTABLISHMENTS (RAISING, REARING, FATTENING, FULL CYCLE, AND PARTIAL CYCLE) AND OF INCUBATION ESTABLISHMENTS

1. Register:

1.1. All ratite breeding and production establishments must be registered with the local veterinary unit of the agency responsible for the state's animal health policy. This will be required for registration with the competent bodies.

2. Registration:

2.1. Registration of commercial ratite breeding and production establishments shall

be done by the following bodies:

2.1.1. Ostrich – MAPA;

2.1.2. Rhea – IBAMA.

2.2. Registration of ostrich establishments shall be done at MAPA, for which the initial register will be required from all establishments that keep ostriches, irrespective of the number of birds; the process starts at the DFA of the state where the establishments are located, and will be concluded in conjunction with the animal production inspection and development and the animal health and inspection sectors, all consistently with the sanitary norms and environmental legislation in force.

2.3. Registration with MAPA shall be done after evaluation by the state or municipal environmental agency, and should include the evaluation report observations.

2.4. Registration with IBAMA shall be done after that agency has issued the pertinent Operating License-LO.

2.5. The registration document shall be issued after technical inspections and submission of the documents required by the respective agencies.

3. A report on the registrations done by MAPA (DDDA/SDA and DFPA/SARC) and IBAMA (Fauna and Fishery Recourses Office) shall be exchanged and shared by these agencies on a half-yearly basis, so that records may be kept current and consistent at the involved institutions.

CHAPTER V

DOCUMENTS AND REQUIREMENTS FOR REGISTRATION OF RATITE ESTABLISHMENTS WITH MAPA

1. Documents required for ostrich establishments:

1.1. Application to DFA in the state where the establishment is located, pursuant to MAPA's standard form.

1.2. Legal data:

1.2.1. A legal entity must attach a copy of its CNPJ identity document, accompanied by a copy of the establishment's registration with the state trade board or of the minutes of the establishment's incorporation, including any modifications, or of its registration with INCRA, or a lease contract duly entered into the records office of the municipality where the establishment is located.

1.2.2. A natural person must attach a copy of his/her CPF identity document, accompanied by a copy of his/her registration with the state trade board or with INCRA, or of enrollment as a rural producer, or a lease contract duly entered into the records office of his/her municipality.

1.3. A disclaimer by the veterinarian in charge of the hygiene and sanitary control of establishments classified under Chapter II hereunder, pursuant to MAPA's standard form.

1.4. Copy of the technician in charge's registration with the Veterinary Medicine Council (CFM or CRMV).

1.5. Duly filled-out MAPA standard registration form.

1.5.1. In the case of rhea establishments, in addition to registration with IBAMA, copies will be required of the registration document issued on behalf of the veterinarian that has technical responsibility for the establishment by the DFA in his/her jurisdiction, as well as a disclaimer of technical responsibility on a MAPA standard form.

1.6. Proof of (microbiologic, physical, and chemical) potability of the water supply, issued by a public, official, or MAPA accredited laboratory, signed by the technician in charge, indicating the source of supply.

1.7. Plan of the establishment, showing all facilities, roads, water courses, and abutting properties on a scale compatible with the property size, or aerophotogametric survey.

1.8. Plan on a scale technically appropriate for visualization of the property's infrastructure and facilities.

1.9. Description of facilities, equipment, and of the hygiene, sanitary, and biosecurity measures to be adopted by the establishments, as well as of the technological incubation processes.

1.10. Protocol, register document, registration, and prior license or importation license from IBAMA, as necessary.

1.10.1. The IBAMA/Fauna and Fishery Resources Office importation license shall be required in case of ostriches and eggs originating in the wilderness.

1.10.2. For the importation of rheas, irrespectively of their origin, in addition to a MAPA license or authorization, a CITES license issued by IBAMA/Fauna and Fishery Resources Office shall be required.

1.11. Inspection report(s) in the state where establishments are located shall be issued by the Federal Agricultural and Livestock Inspector or Official Veterinarian from the Inspection and Development sectors or services on the physical plant and animal health, pertaining to hygiene and sanitary control; said reports shall be issued on a MAPA standard form after on-site inspection;

1.11.1. Sanitary inspection may be done by a state official veterinarian by MAPA delegation.

1.12. Reports shall be issued by MAPA's competent sector in one copy on a standard form.

1.13. A ratite establishment must inform the official service of the state where it is located, within a maximum of 60 (sixty) days, of the change of technician in charge, and send his/her successor a disclaimer and pertinent documentation.

1.14. Any change of address or incorporation articles, as well as alienation or leasing must be brought current at MAPA, through the following:

1.14.1. Application to the Federal Agricultural Enforcement Unit in the state where the establishment is located, requesting regularization of its situation.

1.14.2. Copy of the establishment's new incorporation articles or lease contract.

1.14.3. New inspection report(s) on the physical plant and hygiene and sanitary control.

1.15. MAPA may enter a provisional registration at its discretion.

1.16. Registration with IBAMA/Fauna and Fishery Resources Office shall be subject to the latter's procedures and to the documentation it requires.

CHAPTER VI

NOTIFICATION OF SUSPICION OR OCCURRENCE OF AVIAN DISEASES

1. Veterinarians, owners, or any other citizen aware or suspicion of the occurrence of Newcastle disease and Avian Influenza must promptly notify the official service pursuant to Decree No. 24548 of July 3, 1934 and Ministerial Administrative Ruling No. 70 of March 3, 1994.

1.1. The occurrence of other diseases subject to mandatory notification shall be notified to the Official Animal Health and Inspection Service on a monthly basis.

1.2. Diseases subject to mandatory monitoring shall be subject to the flow established by DDA/SDA/MAPA.

1.3. Notification shall be done in person, by telephone, radio, fax, e-mail or any other available means.

1.4. Noncompliance with the provisions under the preceding articles shall be investigated by the official service, which will employ all the available means to establish liability.

1.4.1. In the case of veterinarians, in addition to abiding by the provisions under this article's heading, the official service shall proceed in accordance with the specific professional legislation.

CHAPTER VII

SANITARY CONTROL AND FLOCK MONITORING

1. As regards ratites or fertile ratite eggs for commercial breeding and production:

1.1. Importation:

1.1.1. Sample collection shall be done at the entry points (ports, airports, and border posts) or on quarantine facilities as determined by DDA/SDA/MAPA, for the performance of laboratorial tests pursuant to specific legislation on importation and laboratories.

1.2. National flock:

1.2.1. Sanitary monitoring shall be permanent at raising, housing, and hatchery establishments, pursuant to the norms established under the Animal Health and Inspection Regulations and under PNSA/DDA/SDA/MAPA.

1.2.2. Half-yearly Survey:

1.2.2.1. Isolation or Polymerase Chain Reaction (PCR) – (*Salmonella gallinarum, S. pullorum, S. enteritidis* and *S. typhimurium*).

1.2.2.2. Isolation or Polymerase Chain Reaction (PCR) – (*Mycoplasma gallisepticum* and *M. synoviae*).

1.2.2.3. Serology for Newcastle disease:

1.2.3. Other diagnostic methodologies may be accepted, once approved by DDA CPS/PNSA and CLA.

1.2.4. Actions for the surveillance and eradication of Newcastle disease and avian influenza shall be carried out in accordance with DDA-CPS/PNSA and CLA norms and specific legislation.

2. Sanitary monitoring shall be carried out through the collection of serum and trachea and cloaca or feces swabs from 10 percent of the flock per age group to be controlled, as follows:

2.1. Birds aged one day to six months;

2.2. Birds aged from six months up to the start of the breeding stage;

2.3. Adult birds at the breeding stage or at rest.

3. Samples shall be collected from all birds in flocks of up to twenty birds; or five to twenty samples may be collected per group; a pool of up to five birds may be adopted, depending on the housed population.

4. The collection of samples from flocks larger than twenty birds may be done by sample pools per group, up to a maximum of fifteen birds per pool.

5. Monitoring analysis for the diseases mentioned hereunder shall be performed at MAPA accredited or official laboratories.

6. Systematic vaccination against Newcastle disease shall be optional in the states; its use in ratites is not recommended, unless indicated by the local epidemiologic situation.

7. Depending on each region's epidemiologic situation, after evaluation by the official service, vaccination of birds against the Newcastle disease may be mandatory on properties under permanent control, and on avian establishments with different ratite species and different production categories it may be regularly done.

8. In emergency situations related to these diseases, the Official Federal Service may establishment vaccination plans for each area.

9. Vaccination against avian diseases must be performed with vaccines registered with and approved by MAPA, according to current legislation, as a prophylactic or disease control measure.

10. In the case of avian influenza, as it is an exotic disease in the country, vaccination shall not be permitted, save under exceptional circumstances, and only if authorized by DDA-CPS/PNSA and CPV after risk evaluation and confirmation of an epidemiologic situation.

11. Only immunogenes, disinfectants, antigens, serum controls and kits registered with CPV/DDA/SDA/MAPA may be used, and only before their expiration date.

12. Only antigens an serum controls provided or approved by MAPA may be used.

13. Laboratory tests shall be used, subject to prior approval by DDA-CPS/PNSA and CLA.

14. Laboratory tests shall be accepted only if performed at an official or MAPA accredited laboratory, and indicate the antigen used, the batch number, and the amount used.

15. A ratite establishment that is a PNSA participant may not use:

15.1. Any vaccine prepared with an oily substance, in the four weeks prior to the tests;

1.5.2. Any drug for which there is scientific evidence that it may interfere in the laboratory tests or hamper the isolation of agents to be researched, in the three weeks prior to the tests.

16. Other laboratory tests may be used, subject to MAPA's approval.

CHAPTER VIII

SAMPLE COLLECTION AND FORWARDING FOR LABORATORY TESTS

1. Ratite establishments registered with local units shall submit to the local unit of the state in which they are located, pursuant to the sanitary control requirements hereunder, a schedule of sample collection and a timetable for hatching and importation, as well as the dates of routine collection of materials, to be performed by the technician in charge, for the purposes of monitoring, inspection, and supervision by the official service.

2. Collections for official monitoring and surveillance will be accepted only if performed by a federal agricultural and livestock inspector or by an official veterinarian, or under his supervision and oversight.

3. For the purposes of sanitary monitoring for the issuance of sanitary certificates and GTAs,

the SSA/DFA of the state where the ratite establishment is located will analyze the samples forwarded by the technician in charge, responsible for the enterprise before MAPA, as well as random samples collected by the official service.

4. Any material destined for laboratory tests must be accompanied by a duly filled-out MAPA collection standard form, signed by the enterprise's technician in charge accredited before MAPA or by the federal agricultural and livestock inspector, or by the official veterinarian.

5. Material for biologic tests or for bacteriologic, mycoplasmatic, and virologic tests should be collected randomly.

6. At the discretion of the Animal Health Service and/or the State Agricultural Department or the executor of these regulations in the state where an establishment is located, double samples may be collected at any time in the presence of the federal agriculture and livestock inspector or of the official veterinarian, to be subjected to confirmation or complementary tests.

7. Official monitoring material may be sent to any of the laboratories accredited by MAPA for this purpose, at the discretion of the federal agriculture and livestock inspector or of the official veterinarian responsible for the collection.

8. Monitoring samples shall be distributed by drawing lots among official laboratories and MAPA accredited laboratories for this purpose. The drawing of lots shall be followed by the federal agriculture and livestock inspector or the official veterinarian responsible for the collection.

9. Costs pertaining to the laboratory tests and shipment of samples to the laboratory accredited by MAPA for this purpose shall be incumbent on the establishment or enterprise.

10. Any officially collected material should be sealed and accompanied by the DDA/SDA/MAPA standard form.

11. Random collections done by the official service may or may not abide by the enterprises' tests timetable; the federal agriculture and livestock inspector or the official veterinarian responsible for collections or for overseeing them shall be responsible for sealing the material and sending it to the laboratory.

CHAPTER IX

ISSUING OF LABORATORY RESULTS

1. Laboratory test results shall be issued by the accredited or official laboratory on the appropriate MAPA standard form, in addition to notifications, according to the following procedure:

1.1. Negative results: should be sent by fax, e-mail, or other fast means of communication to the federal agriculture and livestock inspector or to the official veterinarian that requested the test, as well as to the ratites establishment in question.

1.2. Positive results: should be sent by fax, e-mail or other fast means of communication to the DDA and to the SSA/DFA in the state where the establishment is located, which will notify the establishment.

CHAPTER X

TREATMENT, CONTROL, AND CERTIFICATION MEASURES

1. In case of positive laboratory test results:

1.1. Specific surveillance, control, and eradication of Newcastle disease and avian influenza legislation should be applied.

1.2. In case of salmonellosis and mycoplasmosis:

1.2.1. Breeding ratites should be monitored for salmonellosis (*S. gallinarum, S. pullorum, S. enteritidis* and *S. tiphimurium*) and for mycoplasmosis (*Mycoplasma gallisepticum* and *M. sinoviae*).

1.2.1.1. Complementarily, all isolated Salmonella serovars must be typified and subjected to epidemiologic investigation in relation to the risk to the ratite flock and to public health.

1.2.1.2. *Salmonella pullorum* and *Salmonella gallinarum* are considered as posing a risk to the avian flock, while *Salmonella enteritidis* and *Salmonella tiphimurium* pose a risk to public health.

1.2.1.3. Positive cases of salmonellosis in ratites destined for slaughter should be notified by the Official Animal Health Service to the Official Animal Products Inspection Service (SIF/DIPOA/

MAPA), which will determine slaughter criteria pursuant to the specific norms and legislation.

1.2.1.4. In view of the risk to public health and to animal health, pertinent hygiene and sanitary measures defined by DDA should be applied in breeding pens where proven salmonella positive birds have been kept.

1.2.2. Proven positive mycoplasma breeding ratites may be treated with specific antibiotic, and the flock must remain under control and monitoring.

1.3. After at least three consecutive tests with negative results for salmonellosis and mycoplasmosis, a certificate for the property or breeding sector thereof shall be issued by the official service, testifying that they are free of or under control for the diseases investigated.

CHAPTER XI

BIOSECURITY OF THE SYSTEM FOR RATITE RAISING ESTABLISHMENTS

1. Establishments must be on an appropriate geographic location and maintain the following distances to other ratite or avian establishments with different production purposes:

1.1. From a ratite establishment to an avian slaughterhouse: 5 km.

1.2. From a ratite establishment to a feed plant: 3 km.

1.3. From other avian raising establishments to quarantine facilities for imported ratites: 11 km.

1.4. From a paved road to the entrance of quarantine facilities for imported ratites: 4 km.

1.5. From a ratite establishment to another avian breeding or housing establishment:

1.5.1. Between establishments holding ratite species that are similar or different from each other: 500 m.

1.5.2. Between establishments holding different ratite species on the same property: 100 m (subject to the adoption of biosecurity measures and separate facilities).

1.5.3. Between ratite raising establishments and other industrial poultry establishments for broilers, layers, or for turkeys, quails, partridges, etc: 4 km.

1.5.4. From other avian raising establishments of different exotic or wild species to be sold on the pet market or for the production of parent breeders: 4 km.

1.5.5. Between ratite establishments and establishments geared to industrial poultry farming, breeding (pure breeds, grandparents, great-grandparents, and parent breeders), SPF poultry, and breeding hatchery: 11 km.

1.6. From raising facilities to the property's boundaries: 25 m, including hedges or wall.

1.7. From full-cycle or partial cycle raising, rearing or fattening establishments to the main paved road giving access to the establishment: 50 m.

1.8. Between ostrich groups of different ages: 100 m.

1.9. Between hatcheries of ratites of the same species and raising pens within the property: 50 m (with the adoption of biosecurity measures and separate facilities).

1.10. Between commercial rhea and ostrich production establishments and free-ranging, wild rheas: 25 m (with the adoption of biosecurity measures and separate facilities).

2. Any procedures for releasing or introducing birds into the wilderness is hereby strictly forbidden, as this leads to environmental degradation, entailing consequences that adversely affect the biota, and is subject to the penalties under Law 6938/81 and Law 9605/98.

3. At the discretion of the federal agriculture and livestock inspector or, by delegation, of the federal or state official veterinarian responsible for inspection and for issuing the operation permit, modification of the aforementioned minimum distances may, after sanitary risk evaluation, be allowed on pre-existing establishments, in view of the existence of barriers (reforestation, natural woods, topography, masonry walls, access control, etc.) of the employment of differentiated management and biosecurity measures that prevent the introduction and spread of pathogens.

4. In the case of hatchery, inspection by the official service is mandatory, to ensure the biosecurity and the health of new-born ratites, in this evaluation, shall be considered the existence of masonry walls, hedges, or wire mesh fences sepa-

rating production and incubation areas, with a single entrance, provided with a footbath and shower to be used before entering the clean area.

5. Control of vectors and rodents and of the access of other birds and of people.

6. Adoption of monthly microbiological sanitary control for plating of facilities and equipment, and testing at an accredited or official laboratory; and observation of local situations.

7. Properties must be located at a minimum of 25 m from secondary roads, from which they should be separated by a perennial security hedge.

8. Only one entrance should give access to the property, be protected by security fences, and be equipped with a system for the disinfection of vehicles and materials as they enter or leave the property.

9. The property must maintain strict control of the transit and access of people (gates, doors, reception desk, masonry walls, footbath, and other items).

10. Facilities' interior wall surfaces must be such as to permit proper cleaning and disinfection.

11. The inner fence of adult ostrich pens may be of plain wire or wire mesh, 1.70-m high; and there must be a 2-m wide corridor between pens.

12. Pens must give out on a corridor leading to isolation pens measuring a maximum of 4 m2 x 5 m2 for sanitary inspection, collection of materials, medication, and other purposes, as needed.

13. In raising and rearing pens (for birds aged 4 to 14 months), fences must be of plain wire of at least five wires and be 1.70 m high, or of wire mesh, measuring 50 cm in height from the ground and with plain wire in the upper part; an area of 100 m2 per bird (ostrich) is recommended.

14. Space for adult ostriches may vary from 165 m2 to 500 m2 per bird, i.e., 20 to 60 birds per hectare.

15. Inside pens there must be feed and water troughs.

16. Establishments must have means, duly approved by MAPA and by the competent environmental control bodies, for the disposition of production residues (dead birds, excreta, egg remnants, and packaging, among others).

17. Birds of different age groups must be separated by fences and/or a palisade of trees other than fruit trees; the area must have restricted, controlled access of vehicles, people, and materials, and biosecurity measures pertaining to the internal area must be in place.

18. Admission of people, vehicles, equipment, and materials into the establishments' internal areas should be permitted only after strict compliance with biosecurity measures.

19. Control measures pertaining to liquid effluents must be adopted, consisting of septic tanks, taking into account water courses and underground waters to prevent contamination, pursuant to environmental and health norms.

20. Physical and chemical control of water on a yearly basis; and half-yearly microbiologic control done at a public, official, or MAPA accredited laboratory, with indication of the source of the establishment's water supply.

21. At the discretion of the Official Animal Health Service, after evaluation by DDA/SDA/MAPA, and according to each region's epidemiologic and sanitary situation, measures may be adopted to restrict the transit of vehicles, people, and/or animals in regard to circumscribed regions and establishments referred to hereunder, for the purpose of disease control and mandatory vaccination against Newcastle disease or other diseases likely to place breeding flocks, wild birds, and ratites or public health at risk.

22. Ratites and eggs produced should be individually identified.

22.1. Live ratites: an open or closed ring; a clamp (eartag adapted to the wing), or electronic marking or tattoo with antitoxic ink.

22.2. Eggs: stamp or pen with antitoxic ink insoluble in water, or pencil, with the registration number, laying date, or any other kind of marking that ensures identification.

22.2.1. Whenever possible, besides information referred to in the preceding item 22.2, it should include paternity information.

23. At the property's entrance, biosecurity measures and procedures for the disinfection of vehicles, equipment, and materials must be adopted.

24. Eggs destined for human consumption shall be subject to sanitary procedures pursuant to SIF/DIPO/SDA/MAPA norms.

25. Egg collection in the open should be done at least once a day.

CHAPTER XII

BIOSECURITY OF THE SYSTEM FOR RATITE HATCHERY

1. Facilities must have only one entrance and permit one-way flow, and access to them is subject to the requirements referred to in Chapter XI, 1 hereunder.

1.1. Incubation establishment facilities should be divided into separate work areas (offices and technical facilities), physically separated, with individual ventilation, and should include the following:

1.1.1. Room for receiving and cleaning hatching eggs.

1.1.2. Fumigation chamber for hatching eggs (optional).

1.1.3. Eggs storage room.

1.1.4. Incubation room.

1.1.5. Hatching room.

1.1.6. Maternity room.

1.1.7. Day-old birds shipping room (optional, provided it is possible to maintain a downtime of at least 72 hours).

1.1.8. Room for washing and disinfection equipment.

1.1.9. Locker room, washrooms, and toilets.

1.1.10. Office.

1.1.11. Crate storage outside the incubator.

1.1.12. Machine and generator room.

1.1.13. Adequate system for discarding incubator residues and waste water.

2. All materials and equipment used in the hatchery must be kept clean and disinfected with appropriate products duly registered with MAPA.

3. The area surrounding the incubation facility must be protected by a single entrance equipped with vehicle washing and disinfection means for controlling any kind of transit.

4. At the discretion of the federal agriculture and livestock inspector or of the federal or state official veterinarian, responsible for inspection and for issuing the operation permit, modification of the aforementioned minimum distances may, after sanitary risk evaluation, be allowed on pre-existing establishments, in view of the existence of barriers (reforestation, natural woods, topography, masonry walls, access control, etc.) or of the employment of differentiated management and biosecurity measures that prevent the introduction and spread of pathogens.

5. A permanent sanitary monitoring program must be established pursuant the Animal Health and Inspection Regulations and to PNSA/DDA/SDA/MAPA norms.

6. Monthly microbiologic monitoring during the incubation period through the plating of each incubation area and equipment (incubators and hatching area), done at accredited or official laboratories.

7. Control measures pertaining to liquid effluents must be adopted, consisting of septic tanks, taking into account water courses and underground waters to prevent contamination, pursuant to environmental and health norms.

8. Biosecurity measures should be adopted, such as a footbath at the entrance of the incubation facility, and efficient measures for the disinfection of vehicles at the property's entrance.

9. Exceptionally, in the case of rheas, natural incubation may be admitted, as well as the breeding of naturally or artificially incubated chicks by foster parents.

CHAPTER XIII

BIOSECURITY MEASURES FOR THE TRANSPORT OF EGGS FOR INCUBATION

1. Eggs for incubation should be collected at regular intervals (at least once a day) in clean, disinfected recipients, and the personnel in charge of collection must wash their hands before.

2. Eggs and birds produced should be individually identified in respect of parents, paternity and/or production pens or the property of origin.

3. Eggs that do not meet the hygiene, sanitary, shell porosity and thickness standards, that are broken, or have cracks should be collected in

separate recipients and may not be destined for incubation.

4. After collection, eggs should be disinfected as soon as possible and be stored in an appropriate place, under adequate temperature and humidity.

5. Eggs should be transported from the incubation establishment in appropriate vehicles, in clean, previously disinfected trays or boxes/carts, duly accompanied by a GTA whenever transit from the breeding to the incubation facility is necessary.

5.1. In the specific case of rheas, a transportation permit from IBAMA shall also be required.

CHAPTER XIV

BIOSECURITY IN THE HANDLING OF HATCHING EGGS AND DAY-OLD RATITES

1. Personnel engaged in the internal work of an incubation facility must follow the general personal hygiene measures, and wear clean, disinfected clothing and shoes provided by the incubation enterprise.

2. Day-old ratites must be shipped directly from the incubation facility to the local destination, duly accompanied by a GTA on the way between the two establishments.

2.1. In the specific case of rheas, a transportation permit from IBAMA shall be required.

3. Transport vehicles must be cleaned and disinfected prior to every shipment.

4. Natural residues from day-old ratite incubation and hatching should be incinerated, cremated, or subjected to another treatment approved by MAPA and IBAMA or by state and municipal environmental control agencies, so as to prevent the spreading of any pathogens.

CHAPTER XV

CANCELLATION OF REGISTRATION

1. An establishment's registration may be cancelled at the request of the interested party or by decision of the competent DFA authority in the state where the establishment is located, according to administrative proceedings, while respecting the right to defense.

2. An interested party may request cancellation of its registration by applying to the federal agriculture and livestock inspector in the state where the ratite establishment is located.

3. Penalties imposed on the establishment shall be defined after technical evaluation by the federal agriculture and livestock inspector or, by delegation, by the veterinarian of the state official service(s), in accordance with the following criteria:

3.1. Written warning notice: in case of noncompliance with one of more than one provision of Chapters IV, V, VI, VII, VIII, X, XI, XII, XIII, XIV, and XVI hereunder. The notice shall set a deadline for resolution of the sanitary situation or for ensuring the requisite adequacy of the establishment facilities.

3.2. Establishment's interdiction: in case of noncompliance with technical determinations by the established deadline or with one or more than one provision under Chapters VI, VII, VIII, X, XI, XII, XIII, XIV, and XVI hereunder, which entails the risk of spreading diseases through the ratite flock, the wild fauna, and the national avian flock, or based on suspicion or confirmation of an outbreak of an exotic disease, as established under the Animal Health and Inspection Regulations.

3.3. Temporary suspension of registration: in case of an infraction that entails a risk to public health, biosecurity, the ratite flock, the wild fauna, and the national avian flock through the spread of diseases, or to the safety of the establishment's physical structure.

4. The administrative proceeding shall be started by DFA in the state where the establishment liable to punishment is located; recourse shall be allowed, within fifteen days from the date the interested party receives the notification, to the MAPA central organ, which depending on the reasons for interdiction will entrust the proceeding's evaluation to SARC and SDA as the competent bodies.

5. In case of failure on the part of the interested party to comply with the established requirements, registration with MAPA/DFA may be definitively cancelled.

6. Communications regarding penalties imposed on raising establishments by MAPA or IBAMA must be promptly exchanged between local and national organs, within a maximum of five business days.

7. At the discretion of the official service(s) in the state where the establishment is located, DFA may grant the interested party a new registration, subject to a new technical inspection of the establishment and to the solution of the problems identified earlier, taking into consideration the enterprise's appropriate conduct, after new proceedings have been filed with the aforementioned DFA.

CHAPTER XVI

GENERAL DISPOSITIONS

1. Under agreements with MAPA, the SSA/DFA in the state where the establishment is located, and the Animal Health Service of State Departments of Agriculture, in their area of operation and competence, are responsible for defining the proper measures for solving sanitary problems, pursuant to the Animal Health and Inspection Regulations and the PNSA/DDA/SDA/MAPA.

2. All establishments that hold ratites or incubate ratite eggs shall be subject to sanitary inspection by official services.

3. As they belong to the wild fauna, rheas should be managed according to the norms of IBAMA/Fauna and Fishery Resources Office; those raised for commercial production shall be further subjected to specific sanitary monitoring by PNSA/DDA/SDA/MAPA. At other rhea holdings, sanitary monitoring shall be occasional. In sporadic cases, monitoring shall be done through random sampling determined by PNSA/DDA/SDA/MAPA and IBAMA, so as not to interfere with free-range raising.

4. In view of the differentiated rhea production system, it is hereby established a deadline of 18 months of the publication date for the adaptation of physical facilities.

5. The sanitary and health control of ratites kept in zoos shall be incumbent on qualified professionals at these institutions.

6. In an emergency, MAPA or the official Animal Health and Inspection Service may intervene, safeguarding the provisions under the Animal Health and Inspection Regulations and the PNSA/DDA/SDA/MAPA.

7. The sanitary control of commercial production ratites shall be incumbent on MAPA and the State Agriculture Departments or their executor agencies, by delegation.

8. All ratite production establishments must comply with PNSA norms and legal acts and comply with the following:

8.1. Meet biosecurity requirements, and grant federal agriculture and livestock inspector(s) and official service veterinarian(s) access to documents and facilities at any time.

8.2. Keep records of the annual physical and chemical control and of the half-yearly microbiologic potability control, as well as of water treatment at the establishment, the treatment of liquid effluents, and the cleaning of equipment and facilities.

8.3. Keep records of the sanitary monitoring procedures pertaining to each batch of ratites and hatching eggs in relation to the diseases referred to under PNSA/DDA/SDA/MAPA. Tests must be performed at a laboratory accredited by MAPA for this purpose, or at an official laboratory; lab results should be made available to the official services' veterinarian authorities at request.

8.4. The technician in charge must send the flock's epidemiologic bulletin to the local official service on a monthly basis.

8.5. Records must also be kept on the flock's management as regards each batch of birds and of hatching eggs, including information on mortality, diseases diagnostic, sanitary monitoring, treatments, vaccination, etc. Said records should be available to the official services' veterinarian authorities at request.

8.6. The establishment must submit a trimestral report to DFA's competent sector in the state where it is located, pursuant to a standard MAPA form, under penalty of its registration's cancellation.

9. Depending on a situation identified by the official service(s), noncompliance with the requirements hereunder shall entail the adoption

of the sanctions set forth under Chapter XV hereunder, cumulatively with the following:

9.1. Suspension of the authorization for ratite and hatching eggs importation, exportation, marketing, and the attendant issuing of GTA.

9.2. Interdiction of the raising or hatchery.

9.3. Application of the sanitary measures under PNSA or of pertinent zootechnical measures set by DFPA/SARD/MAPA.

10. Ratite establishments engaged in international trade must also comply with the norms established by MAPA and IBAMA/Fauna and Fishery Resources Office-CITES for this purpose, as well as meeting the importing countries' requirements.

11. IBAMA, pursuant to its legal competence, shall proceed to the registration of all breeders and establishments that keep rheas, ostriches, and other ratites in captivity for scientific and conservation purposes and in zoos.

12. The DFPA/SARC/MAPA shall issue complementary norms pertaining to zootechnical aspects, in consultation with ratite breeders associations with national representativeness.

13. Under the Animal Health and Inspection Regulations and PNSA, the regulation, regularization, and control of animal health and biosecurity measures shall be incumbent on DDA/SDA/MAPA.

14. The cleaning and disinfection measures adopted must comply with the criteria established by OIE and the specific national legislation.

15. MAPA/SDA/DDA and DFA, each within its area of competence, may convene the Consultative Committee of the National Avian Health Program (CC/PNSA) and the State Avian Health Committees (COESAs) as needed to hear their views on specific issues hereunder.

16. Omissive cases and doubts that may rise in the application of these technical regulations and of complementary legislation shall be defined by MAPA, DDA/SDA or DFPA/SARC.

NORMATIVE INSTRUCTION SDA No. 32 OF MAY 13, 2002

Published in the Official Gazette of May 14, 2002, Section 1, Page 28

Approves the technical rules of surveillance for the Newcastle disease and avian influenza, and of control and eradication of the Newcastle disease

THE SECRETARY OF ANIMAL AND PLANT HEALTH AND INSPECTION, OF THE MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY, by the powers invested in him in article 83, clause IV, of the Internal Regulation of the Secretariat, approved by Ministerial Administrative Ruling No.574, of December 8, 1998, in consideration and in light of the provisions of the Ministerial Administrative Ruling No.193, of September 19, 1994, and in File MA 21000.006729/2001-59, decide:

Art. 1. To approve the Technical Rules of surveillance for Newcastle disease and Avian Influenza, and of control and eradication of Newcastle disease.

Art. 2. This Normative Instruction will be in effect on the date of its publication.

Art. 3. Is hereby repealed the Administrative Ruling SDA No.183, of November 8, 1994.

LUIZ CARLOS OLIVEIRA

TECHNICAL RULES OF SURVEILLANCE FOR THE NEWCASTLE DISEASE AND AVIAN INFLUENZA, AND OF CONTROL AND ERADICATION OF THE NEWCASTLE DISEASE.

CHAPTER I

INTRODUCTION

1. The current rule defines surveillance measures for the Newcastle disease and avian influenza, and of control and eradication being applied to the Newcastle disease:

1.1. In the surveillance at the port of entry, focusing on the health control of poultry and generic material from imported poultry.

1.2. At poultry holdings permanently controlled, and eventually controlled.

1.3. At properties that maintain poultry for commercialization or for raising, at backyard flocks and other poultry lodging locations for the ones kept in captivity.

CHAPTER II

DISEASES

1. THE NEWCASTLE DISEASE: is an infectious poultry disease caused by a virus from the Paramixovirus family, aviary Rubulavirus type of serotype 1 (APMV1), representing one of the following criterions of virulence:

• the virus has a pathogenicity index inside the brain of at least 0.7 on Day-old birds (Gallus gallus); or

• the presence of multiple basic amino acids is shown in the virus (directly or by deduction), in the C-terminal fraction of the F2 protein, or the same as the presence of phenylalanine in the 117 residue, which is the N-terminal fraction of the F1 protein. The term "multiple basic amino acids", refers to at least three arginine or lysine residue, between residues 113 and 116.

In this definition, the amino acid residues are numbered from the N-terminal fraction of the amino acid sequence deducted from the nucleotide sequence of the gene. F0 and residues 113-116, correspondents to residues 4 to 1, from the cleavage area.

In case the typical aminoacid residues cannot be distinguished, such as the description above, it is suitable to distinguish the isolated virus determining the pathogenicity index in the brain (RESOLUTION No.XIII, of May 1999, issued by the international OIE committee; OIE Zoosanitary Code, 2001).

2. AVIAN INFLUENZA: is a poultry infectious disease that is caused by a virus of the Orthomixoviridae family, of Influenzavirus A, B that present an Intravenous Pathogenicity Index (IPIV) > 1.2 on chicken that are 6 weeks old; or an infection caused by an Influenza A virus of subtype H5 or H7, with a sequence of nucleotides that present multiple basis of aminoacids in the cleavage area of the hemoagglutinin ((Manual Standards of Diagnostics Test and Vaccines OIE, chapter 2.1.14 year 1996; OIE International Zoosanitary Code, 2001).

CHAPTER III

DEFINITIONS

1. For the purpose of these rules, it is understood:

1.1. OIE: World Organization for Animal Health;

1.2. MAPA: Ministry of Agriculture, Livestock and Food Supply;

1.3. SDA: Animal and Plant Health and Inspection Secretariat;

1.4. DDA: Animal Health and Inspection Department;

1.5. CLA: Animal Laboratory Coordinating Unit;

1.6. CPS: Surveillance and Health Program Coordination;

1.7. PNSA: National Avian Health Program;

1.8. DIPOA: Department of Inspection of Animal Origin Products;

1.9. DFA: Federal Agricultural Delegacy;

1.10. SSA: Animal Health Service;

1.11. SIF: Federal Inspection Service;

1.12. OFfICIAL SERVICE: is the federal, state, and municipal animal health protection service;

1.13. OFFICIAL LABORATORIES: are the laboratories from the MAPA chain;

1.14. ACCREDITED LABORATORIES: are the laboratories of other federal, state, municipal, or private institutions, that have been approved and recognized by the MAPA, to perform laboratory diagnosis of disease agents referred by these rules;

1.15. FEDERAL INSPECTOR: is a MAPA inspector with veterinary qualifications that inspects and supervises matters regarding animal health protection;

1.16. OFFICIAL VETERINARIAN: is the Federal Inspector with veterinary qualifications or the official veterinarian of the official animal health protection service;

1.17. ACCREDITED VETERINARIAN: is the official, state, municipal, private, or an independent professional veterinarian, whom received delegation of competence of the federal official service to issue the Animal Movement Permit (GTA) or similar;

1.18. TECHNICIAN IN CHARGE: is the veterinarian responsible for the hygenic/health control at the flocks of the poultry farming premises, properly registered at the MAPA;

1.19. HEALTH CERTIFICATES: are health inspection certificates;

1.20.ANIMAL MOVEMENT PERMIT (GTA): is the mandatory document used for the transit of poultry, hatching eggs and 1 (one) day old poultry, any type of handling and objective;

1.21. FORM IN: is the standard DDA form, used for opening the outbreaks and to perform an epidemiological investigation;

1.22. FORM COM: is the standard DDA investigation supplement form;

1.23. STATES OF THE PROGRAM: are the states named by the DDA, that develop health monitoring operations for the PNSA diseases and the permanent epidemiological surveillance for aviary diseases;

1.24. EPIDEMIOLOGICAL UNIT: it is a unit of the poultry holding that allows the poultry that are lodged there to be treated and fed separately by distinctive personnel and other employees;

1.25. MONITORING OF FLOCKS: is the laboratory health and analysis follow up, by means of serological tests and other by other means, on other biological material or not, and epidemiological analysis of the health conditions of poultry lodged in an poultry holding and adequate interpretation of the results;

1.26. COMMERCIAL BIRDS: generation of poultry used for producing meats, eggs, derivatives and subproducts;

1.27. SUSCEPTIBLE POULTRY: involves all domestic, wild, exotic and ornamental birds;

1.28. INFECTED POULTRY: is any poultry which has been officially tested positive for the Newcastle disease or avian influenza through conclusive laboratory proof;

1.29. LIVESTOCK PRODUCT: includes meat, eggs, legs, blood, bowels and bones from the susceptible animal;

1.30. POULTRY MEAT: it is poultry meat, muscular eatable part of the slaughtered birds, declared proper for human consumption by an official veterinary inspection performed before and after the slaughter;

1.31. CARCASS: is the full body of a poultry after numbness or not, bleeding, plucking and evisceration, in which craw, trachea, esophagus, intestines, cloacal, spleen, reproductive organs and lungs have been removed. he extraction of kidneys, feet, neck and head is optional;

1.32. SUBPRODUCTS: meat, blood, leg and bowel meal; incubation residues; litter; skin; feather and plume; and phaners;

1.33. VEHICLE: any type of transportation on ground, water or air;

1.34. OUTBREAK: is the establishment in which the presence of the Newcastle disease or avian influenza has affected one or more birds;

1.35. PERIFOCAL AREA: is the area around the outbreak, which limits are established by the official service;

1.36.PROTECTION ZONE: ie the area of 3 (three) km radius around the outbreak, considered as the infected zone;

1.37.SURVEILLANCE ZONE: is the area of 7 (seven) km radius from the protection zone around the outbreak;

1.38. PROTECTION ZONE + SURVEILLANCE ZONE: 10 (ten) km radius around the outbreak;

1.39. DOWNTIME: is the period of which the lodging of an poultry holding is emptied out after the occurrence of an infestation, eliminating all birds and washing and disinfecting the barn;

1.40. SACRIFICE: is the slaughter of all diseased birds with signs of contamination or related to the matter of biosafety, its direct and indirect contacts;

1.41. DESTRUCTION: elimination of poultry, its products, subproducts, meat or carcass, by any physical or chemical means that assures total inactivation of the Newcastle and avian influenza viruses;

1.42. EMERGENCY VACCINATION: is the vaccination applied as means of controlling the disease after one or more cases have been registered, or when the epidemiological or health situation require;

1.43. OWNER: all those who are depositary, or by any means , maintains in their possession one or more susceptible birds;

1.44. PROPERTY: location where birds are lodged for commercialization or not (e.g.: establishment where birds are lodged, for leisure or domestic breeding, and commercial stores);

1.45. POULTRY HOLDING: is the location where poultry is kept for any purpose, which may be constituted of one or more centers.

1.46. POULTRY HOLDING PERMANENTLY CONTROLLED: they are the farms, genetically selected, of primary breeders (pure breeds), great grandparent farms, grandparent farms, head office farms, farms of breeding poultry free of specific pathogens (SPF), and the hatcheries of these establishments.

1.47. POULTRY HOLDING EVENTUALLY CONTROLLED: they are the poultry holdings producing commercial eggs, poultry for slaughter, exploring other wild birds, or ornamental, and/or exotic or not, and the hatcheries of these establishments.

1.48. BARN: is the aviary production unit, characterized as the unit of a center, which lodges a group of breeders, poultry for slaughter or commercial laying hens, of the same age (with exception of pure breeds, genetically selected), and of the same breed.

1.49. CENTER: is the unit with an area adequately isolated, of common handling, constituted of one or more barns.

1.50. BATCH: group of poultry for the same purpose, origin and age, lodged in one or many barns.

1.51. BOXES: are physical sections divided inside a barn.

CHAPTER IV

PROCEDURES THAT MUST BE COMPLIED BY POULTRY HOLDINGS

1. To attend to the PNSA, poultry holdings of permanent and eventual controls must:

1.1. Be registered at the DFA, or registered in the cases established by the MAPA in the official service of the state in which they are located;

1.2. Be under the surveillance and control of the SSA/DFA, or of the State Secretariat of Agriculture, or the department that issued this document, in the state which they are located;

1.3. In the cases defined by the MAPA legislation, they must be supervised by a veterinarian, the vererinarian in charge, registered at the DFA, or of State Secretariat of Agriculture, or by the department that issued this document, in the state which they are located, when the responsibility is passed over;

1.4. Proceed with the notification to the health authorities of any probable signs of the Newcastle or avian influenza diseases;

1.5. Use only immunogens, disinfectants, antigens, control serums, and “kits” registered at the MAPA, observing the starting number, name of the manufacturer, and expiration date.

CHAPTER V

NOTIFICATION

1. The veterinarians, owner, or any other person aware of the occurrence or suspiscion of Newcastle disease and avian influenza, are enforced to communicate the occurrence immediately to the official service (Decree No.24.548, of July 3, 1934, and Ministerial Administrative Rul-

ing No.070/94, of March 3, 1994).

1.1. The notification may be done personally, by telephone, radio, fax, e-mail or any other available way.

2. The infraction as per item 1 will be investigated by the official service that will use available measure to investigate responsibilities.

2.1. In the case of a veterinarian, besides what is mentioned or as per item 2, the official service must proceed according to the specific professional legislation.

3. The official service must be notified of the probable signs, preferably through the local veterinarian service, and sent to the an official laboratory or to one accredited by the MAPA, for this matter, from any lesion caused by the disease that should be found during the inspection, the slaughtering or during the necropsy.

4. At the slaughterhouses, in cases of signs of the disease(s), the slaughtering must be suspended until the conclusion of the cleanup and disinfection as recommended according to the criterions established by the DIPOA, and immediately communicated to the official service.

CHAPTER VI

OPERATION STRATEGIES

1. Monitoring of the Newcastle disease and avian influenza, and control and eradication of the Newcastle diseases will be applied in all states of the country.

1.1. Since the avian influenza is considered an exotic disease at industrial poultry flocks in Brazil, the risk of entry must be evaluated in the country, and permanent surveillance must be kept.

1.2. Because of the economical importance of the aviculture and of the epidemiological characteristics, a study on viral activity will be performed with the implementation of a Newcastle disease free zone in the industrial production area of the country, and the surveillance for the Newcastle disease and avian influenza in the states will be considered priority by the PNSA/DDA/SDA/MAPA.

2. The prophylaxis, the control and the eradication of these diseases consist in the application of the following measures of animal health protection:

2.1. Notification of suspicious signs of the Newcastle disease and avian influenza;

2.2. Assistance to the outbreaks;

2.3. Adopting biosafety measures;

2.4. Applying measures of disinfection;

2.5. Sacrifice;

2.6. Downtime;

2.7.Epidemiological analysis;

2.8. Routine or emergency vaccination at flocks;

2.9. Control and inspection of susceptible animals;

2.10. Transit control;

2.11. Other health measures.

CHAPTER VII

ASSISTANCE TO THE OUTBREAKS

1. SUSPICION:

1.1. All suspicion and occurrence notifications for the Newcastle disease and avian influenza, the second is considered exotic at industrial poultry flocks of the country, must be immediately investigated by the official service following the rules of health protection, sending the samples to the an official laboratory, or to one accredited by the MAPA, for this matter.

1.2. The notification of the probable signs of these diseases will include adopting the following health measures:

1.2.1. Interdiction of the aviary property or premises, opening of the FORM IN, and adoption of specific health measures with immediate collection of samples to be sent to a laboratory of the official network or when authorized by the MAPA, for accredited laboratory , for this matter, along with a copy of the FORM IN;

1.2.2. Registration of all categories of poultry indicating the number of dead birds, with and without clinical sign(s) of the disease(s) by category;

1.2.3. Poultry maintenance at lodging, or other confinement nucleis established by the federal inspector or by the official veterinarian, where they can remain isolated and the movement prohibited;

1.2.4. Control by the federal inspector or by the official veterinarian, of any transit of people, animals, vehicles, meats, carcasses, debris, excrement, litter, fomites and structures that might propagate the disease(s);

1.2.5. Utilization of adequate means to disinfect roads and exits of each aviary lodging premises, according to the recommendations of the OIE;

1.2.6. Conducting the epidemiological investigation with the opening of FORM IN, and later of FORM COM, to determine the origin of the infection and its propagation;

1.2.7. Abduction of the poultry meat and the eggs produced in the period of incubation of the diseases.

2. CONFIRMATION:

2.1. With the confirmation from the laboratory diagnosis of the Newcastle or avian influenza diseases, defined in Chapter II, of this rule, by conclusive laboratory exams, at the property where the outbreak was identified, the federal inspector or the official veterinarian will adopt the following measures:

2.1.1. Immediate sacrifice at the location of all the poultry from the poultry holdings;

2.1.2. Destruction of all poultry that have died or have been sacrificed;

2.1.3. Destruction or appropriate treatment of all residues, such as: feed, litter and feces, and susceptible fomites of being contaminated;

2.1.3.1. The treatment must be conducted in agreement with the instructions of the federal inspector or the official veterinarian, in a way to assure the destruction of the viruses of Newcastle disease and avian influenza.

2.1.4. Destruction of the meat of all poultry originated from the farm and sacrificed during the period of the incubation of the disease;

2.1.5. Destruction of the eggs and sub products that were produced during the probable period of disease incubation;

2.1.6. Cleanup and complete disinfection of the breeding nuclei;

2.1.7. Establish the downtime of at least 21 (twenty one) days before reintroducing poultry into the poultry holding, initiated after the disinfection process is complete;

2.1.8. The measures for the epidemiological evaluation and health risk may be applied at other poultry holdings if instructed to do so by the official service;

2.1.9. The official service will proceed with the epidemiological investigation at all properties with poultry, poultry holdings and other lodging locations, protection zone, constituted in a 3 (three) km radius and a 7 (seven) km radius around the outbreak, from the protection zone (surveillance zone), determined with basis on fact of geographical, administrative, ecological and epizootiological origin related to the disease, registering all visits and stated occurrences;

2.1.10. The official service will establish the prohibition of transit and taking the poultry off the poultry holdings, within the surveillance zone, for the minimum period of 21 (twenty one) days, except for those for sanitary slaughter, preferably at slaughterhouses with the SIF, located within the surveillance zone, designated and supervised by the federal inspector or official veterinarian.

3. The location in which the abducted material is located will be cleaned and disinfected, and products and sub products will be destroyed.

4. PROTECTION ZONE:

4.1.Measures must be adopted regarding the protection zone, as follows:

4.1.1. Immediate visit by the official service and future monitoring of all properties with poultry, poultry holdings and poultry lodging locations, performing clinical evaluation on the lodged birds, and collection of samples for laboratory examinations, registering all visits and occurrences;

4.1.2. Maintenance of all poultry in their lodge or any other location that allows isolation, at the choice of the official service;

4.1.3. Utilization of appropriate disinfection systems according to the criterions of the official service at port of entries and exits of the property or poultry holding;

4.1.4. The official service will proceed with the transit control within this zone, of people, of material, equipment and vehicles that represent a health risk;

4.1.5. The official service will prohibit the

transit and removal of poultry, eggs, manure, feed, sub products of poultry, fomites of the property or of the poultry holding in which they are found, except with the authorization of the official service in charge of transportation, in the following conditions:

4.1.5.1. Poultry for slaughter ,preferably at a slaughterhouse with the SIF, located at the infected area or, if that is not possible it must be performed at an evaluated location, designated and supervised by the federal inspector or by the official veterinarian;

4.1.5.2. Day-old birds or birds for a property located inside the surveillance zone and which does not contain other lodged birds;

4.1.5.3. The eggs for hatching and for birth in a hatchery within the protection or surveillance zones previously designated by the federal inspector or by the official veterinarian, controlled and performed in separate machines.

4.1.5.3.1. The eggs and their packages must be disinfected before transferring them to the hatchery.

4.1.6. The previously mentioned movements must be performed directly under the control of the official service and authorized after the health inspection on the property or poultry holding, performed by a federal inspector or by an official veterinarian;

4.1.7. The means of transportation being applied must be cleaned and disinfected before and after its usage;

4.1.8. The poultry manure withdrawn from the feed and the poultry sub products is subject to the control by the official service as to transportation and destination, after substantial evaluation, and is no longer represents a dissemination risk of the disease(s);

4.1.9. The official service will prohibit fairs, markets, exhibitions and any other poultry gatherings;

4.1.10. The official service will proceed with the introduction of sentinel poultry onto the depopulated outbreak property;

4.1.11. The official service will establish the serological control at official or MAPA accredited laboratories for this matter, every seven days on sentinel poultry until the period of downtime is complete, with the minimum of 21 (twenty one) days;

4.1.12. The measures applied in the zone of protection will be kept until the laboratory diagnosis is concluded, and the epidemiological investigation, for at least 21 (twenty one) days after the result, at the infected property or poultry holding, of the preliminary cleaning and disinfecting operations, or by determination of the official service. After these measures, the protection zone will then be part of the surveillance zone.

5.SURVEILLANCE ZONE:

5.1.Measures must be adopted regarding the surveillance zone, as follows:

5.1.1. Investigation on all properties with poultry, poultry holdings and poultry lodging locations, in a 10 (ten) km radius, registering all visits and occurrences;

5.1.2. Prohibition by the official service of poultry and egg movement within the zone, in the first 15 (fifteen) days;

5.1.3. Maintenance of all poultry in their lodges or any other location that allows isolation, at the choice of the official service;

5.1.4. Prohibition by the official service of the movement and removal of poultry from the property or poultry holding within the surveillance zone, except the ones intended for slaughter, preferably at a slaughterhouse with SIF, located within the surveillance zone or nearby, analyzed and designated by the federal inspector or by the official veterinarian;

5.1.5. Prohibition by the official service to remove eggs from the surveillance zone, except if sent to a hatchery for incubation and birth, evaluated and designated by the federal inspector or by the official veterinarian, with controlled incubation and performed in separate machines;

5.1.5.1.The eggs and their packages must be disinfected before transferring them to the hatchery.

5.1.6. Prohibition for removing and using the manure, feed and poultry sub products without an authorization of the official service;

5.1.7. The official service will prohibit fairs, markets, exhibitions and any other poultry gatherings;

5.1.8. The official service will proceed with the transit control within this zone, of people, of material, equipment and vehicles

that represent a health risk;

5.2. The measure applied to the surveillance zone will be maintained until the conclusion of the laboratory diagnosis and of the epidemiological investigation for at least 30 (thirty) days, determined by the official service, after preliminary cleaning and disinfection operations of the infected holding;.

6. The operations described in this chapter may circumscribe the areas of the establishment which create an epidemiological unit; as long as the official service guarantees that the disease(s) will not spread to the other non infected units.

CHAPTER VIII

COLLECTING SAMPLES AND FORWARDING THEM FOR LABORATORY TESTING

1. Location and events where the collection of the material is performed:

1.1. Of poultry originated from any country, at the port of entry (port, airport or border), in quarantine, at the time of the veterinary inspection for the entry discharge;

1.2. In suspiscion of an outbreak by the official service;

1.3. Performing the study project of virus activity, with focus on applying the free zone for the Newcastle disease within the area of industry production in the country, and surveillance for the Newcastle disease and avian influenza, for the monitoring of domestic flocks by the official service of animal health and inspection, within the areas of competence.

2. Samples

2.1. For isolation and identification of the virus, samples must be collected from live poultry after the necropsy of the sacrificed poultry, or of the ones which died with clinical symptoms suggesting the Newcastle disease or avian influenza.

2.1.1. Live poultry:

2.1.1.1. Serum;

2.1.1.2. Cloacal swab:

2.1.1.3. Tracheal swab:

2.1.1.4. Fresh feces.

2.1.2. Necropsy poultry (collect aseptically, isolated or in “pool”):

2.1.2.1. Spleen;

2.1.2.2. Brain;

2.1.2.3. Heart;

2.1.2.4. Faeces;

2.1.2.5. Liver;

2.1.2.6. Aqueous humour;

2.1.2.7. Bowel;

2.1.2.8. Proventriculus;

2.1.2.9. Lung / trachea;

2.1.2.10. Air sacs;

2.1.2.11. Oronasal swab;

2.1.2.12. Cecal tonsils.

2.2. In a suspected case, focusing on reducing the risk of dissemination and diffusion of the virus(es) of the disease(s) during the transportation to the laboratory, it is recommended to perform the necropsy at the location, with collection of the material and adequate storage to be sent to an official laboratory, or to a laboratory designated by the MAPA.

3. Collection and storage of samples

3.1. They must be collected in PBS, pH 7.2, containing antibiotics in the concentrations of:

ANTIBIOTICS (p/ml of PBS)	SAMPLE			
	SWABS		FAECES	ORGANS
	Trachea	Cloacal		
Penicillin	2000 IU	10000 IU	10000 IU	2000 IU
Etreptomycin	2 mg	10 mg	10 mg	2 mg
Gentamicin	50 µg	250 µg	250 µg	50 µg
Fungizone	1000 IU	5000 IU	5000 IU	1000 IU

3.2. Properly identified, refrigerated, sealed and stored in isothermal boxes;

3.3. Forwarded with FORM IN or a standard DDA collection form, properly filled out;

3.4. They will be registered at official or MAPA accredited laboratories for this matter, on a proper book, according to the model indicated by the CLA/DDA/SDA/MAPA;

3.5. When being sent to the serology, they must be refrigerated or preferably frozen. Blood samples with signs of clots will not be accepted;

3.6. When received, they must be divided in 2 (two) pieces and identified, one as sample and the other as confirmaton sample;

3.7. The identification tag of the confirmaton sample, according to the model indicated by the CLA/DDA/SDA/MAPA, will be fill out and sealed along with the confirmaton samples; the seal will be of plastic material, numbered and secured.

3.8. On the specific cases of study project of the virus activity of the Newcastle disease and of surveillance of the Newcastle disease and avian influenza, items 3.6 and 3.7 are not applied.

4. Conservation and stocking

4.1. The samples that are intended for the virological exams must be kept under refrigeration, preferably frozen until its processing.

4.2. The samples intended for the serology must be kept frozen at –20ºC, until its processing.

4.3. After the result has been issued, the samples must be kept frozen at –20ºC, for at least 30 (thirty) days.

CHAPTER IX

LABORATORY DIAGNOSIS

1. The laboratory procedures and exams for the diagnosis of the Newcastle disease and avian influenza, are determined by strict rules of the SDA/MAPA, with the possibility of performing the following exams:

1.1. Enzyme Linked Immunosorbent Assay (ELISA);

1.2. Hemagglutination test (HA);

1.2. Hemagglutination inhibition test (HI);

1.3. Estimated time for the death of the embryo (TMM);

1.4. Intracerebral pathogenicity index (ICPI);

1.5. Intravenous pathogenicity index (IVPI);

1.6. Agar gel Immunodifusion (AGID);

1.7. Molecular biology techniques.

2. Other exams will only be considered when approved by the PNSA/CPS/DDA/SDA.

3. Only laboratory exams related to the diagnosis of the diseases standardized by the MAPA will be accepted, performed at official or MAPA accredited laboratories for this matter, and confirmed by the Laboratory of National Reference.

4. All professionals and laboratories performing diagnosis on aviary diseases are obligated to immediately notify the suspiscion or occurrences of the Newcastle diseases and avian influenza.

5. All the material for laboratory examinations must be sent along with the FORM IN or by a standard DDA/SDA/MAPA collection form, fill out correctly, signed by the federal inspector or by the official veterinarian, or even by the person responsible for the collection endorsed by the official service.

5.1. At the port of entry, the standard MAPA material importation form will be used.

5.2. During the study project of viral activity of the Newcastle disease, and the surveillance of the Newcastle disease and avian influenza, a standard DDA/SDA/MAPA collection form will be used.

5.3. In the case of probable signs as to an outbreak, the FORM IN will be used.

CHAPTER X

THE FORWARDING OF LABORATORY RESULTS

1. The laboratory test results must be issued on a standard MAPA form, and communications according to the flowchart established:

1.1.Negative result: send FAX or other type of immediate notification to the DDA/SDA/MAPA, and to the SSA/DFA/MAPA of the state in which the establishment is located;

1.2.Positive result: send FAX or other type of immediatre notification to the DDA/SDA/MAPA, which will notify the SSA/DFA/MAPA.

CHAPTER XI

THE STUDY FOR VIRUS ACTIVITY OF THE NEWCASTLE DISEASE AND SURVEILLANCE FOR THE NEWCASTLE DISEASE AND AVIAN INFLUENZA

1. Prophylactic activities will be performed, with focus on controlling entries of possible exotic disease agents into domestic territory such as avian influenza, during the permanent epidemiological and health surveillance of the Newcastle disease:

1.1. During the unloading process at the port of entry, during the health inspection of the genetic material (of poultry or hatching eggs), by the airport surveillance service (SVA/DFA/MAPA);

1.2. During the official quarantine or the incubation of the hatching eggs, by the official service.

2. The material collected from the day-old bird, hatching eggs or cloacal and tracheal swabs from any country, will be forwarded to an official laboratory in a package sealed by the MAPA, to perform the laboratory examinations and identify the disease agents, along with the standard collection form.

3. The study project of virus activity for the Newcastle disease, and the surveillance for the Newcastle disease and avian influenza, for the monitoring of the domestic avian flocks throughout different states will be introduced by the DDA/SDA/MAPA, observing the status of epidemiological diseases, considering the exotic disease status for avian influenza at industrial Brazilian flocks:

3.1. Initially it will be applied in the production area, with the possibility of being applied to other production systems according to the project evaluation, and by the determination of the DDA/SDA/MAPA.

3.2. The states participating in the project will be defined by the DDA/SDA/MAPA.

3.3. The periodic collections of blood serum, tracheal and cloacal swabs form the poultry of the same batch at slaughterhouses with SIF, with the possibility of collections at poultry holdings determined by the PNSA/CPS/DDA/SDA/MAPA, according to this project.

3.4. The laboratory exams performed will be serological, isolation and virus characterization tests;

3.5. The activities regarding samples collection may be performed by the SSA, SIF of the DFA/MAPA, or by the State Departments of Agriculture, or by the ones responsible for these activities, when this activity is authorized in agreement with this project.

3.6. The serological exams in this project will be defined in the scope of the DDA/SDA/MAPA, as per the correlation between them.

3.7. The collections for monitoring and for diagnosis, will only be accepted when performed by the federal inspector or by an official veterinarian, or under their supervision.

3.8. The sampling, period of collection, serological tests, the analyses criterions related to vaccinated and non-vaccinated poultry and the interpretation of the results will be defined in the referred project.

4. The laboratory exams will be performed by the MAPA official laboratory, of national reference to these diseases, and may be performed at federal or state institution laboratories, or when authorized by the CLA/DDA/SDA/MAPA.

5. The epidemiological analysis will be performed according to the information established by the DDA/SDA/MAPA.

6. The result evaluations will be nationally performed at the DDA/SDA/MAPA.

CHAPTER XII

CLEANING AND DISINFECTING MEASURES

1. The cleaning and disinfecting measures used for the control of outbreaks, will proceed with the criterions established on the OIE manual, and in specific manuals of the PNSA/CPS/DDA/SDA/MAPA.

CHAPTER XIII

VACCINATION

1. Systematic vaccination against Newcastle disease is optional throughout the states, as per the local epidemiological status.

2. According to the epidemiological status of each region, after evaluation by the official service, poultry vaccination against Newcastle disease may be enforced on properties and permanently or eventually controlled poultry holdings, or also performed regularly.

3. It is responsibility of the official service during emergency situations to establish vaccination schedules per area.

4. Vaccination against these diseases will only be performed with registered and MAPA approved vaccines (Decree No.1.662, of October 6, 1995, and Ministerial Administrative Ruling No.186, of May 13, 1997), as a measure of prophylactic order or control of the disease.

5. In the case of avian influenza, since it is considered an exotic disease in the country, vaccination can only be performed when authorized by the DDA/SDA after confirmation of the disease, risk evaluation and analysis of the epidemiological status.

CHAPTER XIV

TRANSIT

1. With intensions of avoiding the introduction and the spreading of these diseases, at the time of issuing the GTA for susceptible poultry, or for interstate transit of poultry for slaughter at slaughterhouses, must be demanded by the issuer, among others, the following conditions:

1.1. At poultry holdings providers for international market:

1.2. Birds must be from a property or poultry holding which have not had any signs of infection of Newcastle disease and avian influenza for the last 90 (ninety) days, and that the surroundings within a 10 (ten) km radius, has not been infected by these diseases in the past 30 (thirty) days;

1.3. Based on local epidemiological situation and Chapter XIII of this rule, the requirements for transit of susceptible poultry in locations considered of risk, must prove that they were not vaccinated against the Newcastle disease for at least 30 (thirty) days prior to the slaughter.

2. Poultry will be prohibited for transit when unaccompanied of the GTA, issued as per these rules, the responsible authority must fill in the Term of Incident, and determine the return to the origin, without prejudice to the appropriate sanctions.

3. To perform interstate transit, it is demanded that the GTA be used. For intrastate transit, it is demanded that the GTA be used, being able to be used in exceptional cases that are justified, to the acceptance of the similar transit document established in the state scope.

4. The vehicles for the transportation of susceptible poultry must be washed and disinfected according to the orientation of the official service.

5. The transportation of poultry residues, sub products must be done in vehicles that are protected or closed.

CHAPTER XV

INCUBATION CONTROL

1. Biosafety measures on the incubation, when determined by the official service:

1.1. The egg incubation must meet to carry out the provisions in Chapter VII, of this term, respecting the natural agreements in the control of the protection and surveillance zones;

It is forbidden to incubate hatching eggs from great grandparent, grandparent and parent hatchers, and in the same period, meeting all health criterions of the superior breed.

CHAPTER XVI

GENERAL DISPOSITIONS

The SSA/DFA/MAPA of the State in which the poultry holding is located, and the State Departments of Agriculture, are the responsible and competent offices for defining appropriate measures for handling health issues, as per the established in the Animal Health Protection Regulation and in the PNSA.

2. In consideration to the characteristics of a health emergency in the occurrence of

an outbreak of Newcastle disease or avian influenza, and the need of the official service to apply measures of immediate eradication, the establishments that produce poultry free of specific pathogens (SPF), must provide 10 birds to be used as sentinel upon official solicitation, for evaluation and closure of the outbreak .

3. Since the avian influenza is considered an exotic disease in the industrial domestic avian flock, they must be observed, investigated and evaluated at a laboratory, and epidemiologically by the official service, additionally as described in item 2, of Chapter II, in these rules, for the following situations:

3.1. Any influenza virus that is lethal to 6,7 and 8 susceptible 4-6 week old birds, 10 days after intravenous inoculation with 0,2 ml of corneaallantoids liquid diluted at 1:10, bacteria free;

3.2. Any H5 or H7 influenza virus that does not meet the criterion of the previous item, however that has a sequence of amino acids (in the cleavage site of the hemagglutinin), that is compatible with the highly pathogenicity influenza virus;

3.3 Any influenza virus that is not H5 or H7, that kills 1 to 5 times (pathogenicity), and grows in a cell culture in the absence of trypsin.

3.4. After careful evaluation by the official service and by the PNSA/CPS/DDA/SDA/MAPA, health measures that are relevant to the case will be applied.

4. The omissive cases and the questions created in the application of this rule, and in complementary acts will be voided by the DDA/SDA/MAPA.

NORMATIVE INSTRUCTION No.44 OF AUGUST 23, 2001

Published in the Official Gazette of August 28, 2001, Section 1, Page 68

Approves the Technical Rules for the Control and the Certification of Aviary Centers and Establishment for the Aviary Mycoplasmosis (*Mycoplasma gallisepticum*, *synoviae* and *melleagridis*).

THE SECRETARY OF ANIMAL AND PLANT HEALTH AND INSPECTION OF THE MINISTRY OF LIVESTOCK AND FOOD SUPPLY, using the powers invested in him in article 83, clause IV, of the Internal Regulation of the Secretariat, approved by Ministerial Administrative Ruling Nº.574, of December 8, 1998, in consideration and in light of the provisions of the Ministerial Administrative Ruling No.193, of September 19, 1994, and in File MA 21000.005233/2001-68, decide:

Art. 1. To approve the Technical Rules for the Control and the Certification of Aviary Centers and Establishment for the Aviary Mycoplasmosis (*Mycoplasma gallisepticum*, *synoviae* and *melleagridis*), according to the ANNEX of this Normative Instruction.

Art. 2. Revoke the SDA Normative Instruction Nº.13, of June 29, 1999.

Art. 3. This Normative Instruction will be in effect on the date of its publication.

LUIZ CARLOS DE OLIVEIRA

TECHNICAL RULES FOR THE CONTROL AND CERTIFICATION OF AVIARY CENTERS AND ESTABLISHMENTS FOR AVIARY MYCOPLASMOSIS (*Mycoplasma gallisepticum, synoviae* and *melleagridis*).

CHAPTER I

INTRODUCTION

1. These rules define the measures of monitoring salmonellosis in poultry holdings permanently and eventually controlled (except layers, poultry for slaughter and ratites), that perform the commercial, or domestic and international transference of derived products, intended for breeding and for the production of poultry and hatching eggs, having to perform monitoring of their plants, obeying the directions of the National Avian Health Program (PNSA).

2. To operate in the international market, the poultry holding must be certified as free for aviary mycoplasmosis (*Mycoplasma gallisepticum, Mycoplasma synoviae* and *Mycoplasma melleagridis*), as established in Chapter IV of this ANNEX.

3. The importing businesses or purchasers of genetic material of pure breeds, great grandparents and grandparents, must present the guarantee or certification as to free of the constant mycoplasmas in these rules.

CHAPTER II

DEFINITIONS

1. For the purpose of these rules, it is understood:

1.1. Batch: group of poultry for the same purpose, origin and age, lodged in one or many barns.

1.2. Boxes: are physical sections divided inside a barn.

1.3. Barn: is the aviary production unit, characterized as the unit of a center, which lodges a group of breeders, poultry for slaughter or commercial laying hens, of the same age (with exception of pure breeds, genetically selected), and of the same breed.

1.4. Commercial poultry: generation of poultry meant for slaughter and/or egg production for consumption.

1.5. Center of breeding: is the unit with an area adequately isolated, of common handling, constituted of one or more barns.

1.6. Poultry holding: is the location where poultry is kept for any purpose, which may be constituted of one or more centers.

1.6.1. Poultry holding Permanently Controlled: they are the farms, genetically selected, of primary breeders (pure breeds), great grandparent farms, grandparent farms, parents farms, breeding poultry free of specific pathogens (SPF) farms, and the hatcheries of these establishments.

1.6.2. Poultry holdings controlled eventually: they are the poultry holdings producing commercial eggs, poultry for slaughter, exploring other wild birds, or ornamental, and/or exotic, and the hatcheries of these establishments.

1.7. Official service: Federal, State, and Municipal Animal Health and Inspection Service.

1.8. Official laboratories: are the laboratories of the Ministry of Agriculture, Livestock and Food Supply (MAPA).

1.9. Accredited laboratories: federal, state, municipal or private laboratory units, qualified and recognized by the MAPA, to perform laboratory diagnosis of disease agents to which these rules refer to.

1.10. Federal Inspector or Official Veterinarian: professional veterinarian of the Federal Public Service, who performs activites of Animal Health and Inspection.

1.11. Official Veterinarian: Federal Inspector or Veterinarian of the Federal Public Service.

1.12. Official Veterinarian for Certification: Federal Inspector or Official Veterinarian of the Animal Health and Inspection Service.

1.13. Official Accredited Veterinarian: Veterinarian of the state, district, private sector or

independent professional, with authorization of jurisdiction of the federal official service , to issue the Animal Movement Permit – GTA.

1.14. Responsible Technician: Veterinarian responsible for the sanitary control of the flocks of the aviary centers or premises.

1.15. Monitoring of Flocks: is the sanitary supervision of the serological tests and of other biological exams, as well as the epidemiological analysis related to the health conditions of the birds lodged at an aviary center or premises.

1.16. MAPA : Ministry of Agriculture, Livestock and Food Supply

1.17. SDA : Animal and Plant Health and Inspection Secretariat

1.18. DDA : Animal Health and Inspection Department

1.19. CLA : Animal Laboratory Coordination Unit

1.20. PNSA : National Avian Health Program

1.21. DIPOA : Department of Inspection of Animal Origin Products.

1.22. DFA : Federal Agricultural Delegacy

1.23. SSA : Animal Health Service

1.24. SIF : Federal Inspection Service.

CHAPTER III

DEMANDS

1. To attend to the PNSA, poultry holdings of permanent and eventual controls must:

1.1. Acquire registry and licensing at the DFA of the jurisdiction.

1.2. Be under the suveillance and control of the local Animal Health Service of the DFA or of the State Secretariat of Agriculture.

1.3. Be supervised by the technician in charge, registered at the Federal Agriculture Delegacy of the State.

2. The poultry holding with participation of the PNSA will not be able to use:

2.1. any vaccine for aviary mycoplasmosis at permanently controlled premises.

2.2. any vaccine prepared with oily adjuvant during the four weeks prior to the laboratory tests;

2.3. any drug scientifically proven to interfere in the results of serological tests, and/or interfere with the isolation of the salmonellas in a period of three weeks prior to the tests;

2.4. the exceptional cases must be evaluated by the DDA/SDA, as long as it is presented and approved by a specific technical-scientific project.

3. Only antigen, control serums and "kits" approved by the MAPA, can be used, as per the expiration date.

4. Other laboratory tests will only be able to be used when properly approved by the PNSA.

5. The poultry holding must provide monthly a calendar of samplings, which will be forwarded to the DFA of the State where it is located, along with the schedules of birth, importation and dates of routine sample collection performed by the technician in charge, focusing on the inspection and the supervision of the official service.

CHAPTER IV

CERTIFICATION

1. Certification for the pure line, great grandparent and gradparent breeders centers or establishments .

1.1. Free of *Mycoplasma gallisepticum* and *Mycoplasma synoviae* for chicken.

1.2. Free of *Mycoplasma gallisepticum*, *Mycoplasma synoviae* and *Mycoplasma melleagridis* for turkey.

2. Certification of the centers (parent breeders establishments).

2.1. Free of *Mycoplasma gallisepticum* for chicken.

2.2. Free of *Mycoplasma gallisepticum*, *Mycoplasma synoviae* and *Mycoplasma melleagridis* for turkey.

2.3. Under supervision and monitoring of *Mycoplasma synoviae* for chicken.

CHAPTER V

LABORATORY TESTS

1. The tests used for laboratory monitoring and diagnostic in the different stages of the process are:

1.1. Immunological diagnosis:

1.1.1. Slow Serum Agglutination (SSA), or yolk from embryonated eggs.

1.1.2. animal health and inspection.

1.1.3. Hemagglutination Inhibition, (HI).

1.1.4. Enzyme Linked Immunosorbent Assay (ELISA)

1.2 Mycoplasmalogic diagnosis:

1.2.1. Isolation in culture medium.

1.2.2. Polymerase Chain Reaction (PCR).

1.3. Identificaton of culture:

1.3.1. Indirect fluorescent antibody (IFA).

1.3.2. Direct fluorescent antibody (DFA).

1.3.3. Metabolism inhibition (MI).

1.3.4. Growth inhibition (GI)

1.3.5. Polymerase Chain Reaction (PCR).

2. The completion and interpretation of the tests mentioned above, will obey the criterions established in specific technical rules and regulations of the MAPA.

3. The laboratory exams will only be accepted when performed at an official laboratory, and/or accredited by the MAPA, identifying the antigen, the lot number, and the amount used.

4. Other laboratory exams may be used as long as they are approved by the DDA/SDA/MAPA.

CHAPTER VI

COLLECTION OF SAMPLES

1. The collection of samples for official monitoring will only be accepted when performed by a federal inspector, an official veterinarian, or under the supervision of one of them.

2. To receive certification, the samples will be analyzed by the SSA/DFA of the State in which the establishment is located, the samplings will be forwarded by the company technician in charge before the MAPA, and/or the random collection performed by the official service.

3. All material forwarded for laboratory testining must officially be forwarded with the standard DDA/SDA collection form, filled out correctly and signed by the technician in charge before the MAPA, by the federal inspector, or by the official veterinarian.

4. The official sampling must be performed randomly among the barns in the same center for serological tests, biological exams on SPF poultry, on embryonated eggs, or on mycoplasmologic exams.

5. With the focus on monitoring the health status, certification maintenance and of regular samplings at pure breed premises, great grandparent and grandparent hatcheries, this stage must be performed directly by the federal inspector, or by the official veterinarian, by random double sample collections, at least once a year, being later forwarded for analysis at official or accredited laboratories.

6. DFA's criteria as to the Animal Health Service, and/or of the State Secretariat of Agriculture, of the State in which the poultry holding is located in, at any time and in the presence of the federal inspector, or of an official veterinarian, random double samplings may be collected to be submitted for laboratory exams, respecting the criterions and rules of biosafety, at official or MAPA accredited laboratories.

7. Material collected for official monitoring can be sent to any MAPA accredited laboratory for this matter, chosen by the federal inspector, or by the official veterinarian responsible for the collection. .

8. MAPA will establish a system for the random selection of samples and of official and accredited laboratories, which will be supervised by a federal inspector or by an official veterinarian responsible for the collection.

9. The costs of official collections and of the shipping of this material to be analyzed by accredited laboratories will be at the expense of the requesting company.

10. All the material officially collected must be sealed and sent along with a standard DDA/SDA form.

11. Random samplings performed by the official service may or not meet companies' schedules, of which a federal inspector or an official veterinarian are responsible for, and also responsible for collecting or supervising the process, and for securing the material, being of responsibility of the company to provide the necessary means

and materials for this operation.

12. The same criterions used for parent hatcheries will be applied for ornamental and wild poultry.

CHAPTER VII

PERFORMING LABORATORY TESTS

1. The procedure of laboratory tests per batch for the Certification of aviary centers or establishment free of Mycoplasma gallisepticum and Mycoplasma synoviae for chickens, and *Mycoplasma gallisepticum, Mycoplasma synoviae* and *Mycoplasma melleagridis* for turkeys, in light of the provisions in Chapter IV, will be composed of:

1.1. Poultry or hatching eggss from breeding and commercial breeding stock for restocking imported aviary flocks:

1.1.1. The sample collection will be performed on arrival, and the laboratory tests performed as set forth to the specific rules for poultry and hatching eggss importation and exportation, intended for restocking aviary flocks.

1.1.1.1. When dealing with live or dead poultry, serological and/or mycoplasmologic techniques will be used depending on the case.

1.1.1.2. When dealing with eggs, yolk agglutination from embryonated eggs and mycoplasmologic exams may be used,

1.1.2. The poultry produced from pure breeds, and great grandparents in Brazil, will follow the same procedure mentioned in item 1.1.1., having its first collection performed in the hatcheries at the moment of birth, by the SSA/DFA in the State where it is located, and sent to the official laboratory.

1.2. Health monitoring of aviary flocks

1.2.1. On 12 (twelve) week old breeding stocks:

1.2.1.1. On chickens and turkeys: RSA of at least three hundred samples for *Mycoplasma gallisepticum* and one hundred samples for *Mycoplasma synoviae*, selected randomly, with the presentation of each barn, and/or box per each supplemented center, when concerning reagents with HI or ELISA.

1.2.2. On breeding stocks at the beginning of production, with posture of about 5%:

1.2.2.1. RSA on one hundred and fifty samples per center, for *Mycoplasma gallisepticum* and one hundred for *Mycoplasma synoviae* for chicken.

1.2.2.2. RSA on one hundred and fifty samples per center, for *Mycoplasma gallisepticum* and *Mycoplasma melleagridis* and one hundred for *Mycoplasma synoviae* for turkeys.

1.2.2.3. When result positive on HI or ELISA, collect tracheal swabs from twenty birds for confirmation per cultivation and/or PCR at accredited or official laboratory, chosen by the official animal health and inspection service.

1.2.3. Establishment permanently controlled (periodic control every three months).

1.2.3.1. RSA on ine hundred and fifty samples per aviary center, randomly selected and with the presentation of each barn and/or box from the center, for *Mycoplasma gallisepticum* and *Mycoplasma melleagridis*, the last one excusively for turkeys, and one hundred samples for *Mycoplasma synoviae*, supplementary when as reagents, with HI and ELISA. The tests must be permanently until it is totally eliminated from the batch, allowing a variation of up to two weeks during the intervals, to confortably adapt blood collecting to other handling procedures.

1.2.3.2. When tested positive for HI or ELISA, collect tracheal swabs and serum from twenty birds for confirmation per cultivation and/or PCR at accredited or official laboratory, chosen by the official service.

1.2.4. Establishment eventually controlled, except commercial poultry, chicken for slaughter (periodic control every three months):

1.2.4.1. RSA per center of one hundred and fifty serum samples from poultry randomly selected and with presentation of each barn and/or box of the center for M*ycoplasma gallisepticum* and *Mycoplasma melleagridis*, according to Chapter IV of this rule, and one hundred samples for *Mycoplasma synoviae*, confirmed by HI and ELISA when positive results were observed at RSA, and repeated every three months until full elimination from the batch, allowing a variation of about two weeks to comfortably adapt the blood collection to other handling procedures.

1.2.4.2. On breeding stocks, where there is

no possibility of using swabs, proceed to randomly collect from three birds within every thousand, as long as the minimum is ten and the maximum of twenty per center.

2. On other breeding stocks, the recommended laboratory test is mycoplasmologic technique.

3. In cases of death during the first days of the batch, the poultry holding must forward material from thirty rejected or agonizing birds to a official or MAPA accredited laboratory for isolation of mycoplasmas or PCR.

CHAPTER VIII

INTEPRETATION OF THE RESULTS AND ADOPTION OF BIOSECURITY AND SANITARY MEASURES

1. On poultry or hatching eggss from pure breeds, imported great grandparent and grandparent breeders born in Brazil:

1.1. Positive for *Mycoplasma gallisepticum*, *Mycoplasma synoviae*, sacrifice and destruction/ sanitary slaughter of the center.

1.2. Positive for *Mycoplasma gallisepticum, Mycoplasma synoviae*, *Mycoplasma melleagridis*, exclusive for turkeys, according to Chapter IV of this rule, sacrifice and destruction/sanitary slaughter at the center.

2. Parent Breeders:

2.1. If tested positive for *Mycoplasma gallisepticum* on chickens or *Mycoplasma gallisepticum, Mycoplasma synoviae* or *Mycoplasma melleagridis* on turkeys, there will be sacrifice and slaughter of all center, and the extinguishing of all eggs, hatched or not, originated there, according to Chapter IV of his rule.

2.1.1. Until receiving the results from the tests above, all the batches or centers will be isolated, also prohibited for incubation.

2.2. Two evaluations should be used, considering the free centers or under surveillance, and monitoring for Mycoplasma synoviae.

2.2.1. If tested positive for *Mycoplasma synoviae* on chickens, these centers may be treated with antibiotics and retested after the antibiotic residue is eliminated from the system.

2.2.2. The centers considered under surveillance and inspected for *Mycoplasma synoviae* cannot be commercialized internationally, maintaining production and incubation of the center under surveillance and supervision until the final productive cycle.

2.2.3. The establishment considered under surveillance and control must reinforce measures of biosafety such as:

2.2.3.1. To be protected by security fences with one access only, with a wash and disinfecting system for vehicles.

2.2.3.2. To have available criterions for the strict transit control, and of access to people (gates, doors, receptions, concrete walls and other).

2.2.3.3. To have internal surfaces set up in a way that allows adequate cleaning and disinfection;

2.2.3.4. To dispose of ways legally approved by the MAPA, and by the departments of environmental control, for the destination of production residues (dead poultry, manure, egg remains, packaging, etc.) and others;

2.2.3.5. to isolate different age categories, by fencing and /or by f non fruit-trees, with a restricted single access, controlled flow, measures of biosecurity for the internal area, for vehicles, personnel and material;

2.2.3.6. To allow the entrance of people, vehicles, equipment and material in the internal areas of the property, only when strict biosecurity measures are complied;

2.2.3.7. Must apply control measures of liquid effluents, by means of septic tanks, observing the distance of the water paths and groundwater, to avoid contaminations.

2.2.3.8. Physical-chemical and microbiological water control, performed at a public laboratory.

CHAPTER IX

FORWARDING RESULTS

1. The laboratory test results must be issued on a standard form, and communicated according to the flowchart established:

1.1. Negative result: send FAX or use other means for the immediate communication

to the requesting official veterinarian, and to the poultry holdings.

1.2. Positive result: send FAX or other type of immediate documentation to the DDA and to the SSA/DFA, where the establishment is located, who will notify it.

CHAPTER X

CERTIFICATION OF PREMISES

1. When the result from the laboratory tests referred in Chapter V of these rules test negative, the official service may proceed with the certification of the aviary center and/or premises, as established in Chapter IV.

2. The samplings for the monitoring and certification will be accepted when performed by the technician in charge before the MAPA and by the official service, being that the samplings are exclusively performed by the federal inspector, or by the official veterinarian, or inspected and supervised by one of them.

3. Even after having complied with all previous requirements, in cases of death during the first days of the batch, the poultry holding must forward material from thirty rejected or agonizing birds to a official or accredited laboratory for isolation of mycoplasmas or PCR. If the diagnosis is confirmed, the poultry from the center will be sanitary slaughtered, when dealing with pure breeds, great granparent and grandparent breeders, followed by an epidemiological investigation by the official service.

4. For parent breeders, the treatment will be accepted and retested when positive for *Mycoplasma synoviae*.

5. The poultry holding being certified as a free aviary center will only be authorized to commercialize poultry or hatching eggs from this center. The poultry holding that receives the certificate as a free establishment will be able to proceed with the commercialization of poultry and/or hatching eggs from all the centers.

6. The poultry holding that is under surveillance and supervision for Mycoplasma synoviae cannot commercialize its products internationally (hatching eggs and chicks from the referred center).

7. The MAPA standard Health Certificate will be issued by the DFA of the State of the poultry holding after performing the minimum of three tests, to the establishment or centers free or under surveillance and supervision for the agents treated in this rule.

8. This certificate will have its validity subject to performing the maintenance regarding the health issue of the aviary center or establishment.

9. If the flock's health situation is altered, the certificate will be revoked, with the option of reinstating the certificate after the evaluation of the SSA/DFA, and/or of the State Secretariat of Agriculture of the state in which the poultry holding is located.

CHAPTER XI

GENERAL TERMS

1. The serological laboratory tests are always screening tests, with the possibility of occurring nonspecific crossed reactions. Therefore, only mycoplasmologic diagnostic is considered conclusive for the detection of the mycoplasmas referred in these rules.

2. If the centers that tested positive for the agents of these rules are to be slaughtered, it should be performed at slaughterhouses with the SIF, according to the rules of the DIPOA.

3. The monitoring of ratites will be performed according to the specific legislation of the MAPA for the hygiene-health registry and control for this species.

4. Biosafety measures for incubation:

4.1. It is prohibited to hatch eggs from pure breeds, great grandparent, grandparent, and parent breeders that are under surveillance and official supervision in the same machine and in the same period, following the criterions of the superior provenance.

4.2. It is prohibited to hatch eggs in the centers that are under surveillance and monitored for *Mycoplasma synoviae* in the same machine, and during the same period in which centers that are free of this agent are hatching.

5. The SSA/DFA at which the poultry holding is located and the proper State Secretariat of Agriculture are responsible, for this field and ju-

risdiction, for the definition of appropriate measures for solving health issues, as established in the Regulation of Animal Health and Inspection and in the PNSA/SDA.

6. The relevant questions as to the application of this normative will explained by the Director of the Animal Health and Inspection Department of the Animal and Plant Health and Inspection Secretariat, of the Ministry of Agriculture, Livestock and Food Supply.

SERVICE INSTRUCTION DDA No. 1 OF DECEMBER 14, 1999

Requirements for the entry of Pet Birds into the National Territory

The Ministry of Agriculture, Livestock, and Food Supply-MAPA's Animal Health Department-DDA, by virtue of the powers vested in it under Art. 2 of Administrative Ruling No. 144 of December 23, 1997, hereby establishes the following:

1. Pet birds, i.e., a maximum of four birds that live with their owners and accompany them on this moving or travel occasion and are destined for residential addresses may enter the national territory, accompanied by an International Zoosanitary Certificate, without an authorization issued in advance by MAPA.

2. The aforementioned International Zoosanitary Certificate should be issued by the sanitary authority of the country of origin, attesting that in the thirty days prior to departure for Brazil, the bird(s):

a) did not have any contact with wild fowls or domestic fowls raised in backyards or at industrial establishments; and

b) has(have) not shown any clinical sign of transmissible diseases.

HAMILTON RICARDO FARIAS

COMPLEMENTARY LEGISLATION

ADMINISTRATIVE RULING No. 126 OF NOVEMBER 3, 1995

Published in the Official Gazette of November 6, 1995 Section 1, Page 17694

Approves the "Norms on Accreditation and Monitoring of Diagnostic Laboratories for Avian Salmonellosis (*S. enteritidis, S. gallinarum, S. pullorum,* and *S. typhimurium*)".

ADMINISTRATIVE RULING No. 208 OF DECEMBER 20, 1994

Published in the Official Gazette of December 26, 1994 Section 1, Page 20510

Approves the "Norms on Accreditation and Monitoring of Diagnostic Laboratories for Avian Mycoplasmoses."

ADMINISTRATIVE RULING No. 182 OF NOVEMBER 08, 1994

Published in the Official Gazette of November 11, 1994 Section 1, Page 17003

Approves the "Norms on Accreditation and Monitoring of Diagnostic Laboratories for Newcastle Disease."

NORMATIVE INSTRUCTION No. 6 OF JUNE 2, 2003

Published in the Official Gazette of June 4, 2003 Section 1, Page 1

Provides for the authorization of importation of avian genetic material by the Ministry of Agriculture, Livestock, and Food Supply-MAPA, which shall comply with the sanitary requirements established under the Regulations of the Animal Health and Inspection Service, as well as taking into account the zootechnical conditions.

NATIONAL AQUATIC ANIMAL HEALTH PROGRAM

ADMINISTRATIVE RULING No. 573 OF JUNE 4, 2003

Published in the Official Gazette of June 5, 2003 Section 1, Page 11

Establishes the National Aquatic Animal Health Program.

THE PRO-TEM MINISTER OF AGRICULTURE AND FOOD SUPPLY, by virtue of the powers vested in him under Art. 87, Sole Paragraph, II of the Constitution; having in view the provisions of the Animal Health Defense Regulations approved under Decree No. 24548 of July 3, 1934, and Proceeding No. 21000.007228/202-71,

RESOLVES:

Art. 1. To establish the National Aquatic Animal Health Program.

Art. 2. To assign to the Agriculture and Livestock Health and Inspection Secretary the task of issuing the Program's Internal Regulations and the requisite instructions for full implementation of the Program's activities.

Art. 3. This Administrative Ruling shall enter into force on the day of its publication.

JOSÉ AMAURI DIMARZIO

NORMATIVE INSTRUCTION No. 18 OF MAY 13, 2008

Published in the Official Gazette of May 14, 2008 Section 1, Page 14

Establishes procedures for the importation of aquatic animals for ornamental purposes and destined for sale

THE MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY'S AGRICULTURE AND LIVESTOCK HEALTH AND INSPECTION SECRETARY, by virtue of the powers vested in him under Arts. 9 and 42, Annex I of Decree No. 5351 of January 21, 2005, having in view the provisions of Decree No. 5741 of March 30, 2006, Decree No. 24548 of July 3, 1934, and Proceeding No. 21000.001351/2008-73,

RESOLVES:

Art. 1. To establish procedures for the importation of aquatic animals for ornamental purposes, destined for sale.

Art. 2. Aquatic animals for ornamental purposes and destined for sale are hereby exempted from compliance with the provisions under Art. 26 of SDA Normative Instruction No. 53 of July 2, 2003.

Sole paragraph. The provisions of this article's heading apply also to the importation of aquatic animals for ornamental purposes, owing to change of domicile.

Art. 3. The importation of crustaceans and live fishes of the Cyprinidae family shall be authorized solely for reproduction purposes pursuant to the provisions under art. 26 of SDA Normative Instruction No. 53 of July 2, 2003.

Art. 4. The importation of aquatic animals for ornamental purposes shall be subject to risk analysis and compliance with the requirements under MAPA's prior authorization.

Art. 5. Aquatic animals for ornamental purposes imported for sale shall be subject to at least seven days of quarantine at establishments accredited for this purpose, as provided under the Annex hereto.

Art. 6. Aquatic animals imported by reason of change of domicile must enter Brazil in the company of their owners, subject to prior authorization and to international zoosanitary certification pursuant to Brazilian requirements.

Paragraph 1. The animals referred in this article's heading shall be subjected to a ninety-day observation period under a veterinarian's supervision at the destination domicile.

Paragraph 2. The owner shall act as depositary, and must submit a health certificate of the animals to the Agricultural and Livestock Health Service of the Federal Agriculture Superintendence-SEDESA's state unit at the expiration of the period.

Art. 7. Suspicion of disease in aquatic animals for ornamental purposes must be notified to the pertinent SEDESA state unit.

Sole Paragraph. Treatment of diseases while the animals are in quarantine or under observation may be allowed, subject to express SEDESA authorization.

Art. 8. This Normative Instruction shall enter into force on the day of its publication.

INÁCIO AFONSO KROETZ

ANNEX

REQUIREMENTS FOR ACCREDITATION OF QUARANTINE ESTABLISHMENTS FOR ORNAMENTAL AQUATIC ANIMALS

CHAPTER I

MINIMUM INFRASTRUCTURE

Art. 1. Quarantine establishments must be physically isolated from other facilities and have covered areas for housing quarantined animals for protection from invader animals.

Art. 2. Existing infrastructure should consist of an internal environment, where animals are to be housed, and an outer environment, where the administrative structure should be located.

Support infrastructure for both internal and outer environments should be built so as to minimize the risks of spreading contamination (administration office, room for cleaning equipment and utensils, laundry room, disposal of solid residues, etc.) and have locker rooms and toilets in both environments.

Art. 3. Facilities and their dependencies should be visibly identified with signs indicating their purpose, so as to allow a logical work flow.

Art. 4. The internal finishing of facilities and reservoirs for housing animals must be of waterproof materials capable of enduring frequent cleaning and disinfection, as well as having efficient drainage for disposal of waste water and dirt.

Art. 5. Water supply must be from a safe source and subjected to treatment to ensure the destruction of pathogenic agents. Water reservoirs should be supplied through a water distribution system.

Art. 6. Drained waste waters should be channeled to a treatment system approved by the Official Veterinary Service and by the environmental agency and sanitation agencies.

Art. 7. The quarantine establishment must have a fumigation or similar system for the disinfection of objects and utensils required by the work, located at the division between the internal and external areas.

Art. 8. Facilities must have wash basins in each dependency where animals are held.

CHAPTER II

STAFF AND PEOPLE TRANSIT CONTROL

Art. 9. The quarantine establishment must operate under a Veterinarian's Technical Responsibility homologated by his Professional Council.

Art. 10. Staff must wash themselves upon entering or leaving the quarantine facilities.

Art. 11. Staff must wear appropriate working clothes, which should be used exclusively at the quarantine facilities.

Art. 12. Visits must be restricted, controlled, and allowed solely with prior authorization by the Technical Person in charge.

Art. 13. Visitors must be entered into a log, and their last visit to an aquatic holding establishment or other risk locations should be recorded.

Art. 14. A minimum period of 48 (forty-eight) hours after a visitor has been near aquatic animals or at risk locations is required for granting him/her authorization to visit the quarantine establishment.

CHAPTER III

CONTROL PROCEDURES AND SANITARY RECORDS

Art. 15. All documents pertaining to the movement of animals, people, and inputs as well as any other quarantine establishment sanitary records must be filed on the premises and remain available to the Official Veterinary Service.

Art. 16. Protocols of procedures followed on the quarantine establishment must be in print and manually organized, describing the management of the animals, disinfections, as well as the physical,

chemical, and biologic treatments dispensed, the products and dosage or concentration employed, and the technical or scientific reference used.

Art. 17. The quarantine establishment shall prepare and adopt zoosanitary reports containing data on the animal stock, deaths, personnel, downtimes and disinfections, monitoring of waters to be utilized, currently used or discarded, documentation on the movements of animals entering or leaving, control of origin, and date of the entry and destination of feed. These reports should be daily updated under the supervision of the Technical Person in charge.

Art. 18. The quarantine establishment must have a log with typographically numbered pages, into which the Technical Person in charge shall enter events of sanitary relevance.

Art. 19. The quarantine establishment shall maintain a program for the control of vermin and rodents and for preventing the presence of any animals other than those under quarantine.

Art. 20. The lots of imported animals should be kept separate in different tanks according to origin and to species, so as to allow isolation, disinfection, and treatment separately.

Art. 21. Each tank should keep current information including tank number and the origin, family, species, and number of individuals it houses, as well as mortality record.

Art. 22. Each tank should have its own utensils routinely used in handling the animals.

Art. 23. Organic residues or waste should be incinerated or subjected to a treatment capable of ensuring the destruction of pathogenic agents.

Art. 24. Inorganic materials should de disinfected and appropriately discarded.

CHAPTER IV

QUARANTINE CONDITIONS AND DISEASE OCCURRENCES

Art. 25. The quarantine period may be extended according to the requirements set forth in the prior import authorization, or to a change in the animals' health condition.

Art. 26. The admission of new lots of animals shall be allowed while quarantine is on, but the quarantine period shall start anew.

Art. 27. At the expiration of the quarantine period, the facilities must be totally vacated and observe a downtime of at least 24 (twenty-four hours) after the completion of cleaning and disinfection.

Art. 28. Expenditures on the forwarding of the official samples and of laboratory tests required for the monitoring of diseases shall be incumbent on the animals' owner.

Art. 29. In case of occurrence of a disease of mandatory notification or of high mortality with no definite cause, all quarantined animals shall be preventatively destroyed and samples shall be collected for investigation.

Art. 30. Any quarantine establishment in noncompliance with the provisions hereunder shall be subject to the following administrative sanctions:

a) temporary disaccreditation; or

b) definitive disaccreditation.

NORMATIVE INSTRUCTION No. 53 OF JULY 2, 2003

Published in the Official Gazette of July 4, 2003 Section 1, Page 2

Approves the Technical Regulations of the National Program on Aquatic Animal Health

THE MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY'S AGRICULTURE AND LIVESTOCK HEALTH AND INSPECTION SECRETARY, by virtue or the powers vested in him under Art. 15, II, a of Decree No. 4629 of March 21, 2003 and Art. 2 of Administrative Ruling No. 573 of June 4, 2003; having in view the provisions under the Animal Health and Inspection's Regulations ap-

proved under Decree no. 24548 of July 3, 1934;

Whereas there is a need to standardize prophylactic actions, diagnostic, and sanitation in aquaculture establishments and to define the role of public animal health defense agencies in jointly combating diseases that affect aquatic animals with breeders, private sector veterinarians, and laboratories outside the Ministry of Agriculture, Livestock, and Food Supply's laboratory network; and in view of Proceeding No. 21000.007229/2002-15,

RESOLVES:

Art. 1. To approve the Technical Regulations of the National Program on Aquatic Animal Health.

Art. 2. To delegate competence to the Animal Health and Inspection Department to issue instructions complementary hereto.

Art. 3. This Normative Instruction shall enter into force on the day of its publication.

MAÇAO TADANO

ANNEX

TECHNICAL REGULATIONS OF THE NATIONAL PROGRAM ON AQUATIC ANIMAL HEALTH - PNSAA

These technical regulations shall apply to sanitary control at aquaculture establishments engaged in activities connected with aquatic animal farming and marketing and related activities, as well as preventing the introduction of exotic diseases and controlling or eradicating existing diseases in the country.

CHAPTER 1

DEFINITIONS

For the purposes of these regulations, the following definitions shall apply:

ALEVIN: the first life stage of a fish after hatching, morphologically similar to the adult of the same species.

AQUATIC ANIMAL: fishes, mollusks, crustaceans, and other animals appropriate for aquaculture at any development stage.

AQUACULTURE: farming of aquatic animals, including fishes, mollusks, crustaceans, and other animals that have in water their first development stage.

BIOSECURITY: measures pertaining to sanitary issues, cleaning, and disinfection; control of the transit of people, animals, and vehicles; garbage and effluents disposal; control of the security of the physical facilities of quarantine establishment and of zones of farming of aquatic animal populations so as to ensure sanitary control and aquatic animals' health, thereby reducing the risk of introduction and dissemination of pathogenic agents.

SANITARY CERTIFICATE: document issued by the pertinent official agency indicating the sanitary status of the breeding establishment in respect of the monitoring of diseases of mandatory notification and of those subject to certification, pursuant to current legislation.

CYST: a latent, dry egg (*Artemia spp*).

OFFICIAL VETERINARY CONTROL: routinely performed service by the competent veterinary authority at aquaculture establishments and zones to ensure the animals' health and compliance with PNSAA requirements.

CRUSTACEAN: aquatic animals belonging to the Arthropoda phylum, characterized by a chitin exoskeleton, articulated appendages, and including shrimp, crab, freshwater crab, crayfish, mangrove crab, isopod, ostracod, and amphipod.

ORNAMENTAL SPECIES: aquatic animal at any development stage for the purposes of display or ornament.

EXOTIC SPECIES: aquatic animals originating and occurring naturally outside the limits of Brazilian waters, irrespective of whether they have already been artificially introduced in these waters.

AQUACULTURE ESTABLISHMENT: establishment where aquatic animals are breed or kept for reproduction or selling purposes.

OUTBREAK: emergence of a disease at an aquaculture establishment.

GAMETE: genetic material (semen/ovule) of aquatic animals, separately kept or transported before fecundation.

ANIMAL MOVEMENT PERMIT-GTA: mandatory document for the movement of aquatic animals, required for any movement or purpose.

QUARANTINE UNIT QUALIFICATION: Official Veterinary Service's evaluation of an establishment destined for quarantining aquatic animals in view of the risk of introduction and dissemination of pathogenic agents.

ACCREDITED LABORATORY: laboratory of a federal, state, municipal institution, or private qualified and accredited by MAPA for the identification of pathogenic agents.

OFFICIAL LABORATORY: laboratory belonging to the Ministry of Agriculture, Livestock, and Food Supply's laboratory network.

LARVA: stage of aquatic animal's life that follows the embryonic stage, susceptible of presenting various development phases.

LOT: group of aquatic animals at an aquaculture establishment belonging to the same species, originating from the same hatching, and that have shared the same water supply.

HYDROGRAPHIC MICROBASIN: physiographic area circumscribed by watersheds and drained by a water course or a system of interconnected water courses converging, directly or indirectly, into a bed or pool.

MOLLUSC: aquatic animal of the *Mollusca phylum,* of the Metazoa subgenus, characterized by a soft body without segmentation, most of whose species are protected by a calcareous shell, and including oysters, mussels, and scallops (pectines).

MONITORING OF POPULATIONS: sanitary follow-up combined with laboratory analyses, including serologic tests, experiments with biological and nonbiological materials, and epidemiologic analysis of aquatic animals' health conditions, and standardizing results.

QUARANTINE PERIOD: Period between the reception of live aquatic animals at the quarantine establishment and their release by the Official Veterinary Service.

AQUATIC ANIMAL PRODUCTS: products destined for breeding (eggs, embryos, cysts, gametes, larvae, alevins, etc.), human or animal consumption, or for pharmaceutical, biological, or industrial purposes.

BIOLOGIC PRODUCT: biological reagent used for the diagnostic of certain diseases, serum for prevention and treatment of some diseases, vaccines for disease prevention, genetic material of infectious agents, and endocrine tissue from fish or used in fishes.

TECHNICAL PERSON IN CHARGE: veterinarian responsible for sanitary control at aquaculture establishments.

SEED: any young aquatic animal form, including egg, embryo egg, alevin, nauplius, larva, and post-larva.

OFFICIAL VETERINARY SERVICE: animal health and inspection service at the federal, state, and municipal level.

QUARANTINE UNIT: wholly separated facility or ensemble of facilities under biosecurity conditions, destined for receiving live aquatic animals at any development stage after transportation or importation.

CHAPTER II

COMPETENCES

Art. 1. It shall be incumbent on the Animal Health and Inspection Department, Agriculture and Livestock Defense Office-SDA, Ministry of Agriculture, Livestock, and Food Supply-MAPA, to normalize, coordinate, and execute the Program activities, while field actions shall be incumbent on the Animal Health Sector/Section/Service, Federal Agriculture Office-DFA, and on the State Departments of Agriculture or their animal health and inspection agencies, under agreements celebrated with MAPA.

CHAPTER III

PRELIMINARY DISPOSITIONS

Art. 2. The Animal Health and Inspection Department shall coordinate the disease pre-

vention measures hereunder so as to bar the introduction of exotic diseases and to control or eradicate existing diseases on the national territory.

Art. 3. The entry into the national territory of aquatic animals affected or under suspicion of being affected by directly or indirectly transmissible diseases, even if apparently healthy, is hereby prohibited, as is the entry of bearers of external or internal parasites whose dissemination might pose a threat to the national aquatic animal population.

Art. 4. The entry of aquatic animal products, subproducts, remains, viscera, living feed, or any other material assumed to be a vehicle of agents of contagious diseases is also hereunder prohibited.

Art. 5. The entry of aquatic animals from countries where the diseases referred to hereunder exist in an enzootic state shall be allowed solely with prior DDA authorization, which shall set the conditions under which importation will be allowed.

CHAPTER IV

CLASSIFICATION OF AQUACULTURE ESTABLISHMENTS

Art. 6. For the purposes hereunder, establishments engaged in aquaculture activities are classified as follows:

I – REPRODUCTION ESTABLISHMENT: establishment destined for reproduction or manipulation of genetic material (gametes/eggs/nauplius/seed).

II – BREEDING ESTABLISHMENT: culture establishment or zone destined for the breeding of aquatic animals (alevin/larva/post larva).

III – FATTENING ESTABLISHMENT: culture establishment or zone engaged in raising aquatic animals from early in the life cycle up to the marketing stage.

IV – RECREATION ESTABLISHMENT: establishment where aquatic animals are destined for pleasure fishing (fish and pay).

VI – SELLING ESTABLISHMENT: establishment engaged exclusively in the sale and resale of ornamental aquatic animals, live bait, and live aquatic animals for consumption.

CHAPTER V

REGISTER OF AQUACULTURE ESTABLISHMENTS

Art. 7. The aquaculture establishment register shall be incumbent on the State Departments of Agriculture or their animal health and inspection agencies.

CHAPTER VI

NOTIFICATION OF SUSPICION OR OCCURRENCE OF DISEASE

Art. 8. Diseases of mandatory notification are exotic diseases and those that pose a threat to the country's economic, public health, and environment.

Art. 9. The veterinarian, owner, or any other individual that has knowledge or suspicion of the occurrence of diseases of mandatory notification should promptly notify the Official Veterinary Service.

CHAPTER VII

INSPECTION AND SANITARY CONTROL OF AQUACULTURE ESTABLISHMENTS

Art. 10. All aquaculture establishments are subject to inspection by the Official Veterinary Service.

Art. 11. In case of noncompliance with the requirements hereunder, as identified by the official service, the following sanctions may be adopted:

I – Suspension of the importation, exportation, and marketing authorization and of the issuance of GTAs;

II – Establishment's interdiction; or

III - Application of other sanitary measures determined by DDA.

CHAPTER VIII

IMPORTATION AND EXPORTATION OF ANIMALS

Art. 12. Any aquaculture establishment engaged in international trade must comply with DDA norms.

Art. 13. For the purposes of importation of aquatic animal products, the interested party should secure prior importation authorization from the DFA in the state where the aquaculture establishment is located.

Art. 14. In the case of importation of wild exotic or ornamental species, prior IBAMA authorization shall be required.

Art. 15. Upon arrival at the national territory, imported aquatic animals and aquatic animal products shall be transferred in their still sealed shipment containers to the quarantine unit previously qualified by DDA, for sanitary monitoring and confirmation of the absence of pathogenic agents of the diseases specified by DDA, according to the origin of said animals and products.

Art. 16. Sanitary monitoring shall be carried out at the quarantine unit in accordance with the quarantined species, and controlled by the Official Veterinary Service.

Art. 17. The collection of samples from aquatic animals and aquatic animal products shall be done by the Animal Health Service/DFA upon arrival at the quarantine unit, and shall be sent for laboratory tests, accompanied by the appropriate form, pursuant to the provisions of specific legislation.

Art. 18. Any material officially collected by the veterinarian must be sealed and accompanied by the requisite standard DDA form.

Art. 19. If a disease causing agent is identified during the quarantine period, the DDA shall notify the interested party in writing of the test results within a maximum of 72 (seventy-two) hours and proceed to the destruction of the positive lots.

Art. 20. Laboratory test results must be issued on the DDA's appropriate standard form and transmitted according to the following flowchart:

I – Negative results: To be immediately sent by fax, e-mail, or another means of communication to the official veterinarian requesting the tests and to the establishment in question; and

II – Positive results: To be immediately sent by fax, e-mail, or another means of communication to the DDA and to the SSA/DFA under whose jurisdiction the establishment is located.

Art. 21. Once the identification of the pathogenic agent referred to under Art. 8 hereunder is confirmed, all aquatic animals in a shipment must be immediately sacrificed and destroyed, and every necessary prophylactic measure shall be taken, and the owner shall not be entitled to any indemnification of any kind.

Art. 22. The sacrifice of animals referred to in the preceding article shall be done as provided under Decree No. 24548 of July 3, 1934.

Art. 23. The costs of official sample collection for laboratory tests and of samples' remittance to reference or MAPA-accredited laboratories for this purpose shall be fully born by the interested party.

Art. 24. If no positive result has been recorded by the expiration of the quarantine period, the state SSA/DFA shall inform the interested party about the lot's release.

Art. 25. The quarantine period for the different species of aquatic animals at any development stage shall last long enough for the analysis and conclusions by official laboratory results.

Art. 26. Release into bodies of water shall be permitted solely of an imported lot's first-generation offspring (F1). The original lot shall remain under isolation and sanitary surveillance at the reproduction establishment for the entire reproduction period.

Art. 27. The downtime between quarantines must be for a minimum period sufficient for the cleaning and disinfection of all facilities.

Art. 28. DDA shall authorize, register, and revoke any authorization for the operation and functioning of all quarantine units as well as maintaining current information on the disease causing agents identified in quarantine units, the procedures adopted in case of diseases of mandatory notification, and test results.

Art. 29. All materials and equipment used at the quarantine unit must be kept clean and disinfected with specific products duly registered with DDA.

Art. 30. The admission of people, vehicles, equipment, and materials to the quarantine unit's internal areas shall be permitted only in compliance with strict biosecurity measures.

Art. 31. Access to the quarantine facility must be through a single entry and exit point provided with washing and disinfection equipment.

Art. 32. In the case of fairs and expositions, the following conditions must be observed:

I – Compliance with DDA's pertinent norms and specific legislation;

II – Control of diseases of mandatory notification; and

III – Should diseases of mandatory notification occur in the region, the Official Veterinary Service shall adopt restrictive measures for the event's realization.

CHAPTER IX

ACTIVITIES IN THE OCCURRENCE OF A OUTBREAK

Art. 33. Whenever there is notification of a suspected outbreak of a disease of mandatory notification, the following procedures shall be adopted:

I – Visit to the outbreak: initial visit, collection of material and its shipment to the laboratory, accompanied by the duly filled-out requisite forms;

II – Epidemiologic tracing: based on information that leads the veterinarian to determine the outbreak's origin, and define its extent, evolution, spread, and consequences;

III – Interdiction of the outbreak and perifocal areas: according to the diseases' seriousness, the culture establishments or zones shall be interdicted, together with the neighboring properties and microbasins;

IV – Outbreak notification: the outbreak shall be notified to the local Official Veterinary Service, which in turn shall notify the state veterinary service through the appropriate form, for epidemiologic analysis and the adoption of a pertinent decision consistent with the disease's seriousness. Notification must be immediate in case of suspicion of the diseases referred to under Art. 8 hereunder;

V – Sanitary sacrifice: depending on the disease, all the animals on the farm establishment or zone shall be sacrificed, and their conditional use shall be defined by the Official Veterinary Service;

VI – Therapeutic treatment: in viable cases, diseased animals shall be treated;

VII – Disinfection: if disinfection is needed, a harvest shall be undertaken, followed by total emptying and appropriate disinfection for the time necessary to exterminate the disease causing agent, and all requisite measures shall be taken to prevent it from invading natural water bodies;

VIII – Outbreak monitoring: the farm establishment or zone as well as the other establishments located in the perifocal area and basin should be regularly visited for the purposes of monitoring the disease's status and the execution of the recommended measures as well as the adoption of other procedures aimed at the disease's control or total eradication; and

IX – Outbreak closing: once the inexistence of pathogenic agents is confirmed, as well as the successful emptying and disinfection of the farm establishments or zones, the outbreak shall be declared closed and the interdiction shall be lifted.

CHAPTER X

MOVEMENT OF ANIMALS

Art. 34. The movement of aquatic animals shall be authorized only if accompanied by the Animal movement permit-GTA.

Art. 35. The issuance of a GTA for any purpose shall be subject to compliance with the requirements under DDA norms and specific legislation.

Art. 36. Vehicles or containers used in the transportation of aquatic animals should be designed, built, and conditioned so as to bear the combined weight of the animals and the water, to ensure their safety in transit.

Art. 37. The vehicles carrying aquatic animals should be washed and disinfected pursuant to DDA norms.

Art. 38. Containers for transporting aquatic animals should be watertight.

Art. 39. Aquatic animals should be packed in a transport container appropriate for allowing easy inspection during transportation.

Art. 40. Residual and rinsing water should not be drained in a way susceptible of reaching natural waters.

Art. 41. Waste water from transport containers may be discarded on lands that do not drain into waters peopled by aquatic animals, or treated according to DDA standard procedures.

Art. 42. GTAs shall be issued solely in case of animals and products from aquaculture establishments in which, during the previous cycle, no outbreak of diseases of mandatory notification has occurred or from a farm zone where none of such diseases has been detected in the previous 90 (ninety) days.

CHAPTER X

GENERAL DISPOSITIONS

Art. 43. To advise DDA in reference to specific issues hereunder, a Consultative Committee on the National Program on Aquatic Animal Health-CC/PNSAA shall be set up as well as State Animal Health Committees-COESAAs).

Art. 44. Omissive cases and doubts pertaining to these regulations' application shall be resolved by DDA.

NORMATIVE INSTRUCTION No. 39 OF NOVEMBER 4, 1999

Published in the Official Gazette of November 8, 1999 Section 1, Page 43

Temporarily suspends the admission into the national territory of all crustacean species, whether salt or fresh water, at any development stage of their biologic cycle, whether fresh, frozen, or cooked, whole in their carapaces or parts thereof, from any origin.

THE MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY'S AGRICULTURE AND LIVESTOCK HEALTH AND INSPECTION SECRETARY, by virtue of the powers vested in him under Art. 83, IV of the Department's Internal Regulations approved under Ministerial Administrative Ruling No. 574 of December 8, 1998, having in view the provisions under the Animal Health and Inspection Service's Regulations approved under Decree no. 24548 of July 3, 1934;

Whereas the diseases known as White Shrimp Spot Virus-WSSV and Yellow Head Virus-YHV included on List b of the World Organization for Animal Health-OIE have been detected in shrimp farming facilities in various countries;

Whereas the countries where these viruses' presence has been confirmed have adopted measures restricting the importation of crustaceans and products and subproducts thereof;

Whereas the admission of live or processed crustaceans and their subproducts for cultivation, marketing, or research into the Brazilian territory poses a high dissemination risk of the causing agents of these diseases, which may entail losses to aquaculture and the natural crustacean populations;

Whereas to date there has been no occurrence of these diseases in crustacean farms in Brazil,

RESOLVES:

Art. 1. Temporarily to suspend the admission into the national territory of all crustacean species, whether salt or fresh water, at any development stage of their biologic cycle, whether fresh, frozen, or cooked, whole in their carapaces or parts thereof, from any origin.

Sole Paragraph. The suspension hereunder is extensive to Artemia salina and all marine polyquet species.

Art. 2. To subject import authorizations hereunder to prior risk analysis by the Animal and Plant Health and Inspection Secretariat's Animal Health and Inspection Department, which shall take into account the zoosanitary situation of the countries of origin and their production areas.

Art. 3. Import authorizations already issued and not yet used are hereby cancelled.

Art. 4. This Normative Instruction shall enter into force on the day of its publication.

LUÍS CARLOS DE OLIVEIRA

NATIONAL CAPRINE AND OVINE HEALTH PROGRAM

NORMATIVE INSTRUCTION No. 20 OF AUGUST 15, 2005

Published in the Official Gazette of September 12, 2005, Section 1, Page 20.

Approves the Procedures for the Operationalization of the Sanitary Register of Goat and Sheep Raising Establishments.

THE ANIMAL AND PLANT HEALTH AND INSPECTION SECRETARY, MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY, by virtue of the powers vested in him under Art. 42, Annex I of Decree No. 5351 of January 21, 2005; having in view the Animal Health and Inspection Regulations approved under Decree No. 24548 of July 3, 1934; SDA Normative Instruction No. 87 of December 10, 2004; and Proceeding No. 21000.008578/2004-16;

Whereas there is a need to define aspects related to the National Caprine and Ovine Health Program-PNSCO, RESOLVES:

Art. 1. To approve the PROCEDURES FOR THE OPERATIONALIZATION OF THE SANITARY REGISTER OF GOAT AND SHEEP RAISING ESTABLISHMENTS, pursuant to Annex I hereto, as well as the form model shown in Annex II, for information on the private veterinarian that will follow up such establishments in connection with PNSCO certification programs, and the form model shown in Annex III, for minimum information for the inclusion of such establishments in the sanitary register.

Art. 2. This Normative Instruction shall enter into force on the day of its publication.

GABRIEL ALVES MACIEL

ANNEX I

PROCEDURES FOR THE OPERATIONALIZATION OF THE SANITARY REGISTER OF GOAT AND SHEEP RAISING ESTABLISHMENTS

Art. 1. This Normative Instruction applies to the procedures for the operationalization of the National Caprine and Ovine Health Program

CHAPTER I

DEFINITIONS

Art. 2. For the purposes hereunder, the following definitions shall apply:

I – ESTABLISHMENT CERTIFICATION: confirmation of an establishment as disease free after compliance with Animal Health Department requirements;

II – DISEASE OF MANDATORY NOTIFICATION: any disease classified by the Animal Health Department as being of mandatory notification to the Official Service;

III – ESTABLISHMENT: property on which goats and sheep are kept under common management conditions;

IV – ACCREDITED LABORATORY: laboratory approved for performing diagnostic tests by using techniques recognized and approved by the Agriculture and Livestock Defense's Laboratory Support Coordinating Office;

V – MAPA: Ministry of Agriculture, Livestock and Food Supply;

VI – OFFICIAL VETERINARIAN: Federal and State Official Service Veterinarian;

VII – PRIVATE VETERINARIAN: Private sector veterinarian who may be hired by an establishment owner to perform tasks for the establishment in connection with certification and certificates, without costs for the State;

VIII – OIE: World Organization for Animal Health;

IX – PNSCO: National Caprine and Ovine Health Program;

X – OFFICIAL SERVICE: Federal and State Animal Health and Inspection Services; and

XI – SFA: Federal Agriculture, Livestock, and Food Supply Superintendence.

CHAPTER II

ACTION STRATEGIES

Art. 3. PNSCO action strategies are based on mandatory animal health and inspection procedures, complemented by voluntary adhesion measures, including the following:

I – Sanitary register of establishments;

II – Control of the movement of animals; and

III – Voluntary certification of establishments.

CHAPTER III

OFFICIAL SERVICE COMPETENCE

Art. 4. It is incumbent on the Disease Combating General Coordination Office, Animal Health Department, to plan, control, and evaluate the execution of plans under the National Caprine and Ovine Health Program aimed at the surveillance, control, prophylaxis, and eradication of goat and sheep diseases, under official control.

Sole Paragraph. PNSCO addresses the techniques available in Brazil and recommended by OIE. Diagnostic technologies and vaccines may be adopted and recommended after being evaluated by the Animal Health Department.

Art. 5. It is incumbent on the Agriculture and Livestock Health and Inspection's Laboratory Support Coordinating Office to standardize diagnostic techniques used as a tool in the detection of diseases encompassed by PNSCO, to do the yearly verification of records and provide information to PNSCO upon request.

…

Art. 7. It is incumbent on the SFA in each

state to issue and renew certificates to disease-free establishments, pursuant PNSCO norms.

CHAPTER IV

ESTABLISHMENTS REGISTER

Art. 8. For the purposes hereunder, establishments engaged in raising goats and sheep must apply for registration with the State Official Services by filling out the standard form for basic information (Annex III).

Paragraph 1. Another form may be used, provided they contain the basic information required for filling out the form shown in Annex III.

Paragraph 2. Information provided for registration must be updated within a period not to exceed one year.

Art. 9. As of the date to be set by the Animal Health Department, GTAs for the interstate movement of goats and sheep not destined for slaughter shall be issued only if the animals to be transported originate in establishments that are current with their sanitary register.

Art. 10. The Animal Health Department may prohibit the movement of goats and sheep from a registered establishment in case of confirmed sanitary risk of transmission of infecto-contagious diseases to other establishments that keep goat and sheep herds.

CHAPTER V

INDEPENDENT VETERINARIAN

Art. 11. All establishments that participate in the Official Certification Programs under PNSCO must be monitored by an Independent Veterinarian, who shall be responsible for the activities necessary for the establishments to achieve and maintain the status as being free of the diseases that are the target of the official programs, pursuant to the requirements under the pertinent normative acts.

Sole Paragraph. In case of replacement of the Independent Veterinarian responsible for monitoring a certified establishment or an establishment in the process of obtaining certification, the establishment's owner should immediately forward the data on the new Independent Veterinarian to the SFA of the state in which the establishment is registered, and the new professional must comply with the provisions under Art. 13 hereunder within a maximum of fifteen days of the communication.

Art. 12. The Veterinarian responsible for an establishment in the process of certification or already certified must attend meetings and encounters promoted in the respective region by the Animal Health Department/MAPA or Official Service to address issues pertaining to PNSCO.

Art. 13. To undertake the monitoring of an establishment in the process of certification or already certified, an Independent Veterinarian must submit to the SFA in the state where the monitored establishment is located the following documents:

I – A filled-out information form (Annex II);

II- Statement of being current with the Regional Veterinary Medicine Council-CRMV of the state where he works; and

III – An Affidavit pursuant to the model established by the Animal Health Department for every Certification Program that includes monitoring.

Sole Paragraph. In case of noncompliance with the legislation, the Independent Veterinary responsible for an establishment in the process of certification or already certified shall be subjected to the applicable sanctions.

ANNEX II

MODEL OF FORM TO BE FILLED OUT WITH INFORMATION ON AN INDEPENDENT VETERINARIAN RESPONSIBLE FOR MONITORING AN ESTABLISHMENT IN THE PROCESS OF CERTIFICATION OR ALREADY CERTIFIED UNDER PNSCO

3 cm x 4cm Photo

Name: _____

Parents' names: _____

ID: _____ Taxpayer ID: _____ CRMV _____

Graduating Institution: _____ Year of graduation: _____

Post-graduation (1): _____ Year of completion: _____

Post-graduation (2): _____ Year of completion: _____

Current job / Main activity _____

Home address: _____

Business address: _____

Telephone: _____ Fax: _____ Cell phone: _____

E-mail: _____

Attachments:

1. Statement from the CRMV in the state with which the interested party is registered and current.
2. Signed affidavit pursuant the model established by the Animal Health Department.

ANNEX III

MODEL FORM FOR MINIMUM INFORMATION FOR THE SANITARY REGISTER OF GOATS AND SHEEP ESTABLISHMENTS

Name: _____ C.G.C.: _____

Name of the establishment's owner: _____

C.P.F.: _____ Telefone: _____

e-mail: _____

Full address: _____

Postal Code: _____ Municipality: _____ State: _____

Latitude/Longitude: _____ Total area: _____

Facilities total area: _____

Establishment's Category:

_____ Reproduction _____ Production

Management type: _____

_____ Intensive _____ Extensive _____ Mixed

Purpose:

_____ Meat _____ Leather _____ Wool _____ Milk _____ Mixed

Handles animal products or subproducts for commercial purposes Yes ____ No ____

Origin of animals:

_____ Importation _____ Genetic bank _____ Own _____ Another property _____ Mixed

Specify origin:

Trade in animals or animal multiplication material:

_____ Local _____ Intrastate _____ Interstate _____ International

Number of animals:

Goats

_____ Males _____ Females

_____ <6 months _____ > 6 months < 3 years _____ >3 years

Sheeps

_____ Males _____ Females

_____ <6 months _____ > 6 months < 3 years _____ >3 years

Animal identification system:

_____ Tattoo _____ Earring _____ Electronic _____ Other*

(*Specify)

Breed (Check the code in the list below):

Goat breeds code:
1.1. Anglo Nubian
1.2. Azul
1.3. Bhuj
1.4. Boer
1.5. Canindé
1.6. Graúna
1.7. Gurguéia
1.8. Marota
1.9. Moxotó

1.10. Murciana
1.11. Alpine
1.12. Repartida
1.13. Saanen
1.14. Savanna
1.15. Toggenburg
1.16. Other (include on the form)
1.17. SRD (not well-defined breed)

Sheep breeds code:
2.1. Bergamasca
2.2. Blackface
2.3. Border Leicester
2.4. Cariri
2.5. Corriedale
2.6. Crioula
2.7. Deslanado do Nordeste
2.8. Dorper
2.9. Dorset
2.10. East Friesian
2.11. Hampshire Down
2.12. Hardwick
2.13. Highland
2.14. Ideal
2.15. Ile de France
2.16. Lacaune
2.17. Karakul
2.18. Merino
2.19. Merlin
2.20. Morada Nova
2.21. Oxsfordshire
2.22. Polypay
2.23 Ryeland
2.24. Romeldale
2.25. Romney Marsh
2.26. Santa Inês
2.27. Shrospire
2.28. Somalis
2.29. Suffolk
2.30. Targhee
2.31. Texel
2.32. Wilstermach
2.33. Other (specify on the form)
2.34. SRD (without well-defined breed)

NORMATIVE INSTRUCTION No. 87 OF DECEMBER 10, 2004

Published in the Official Gazette of December 20, 2004 Section 1, Page 21

Approves the National Caprine and Ovine Health Program Technical Regulations

THE MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY'S AGRICULTURE AND LIVESTOCK HEALTH AND INSPECTION SECRETARY, by virtue of the powers vested in him under Art. 15, II of Annex I to Decree No. 4629, of March 21, 2003, having in view the Animal Health and Inspection Regulations approved under Decree No. 24548 of July 3, 1934, and Proceeding No. 21000.011263/2003-75,

RESOLVES:

Art. 1. To approve the NATIONAL CAPRINE AND OVINE HEALTH PROGRAM TECHNICAL REGULATIONS hereto annexed.

Art. 2. This Normative Instruction shall enter in force on the date of its publication.

Art. 3. Normative Instruction No. 53 of July 12, 2004 is hereby revoked.

MAÇAO TADANO

ANNEX

NATIONAL CAPRINE AND OVINE HEALTH PROGRAM TECHNICAL REGULATIONS-PNSCO

Art. 1. These National Caprine and Ovine Health Program Technical Regulations-PNSCO apply to activities geared to the production and marketing of goats and sheep and their genetic material nationwide in connection with regards zoosanitary surveillance and health and inspection.

CHAPTER I

DEFINITIONS

Art. 2. For the purposes hereunder, the following definitions shall apply:

I – DDA: Animal Health and Inspection Department;

II – DESTRUCTION – Procedure for the elimination of animals without their utilization for consumption, done on the raising establishment itself or on a location approved by the Official Service pursuant to DDA approved criteria;

III – DFA: Federal Agricultural Office;

IV – DISEASE: alteration in an individual [animal]'s balanced condition vis-à-vis itself or the environment;

V – DISEASE OF MANDATORY NOTIFICATION: disease classified as such by DDA, which should be compulsorily notified to the Official Service after detection of clinical suspicion of the disease;

VI – ESTABLISHMENT: location where goats and sheep are raised under common management conditions;

VII – GTA: Animal movement permit;

VIII – INTERDICTION: prohibition, at the Official Service's discretion, of the admission to or exit from any establishment of animals, their products and subproducts as well as any other material likely to be the means of transmission or spread of a disease;

IX – MAPA: Ministry of Agriculture, Livestock, and Food Supply;

X – GENETIC MATERIAL: semen, embryo, ovocyte, cell nucleus, or any other material capable of transmitting genes to the offspring;

XI – OFFICIAL VETERINARIAN: a veterinarian belonging to the federal or state Official Service;

XII – INDEPENDENT VETERINARIAN: a veterinarian from the private sector who monitors registered establishments without entailing costs to the State;

XIII – DISEASE NOTIFICATION: official communication of the occurrence of cases of a given disease to the competent authority;

XIV – PARASITE: organism or micro-organism which exists at a host's expense;

XV – OWNER: natural person or legal entity, public or private, which owns animals or real estate for any purpose;

XVI – QUARANTINE: restraining of people, plants, and animals for a given period during which measures determined by the sanitary authorities are applied to prevent the introduction and spread of disease, its hosts or vectors;

XVII – HERD: a group of animals kept under common management conditions at the same raising establishment;

XVIII – SANITARY SACRIFICE: slaughter of animals for controlling diseases, at slaughterhouses under federal, state, or municipal inspection;

XIX – SDA: Animal and Plant Health and Inspection Secretariat;

XX – OFFICIAL SERVICE: animal health and inspection service at the federal and state level.

XXI – EPIDEMIOLOGIC SURVEILLANCE: ongoing, systematic investigation of health data pertaining to a given population (sample collection, analysis, and interpretation) to verify a disease's occurrence, an activity that is essential to the planning, implementation, and evaluation of sanitary measures aimed at controlling or eradicating the disease; and

XXII – SANITARY SURVEILLANCE: a set of measures aimed at eliminating, reducing, or preventing risks to public health, as well as controlling and ensuring compliance with sanitary norms and standards.

CHAPTER II

COMPETENCE

Art. 3. It shall be incumbent on DDA/SDA/MAPA to establish norms and to coordinate and

supervise activities under PNSCO. It shall be incumbent on State Agriculture Departments or their Animal Health and Inspection agencies to execute activities by delegation.

CHAPTER III

PRELIMINARY DISPOSITIONS

Art. 4. The admission into the National Territory of goats and sheep that are bearers of directly or indirectly transmissible diseases and of internal or external parasites whose dissemination may pose a threat to national herds is hereby prohibited.

Art. 5. The admission into the National Territory of animal products and any other materials that pose a risk of introducing diseases affecting goats and sheep is hereby equally forbidden.

CHAPTER IV

OBJECTIVES

Art. 6. To undertake the epidemiologic and sanitary surveillance of goat and sheep diseases in Brazil through measures defined by DDA and implemented by the Official Services and independent veterinarians.

CHAPTER V

RAISING ESTABLISHMENTS REGISTER

Art. 7. All establishments must be registered by the state Official Services pursuant to a DDA standard form.

Sole Paragraph. The register must be annually updated.

CHAPTER VI

INDEPENDENT VETERINARIANS

Art. 8. All establishments in the process of certification or already certified must be monitored by an independent veterinarian, who shall be responsible for keeping records and for undertaking the activities required for securing and maintaining the certification status, pursuant to the requirements of Normative Acts.

Sole Paragraph. The federal and state Official Services may at any time audit the activity of the veterinarians responsible for executing the planned activities at establishments in the process of certification or already certified.

Art. 9. The veterinarian responsible for an establishment in the process of certification or already certified must attend meetings and encounters promoted in his region by DDA/MAPA or Official Services on issues pertaining to PNSCO.

CHAPTER VII

DISEASE NOTIFICATION AND SURVEILLANCE

Art. 10. Under current legislation, public or independent veterinarians and owners or their deputies, must immediately inform the Official Service of any suspicion of goat and sheep disease of mandatory notification.

Paragraph 1. In the specific case of foot-and-mouth disease, the measures called for under current legislation must be taken,

Paragraph 2. The Official Service shall adopt the veterinary care and surveillance measures determined by DDA for each specific disease.

CHAPTER VIII

INSPECTION AND SANITARY CONTROL OF ESTABLISHMENTS

Art. 11. All establishments shall be subject to inspection by the Official Service.

Art. 12. In case of noncompliance with the requirements under the PNSCO legislation, the following measures may be adopted, at the Official Service's discretion:

I – Suspension of the importation or exportation authorization and of the issuance of GTAs;

II – Establishment's interdiction;

III – Destruction;

IV – Sanitary sacrifice; and

V –Adoption of other sanitary measures established by DDA.

CHAPTER IX

CERTIFICATION REQUIREMENTS

Art. 13. DDA shall implement the strategy for certification of establishments that meet the specific sanitary requirements under current legislation, as well as complying with the norms pertaining to sanitation, surveillance, and control of the diseases specified under PNSCO.

CHAPTER X

PRODUCTION, MARKETING AND IMPORTATION OF GENETIC MATERIAL

Art. 14. For the purposes of production and marketing of genetic material, establishments must comply with DDA sanitary norms.

Art. 15. For the purposes of importation of goats, sheep, and their genetic material, the interested party must apply for prior authorization from the DFA in the state where his establishment is located.

Paragraph 1. Upon arrival in the National Territory, imported goats and sheep must be kept in a quarantine unit previously qualified by DDA until their release by the Official Service.

Paragraph 2. In case of occurrence of diseases during the quarantine period, the Official Service shall adopt the sanitary measures pertinent to each situation.

CHAPTER XI

MOVEMENT OF GOATS AND SHEEP

Art. 16. The movement of goats and sheep shall be allowed only if accompanied by a GTA in accordance with current normative requirements.

Art. 17. Goats and sheep must be transported in appropriate vehicles that have been cleaned and disinfected prior to shipment.

CHAPTER XII

EXPOSITIONS, FAIRS, AUCTIONS AND OTHER CONGLOMERATIONS

Art. 18. The participation of goats and sheep in expositions, fairs, actions, and other conglomerations shall be subject to compliance with current norms and legislation.

CHAPTER XIII

GENERAL DISPOSITIONS

Art. 19. To advise DDA on the specific issues hereunder, a National Caprine and Ovine Health Program National Consultative Technical Committee shall be established as well as State Caprine and Ovine Health Committees.

Sole Paragraph. In each state, the Federal Agriculture Office Director shall set up a State Committee on Caprine and Sheep Health, consisting of representatives from DFA's Animal Health and Inspection, the State Health and Inspection Services, research and teaching institutions, and the productive sector.

Art. 20. Omissive cases and doubts about the application of these Regulations and the complementary legislation shall be resolved by DDA.

ADMINISTRATIVE RULING SDA No. 47 OF JULY 20, 2004

Establishes the National Consultative Committee on the National Caprine and Ovine Health Program's

NATIONAL BEEKEEPING HEALTH PROGRAM

NORMATIVE INSTRUCTION No. 16 OF MAY 8, 2008

Published in the Official Gazette of May 9, 2008 Section 1, Page 27

Establishes the National Beekeeping Health Program-PNSAp under the Ministry of Agriculture, Livestock, and Food Supply.

THE MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY'S AGRICULTURE AND LIVESTOCK HEALTH AND INSPECTION SECRETARY, by virtue of the powers vested in him under Arts. 9 and 42 of Annex I to Decree No. 5351 of January 21, 2005, having in view the provisions of Decree No. 24548 of July 3, 1934; Decree No. 5741 of March 30, 2006; and Proceeding No. 21000.002627/2008-31,

RESOLVES:

Art. 1. To establish the National Beekeeping Health Program-PNSAp under the Ministry of Agriculture, Livestock, and Food Supply.

Paragraph 1. PNSAp aims at strengthening the beekeeping productive chain through animal health and inspection and surveillance actions.

Paragraph 2. PNSAp shall be coordinated by a representative from the Animal Health Department-DSA.

Paragraph 3. So as to prevent, control, and eradicate diseases and pests susceptible of causing damage to the beekeeping productive chain, PNSAp shall carry out the following activities:

I – Sanitary education;

II – Epidemiologic studies;

III – Movement control;

IV – Registration, inspection, and sanitary certification; and

V – Prompt intervention in case of suspicion or occurrence of disease or pest of mandatory notification.

Art. 2. This Normative Instruction shall enter into force on the day of its publication.

INÁCIO AFONSO KROETZ

ADMINISTRATIVE RULING No. 9 OF FEBRUARY 18, 2003

Published in the Official Gazette of February 20, 2003 Section 1, Page 10

Establishes the Consultative Scientific Committee on Beekeeping Health-CCCSA to provide technical and scientific input to the Animal Health and Inspection Department-DSA on the drafting of norms and procedures related to the health of the Brazilian bee population and to the importation of bees and bee products.

ADMINISTRATIVE RULING No. 248 OF DECEMBER 30, 1998

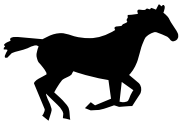
Published in the Official Gazette of January 5, 1999 Section 1, Page 13

Establishes the analytical methodology for the detection of Bacillus larvae, an agent of bee larvae disease, known as American foulbrood, in honey.

NORMATIVE INSTRUCTION No. 18 OF APRIL 8, 2008

Published in the Official Gazette of April 9, 2008 Section 1, Page 8

Incorporates into the Brazilian legislation the "Zoosanitary requirements for the importation of queen bees and bee products destined for the States Parties," approved under Resolution GMC-MERCOSUR NO. 23/07.



NATIONAL EQUID HEALTH PROGRAM

NORMATIVE INSTRUCTION No. 17 OF MAY 8, 2008

Published in the Official Gazette of May 9, 2008 Section 1, Page 27

Establishes the National Equid Health Program-PNSE under the Ministry of Agriculture, Livestock, and Food Supply.

THE MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY'S AGRICULTURE AND LIVESTOCK HEALTH AND INSPECTION SECRETARY, by virtue of the powers vested in him under Arts. 9 and 42 of Annex I to Decree No. 5351 of January 21, 2005, having in view Decree No. 24548 of July

3, 1934; Decree No. 5741 of March 30, 2006; and Proceeding No. 21000.002656/2008-96,

RESOLVES:

Art. 1. To establish the National Equid Health Program-PNSE, under the Ministry of Agriculture, Livestock, and Food Supply.

Paragraph 1. PNSE aims at strengthening the equine agricultural and livestock sector by means of animal health and inspection and surveillance.

Paragraph 2. PNSE shall be coordinated by a representative from the Animal Health and Inspection Department.

Paragraph 3. To prevent, diagnose, control, and eradicate diseases susceptible of causing damage to the equine agriculture and livestock sector, PNSE shall carry out the following actions:

I – Sanitary education;

II – Epidemiologic studies;

III – Animal movement control;

IV – Registration, inspection, and sanitary certification; and

V – Prompt intervention in case of suspicion or occurrence of diseases of mandatory notification.

Art. 2. This Normative Instruction shall enter into force on the day of its publication.

INÁCIO AFONSO KROETZ

NORMATIVE INSTRUCTION No. 45 OF JUNE 15, 2004

Published in the Official Gazette of July 7, 2004 Section 1, Page 7

Approves Norms for the Prevention and Control of Equine Infectious Anaemia-EIA.

THE MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY'S AGRICULTURE AND LIVESTOCK HEALTH AND INSPECTION SECRETARY, by virtue of the powers vested in him under Art. 15, II of Annex I to Decree No. 4629 of March 21, 2003, having in view Decree No. 24548 of July 3, 1934, and Proceeding No. 21000.001089/2002-71,

RESOLVES:

Art. 1. To approve Norms for the Prevention and Control of Equine Infectious Anaemia-EIA.

Art. 2. To delegate to the Director of the Animal Health and Inspection Department the competence for issuing administrative rulings and other requisite acts to enforce the norms hereunder.

Art. 3. This Normative Instruction shall enter into force on the day of its publication.

Art. 4. Normative Instruction No. 16 of February 18, 2004 is hereby revoked.

MAÇAO TADANO

ANNEX

NORMS FOR THE PREVENTION AND CONTROL OF EQUINE INFECTIOUS ANAEMIA-EIA.

Art. 1. For the purposes hereunder, the following definitions shall apply:

I – Sanitary slaughtering: slaughtering of EIA-infected equines at slaughterhouses under Federal Inspection, subject to prior authorization by the Animal Health Department of the state of the animals' origin;.

II- Equine Infectious Anaemia-EIA: infectious disease caused by a lentivirus and which may assume the following clinical conditions: acute, chronic, and no apparent symptoms;

III – Carrier animal: any equine tested EIA positive by an official laboratory;

IV – High-risk area: geographical region

where EIA is known to be endemic and where environmental conditions help maintain and disseminate the disease;

V – Perifocal area: area surrounding the outbreak, to be circumscribed by the Official Veterinary Service;

VI – Confirmation test: laboratory EIA diagnostic testing of original sample that has been labeled, sealed, and kept at -20ºC for diagnostic confirmation;

VII – Equine: any animal of the Equidae family, including horses, donkeys, and mules;

VIII – Outbreak: property on which there is one or more than one EIA carrier equine;

IX – Isolation: keeping of an EIA carrier equine in a circumscribed area as determined by the Official Veterinary Service so as to prevent the disease's transmission to other equines;

X – Accredited laboratory: a laboratory that has been accredited by the Animal Health and Inspection Department-DDA for EIA diagnostic testing;

XI – Official laboratory: a DDA laboratory;

XII – Numbered seal: inviolable numbered seal;

XIII – Property: public or private rural or urban establishment holding equines for any purpose;

XIV – Owner: natural person or legal entity that owns or keeps one or more than one equine for any purpose;

XV – Quarantine: isolation of a clinically healthy equine recently arrived at a controlled property from a noncontrolled property in a specific location at least 200 (two hundred) meters from any other property, or protected with an insect-proof screen until said animal tests negative at two consecutive EIA tests at a 30-60 day interval;

XVI – Retesting: EIA laboratory diagnostic testing by an official laboratory of sample from animals tested positive; and

XVII – Official Veterinary Service: the Animal Health Service under the Federal Agricultural Office-DFA in each state, and the Animal Health and Inspection under the State Secretariat of Agriculture.

CHAPTER II

GENERAL PROCEDURES

Art. 2. Field actions pertaining to EIA prevention and control are incumbent on the Official Veterinary Service in each state, under DDA coordination.

Art. 3. EIA prevention and control measures shall be adopted in the states in accordance with their specific epidemiologic conditions.

Art. 4. The Director of the Federal Agricultural Office in each state shall appoint a State Commission on the Prevention and Control of Equine Infectious Anaemia-EIA (CECAIE), which shall have the following attributions:

I – To propose sanitary measures for EIA prevention and control in the state; and

II – To evaluate the work done in the state.

Art. 5. CECAIE shall consist of ten members –five office holders and five deputies, as follows:

I – One veterinarian from DFA's Animal Health and Inspection Service-SSA, who shall act as coordinator;

II – One veterinarian from the state Animal Health and Inspection Service;

III – One veterinarian designated by equine raisers;

IV – One veterinarian designated by the State Veterinary Medicine Society; and

V – One veterinarian who is a specialist or experienced in EIA, designated by Veterinary Medicine educational or research institution.

CHAPTER III

PERSON RESPONSIBLE FOR REQUESTING EIA DIAGNOSTIC TESTS

Art. 6. To be able to request an EIA diagnostic test, a veterinarian must be registered with the Regional Veterinary Medicine Council in the respective state.

Art. 7. It shall be incumbent on the veterinarian:

I – To collect test material; and

II – To submit a filled-out official request

form (Annex I) to a DDA-accredited diagnostic laboratory.

Sole Paragraph. For an animal's identification, an accurate, full written, graphic description of it, including all marks, shall be required.

Art. 8. The requesting veterinarian shall be liable for the veracity and accuracy of the information submitted by him.

CHAPTER IV

EIA LABORATORY DIAGNOSTIC TESTS

Art. **9**. For EIA diagnostic tests, the serologic agar-gel immunodiffusion (AGID) test shall be used and shall be performed with an antigen registered with and approved by DDA; or any other officially accepted serologic test.

Art. **10**. The laboratorial diagnostic test results shall be released on the same request form.

Paragraph 1. Positive results must be immediately forwarded to the DFA's SSA of the state where the positive tested animal is located.

Paragraph 2. Negative results must be forwarded to the requesting veterinarian or to the animal's owner.

Art. **11**. For a serologic survey aimed at property control, the form titled "Request and results of Equine Infectious Anaemia test for the purpose of a serologic survey" (Annex II) shall be used. This form is not valid for the movement of animals.

Art. **12**. EIA laboratory tests' negative results shall be valid for 180 (one hundred eighty) days for controlled properties, and for 60 (sixty) days for other cases, as of the date of sample collection.

Art. **13**. The animal's owner may request retesting, by applying to the DFA's SSA of the respective state within a maximum of eight days after receiving notification of the results. The confirmatory test shall be performed by the same laboratory that did the first testing.

Art. **14**. Retesting shall be performed by an official laboratory on sample collected by the official service for investigation purposes.

Sole Paragraph. Should an owner request confirmatory test or retesting in case of positive results, the animal must remain in isolation after receipt of the positive results of the first test until the final determination, when the pertinent measures shall be adopted.

Art. **15**. Accredited laboratories must submit a report on its activities to the Federal Agricultural Office's Animal Health Service of the respective state by the fifth working day of the subsequent month (Annex III).

Art. **16**. Producers of antigen for EIA diagnostics must submit to the state SSAs a monthly report on the product's sale to their respective states (Annex IV).

CHAPTER V

OUTBREAK

Art. **17**. Once a outbreak is detected, the following measures shall be adopted:

I – Interdiction of the property after identification of the carrier equine, entry of the occurrence into the records, notification of the owner of the prohibition of the exit of equines from the property and of the movement of items susceptible of being carriers of the EIA virus;

II – Epidemiologic investigation of all animals that tested EIA positive, including their movement record;

III - Permanent branding of EIA carrier animals with a hot iron on the left shoulder, with an "A" within a circle 8 cm (eight centimeters) in diameter, followed by the state abbreviation, pursuant to the model in Annex V;

IV – Sacrifice or isolation of carrier equines;

V – Laboratory EIA testing of all equines on the property;

VI – Lifting of the interdiction of the outbreak property after two EIA negative tests on all equines on the property, at an interval of 30 (thirty) to 60 (sixty) days; and

VII – Orientation to the owners of properties in the perifocal area, by the Official Veterinary Service, to submit their animals to laboratory testing for EIA.

Sole Paragraph. Branding of equines is incumbent on the Official Veterinary Service, and shall not be required if the animals are immediately sacrificed or sent for sanitary slaughtering.

If the transportation of the animals to the slaughterhouse requires a stop for rest or feeding, the animals must be branded and the rest stop must be previously approved by the respective state's Animal Health Service.

CHAPTER VI

SACRIFICE OR ISOLATION

Art. 18. The sacrifice or isolation of EIA carrier equines shall be determined pursuant to DDA norms after analysis of the measures proposed by CECAIE.

Art. 19. The sacrifice of a carrier animal shall be done by the Official Veterinary Service within a maximum of 30 (thirty) days as of the diagnostic test result, preferentially on the property where the animal is located.

Sole Paragraph. If the sacrifice of the carrier animal cannot be done on the property, the sanitary slaughter may be done at a slaughterhouse with Federal Inspection Service, and the animal should be transported in an appropriate vehicle with a numbered seal applied at the origin.

Art. 20. The sacrifice of a carrier animal must be fast and painless and done under the responsibility of the Official Veterinary Service.

Art. 21. The sanitary sacrifice shall be entered into the records (Annex VI). The entry shall be signed by the official veterinarian, the animal's owner or his legal proxy, and at least one witness.

Art. 22. The sacrificed animal's owner shall not be entitled to indemnification.

Art. 23. Should the owner or his legal proxy refuse to accept the notification of the property's interdiction or the carrier animal's sacrifice, such refusal shall be entered into the records in the presence of two witnesses, and the police shall be called in to ensure the enforcement of the sanitary measure, while the infringer shall be subjected to the penalties under the law.

Art. 24. Should the measure adopted be the carrier animal's isolation, the animal must be branded as provided under Art. 17, III hereunder.

Sole Paragraph. Isolation shall be allowed only in the case of carrier animals in a high-risk area, as indicated by the CECAIE of the respective state.

Art. 25. The equine permanently branded as EIA carrier found in another property or in transit shall be summarily sacrificed in the presence of two witnesses, save if confirmedly destined for slaughter. The property on which such an animal is found shall be considered as an outbreak.

CHAPTER VII

CONTROLLED PROPERTY

Art. 26. A property shall be considered controlled if it has no animal that has tested positive in two consecutive EIA diagnostic tests performed at a 30 (thirty) to 60 (sixty) day interval.

Art. 27. To maintain its EIA controlled status, a property must submit its entire equine herd to testing once every six months, with negative results,

Sole Paragraph. Testing at a shorter interval may be determined at the discretion of the state's Official Veterinary Service.

Art. 28. A property declared as controlled for EIA by the respective state's SSA shall be granted a certificate at the request of the interested party, who should use the form shown in Annex VII hereto for the purpose. This certificate shall be renewed every 12 (twelve) months, after testing of the entire equine herd

Art. 29. The sanitary monitoring of a controlled property shall be incumbent on an independent veterinarian under the supervision of the respective state's Official Veterinary Service.

Art. 30. It shall be incumbent on the independent veterinarian referred to in the preceding:

I – To keep current the clinical and laboratorial control of the equines on the property;

II – To report immediately any EIA suspected case to the Official Veterinary Service and to adopt the sanitary measures envisaged hereunder;

III – To watch over the property's hygiene and sanitary conditions;

IV – To submit equines from noncontrolled properties to quarantine before incorporating them into the controlled herd; and

V – To see that the controlled property submits a monthly report on its activities to the respective state's SSA by the fifth working day of the subsequent month (Annex VIII).

Art. 31. A controlled property shall lose its status in case of noncompliance with any of the conditions set forth under this chapter.

CHAPTER VIII

MOVEMENT CONTROL

Art.32. The interstate movement of equines shall be permitted only if accompanied by an official movement permit and proof of negative results of the EIA laboratory diagnostic test.

Sole Paragraph. Equines destined for slaughter are exempted from the proof of having been tested for EIA. The transporting vehicle must be sealed at the origin with a numbered seal entered into the movement permit; the seal shall be broken at the final destination by the Federal Inspection Service.

Art. 33. The participation of equines in agricultural and livestock events shall be allowed only if tested negative for EIA.

Sole Paragraph. The events should fall within the period of validity of the negative test certificate.

Art. 34. The validity of an EIA negative test certificate of an equine from a controlled property shall be shortened from 180 (one hundred eighty) days to 60 (sixty) days as of the sample collection date, in case such an equine crosses or remains in an uncontrolled property.

Art. 35. An equine under six months of age is exempted from EIA testing, if accompanied by its mother, provided the latter has tested negative for EIA.

Sole Paragraph. An equine under six months age descending from a positive tested animal, shall be isolated for a minimum of 60 (sixty) days, and at the expiration of this period must be submitted to two consecutive laboratory diagnostic tests for EIA with negative results at an interval of 30 (thirty) to 60 (sixty) days before being incorporated into the negative herd.

Art. 36. The entry of equines into the National Territory shall be subject to proof of negative EIA test results, in addition to other sanitary requirements.

CHAPTER IX

GENERAL DISPOSITIONS

Art. 37. All biological products from equine origin for prophylactic or therapeutic use must have been prepared from animals from controlled properties.

Art. 38. For the purposes of definitive genealogic records, equines must be tested negative for EIA.

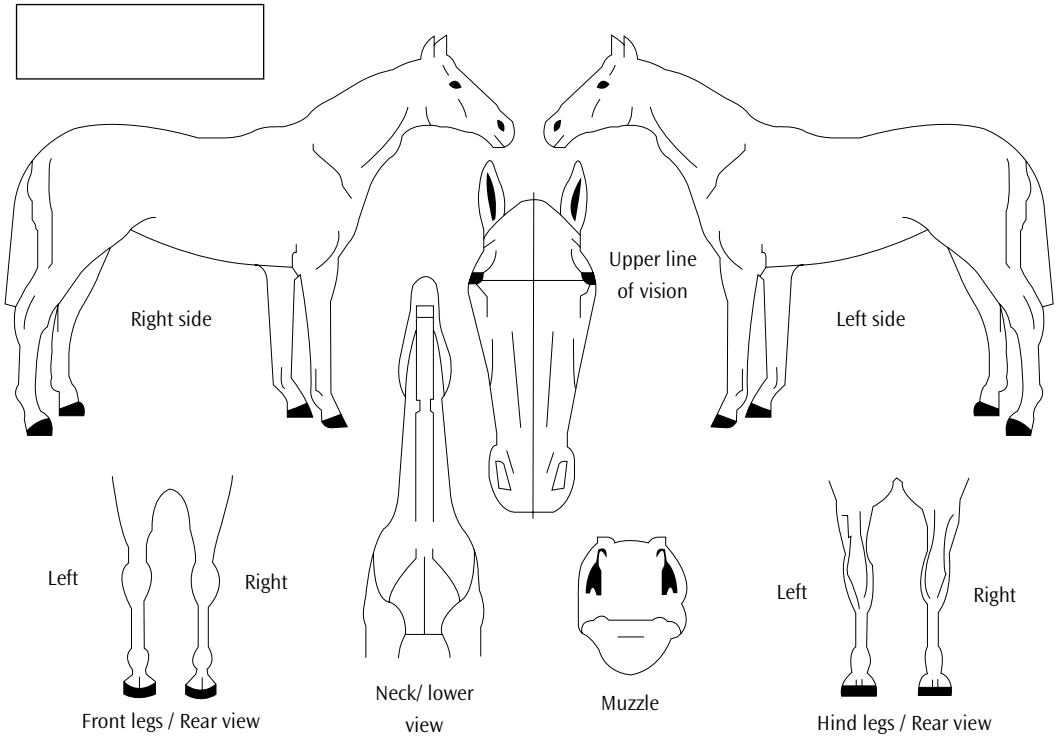
Art. 39. Omissive cases hereunder shall be resolved by the Animal Health and Inspection Department.

ANNEX I

REQUEST AND RESULT OF DIAGNOSTIC TEST FOR EQUINE INFECTIOUS ANAEMIA

Laboratory	Accreditation Administrative Ruling	Test nº.:
Address:	Telephone:	
City / State:	E-mail:	
Animal's owner:	Full address:	Telephone:
Requesting Veterinarian:	Full address:	Telephone:

Name of animal	Brand Record nº.	CLASSIFICATION					
Species:	Breed:	JC	ES	H	F	MU	OTHER
Sex:	Age:						
Property where located:		Nº. of equines on the property:					
Municipality/State:							



Animal's description

REQUESTER: The sample collection from and description on this animal are under my responsibility. _____, _____,_____ Municipality and date of sample collection _____ Requesting Veterinarian's signature and seal

LABORATORY:
Antigen – Brand or Name
Lot nº.
Test result date
Result
Validity date
Signature and seal of Professional in charge

JC: Jockey Club; ES: Equestrian Society; H: Haras; F: Farm; MU: Military Unit

ANNEX II

MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY
ANIMAL AND PLANT HEALTH AND INSPECTION SECRETARIAT
ANIMAL HEALTH AND INSPECTION DEPARTMENT

REQUEST AND RESULT OF DIAGNOSTIC TEST FOR EQUINE INFECTIOUS ANAEMIA
(FOR THE PURPOSE OF SEROLOGIC SURVEY)

			No.
LABORATORY:		TELEPHONE:	
ADDRESS:			
REQUESTING VETERINARIAN		TELEPHONE:	CRMV
ADDRESS:			
OWNER OF ANIMAL(S):		TELEPHONE:	FAX:
ADDRESS:			

ANIMALS' IDENTIFICATION

No. IN ORDER	Name or No.	Test No.	Species (H, D, M)	Breed	Gender	Age in months	Pelage	Result

MANUFACTURING LABORATORY	ANTIGEN USED: _____ LOT No.: _____ VALIDITY: _____

REQUESTING VETERINARIAN:

Place and date _____ Seal and signature _____

PROFESSIONAL IN CHARGE OF LABORATORY

Place and date _____ Seal and signature _____

1st copy – owner (attached to GTA) 2nd copy - SSA-DFA 3rd copy- Laboratory

ANNEX III

MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY ANIMAL AND PLANT HEALTH AND INSPECTION SECRETARIAT ANIMAL HEALTH AND INSPECTION DEPARTMENT	MONTHLY REPORT ON EQUINE INFECTIOUS ANAEMIA	LABORATORY:

MONTH / YEAR:	Page:

STATE	MUNICIPALITY	TOTAL			
		PROPERTIES	POSITIVE	NEGATIVE	TESTED
TOTAL					

No. OF PROPERTIES WITH CARRIER ANIMALS, ACCORDING TO THEIR CLASSIFICATION					
JC	ES	H	F	UM	OTHER

Signature and seal

JC: Jockey Club
ES: Equestrian Society
H: Haras
F: Farm
MU: Military Unit

ANNEX IV

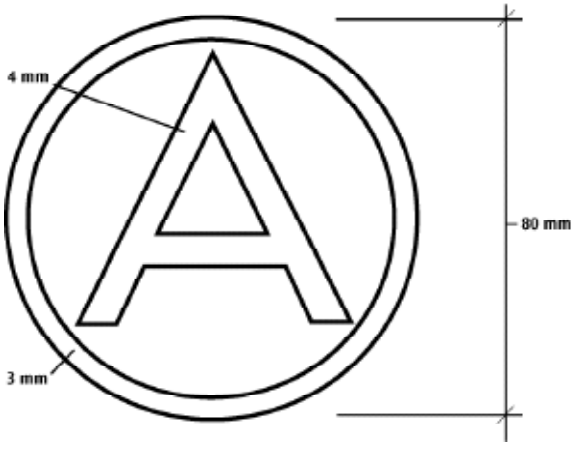
Monthly report on the marketing of “EIA diagnosis Kit”

Month / Year _____ / _____

State	Accredited Laboratory	Municipality	Veterinarian in Charge	Lot	Validity	Kits Qty.

Signature / Seal

ANNEX V



ANNEX VI

SANITARY SACRIFICE AFFIDAVIT

On _____ (month / day / year, at _____ (hour) on the (Property's name) _____ located at _____ the equines indicated below were sacrificed pursuant to DAS Normative Instruction No. _____, of (month / day / year _____ _____, in accordance with the attached test(s)

Animal's name or number	Test No.	Date	Laboratory
Total			

Veterinarian in charge

_____

Name/Seal Signature

Animal's owner or legal proxy

_____

Name/ID Signature

Witness

_____

Name/ID Signature

Witness

_____

Name/ID Signature

ADMINISTRATIVE RULING No. 24 OF APRIL 5, 2004

Published in the Official Gazette of April 12, 2004 Section 1, Page 7

Approves Norms on Glanders Control and Eradication.

THE MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY'S ANIMAL AND PLANT HEALTH AND INSPECTION SECRETARY, by virtue of the powers vested in him under Art. 83, IV of the Department's Internal Regulations approved under Ministerial Administrative Ruling No. 574 of December 8, 1998; having in view the provisions of the Animal Health and Inspection Regulations approved under Decree no. 24548 of July 3, 1934, and Proceeding NO. 21000.001675/2003-5,

RESOLVES:

Art. 1. To approve Norms on Glanders Control and Eradication.

Art. 2. The Animal Health and Inspection Department-DDA shall issue norms complementary to this Normative Instruction as necessary.

Art. 3. This Normative Instruction shall enter into force on the day of its publication.

MAÇAO TADANO

ANNEX

NORMS ON GLANDERS CONTROL AND ERADICATION

CHAPTER I

DEFINITIONS

Art. 1. For the purposes hereunder, the following definitions shall apply:

Equid: Any animal of the Equidae family, including horses, donkeys, and mules;

Outbreak: Any establishment where the existence of one or more than one animal infected with the glanders agent (*Burkholderia mallei)* is detected and confirmed by the Official Veterinary Service;

Fomites: materials supposedly or provenly contaminated with the glanders agent;

Accredited Laboratory: a laboratory officially qualified by the Ministry of Agriculture, Livestock, and Food Supply-MAPA for performing glanders diagnostic testing;

Official Laboratory: a laboratory belonging to MAPA's diagnostic laboratories network;

Registered Veterinarian: a veterinarian registered with the DFA Animal Health Service in the state and qualified for collecting and submitting material for the performance of laboratory glanders diagnostic testing;

Official Veterinarian: a veterinarian of the state or federal animal health and inspection service**;**

Property subject to sanitation procedures: establishment subjected to sanitation procedures after its confirmation as a outbreak;

Interdicted property: establishment where the Official Veterinary Service has suspected the occurrence of glanders, and where animal health and inspection measures have been applied by the Official Veterinary Service, including the temporary prohibition of the entry and exit of equids;

Monitored property: establishment whose equid herd is periodically subjected to clinical ex-

ams and laboratory tests pursuant to DDA norms, with a view to the property's certification;

Property: any establishment, public or private, rural or urban, where equids are kept for any purpose;

Owner: any natural person or legal entity that owns or holds one or more than one equid for any purpose;

Mallein Test: allergic hypersensitivity test performed by inoculation of Mallein Purified Protein Derivative (PPD) on the lower eyelid of equids suspected of being affected by glanders;

Complement Fixation Test (CF): serologic test based on the detection of glanders specific antibodies in equids;

Sanitary Regime: set of animal health and inspection measures applied by the Official Veterinary Service, consisting of the Animal Health and Inspection Department-DDA/SDA/MAPA; the Animal Health Service of the Federal Agricultural Office in the states; and the Animal Health and Inspection Service of the Agricultural Secretariat, or other specific state agencies.

CHAPTER II

DIAGNOSTIC

Art. 2. For the purposes of glanders serologic diagnostic, the Complement Fixation (CF) test or another test previously approved by the Animal Health and Inspection Department-DDA shall be adopted.

1. The CF test may be performed solely by an official or accredited laboratory.

2. A negative CF test result shall be valid for 180 (one hundred days) in the case of animals from monitored properties, and for 60 (sixty) days in other cases.

3. The collection of material for glanders testing for any purpose must be done by an official or registered veterinarian.

4. Forwarding material for glanders testing must be done only by an official or registered veterinarian.

5. The result of the laboratory diagnostic test shall be issued on the respective application form.

Paragraph 1. Positive results must be promptly communicated to the SSA/DFA of the state where the reactive animal is located. Positive results may be sent directly to the Animal Health and Inspection Service of the State Secretariat of Agriculture, at the discretion of the state SSA.

Paragraph 2. Negative results should be sent to the requesting veterinarian or to the animal's owner.

6. Samples for glanders testing from any state should be accompanied by the request/result form approved under Normative Instruction (Annex I).

Art. 3. CF reactive animals may be subjected to complementary diagnostic testing, namely, the mallein test, in the following cases:

1. CF reactive animals that show no clinical symptoms of the disease.

2. CF non-reactive animals that show clinical symptoms of the disease.

3. Other cases, as the DDA may deem necessary.

Art. 4. The mallein complementary testing shall not be done in the following cases:

1. CF reactive animals that show clinical symptoms of the disease; in this case, the CF test shall be considered conclusive.

2. Animals from a relapsing property, which shall be immediately subjected to the Sanitary Regime; in this case, the CF test shall be considered conclusive.

Art. 5. The mallein test shall be performed through intradermal application of a Mallein PPP at a dosage of 0.1 ml on the lower eyelid of one of the animal's eyes; the reading should be done 48 hours after the application.

Sole Paragraph. The mallein test must be performed by an official service veterinarian.

1. Animals showing oedematous swelling of the eyelid with or without purulence after mallein application shall be considered positive.

2. Animals that do not show reaction to mallein must be retested 45 (forty-five) to 60 (sixty) days after the first mallein application.

3. The diagnostic of animals remaining non-reactive after the second mallein application shall be considered conclusive, and the official health and inspection service shall issue the pertinent certificate (Annex II), which shall be valid for 120 (one

hundred twenty) days, during which period the animals may not be submitted to the CF test again.

Art. 6. At DDA's discretion, other measures may be adopted in accordance with the assessment of epidemiological conditions and with the advance of diagnostic means for the control and eradication of glanders.

CHAPTER III

CERTIFICATION OF PROPERTIES MONITORED FOR GLANDERS

Art. 7. The certification of properties being monitored for glanders shall be voluntary and the requisite conditions shall be subject to specific regulations to be issued by the DDA.

CHAPTER IV

ERADICATION OF A GLANDERS OUTBREAK

Art. 8. A property found to have one or more than one animal conclusively tested for glanders shall be considered an outbreak of the disease and immediately interdicted and subjected to the Sanitation Regime measures.

Art. 9. Positive animals shall be immediately sacrificed and no indemnification shall be granted (pursuant to Decree No. 24538 of July 3, 1934). After the sacrifice, the carcasses shall be incinerated or buried on the same site, and the premises and fomites shall be disinfected by the Official Veterinary Service. All the remaining equids shall be subjected to the glanders diagnostic tests referred to in Chapter II hereunder.

1. The sacrifice of positive equids must be done by an Official Veterinary Service professional in the presence of two reliable witnesses.

Art. 10. The property's interdiction shall be lifted by the Official Veterinary Service after the sacrifice of positive animals only after the performance of two successive CF tests of the entire herd at 45- and 90- day intervals, with negative diagnostic test results.

CHAPTER V

EQUIDS' PARTICIPATION IN HORSE EVENTS

Art. 11. The participation of equids in equestrian events in states where glanders cases have been confirmed shall be restricted to animals meeting the following requirements:

1. Valid proof of negative glanders test results, pursuant to Annex I or Annex II.
2. Absence of glanders clinical signs.

CHAPTER VI

CONTROL OF INTERSTATE MOVEMENT OF EQUIDS

Art. 12. The interstate movement of equids from a state where the occurrence of the glanders agent has been confirmed must meet the following sanitary requirements:

1. Valid proof of negative glanders test results, according to Annex I or to Annex II.
2. Absence of glanders clinical signs.

Art. 13. Equids from glanders-free states entering states where the glanders agent has been detected; and returning to their state of origin or to another glanders-free state must be in compliance with the requirements listed in the preceding Art. 12.

CHAPTER VII

CONTROL OF THE INTRASTATE MOVEMENT OF EQUIDS

Art. 14. The state animal health and inspection services shall issue norms on the control of the intrastate movement of equids.

CHAPTER VIII

GENERAL DISPOSITIONS

Art. 15. Notification of a suspected outbreak may be done by the owner, surveillance

services, or third parties.

Art. 16. The costs of glanders diagnostic tests shall be defrayed by the animal's owner, except for tests performed for the purposes of sanitary surveillance or of interest to the animal health service.

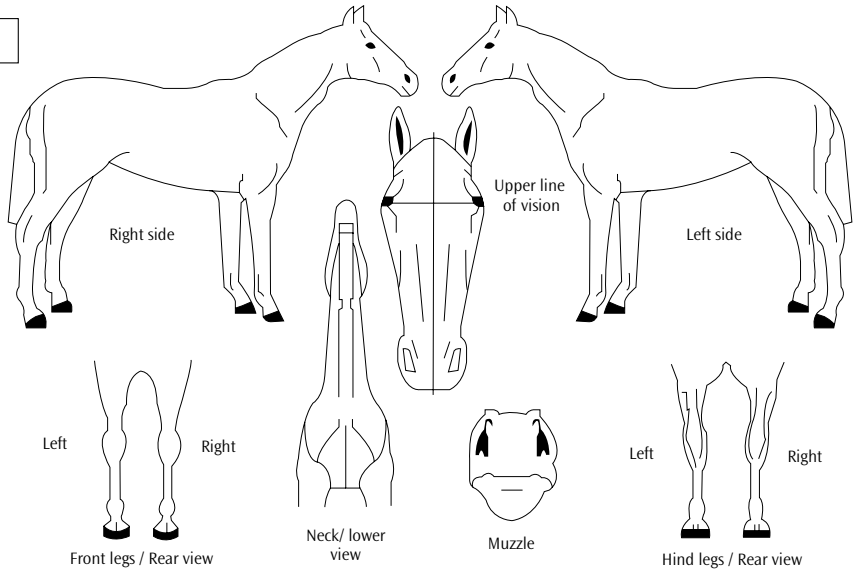
Art. 17. Omissive cases shall be resolved by DDA.

ANNEX I

GLANDERS DIAGNOSTIC CF TEXT REQUEST AND RESULT FORM

<table>
<tr><td colspan="3">Laboratory</td><td colspan="3">Accreditation Normative Ruling</td><td colspan="2">Test Nº.
(State) SERIALS Nº.</td></tr>
<tr><td colspan="3">Animal's Owner</td><td colspan="3">Address</td><td colspan="2">Telephone</td></tr>
<tr><td colspan="3">Requesting Veterinarian</td><td colspan="3">Address</td><td colspan="2">Telephone</td></tr>
<tr><td colspan="2">Name</td><td colspan="2">Registration Nº. / Mark</td><td colspan="4">CLASSIFICATION</td></tr>
<tr><td colspan="2">Species:</td><td colspan="2">Breed:</td><td>JC</td><td>ES</td><td>CR</td><td>H</td><td>BF</td><td>MU</td></tr>
<tr><td colspan="2">Gender:</td><td colspan="2">Age:</td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="4">Property where the animal is located</td><td colspan="4" rowspan="2">Number of equids on the property</td></tr>
<tr><td colspan="4">Municipality/State</td></tr>
</table>

Pelage:



Animal's description:

OFFICIAL REQUESTER:	LABORATORY:
The animal was examined by me today: Place and date: _____ Professional in charge's signature and seal	Test date: Result: Validity: _____ Veterinarian's hand and seal Professional in charge's signature and seal

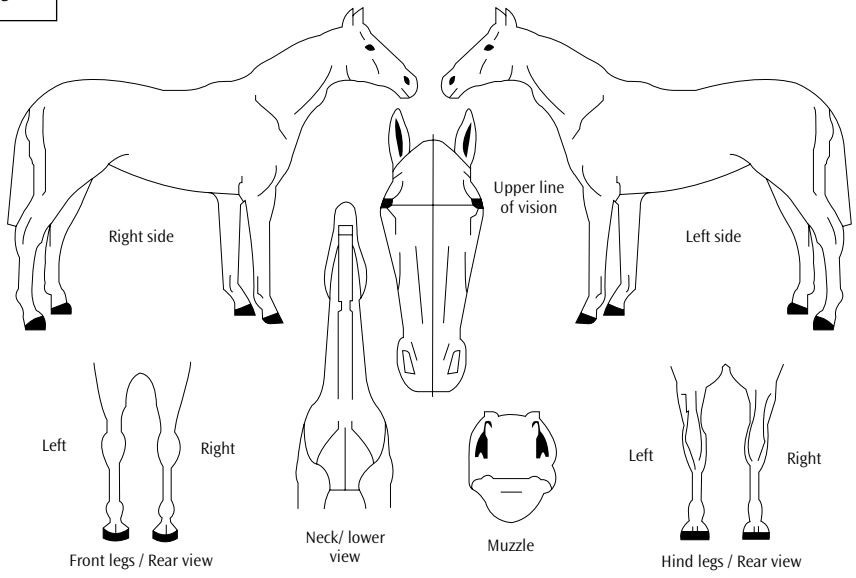
JC: Jockey Club; ES: Equestrian Society; CR: Cancha reta;
; H: Haras; F: Breeding Farm; MU: Military Unit

ANNEX II

MALLEIN TEST REQUEST AND RESULT FORM

Animal's owner		Address					Telephone
Requesting veterinarian		Address					Telephone
Name	Registration/ No./Mark	CLASSIFICATION					
Species:	Breed:	JC	ES	CR	H	BF	MU
Gender:	Age:						
Property where the animal is located		No. of equids on the property					
Municipality/State							
CF test No.:	Laboratory where the CF test was performed:						

Pelage



MALLEIN APPLICATION DATE:	READING DATE
TEST RESULTS INTERPRETATION: ( ) POSITIVE ( ) NEGATIVE ( ) VALID	
NAME OF PROFESSIONAL IN CHARGE OF THE TEST:	
SIGNATURE AND SEAL	

JC: Jockey Club; ES: Equestrian Society; CR: Cancha reta;
; H: Haras; BF: Breeding Farm; MU: Military Unit

NORMATIVE INSTRUCTION No. 12 OF JANUARY 29, 2004

Published in the Official Gazette of February 5, 2004 Section 1, Page 1

Defines Quality Criteria for Accreditation and Monitoring of Laboratories for Glanders Serologic Diagnostic based on the Complement Fixation Technique.

THE MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY'S AGRICULTURE AND LIVESTOCK HEALTH AND INSPECTION SECRETARY, by virtue of the powers vested in him under Art. 15, II of Annex I to Decree No. 4629 of March 21, 2003 and under Art. 4 of Ministerial Normative Instruction No. 516 of December 9, 1997, having in view SDA Normative Instruction No. 51 of June 27, 2003 and Proceeding No. 21000.000039/2004-39,

RESOLVES:

Art. 1. To define Quality Criteria for Accreditation and Monitoring of Laboratories for Glanders Serologic Diagnostic based on the Complement Fixation Technique, the pertinent procedures, and annexes.

Art. 2. Accreditation referred to in the preceding article shall be granted Public Laboratories for official serologic surveys, movement of animals, and surveillance in case of outbreaks, and Private Laboratories in regard solely to the movement of animals. In addition, the Animal Health and Inspection Department-DDA may establish other criteria as needed.

Art. 3. This Normative Instruction shall enter into force on the day of its publication.

RUI EDUARDO SALDANHA VARGAS

ANNEX

QUALITY CRITERIA FOR ACCREDITATION AND MONITORING OF LABORATORIES FOR GLANDERS SEROLOGIC DIAGNOSTIC

1. OBJECTIVE

To define quality criteria for the accreditation of laboratories by the Animal Laboratory Coordinating Office-CLA, Animal Health and Inspection Department-DDA.

2. APPLICATION

The criteria hereunder shall apply to both public and private laboratories solely in respect of DDA needs as regards their number and geographical location.

3. MATERIAL

3.1. Antigen

3.1.1. Only controlled antigens and serums registered with the Ministry of Agriculture, Livestock, and Food Supply-MAPA or imported under MAPA authorization may be used, within their validity period.

3.2. Reference inputs:

-Complement

- Hemolysin
- sheep red blood cells at 2 percent
- Glanders antigen
- High positive control serum
- Low positive control serum
- Negative control serum
- Reagent and cyanmethemoglobin standard kit

Provision of these inputs shall be incumbent on each accredited laboratory.

3.3. Sample to be analyzed: equine blood serum.

4. SAMPLE HANDLING

4.1. Samples must be properly identified and kept under refrigeration;

4.2. Samples must be accompanied by application and results report forms, pursuant to the model in Annex III hereto;

4.2.1. Public accredited laboratories shall receive samples equally accompanied by the forms indicated by DDA for cases of the disease's epidemiologic surveillance;

4.3. Samples must be daily entered into an appropriate log, pursuant to the model provided by CLA in Annex IV;

4.4. Samples must be divided into two portions of equal volume sufficient for the performance of tests and confirmation tests;

4.5. The test confirmation label (Annex V) must be filled out and sealed together with the confirmation test samples. The seal shall be made of plastic, numbered, and inviolable.

5. CONSERVATION AND STORING

5.1 The sample to be analyzed must be kept under refrigeration for a maximum of seven days, and shall be frozen thereafter;

5.2. Samples must be stored in a freezer at -20ºC for thirty days for the confirmation test.

6. BIOSECURITY

6.1. Individual protective equipment (IPE) is recommended while laboratory activities are being carried out.

6.2. As samples fall into the A category of solid residues (National Environmental Council's Resolution No.5 of August 5, 1993, published in the Official Gazette no. 166 of August 31, 1993), they must be autoclaved at 120ºC for thirty minutes under one-pound pressure before being discarded. Current biosecurity norms should be complied with.

7. RESULTS AND REPORTS

7.1. Test results must be released on appropriate forms, pursuant to item 4.2 hereunder and to an established flowchart.

7.1.1 POSITIVE RESULT: should be promptly and confidentially communicated to the Animal Health Service/Section/Sector (SSA) of the Federal Agriculture Office-DFA in the State where the reactive animal located. The pertinent service/section/sector shall officially notify the interested party. The local DFA may determine that notification be sent directly to the executing body.

7.1.2. NEGATIVE RESULT: should be communicated to the veterinarian who signed the test request and/or to the interested party.

7.2. Every accredited laboratory must submit a monthly report on its activities by the fifth business day of the subsequent month to the DFA's SSA where the laboratory is located, as well as to CLA, pursuant to Annex IV hereto, whether tests have been performed or not.

7.3. Only the technical professional or his deputy may sign the test result form and the monthly report.

8. LABORATORY

8.1. A laboratory must have the facilities, equipment, glassware, utensils, and solutions appropriate for the performance of the Complement Fixation test.

8.2. The facilities should allow an operating flow appropriate for the activities to be carried out by the laboratory.

9. FACILITIES

9.1. Protocol: a room reserved for receiving samples and entering them into the records, and for issuing and filing results.

9.2. Testing room: a room where samples will be processed. It should have a waterproof counter resistant enough to stand disinfection, washable walls and sufficient, adequate power supply outlets for the operation of equipment.

9.3. Washing and sterilization room: a room provided with power supply outlets, and tanks or sinks for washing and sterilizing the material used in the performance of diagnostic tests. Wall surfaces must be washable.

10. TECHNICAL PROFESSIONAL IN CHARGE OR DEPUTY

10.1. The technical professional(s) in charge must be qualified for test performance under the protocol established by CLA herein.

10.2. For the purposes of a laboratory's accreditation and monitoring, the professional(s) in charge shall be subject to technical auditing by CLA auditors, through test performance monitoring at their respective laboratory.

10.2.1. As an alternative, qualification exams will be held at units of the CLA/MAPA laboratories network, pursuant to criteria and schedule established by CLA.

11. PERFORMANCE OF CONFIRMATION TESTS

11.1. Confirmation tests shall be performed

solely at the laboratory that did the first tests.

11.2. Confirmation tests must be applied for by the interested party (pursuant to form shown in Annex VI) within eight days as of receipt of results.

11.3. Confirmation tests must be applied for to the SSA/DFA of the state where the reactive animal is located. SSA/DFA shall notify the laboratory that did the first test, setting the date and hour for the performance of the confirmation test. An SSA/DFA technician may attend and inspect the testing and check the result.

11.4. Absence of an SSA/DFA representative shall not prevent the performance of confirmation tests, provided the dispositions under the preceding item are complied with.

11.5. Samples for confirmation test should be kept for a minimum of thirty days as of issuance of the result, to be available to MAPA upon request.

11.6. It shall be incumbent on the veterinarian that has requested the confirmation test to attend it and to check the accuracy of the result(s).

11.7. The result of a glanders confirmation test shall be issued in a new application and result notification form, and forwarded as described under 7.1. above.

11.7.1. The seal number and the record number must be entered in the form's slot for observations to identify the test as a confirmation test.

11.8. Should the requesting veterinary or his deputy waive the performance of a conformation test in a written statement or by failing to attend the confirmation test, the result of the first test shall prevail.

12. DOCUMENTS REQUIRED FOR ACCREDITATION

12.1. Accreditation application submitted by the enterprise's legal representative.

12.2. Filled-out Laboratory Registration form.

12.3. Resume of the technical professional in charge and/or his deputy (activities related to accreditation).

12.4. Statement from the Regional Veterinary Medicine Council-CRMV with which the applicant and/or his deputy is registered, to the effect that he is current with his obligations and is not subjected to any ethical proceedings.

12.5. Copy of his and/or his deputy's CRMV professional registration card.

12.6. Documents pertaining to the qualification of the technical professionals (senior and his deputy): qualification certificate issued by MAPA and CLA's audit report.

12.7. Current registration as legal entity (CNPJ).

12.8. Plan or sketch of the laboratory facilities, indicating the position of the equipment required for accreditation.

12.9. Copy of the current operation permit issued by the competent local Sanitary Authority, specifying the activities for which the laboratory is qualified.

12.10. Operation permit issued by a senior authority, in the case of an educational and/or research institution.

12.11. Quality and Technical Procedures Manuals.

12.12. Statement by the senior professional in charge and his deputy to the effect that they are familiar with the current legislation on accreditation and monitory of glanders diagnostic laboratories.

12.13. List of employees involved in the analysis subject to accreditation, their employee status, and work schedule.

OBSERVATION:

(1) In the case of a technical professional in charge and/or his deputy working in a laboratory belonging to third parties, the application documents must be issued by the laboratory's owner, director and/or professional in charge.

(2) In case the qualification test is performed at the same time as the audit, all the requisite documents must be handed to the auditor in charge, who will forward them to the accreditation unit.

I – PROCEDURES

1. INTRODUCTION

Complement fixation consists in a chosen glanders serologic method, as it is a highly sensitive, specific test according to OIE.

This technique detects almost only IgG1 anti-

bodies, which are specific to the infection. An antiserum test is titrated through serial dilution and a fixed antigen quantity is added to each well. If the antibody is present in the antiserum, immune complexes are formed. The complement is then added to the solution. At this stage, antigen, test serum, and complement react together. If complexes are present, the complement is activated and is fixed and consumed. At the reaction's final stage, the indicator cells (erythrocytes), together with a sub-agglutinating quantity of antibody (anti-erythrocyte antibody), are added to the mixture. If there is any remaining complement, these cells will be lysed; if the complement has been entirely consumed in the preceding stage, the cells will not be lysed, owing to insufficient quantity of complement in the solution. The quantity of complement used will be sufficient for lysing indicator cells only if none of the complement is consumed.

Under this method, adequate controls are vitally important because some antibody preparations consume complement without the addition of antigen, as is the case with serums that already contain immune complexes. Some antigens may also have an anti-complement activity. Thus, controls should include only antibody and only antigen to find out if none of them by itself is fixing complement. The result of the Complement Fixation test is based on the percentage of sensitized erythrocytes hemolysis.

2. EQUIPMENT

Microplate shaker
Autoclave
Scales
Bain-marie: 58ºC
Bain-marie: 62ºC
Bain-marie: 37ºC
Centrifuge (900 x g) for 15 mL tubes
Centrifuge (900 x g) for 50 mL tubes
Refrigerated centrifuge*
Distiller
Digital spectrophotometer (540 mm range)
Reading mirror*
Bacteriological oven: 37ºC
Freezer: -70ºC*
Refrigerator
Potentiometer
60-minute timer
Vortex mixer
(*) Optional equipment

3. GLASSWARE AND UTENSILS

Pan for ice bath – approximately 44 cm x 30 cm x 08 cm
Cuvette for reagents
Test tube rack
Gauze
96-well round-bottom microtitre plates
Rectangular filter paper
Contact or aluminum paper
di-Log milimeter paper
Monochannel pipette – 100 to 1,000 µl
Multichannel pipette – 10 to 200 µl
Glass pipettes – 1 mL
Glass pipettes– 10 mL
Glass pipettes – 2 mL (1:10 scale)
Glass pipettes – 2 mL (1:100 scale)
Glass pipettes – 5 mL
Bulb or automatic pipeting device
Disposable pointers for automatic pipeting device
100 mL test tubes
15 mL millimeter conic test tubes (for centrifuging)
50 mL conic test tubes (for centrifuging)
13 x 150 mm test tubes
18 x 180 mm test tubes
10 x 70 mm test tubes
10 x 50 mm test tubes
250 mL and 1,000 mL Flat-bottom flasks
50 mL, 250 mL, and 1,000 mL Erlenmeyer flasks

4. SOLUTIONS

Trietanolamin or Veronal concentrated solution
Trietanolamin or Veronal working solution
Distilled water

5. SAMPLE RECEPTION AND PREPARATION

The Complement Fixation test detects antibodies only in serum. Plasma is not acceptable for this test. The serum must be of good quality and free of bacterial contamination and excessive hemolysis. Samples must be properly identified in the tubes by the animal's name or number. They must be forwarded refrigerated or frozen, if centrifuged, and packed in Styrofoam containers with ice.

Test samples and the control serum (high and low positive, and negative) will be diluted at 1:5 in the working solution (125 µl serum + 500 µl).

Equine samples and controls must be inactivated in bain-marie at 58ºC for 35 minutes. Mule, donkeys, and pregnant mare samples must be inactivated at 62.5ºC for 35 minutes.

After the inactivation period, samples should be removed and left at room temperature if they are going to be immediately tested; otherwise, they should be kept at 4ºC for a maximum of 24 hours.

Preparation and washing of red blood cells (RBCs)

Determine the volume of red blood cells necessary for a 2-percent suspension:

For preparing the color standard, 12.0 mL of 2% RBCs will be necessary. Determine if hemolysin titrating is necessary. If it is, increase the volume of 2% RBCs to 36.0 mL;

For titrating complement, increase volume to 12.0 mL;

For the diagnostic test, add 2.0 mL for serum titration, and 1.2 mL for each screening test serum.

Calculate the total volume of 2% RBCs necessary for the following stage:

1. Ignore floating solution (Alserver). Wash RBC three times with diluter.

2. Filter the preserved blood in sterile gauze into a 50 mL centrifuge tube, add working solution, and centrifuge at 900 x g for 10 minutes.

3. Remove the floating solution by suction. Add working solution to the tube, gently mix by inverting the tube, suspending the erythrocyte again, and centrifuge it again at 900 x g for 10 minutes.

4. Carefully remove the floating solution and leucocytes by suction. Add working solution to suspend the erythrocyte again, and transfer it to a 15 mL volumetric centrifuge tube. Gently mix and centrifuge it again as before.

5. Check the color of the floating solution. If it has color, discard the erythrocyte and repeat the initial procedure with a new erythrocyte.

6. Carefully remove the floating solution by suction without destroying the cells. Check the final erythrocyte volume.

7. Calculate the quantity of diluter needed for re-suspending the erythrocyte. For each 1.0 mL of compacted erythrocyte, add 34 mL of diluter.

8. Standardization of erythrocyte at 2%:

Turn on the spectrophotometer beforehand, as per maker's instructions.

Carefully pipet 1.0 mL of the erythrocyte suspension into a volumetric flask containing 25 mL of Drabkin's solution. Mix well, by inverting the tube ten times to lyse the cells. Set the device to the cyanmethemoglobin standard, with a 540 nm wavelength. Calculate the final cell suspension volume, by employing the following formula:

$$\text{Final Volume} = \frac{\text{(test suspension optical density-OD) x (original volume of the 1 mL test suspension)}}{\text{target optical density-OD for an erythrocyte suspension at 2\%}}$$

Dilute suspension with diluter in the estimated quantity.

Reagent and Cyanmethemoglobin (CMH) standard.

(a) Drabkin's Solution (DS):

Prepare a 1:100 dilution of the stock Drabkin's solution in distilled water. This solution remains stable for at least six months in a dark flask. Discard it if it shows cloudiness or precipitates.

(b) Hemoglobin Standard (HS):

Pepare an HS solution by adding 0.1 mL of HS

to 12.5 mL of Drabkin's solution and mix well.

(c) Prepare the CMH Standard:

Label five 12mm x 100mm tubes for standard concentrations of 80, 60, 40, 20, and 0 mg%.

Add DS and HS to the tubes as follows:

CMH Concentration (mg %)

	80	60	40	20	0
HS (mL)	4.0	3.0	2.0	1.0	0.0
DS (mL)	0.0	1.0	2.0	3.0	4.0

Set the spectrophotometer to zero with a tube with 0.0 mg% of CMH.

Proceed to three readings of the optical density (OD) in each tube. Set the apparatus to zero for each time period and estimate the readings' average.

(d) Estimate the target's optical density:

CHM Concentration	OD Readings
80	0.492
60	0.369
40	0.246
20	0.128
200	1.236

$$\text{Instrument factor} = \frac{200 \text{ mg\%}}{1.236} = 161.81 \text{ mg\%/OD}$$

Each target OD of sheep cell suspension is the CMH mg% standard divided by the instrument factor. The mg% CMH standard is the average for a pool of sheep erythrocytes.

Lamb cell suspension (%)	CMH mg% Standard
2.0	25.03
2.8	35.04
3.0	37.54

Example: Target OD for suspension at 2%:

$$\frac{25.03}{161.81} = 0.15$$

Color standard

1. Preparation of the Hemoglobin (Hg) Solution:

Add 18.0 mL of distilled water to Erlenmeyer solution

Add 6.0 - mL of the erythrocyte suspension at 2%

Mix in vortex mixer until cell is completely lysed.

Add 6.0 mL of the mother solution.

Mix the hemoglobin solution and put aside until use.

2. Preparation of erythrocyte solution at 4%:

Add 24.0 mL of the working solution to the Erlenmeyer solution.

Add 6.0 mL of the erythrocyte suspension at 2% to obtain a 4% erythrocyte suspension.

Mix gently by inversion.

3. Color standard

Label 13 serologic tubes (10 mm x 50 mm) at the hemolysis rate shown in Table 1 below. Label the 0% standard with the date and time of preparation.

Table 1:

	0%	10%	20%	25%	30%	40%	50%	60%	70%	75%	80%	90%	100%
Hg	0	0.4	0.8	1.0	1.2	1.6	2.0	2.4	2.8	3.0	3.2	3.6	4.0
Cel	4.0	3.6	3.2	3.0	2.8	2.4	2.0	1.6	1.2	1.0	0.8	0.4	0

Mix tubes in vortex mixer and centrifuge 900 x g for 10 minutes and proceed to OD reading. Store at 4ºC until time for use.

4. Preparation of sensitized blood cells (RBCs)

(a) Add 12.0 mL of erythrocyte at 2% to a 50 mL flask.

Prepare an hemolysin dilution from the stock 1: 10

Add 12.0 mL of the solution resulting from the above dilution to the erythrocyte solution.

Mix rapidly.

Incubate for ten minutes in bain-marie at 37ºC.

Complement titration (C')

The work with complement requires ice bath throughout.

Add 9.0 mL of working solution to a 13 mm x 150 mm tube.

Take out a portion of C' from the -70ºC or -20ºC freezer

Take 1.0 mL of C', add to the working solution, and gently mix to obtain a 1:10 complement dilution. Let solution stabilize for 20 minutes.

Prepare 1:500, 1:600, and 1:700 C' dilutions. Dilutions indicated here are just examples and may vary according to the complement's titration. Add working solution and C' according to the following Table 2:

Table 2:

TITLE	C 1:10	DILUTER
200	0.4	7.6
250	0.3	7.2
300	0.3	8.7
400	0.3	11.7
500	0.3	14.7
600	0.3	17.7
700	0.3	20.7

Gently mix by inversion.

Let diluted C' stabilize for 20 minutes.

Label three series of 10 mm x 50 mm tubes; one series for each C' dilution.

Add working solution to the tubes in the quantities indicated in Table 3.

Add diluted C' to the tubes in the quantities indicated in Table 3.

Add 1.6 mL of sensitized cells to each tube.

Mix tubes in the vortex mixer and set in bain-marie at 37ºC for 15 minutes.

Remove the tubes and mix in vortex mixer.

Replace tubes in bain-marie at 37ºC for another 15 minutes.

Table 3:

REAGENT	TUBE 1	TUBE 2	TUBE 3	TUBE 4
DILUTER	1.0	0.6	0.22	0.0
COMPLEMENT	1.0	1.4	1.8	2.2
HEMOLYTIC SYSTEM	1.4	1.4	1.4	1.4

Remove tubes from bain-marie and centrifuge 900 x g for 10 minutes.

Read optical density of tubes with 50 nm wavelength.

Compare each tube of the series with the color standard.

Determine the hemolysis percentage for each tube.

Draw a Logarithmic Chart:

1. For each series of four titration tubes, plot on a logarithmic paper the C' volume in mL (axis Y) versus the corresponding hemolysis percentage (axis X).

Tubes 1, 2, 3, and 4 correspond to logarithmic numbers 3, 4, 5, and 6 on axis Y.

In addition, logarithmic numbers 3, 4, 5, and 6 on axis Y correspond to 0.3, 0.4, 0.5, and 0.6 mL of C' (Figure 1).

2. A chart is valid when two points are on the left and two points are on the "50" vertical line. A chart is also valid if a middle point crosses the "50" line. If all charts are invalid, titration of C' should be done again with different C' dilutions.

3. On a valid chart, plot the tubes 1 and 2 points and mark the middle point.

Repeat the procedure with points 3 and 4. Draw a straight line connecting middle points.

4. Determine the line inclination angle

On any point of the straight line, measure a 10 cm line to the right.

Measure the vertical line in mm from the end of the horizontal line to the middle points inclined line.

To obtain the inclination angle, measure the two middle points and mark the center.

From this point, draw a line to axis Y. If the inclination angle is 0.44 ± 20º, continue as described below. If the inclination angle is not within this range, repeat the titration of C' with the reserved erythrocyte batch.

Determination of the C' dilution required for the diagnostic test:

From the middle point of the middle points, draw a horizontal line to axis Y;

Read the mL volume for the Chart. This volume contains a 50% unit of C' hemolysis (C'H50);

Determine the volume containing 5.0 C'H50 by multiplying the volume contained in a C'H50 unit by 5 (5.0 C'H50 in 0.2 mL is the quantity needed for the diagnostic test).

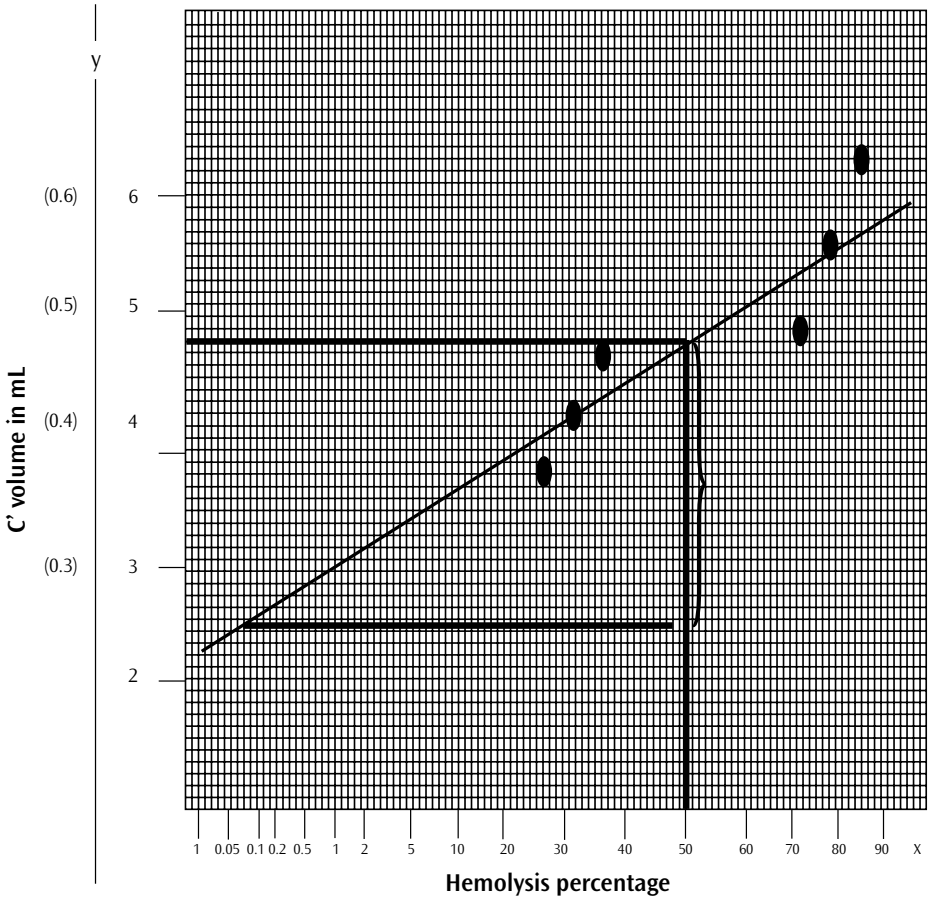
Based on the valid chart, calculate the C' dilution necessary for obtaining 5.0 C'H50 in 2.0 mL through the following equation:

$$\frac{\text{C' dilution used in titration}}{\text{Quantity of C' used in titration}} = \frac{\text{dilution in the test}}{\text{C' quantity used in the test}}$$

Example: The C' titration volume in the 1:500 dilution is 2.15 mL (5.0 x 0.43 mL). The quantity of C' in the test is 0.2 mL (0.025 mL/well x 8 wells). The C' dilution for the test is calculated as follows:

$$\frac{500}{2.15} = \frac{X}{0.2} \Longrightarrow 2.15x = 500 \times 0.2 = 100$$

$$x = \frac{100}{2.15} = 46.5$$



Test performance

1. Preparation of diluted C'

Determine the volume of diluted C' required for the text, by multiplying the number of wells in the test by 0.025 mL.

Calculate the volume of the working solution and of C'1:10 containing 5.0 C'H50, as determined by the C' titration.

Put the calculated solution volume in a small flask or test tube, depending on the quantity.

Add the volume of C'1:10 in the flask with the working solution and gently mix.

Keep this dilution at 4ºC. Let it stabilize for 20 minutes.

2. Microplate labeling

Serum titration plate:

A 1:5	1	2	3	3	3	3	3	CH	CL	CN	0%	1
B 1:10											25%	2
C 1:20											50%	3
D 1:40											75%	4
E 1:80											100%	5
F 1:160												6
G 1:320												7
AC											9	8

3. Antigen preparation:

Determine the required antigen volume by multiplying the number of wells receiving 0.025 of antigen. Dilute the antigen at 1:125.

Prepare the required working solution volume and mix.

Store the antigen solution at 4ºC until time to use.

4. Adding reagents and samples to the plates:

4.1. Serum titration:

Add 25 µl of the test serum to the 1:10-1:320 dilution wells and on the AC line.

Add 25 µl of the test serum to the 1:5 and 1:10 dilution and AC line.

Add 25 µl of the control serums (high and low positive and negative) to the 1:5, 1:10, and AC wells on the respective columns as shown in Figure I.

In a 25 µl diluter, mix the control serums and the test serums in the 1:10 titration wells for four seconds. Transfer and mix serum in the successive dilutions to each well. At the last dilution (1:320), ignore 25 µl.

Add 25 µl of the diluted antigen to the 1:5-1:320 dilution wells. Add 25 µl of diluted C' to the 1:5 to 1:320 dilution wells and on AC line.

Reagents control (see Table 4).

Mix plates for one minute. Cover plates to minimize evaporation and incubate in an oven at 37ºC for one hour.

4.2. Addition of sensitized and non-sensitized cells

Determine the volume of sensitized cells required for the test by multiplying the total number of wells by 0.05 mL.

Remove the 2% erythrocyte stored at 4ºC and gently agitate for re-suspension.

Add to a flask an erythrocyte volume equal to the volume of the working solution with diluted hemolysin.

Incubate in bain-marie at 37ºC for ten minutes.

Remove the hemolytic system from the bain-marie.

Add 50 µl of sensitized cells to the 1:5-1:320 dilution wells and the AC titration plates and the M and CC screening test columns.

Add 25 µl of the 2% erythrocyte to wells 7, 8, and 9 of the reagents control.

4.3. Addition of other reagents and incubation:

Add 125 µl of each color standard separately to the wells labeled from 0 to 4+.

Cover plates and mix for one minute.

Incubate plates in an oven at 37ºC for 20 minutes.

Remove plates and mix for re-suspending non-lysed cells.

Incubate again for 25 minutes.

Centrifuge plates for 5 minutes at 300 x g, or let rest for at least two yours in the refrigerator.

Table 4 – Reagents Control

WELL	µl DIL	µL Ag	µl C'	µl SH	µl H2%	Results
1	25	25	25	50		0
2	50	25		50		4+
3	50		25	50		0
4	50		25: 1/2	50		Traces at 3+
5	25	25	25: 1/2	50		Traces at 3+
6	75			50		4+
7	100				25	4+
8	75		25		25	4+
9	75	25			25	4+

Antigen anticomplementary control

2 – If hemolysis occurs, there is a problem with the erythrocytes

3 – Free C', total hemolysis

4 – Check the strength of C': 1+ is the ideal

5 – Antigen anticomplementary control if there is much C'

6 – Hemolysin control

7 – Cells control

8 – Cells control

9 – Cells in the presence of antigen

Interpretation of results

Read the results of the reagents' controls, comparing the percentage of hemolysis with the color standard. Interpret results on the basis of Table 5

Compare the reagents controls to determine if they match the standards established in Table 4. If not, repeat the entire procedure.

Read the hemolysis percentage for each tested well. This percentage is based on the size, color of the floating element, and thickness of the bud, in order of their importance.

Sensitized cells should be completely hemolysed in the AC control. If not, the serum is considered anticomplementary, and a new sample should be requested.

The title entered into the records is the dilution subsequent to the last complement fixation.

If few cells remain in the well, the serum is considered inconclusive, and a new sample should be requested.

Table 5. Hemolysis percentage readings' equivalency and numeric values

Hemolysis Percentage	Interpretation	Diagnostic
0	4+	Positive
25	3+	Positive
50	2+	Positive
75	1+	Positive
100	Negative	Negative

If few cells remain, the sample will be considered inconclusive.

OBSERVATION: The report should be conclusive and contain the following information:

☐ NEGATIVE

☐ POSITIVE: Indicate the title found.

☐ INCONCLUSIVE: Requires new sample collection.

☐ ANTICOMPLEMENTARY: Requires new sample collection.

ANNEX I

Hemolysin Titration:

Wash erythrocytes: Calculate the required volume of 2% erythrocyte.

Wash three times at 900 x g for 10 minutes.

From pure hemolysin (HL), make a 1:10 dilution in an 0.85 saline solution.

From 1:10 HL, make 1:1000 HL = 1mL 1:10 HL + 9.0 mL diluter.

Dilute 1:1000 HL = 18 mL diluter + 2.0 1:100.

Label 15 x 180 or 18 x 180 tubes for 1:1500, 2000, 2500, 3000, 4000, 8000, and 16000.

Dilute hemolysin according to the table below:

FINAL HL DIL.	DIL (mL)	HL 1:1000 mL
1:1500	1.0	2.0
1:2000	2.0	2.0
1:2500	3.0	2.0
1:3000	2.0	1.0
1:4000	3.0	1.0
1:8000	7.0	1.0
1:16000	15.0	1.0

Hemolytic System:

Label 12 x 100 mm or 13 x 100mm tubes from 1:1000 to 1:16000 and place in each tube 2.0 mL of 2% H and 2.0 mL of HL dilution as in the above table.

Agitate each tube in a vortex agitator and set in bain-marie at 37ºC for 10 minutes.

Prepare Complement (C') at 1:200, 1:250, and 1:300.

Label three series of tubes for reading the C' dilutions in a spectrophotometer.

	0.8 mL dil
1/1000 – 1/1500 – 1/2000 up to 1/16000 – C' 1/200	0.4 mL C'1/200
	0.8 mL SH

	0.8 mL dil
1/1000 – 1/1500 – 1/2000 up to 1/16000 – C' 1/250	0.4 mL C'1/250
	0.8 mL SH

	0.8 mL dil
1/1000 – 1/1500 – 1/2000 up to 1/16000 – C' 1/300	0.4 mL C'1/300
	0.8 mL SH

Mix for shaking and set in bain-marie at 37ºC for 30 minutes (agitate for 15 minutes).

Preparation of the color standard:

Prepare the color standard (CS) as in the glanders test. Record the optical density values.

Centrifuge tubes at 900 x g for 10 minutes. Recording the CS readings from the spectrophotometer.

Draw the chart:

On milimetered chart paper draw a 20 cm (30 cm) straight line and mark the 1:1000 dilution. To calculate the other fractions, divide 20.000 for each dilution.

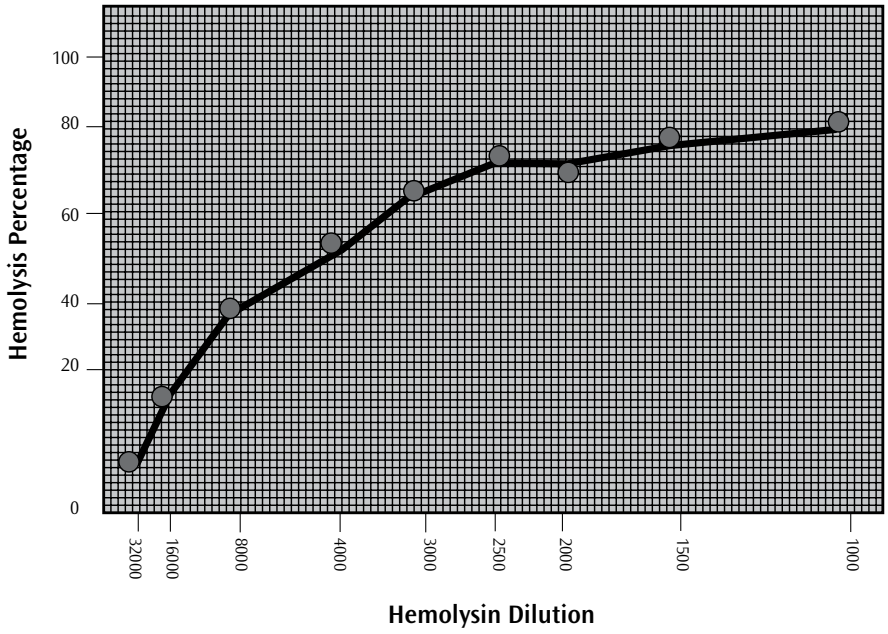
Example:

$\frac{20000}{1500} = 13.3$

From zero point (0), mark 13.3 cm. Calculate up to 1:16000 dilution.

On the vertical line, mark the hemolysis percentages from 10% to 100%, every two squares (every 2.0 cm).

Marking points: Read the optical density of the three c' dilutions for all values, from 1:1000 to 1:16000. Associate the optical density value to the hemolysis percentage CS. Mark the points and plot the graph. The optimum point will be the one showing stability (Figure 2).



Bibliographic References:

United States Department of Agriculture/National Veterinary Services Laboratories - Testing Protocol. Complement Fixation Test for Detection of Antibodies to Burkholderia mallei: Microtitration test. Ames, IA - April 30, 1997.

ROITT, I; BROSTOFF, J; MALE, D. Imunologia. Editora Manole, 5th ed., 1999, 421 pp.

ANNEX II

SOLUTIONS AND REAGENTS

Trietanolamin buffer (TEA) – Mother solution

Place in a 1-liter graduated flask:

28 mL of trietanolamin (Merck 108379)

180 mL of 1N chloridric acid (Merck PA 15893)

75 g sodium chloride (Merck 6404)

1 g hydrated magnesium chloride (Merck5833)

0.2 g calcium chloride (Merck 2382)

Add distilled water to make one liter

Diluted trietanolamin solution – Working solution

Place in a 1-liter graduated flask:

100 mL of mother solution

0.5 g of gelatin in boiling water (Merck 4070)

Measure pH, which should be between 7.3 and 7.4. Citric acid may be used to correct pH.

Dissolve the sodium chloride in approximately 600 ml of distilled water in a 1-liter volumetric flask. Add the other reagents in the order mentioned.

Trietanolamin is a very viscous liquid and should be carefully measured by, for example, transferring it to a graduated cylinder with a

glass rod or pipette, so that the trietanolamin do not touch the cylinder walls, up to 28 mL. The trietanolamin may also be weighed in a precipitate recipient (28 mL is equivalent to 31.45 g). As the density of the different lots may vary slightly, the required weight should be adjusted. Whatever the method used, the recipient in which the trietanolamin was measured should be completely rinsed with the solution in the volumetric flask, to ensure that all the trietanolamin has been incorporated into the diluter. The magnesium chloride and the calcium chloride mother solutions should be prepared just as the first diluter cited, but to a ten-times higher degree of concentration, i.e., 10 g of MgCl26H2O yield 11.8 mL of 4.16 mol/L mother solution and 10 g of CaCl26HO yield 54.4 of 1.25 mol/L mother solution.

The diluted solution pH should be 7.3-7.4 at 20ºC; each new batch of diluter with a concentration of 1:10 should be measured before use.

Veronal buffer (mother solution)

Add 100 mL distilled in 250 mL of Erlenmeyer.

Add 20.3 g of MgCl126H2O

Add 4.4 of CaCl22H2O

Mix gently

Store under refrigeration.

Alsever's solution

Glycose – 18.66 g

Sodium chloride – 4.18 g

Sodium citrate – 8.0 g

Citric acid – 0.55 g

Distills water sufficient to make up 1000 mL

The solution should be sterilized in autoclave, after being filtered in a Seitz filter. Sheep blood may be aseptically kept in the refrigerator in flasks with screw caps. It should not be used before at least five days after bleeding and may be utilized for up to six weeks as long it has not been contaminated.

SHEEP ERYTHROCYTES

Sheep erythrocytes should be chosen from one or more than one sheeps that produce erythrocytes with a satisfactory, consistent degree of sensitivity and taken always from the same animals.

The blood should be aseptically collected in a recipient containing Alsever's solution in the same quantity as the blood.

The mixture should be carefully shaken and distributed into 18 x 180 test tubes and refrigerated. Use after five days.

Hemolysin (Amboceptor)

This is a serum with a high titer of antibodies against sheep erythrocytes. When these antibodies are combined with erythrocytes in suspension, these erythrocytes are sensitized, i.e., they are lysed in the presence of free complement.

Hemolysin should be prepared only in rabbits. Most works on serologic techniques (Campbell et al., 1963 or Cruickshank, 1965) give details on the hemolysin preparation method. Hemolysin sold on the market is usually in liquid form and is preserved in an equal volume of glycerin.

Complement

Bleed at least four rabbits, separate the serum from clotting as soon as possible and mix it to prepare the complement. Adult rabbits, well fed with fresh vegetables yield good quality complement. The animals must not take in any food for 12 hours. Pregnant or recently delivered females should not be used. The complement should remain frozen at -40ºC or at lower temperature, if this is done properly. The storage of liquid nitrogen is an effective, practical means. The complement may be purchased in cold-dried and or dehydrated form but even in this form it must be stored in a refrigerator or freezer.

Instructions:

1. The slot assigned to "Observations," should contain information pertaining to the animal's history, any symptoms, contacts, transfers.

2. Report

- Write the report as accurately as possible
- Use blue or black ink pen
- Indicate whorl with a plain "x" on the site, stretching the line, which should end with an "R"
- Indicate elongated whorls by a waving line
- Indicate only the outline of spots, stars, or foot spots
- Never paint or fill out the outlines, shading the spot areas
- Two parallel lines on a member indicate

that the member has no white spot

- Scars should be drawn

- Hoof: black - Neither write nor indicate anything.

White – Indicate with Br (for branco = white)

Mottled – Indicate with Rj (for rajado = mottled)

White spot – should be indicated with MB (for mancha branca = white spot)

- LADRE is the pinkish spot on the upper lip, between the nostrils. Should be indicated by the word LADRE written out

- BETA is the pinkish spot on the lower lip

- If there is no discolored area (an area the color of the animal's skin inside the LADRE or BETA, this should be indicated by AND.

- For pampa (pied) animals, indicate only the outline of the color areas, writing in inside the outline the color initial (B for branco, or white; C for castanho, or chestnut brown; A for alazão, or sorrel).

ANNEX III

Seal of the laboratory accredited under Normative Instruction No/2003

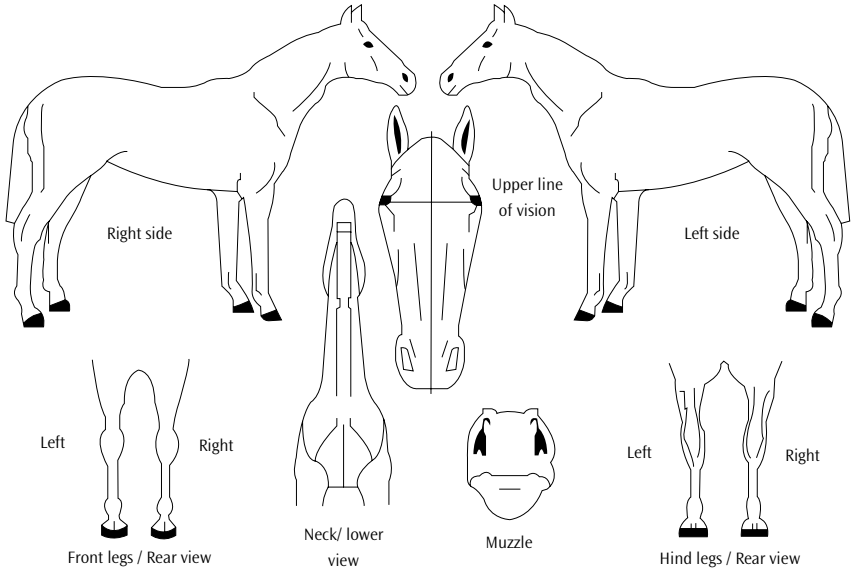
GLANDERS DIAGNOSTIC TEST REQUEST AND RESULT NOTIFICATION FORM

Owner	Property	
Property address/Contact address:	No. State Register	Telephone

Name:	Species:	Equine:	Donkey:	Mule:
Breed:	Age:		Gender/Gestation:	
Registration No./mark:	CLASSIFICATION			

Use:	JC	ES	CR	H	BR	MU
Current location:						

Pelage



Signs's Description :
Observations:

OFFICIAL REQUESTER	LABORATORY
The animal was examined by me on this date: Place and date	Test date: Result: Validity:

Veterinarian's hand and seal	Professional in charge's signature and seal

JC: Jockey Club	ES: Equestrian Society	CR: Cancha reta	H: Haras	BF: Breeding Farm	MU: Military Unit

OBSERVATION: A XEROX COPY OF THIS DOCUMENT IS NOT VALID.

LEGEND:

R- Whorl	⌥ Scar
Br- White	AND- area not discolored
RJ- Motley	LADRE- Pinkish spot (Upper lip)
Pbs- White hairs	BETA-Pinkish spot (Lower lip)
MB- White spot	ᔓᔓᔓᔓᔓ Elongated whorl

ANNEX IV

RECORD LOG

Reg.	Date	Reference	Sender	Municipality/ State	Owner	Property	Animal's Name or No.	Species	Age/ gestation	Obs	Seal No.	Test Result	Date Result issued

ANNEX V

CONFIRMATION IDENTIFICATION CARD

CONFIRMATION IDENTIFICATION CARD

SEAL No.

SAMPLE No.

DATE

OBSERVATIONS:

CARRIER

LABORATORY REPRESENTATIVE

ANNEX VI

MONTHLY REPORT OF ACTIVITIES

MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY ANIMAL AND PLANT HEALTH AND INSPECTION SECRETARIAT ANIMAL HEALTH AND INSPECTION DEPARTMENT ANIMAL LABORATORY COORDINATION	MONTHLY REPORT ON GLANDERS	LABORATORY:

MONTH / YEAR	Page:

State	Municipality	TOTAL							
		SPECIES	POSITIVE	NEGATIVE	INCONCLUSIVE	ANTI COMPLEMENTARY	TOTAL No. SAMPLES RECEIVED	TOTAL No. OF APPROPRIATED SAMPLES	TOTAL No. OF TESTED SAMPLES
TOTAL									

No. OF PROPERTIES WITH CARRIER ANIMALS PER CLASSIFICATION					
JC	ES	H	F	MU	OTHERS

Signature and seal

JC: Jockey Club;
ES: Equestrian Society;
H: Haras;
F: Farm;
MU: Military Unit

ANNEX VII

CONFIRMATION TEST REQUESTED

To SSA/DFA/ _____
Laboratory: _____
Address: _____
I, _____, bearer of ID No. _____ issued by _____ (State) on _____ (M/D/Y) hereby request the performance of a glanders confirmation test on sample No. _____ pertaining to test Nº. _____.
JUSTIFICATION: _____
_____
_____

Interested party's signature:

_____

Place and date _____, ____/____/____ (M/D/Y)

_____

Aware by Professional in charge of the accredited laboratory.

COMPLEMENTARY LEGISLATION

ADMINISTRATIVE RULING No. 84 OF OCTOBER 19, 1992

Published in the Official Gazette of October 22, 1992 Section 1, Page 14874

Approves Norms for the Accreditation and Monitoring of Equine Infectious Anaemia Laboratories.

ADMINISTRATIVE RULING No. 200 OF AUGUST 18, 1981

Adds EIA to the list of diseases subject to the application of animal health and inspection measures (Decree No. 24548 of July 3, 1934).

DDA SERVICE INSTRUCTION No. 17 OF NOVEMBER 16, 2001

Determines the adoption of sanitary measures pertaining to the occurrence of equine influenza.

NORMATIVE INSTRUCTION No. 8 OF APRIL 3, 2007

Published in the Official Gazette of October 4, 2007 Section 1, Page 1
Replaced by the Normative Instruction No. 22 of May 22, 2007

Approves the Rules for the Control and Eradication of Aujeszky's Disease (AD) in domestic pigs, to be complied with all over the national territory

THE STATE MINISTER OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY, in accordance with the duties and responsibilities assigned thereto by Article 2 of Decree No. 5,741 of March 30, 2006, and according to the Judicial Proceeding No. 21000.005409/2006-96, hereby resolves:

Art. 1. To approve the Rules for the Control and Eradication of Aujeszky's Disease (AD) in domestic pig, to be complied with all over the national territory, as provided for in Annex I of this Normative Instruction.

Art. 2. To approve the Contingency Plan for Aujeszky's Disease in domestic pig, as provided for in Annex I of this Normative Instruction, specifying the measures to be taken all over the national territory should the disease be detected in pig, for the purpose of its prompt eradication.

Art. 3. To regulate the use and trade of Aujeszky's Disease vaccine all over the national territory.

Art. 4. This Normative Instruction shall enter into force on the date of publication thereof.

Art. 5. Normative Instruction DIPROD No. 01 of April 8, 1985 is hereby revoked.

REINHOLD STEPHANES

ANNEX I

RULES FOR THE CONTROL AND ERADICATION OF AUJESZKY'S DISEASE (AD) IN PIGS

CHAPTER I

DEFINITIONS

Art. 1. For the purpose of these Rules, the following words and terms shall have the following meaning:

I – Sanitary Slaughter means the slaughter of infected animals or their direct and indirect contacts pursuant to the legislation in force, performed at a slaughterhouse recognized by the Brazilian System of Inspection of Products of Animal Origin;

II – Aujeszky's Disease (AD) means the disease caused by a herpesvirus. Also known as pseudorabies, the disease, which affects several animal species causing nervous complications in piglets, respiratory problems in adult pig and delivery complications in pregnant sow;

III – Rearing establishments means the places where pig are kept or bred for any purpose whatsoever;

IV – Outbreak means the Rearing establishment or any other place where the AD virus has been isolated or detected, or a positive serology

result (total antibodies or antibodies against the viral glycoprotein gE, in those rearing establishments where vaccination is carried out) has been confirmed by an Accredited Laboratory or by the National Agriculture and Livestock Laboratories;

V – Accredited Swine Breeding Farm (ASBF). means the establishment officially certified and monitored according to the legislation in force, where pigs are bred or kept for the purpose of trade or distribution and whose final product is intended for reproduction;

VI – Interdiction means to prohibit, at the Official Veterinary Service discretion, pig and other animals as well as people or materials that could be potential carriers of the disease from entering into and exiting a rearing establishment for any purpose whatsoever;

VII – Accredited laboratory means the public or private laboratory that is granted by the competent authority of one of the three levels of authority that form the Agriculture and Livestock Health Care Unified System, the accreditation to make AD diagnosis as set forth by the Ministry of Agriculture, Livestock and Food Supply the Central- and Higher-level Authority;

VIII – National Agriculture and Livestock Laboratories means the official laboratories of the Ministry of Agriculture, Livestock and Food Supply;

IX – Accredited Veterinarian means the private sector professional accredited by an entity of one of the three levels that form the Agriculture and Livestock Health Care Unified System to perform specific animal sanitary and Inspection activities aimed at the rearing of pig, as set forth by the Ministry of Agriculture, Livestock and Food Supply, in its capacity as the Central- and Higher-level Authority;

X – Official veterinarian means a professional of the Official Veterinary Service;

XI – Contingency Plan means a set of procedures to be adopted should a outbreak occur, for the purpose of controlling and eradicating the AD agent;

XII – Breeding Stock means the group of animals, both male and female, used in a breeding establishment for reproduction purposes;

XIII – Prevalence means the total number of animals infected at a given time, divided by the total number of animals running the risk of getting the infection at the same time;

XIV – Owner means any natural person or legal entity that owns one or more pigs;

XV – Herd means de group of pigs raised under common management conditions, in the same rearing establishment;

XVI – Sacrifice and destruction means the operation carried out by the Official Veterinary Service when the occurrence of AD has been confirmed. It consists in killing all the animals in the herd that have tested positive for the disease and, if necessary, other herds that have been exposed to direct or indirect contact with the AD virus as well as destroying their carcasses;

XVII – Official Veterinary Service means the body responsible for animal sanitary health and inspection activities at any of the three levels;

XVIII – Pigs means any animal of the *Sus scrofa domesticus* (pigs) and *Sus scrofa scrofa* (European wild pig) families;

XIX – AD infected pig means any pig with clinical symptoms or signs consistent with AD, with a diagnosis confirmed by tests carried out in official or accredited laboratories;

XX – ADV infected pig means any pig with no clinical signs or injuries consistent with AD, but that has shown a positive reaction to the lab test carried out in an official or accredited laboratory;

XXI – Downtime means the period when a rearing establishment stays empty following cleaning and disinfection;

XXII – Aujeszky's Disease Virus (ADV) means the AD etiological agent of which pigs are the sole natural host. In pig, the virus can survive in the form of unapparent infections and be reactivated by transmission to susceptible pig;

XXIII – Zone Free of AD means a zone or region in a country where the absence of AD has been systematically determined, in accordance with the recommendations of the Terrestrial Animal Health Code of the World Organization for Animal Health (OIE), and where vaccination has been prohibited for at least two (2) years; and

XXIV – Zone temporarily free of AD means the zone or region in a country where AD outbreaks affect less than 1% of the pig herd and less than 10% of the existing rearing establishments, according to the recommendations of the Terrestrial Animal Health Code of the World Organization for Animal Health (OIE).

CHAPTER II

OBJECTIVE

Art. 2. The objective of these Rules is to lay the foundation for implementing coordinated actions in each Unit of the Federation participating in the Agriculture and Livestock Health Care Unified System, with a view to Controlling and Eradicating AD in domestic pig.

Sole Paragraph. Compliance with the provisions contained herein and in the Terrestrial Animal Health Code of the World Organization for Animal Health will enable the Ministry of Agriculture, Livestock and Food Supply, as the central- and higher-level authority, to recognize a Unit of the Federation as a zone temporarily free of AD or a zone free of AD.

CHAPTER III

BASIC AND SPECIFIC CONDITIONS

Art. 3. The activities to control and eradicate AD are coordinated by the Ministry of Agriculture, Livestock and Food Supply as the Central- and Higher-level Authority, and should be implemented with the voluntary participation of the Federative Unit as the Intermediate-level Authority.

Art. 4. The Units of the Federation interested in participating should prepare a Sate Plan for the Control and Eradication of AD, which will then be submitted for approval to the Ministry of Agriculture, Livestock and Food Supply as the Central- and Higher-level Authority.

Sole Paragraph. The Federative Unit that fails to submit a State Plan shall not be exempted from adopting the AD Contingency Plan, pursuant to Annex II of this Normative Instruction and the legislation in force.

Art. 5. Prior to developing a State Plan for the Control and Eradication of AD, the Intermediate-level Authority should assess the situation for the disease, based on serum epidemiological investigations carried out in those rearing establishments with a history of AD outbreaks and of the use of vaccines, as well as in other locations somehow linked to these establishments.

Art. 6. As a basic condition for preparing the State Plan, the Unit of the Federation should, after having fulfilled the provisions of Art. 5, request that the Ministry of Agriculture, Livestock and Food Supply, as the Central- and Higher-level Authority, take the necessary steps for carrying out a serum epidemiological inquiry into the local epidemiological situation for AD (presence or absence of ADV).

Paragraph 1. The sampling design shall be determined by the Ministry of Agriculture, Livestock and Food Supply, taking into account the pig populations from different productive strata (technified and subsistence rearing establishments) and using a minimum estimated prevalence of 1% of infected establishments and 5% in rearing stocks, with a confidence level of 95%, according to the table shown in Art. 23.

Paragraph 2. Based on the analysis of the serum epidemiological inquiry results, the Intermediate-level Authority in the Federative Unit shall propose the most suitable action strategy for the situation and its position in the State Plan for the Control and Eradication of AD.

Art. 7. The State Plan shall meet certain specific conditions such as:

I – the existence of an active state-level committee on swine health, with the preparation of minutes of meetings that should be forwarded to the Federal Superintendency of Agriculture, Livestock and Food Supply, as the Central- and Higher-level Authority;

II – to have public or private funds to finance the Plan and compensate pig owners that are affected by the sanitary measures resulting from the implementation and maintenance of the actions provided for in these Rules and in the State Plan;

III – to have Rules that are complementary

to the federal legislation, so as to support Plan actions within the Intermediate-level Authority;

IV – to submit a sanitary education project aimed at raising popular awareness of the State Plan for the Control and Eradication of AD to be implemented;

V – to have an emergency group appropriately trained to carry out sanitary health and inspection actions in swine, as well as other actions resulting from the enforcement of these Rules and the State Plan; and

VI – have a well structured animal sanitary health and inspection service within the Intermediate- and Local-level Authorities.

Art. 8. The development of the State Plan for the Control and Eradication of AD will be periodically reviewed through audits to be performed by the Central- and Higher-level Authority in the Intermediate- and Local-level Authorities.

Sole Paragraph. The Official Veterinary Service of the Federative Union that has in place a State Plan for the Control and Eradication of AD, should submit to the Central- and Higher-level Authority a quarterly report on the actions carried out in the period.

Art. 9. The region that succeeds in implementing a State Plan for the Eradication of AD should be subject to a new serum epidemiological inquiry as provided for in Art. 5, in order to request the certification as a zone free or temporarily free of AD from the Ministry of Agriculture, Livestock and Food Supply, as the Central- and Higher-level Authority, provided that the other rules of the International Zoosanitary Code of the World Organization for Animal Health have been complied with.

Sole Paragraph. Where the presence of viral activity is not detected during the initial serum epidemiological inquiry into the epidemiological situation for AD, the Unit of the Federation that meets the provisions contained herein as well as the requirements of the World Organization for Animal Health may request immediate certification as a zone free or temporarily free of AD from the Ministry of Agriculture, Livestock and Food Supply, as the Central- and Higher-level Authority.

Art. 10. Units of the Federation that have been certified by the Central- and Higher-level Authority as free or temporarily free of AD should implement a serum epidemiological monitoring system on a yearly basis, covering all swine rearing establishments that pose a risk, and carry out periodic investigations based on samples collected by the inspection service from swine slaughterhouses, so as to contribute in sustaining this sanitary condition.

CHAPTER IV

DIAGNOSIS

Art. 11. Diagnosing AD in pig will include performing serological tests of Enzyme-linked immunosorbent assay (screening ELISA or differential ELISA for the viral glycoprotein gE, in those establishments where vaccination is adopted) and the Neutralization Test, which are performed exclusively in official or accredited laboratories.

Paragraph 1. Samples of the brain, spleen, lungs and aborted fetuses may be submitted to a virus isolation attempt or to molecular tests (polymerases chain reaction - PCR).

Altered by Administrative Ruling 022 of 05/22/2007.

Paragraph 2. Other diagnostic tests may be used provided that they are approved by the Ministry of Agriculture, Livestock and Food Supply as the Central- and Higher-level Authority.

Art. 12. Manipulation of the AD virus is prohibited all over the national territory, except in official or accredited laboratories or institutions previously authorized by the Ministry of Agriculture, Livestock and Food Supply as the Central- and Higher-level Authority, provided that these have an appropriate level of biosafety to contain the ADV.

Sole Paragraph. Only the aforementioned establishments can own AD diagnosing kits.

Art. 13. The competent authorities at the three levels shall accredit laboratories as determined by the Ministry of Agriculture, Livestock and Food Supply, which will establish the requirements to be met for obtaining the accreditation.

CHAPTER V

VACCINATION OF PIGS

Art. 14. Only vaccines (inactivated or live attenuated) deleted at least for the viral glycoprotein gE, as well as diagnosis kits that enable identifying antibodies against this specific viral particle are permitted in the country. In addition, both should be duly licensed at the Ministry of Agriculture, Livestock and Food Supply as the Central- and Higher-level Authority.

Art. 15. Vaccination is only permitted in those establishments with a positive diagnosis for AD made by an official or accredited laboratory.

Sole Paragraph. Rearing establishments related to the outbreak establishment, as well as those where there is a risk of infection may, at the discretion of the Official Veterinary Service, vaccinate their animals against AD.

Art. 16. The Central- and Higher-level Authority in the Federative Unity should have some form of control over all vaccine doses used in their scope of action, with due regard to the following criteria:

I – The Central and Higher-level Authority in the Federative Unit shall officially authorize sale of the AD vaccine by the manufacturing laboratory or its legal representative, which should indicate the name and address of the owner(s) and the number of doses;

II – The manufacturing laboratory or its legal representative shall sell the vaccine directly to the indicated owner(s) and immediately send to the requesting Federal Superintendency of Agriculture, a copy of the corresponding invoice;

III – In no way the sale of vaccines by the manufacturing laboratory can be made through a dealer or retail network; and

IV – On a monthly basis, the Federal Superintendencies of Agriculture will submit to the Ministry of Agriculture, Livestock and Food Supply a report indicating the owners' names and the number of vaccines used within their scope of action.

Art. 17. By assessing the epidemiological situation of the region for AD, the Intermediate-level Authority may propose in its State Plan a strategy or strategies for using the vaccine as follows:

I – Use of the vaccine is prohibited in the Federative Unit;

II – Use of the vaccine is permitted only during sanitary emergencies resulting from the occurrence of an outbreak, so as to contribute to the sanitation thereof; and

III – Use of the vaccine is permitted for the purpose of reducing prevalence in endemic regions, for a limited time and under the control of the Official Veterinary Service.

CHAPTER VI

SURVEILLANCE AND INFORMATION SYSTEM

Art. 18. The Official Veterinary Service shall maintain a zoosanitary surveillance and information system covering all levels of authority, including a systematic analysis of the data collected and the preparation of periodic reports to meet the requests of the Ministry of Agriculture, Livestock and Food Supply as the Central- and Higher-level Authority.

Art. 19. Every veterinarian, owner, holder and transporter of animals or any other citizen who learns about a possible outbreak of AD or of diseases with a similar clinical picture should immediately notify the Official Veterinary Service.

Paragraph 1. Violations of the provisions of this Article will be investigated accordingly by the Official Veterinary Service, which will lodge a complaint against the offender with the Public Prosecution Service, so that the appropriate liability can be assessed.

Paragraph 2. Where the offender is a veterinarian, a complaint against such professional shall be lodged with the Regional Council of Veterinary Medicine where he/she is registered, so that the appropriate measures can be taken.

Paragraph 3. Where the offender is an accredited veterinarian, in addition to the provisions of paragraph 1 and 2 above, the Official Veterinary Service shall proceed according to the specific legislation.

CHAPTER VII

STRATEGIES FOR ACTING ON AD OUTBREAK

Art. 20. All suspected AD outbreaks AD should be investigated by the official veterinarian, no later than twelve (12) hours after notification thereof, with due regard for biosafety procedures.

Art. 21. The confirmation by the official veterinarian of a suspected case of AD in a rearing establishment shall imply the immediate interdiction thereof.

Art. 22. The confirmation by a laboratory of a suspected case of AD in a rearing establishment shall imply the immediate adoption of measures for sanitation of the outbreak and prevention of dissemination to other rearing establishments as provided for in these Rules and in the AD Contingency Plan (Annex III).

Art. 23. A serum epidemiological investigation shall be carried out in rearing establishments located within a minimum radius of five (5) kilometers from the outbreak as well as in other properties related to the outbreak within a minimum period of thirty (30) days prior to the diagnosis, at the discretion of the Official Veterinary Service, with a view to determining the origin and dissemination of the infection.

Paragraph 1. To evaluate the sanitary situation of a rearing establishment regarding AD, the official veterinarian shall collect samples from swine and send such samples to the official or accredited laboratory for the purpose of diagnosis, using the minimum estimated prevalence of 5% and confidence level of 95%, according to the table below:

HERD	SAMPLED ANIMALS
1-25	ALL
26 - 30	26
31 - 40	31
41 - 50	35
51 - 70	40
71 - 100	45
101 - 200	51
201 - 1200	57
Above 1200	59

Paragraph 2. The table should be used independently for rearing stock and fattening animals.

Art. 24. In an AD outbreak, the Official Veterinary Service may, based on the results of either the serology tests or the estimated degree of herd infection and as provided for in the State Plan, use one of the following sanitation strategies:

I – Immediate depopulation;

II – Gradual depopulation; and

III – Eradication by serology.

Art. 25. In the AD eradication methodology by immediate depopulation, the rearing establishment will go through immediate sanitation procedures as a result of the sacrifice and slaughtering of the whole swine herd, regardless of the age and physiological state of the females in the herd, with an emphasis on the following sanitary measures:

I – The loading of pig should be followed by the Official Veterinary Service, which will seal the transportation vehicle and include the seal number in the transit document;

II – The rearing establishment will comply with a downtime of at least thirty (30) days after the last animals have been removed from the herd; and

III – The sanitary slaughter should take place in a swine slaughterhouse recognized by the Brazilian Animal Products Inspection System.

Art. 26. In the AD eradication methodology by gradual depopulation, the herd should be sanitary slaughtered within a maximum period of ninety (90) days from the diagnosis, based on the following principles:

I – Immediate sanitary slaughter of pigs determined to be infected;

II – Vaccination of herd seven (7) years of age and older, until depopulation of the rearing establishment has been completed, so as to avoid dissemination of the clinical disease;

III – Immediate sanitary slaughter of non-pregnant sows, sows up to the 60th day of pregnancy and replacement sows;

IV – Immediate castration of boars, which should be sent for sanitary slaughtering when in good conditions, pursuant to the legislation in force;

V – Lactating sow should wait until the weaning period is over and then be sent for sanitary

slaughtering when in good conditions, pursuant to the legislation in force;

VI – Sow sixty (60) days pregnant or more should wait for delivery, in which case the provisions of item V will apply;

VII – Piglets in nursery or crèche should be sent for sanitary slaughtering at approximately twenty three (23) kilos of live weight;

VIII – The loading of pigs should be followed by the Official Veterinary Service, which will seal the transportation vehicle and include the seal number in the transit document;

IX – Disinfection will take place as provided for in the Contingency Plan (Annex II) and the rearing establishment will comply with downtime of at least thirty (30) days after the last animals have been removed from the herd;

X - The sanitary slaughter should take place in a swine slaughterhouse recognized by the Brazilian Animal Products Inspection System; and

XI – Piglets in the fattening stage should be sent for sanitary slaughter when they reach the optimal weight.

Art. 27. In the AD eradication methodology by serology, the rearing establishment shall be submitted to periodic serological tests that are capable of telling if the humoral titers result from the infection by ADV or from the vaccination process, with a gradual elimination of the animals that tested positive for AD as follows:

I – Scrifice or Sanitary slaughter of the initially infected animals;

II – Vaccination of herd seven (7) years of age and older, so as to avoid dissemination of the clinical disease, to be suspended at the end of the process, at the discretion of the Official Veterinary Service;

III – New serology of the whole rearing stock thirty (30) days after the infection was detected in the herd, with immediate sanitary slaughter of the infected animals, pursuant to the legislation in force;

IV – Repetition of serologies in 100% of the stock, with 60-day intervals between the tests, as provided for in item III above, until two consecutive negative serological results are obtained; and

V – The sanitary slaughter should take place in a swine slaughterhouse recognized by the Brazilian Animal Products Inspection System.

Art. 28. When authorized by the Official Veterinary Service, the repopulation of the rearing establishment(s) shall be carried out with animals originating in ASBF.

Sole Paragraph. Fattening establishments should be repopulated with animals originating in rearing establishments that have tested negative for ADV in a test carried out at an official or accredited laboratory, based on the sampling shown on the table of Art. 23.

Art. 29. Rearing establishments submitted to any of the control and eradication strategies described in Articles 25, 26 and 27 should have their AD-free condition confirmed by two (2) consecutive negative serologies at two-month intervals carried out independently for the rearing stock and fattening animals, based on the sampling shown on the table of Art. 23.

Sole Paragraph. The first serology should be carried out immediately after the parturition of the first batch of sows introduced.

CHAPTER VIII

TRANSIT OF PIGS AND OTHER MATERIALS

Art. 30 . The transit of pigs vaccinated against AD for any purpose is prohibited, except for immediate slaughter in slaughterhouses recognized by the Brazilian Animal Products Inspection System.

Paragraph 1. Where he rearing establishment does not have sufficient stocking capacity, it may be authorized, at the discretion of the Official Veterinary Service, to transfer piglets to be fattened in another establishment, provided that this is located in the same Federative Unit where the pig will be kept under supervision until they reach the optimal slaughtering weight.

Paragraph 2. Transit should take place in a vehicle sealed by the Official Veterinary Service and accompanied with the transit document issued by an official veterinarian containing the seal number and the indication of vaccinated against AD.

Paragraph 3. The rearing establishment of destination of vaccinated animals shall adopt the same restriction conditions as those of the establishment of origin.

Art. 31. Pigs in interstate transit for fatten-

ing purposes shall be accompanied with the transit document and the certificate issued by the Official Veterinary Service attesting that the animals originate in a rearing establishment where there has been no AD outbreaks in the past twelve (12) months, except in the case of those Units of the Federation recognized as free of AD by the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher-level Authority.

Sole Paragraph. The entry of pigs originating in other Federative Units for the purpose of immediate slaughter regardless of their sanitary condition for AD is hereby permitted, provided that in compliance with the legislation in force.

Art. 32. The transit of pigs between zones in the same sanitary conditions for AD through zones in inferior sanitary conditions should take place in a vehicle sealed by the Official Veterinary Service of the Federative Unit of origin.

Sole Paragraph. No one other than a member of the Official Veterinary Service should break the seal at the place of destination.

Art. 33. The interstate transit of products and byproducts of pigs that have been submitted to sanitary slaughter due to an AD outbreak is hereby prohibited.

Art. 34. Where the non-fulfillment of the rules approved for the transit of pig and products and byproducts thereof is detected, the competent authorities at the Intermediate Level will be responsible for impeding the transit and registering the fact, pursuant to the applicable law.

Paragraph 1. Where irregular transit is intercepted within the borders of the Federative Unit where an Eradication Plan is being implemented, the vehicle should be ordered to return to its place of origin - except for animals affected by the disease - and the appropriate legal sanctions applied.

Paragraph 2. Where irregular transit is intercepted in the interior of the Federative Unit where an Eradication Plan is being implemented, the vehicle should be seized, the animals sacrificed, and the appropriate legal sanctions applied.

Paragraph 3. In the case of products and byproducts of swine origin, these should be seized and destroyed or otherwise disposed of at the discretion of the competent authority, and the appropriate legal sanctions applied.

CHAPTER IX

GENERAL PROVISIONS

Art. 35. Where AD is detected in slaughterhouses, exhibits, auctions and other areas of pig concentration, the whole area shall be considered a outbreak and the sanitary measures provided for herein and in the AD Contingency Plan shall apply, as appropriate.

Art. 36. The measures provided for herein should be implemented with due regard for the other recommendations contained in the AD Contingency Plan.

Art. 37. Other situations not mentioned herein shall be addressed by the Ministry of Agriculture, Livestock and Food Supply, as the Central- and Higher-level Authority.

ANNEX II

CONTINGENCY PLAN

I - INTRODUCTION

1. Background

In 1908, Carini had the opportunity to work with material derived from cattle and dogs infected with the so-called “Scratching Pest”. Outbreaks of the disease, then of obscure etiology and detected in several Brazilian states, were rather frequent. It was only in 1912, with the cooperation of Jezuíno Maciel, that the “Scratching Pest” was found to be nothing more than Aujeszky’s Disease (AD). The finding was confirmed during an AD outbreak in the municipality of Araras, in the State of São Paulo.

In 1934, Decree No. 24,548 defined AD as a disease of mandatory notification in Brazil and subject to animal sanitary health and in-

spection measures. In 1939, Carneiro & Leme diagnosed AD in sheep and goat. In the same year, Carneiro detected the disease in pigs by performing the viral Neutralization Test during a DA outbreak in bovine. The ADV was first isolated in Brazil in 1947.

Since 2001, the State of Santa Catarina has implemented a program to eradicate AD in swine, with the participation of EMBRAPA Swine and Birds, the Intermediate Stage of the System of Attention to Agriculture and Livestock Health in the state (CIDASC), the public accredited laboratory (CEDISA), the Association of Swine Breeders in the state (ACCS), agroindustries and the support of the Ministry of Agriculture, Livestock and Food Supply and the State Agriculture and Rural Development Secretariat.

2. Justification

In the past decades, swine culture in Brazil went through intensive technification with respect to management practices by increasing confined production and the movement of animals. These factors enhance the risk of disease outbreaks and dissemination amongst the country's swine herd. Regardless of how strict the protection sanitary measures taken by a country, a region or a zone free of a disease might be, there is no absolute guarantee that the infectious agent will not be introduced or reintroduced.

When there is an outbreak in a herd, the actions to control or eradicate it should be carried out in an organized, quick and effective way, with a view to minimizing the impact of resulting losses. In this regard, it is necessary to maintain both the technical staff of the three levels of Authority that make up the Unified System of Agriculture and Livestock Health and the supporting staff permanently trained and with access to adequate equipment and materials, sufficient and easily available funds, as well as rules that enable guiding the procedures to be adopted and the necessary legal support.

3. Objective

This CONTINGENCY PLAN contributes to guide actions and procedures towards the early and immediate notification and confirmation of suspected outbreaks of AUJESZKY'S DISEASE (AD), as well as to the implementation of the animal sanitary health and inspection measures required to control and eradicate the disease throughout the national territory.

II - EPIDEMIOLOGICAL CHARACTERIZATION

1. Minimum sanitary conditions

The zoosanitary management strategy should outbreak on the design and adoption of measures that minimize the risk of introduction or reintroduction of a disease in a free country or zone.

Effective activities of different natures are required to minimize the risk of DA outbreaks and ensure the immediate detection and adoption of the measures required to control and eradicate any possible outbreak. The Official Veterinary Service should be underpinned in the following conditions:

- An appropriate operational framework;
- Legal support for the actions, provided for in specific legislation;
- Sufficient and readily available financial resources;
- Sufficient and appropriate human and material resources and equipment;
- A permanently updated register of swine breeders and transporters;
- Staff trained in sanitary emergency;
- A sanitary Education Program that takes into account the habits of each region;
- Active surveillance in commercial and subsistence swine exploitation activities;
- Information systems that enable the quick adoption of sanitary measures;
- An updated list of risk sites such as agroindustries, slaughterhouses, landfills, pet food industries, agriculture and livestock shops, bus stations, airports, ports, and post offices among others;
- Permanent inspection and evaluation of animal health activities, with a view to improving and standardizing actions;
- Active action by the State Swine Health Committee;
- Performance of periodic serum epidemiological inquiries for monitoring disease free zones;
- Control and inspection of pig transit, products and byproducts thereof, pathological and biological products, and animal reproduction materials;

- Sanitary surveillance in ports, airports, frontier posts and post offices;

- Control and inspection of areas of pig concentration;

- Diagnosis laboratories capable of performing tests with the required swiftness and efficacy;

- Funds for payment of compensations relating to herds affected by sanitary measures and the destruction of things;

- Systematic fight against clandestine slaughter;

- Washing and disinfection of swine transportation vehicles after unloading in slaughterhouses, with inspection of such actions in fixed and mobile control posts;

- Prohibition to raise pigs in city dumps;

- Control in the use of leftovers to feed pigs;

- Pig identification systems that enable traceability;

- Interaction between animal sanitary health and inspection services at their different levels;

- Interaction with environmental and rural extension agencies, agricultural schools, rural schools and agrarian science schools;

- Interaction with municipal agriculture and health secretariats;

- Interaction with agroindustries, cooperatives, rural unions, producers' associations and other agribusiness sectors;

- Support of agencies and entities linked to the swine production chain and other public entities (City Halls, the Military Police, Finance Secretariat, etc.); and

- Maintenance of a strategic stock of vaccines.

III – SANITARY EMERGENCY

1. Definition

A sanitary emergency is the set of sanitary actions required to prevent the dissemination and eradicate a outbreak of the disease within the shortest time possible and at the lowest cost for the country. These actions should be carried out by a group of professionals trained in sanitary emergency.

2. Sanitary emergency team

The sanitary emergency team should be established by legal act and comprised of professionals from the Official Veterinary Service, distributed according to the following areas of action:

- General Coordination Unit;

- Field Coordination Unit;

- Laboratory Coordination Unit;

- Administrative/Financial Coordination Unit;

- Communications and Public Relations Coordination Unit;

- Legal Affairs Coordination Unit.

In order to ensure the efficacy of the actions implemented by the sanitary emergency team, the members thereof should be submitted to periodic technical and operational training in the form of simulation of outbreaks of swine disease outbreaks.

3. Responsibilities of the sanitary emergency team

- To implement the animal sanitary health and inspection policy determined by the Contingency Plan;

- To request, where necessary, the collaboration of other sectors concerned in implementing the actions;

- To meet on a regular basis in order to follow up and evaluate all aspects related to field operations;

- To request, where necessary, the technical assistance and cooperation of national or international consultancy;

- To appoint an epidemiologist to advise the Field Coordinator.

4. Duties and responsibilities of the Coordination Units

4.1. General Coordination Unit

a) To mobilize and coordinate the emergency team and necessary staff;

b) To involve the institutions and entities that will participate in the works; and

c) To establish the evaluation and taxation committee, comprised of a representative of the Production Sector, a representative of the Central- and Superior- level Authority and a representative of the Intermediate-level Authority of the Official Veterinary Service.

4.2. Field Coordination Unit

a) To coordinate all routine operations related to sanitary emergencies at field level as well as action strategies adopted;

b) To appoint and oversee the following committees:

Epidemiological surveillance: responsible for the information system and activities involving tracing, inspection, repopulation, quarantine, animal transit, establishment of fixed and mobile posts, and control of animal concentration sites;

- Sacrifice and destruction, sanitary slaughter and destruction of things;

- Cleaning and disinfection of facilities and vehicles and other biosafety procedures;

- Control of vaccines and vaccinations;

- Communication and sanitary education.

Note: The heads of these committees will be in charge of leading and executing the actions related to their tasks, so as to achieve the specific objectives thereof.

c) To ensure logistic support for the committees;

d) To demarcate protection and surveillance areas;

e) To make contact with authorities and other local segments that could provide assistance; and

f) To ensure that all field reports are prepared and submitted to the General Coordination Unit in a timely manner.

4.3. Laboratory Coordination Unit

a) To work with the Field Coordination Unit so as to ensure that samples are properly collected, processed, identified, packed and dispatched.

4.4. Administrative and Financial Coordination Unit

a) To work with the General Coordination Unit with a view to preparing budgets and procuring, distributing and ensuring the supply of materials and services;

b) To coordinate and manage the evaluation and taxation committee.

4.5. Communications and Public Relations Coordination Unit

a) To work with the General and Field Coordination Units by collecting information and making sure that this reaches the media and competent authorities in a properly manner.

4.6 Legal Affairs Coordination Unit

a) To advise the General and Field Coordination Units on legal matters and handle all legal processes inherent in sanitary emergencies.

IV - OPERATION PROCEDURES IN VETERINARY CARE

1. Notification of suspicion

- Every veterinarian, owner and transporter of animals, or any other citizen that gains knowledge of a suspected outbreak of AD or of any other disease with a similar clinical picture should immediately notify the closest unit of the Official Veterinary Service, pursuant to the legislation in force.

- The notification can be provided personally, by telephone, fax or any other available media.

2. Attention to the notification

- Where the person providing the notification is the owner or person in charge, he/she should be informed of the prohibition to remove pig and other animals as well as products and byproducts thereof from the farm, until the Official Veterinary Service has defined the measures to be taken;

- To record the fact, including date and time, in the Local Unit of Care to Agriculture and Livestock Health;

- To gather as much information as possible on the rearing establishment under suspicion, such as geographic location, natural barriers, access routes, registration data, type of rearing establishment, neighboring establishments, existing pig population, entry and exit of animals in the past 30 days, production data, previously notified diseases, slaughterhouses and establishments selling products and byproducts of swine origin;

- To inform immediate management;

- To have the materials and equipment required for handling a outbreak as specified in this Contingency Plan as well as the following documents: Initial Disease Investigation Form (FORM-IN), Term of Visit to a Swine Farm (Annex IV of Service Instruction DDA No. 12A, of 2002, and Interdiction Notice.

3. Visit to the rearing establishment suspected of being infected with Aujeszky's Disease

a) To organize the visit on a priority character no later than 12 hours after notification and follow the procedures below:

- First of all, visit the rearing establishment

suspected of AD by going straight to the main house, office or management, in order to collect information from the owner or person in charge. Avoid driving an official vehicle into the property;

- Change clothes, wearing preferably disposable clothes and using disposable materials when entering the premises where the animals are kept;

- Start by performing a clinical examination in apparently healthy animals;

- Perform the clinical examination in sick animals with the assistance of official or private staff;

- Where the suspicion is confirmed, fill out the FORM-IN and the Interdiction Notice;

- Where the suspicion is not confirmed, fill out the Term of Visit to a Swine Farm or a similar form available from the Intermediate-level Authority;

- Prescribe spraying of the facilities with a solution of one of the disinfectants described in this Contingency Plan, once a day, as a way to reduce the pressure of infection in the rearing establishment;

- Collect samples and immediately notify the superior sanitary authority, so that the emergency actions can be started forthwith;

- Send the material collected to the closest official or accredited laboratory, with a view to obtaining an AD diagnosis.

IMPORTANT: The destination laboratory should be previously informed that the suspicious material is being sent.

b) To collect the Material

- Sacrifce sick animals and collect samples of tissues, preferably brain, spleen, tonsils and lungs;

- A miscarried fetus could be collected, provided that accompanied with other materials, so as not to mask the diagnosis in case the miscarriage is secondary to the infection by ADV;

- The materials should be sent to the laboratory in the following conditions:

. Send at least 50 grams of each organ in separate collection vials properly identified by animal;

. Send also fine fragments of brain and lungs preserved in a formaldehyde solution at 10%;

. All samples collected should be listed in the FORM-IN and carefully identified with a label or adhesive tape written in pencil, and protected with transparent tape;

. Place the samples in isothermal boxes containing dry or recyclable ice and send them immediately to the laboratory. If it is not possible to have the material arrive at the Laboratory within 24 hours after collection, this should be frozen, except for the material preserved in formaldehyde;

- For the serological diagnosis, collect blood samples of sick pig, sows that have had recent miscarriages or other reproduction problems, and those sows whose piglets display clinical signs of AD;

- If possible, the blood should be turned into serum still at the rearing establishment. Serum samples should be clear, free of hemolysis, at a minimum of 2ml per animal. The serum should be frozen and sent to the official or accredited laboratory;

- Each and every collection of suspicious material must be accompanied with the FORM-IN;

- Arrange for the destruction of the carcasses of sacrificed pigs for sample collecting purposes, by incineration or cremation followed by burial;

- Prescribe the destruction, by incineration or cremation followed by burial, of all animals killed in the rearing establishment as well as remains of deliveries and miscarriages. Never allow these materials to be fed to other animals such as dogs and cats;

- When leaving the suspected establishment, clean up and disinfect the equipment and materials used in clinical examinations and sample collections, doing the same to the vehicle;

- Incinerate all disposable working clothes. When clothes and other materials cannot be cleaned and disinfected still at the rearing establishment, put them in plastic bags and make sure they are washed and disinfected as soon as possible;

- As a precaution, all personnel in the official service and other people who had contact with the suspected herd, as well as employees of the rearing establishment, should not be in contact with other pig for the following forty eight (48) hours;

- Where the laboratory result is negative for AUJESZKY'S DISEASE, interdiction of the establishment should be suspended, but the epidemiolog-

ical surveillance should continue for 21 days. The samples will be used for a differential diagnosis, which will determine the measures to be taken.

V - PROCEDURES TO BE ADOPTED DURING A SANITARY EMERGENCY

Where the laboratory diagnosis is positive for AD, the emergency team should be called in so the Contingency Plan can be implemented and the necessary legal measures taken.

1. Demarcation of the action zone

Once the primary outbreak has been determined, this should be georeferenced according to the Geodesic Geographic Coordinate System, using the Global Position System (GPS) set at the Datum Horizontal "South America Datum 1969 - SAD69", so as to demarcate the protection and surveillance zone that will be comprised by the area adjacent to the outbreak, within a minimum radius of five (5) kilometers from the outbreak, taking into account geographic and epidemiological factors.

Depending on the density of the pig population, geographic barriers or any factor that favors or hinders ADV dissemination, the size of the protection and surveillance zone can be altered, at the discretion of the Official Veterinary Service.

The General Coordination Unit will request the cooperation of public entities and agencies (the military police, city halls and others), with a view to isolating the outbreak, strengthening preventive sanitary measures and guaranteeing implementation of the Contingency Plan.

Where an AD outbreak is confirmed in exhibit, fair or auction facilities or other sites of pig concentration, the whole area should be considered a outbreak and be subject, as appropriate, to the sanitary measures provided for in this Contingency Plan.

The Field Coordination Unit will immediately determine the following actions:

a) Establishment of the main office headquarters;

b) Establishment of the following areas of action:

- Outbreak
- Protection and surveillance zones

c) Establishment of fixed and mobile inspection posts in the demarcated zone;

d) Review of the demarcated affected zone, with possible expansion thereof, according to the information collected during complementary investigations;

e) Placement of interdiction signs in strategic locations;

f) Inspection of rearing establishments and swine slaughterhouses located in the demarcated zone; and

g) Composition of the committees in charge of emergency actions.

2. Strategies to be adopted in the outbreak and direct contacts thereof

Taking into account factors such as size, degree of herd segregation, estimated number of AD-infected animals, and the risk of dissemination to other establishments, as well as in view of the results of the serum epidemiological investigation performed, or in accordance with the provisions of the State Plan to Eradicate AD approved by the Ministry of Agriculture, Livestock and Food Supply, rearing establishments associated with the sanitary emergency may be submitted to one or more of the action strategies described in this chapter.

Rearing establishments submitted to any of the eradication strategies should have their status of free of DA confirmed by obtaining two consecutive negative serologies at two- month intervals and performed independently for the rearing stock and fattening animals, pursuant to the sampling shown on the table below. The first serology should be performed right after parturition of the first batch of sows introduced.

HERD	SAMPLED ANIMALS
1 – 25	ALL
26 – 30	26
31 – 40	31
41 – 50	35
51 – 70	40
71 – 100	45
101 – 200	51
201 – 1200	57
+ 1200	59

2.1 Immediate depopulation

In this sanitation strategy, the rearing establishment(s) involved will go through immediate sanitation procedures, with the sacrifice and sanitary slaughter of the whole pig herd, regardless of the age and physiological state of the females in the herd, and will be repopulated with pigs free of ADV.

This strategy is more expensive in the short term, as it requires compatible funds for the payment of compensations, in addition to involving a large apparatus. However, it minimizes complications inherent in a longer term strategy.

2.1.1 Evaluation of animals, products and materials

Exposed pigs, as well as contaminated products, byproducts and materials should be evaluated before the sacrifice or sanitary slaughter.

The form of animal evaluation for further compensation will be regulated by the State Plan or, in the absence thereof, according to the regulation in force and will be performed by the corresponding committee and the values recorded in the Term of Evaluation, which will contain all the criteria used (race, age, gender, identification and weight among others).

Any dispute with respect to the values assigned will not prevent the sanitary action from going forward.

2.1.2 Sacrifice and destruction

a) AD infected pig, direct contacts thereof, waste, as well as those piglets that have not reached the appropriate weight for sanitary slaughter will be submitted to sacrifice and destruction at the rearing establishment, or any other adequate location at the discretion of the Field Coordinator, after an evaluation and within no more than twenty four (24) hours after receipt of the killing order issued by the Sacrifice and Destruction Committee;

b) In the case of sacrifice and destruction of pig, the provisions of specific legislations should be complied with;

c) These tasks are performed by the Sacrifice and Destruction Committee under the supervision of an official veterinarian;

d) Operationalization:

- Written notification should be sent to the owner of the animals to be destroyed, with the necessary details to prevent the work from being delayed;

- The sacrifice can be carried out by members of the public security forces, with subsequent destruction by incineration or cremation followed by burial. Burial is, in general, the most suitable and practical method;

- The pigs should be sacrificed preferably inside the trenches and will have their abdominal cavities open;

- Any unnecessary movement of the animals should be avoided and care should be taken to prevent them from escaping when being conducted to the trenches;

e) Destruction of sacrificed animals:

The place for the destruction of sacrificed animals should be carefully selected, according to the directions of the environmental protection agency. Factors such as soil condition, proximity to the outbreak, water-bearing stratum, safety of facilities, dominant winds and isolation of the area to avoid public presence should be taken into account.

f) Cremation

- A shallow trench, no deeper than one meter, should be excavated. A layer of firewood or thick wood should be placed diagonally in the trench, which should be filled with straw, thin wood or charcoal soaked in kerosene or diesel oil;

- The dead animals should be lined up on this layer of firewood, alternating head and tail. Additional wood or charcoal soaked in diesel or kerosene should be placed over and around the dead animals. Use a torch launched from a safe distance or a trail of gunpowder to light the fire;

- Estimates show that cremating 250 adult pigs requires around 6 tons of charcoal, ½ a ton of wood, 75 liters of diesel and 45 kilos of thin wood;

g) Cremation should be followed by burial; the whole process should be monitored by an official employee;

- The trenches should be built preferably in the dominant direction of the winds, and be 2.5 meters deep and 2.5 meters wide. The length will depend on the number of animals – 1.5 meter per each 5 adult pigs. Dead animals should be

laid down side by side, alternating head and tail;

- The ramp down the trench should be smooth. Lime should not be used, as it delays the natural decomposition process that favors inactivation of the virus;

- Once the trenches have been covered, it is recommended that the area be surrounded with a wire mesh, so as to prevent small animals from excavating the site;

- It is recommended that the trenches and adjacent areas be inspected at least once a week, until the rearing establishment has been repopulated.

NOTE: Where the competent environmental agency prohibits burial in the property, other locations designated by the Ministry of Agriculture, Livestock and Food Supply will be used.

2.1.3 Sanitary slaughter

a) Healthy pigs and indirect contacts thereof residing in the same rearing establishment (outbreak) will be submitted to a risk assessment and may be sent for sacrifice and destruction or immediate sanitary slaughter, at the discretion of the Official Veterinary Service;

b) In the case of sanitary slaughter, the animals will be sent to swine slaughterhouses recognized by the Brazilian Animal Products Inspection System;

c) Loading of the pigs should be supervised by the Official Veterinary Service, which will seal the transportation vehicle and include the seal number in the transit document;

d) The inspection service in the establishment of destination should be notified at least 24 hours in advance, so as to take the measures provided for in the applicable legislation;

e) The disposal of products resulting from sanitary slaughter will comply with the legislation in force;

f) If it is impossible to have the sanitary slaughter in establishments recognized by the Brazilian Animal Products Inspection System, the animals will be submitted to sacrifice and destruction in the farm itself, under the direct supervision of the Official Veterinary Service.

2.1.4 Clean-up and Disinfection

a) As soon as a room or facility is free of animals, dry cleaning with broom and shovel should start immediately, followed by the removal of waste from collecting tranches;

b) All materials (organic matter, food leftovers and others) resulting from dry cleaning should be buried or completely destroyed by incineration;

c) Proceed to the first wet cleaning, using water under pressure pipe systems:

- Use a high-pressure jet washer (1.000 to 2.000 pounds);

- Start by washing the premises with water, preferably containing a detergent (1 to 1.5 liter of solution per m2), to facilitate removing the organic matter stuck to walls and floors;

-Remove, disassemble and wash the equipment (food-trough, drinkers and others);

- Wash all surfaces in the facilities (inside and outside areas, ceiling and walls);

- Finally, wash the waste collection trenches (both internally and externally).

d) Perform the first disinfection (24 to 48 hours later, after the facilities have dried up completely):

- Use a motorized sprayer;

- Use one of the disinfectants listed in this Contingency Plan, diluted and prepared as recommended by the manufacturer so as to inactivate the virus;

- Clean all the surfaces of the facilities and equipment, including ceiling, walls and waste collection trenches, using 400 ml of the disinfecting solution/m2 of surface, unless otherwise recommended in the manufacturer's directions;

- Keep all doors, windows and curtains closed for 48 hours;

- After that, open windows and curtains so as to allow the sun to come in.

e) Second disinfection (15 to 20 days after the first one):

- Use one of the disinfectants listed in this Contingency Plan, with an active principle different from that used in the first disinfection, diluted as recommended by the manufacturer in order to inactivate the virus;

- Clean all the surfaces of the facilities and equipment, including ceiling, walls and waste collection trenches, using 400 ml of the disinfecting solution/m2 of surface, unless otherwise

recommended in the manufacturer's directions;

- Keep all doors, windows and curtains closed for 48 hours;

- After that, open windows and curtains so as to allow the sun to come in.

f) Two days after the second disinfection, it is recommended that the producer paint the facilities with hydrated virgin lime;

g) As the facilities are occupied over time, one day before lodging the swine in a room or house, a third disinfection using sodium hypochlorite-based disinfectant is recommended.

2.1.5 Downtime

a) The minimum period a rearing establishment should be empty (void of any pig) is thirty (30) days;

b) As soon as the rearing establishment has been depopulated and during the downtime period, some actions must be taken:

- Empty laystalls;

- Implement a systematic plan to eliminate rodents;

- Eliminate leftovers of inputs and animal food;

- Clean the area around the premises, removing garbage and debris;

- Clean and maintain the animal food factory.

c) As provided for in the State Plan to Eradicate AD, the Federative Units may consider the introduction of sentinel pigs in the rearing establishment once the downtime period is over. These sentinels will be monitored so as to prove the absence of viral activity in the environment. The sentinels should originate in ASBF (Granja de Reprodutores Suídeos Certificada) or in another establishment that has tested negative for AD, by obtaining two consecutive negative serologies at an interval of 14 to 21 days between them. The number should correspond to 5% of the population that existed in the outbreak or a minimum of five sensitive pigs no more than 60 days old. These animals should be distributed in such a way so as to cover all premises in the rearing establishment.

2.1.6 Repopulation

a) Repopulation will only be authorized after the rearing establishment has been inspected by the Official Veterinary Service, which will perform an assessment of the risk of reintroduction of ADV in each area to be repopulated;

b) The rearing establishment should be repopulated only with animals originating in ASBF;

c) Fattening establishments should be repopulated with animals originating in rearing establishments that have tested negative for AD;

d) Actions to improve the biosecurity of the breeding establishment should be encouraged. These include: isolation with perimeter fence or vegetal cord and construction of carrier for pigs far from the facilities, among others.

2.2 Gradual depopulation

In the AD eradication methodology by gradual depopulation of a rearing establishment identified as an outbreak, the swine herd should be submitted to sanitary slaughter no later than ninety (90) days from the initial diagnosis.

This strategy is less expensive, but requires great power of organization and interaction on the part of the official service and other segments involved in enforcing eradication measures. It may be adopted, depending on the State Plan, in the following situations:

- In sucking pig production units or full-cycle production establishments, where the prevalence of ADV is high;

- In continuous cycle pig fattening units with any prevalence of ADV infection, where the "all in/all out" system is not used;

- In regions with low pig density where AD has been detected, even with a low ADV prevalence in the herds;

- In the outbreak of the clinical disease.

2.2.1 Evaluation of animals, products and materials

Exposed pig, as well as contaminated products, byproducts and materials should be evaluated before sacrifice and destruction or sanitary slaughter.

The form of animal evaluation for subsequent compensation will be regulated by the State Plan or, in the absence thereof, by the regulation in force, and will be performed by the corresponding committee and the values recorded in the Term of Evaluation, which will contain all the criteria used (race, age, gender,

identification and weight among others).

Any dispute with respect to the values assigned will not prevent the sanitary action from going forward.

2.2.2 Vaccination of the herd

a) There should be a mass vaccination of herd above seven years of age, until the complete depopulation of the rearing establishment, so as to prevent dissemination of the clinical disease;

b) Where the rearing establishment adopts vaccination against AD, piglets born from vaccinated mothers should not be vaccinated;

c) Vaccination procedures should comply with the legislation in force.

2.2.3. Sacrifice and destruction

a) AD-infected pig, direct contacts and waste thereof, as well as those piglets that have not reached the appropriate weight for sanitary slaughter will be submitted to sacrifice and destruction at the rearing establishment, or any other adequate location at the discretion of the Field Coordinator, after an evaluation and within no more than twenty four (24) hours after receipt of the killing order issued by the Sacrifice and Destruction Committee;

b) In the case of sacrifice and destruction of pig, the provisions of specific legislations should be complied with;

c) These tasks will be performed by the Sacrifice and Destruction Committee under the supervision of an official veterinarian;

d) Operationalization:

- Written notification should be sent to the owner of the animals to be destroyed, with the necessary details to prevent the work from being delayed;

- The killing can be carried out by members of the public security forces, with subsequent destruction by incineration or cremation followed by burial. Burial is, in general, the most suitable and practical method;

- The pigs should be sacrificed preferably inside the trenches and will have their abdominal cavities open;

- Any unnecessary movement of the animals should be avoided and care should be taken to prevent them from escaping when being conducted to the trenches;

e) Destruction of sacrificed animals:

The place for the destruction of sacrificed animals should be carefully selected, according to the directions of the environmental protection agency. Factors such as soil condition, proximity to the outbreak, water-bearing stratum, safety of facilities, dominant winds and isolation of the area to avoid public presence should be taken into account.

f) Cremation

- A shallow trench, no deeper than one meter, should be excavated. A layer of firewood or thick wood should be placed diagonally in the trench, which should be filled with straw, thin wood or charcoal soaked in kerosene or diesel oil;

- The dead animals should be lined up on this layer of firewood, alternating head and tail. Additional wood or charcoal soaked in diesel or kerosene should be placed over and around the dead animals. Use a torch launched from a safe distance or a trail of gunpowder to light the fire;

- Estimates show that cremating 250 adult pigs requires around 6 tons of charcoal, ½ a ton of wood, 75 liters of diesel and 45 kilos of thin wood;

g) Cremation should be followed by burial; the whole process should be monitored by an official employee;

- The trenches should be built preferably in the dominant direction of the winds, and be 2.5 meters deep and 2.5 meters wide. The length will depend on the number of animals – 1.5 meter per each 5 adult pigs. Dead animals should be laid down side by side, alternating head and tail;

- The ramp down the trench should be smooth. Lime should not be used, as it delays the natural decomposition process that favors inactivation of the virus;

- Once the trenches have been covered, it is recommended that the area be surrounded with a wire mesh, so as to prevent small animals from excavating the site;

- It is recommended that the trenches and adjacent areas be inspected at least once a week, until the rearing establishment has been repopulated.

NOTE: Where the competent environmental agency prohibits burial in the property, other locations designated by the Ministry of Agriculture, Livestock and Food Supply will be used.

2.2.4 Sanitary slaughter

a) The following principles should be complied with in the sanitary slaughter of the herd in establishments recognized by the Brazilian Animal Products Inspection System:

- Immediate sanitary slaughter of non-pregnant sows up to the 60th day of pregnancy and replacement sows;

- Immediate castration of boars, which should be sent for sanitary slaughtering when in good conditions, pursuant to the legislation in force;

- Lactating sow should wait until the weaning period is over and then be sent for sanitary slaughtering when in good conditions, pursuant to the legislation in force;

- Sow sixty (60) days pregnant or more should wait for delivery, in which case the provisions of the previous item will apply;

- Piglets in nursery or crèche should be sent for sanitary slaughter at approximately twenty three (23) kilos of live weight;

- Piglets in the fattening stage should be sent for sanitary slaughter when they reach the optimal weight.

b) The loading of pigs should be followed by the Official Veterinary Service, which will seal the transportation vehicle and include the seal number in the transit document;

c) The inspection service in the establishment of destination should be notified at least 24 hours in advance, so as to take the measures provided for in the applicable legislation;

d) The disposal of products resulting from sanitary slaughter will comply with the legislation in force;

e) If it is impossible to have the sanitary slaughter in establishments recognized by the Brazilian Animal Products Inspection System, the animals will be submitted to sacrifice and destruction in the farm itself, under the direct supervision of the Official Veterinary Service.

2.2.5 Clean-up and disinfection

a) As soon as a room or facility is free of animals, dry cleaning with broom and shovel should start immediately, followed by the removal of waste from collecting tranches;

b) All materials (organic matter, food leftovers and others) resulting from dry cleaning should be buried or completely destroyed by incineration;

c) Proceed to the first wet cleaning, using water under pressure pipe systems:

- Use a high-pressure jet washer (1.000 to 2.000 pounds);

- Start by washing the premises with water, preferably containing a detergent (1 to 1.5 liter of solution per m2), to facilitate removing the organic matter stuck to walls and floors;

-Remove, disassemble and wash the equipment (food-trough, drinkers and others);

- Wash all surfaces in the facilities (inside and outside areas, ceiling and walls);

- Finally, wash the waste collection trenches (both internally and externally).

d) Perform the first disinfection (24 to 48 hours later, after the facilities have dried up completely):

- Use a motorized sprayer;

- Use one of the disinfectants listed in this Contingency Plan, diluted and prepared as recommended by the manufacturer so as to inactivate the virus;

- Clean of the surfaces of the facilities and equipment, including ceiling, walls and waste collection trenches, using 400 ml of the disinfecting solution/m2 of surface, unless otherwise recommended in the manufacturer's directions;

- Keep all doors, windows and curtains closed for 48 hours;

- After that, open windows and curtains so as to allow the sun to come in.

e) Second disinfection (15 to 20 days after the first one):

- Use one of the disinfectants listed in this Contingency Plan, with an active principle different from that used in the first disinfection, diluted as recommended by the manufacturer in order to inactivate the virus;

- Clean the surfaces of the premises and equipment, including ceiling, walls and waste collection trenches, using 400 ml of the disin-

fecting solution/m2 of surface, unless otherwise recommended in the manufacturer's directions;

- Close all doors, windows and curtains for 48 hours;

- After that, open windows and curtains so as to enable the action of solar beams.

f) Two days after the second disinfection, it is recommended that the producer paint the facilities with hydrated virgin lime;

g) As the facilities are occupied over time, one day before lodging the pigs in a room or premises, a third disinfection using sodium hypochlorite-based disinfectant is recommended.

2.2.6 Downtime

a) The minimum period a rearing establishment should be empty (void of any pig) is thirty (30) days;

b) As soon as the rearing establishment has been depopulated and during the downtime period, some actions must be taken:

- Empty laystalls;

- Implement a systematic plan to eliminate rodents;

- Eliminate leftovers of inputs and animal food;

- Clean the area around the facilities, removing garbage and debris;

- Clean and maintain the animal food factory.

c) As provided for in the State Plan to Eradicate AD, the Federative Units may consider the introduction of sentinel pig in the rearing establishment once the downtime period is over. These sentinels will be monitored so as to prove the absence of viral activity in the environment. The sentinels should originate in Accredited Swine Breeding Farms (ASBF) or in another establishment that has tested negative for AD, by obtaining two consecutive negative serologies at an interval of 14 to 21 days between them. The number should correspond to 5% of the population that existed in the outbreak or a minimum of five susceptible pigs no more than 60 days old. These animals should be distributed in such a way so as to cover all premises in the rearing establishment.

2.2.7 Repopulation

a) Repopulation will only be authorized after the rearing establishment has been inspected by the Official Veterinary Service, which will perform an assessment of the risk of ADV reintroduction in each area to be repopulated;

b) If the risk is identified, the repopulation should be delayed, or at the discretion of the State Plan, will be made the vaccination of the animals destinated to the breeding establishment

c) The rearing establishment should be repopulated only with animals originating in ASBF;

d) Fattening establishments should be repopulated with animals originating in rearing establishments that have tested negative for AD;

e) Actions to improve the biosecurity of rearing establishment should be encouraged. These include: isolation with perimeter fence or vegetal cord and construction of carrier for pigs far from the facilities, among others.

2.3 Eradication by serology

In the AD eradication methodology by serology, the rearing establishment will be submitted to periodic serological tests that are capable of telling if the humoral titers result from the ADV infection or from the vaccination process (if adopted), with a gradual elimination of the herds that tested positive for AD.

This strategy can be adopted, depending on the State Plan, in those rearing establishments where the prevalence of ADV is low, or in those establishments infected with ADV but with no manifestation of the clinical disease. This process is quite toilsome from the standpoint of vaccination management, frequent collections of material for serology tests and laboratory capacity to produce diagnoses.

2.3.1 Vaccination of the herd

a) There should be a mass vaccination of herd above seven years of age, until the complete depopulation of the rearing establishment, so as to prevent dissemination of the clinical disease;

b) Where the rearing establishment adopts vaccination against AD, piglets born from vaccinated mothers should not be vaccinated;

c) Vaccination procedures should comply with the legislation in force.

2.3.2 Serological tests performed in the rearing stock

a) Material for serology should be collected in 100% of the rearing stock, thirty (30) days after identification of the ADV infection in the herd, from the date of the first laboratory diagnosis;

b) Animals testing positive for ADV should be isolated for immediate sacrifice and destruction, as already described;

c) The tests should be repeated in 100% of the stock, with 60-day intervals using the same procedure, until two consecutive negative serological results are obtained;

d) In the second collection of material for testing the stock, a collection by sampling of the fattening herd (where it exists) should also be performed and yield negative results, according to the table contained in this Contingency Plan.

2.3.3 Evaluation of the animals

Animals destined for sacrifice or sanitary slaughter should be evaluated beforehand.

The form of animal evaluation for subsequent compensation will be regulated by the State Plan or, in the absence thereof, by the regulation in force and will be performed by the corresponding committee, and the values recorded in the Term of Evaluation, which will contain all the criteria used (age, gender, weight, physiological status and loss of profits among others).

2.3.4 Sacrifice and Destruction

a) AD-infected pig, direct contacts and waste thereof, as well as those piglets that have not reached the appropriate weight for sanitary slaughter will be submitted to sacrifice and destruction at the rearing establishment, or any other adequate location at the discretion of the Field Coordinator, after an evaluation and within no more than twenty four (24) hours after receipt of the killing order issued by the Sacrifice and Destruction Committee;

b) In the case of sacrifice and destruction of pigs, the provisions of specific legislations should be complied with;

c) These tasks are performed by the Sacrifice and Destruction Committee under the supervision of an official veterinarian;

d) Operationalization:

- Written notification should be sent to the owner of the animals to be destroyed, with the necessary details to prevent the work from being delayed;

- The sacrifice can be carried out by members of the public security forces, with subsequent destruction by incineration or cremation followed by burial. Burial is, in general, the most suitable and practical method;

- The pigs should be killed preferably inside the trenches and will have their abdominal cavities open;

- Any unnecessary movement of the animals should be avoided and care should be taken to prevent them from escaping when being conducted to the trenches;

e) Destruction of sacrificed animals:

The place for the destruction of sacrificed animals should be carefully selected, according to the directions of the environmental protection agency. Factors such as soil condition, proximity to the outbreak, water-bearing stratum, safety of facilities, dominant winds and isolation of the area to avoid public presence should be taken into account.

f) Cremation

- A shallow trench, no deeper than one meter, should be excavated. A layer of firewood or thick wood should be placed diagonally in the trench, which should be filled with straw, thin wood or charcoal soaked in kerosene or diesel oil;

- The dead animals should be lined up on this layer of firewood, alternating head and tail. Additional wood or charcoal soaked in diesel or kerosene should be places over and around the dead animals. Use a torch launched from a safe distance or a trail of gunpowder to light the fire;

- Estimates show that cremating 250 adult swine requires around 6 tons of charcoal, ½ a ton of wood, 75 liters of diesel and 45 kilos of thin wood;

g) Cremation should be followed by burial; the whole process should be monitored by an official employee;

- The trenches should be built preferably in the dominant direction of the winds, and be 2.5 meters deep and 2.5 meters wide. The length will depend on the number of animals – 1.5 meter per each 5 adult pigs. Dead animals should be laid down side by side, alternating head and tail;

- The ramp down the trench should be smooth. Lime should not be used, as it delays the natural decomposition process that favors inactivation of the virus;

- Once the trenches have been covered, it is recommended that the area be surrounded with a wire mesh, so as to prevent small animals from excavating the site;

- It is recommended that the trenches and adjacent areas be inspected at least once a week, until the rearing establishment has been repopulated.

2.3.5 Sanitary slaughter

a) All pig identified as asymptomatic carriers of ADV during the serological tests should be isolated and sent for sanitary slaughter;

b) ADV-infected animals which, according to the legislation in force are not qualified to be immediately sent for sanitary slaughter should be submitted to sacrifice and destruction, according to the provisions of item 2.3.4;

c) Loading of the pigs should be supervised by the Official Veterinary Service, which will seal the transportation vehicle and include the seal number in the transit document;

d) Sanitary slaughter should take place in swine slaughterhouses recognized by the Brazilian Animal Products Inspection System;

e) The inspection service in the establishment of destination should be notified at least 24 hours in advance, so as to take the measures provided for in the applicable legislation;

f) The disposal of products resulting from sanitary slaughter will comply with the legislation in force;

g) If it is impossible to have the sanitary slaughter in establishments recognized by the Brazilian Animal Products Inspection System, the animals will be submitted to sacrifice and destruction in the farm itself, under the direct supervision of the Official Veterinary Service.

3. Epidemiological investigation

Tracing at field level and an analysis of the transit of live pig and products that are potential carriers of ADV, should be performed together with the actions carried out in the outbreak and direct contacts thereof, with the objective of producing a diagnosis of the situation based on the identification of exposed herds, so as to prevent AD from disseminating.

The transit of pigs should be assessed as a potential factor of disease dissemination. Depending on what is found in the transit assessment, tracing might require the intervention of a large number of people, under careful and systematic coordination.

Sanitary emergency activities should be carried out by specific teams in each zone of action (outbreak and direct contacts, protection and surveillance zone, and in other areas when the investigation so recommends). Tracing in areas outside the protection and surveillance zone will be the responsibility of the corresponding Local-level Authorities.

Veterinarians and independent professionals linked to the field performing their activities in the infected zone, should be informed of the presence of the disease and provide the Official Veterinary Service with a list of all the rearing establishments visited in the past seven days.

All pig slaughterhouses located in the action zone and those that had some sort of relation with the outbreak and direct contacts thereof, could also be the object of serological investigation by the Official Veterinary Service.

3.1 Measures to be adopted in the outbreak and direct contacts thereof

a) Tracing

A complete investigation of the transit of animals, persons, vehicles, equipment, food leftovers, excrements, animal food and other inputs destined to the rearing establishment identified as a outbreak and originating therein at least thirty (30) days before the beginning of the clinical manifestation of AD or of the laboratory diagnosis, should be traced, for the purpose of identifying the origin of the outbreak as well as its possible dissemination to other rearing establishments.

Rearing establishments receiving pigs originating in the outbreak should be considered as suspicious and be subject to the same measures taken in the outbreak. Details such as date, type of vehicle, route, destination and exact location should be determined, so as to

ensure the quick identification of exposed rearing establishments.

Past activities of all those who worked or visited the rearing establishment during this period should be assessed, as well as their relation with other rearing establishments, pig concentrations and slaughterhouses.

b) Transit restrictions

Interdiction of the outbreak and direct contacts thereof shall remain in force until the eradication strategy used has been completed, with the exception of the transit of pigs for immediate sanitary slaughter, originating in rearing establishments where there are no clinical signs in the herd.

Where the rearing establishment is incapable of holding sufficient stock, it may be authorized, at the discretion of the Official Veterinary Service, to transfer piglets for fattening in another establishment, provided that it is located in the same Federative Unit, where the pigs will be under supervision until they reach the optimum weight for slaughter.

The transit of animal reproduction material (semen) should also be prohibited. Vehicles transporting pigs for sanitary slaughter should not be used to transport animal food or inputs or replacement animals.

c) Serological investigation

In those rearing establishments that received pigs from the outbreak as well as in those that provided animals to the outbreak (except ASBF), blood from the herd should be collected, so that the sanitary situation can be known, using the table contained in this Contingency Plan, with a view to providing guidance on the choice of the best eradication strategy. In rearing establishments that received pigs from the outbreak, this sample should be guided, so that samples from animals originating in the outbreak can be obtained.

d) Vaccination

Depending on the State Plan, the immediate vaccination of pigs from the outbreak and other rearing establishments at risk of getting the infection could be recommended, according to the vaccination protocol contained in this Contingency Plan or in the State Plan approved by the Ministry of Agriculture, Livestock and Food Supply as a Central- and Higher-Level Authority.

3.2 Measures to be taken in the protection and surveillance zone

a) Population census

The Official Veterinary Service will carry out a census of the pig population existing in all establishments located in the protection and surveillance zone, no later than seven days after establishment thereof.

To this end, the tracing team should visit all properties located within the established radius and perform an epidemiological assessment by applying an Epidemiological Investigation Questionnaire, which is contained in this Contingency Plan, with a view to determining current population data, the type of swine exploration activities in the rearing establishments and any links with the outbreak establishment and direct contacts thereof.

b) Serum epidemiological inquiry

All pig rearing establishments located in the interior of the protection and surveillance zone should be submitted to a serum epidemiological survey based on the collection of blood from the rearing stock and the herd in termination stage, in an independent manner, using the table contained in this Contingency Plan.

In the sample from the breeding stock, it is recommended that material be collected from 100% of existing boars . In the case of females, the sample should be proportional to their physiological status, based on the following parameters: 70% of the samples from pregnant sows, 20% from lactating sows, 5% from non-copulated replacement sows. In the case of herd in termination stage, samples should be collected in all stall lodging pigs.

Instructions for collecting blood:

Collect a minimum of 7 ml of blood by puncturing the inferior cava vein or jugular vein of each animal to be sampled, using clean and sterile vials and needles. Use a set (a needle and a vial) for each sample.

Right after collection, keep the vials in an inclined angle and in a fresh place, until retraction of the clot. Centrifuge the vials at a minimum speed of 2,000 rpm for five minutes. The serum obtained (at least 2 ml) should not show evident sings of hemolysis and should then be transferred

to individual sterilized glass vials appropriately numbered and identified and be immediately frozen. Fill out the dispatching forms and pack the material in isothermal boxes with dry or recyclable ice. Keep the serum frozen throughout the process, until it arrives at the laboratory.

c) Control of pig transit

In the protection and surveillance zone, the interdiction period of any rearing establishment will be of at least twenty one (21) days after completion of the sacrifice and destruction of pigs infected with ADV, except for the transit of animals intended for slaughter, which should be made in sealed vehicles under control of the Official Veterinary Service.

Restriction involving the circulation and transportation of pigs and animal reproduction material in public or private routes. This restriction may not be applied in the following situations:

- Transit through the protection and surveillance zone by road or railway, without stops or unloading therein;

- Pigs originating outside the protection and surveillance zone and intended directly to slaughterhouses located in the same zone, as long as they are transported in vehicles sealed by the Official Veterinary Service in the origin or within the limits of the zone.

So that transit restriction measures in the action zone can be totally fulfilled, as many fixed and mobile barriers as necessary should be established in strategic locations, at the discretion of the Field Coordination Unit, with a view to covering every vehicle passing through the area.

These barriers should be located within the perimeter of the demarcated zone and be in operation no later than twelve (12) hours after the emergency has been established. The main objective of these posts is to ensure compliance with the measures relating to the transit of animals, animal reproduction materials, vehicles and other materials that could be potential ADV carriers, such as animal food, excrements and effluents originating in rearing establishment or slaughterhouse located in the protection and surveillance zone.

The teams that will be working in these posts should include representatives of the Official Veterinary Service and of the public security forces, equipped with permanent means of communication with each other and with the Field Coordination, so as to ensure fulfillment of the sanitary measures adopted. Case reports should be prepared and submitted to the Field Coordination Unit.

Only the transit of clean and disinfected vehicles and equipment will be permitted, pursuant to the procedures defined by the Official Veterinary Service following inspection by an official employee.

Permission to remove pigs from the protection and surveillance zone may be granted in the following circumstances:

- Directly to slaughterhouses

At the end of the serum epidemiological investigation, the Official Veterinary Service may authorize the removal of pigs directly to a swine slaughterhouse recognized by the Brazilian Animal Products Inspection System, preferably located as close as possible to the protection and surveillance zone, provided that the following conditions are satisfied:

- Transportation in disinfected and sealed vehicles, accompanied with the Animal Movement Permit (GTA), with identification of the route on the back thereof;

- Notification to the sanitary authority responsible for the slaughterhouse at least twenty four (24) hours in advance, so that the measures provided for in the legislation can be taken;

- The vehicle and equipment used to transport the pigs should be immediately washed and disinfected, under the guidance of the official veterinarian.

- To rearing establishments within the protection or surveillance zone

Twenty one days after completion of the preliminary cleaning and disinfection operations in the outbreak and subject to a risk assessment, the Official Veterinary Service may authorize the removal of pigs from establishments located in the protection and surveillance zone directly to another rearing establishment in the same zone, provided that the following conditions are satisfied:

- Transportation in disinfected and sealed

vehicles, accompanied with the Animal Movement Permit;

- Cleaning and disinfection, after each operation, of the vehicles and equipment used to transport pigs.

d) Maintenance of measures:

The measures applied in the protection and surveillance zone will be maintained until all eradication strategies set out in this Contingency Plan have been competed and a serum epidemiological inquiry covering all rearing establishments at risk, located inside or outside the protection and surveillance zone has been performed and no viral activity has been detected.

Depending on the State Plan, a monitoring operation could be performed at slaughterhouse level, in boars intended for killing or animals intended for slaughter.

This inquiry will be carried out at least thirty (30) days after completion of the killing or slaughter of pigs infected with ADV in the rearing establishments affected, according to the sample defined on the table contained in this Contingency Plan.

VI – PROCEDURES FOR VACCINATION AGAINST AD

The vaccination of pigs is an important instrument to control the clinical manifestation of AD in outbreaks submitted to any of the disease eradication strategies, as well as in those rearing establishments considered at risk of getting the infection.

Vaccination does not prevent the infection by ADV, but reduces the economic impact of the disease. Vaccination reduces and prevents the manifestation of clinical signs by decreasing intensity of the agent and the time required to eliminate it; reducing tissue invasion; increasing the viral dose required to infect vaccinated animals; and inducing reduced tissue invasion (prevents transplacentary transmission), in addition to reducing excretion of the agent from infected pigs. All this ends up by contributing to reduce the incidence of AD in rearing establishments that adopt vaccination.

In a pig rearing establishment, the vaccines should always be used by a fixed period of time, until the herd is considered safe, and under control of the Official Veterinary Service. There are serological tests that enable distinguishing the presence of antibodies originating in the infection by the field virus from those induced by vaccination.

The State Plan to Control and Eradicate AD of each Unit of the Federation should contain the strategy to use the vaccine within its area of action. Where the Federative Unit does not have a State Plan, the vaccination scheme below should be followed:

- Inactivated Vaccine:

Rearing Stock: vaccinate three (3) times a year. Each vaccination should be given within a maximum of one (1) week, regardless of the physiological status of the females in the stock;

Sows and replacement males: give the first dose of the vaccine upon arrival of the pigs and the second 2-4 weeks later (depending on the recommendation of the product manufacturer).

These vaccinations should be given during the quarantine or isolation period in the farm, before the pigs are introduced into the herd.

IMPORTANT: Not applicable to rearing establishments under interdiction.

- Attenuated Live Vaccine (in those Federative Units where its use is provided for in the State Plan approved by the Ministry of Agriculture, Livestock and Food Supply as the Central- and Higher-Level Authority):

Piglets: give one single dose between nine (9) and fourteen (14) weeks of life.

Vaccinated piglets should, under no circumstance, have a final destination other than slaughter.

If the emergency action in a outbreak includes vaccination, give the vaccine to all pigs in the herd over seven days of age, following the strategy used to eradicate the disease.

In the case of emergency use of AD vaccine in a free zone, this will lose its sanitary status, which can only be regained when the conditions set by the federal legislation in force and by the Sanitary Code of Terrestrial Animals of the World Organization for Animal Health (OIE) are met. The rules to control the sale of AD vaccines by the Official Veterinary Service should comply with the legislation in force. Only DA vaccines licensed by the Ministry of Agriculture, Livestock and Food Supply as the Central- and Higher-level Authority, can be used.

VII – PROCEDURES IN SLAUGHTERHOUSES

The sanitary slaughter of pigs involved in sanitary emergencies will be performed exclusively in slaughterhouse recognized by the Brazilian Animal Products Inspection System, and the resulting products cannot be exported.

The inspection service in the establishment of destination should be informed at least twenty four (24) hours in advance, so as to adopt the measures provided for in the applicable legislation.

The transporting vehicle should be sealed by the Official Veterinary Service and checked before the animals are unloaded.

The sanitary slaughter of pigs resulting from a sanitary emergency should be performed according to the legislation in force.

VIII – CHARACTERISTICS OF AUJESZKY'S DISEASE

ETIOLOGY

1. Characteristics of the etiological agent

DNA virus from the Herpesviridae family, Alphaherpesvirus subfamily.

Its viral envelope has glycoprotein structures on the surface such as the gE, which is important due to its implication in the development of marked vaccines and serological diagnosis techniques that enable distinguishing between infected and vaccinated animals. It has one single antigenic type, although there are many viral strains that produce, in a predominant fashion, a respiratory or a nervous picture of the disease.

An important characteristic of the agent is its ability to remain in a latent state (subclinical infection) in sensorial ganglions of the nervous system (trigeminus) and in the lymphoid tissue of pig tonsils.

The latent condition of the agent makes the pig a source of viral dissemination throughout its life.

2. Reaction to physical and chemical action

Temperature:	Nearly instant inactivation when exposed to exsiccation, mainly in the direct presence of sun beams. At 20ºC, the virus can be infectious and transmitted by flies for up to six (6) hours. In nasal discharges and saliva at 25ºC, the virus is inactivated in one (1) day on clothes and boots; four (4) days on several types of equipment and material (concrete, plastic, iron) existing in the rearing establishment; three (3) days in pelleted food; two (2) days in meat flour; and four (4) days on a wood shavings bed.
pH:	Inactivated within seven (7) days in pH < 4.3 or pH > 9.7.
Chemical products:	Sensitive to grease solvents such as ether and chloroform.
Disinfectants:	Inactivated by disinfectants containing sodium hypochlorite, quaternary ammonia, peroxide and iodophor.
Survival:	Survives in cold environments but is not subject to temperature fluctuations. It is stable in pH between 6 and 8, in humid environments and stable temperature.
	It survives for two (2) days in anaerobic lagoons and for up to four (4) days in non-chlorinated water at 25ºC. It survives for seven (7) days in the air with humidity of 55% or higher, in humid soil and in organic matter.

EPIDEMIOLOGY

3. Hosts

The virus has a wide range of hosts, but pigs and boars are the only natural hosts of the Aujeszky's Disease virus (ADV). Wild animals could be infected and serve as a reservoir. cattle, sheep, goat, dogs, cats, equine, rats and mice are susceptible. In these species the disease is terminal, with a short incubation period (3 days) and death between forty eight (48) and seventy two (72) hours after manifestation of nervous symptoms (itching with a tendency towards self-mutilation). Reports in humans are not sufficiently documented.

4. Transmission (direct and indirect)

. Introduction of infected pigs;

. Direct contact among animals (nasal secretions, saliva, faeces, blood, milk);

. Vaginal and prepucial mucosa (natural copulation);

. Semen (contamination at the time of collection);

. Aerogenous way (suspended aerosol, wind of at least 3 kilometers);

. Water, food, contaminated equipment and bed;

. Transplacentary infection (congenital);

. Remains of deliveries and abortions/miscarriages; and

. Dissemination by people and vehicles.

5. Virus sources

Elimination of ADV starts about seven (7) to ten (10) days after disinfection.

. Blood and all tissues, secretions, and excretions of sick and dead animals;

. Congenitally infected piglets;

. Pigs suffering from reactivation of the latent state of the virus due to adverse environmental conditions or other stress sources;

. Infected animals introduced in the rearing establishment;

. Contaminated semen used in artificial insemination;

. Animal food and bed in non-controlled rearing establishments;

. Wild swine and tayassuidae (cateto, wild boar, wild hog, and peccary), which are ADV reservoirs; and

. Other infection ways described in item 2.

DIAGNOSIS

The disease incubation period is from two (2) to six (6) days.

6. Clinical diagnosis

The emergence of clinical signs depends on the age of infected pig; the degree of their exposure to the etiological agent (level of herd segregation); the infecting viral dose; and the immunity level of the animals.

. Piglets in nursery (1 to 21 days old):

- Fever (41ºC), anorexia, apathy;
- Tremors, ataxia, hypersalivation;
- Epiletiform convulsions, pedaling movements, nystagmus and o e opisthotonus.
- Paralysis of posterior members (sitting dog position); walk in circles;
- Vomit and diarrhea;
- Do not respond to antibiotics therapy;
- Death within 24 to 36 hours;
- In infected females close to delivery, the young are born weak, with immediate clinical signs; and
- Mortality rate among nursing piglets close to 100%.

. Piglets in crèche (21 to 63 days old):

- Apathy, anorexia and fever (41 - 42ºC);
- Respiratory signs: sneezes, nasal discharges and dyspnea evolving to severe cough;
- Animals with nervous signs similar to those of nursing piglets invariably die;
- Refusal to return to the corral; and
- Recovery within five (5) to tem (10) days; mortality rate in general does not exceed 10%.

. Fattening pigs (63 days old to slaughter):

- Apathy, anorexia and fever (41 - 42ºC);
- Sneezes, nasal discharges, sever cough, difficult breathing, mainly when the animals are forced to move;
- Respiratory signs reach morbidity rates close to 100%;
- Low mortality rate (1 - 2%) in cases not aggravated by secondary bacterial infection;
- Sporadic nervous signs;
- Stunting; and
- Recovery within six (6) to ten (10) days.

. Breeding pigs (females and males):

- Anorexia and fever (as high as 42ºC);

- Agalaxy;
- Constipation;
- Movements of false chewing and hypersalivation;
- Reproductive signs: abortions/miscarriages, return to the oestrus cycle, still born and mummified;
- Respiratory signs similar to those of fattening animals;
- Reproductive failures do not reach 20% of the breeding stock;
- Occasional nervous signs: slight lack of coordination or paralysis of the posterior train;
- Low mortality rates (1 - 2%); and
- Infertility.

Macroscopic injuries

Many times, macroscopic injuries are not observed. Should they occur, look particularly for:

- Yellowish necrosis outbreaks in the spleen and liver;
- Hemorrhagic necrosis outbreaks in lymphonodes and tonsils;
- Pulmonary consolidation with areas disseminated through the different lobes;
- Conjunctivitis; and
- Necroctic placentitis.

7. Differential diagnosis

. Swine influenza;
. Enzootic pneumonia;
. Swine pasterurelosis;
. Classical swine fever;
. Streptococcus meningitis;
. Neonatal hypoglicemia;
. Intoxication by salt;
. Leptospirosis;
. Other causes of abortion/miscarriage; and
. Other viral encephalomyelitis.

8. Laboratory Diagnosis

. Identification of the agent:

- Virus isolation from sick piglets or from organs and tissues such as brain, spleen, tonsils, lungs, and aborted fetuses; and
- Polymerase chain reaction (PCR), capable of showing the presence of the viral DNA from brain, spleen, tonsils, lungs, aborted fetuses or semen samples.

. Serological tests:

- Enzyme-linked immunosorbent assay (screening ELISA and differential ELISA for gE); and
- Virus neutralization test (VN).

. Histopathology: for the differential diagnosis, from brain and lung samples preserved in a formaldehyde solution at 10% (formol).

In those establishments without clinical signs, where the intention is to investigate the presence of ADV from samples of blood serum collected by sampling (according to the table contained in this Contingency Plan), the serological tests should be aimed at those sows whose pig litters show signs consistent with AD.

PREVENTION AND CONTROL

There is no specific treatment for Aujeszky's Disease.

- Application of the measures described in the Contingency Plan in AD outbreaks;
- Active serum epidemiological surveillance for the identification of rearing establishments free of AD;
- Eradication of the infection by complete and immediate depopulation in regions where vaccination is prohibited;
- Mass vaccination of the herd and eradication of infection by gradual depopulation, within a maximum of ninety (90) days in those herds whose serology by sampling indicates a prevalence above 10% or in rearing establishments with manifestation of the clinical disease;
- Mass vaccination of the herd and eradication of soropositive animals after bimonthly testing of 100% of the rearing stock in those herds whose serology by sampling indicate prevalence of the infection equal to or below 10%;
- Replacement of the breeding stock only with swine originating in Accredited Swine Breeding Farms(ASBF);
- Introduction of piglets for fattening originating in breeding establishments free of ADV;
- Quarantine, with the performance of serological tests in animals originating in rearing establishments with unknown sanitary status for AD;
- Control of rodents;
- Treatment of products and byproducts of animal origin;

- Control of wild animals; and
- Sanitary education.

IX - EQUIPMENT AND MATERIALS FOR EMERGENCY ACTIONS

Have the following equipment and materials available, preferably disposable, where possible. As a good management practice, units of these materials, organized in metallic or plastic boxes, should be permanently ready:

1) 100x20 or 80x15 needles;
2) Pliers;
3) 18 wire;
4) Saw arch and blade;
5) GPS equipment;
6) Aprons;
7) Plastic buckets;
8) Manual or mechanical spraying pump;
9) Rubber boots and shoe protector;
10) Scalpel handle/blade;
11) Pipe;
12) Box with necropsy instruments;
13) Isothermal boxes and ice;
14) Impermeable pants, jacket and cap;
15) Cones to control the traffic of vehicles;
16) Chains/ padlocks;
17) Disinfectant with virus specification;
18) Portable sprinkler system;
19) Brush;
20) Adhesive tape or other label for identification;
21) Sponge;
22) Knife for necropsy;
23) Adhesive tape;
24) FORM-IN and FORM-COM;
25) Gauze;
26) Bow or thick rope;
27) Flashlight/ batteries or another source of light;
28) Pencil and pen;
29) Rubber or disposable gloves;
30) Map of the municipality and region;
31) Means of identification: eartags, pliers for eartags, marking stick;
32) Tweezers;
33) Interdiction / direction signs;
34) Drawing boards;
35) Soap;
36) Trash bags;
37) Plastic bags for packing samples;
38) Syringes;
39) Syringe and needle;
40) Term of Interdiction;
41) Term of Visit to a Swine Farm;
42) Clinical thermometers;
43) Scissors;
44) Cotton or paper towels;
45) Vials and needles for blood collection; and
46) Restraining blindfolds for boars.

X – EPIDEMIOLOGICAL INVESTIGATION QUESTIONNAIRE

1. Veterinarian of the official service responsible for filling out the questionnaire:
Name: _____
Address: _____
Telephone: _____ E-mail: _____

2. Property identification:
Name of property: _____
Name of owner: _____
General Registry No.: _____ Tax Roll No.: _____
Address: _____
Municipality: _____ Telephone: _____
Georeferencing: coordinates: S: _____ W: _____

3. Herd:
Number of pigs currently existing in the property, by category:
( ) Boars
( ) Parent breeders

( ) Empty sows
( ) Lactating sows
( ) Pregnant sows less than sixty (60) days pregnant
( ) Pregnant sows more than sixty (60) days pregnant
( ) Replacement female piglets
( ) Nursing piglets
( ) Piglets in crèche
( ) Fattening piglets

4. What is the type of pig rearing?

( ) Independent
( ) Integrated or cooperative
( ) Subsistence (self-consumption only)

5. If integrated, what is the integrating company?

6. What is the type of rearing establishment?

( ) Pig farm
( ) Pig rearing
( ) Wild Boar farm
( ) Other(s). Which one(s)? _____

7. What is the type of exploitation?

( ) Full cycle
( ) Production of piglets
( ) Breeders or semen trade
( ) Fattening

8. What is the rearing system used?

( ) Confinement
( ) Semi-confinement
( ) Rearing technified in pickets (SISCAL)
( ) Extensive
( )
Other(s):_____

9. When was Aujeszky's Disease identified in the rearing establishment?

( ) Month _____ Year: _____
( ) It was never identified

10. Have there been clinical signs of the disease in the past twelve (12) months?

( ) Yes. Which one(s)? _____
( ) No

11. Has the vaccine against Aujeszky's Disease been used or is it being used? Why?

( ) Outbreak of the disease
( ) Is located next to a farm where an outbreak has occurred
( ) Other reason(s). Which one(s)? _____

12. Has the origin of the infection been identified, i.e. how the disease infected the herd?

( ) Yes. What is it: _____
( ) No

13.How long have you been using the vaccine against Aujeszky's Disease?

( ) Less than one (1) year
( ) One (1) to two (2) years
( ) Two (2) to four (4) years
( ) More than four (4) years

( ) Never used it
( ) Have used but stopped using it. When did you stop? _____ Month: _____ Year:

14. What vaccination scheme against Aujeszky's Disease is being used?

a) Sows and boars: _____

_____

b) Replacement male and female piglets: _____

_____

c) Piglets: _____

_____

15. What is the brand and name of the vaccine being used? _____

_____

16. How is the vaccine used?

( ) Irregularly
( ) Regularly
( ) Occasionally

17. If you have stopped using the vaccine, why did it happen?

( ) Technical advice
( ) Difficulty to buy
( ) High price
( ) It doesn't work
( ) Own decision
( ) Other reason(s).Which one(s)? _____
( ) Solved the piglets' mortality problem
( ) Never stopped

18. Are there any other pets in direct or indirect contact with the swine?

( ) Cats
( ) Dogs
( ) Cattle
( ) Sheep and goat
( ) Free-range hens
( ) Pigeons
( ) Other(s): Which one(s)? _____
( ) None

19. Has there been mortality amongst any of these species when Aujeszky's Disease was detected in the pigs?

( ) Yes. Which one(s)? _____
( ) No

20. What is the origin of replacement male and female piglets? _____

_____

_____

_____

( ) The herd itself
( ) The integrating company only
( ) Neighboring farms. Which one(s)? _____
( ) Other suppliers of genetic material. Which one(s)? _____

_____

21. Provide additional information on Aujeszky's Disease in the farm you deem relevant:

_____

_____

_____

_____

_____

_____

_____

Signature of the person responsible for the information

_____

Stamp and signature of official veterinarian responsible
for filling out the questionnaire

NORMATIVE INSTRUCTION No. 47 OF JUNE 18, 2004

Published in the Official Gazette of June 23, 2004 Section 1, Page 64

Approves the National Swine Health Program's (PNSS) Technical Regulation in the form of the annex to this Normative Instruction.

THE MINISTRY OF AGRICULTURE, LIFESTOCK AND FOOD SUPPLY'S SECRETARY OF ANIMAL AND PLANT HEALTH AND INSPECTION, through the jurisdiction conferred to it by Article 15, Section II, Annex I, Line 'A' of Decree No. 4,629 of March 21, 2003, taking into consideration that contained within the Animal Health and Inspection Regulation approved by Decree No. 24,548 of July 3 1934 and the outcome of Process No. 21000.012585/2003-31, resolves:

Art. 1. To approve the NATIONAL SWINE HEALTH PROGRAM'S (PNSS) TECHNICAL REGULATION in the form of the annex to this Normative Instruction.

Art. 2. To delegate to the Director of the Animal Health and Inspection Department the power, where applicable, to add to this Regulation.

Art. 3. This Normative Instruction will enter in vigour on the date of its publication.

MAÇAO TADANO

ANNEX

THE NATIONAL SWINE HEALTH PROGRAM'S (PNSS) TECHNICAL REGULATION

Art. 1. The present Technical Regulation applies to the sanitary controls to be enforced in swine-rearing establishments involved in the production, reproduction,commercialisation and distribution of pigs and reproduction material of swine origin with the aim of impeding the introduction of exotic diseases and controlling or eradicating those already existent within the country.

CHAPTER 1

CONCERNING DEFINITIONS

Art. 2. For the purposes of this Regulation, terms are defined as follows:

I – Sanitary Slaughter: The slaughter of animals in establishments designated by the Official Veterinary Service for the conditional use of carcasses and viscera;

II – Rearing Establishment: A place where pigs are reared for whatever purpose.

III – Interdiction: The prohibition of entrance and exit of pig in a rearing establishment, for whatever purpose, along with swine products or byproducts or materials that may constitute a medium for the transmission or propagation of disease according to criteria laid out by the Official Veterinary Service;

IV – Official Veterinarian: Professional of the Official Veterinary Service;

V – Owner: Any person, either an individual or an enterprise, in possession or control of one or more pigs;

VI – Sacrifice and destruction : Following confirmation of the occurrence of an emergency disease, a process carried out by the Official Veterinary Service consisting of the sacrifice of all animals pertaining to a herd that are either sick or have come into contact with those that are and the subsequent incineration or burial of their remains. This process, if necessary, will be extended to other herds exposed, either directly or indirectly, to the pathogenic agent;

VII – Official Veterinary Service: The official federal, state or municipal animal health and inspection body.

VIII – Pig: Any animal belonging to the Sus scrofa domesticus (domestic pig) and Sus scrofa (wild pig) genera.

CHAPTER II

CONCERNING RESPONSIBILITIES

Art. 3. The Animal Health and Inspection Depatarment (DSA) of the of Animal and Plant Health and Inspection Secretariat - part of the Ministry of Agriculture, Livestock and Supply (MAPA) – is granted the following functions:

I – To regulate, implement, control and evaluate the execution of the National Swine Health Program's activities in order to prevent, control and eradicate diseases that affect the nation's swine population;

II – To carry out inspections and technical supervision in swine-rearing establishments;

III – To carry out supervisions and technical audits in state and municipal Official Veterinary Service units.

IV – To control the production and quality of vaccines and pharmaceutical products approved by the Programme;

V – To define criteria for the adoption of diagnostic techniques concerned with the importation and utilisation of raw materials and immunobiologicals;

VI – To propose and accompany epidemiological studies concerning the creation and maintenance of disease-free zones;

VII – To guarantee the health of pigs in all productive networks and the sanitary and hygienic control of the herds;

VIII – To propose technical training events.

Sole paragraph. The State Agriculture Secretaries or competent animal heath authorities in the States and at the Federal District will carry out the field activities of the PNSS, subject to delegated responsibilities.

CHAPTER III

CONCERNING PRELIMINARY CLAUSES

Art. 4. The DSA will coordinate animal sanitary health and inspection procedures aimed at the control or eradication of existing swine diseases and also impede the introduction of exotic diseases within the National Territory.

Art. 5. The entry into National Territory of pigs carrying directly or indirectly-transmissible disease or either internal or external parasites, the dissemination of which could constitute a threat to domestic swineherds, is forbidden.

Art. 6. The entry into National Territory of products and byproducts derived from animals, or any other material that could act as a vehicle for the dissemination of swine diseases, is forbidden.

CHAPTER IV

CONCERNING THE REGISTRATION OF SWINE-REARING ESTABLISHMENTS

Art. 7. the State Secretary of Agriculture or competent animal health authority in accordance with both the national model and instructions established by the DSA will register all swine-rearing establishments.

Sole paragraph. The registration of swine-rearing establishments will be carried out annually.

CHAPTER V

CONCERNING SURVEILLANCE AND THE NOTIFICATION OF DISEASES

Art. 8. The Official Veterinary Service will maintain a system of zoo-sanitary surveillance and information covering all levels, as well as carrying out systematic analysis of collected data and periodic notifications in order to comply with national and international obligations.

Art. 9. Any veterinarian, owner, animal transporter or any other citizen who suspects the outbreak of a listed swine disease must notify the Official Veterinary Service immediately. The owner should suspend the transportation of pigs and their products and byproducts, regardless of to whom, until the Official Veterinary Service decides the measures to be adopted.

Paragraph 1. All diseases designated by the DSA are subject to compulsory notification.

Paragraph 2. The Official Veterinary Service will adopt immediately the veterinary attention and surveillance measures defined for each disease.

Paragraph 3. Any infraction of the rules contained within this article will be investigated by the Official Veterinary Service which, together with the Public Ministry, will pursue criminal charges against those identified as responsible.

Paragraph 4. In cases where the offender is an accredited veterinarian, as well as that contained in paragraph 3, the Official Veterinary Service should proceed in accordance with specific legislation.

CHAPTER VI

CONCERNING THE SANITARY INSPECTION AND CONTROL OF REARING ESTABLISHMENTS

Art. 10. All swine-rearing establishments will be subject to Official Veterinary Service inspection.

Art. 11. In the event of non-compliance with the requirements of this Regulation, the following measures may be adopted according to the criteria of the Official Veterinary Service:

I – The suspension of importation and exportation permit and the issuance of permits for domestic transportation;

II – Interdiction of the establishment;

III – Sanitary slaughter;

IV – Sacrifice and destruction of the animals;

V – Application of other sanitary measures established by the DSA.

CHAPTER VII

CONCERNING ANIMALS FOR BREEDING AND ANIMAL REPRODUCTION MATERIALS

Art. 12. The commercialisation and distribution, in National Territory, of pigs destined

for breeding, as well as participation in expositions, fairs and auctions, will only be permitted for those animals derived from farms certified by the Ministry of Agriculture, Livestock and Supply (MAPA).

Art. 13. All specific norms in force must be observed in relation to the importation of pigs and their animal reproduction materials.

CHAPTER VIII

CONCERNING THE TRANSPORTATION OF ANIMALS

Art. 14. Pigs may only be transported within National Territory when accompanied by specific transportation documentation defined by the DSA in accordance with all relevant norms.

Art. 15. Pig transporter vehicles and their drivers must be registered by the Official Veterinary Service.

Paragraph 1. These vehicles must be washed and disinfected in accordance with the specific norms in force.

Paragraph 2. The registration of pig transporter vehicles and their drivers must be renewed annually.

CHAPTER IX

CONCERNING EXPOSITIONS, FAIRS AND AUCTIONS

Art. 16. All specific norms in force must be observed for the participation of pigs in expositions, fairs and auctions.

CHAPTER X

CONCERNING GENERAL ARRANGEMENTS

Art. 17. As part of the National Swine Health Program, a Technical and Scientific Committee will be created to assist he DSA in matters specifically relating to this Regulation.

Art. 18. The State Secretaries of Agriculture or competent animal heath authorities of the States will promote, by way of effective measures, the creation of State Committees of Animal Health and private funds to compensate pig owners affected by sanitary measures relating to sanitary slaughter, sacrifice or destruction of property.

Art. 19. Field actions, the use of vaccines, disease diagnosis and the classification of diseases to be controlled or eradicated will be defined by the DSA in specific legislation.

NORMATIVE INSTRUCTION No. 27 OF APRIL 20, 2004.

Published in the Official Gazette of April 27, 2004 Section 1, Page 7

Approves the Contingency Plan for Classical Swine Fever, which shall be effective throughout the national territory, as provided for in the Annex to this Normative Instruction

THE SECRETARY OF AGRICULTURE AND LIVESTOCK HEALTH AND INSPECTION OF THE MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY, in accordance with the duties and responsibilities assigned thereto by Article 15, item II, Annex I, Decree No. 4,629, of March 21, 2003, and in compliance with the provisions of the Animal Sanitary Health And Inspection Regulation, approved by Decree No. 24,548, of July 3, 1934, and

Considering the existence of a Zone Free of the Classical Swine Fever in the Country, as declared by Normative Instruction No. 01, of January 4, 2001, and in accordance with Judicial Proceeding No. 21000.001074/2006-37, hereby resolves:

Art. 1. To approve the CONTINGENCY PLAN FOR CLASSICAL SWINE FEVER, which shall be effective throughout the national territory, as provided for in the Annex to this Normative Instruction.

Art. 2. This Normative Instruction shall enter into force on the date of publication thereof.

MAÇAO TADANO

ANNEX

I. DEFINITIONS

1. Rearing establishment means the places where pigs are maintained or reared for any purpose.

2. Outbreak means the rearing establishment or any other place where the presence of one or more pigs infected with CSF has been detected.

3. Interdiction means prohibiting pigs as well as products or byproducts thereof or materials that could be a potential source of transmission of the disease, at the discretion of the Official Veterinary Service, from entering and exiting a rearing establishment for any purpose.

4. Official laboratory means the laboratory belonging to the network of the Ministry of Agriculture, Livestock and Food Supply.

5. Slaughterhouse means the facilities used for slaughtering animals intended for human consumption or other purposes and which are submitted to official veterinary inspection.

6. Accredited veterinarian means the professional accredited by the Official Veterinary Service, pursuant to specific legislation.

7. Official veterinarian means the professional of the Official Veterinary Service.

8. Classical Swine Fever (CSF) means the communicable disease caused by a pestivirus that infects pigs.

9. Contingency Plan means the set of emergency procedures and decisions to be made in the case of unexpected outbreak of a outbreak, for the purpose of controlling and eradicating the CSF agent as soon as possible, thus reducing as much as possible consequent productive and economic losses.

10. Owner means any natural person or legal entity that is either the owner, depositary, or at any other title, holds in his/her power or under his/her custody one or more pigs.

11. Quarantine means the transit restriction and observation of groups of apparently healthy animals that are exposed to the risk of infection and that, at the moment in question, have no direct contact with infected animals. The purpose of the quarantine is to prevent possible chain transmission of the disease to other animals that are not directly exposed to it.

12. Sacrifice and destruction means the operation carried out by the Official Veterinary Service when an outbreak of CSF is confirmed. It consists in killing all sick, contact and contaminated animals in the herd and, if necessary, other herds that have been exposed to the infection by direct or indirect contact with the pathogenic agent, and destroying the carcasses by incineration or burial.

13. Official Veterinary Service means the federal, state or municipal animal sanitary and Inspection agency.

14. Pig means all varieties of Sus scrofa, (both domestic and wild pigs).

15. Pig infected with CSF means any swine in which clinical symptoms or signs consistent with CSF have been officially detected and the diagnosis confirmed by laboratory tests.

16. Pig with suspicion of having been infected with CSF means any pig with clinical symptoms or signs consistent with CSF, or a reaction to a laboratory test indicating the possible presence of CSF.

17. External surveillance zone means the area established by the Official Veterinary Service around the internal protection zone, within a minimum radius of 10 km from the outbreak.

18. Internal protection zone means the area adjacent to a outbreak, the limits of which will

be established by the Official Veterinary Service, with due regard for geographic and epidemiological factors, within a minimum radius of 3 km.

19. Zone free of CSF means the zone where the absence of the disease has been demonstrated according to the recommendations of the International Zoosanitary Code of the World Organization for Animal Health (OIE).

II – INTRODUCTION

1. Background

The activities to combat Classical Swine Fever (CSF) were first introduced in priority zones selected according to the economic relevance of the swine producing zone and based on the existence of epidemiological conditions favorable for obtaining free zones, for the ultimate purpose of eradicating the disease in the national territory.

The National Program for the Control and Eradication of Classical Swine Fever was introduced in 1992, initially in adjacent municipalities in the states of Rio Grande do Sul, Santa Catarina and Paraná. The Program was gradually extended to other municipalities in these three states and later on to the other Brazilian states.

On January 4, 2001, through Normative Instruction No. 1, the Brazilian Minister of Agriculture, Livestock and Food Supply declared the region formed by the States of Rio Grande do Sul, Santa Catarina, Paraná, São Paulo, Minas Gerais, Mato Grosso do Sul, Mato Grosso, Goiás, Tocantins, Rio de Janeiro, Espírito Santo, Bahia, Sergipe and the Federal District as a Zone Free of Classical Swine Fever.

2. Justification

Regardless of how strict the protection sanitary measures taken by a country, a region or a zone free of a disease might be, there is no absolute guarantee that the infectious agent will not be introduced or reintroduced.

Nowadays, as a result of technological advances, the international transit of people, animals and animal reproduction materials as well as products and byproducts of animal origin has grown significantly, thus increasing the risk of disseminating diseases among countries.

When a disease is introduced in a country or zone that had so far been free of such disease, the actions to be taken in order to eradicate it must be strong, quick and effective. It becomes therefore necessary to have an appropriate organization, trained personnel, legal support, suitable equipment and materials, and sufficient funds.

Classical Swine Fever is classified as a disease in the A list of the World Organization for Animal Health (OIE) and its occurrence results in serious consequences to animal welfare, the swine production, the exporting of animals and products thereof, and the environment. This disease in highly contagious, has a great power of dissemination, is especially serious and may extend beyond national borders, causing serious socioeconomic and sanitary damages or hindering or disabling the international trade of animals and products of animal origin.

3. Objective

The objective here is to guide actions and procedures towards the early and immediate notification and confirmation of suspected outbreaks of Classical Swine Fever in the national territory, by taking the necessary sanitary and Inspection measures aimed at eradicating the disease within the shortest time possible, and resuming the sanitary condition of free of CSF. For this objective to be achieved, it is indispensable to have a CONTINGENCY PLAN in place establishing, step-by-step, the required sanitary measures.

III. EPIDEMIOLOGICAL CHARACTERIZATIONS

1. Minimum sanitary conditions

In most countries, the prevailing zoosanitary management strategy is outbreaked on designing and applying measures that minimize the risk of introduction or reintroduction of a disease in a free country or zone.

Effective activities of different natures are required to minimize the risk of CSF reintroduction and to enable the immediate detection and adoption of the necessary measures to eradicate any possible outbreak. The Official Veterinary Service should be underpinned in the following conditions:

- Appropriate operational framework;
- Sufficient financial resources;
- Legal support for the actions, provided for in specific legislation;
- Human and material resources and equip-

ment for effective epidemiological surveillance and veterinary care;

- Personnel trained in sanitary emergency, with an emphasis on CSF;

- Permanent and effective Sanitary Education Program, so as to ensure effective community participation. Farmers should be aware of and motivated towards the actions developed and recognize the relevance of each of such actions;

- Pig identification tracing system, which is a fundamental action for the successful management of sanitary emergencies;

- Prohibition to raise pigs in city dumps;

- Control the use of leftovers to feed pig;

- Interaction between the Official Federal, State and Municipal Inspection and Animal Sanitary Health and Inspection Services, with a view to the immediate exchange of information in case of suspicion of CSF;

- Information system that enables the timely adoption of sanitary measures to prevent and control animal diseases;

- Exchange of sanitary information among the sanitary departments of corporations/integrating cooperatives, accredited and private sector veterinarians and the Official Veterinary Service;

- Active surveillance of independent swine culture, including in subsistence farming;

- Updated register of swine breeders and transporters;

- Support from agencies and entities linked to the swine production chain and public bodies (City Halls, the Military Police, Finance Secretariat, etc.);

- Updated list of risk sites: agroindustries, slaughterhouses, landfills, dairy industries, pet food industries, agriculture and livestock shops, bus stations, airports, ports, tanning establishments, etc.;

- Permanent monitoring and evaluation of animal health activities, with a view to ensuring the standardization of actions;

- Effective official follow-up of the sanitary activities adopted in Accredited Swine Breeding Farms (ASBF);

- Funds for payment of compensations for the sacrifice and destruction of herds and things;

- Cleaning and disinfection of pig transportation trucks after unloading in slaughterhouses; these actions should be inspected at fixed and mobile posts, with a view to controlling the transit of animals and products and byproducts thereof;

- Effective action by the State Swine Health Committee;

- Performance of periodic serum epidemiological inquiries for keeping the Zone Free of CSF;

- Control and inspection of pig transit, products and byproducts thereof, pathological and biological products;

- Sanitary surveillance in ports, airports, frontier posts and collis posteaux;

- Control and inspection of areas of pig concentration;

- Updated sanitary requirements for authorizing the importing of pigs, animal reproduction materials (semen and embryos), and of products and byproducts of pig origin;

- CSF diagnosis laboratories capable of performing the tests with the necessary swiftness and efficacy; and

- Maintenance of a strategic stock of vaccine against CSF.

2. Epidemiological situations

The actions of the animal sanitary health and inspection system are based on the existing level of sanitary risk in each situation, as follows:

2.1 RISK I

• Absence of CSF outbreaks in the past 12 months;

• All minimum conditions are met;

• Situation in the states that make up the zone free of CSF.

2.2 RISK II

• Absence of CSF outbreaks in the past 12 months;

• All minimum conditions are met;

• Characterized by the identification of internal and/or external sanitary risks that could lead to the reintroduction of CSF.

In this situation, depending on the risk assessment, the Official Veterinary Service can declare a "state of animal sanitary emergency" and all actions related to the minimum risk situation should be taken and those related to the items below strengthened:

- Epidemiological surveillance;
- Serological investigation;
- Control and inspection of animal concentration sites;
- Control and inspection of interstate transit by mobile teams;
- Control and inspection of the entry of animals, animal reproduction materials, products and byproducts of swine origin, people and equipment in ports, airports, and frontier posts;
- Control and inspection of the entry of aircrafts, vessels and terrestrial vehicles coming from abroad;
- Exchange of sanitary information among countries.

2.3. RISK III

• Characterized by the emergence of CSF outbreaks – SANITARY EMERGENCY.

IV. SANITARY EMERGENCY

Is the set of sanitary actions aimed at preventing dissemination of the disease and eradicating the CSF outbreak within the shortest time possible and at the lowest cost for the country. These actions should be carried out by a group of professionals trained in sanitary emergency.

V. SANITARY EMERGENCY TEAM

The sanitary emergency team should be established by legal act and comprised of professionals from the federal and state Official Veterinary Services and include, as a minimum a(n):

- General Coordination Unit;
- Field Coordination Unit;
- Laboratory Coordination Unit;
- Administrative/Financial Coordination Unit;
- Communications and Public Relations Coordination Unit;
- Legal Affairs Coordination Unit.

1. Responsibilities of the sanitary emergency team

- To implement the animal sanitary health and inspection policy determined by the Contingency Plan;
- To request, where necessary, the collaboration of representatives of other sectors involved in the eradication and meet with these regularly, so as to follow up and evaluate all aspects related to field operations;
- To request, where necessary, the technical assistance and cooperation of national or international consultancy;
- To appoint an epidemiologist to advise the Field Coordinator.

2. Duties and responsibilities of the Coordination Units

2.1. General Coordination Unit

a) To mobilize and coordinate the emergency team and required professionals;

b) To involve the institutions and entities that will participate in the works;

c) To establish the evaluation and taxation committee, comprised of a representative of the Production Sector, a representative of the federal Official Veterinary Service, and a representative of the state Official Veterinary Service.

2.2. Field Coordination Unit

a) To coordinate all daily operations related to field emergencies and the action strategies adopted;

b) To appoint and oversee the following committees:

- Epidemiological surveillance: responsible for the information system as well as for activities involving tracing, inspection, the use of sentinel animals, repopulation, quarantine, animal transit, installation of fixed and mobile posts, and control of animal concentration sites;
- Sacrifice and destruction;
- Cleaning and disinfection of facilities and vehicles and other biosecurity procedures;
- Communication and sanitary education;

Note: The heads of these committees will be in charge of leading and executing the actions related to their tasks, so as to achieve the specific objectives thereof.

c) To ensure logistic support for the committees;

d) To demarcate protection and surveillance areas as well as areas for the establishment of fixed and mobile posts;

e) To make contact with authorities and other local segments that could provide assistance or be linked to the swine sector;

f) To ensure that all field reports are prepared and submitted to the General Coordination Unit in a timely manner.

2.3. Laboratory Coordination Unit:

To work with the Field Coordination Unit so as to ensure that samples are properly collected, processed, identified, packed and dispatched.

2.4. Administrative and Financial Coordination Unit:

To work with the General Coordination Unit with a view to preparing budgets and procuring, distributing and ensuring the supply of materials and services.

To coordinate and manage the evaluation and taxation committee.

2.5. Communications and Public Relations Coordination Unit:

To work with the General and Field Coordination Units by providing information and ensuring that this reaches the media and competent authorities in a properly manner.

2.6. Legal Affairs Coordination Unit:

To advise the General and Field Coordination Units with respect to legal matters and handle all legal processes inherent in sanitary emergencies.

VI. OPERATION PROCEDURES IN VETERINARY CARE

1. Notification of suspicion

- A permanent information system shall be maintained on a permanent basis, so that disease outbreaks can be promptly notified and handled;

- Every veterinarian, owner and transporter of animals, or any other citizen aware of a suspected outbreak of CSF or of any other disease with a similar clinical picture should, pursuant to the legislation in force, immediately notify the closest unit of the Official Veterinary Service;

- The notification can be provided personally, by telephone, fax or any other available media.

2. Attention to the notification

- Where the person providing the notification is the owner or person in charge, he/she should be informed of the prohibition to move pigs and products and byproducts thereof from the farm, until the Official Veterinary Service has defined the measures to be taken;

- To record the fact, including date and time, in the Local Unit's log;

- To gather as much information as possible on the rearing establishment under suspicion, such as geographic location, natural barriers, access routes, registration data, type of rearing establishment, neighboring establishments, existing swine population, entry and exit of animals in the past 30 days, production data, previously notified diseases, slaughterhouses and establishments selling products and byproducts of swine origin;

- To inform the sanitary management immediately;

- To have the materials and equipment required to handle an outbreak(Annex I) as well as the following documents: FORM-IN, Term of Visit to the Swine Farm, and Interdiction Notice.

3 – Visit to the farm suspected of CSF

a) To organize the visit on a priority basis, no later than 12 hours after notification, and follow the procedures below:

- First of all, visit the rearing establishment suspected of CSF by going straight to the main house, office or management, in order to collect information from the owner or person in charge. Avoid driving an official vehicle into the property;

- Change clothes, wearing preferably disposable clothes and using disposable materials when entering the premises where the animals are kept;

- Fill out the Term of Visit to a Swine Farm;

- Perform the clinical examination of sick animals with the assistance of a minimum of official or private staff and avoid moving or grouping susceptible animals;

- Investigate the establishment and perform a clinical examination in apparently healthy animals;

- Where the suspicion is unquestionable and confirmed, fill out the FORM-IN and the Interdiction Notice, collect samples and communicate the sanitary authority immediately, so that all necessary emergency actions can be promptly taken;

- Send the material collected to the laboratory at:

Laboratorio de Apoio Animal – LAPA/RECIFE
Address: Rua Dom Manoel de Medeiros, s/No.
Dois Irmãos – Campus UFPE
CEP: 52171 - 030
RECIFE – PE
TELEPHONE: (081) 3441-6311

IMPORTANT: Inform the LAPA/Recife immediately of the airway bill number as well as the flight number and time of arrival of the material.

b) To collect the material

- Collect blood samples from sick and healthy animals so as to compare antibody titers for the CSF virus. For the serological diagnosis, send to the laboratory clear serums, free of hemolysis, at a minimum of 3 ml per animal. The serums should be frozen and immediately sent to the Laboratório de Apoio Animal (Animal Support Laboratory) – LAPA – Recife/PE;

- Sacrifice sick animals and collect samples of tissues, preferably tonsils, spleen, pharynx and mesenteric ganglions and distal portion of the ilium, in the following conditions:

• Send at least 20 grams of each organ;

• Send organ fragments in separate plastic bags properly identified by animal;

• Pack samples under refrigeration and send them immediately to the LAPA –Recife/PE. If it is not possible to have the material arrive at the Laboratory within 48 hours after collection, freeze the material;

• All collected materials should be listed in the FORM-IN and carefully identified with a label or adhesive tape written in pencil, and protected with transparent tape.

- Each and every collection of suspected material should follow the rules of the LAPA – Recife/PE and be sent accompanied with the FORM-IN and a memorandum forwarding the material and requesting the tests and indicating the number and type of samples being sent.

- Arrange for the destruction (burial or cremation) of the carcasses of the animals sacrificed for sample collecting purposes.

- When leaving the suspected establishment, clean up and disinfect the equipment and materials used in clinical examinations and sample collections, doing the same to the vehicle. Incinerate all disposable working clothes.

- Where the laboratory result is negative for CSF, interdiction of the establishment should be suspended, but the epidemiological surveillance should be maintained for 21 days. The samples will be used for a differential diagnosis, which will determine the measures to be taken.

VII. DETERMINATION OF THE AFFECTED ZONE AND SANITARY MEASURES TO BE TAKEN IN THE CSF OUTBREAK

Where the laboratory diagnosis is positive for CSF or the suspicion is unquestionable and confirmed, the emergency team should be called in so that the Contingency Plan can be executed and the necessary legal measures taken.

Where a CSF outbreak is confirmed in exhibit, fair or auction facilities or other sites of swine concentration, the whole area should be considered an outbreak and be subject, as appropriate, to the sanitary measures provided for in this Contingency Plan.

The General Coordination Unit will request the cooperation of public entities and agencies (the military police, city halls and others), with a view to ensuring isolation of the outbreak, strengthening preventive sanitary measures and guaranteeing implementation of the Contingency Plan.

The Field Coordination Unit will immediately determine the following actions:

a) Establishment of the main office headquarters;

b) Establishment of the following areas of action:

- Outbreak
- Internal protection zone
- External surveillance zone

c) Establishment of fixed and mobile inspection posts in the affected zone;

d) Review of the demarcation of the affected zone, with possible expansion thereof, according to the information collected during inspections/investigations;

e) Placement of interdiction signs in strategic locations;

f) Inspection of rearing establishments and swine slaughterhouses located in the internal protection and external surveillance zones;

g) Composition of the committees in charge of emergency actions.

VIII. PROCEDURES TO BE ADOPTED DURING A SANITARY EMERGENCY

1. Measures related to the outbreak

1.1 Evaluation of animals, products and materials

Exposed animals as well as contaminated products and materials should be previously evaluated before sacrifice and destruction.

The evaluation will be performed by the corresponding committee and the values recorded in the Term of Evaluation, which will contain all the criteria used (race, age, gender, identification and weight among others).

Any dispute with respect to the values assigned will not prevent the sanitary action from going forward.

1.2. Sacrifice and Destruction:

a) Pigs infected with CSF and direct contacts thereof will be submitted to sacrifice and destruction in breeding establishment itself or in any other suitable location, at the discretion of the Field Coordinator, after having been evaluated and within no more than 24 hours after receipt of the sacrifice order issued by the Animal Health and Inspection Department (DDA);

b) Indirect contact pigs housed in the same rearing establishment (outbreak) will be submitted to a risk assessment and may be sent for sacrifice and destruction or sanitary slaughter.

In the case of sanitary slaughter, contact animals will be sent to slaughterhouses subject to federal or state inspection, at the discretion of the Official Veterinary Service.

c) In the case of sacrifice and destruction of pigs, the provisions of specific legislations should apply;

d) These tasks are performed by the Sacrifice and Destruction Committee under the supervision of an official veterinarian, and public access to the site should be prevented by the military police;

e) Operationalization:

- Written notification should be sent to the owner of the animals to be destroyed, with the necessary details to prevent the work from being delayed;

- The sacrifice will be carried out by members of the armed or public security forces, with subsequent destruction of the carcasses by burial and/or cremation. Burial is, in general, the most suitable and practical method;

- The operation should be scheduled in such a way so as to allow the Sacrifice and Destruction Committee to arrive at the site after completion of the preliminary work;

- Caliber 22 firearms can be used to kill sick animals and their contacts, with a shot in the cranial region or other appropriate method. The animals should be sacrificed inside trenches and their abdominal cavities open;

- Any unnecessary movement of the animals should be avoided and care should be taken to prevent them from escaping when being conducted to the trenches.

1.3. Destruction of sacrificed animals

The place for the destruction of sacrificed animals should be carefully selected, according to the directions of the environmental protection agency. Factors such as soil condition, proximity to the outbreak, safety of facilities, dominant winds and isolation of the area to avoid public presence should be taken into account.

1.3.1 - Cremation

a) A shallow trench, no deeper than one meter, should be excavated. A layer of firewood or thick wood should be placed diagonally in the trench, which should be filled with straw, thin wood or charcoal soaked in kerosene or diesel oil;

b) The dead animals should be lined up on this layer of firewood, alternating head and tail. Additional wood or charcoal soaked in diesel or kerosene should be placed over and around the dead animals. Use a torch launched from a safe distance or a gunpowder trail to light the fire;

c) Estimates show that cremating 250 adult pigs requires around 6 tons of charcoal, ½ a ton of wood, 75 liters of diesel, and 45 kilos of straw or thin wood;

d) Cremation should be followed by burial; the entire process should be monitored by the official service.

1.3.2 – Burial

a) The trenches should be built preferably in the dominant direction of the winds, and be 2.5 meters deep and 2.5 meters wide. The length will depend on the number of animals – 1.5 meter per each 5 adult pig. Dead animals should be laid down side by side, alternating head and tail;

b) The ramp down the trench should be

smooth. Lime should not be used, as it delays the natural decomposition process that favors inactivation of the virus;

c) Once the trenches have been covered, it is recommended that the area be surrounded with a wire net, so as to prevent small animals from approaching and excavating the site;

d) It is recommended that the trenches and adjacent areas be inspected at least once a week, until the rearing establishment has been repopulated.

1.4 – Clean-up and Disinfection

Clean-up and disinfection are very important operations to ensure the inactivation of an infecting agent in a establishment and, consequently, to prevent the disease from disseminating. They include preliminary disinfection, followed by thorough cleaning and washing and, finally, definitive disinfection. The material collected in the facilities after the first disinfection operation should be completely destroyed by burial or cremation.

Following the sacrifice and burial or cremation, all machines, equipment and materials used by the team that carried out the work should be disinfected using one of the following products:

a) Phenol at 3%;

b) Strong iodophors (1%) in phosphoric acid;

c) Cresol;

d) Sodium hydroxide at 2%;

e) Formalin at 1%;

f) Sodium carbonate (4% anhydrous or 10 % crystalline, with 0.1 % detergent);

g) Ionic and non-ionic detergents;

1.5 – Downtime, introduction of sentinels and repopulation

a) Downtime

Downtime is the time period between the completion of cleaning and disinfection and the introduction of sentinel pigs, with the objective of destroying the natural infectious agent in the environment. This stage should last a minimum of 10 days and during this time other disinfection operations can be performed.

b) Introduction of sentinel pigs

- Cleaning, disinfection and downtime do not fully guarantee the destruction of the CSF virus in an infected establishment. As a result, the entry, under strict control, of susceptible animals is authorized, so as to prove the absence of viral activity in the environment;

- The introduction of sentinel pigs in the outbreak under eradication will start after the end of the downtime and the adoption of other measures provided for in this Contingency Plan. It should start with 5% cent of the population that existed in the outbreak or at least 5 pigs no older than 60 days. These animals should be distributed in such a way so as to cover all premises in the rearing establishment;

- The sentinel pig must have been born and resided in farms officially recognized as free of CSF. Pigs born and raised in rearing establishments with a different sanitary status should be submitted to individual serological control; the presence of antibodies specific to the CSF virus should not be detected;

- Sentinel pigs should be identified by eartags and will be submitted to individual serological control at 15 and 30 days from the date of introduction, with the objective of detection of antibodies specific to the CSF virus;

- Sentinel pigs will remain in the property until the second laboratory report is received, showing negative results. During this time, the animals should be submitted to weekly clinical examinations, with their body temperature taken. Cleaning and disinfection measures should be maintained for those entering or exiting the rearing establishment.

c) Control of sentinel animals

Where a sentinel pig yields a positive serological result, all the other animals will be killed, and the process of cleaning, disinfection, downtime and new introduction of sentinels will be restarted;

Where sentinel pigs yields negative serological result, the animals should be sent for slaughter in a slaughterhouse subject to federal inspection and the repopulation process will start.

d) Repopulation

Repopulation of the rearing establishment will only be authorized after the results of the second serology of pig sentinels, yielding negative results, are received. After this period of time, the establishment will be released.

2. Epidemiological Tracing

Once the outbreak has been confirmed, a quick and effective field tracing should be performed and the transit of animals, products and byproducts of pig origin should be assessed, with the objective of controlling the situation by determining the origin of the outbreak. Tracing is necessary to enable identifying the herds exposed and prevent the disease from spreading.

It should be performed by a specific team in each zone (zones of internal protection and external surveillance) and in other areas as well, when the investigation so recommends. Tracing in those other areas will be determined by the Field Coordinator and will be under the responsibility of the corresponding Local Unit.

Depending on the transit survey, tracing can require a large number of people, under systematic and careful coordination.

Aspects to be traced:

a) Previous facts relating to the origin of the outbreak, as well as its possible dissemination to other establishments and municipalities in the 30 days before the disease was detected, with an investigation of the transit of animals and people, transportation of products, fairs, slaughterhouses and buyers that had contact with the infected establishment before the restrictions had been defined.

b) As regards the transit of pigs, reproduction materials, products and byproducts of swine origin:

- If the establishment is being disinfected for some time already, all possible information on the movement of pigs, products and byproducts thereof, excrements, equipment belonging to the rearing establishment, vehicles, food leftovers, people, pets and other relevant information should be obtained from the owner and his/her employees immediately after confirmation of the diagnosis and together with the beginning of eradication actions;

- Determine the date, type of transit and destination with the exact location, so as to ensure the quick identification of the rearing establishments exposed;

- Record on the municipality's map, in details, the transit involving existing rearing establishments.

c) As regards slaughterhouses and byproduct industries:

- Trace fresh, cold or frozen products and byproducts of animal origin. The transit should be evaluated by risk analysis as a potential factor of disease dissemination.

d) Veterinarians and independent professionals linked to the field, who perform their activities in the infected zone should be informed of the presence of the disease and provide the Official Veterinary Service with a list of all the rearing establishments visited in the past seven days.

3. Measures to be taken in the internal protection zone

- Prohibit the transit of pigs from establishments located in the internal protection zone as well as the transit of materials that could be contaminated, such as animal food and excrements originating in the internal protection zone;

- Immediately perform the epidemiological tracing;

- Permit only the transit of clean and disinfected vehicles and equipment, pursuant to the procedures defined by the Official Veterinary Service following inspection by the Official Veterinary Service;

- The transit of animals of other species from rearing establishments located in the internal protection zone as well as the entry of animals in those same rearing establishments will only be permitted if authorized by the Official Veterinary Service.

3.1 – Actions to be developed:

3.1.1 – Interdiction:

In the internal protection zone, the interdiction period of any rearing establishment will be of up to 21 days after completion of the preliminary outbreak cleaning and disinfection operations. The animals may be sent for slaughter, subject to a risk assessment and control by the Official Veterinary Service.

In the interdiction process, the quarantine may be one of the following:

• Full quarantine: full restriction of animal transit for a minimum period of 21 days;

• Short quarantine: selective restriction of the transit of animal and products and byproducts of animal origin. It is generally applied according to actual or presumed differences in sus-

ceptibility and justifiable economic reasons.

3.1.2. Population census

The Official Veterinary Service should carry out a census of the pig population existing in all establishments located in the zone, no later than seven days after establishment thereof.

a) Controlling the Transit of Pigs and Animal Reproduction Material

I. Restriction involving the circulation and transportation of pigs and animal reproduction material in public or private routes. This restriction may not be applied in the following situations:

Transit through the internal protection zone by road or railway, without stops or unloading therein;

Pigs originating outside the internal protection zone and intended directly to slaughterhouses located in the same zone, as long as they are transported in vehicles sealed in the origin by the Official Veterinary Service.

II. Restriction involving the transit of animals of other species originating in establishments located in the internal protection zone.

III. Prohibition to take pigs and animal reproduction material out of any breeding establishments, up to 21 days after completion of the preliminary cleaning and disinfection operations in the outbreak. The animals may be sent for slaughter, subject to a risk assessment and control by the Official Veterinary Service.

3.1.3. Transit of products and byproducts of swine origin and other materials

Only the transit of clean and disinfected vehicles and equipment will be permitted, pursuant to the procedures defined by the Official Veterinary Service following inspection by an official employee.

The transit of materials that could be contaminated such as animal food, excrements and garbage leak originating in the internal protection zone, as well as in any rearing establishment or slaughterhouse.

3.1.3.1. Permission for the removal of pigs

I. Directly to slaughterhouses

At the end of the epidemiological tracing period and after the risk assessment, the Official Veterinary Service may authorize the removal of pigs directly to slaughterhouses under federal or state inspection, provided that the following conditions are satisfied:

- Inspection of all pigs in the rearing establishment;
- Clinical examination of pigs intended for immediate slaughter, including taking the temperature of some animals selected at the discretion of the official veterinarian;
- Identification of the animals by the official veterinarian, using eartags or any other approved identification system;
- Transport of the animals in disinfected and sealed vehicles, accompanied with the Animal Movement Permit (GTA), with identification of the route on the back thereof;
- Communication to sanitary authority responsible for the slaughterhouse;
- Upon arrival in the slaughterhouse, pigs originating in the internal protection zone should be kept isolated and be slaughtered at the end of the killing. During ante- and post-mortem inspection, the sanitary authority should look for signs and injuries related to the presence of infection by the CSF virus;
- The vehicle and equipment used to transport the pigs should be immediately washed and disinfected, under the supervision of the official veterinarian.

II. To rearing establishments within the internal protection zone

Twenty one days after completion of the preliminary cleaning and disinfection operations in the outbreak and subject to a risk assessment, the Official Veterinary Service may authorize the removal of pigs from establishments located in the internal protection zone, directly to another rearing establishment in the same zone, provided that the following conditions are satisfied:

- Inspection of all pigs in the rearing establishment;
- Clinical examination of the pigs to be removed, including taking the temperature of some animals selected at the discretion of the official veterinarian;
- Identification of the animals by the official veterinarian, using eartags or any other approved identification system;

- Cleaning and disinfection, after each operation, of the vehicles and equipment used to transport pigs.

3.1.4 – Maintenance of measures:

The measures applied in the internal protection zone will be maintained until the established actions have been completed and a serological inquiry comprising all the rearing establishments in the zone has been performed. This inquiry will be performed when at least 30 days have elapsed after completion of the preliminary cleaning and disinfection operations in the outbreak, according to a sample to be defined by the Animal Health and Inspection Department of the Ministry of Agriculture, Livestock and Food Supply (DDA/MAPA), and no antibodies specific to the CSF virus have been detected.

4. Measures to be taken in the external surveillance zone

4.1. Action to be developed:

4.1.1. Interdiction:

In the external surveillance zone, the interdiction period of any rearing establishment will be of up to 10 days after completion of the preliminary outbreak cleaning and disinfection operations. The animals may be sent for slaughter subject to a risk assessment and control by the Official Veterinary Service.

In the interdiction process, the quarantine may be one of the following:

• Full quarantine: full restriction of animal transit for a minimum period of 21 days;

• Short quarantine: selective restriction of the transit of animal and products and byproducts of animal origin. It is generally applied according to actual or presumed differences in susceptibility and justifiable economic reasons.

4.1.2. Population census

The Official Veterinary Service should carry out a census of the pig population existing in all establishments located in the zone, no later than seven days after establishment thereof.

4.1.3. Transit of products and byproducts of swine origin and other materials

I. Restriction involving the circulation and transportation of pigs and animal reproduction material in public or private routes. This restriction may not be applied in the following situations:

Transit through the external surveillance zone by road or railway, without stops or unloading therein;

Pigs originating outside the internal protection zone and intended directly to slaughterhouses located in the same zone, as long as they are transported in vehicles sealed in the origin by the Official Veterinary Service.

II. Restriction involving the transit of animals of other species originating in establishments located in the external surveillance zone.

III. Prohibition to take pigs and animal reproduction material out of any rearing establishments, up to 21 days after completion of the preliminary cleaning and disinfection operations in the outbreak. The animals may be sent for slaughter subject to a risk assessment and control by the Official Veterinary Service.

4.1.3.1. Permission for the removal of pigs

I. Directly to Slaughterhouses

The Official Veterinary Service may authorize the removal of pigs directly to slaughterhouses subject to federal or state inspection, preferably located in the internal protection zone or in the external surveillance zone, provided that the following conditions are satisfied:

- Inspection of all pigs in the rearing establishment;

- Clinical examination of the pigs intended for immediate slaughter, including taking the temperature of some animals selected at the discretion of the official veterinarian;

- Identification of the animals by the official veterinarian, using eartags or any other approved identification system;

- Transport of the animals in disinfected and sealed vehicles, accompanied with the Animal Movement Permit (GTA), with identification of the route on the back thereof;

- Communication to the sanitary authority responsible for the slaughterhouse;

- Upon arrival in the slaughterhouse, pigs originating in the internal protection zone should be kept isolated and slaughtered at the end of the killing. During ante- and post-mortem inspection, the sanitary authority should look for signs and injuries related to the presence of infection by the CSF virus;

- The vehicle and equipment used to transport the pigs should be immediately washed and disinfected, under the supervision of the official veterinarian.

II. To rearing establishments located in the external surveillance zone:

Ten days after completion of the preliminary cleaning and disinfection operations in the outbreak and subject to a risk assessment, the Official Veterinary Service may authorize the removal of pigs from establishments located in the external surveillance zone, directly to another rearing establishment in the same zone, provided that the following conditions are satisfied:

- Inspection of all pigs in the rearing establishment;

- Clinical examination of the pigs before loading, including taking the temperature of some animals selected at the discretion of the official veterinarian;

- Identification of the animals by the official veterinarian, using eartags or any other approved identification system;

- Cleaning and disinfection, after each operation, of the vehicles and equipment used to transport pigs.

4.1.4. Maintenance of measures

The measures applied in the in the external surveillance zone will be maintained until the established actions have been carried out and a serological inquiry comprising all the rearing establishments in the zone has been performed. This inquiry will be performed when at least 15 days have elapsed after completion of the preliminary cleaning and disinfection operations in the outbreak, according to a sample to be defined by the Animal Health and Inspection Department of the Ministry of Agriculture, Livestock and Food Supply (DDA/MAPA), and no antibodies specific to the CSF virus have been detected.

5. Procedures in Slaughterhouses

a) Receiving of animals from the internal protection zone – already described in the item on internal protection zone.

b) Receiving of animals from the external surveillance zone – already described in the item on external surveillance zone.

c) Findings suspicious of CSF – where the ante-mortem examination reveals clinical signs or findings of injuries consistent with CSF in the slaughter line, the veterinarian responsible for the sanitary inspection in the slaughterhouse will take the following measures:

I. Immediately notify the Official Veterinary Service, so that it can perform an epidemiological investigation;

II. Immediately slaughter all pigs in the slaughterhouse and collect material for laboratory diagnosis;

III. Collect material from carcasses with injuries suspicious of CSF and forward it to the laboratory;

IV. Destroy, under official control, all carcasses and offal, so as to prevent CSF from disseminating. The products could be used under certain conditions, after a risk assessment has been performed by the Official Veterinary Service. In this case, the products will be prohibited for exporting;

V. Wash and disinfect all premises and equipment, including the vehicles used to transport infected pigs, under the surveillance of the veterinarian responsible for the sanitary inspection in the slaughterhouse, according to the rules of the Official Veterinary Service;

VI. Reintroduction of pigs for slaughter in slaughterhouses where CSF outbreaks have been identified, will only be authorized at least 24 hours after completion of the cleaning and disinfection operations.

6. Fixed and mobile inspection posts

These posts are used with the objective of circumscribing an emergency zone using transit control and disinfection measures to prevent CSF from spreading.

The main objective of these posts is to ensure fulfillment of the measures relating to the transit of animals, product, byproducts, animal reproduction material, vehicles, people, and other materials that could transmit the agent between each of the areas.

They will be established within the perimeter of each of the demarcated zones and should be in operation within 12 hours after the emergency has been established.

The teams that will be working in these posts should include representatives of the Official Veterinary Service and of the public security forces and be equipped with permanent means of communication with each other and with the Field Coordination, so as to ensure fulfillment of the sanitary measures adopted.

7. Vaccination against CSF

a) In exceptional cases, where the risk of CSF dissemination has been determined after an evaluation of the epidemiological situation and at the discretion of the Official Veterinary Service, the emergency use of vaccine may be authorized, subject to a specific plan approved by the DDA that includes:

Extension and demarcation of the geographic area where the vaccination will take place;

Categories and estimated number of pigs to be vaccinated;

Duration of the vaccination schedule;

Measures applicable to the transportation of pigs and products thereof;

Identification of vaccinated pigs, in the case of vaccination in rearing establishments located in a free zone, for subsequent sanitary slaughter;

Supervision and follow-up of vaccination by the Official Veterinary Service.

b) In the case of emergency use of vaccine against CSF in a free zone or in part of the territory of a free zone, this will lose the status of free, which can only be regained when the conditions set out in the OIE International Zoosanitary Code are met.

c) Only vaccines against CSF registered with MAPA and produced under the control of the Official Veterinary Service can be used.

ANNEX I

EQUIPMENT AND MATERIALS FOR EMERGENCY ACTIONS - CSF

Have the following equipment and materials available, preferably disposable, where possible. As a good management practice, units of these materials, organized in metallic or plastic boxes, should be permanently ready.

1) Aprons
2) Rubber boots and shoe protectors
3) Impermeable pants, jacket, and cap
4) Rubber and/or disposable gloves
5) Cotton and/or paper towels
6) Clinical thermometers
7) Tweezers
8) Scissors
9) Syringes and needles
10) Gauze
11) Blindfold for containing wild pigs
12) Adhesive tape and/or another identification label
13) Pencil and pen
14) Plastic bags for samples
15) Vials and needles for collecting blood
16) 100x20 or 80x15 needles
17) Syringes
18) Pipe
19) Thick bow or rope
20) Plastic bucket
21) Sponge
22) Brush
23) Soap
24) Sodium carbonate or another agent
25) Portable sprinkling equipment
26) FORM-IN
27) Term of interdiction
28) Term of Visit to a Swine Farm
29) Box with necropsy instruments
30) Bags for residues
31) Means of identification: tattoer, pliers for eartags, eartags, marking stick
32) Isothermal boxes and ice
33) Manual spraying pump
34) Mechanical spraying pump
35) Map of the municipality and region
36) GPS
37) Drawing boards

ANNEX II

CHARACTERISTICS OF CLASSICAL SWINE FEVER – OIE

ETIOLOGY

1. Classification of the causal agent

Virus of the *Flaviviridae family,* Pestivirus gender.

2. Reaction to physical and chemical action

Temperature: Partially resistant to moderate heat (56ºC)

pH: Inactivated at pH < 3.0 or pH >11.0

Chemical products: Sensitive to ether, chloroform, β--propiolactone 0.4%

Disinfectants: Inactivated by cresol, sodium hydroxide (2%), formalin (1%), sodium carbonate (4% anhydrous or 10% crystalline, with 0.1% detergent), ionic and non-ionic detergents, strong iodophors (1%) in phosphoric acid

Survival: Survives well in cold environments and can survive some meat processing methods (cured and smoked)

EPIDEMIOLOGY

1. Hosts

Domestic and wild pigs are the only natural reservoirs of the Classical Swine Fever (CSF) virus.

2. Transmission

• Direct contact between animals (secretions, excretions, semen, blood);

• Dissemination by persons, utensils, vehicles, clothes, instruments and needles;

• Use of food leftovers without appropriate thermal treatment for animal food;

• Transplacentary infection.

3. Virus sources

• Blood and all tissues, secretions and excretions of sick and dead animals;

• Infected piglets have a congenital persistent viremy and can excrete viruses for months;

• Infection paths: ingestion, contact with conjunctives, skin injuries, insemination, percutaneous penetration of blood.

4. Geographic distribution

The disease is distributed in most of Asia, South America, parts of Europe and Africa.

5. Diagnosis

The incubation period of the disease is from 7 to 10 days.

a. Clinical diagnosis

• Acute form

- Fever (41ºC), anorexia, lethargy;

- Multifocal Hyperemia and hemorrhagic skin injuries, conjunctivitis;

- Skin cyanosis, especially in the extremities (ears, members, snout, tail);

- Intestinal constipation followed by diarrhea;

- Vomit;

- Ataxia, paresis and convulsion. Animals pile up on top of each other;

- Death within 5 to 14 days from start of the disease;

- Young animals' mortality rate close to 100%.

• Chronic form

- Prostration, irregular appetite, fever, diarrhea;

- Apparent recovery with subsequent relapse and death.

• Congenital form

- Congenital tremor and weakness;

- Stunting and death;

- Clinically normal piglets, but with persistent viremy and no immunitary response.

• Mild form (females)

- Fever and lack of appetite;

- Fetal death and re-absorption or mummification, stillbirth;

- Birth of congenitally infected pigs;

- Miscarriage (less frequent).

Injuries

• Acute form

- Leucopeny and trombocytopeny;

- Petechias spread ecchymosis, mainly on the skin, in the lymphatic ganglions, larynx, bladder, kidneys and ileocecal valve;

- Multifocal infarct on the border of the spleen;

- Hemorrhagic lymphatic ganglions;

- Encephalomyelitis with perivascular cuffs.

• Chronic form

- Button-shaped ulcers next to the ileocecal valve and the large intestine;

- Generalized depression of the lymphoid tissue;

- Hemorrhagic and inflammatory injuries could be absent.

• Congenital form

- Cerebellar hypoplasia, microencephaly, pulmonary hypoplasia, hydropsis and other malformations.

a. Differential diagnosis

• African swine fever (the clinical-pathological differentiation is impossible. Material needs to be sent for laboratory diagnosis);

• Infection by bovine diarrhea virus;

• Salmonellosis;

• Erysipelosis;

• Acute pasteurellosis;

• Other viral encephalomielites;

• Estreptococosis;

• Leptospirosis;

• Intoxication by cumarin.

b. Laboratory diagnosis

• Identification of the agent

- Fluorescent antibody test;

- Virus isolation in cellular culture, with detection of the virus by immunofluorescence or immunoperoxidase. Identification confirmed with monoclonal antibodies.

• Serological tests

- ELISA

- Virus neutralization revealed by peroxidase or by fluorescent antibodies.

• Samples for identification of the agent: should be kept under refrigeration and sent to the laboratory as soon as possible.

- Tonsils

- Lymphatic ganglions (pharyngeal and e mesenteric)

- Spleen

- Kidneys

- Distal ileum

- Blood in EDTA (live animals)

• Samples for serological tests:

- Samples of animal serum.

PROPHYLAXIS AND PREVENTION

There is no possible treatment. Infected piglets must be sacrifaced and their carcasses buried or incinerated.

1. Sanitary prophylaxis

• Effective communication among veterinary authorities, independent veterinarians and swine producers;

• Efficient disease notification system;

• Strict policy for the importing of live pigs, fresh and cured pork meat;

• Prohibition to use or obligation to adopt adequate thermal treatment for the use of food leftovers for pigs;

• Efficient control over swine slaughterhouses;

• Systematic serological surveillance of pigs intended for breeding;

• Maintenance of an efficient swine identification system.

2. Medical prophylaxis

• Free countries: vaccination is prohibited;

• Infected countries: vaccination with modified live virus is efficient to control the disease, but by itself will not completely eliminate the infection.

3. Measures to be taken in the outbreak

• Sacrifice of all infected pigs;

• Elimination of carcasses, beds, excretions, etc.;

• Thorough disinfection;

• Identification of the infected zone, with transit control;

• Detailed epidemiological investigation, with tracing of possible sources of infection and dissemination of the disease;

• Surveillance in the infected zone and surrounding region.

NORMATIVE INSTRUCTION No. 6 OF MARCH 9, 2004

Published in the Official Gazette of March 10, 2004 Section 1, Page 3

Approves the Rules for Eradication of the Classical Swine Fever (CSF), which shall be complied with throughout the entire National Territory, in the manner described in this Normative Instruction

THE MINISTRY OF STATE OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY, in accordance with the duties and responsibilities assigned thereto by Article 87, subsection II, of the Constitution, and in compliance with article 71 of the Animal Sanitary Health and Inspection Regulation as approved by Decree No. 24,548 of July 3, as well as the contents of the Judicial Proceeding No. 21000.011262/2003-21, hereby resolves:

Art. 1. To approve the Rules for Eradication of the Classical Swine Fever (CSF), which shall be complied with throughout the entire National Territory, in the manner described in this Normative Instruction.

Art. 2. To forbid vaccination of pigs against the CSF in the entire National Territory, except in zones to be defined by the Animal Health and Inspection Department - DDA.

Art. 3. To forbid the entry or transit, within the CSF zone free, of pigs, and its products and byproducts, animal multiplication material of swine origin, pathological and biological products, and presumable carriers and propagators of the disease's virus, coming from infected zones; with the purpose of maintaining CSF zone frees in the country, in accordance with the principles ruling zone and regions, as set out by the World Animal Health Organization (OIE).

Sole Paragraph. In exceptional cases, the entry or transit of animals referred to in this article, if authorized, shall be ruled by specific legislation addressing the matter, and sustained by regularly issued official certification.

Art. 4. To delegate authority to the Animal and Plant Health and Inspection Secretariat to pass supplementary rules to assure thorough implementation of CSF eradication activities in the country, through proposal/bill submitted by the Animal Health and Inspection Department, which shall include a Contingency Plan setting out specific measures to be adopted in the event of the disease to allow for its immediate elimination.

Art. 5. The Animal and Plant Health and Inspection Secretariat shall carry out activities to promote the creation and establishment of state committees for swine health, and to raise private funds to compensate pig owners that are affected by the sanitary measures implicating in the slaughter of animals and destruction of goods.

Art. 6. State Secretariats for Agriculture or competent animal health and inspection authorities within the States will promote, through effective measures, the activities as provided by the Rules approved by this Normative Instruction, and the other legal orderings arising from it.

Art. 7. This Normative Instruction shall enter into force on the date of publication thereof.

Art. 8. This Normative Instruction revokes Administrative Ruling No. 201, of May 15, 1998.

ROBERTO RODRIGUES

ANNEX

RULES FOR THE ERRADICATION OF CLASSICAL SWINE FEVER (CSF)

CHAPTER I

DEFINITIONS

Art. 1. For the purpose of these Rules:

I - Swine farm: places where pigs are raised or kept, regardless of their purpose;

II - Outbreak: a swine farm or any other place with one or more pigs presenting CSF;

III - Interdiction: forbidden entry or exit of pigs from a swine farm, regardless of the purpose, as well as of swine products or byproducts, or materials that may be a source of transmission of the disease, to be decided and defined by the Official Veterinary Service.

IV – Official Laboratory: Laboratory belonging to the Ministry of Agriculture, Livestock & Food Supply network;

V – Slaughterhouse: facility used for the slaughtering of animals for human consumption, or for other purposes, and that are to be submitted to official veterinary inspection;

VI – Accredited Veterinarian: professional accredited by the Official Veterinary Service, as provided by specific legislation;

VII – Official veterinarian: professional from the Official Veterinary Service;

VIII – Classical Swine Fever (CSF): transmissible disease that attacks pigs and is caused by a pestivirus;

IX – Contingency Plan: set of emergency procedures and decisions to be followed in the event of an unexpected outbreak, with the aim of controlling and eradicating the CSF agent as fast as possible, thus reducing arising production and economic losses as much as possible;

X - Owner: any person, individual or corporation that owns, safe-keeps or withholds in custody, or upon any other condition, one or more pigs;

XI – Sacrifice and destruction : operation carried out by the Official Veterinary Service whenever a case of CSF is confirmed, and that consists in sacrificing every animal of the herd that is sick, in contact and contaminated, and, if necessary, other herds that have been exposed to the infection, through direct or indirect contact with the pathogenic agent, by destroying carcasses, through incineration or land filling;

XII – Official Veterinary Service: federal, state or municipal official agency for animal health and inspection;

XIII - Pig: any animal belonging to the Sus scrofa (domestic pig) and Sus scrofa scrofa genera (wild pig);

XIV – CSF affected pigs: any pig which presents officially proved clinical symptoms or lesions that are compatible with CSF, having its diagnosis confirmed by laboratory tests;

XV - Pig under suspicion of CSF infection: any pig that presents clinical symptoms or CSF compatible lesions, or yet that its reaction to laboratory tests indicates the possibility of existing CSF;

XVI – External surveillance zone: the area around an internal protection zone, defined by the Official Veterinary Service, at a minimum 10 km ratio from the outbreak;

XVII – Internal protection zone: area neighboring an outbreak and which limits are defined by the Official Veterinary Service, based on geographic and epidemiological factors, at a minimum 3 km ratio.

XVIII – CSF zone free: zone in which the inexistence of the disease has been confirmed based on the International Animal Health Code issued by the World Animal Health Organization – OIE.

CHAPTER II

STRATEGIES FOR PROCEDURES TO BE UNDERTAKEN

Art. 2. CSF eradication measures shall be carried out in the zone free, and expanded with

the purpose of eradicating the disease from the National Territory.

Art. 3. Strategies include, among others, implementing the following measures:

I – sanitary surveillance;

II – mandatory and immediate reporting in the event of or suspected presence of CSF;

III – immediate assistance to outbreaks;

IV – controlling the transit of pigs, its products and byproducts, animal multiplication material, pathological and biological products that may carry the CSF virus, and the facilities that concentrate pigs;

V – controlling the disinfection of vehicles, equipment, and environments;

VI – Sacrifice and destruction of CSF infected or suspected animals, and those they have had contact with;

VII – forbidding the use of vaccinations against CSF in the entire National Territory, except in the zones defined by the Animal Health and Inspection Department - DDA;

VIII – controlling production and supervising vaccine trade;

IX – restricting CSF virus handling, except in duly authorized diagnosis or vaccine production laboratories.

CHAPTER III

SURVEILLANCE AND INFORMATION SYSTEM

Art. 4. The Official Veterinary Service will maintain a zoosanitary surveillance and information system, at all levels, providing systematic analysis of the data collected, and the production of a periodical bulletin in order to satisfy national and international commitments.

Art. 5. Every veterinarian, animal owner or transporter, or any other citizen that is aware of a suspected case of CSF, or of any other disease presenting a similar clinical condition, is obligated to immediately report such fact to the Official Veterinary Service.

Paragraph 1. Whenever facing a suspected case of CSF on his land, the owner must immediately suspend any kind of movement of pigs, swine products and byproducts existing in the location, until the Official Veterinary Service decides on measures to be adopted.

Paragraph 2. Any infliction to what is set out amidst this article shall be duly investigated by the Official Veterinary Service, which, if necessary, will press criminal charges against the inflictor, to the Federal Attorney, to identify responsibilities.

Paragraph 3. In case the inflictor is an accredited veterinarian, in addition to what is set out in Paragraph 2, the Official Veterinary Service shall proceed in accordance with what is provided in its specific legislation.

CHAPTER IV

WATCH OUT FOR CSF OUTBREAKS

Art. 6. All reporting on CSF suspected cases or on diseases presenting similar clinical conditions shall be investigated by the official veterinarian, in up to 12 hours maximum after the reporting, and observing biosecurity technical procedures.

Art. 7. Confirmation of a CSF suspicion by a veterinary in a swine farm will imply in immediate adoption of sanitary measures to eliminate it, as well as to keep it from being spread out to other swine farms, and must always be followed by an epidemiological survey in order to determine the origin of the infection.

Sole Paragraph. The official veterinarian will collect samples from the pigs and send them to the official diagnosis laboratory.

Art. 8. The swine farm in which a clinical or epidemiological suspicion of CSF has been identified will be immediately interdicted by the official veterinarian.

Art. 9. If the CSF is officially confirmed by laboratory diagnosis, the Official Veterinary Service will define and establish an internal protection zone, up to a minimum ratio of 3 km around the area of the outbreak, and an external surveillance zone at a minimum 10 km ratio from the outbreak.

Art. 10. The pigs infected with CSF and those they have had contact with will be submitted to sacrifice and destruction in their respective swine farm, or in another appropriate location,

to be decided by the Official Veterinary Service, in up to 24 hours maximum, starting from the receipt of the order to slaughter issued by the competent authority.

Art. 11. The following measures shall be taken by the official veterinarian upon the CSF outbreak:

I –pigs infected with CSF and those that have had direct contact with them will be submitted to sacrifice and destruction in their swine farm, premises, or any other appropriate location, to be decided by the Official Veterinary Service, after evaluating them, and in up 24 hours maximum, starting from the receipt of the order to slaughter, issued by the Animal Health and Inspection Department - DDA;

II –pigs that have had indirect contact with the animals infected with the CSF agent and that are within the same swine farm will be submitted to a risk evaluation, and may be sent to sacrifice and destruction or sanitary slaughtering, which is to be decided by the Official Veterinary Service;

III – destruction of any and every material suspected to be contaminated by the CSF virus, including food, excreta, and leachate;

IV – disinfection of facilities, equipment and vehicles belonging to the farm;

V – sanitary depopulation and introduction of sentinels;

VI – measures and procedures to eliminate insects and rodents.

Sole Paragraph. On farms located at a ratio of at least 500 m of the outbreak, and after risk analysis, the same measures undertaken against the outbreak may be adopted, based on judgment and decision to be made by the Official Veterinary Service

Art. 12. The introduction of sentinel pigs within the outbreak that is being extinct may only begin 10 days after undertaking clearing and disinfection measures, as well as after the application of other rules foreseen in this Ruling have been concluded.

Art. 13. The swine farm will only be authorized for repopulation after presenting two negative outcomes to serological tests, being carried out with an interval of 15 and 30 days respectively. After this period has elapsed, the interdiction of the swine farm will be suspended.

Art. 14. In the Internal Protection Zone, the following measures will be adopted:

I – census on all farms located within the zone;

II – forbidden circulation and transportation of pigs through public or private routes;

III – forbidden transportation of materials that may be contaminated, except for those that have been cleaned and disinfected, in accordance to the procedures defined by the Official Veterinary Service and after the inspection by the official veterinarian.

IV – forbidden entry and exit of animals of other species located in the internal protection zone, except if authorized by the Official Veterinary Service;

V – forbidden removal of pigs from any farm, regardless of the purpose, in up to 21 days after the conclusion of the preliminary cleaning and disinfection operations on the outbreak. Exception may be made, to be decided by the Official Veterinary Services, to those animals intended for immediate slaughter in state or federally inspected slaughterhouses.

Paragraph 1. Once the time period referred to in subsection V has elapsed, the Official Veterinary Service may authorize the removal of pigs from any farm located in the internal protection zone, directly to another farm, in the same zone.

Paragraph 2. Those measures adopted within the internal protection zone will be carried out and maintained until every existing pig within the outbreak and all of those they have had contact with, have been submitted to sacrifice and destruction, and all the pigs from all farms located in the zone have been submitted to clinical and serological tests.

Art. 15. In the external surveillance zone, the following measures will be adopted:

I – census on all farms located within the zone;

II – forbidden circulation and transportation of pigs through public or private routes;

III – forbidden transportation of materials that may be contaminated, except for those that have been cleaned and disinfected, in accordance to the procedures defined by the Official

Veterinary Service and only after inspection by the official veterinarian.

IV – forbidden entry and exit of animals of other species located in the external surveillance zone, except if authorized by the Official Veterinary Service;

V – forbidden removal of pigs from any farm, regardless of the purpose, in up to 10 days after the conclusion of the preliminary cleaning and disinfection operations on the outbreak. Exception may be made, to be decided by the Official Veterinary Services, to those animals intended for immediate slaughter in state or federally inspected slaughterhouses.

Paragraph 1. Once the time period referred to in subsection V has elapsed, the Official Veterinary Service may authorize the removal of pigs from any farm located in the internal protection zone, directly to another farm, in the same zone.

Paragraph 2. Those measures adopted within the external surveillance zone will be carried out and maintained until every existing pig within the outbreak and all of those they have had contact with, have been submitted to sacrifice and destruction, and all the pigs from all farms located in the zone have been submitted to clinical and serological tests.

Art. 16. If *ante mortem* tests, made at the slaughterhouses, reveal clinical signs that are compatible with CSF, or if lesions compatible with CSF are found among the animals intended for slaughter, the slaughterhouse's sanitary inspection service will adopt the following measures:

I – immediate reporting to the Official Veterinary Service, so it can carry out epidemiological investigation;

II – immediate slaughtering of all existing pigs in the slaughterhouse, and collection of material for laboratory diagnosis;

III – officially controlled destruction of all carcasses and offal in as to prevent CSF propagation. Conditional utilization may be permitted, based on risk analysis performed by the Official Veterinary Service. In such case, those products will not be intended for exports;

IV – washing and disinfecting facilities and equipment, including the vehicles used for transportation of the infected pigs, under surveillance of the veterinarian responsible for the slaughterhouse's sanitary infection, as provided by the rules set out by the Official Veterinary Service.

Sole Paragraph. The reintroduction of pigs intended for slaughter into a slaughterhouse that has recorded a case of CSF will only take place after at least 24 hours have elapsed from the completion of cleaning and disinfection operations, as set out by subsection IV of this article.

CHAPTER V

VACCINATION OF ANIMALS

Art. 17. Vaccination against CSF shall be forbidden in the entire National Territory.

Sole Paragraph. In exceptional situations, when clearly demonstrated risk of dissemination of the disease, after carrying out study on the epidemiological situation, and based on judgment and decision made by the Official Veterinary Service, emergency use of the vaccine may be authorized, through design of a specific plan approved by the DDA.

CHAPTER VI

ON THE TRANSIT OF SWINE, PRODUCTS, BYPRODUCTS AND OTHER MATERIAL

Art. 18. The transit of pigs, its products and byproducts, animal multiplication material, pathological and biological products that are presumable carriers and propagators of the disease's virus, will be sustained by regularly issued official certification, by the Official Veterinary Service or accredited veterinarian, as provided in this and other relevant Rules.

Art. 19. The entry or transit, in the CSF zone free, of live pigs, its products and byproducts, pathological and biological products that are presumable carriers and propagators of the disease's virus, coming from infected regions, countries or zones, will only be permitted in those situations foreseen in the spe-

cific legislation that regulates transit in the CSF zone free.

Art. 20. Whenever it is confirmed non-compliance to the rules approved for the transit of pigs, its products and byproducts, the Official Veterinary Service's competent authority will be in charge of hindering the transit and reporting the event.

Paragraph 1. If intercepted on the borders of the CSF zone free, to order the animals to return to their origin, except those infected with the disease, and apply the appropriate legal sanctions.

Paragraph 2. If intercepted within the CSF zone free, to order the pig's apprehension and slaughter, in addition to applying the appropriate legal sanctions. Regarding products and byproducts, they shall be apprehended and destroyed; and depending on the case and based on judgment made by the competent authority may they be given another destination.

Art. 21. The vehicles used for the transportation of pigs must be washed and disinfected after unloading the animals; and the transit of empty and unclean vehicles shall be forbidden, as provided by the rules in force.

CHAPTER VII

GENERAL PROVISIONS

Art. 22. Whenever CSF is confirmed in slaughterhouses, exhibition sites, fairs, auctions, and other pig gatherings, the entire site will be considered an outbreak, and whenever applicable, the sanitary measures set out in Chapter IV of this Normative Instruction will be adopted.

Art. 23. It is forbidden to use, for pig feed, rests of food containing protein of animal origin regardless of where it comes from, except when submitted to thermal treatment to assure inactivation of the CSF virus.

Paragraph 1. CSF virus inactivation as referred to in this article takes place at a minimum temperature of 90ºC during 60 minutes, and with continuous agitation.

Paragraph 2. It is forbidden to keep pigs in waste deposit sites, and to collect and use rests of food from these locations for animal feed.

Art. 24. The disinfection of vehicles and facilities as set out in this Normative Instruction must be carried out with disinfectants approved and recommended by the Contingency Plan.

NORMATIVE INSTRUCTION SDA No. 19 OF FEBRUARY 15, 2002

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Standards for Accreditation of Swine Breeding Farms

THE SECRETARY OF ANIMAL AND PLANT HEALTH AND INSPECTION – SUBSTITUTE, OF THE BRAZILIAN MINISTER OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY, proceeding from his attributions established by Article 83, Item IV, of the Internal Regulation Manual of the Secretariat, approved by Ministerial Decree No. 574 of 8 December 1998, pursuant to the Animal Health and Inspection Regulation, approved by Decree No. 24548, 3 July of 1934,

Whereas the economic importance of swine farming and the need to maintain an appropriate health level in farms that sell, distribute or keep swine breeders for animal breeding purposes, in order to prevent the spread of diseases and provide desirable levels of productivity, and the contents of Process No. 21000.005128/2001-29, decides:

Art. 1. To approve standards for the accreditation of swine breeding farms, as the APPENDIX.

Art. 2. The marketing and distribution within Brazilian territory of pigs intended for breeding, as well as its participation in exhibitions, fairs and auctions, shall only be allowed if it comes from

Accredited Swine Breeding Farms (ASBF – *Granjas de Reprodutores Suídeos Certificadas*).

Sole paragraph. Institutions keeping livestock for animal breeding purposes shall comply with the standards of Accredited Swine Breeding Farms .

Art. 3. To delegate powers to the Director of the Animal Health Department (DSA – *Departamento de Saúde Animal*), to publish additional standards for accreditation of swine breeding farms, from proposals submitted by the Coordination for Surveillance and Health Programs.

Art. 4. Recommend that Secretaries of Agriculture and animal health and inspection authorities of the States, to support the development of activities under this Normative Instruction.

Art. 5. This Normative Instruction shall come into effect on the date of its publication.

Art. 6. – It is abrogated Normative Instruction No. 12, 23 June 1999.

RUI EDUARDO SALDANHA VARGAS

APPENDIX

STANDARDS FOR ACCREDITATION OF SWINE BREEDING FARMS

1. DEFINITIONS

1.1. For the purpose of this Instruction:

1.1.1. Pig: any animal of the gender Sus sp.;

1.1.2. Swine breeder: pigs kept on a farm and used for animal breeding purposes;

1.1.3. Institutions keeping swine breeding material: central units of artificial insemination and disseminators of genes;

1.1.4. Breeding farm: establishment or property where pigs are reared or kept for sale or distribution purposes, whose final product is intended for breeding;

1.1.5. Accredited Swine Breeding Farms (ASBF – *Granja de Reprodutores Suídeos Certificada*): farm which fully comply with basic and specific standards for accreditation. Farm's accreditation shall be based on serological monitoring and health classification pursuant to this Normative Instruction;

1.1.6. Owner: any person or company who hold under its responsibility pigs whose final product is intended for reproduction;

1.1.7. Official service: federal, state or municipal animal health body;

1.1.8. Official Veterinarian: veterinarian of the official service;

1.1.9. Accredited veterinarian: professional accredited by the official service in accordance with Decree-Law No. 818, dated 5 September 1969;

1.1.10. Technician in charge: veterinarian, appointed by the owner, responsible for compliance with the standards set by this Instruction;

1.1.11. Official laboratory: animal laboratory belonging to the network of the Ministry of Agriculture, Livestock and Food Supply;

1.1.12. Accredited laboratory: laboratory belonging to a public institution that receives, by delegation of powers of the Ministry of Agriculture, Livestock and Food Supply, act of accreditation;

1.1.13. Production of breeders: activity whose main purpose is producing boars and sows;

1.1.14. Full cycle production of breeders: complete swine breeding farm, involving all stages in facilities in the same geographical area;

1.1.15. Site 1: producing unit of piglets, involving the stages of insemination, pregnancy, maternity, weaning and, depending on the establishment, nursery and central of insemination for exclusive use;

1.1.16. Site 2: unit that receives piglets from Site 1 to foster them at the nursery, nursery and growth or growth only until the reproduction phase;

1.1.17. Site 3: unit that receives pigs from Site 2 to foster them until the reproduction phase;

1.1.18. Health surveillance: periodic and systematic procedures aimed to test, qualify and quantify the level of health in breeding farms for a specific disease or infection;

1.1.19. Degree of vulnerability: set of rules aimed to prevent the ingress of pathogens at breeding farms;

1.1.20. Biosafety: Development and implementation of strict rules to protect the herd of swine against the ingress and spread of infectious agents in breeding farms;

1.1.21. Zootechnical data: set of parameters of productivity of a breeding farm, intended to characterize and evaluate its performance;

1.1.22. Quarantine area: a zone aimed to keep newly admitted animals, apparently healthy, isolated and under observation, to perform diagnostic tests and prophylactic measures to prevent the ingress of pathogens in breeding farms.

2. BASIC STANDARDS

2.1. Swine breeding farms shall comply with the following basic standards, in order to be accredited:

2.1.1. Be registered in the proper body of the Ministry of Agriculture, Livestock and Food Supply and keep a record system that allows the identification of animals and their genetic ancestry.

2.1.2. Be registered in the official service with jurisdiction in the area, as well as a complete animal health record (birth, death, diagnosis of diseases, treatments, and vaccination program for health monitoring of swine breeders), with information covering all pigs of the establishment, available to the official service;

2.1.3. Adopt biosafety procedures against the ingress of pathogens and to prevent the spread or exacerbation of diseases in breeding farms;

2.1.4. Keep veterinary assistance and a technician in charge, which shall represent the establishment before the official service, notifying sanitary related events and zootechnical data through the quarterly technical report submitted to the official service, or immediately in case of diseases of immediate notification. The technician shall collect material for laboratory tests, to perform examinations of the herd, and also implement a program of cleaning and disinfection and vaccination, keeping record of such measures and other activities of health control, according to this Instruction, supervised by the official service;

2.1.5. The collection of material for laboratory tests, inoculation of tuberculin and its interpretation for the purpose of health surveillance of farms to be accredited and reaccredited shall be performed under direct supervision of the official service, and the cost of examinations shall be paid by the owner;

2.1.6. The ingress of pigs for animal replacement and breeding material collection in accredited breeding farm shall only occur if the animals come from Accredited Swine Breeding Farms (ASBF), and accredited at least to the same optional diseases.

2.1.7. Accreditation is valid for six months. It shall be printed in a specific form by the official service, based on clinical test results of the herd, performed by official or accredited laboratories and, in the case of tuberculosis, based on results of diagnostic tests performed by the technician in charge of the farm and proof of compliance with other requirements of these Instruction;

2.1.8 Pigs in transit shall be accompanied by official transit permit and copy of the ASBF, attested by official agent;

2.1.9. Accreditation may be suspended at any time by the official service, in case of non-compliance with this Instruction or upon request of the establishment.

3. SPECIFIC STANDARDS

3.1. Sanitary and biosafety standards that shall be met by swine breeding farms to be accredited are:

3.1.1. Have a surrounding fence with single entry and disinfection system for people or vehicles at the entrance;

3.1.2. Have loading and unloading station close to the fence;

3.1.3. Have a guest book, identifying the last date and place of visits to other swine farms, laboratories, slaughterhouses or other places with the presence of pigs, with a minimum fallow period of 24 hours;

3.1.4. Have a disinfection system for the in-

gress of materials and equipment into the farm;

3.1.5. Have wardrobe with impervious walls and floors, with bath, shower and clothing for the visitors and staff of the breeding farm;

3.1.6. Have known source of water, which is not a natural course, to supply the farm with tanks protected, cleaned and disinfected at least every six months;

3.1.7. Hold state environmental agency permission, covering the treatment and disposal of manure;

3.1.8. Have an adequate system, accredited by the official body, to manage corpses and remains of births (stillbirths, mummified, placentas);

3.1.9. Breeding farms with two sites of production shall comply, in both sites, with all standards for accreditation, regardless whether the sites are located in the same property or not;

3.1.10. Farms with three sites of production shall comply with all standards for accreditation in sites 1 and 3, whereas the site 2 shall only comply with conditions of biosafety, regardless whether the sites are located in the same property or not.

3.1.11. In breeding farms with 2 or 3 sites, in case of suspicion of any of the diseases described in this Instruction, in any of the sites of production, at the discretion of the Ministry of Agriculture, Livestock and Food Supply, tests shall be performed at all sites, according to sampling standards of this Instruction, even beyond the date of reaccreditation, and the accreditation of production sites may be suspended until the outcome of tests.

3.2. Accredited Swine Breeding Farms , satisfied the items above, shall be evaluated for an initial classification to be reviewed annually, about their degree of vulnerability to pathogens ingress, as Table 1.

Tabela 1 – EVALUATION OF THE DEGREE OF VULNERABILITY OF ASBF TO THE INGRESS OF EXTERNAL PATHOGENS

Variables	Criteria	Points	Score of the farm
1. Distance to a non-accredited swine farm or swine slaughterhouse.	more than 3.5 Km	0	
	1 - 3.5 Km	1	
	from 500 m to 1 Km	2	
	less than 500 m	3	
2. Density of swine herds in a radius of 3.5 Km	1 herd	0	
	2-3 herds	1	
	4 or more herds	2	
3. Farms supplying pigs for herd replacement	own replacement or by hysterectomy	0	
	1 farm	1	
	2 farms	2	
	3 or more farms	3	
4. Distance from highway where pigs are transported	more than 500 m	0	
	from 300 m to 500 m	1	
	less than 300 m	2	

Variables	Criteria	Points	Score of the farm
5.1. Quality of the isolation of the farm - fence	excellent – double fence interspersed with green belt	0	
	very good – fence screen at least 50 m away from sheds	1	
	good – fence screen less than 50 m away from sheds	2	
	reasonable – non-screened fence only	3	
5.2. Quality of the isolation of the farm - green belt	outside line of the green belt at least 50 m away from farm's facilities	1	
	outside line of the green belt less than 50 m away from farm's facilities	1	
	no green belt	2	
6. Control of visits in the farm	occasional visits, with 72h of fallowing. Regime of bath with exchange of clothes and shoes. Bathroom with clean and dirty area.	1	
	occasional visits, with 48h of fallowing. Regime of bath with exchange of clothes and shoes. Bathroom with clean and dirty area.	1	
	occasional visits, with 24h of fallowing. Regime of bath with exchange of clothes and shoes. Bathroom with clean and dirty area.	2	
7. Existing Quarantine area	yes, at least 500 m away from the herd, with green bell; or no external pigs admissions.	0	
	yes, less than 500 m away from the herd or without green belt.	1	
	no quarantine for admitted pigs.	2	

Variables	Criteria	Points	Score of the farm
8. Feed given to animals	no use of feeding flour of animal origin	0	
	use of feeding flour of animal origin	2	
9. Source of the feed given to animals	own factory inside the establishment	0	
	third factory	1	
10. Transport of feed used in the farm	bulk trucks or vehicles that do not carry pigs	0	
	the same trucks that carry pigs	2	
Farm total score:			

3.2.1. Classification of farms in the degree of vulnerability to external pathogens:

a) farm "A": well-protected - from 0 to 5.0 points, since that has no criteria with a score 2 or 3;

b) farm "B": low vulnerability - up to 8.0 points, since that has no criteria with score 3 and is not included as farm "A";

c) farm "C": moderate vulnerability – from 8.0 to 12.0 points, since that is not included as farm "B";

d) farm "D": highly vulnerable - with 13.0 or more points.

3.2.2. Evaluating the degree of vulnerability of Artificial Insemination Centers (CIA – *Centrais de Inseminação Artificial*), Item 3 of the Table 1 shall not be applied. However, all breeders admitted to CIA shall be tested for the basic diseases of accreditation.

3.3. Health Levels of Accredited Swine Breeding Farms:

3.3.1. All Accredited Swine Breeding Farm shall be free from classical swine fever, Aujeszky's disease, brucellosis, tuberculosis, scabies and free or controlled from leptospirosis.

3.3.2. ASBF shall comply with the following standards for classical swine fever - CSF:

3.3.3. Perform serological tests, every six months, by means of ELISA, using kits registered in the Ministry of Agriculture, Livestock and Food Supply, and the sera that tested positive or is suspected shall undergo additional differential tests, by neutralization tests, including the differentials ones for the Bovine Viral Diarrhoea.

3.3.4. Breeding farm shall achieve compliance with CSF only if all tests are negative. In the case of positive test, standard prophylaxis measures for classical swine fever shall be implemented, pursuant to current regulations.

3.3.5. ASBF shall comply with the following standards for Aujeszky's disease:

3.3.5.1. Not to perform vaccination of pigs housed in the breeding farm.

3.3.5.2. Perform serological tests, every six months by means of ELISA, using kits registered in the Ministry of Agriculture, Livestock and Food Supply, and the sera that tested positive shall undergo neutralization test;

3.3.5.3. Breeding farm shall achieve compliance with serological standards for Aujeszky's disease only if all tests are negative. In the case of positive test, accreditation shall be suspended and serology tests shall be performed to 100% of the herd of breeders, with an interval of 30 and 60 days. Remaining positive, the farm will lose accreditation.

3.3.6. For brucellosis, serologic tests shall be performed every six months, using the Rose Bengal test or another one approved by the Ministry of Agriculture, Livestock and Food Supply and indicated for the case, and the seroreactive shall be submitted to additional tests for the 2-mercaptoethanol or complement fixation test;

3.3.6.1. Breeding farm shall achieve compliance with serologic conditions for brucellosis only if all tests are negative. In the case of positive test, accreditation shall be suspended. Positive tests shall be eliminated and the herd completely retested within 30 days. Remaining positive, the farm will lose accreditation.

3.3.7. For tuberculosis, male and female breeders shall be tested, by sampling, as the table of Item 3.3.11.1, every 6 (six) months in the comparative test with bovine PPD and avian PPD tuberculin.

3.3.7.1. The reading shall occur after 48 hours, using millimetric ruler, measuring the largest diameter of the reaction. The interpretation of the test will be based on the herd, whereas the arithmetic mean of reactions greater than 0.5 cm.

3.3.7.2. The farm shall achieve compliance with standards for tuberculosis if all animals are negative for bovine PPD or in case of a positive reaction, the average diameter of reactions to bovine PPD is lower than the average diameter of PPD reactions to influenza.

3.3.7.3. The farm shall be considered positive for tuberculosis if the average diameter of reactions to bovine PPD is greater than the mean diameter of avian PPD reactions. In this case, accreditation shall be suspended and sanitation measures implemented.

3.3.7.4. If the average diameter of tuberculin reactions to avian PPD is higher than the average of the reactions to bovine tuberculin PPD, the farm shall be considered infected with Mycobacterium Avium Complex (MAC). In this case, the farm does not lose accreditation and a program of control shall be implemented.

3.3.7.5. In case of suspicious interpretation of reactions to tuberculin, the farm shall temporarily lose accreditation, until diagnosis is completed, based on laboratory testing for identification of the mycobacteria involved.

3.3.8. For Leptospirosis, farms shall have two options:

3.3.8.1. Breeding farms considered free from Leptospirosis will be subject to serologic control. Serological tests of microagglutination shall be performed every six months. Sera shall be tested against the serovars *L. canicola, L. grippothyphosa, L. hardjo, L. icterohaemorrhagiae, L. pomona and L. bratislava*, showing negative results.

3.3.8.2. At the discretion of the sanitary authority, additional serovars may be included.

3.3.8.3. Breeding farms considered controlled for Leptospirosis (with vaccination), the accreditation shall contain the words "farm vaccinated for Leptospirosis". The vaccine shall contain all serovars contained in Section 3.3.8.1.

3.3.9. For scabies, two tests of scraping of the skin shall be performed, every 2 or 3 months, including 5 breeders and 5 pigs for slaughter, identified by the official veterinarian, using clinical examination as potential carriers of scabies. Everyone shall present negative results.

3.3.9.1. If positive, accreditation shall be suspended and eradication performed through drug treatment, developed and implemented by the technician in charge.

3.3.10. Farms that do not fully comply with standards mentioned in this Instruction shall lose the condition of Accredited Swine Breeding Farms (ASBF).

3.3.11. Farms will be accredited after the completion of two consecutive negative tests at intervals of two to three months for all diseases described in this Instruction, except for scabies. In this particular case, it will be according to item 3.3.9.

3.3.11.1. In the first test, 100% of the breeder herd shall be tested. Table 2 shall be used in the sampling for the second test and subsequent monitoring. In the case of new farms, populated with the surveillance of the official service, with animals proceeding from already accredited farms, there shall be no need for testing 100% of the herd. In this case, prescriptions of Table 2 are enough.

Table 2 - SAMPLING OF ACCREDITED SWINE BREEDING FARMS (ASBF).
Number of animals for blood collection and completion of comparative tuberculin test, according to the number of swine breeders in the herd, considering an estimated prevalence at 5% and a confidence level of 95%.

Nº. OF BREEDERS IN THE HERD	Nº. OF ANIMALS TO BE SAMPLED	Nº. OF BREEDERS IN THE HERD	Nº. OF ANIMALS TO BE SAMPLED
10	10	350	54
20	19	400	55
30	25	450	55
40	31	500	56
50	35	600	56
60	38	700	57
70	40	800	57
80	42	900	57
90	43	1000	57
100	45	1200	57
120	47	1400	58
140	48	1600	58
160	49	1800	58
180	50	2000	58
200	51	3000	58
250	53	4000	58
300	54	> 5000	59

4. DISEASES FOR OPTIONAL ACCREDITATION

At the discretion of the owner of the breeding farm, the Ministry of Agriculture, Livestock and Food Supply, from June 2002 on, can issue optional accreditation free from any of the diseases listed below:

4.1. Progressive Atrophic Rhinitis (PAR):

4.1.1. Breeding farm shall be considered free from PAR if:

- No Toxigenic type *D Pasteurella multocida* is detected in 3 starting consecutive tests with

an interval of 30 days. It shall be collected nasal and tonsil swabs of 30 piglets with 8 weeks of age that are not being treated with antibiotics. The swabs shall be placed in a transport medium (0.5 ml) and kept at 4 Celsius degrees. In the laboratory, the swabs shall be cultured on selective medium Agar 8HPG, blood agar and placed back in the transport medium. Then it is shaken in vortex, and with the suspensions obtained, a pool of five animals is selected (0.10 ml x 5> 0.50 ml), which shall be inoculated in mice. After 7 days, the mice will be sacrificed, an attempt to isolate *P. multocida*. Samples of *P. multocida* will be tested to identify their toxigenicity by ELISA, Seroneutralization Assay or PCR.

- No damage is found in nasal turbinate superior than 1 by the method of visual assessment (the scale is 0> no lesion, 1> slight deviation from normality; 2> moderate damaged and 3> serious damaged), 3 starting consecutive tests, with an interval of 30 days. Tests shall be performed in a group of at least 30 pigs aged five to six months.

4.1.2. To maintain the accreditation, tests shall be repeated every 6 months, all with negative results.

4.2. Mycoplasma pneumonia (MP)

4.2.1. Breeding farm shall be considered free from Enzootic Pneumonia if:

- *Mycoplasma hyopneumoniae* is not detected in 3 starting consecutive serological tests, with an interval of 30 days, 30 pigs aged over 10 weeks. If there is positive serology and absence of damage at slaughter, live animals with positive serology shall be submitted to bronchial washing and collection of material for Nested-PCR and/or cultivation of *Mycoplasma hyopneumoniae*.

- No pulmonary damage caused by MP is found in 3 starting consecutive tests at the slaughterhouse, with an interval of 30 days, 30 piglets aged 5 to 6 months. If damages caused by MP are found, they shall be submitted to histopathology, followed by immunofluorescence or immunoperoxidase test for Mycoplasma hyopneumoniae.

4.2.2. To remain accredited these tests shall be repeated, once, every 6 months, all with negative results.

4.3. Porcine Pleuropneumonia

4.3.1. Breeding farm shall be considered free from Porcine Pleuropneumonia if:

- No pathogenic serovars of *Actinobacillus pleuropneumoniae* is detected in 3 starting consecutive tests, with an interval of 30 days, by the polyvalent ELISA test on 30 piglets with 13 or more weeks of age. If damages caused by Porcine Pleuropneumonia are detected at the slaughterhouse, secretions and fragments of tonsil shall be collected from positive animals and submitted to direct bacteriological tests in selective medium, applying the immunomagnetic separation for isolation of *Actinobacillus pleuropneumonia*, or PCR test.

- No damages caused by Porcine Pleuropneumonia is detected in 3 starting consecutive tests with an interval of at least 30 days, 30 piglets aged 5 to 6 months. If any damage consistent with PPS is observed, it shall be used in serotyping test and to perform tests intended to isolate *Actinobacillus pleuropneumoniae*.

4.3.2. To remain accredited, tests shall be repeated, once, every 6 months, with all results negative.

4.4. Swine Dysentery (SD)

4.4.1. Breeding farm shall be considered free from SD if:

- *Brachyspira hyodysenteriae* is not detected in 3 starting consecutive tests with an interval of 30 days, by laboratory tests of a pool of feces from 6 pigs per pen, taken from 6 different pens of pigs on growth. The feces shall be tested by direct immunofluorescence and confirmed by PCR. To remain accredited tests shall be performed every six months, of a pool of feces from 6 pigs, from 6 different pens of pigs on growth.

4.4.2. To remain accredited, tests shall be repeated, once, every 6 months, with all results negative.

4.5. Concerning diseases described in items 4.1, 4.2, 4.3, 4.4, the ASBF shall be classified into four levels, as follow:

a) Level 1: free from four optional diseases;

b) Level 2: free from at least two optional diseases;

c) Level 3: free from one optional disease;

d) Level 4: no accredited for optional diseases.

5. FINAL DECISIONS

5.1. At the discretion of the Animal Health and Inspection Department additional diseases can be required for accreditation.

5.2. Penalties resulting from non-compliance with standards of this Normative Instruction are described in the legislation of Animal Health , regardless of the loss of accreditation.

5.3. Cases not covered by this Normative Instruction shall be addressed by the Animal Health and Inspection Department.

(Of. El. No. OF-SDA019-02)

CCOMPLEMENTARY LEGISLATION

NORMATIVE INSTRUCTION No. 1 OF JANUARY 4, 2001

Published in the Official Gazette of January 22, 2001 Section 1, Page 11

Approves Norms for the admission of pigs, their products and subproducts in the Zone Free of Classical Swine Fever, consisting of the States referred to therein.

NORMATIVE INSTRUCTION No. 1 OF JANUARY 4, 2001

Published in the Official Gazette of January 16, 2001 Section 1, Page 6
(Modified by IN No 7 of February 27, 2009)

Declares the region consistent of the States of Rio Grande do Sul, Santa Catarina, Paraná, São Paulo, Minas Gerais, Mato Grosso do Sul, Mato Grosso, Goiás, Tocantins, Rio de Janeiro, Espírito Santo, Bahia, Sergipe, Rondônia and the Federal District as a classical swine fever free zone.

PART III

Animal Movement and Quarantine Control

ADMINISTRATIVE RULING No. 162 OF OCTOBER 18, 1994

Published in the Official Gazette of October 21, 1994 Section 1, Page 15934
Altered by Normative Instruction No. 44 of October 02, 2007

Approves complementary Norms attached to this Administrative Ruling, issued by the Animal Health and Inspection Department, which deal with Inspection and Animal Health Control in Exhibitions, Agricultural Fairs, Auctions and other livestock agglomerations, throughout the national territory.

THE SECRETARY OF ANIMAL AND PLANT HEALTH AND INSPECTION, through the jurisdiction conferred to him by Article 78, item VI, of the Internal Rules of the Secretariat, approved by Ministerial Administrative Ruling No. 212, August 21, 1992, and taking into consideration that contained within Article 2 of the Ministerial Administrative Ruling No. 108 of March 17, 1993, resolves:

Art. 1. Approve complementary Norms attached to this Administrative Ruling, issued by the Animal Health and Inspection Department, which deal with Inspection and Animal Health Control in Exhibitions, Agricultural Fairs, Auctions and other livestock agglomerations, throughout the national territory.

Art. 2. This Administrative Ruling shall come into effect on the date of its publication, revoking all contrary provisions.

TÂNIA MARIA DE PAULA LYRA

ANNEX

COMPLEMENTARY NORMS TO THE MINISTERIAL ADMINISTRATIVE RULING No. 108, OF MARCH 17, 1993, ABOUT INSPECTION AND ANIMAL HEALTH CONTROL IN EXHIBITIONS, FAIRS, AUCTIONS AND OTHER LIVESTOCK AGGLOMERATIONS, THROUGHOUT THE NATIONAL TERRITORY

CHAPTER I

ABOUT PRIOR AUTHORIZATION FOR EXHIBITIONS, AGRICULTURAL FAIRS, AUCTIONS AND OTHER LIVESTOCK AGGLOMERATIONS.

Art. 1. The holding of fairs and exhibitions of livestock shall be previously authorized by the national or state level animal health and inspection body, as provided for in Article 6 of Administrative Ruling No. 108 of 17 March 1993, of the Minister of State of Agriculture, Food Supply and Agrarian Reform.

Paragraph 1. For exhibitions and fairs of interstate, national or international jurisdiction, prior authorization from the Federal Board of Agriculture, Food Supply and Agrar-

ian Reform in the States will be also required.

Paragraph 2. The authorization must be sought in the following terms:

a) – 30 days in advance for events of municipal and regional jurisdiction;

b) – 60 days in advance for events of state, interstate and national jurisdiction;

c) – 90 days in advance for events of international jurisdiction.

Art. 2. The completion of auctions depends on prior authorization of the veterinary authority of the city, except those involving only animals raised in the establishment where it will be held.

Art. 3. The request for authorization to conduct the auction must be done to animals, enclosing statement of technical responsibility in the case of private professional, signed by him and by the sponsor of the event, with at least three (3) working days in advance, including:

I – Place and date;

II – Number of animals per species, gender and age;

III – Source of animals (city and state);

IV – The name of the veterinarian, private or official, responsible for veterinary care for animals, enclosing statement of technical responsibility in the case of private professional, signed by him.

CHAPTER II

ABOUT THE INTERNAL RULES OF EXHIBITIONS, FAIRS AND AUCTIONS OF LIVESTOCK.

Art.4. The promoters of exhibitions, fairs and auctions of livestock must prepare internal rules of the event, with the required prior, to be distributed to exhibitors (farmers) at the event by the time of their application.

Art. 5. The internal rules of the event, provided for in Article 7 of Ministerial Administrative Ruling No. 108, of March 17, 1993, must include, among others:

I – general and specific sanitary requirements – tests for diagnosis of diseases, vaccinations and treatment, required for admission of animals in the enclosure of the fair, according to species and purpose;

II – in the case of exhibitions and fairs, the indication of the veterinarians of the Animal Health and Inspection Committee;

III – in the case of actions, the indication of the veterinarian responsible for animal care;

IV – Deadline for the entry of animals in the enclosure of the event.

CHAPTER III

ABOUT THE FACILITIES

Art. 6. The holding of exhibitions, fairs and auctions of livestock shall only be permitted in places that have the following facilities:

I – place for reception of animals, with the landing pad, restrainer and pens;

II – place for government services and animal health and inspection;

III – site for housing of animals;

IV – location for isolation of sick animals;

V – track for animal judgment;

VI – pediluvium (foot bath) and road bath on all accesses to the park;

VII – water and electricity supply;

VIII – toilets for visitors and staff team;

IX – ration warehouse.

Sole paragraph. for the auctions, the facilities listed in items IV, V and IX will not be required.

Art. 7. The facilities where the animals move and remain, including the floors should be constructed of resistant materials which allow their complete cleaning and disinfection.

Art. 8. The facilities for which the animals have moved or remained must be washed and disinfected after leaving them at least twenty-four (24) hours before the entry of new batch of animals, in a satisfactory way for the local veterinary authority.

Sole paragraph. in the case of auction places without cement floor, all manure must be removed and possibly used materials (sawdust, etc.) before the entry of new batch of animals, being applied an appropriated disinfectant to the floor and facilities, in a satisfactory way for the veterinary authority.

Art. 9. To disinfect the facilities, it may be used, among others, sodium carbonate (4%), sodium hydroxide (2%) and oxide lime (5%).

CHAPTER IV

SANITARY REQUIREMENTS FOR ISSUANCE OF ANIMAL MOVEMENT PERMIT, FOR ANIMALS INTENDED FOR EXHIBITIONS, FAIRS AND AUCTIONS.

Section I

General Requirements

Art. 10. In the issuance of the Animal Movement Permit (GTA), for participation of animals in exhibitions, fairs and auctions, the following requirements must be fulfilled:

I - animals must be in good health without signs of disease and free of external parasites;

II - animals must come from establishment where, within 60 days prior to the date of issue of authorization, there was no occurrence of clinical disease for which the species is susceptible;

III - animals must be identified in accordance with the standards established by this Complementary Norms.

Section II

Minimum Requirements for cattle and buffaloes

Art. 11. In the issuance of the Animal Movement Permit (GTA) for cattle and buffaloes, for participation of animals in exhibitions, fairs and auctions, the following requirements must be fulfilled:

I – revoked

II – for bovine brucellosis (*B. abortus*)

a) Negative serum-agglutination test, carried out up to 60 days before the event, except for male cattle and buffaloes for cow calf, rearing or fattening, castrated or not, whose final destination is slaughter, or for immediate slaughter;

b) In the case of female with up to 30 months old, vaccinated between 3 and 8 months of age with B-19 vaccine, the laboratory test may be replaced by a certificate of vaccination;

c) The test referred to in the item may be waived for general herd cattle (registered or controlled), for participation in auctions, at the discretion of the state veterinary authorities.

III - for bovine tuberculosis, intra-dermal inoculation carried out up to 60 days before the event, for cattle and buffaloes with twelve (12) months or older, except for cattle and buffaloes for cow calf, rearing or fattening, whose final destination is slaughter, or for immediate slaughter.

Section III

Minimum Requirements for equidae

Art. 12. In the issuance of the Animal Movement Permit (GTA) for equidae, for participation of animals in exhibitions, fairs and auctions, the following requirements must be fulfilled:

I - for equine infectious anaemia (EIA), negative laboratory test, performed in the following periods, counted before the event:

a) up to 180 days, for equid coming from controlled entities;

b) up to 60 days, in other cases.

II - vaccination against equine influenza (type A) performed from the minimum of fifteen (15) days and a maximum of one hundred eighty (180) days before the start of the event, when appropriate, according to the epidemiological situation of the disease.

Section IV

Minimum Requirements for pigs

Art. 13. In the issuance of the Animal Movement Permit (GTA) for pigs, for participation of animals in exhibitions, fairs and auctions, the following requirements must be fulfilled:

I - for classical swine fever (CSF):

a) in exhibitions, fairs and auctions conducted in the regions controlled, where vaccination against CSF is not allowed, pigs must come from region with same sanitary status and from establishment where there is no record of the CSF within 180 days preceding the date of event;

b) in exhibitions, fairs and auctions conducted in regions where vaccination against CSF is permitted, the pigs must come from establishments where there is no record of the CSF within 180 days preceding the date of commencement of the event and must demonstrate the CSF vaccination done up to 180 days before the event;

II - for FMD, the animals must come from establishment where, within 60 days prior to the start of the event, there has been found no case of FMD, as well as in the neighborhood in the last 30 days;

III – for brucellosis, tuberculosis, Aujeszky's

disease, the breeding male and female, must come from herds officially free of these diseases, bought by official certificate issued by the competent veterinary authority of the place of origin.

Section V

Specific Requirements for goats

Art. 14. When issuing GTA for goats, for participation in exhibitions, fairs, auctions and other animals aglomerations, should be observed the following requirements:

I - for FMD, coming from establishment where, within 60 days prior to the start of the event, no case of FMD has been found, as well as in the neighborhood within the last 30 days;

II-to caprine arthritis encephalitis (CAE):

a) - breeding males and females, with more than one year of age should present negative results on the agar gel immunodiffusion test for the diagnosis of CAE, conducted one hundred and eighty (180) days before the event;-orb) - at the discretion of the state veterinary authorities, IF is not possible to proceed the laboratory test, the goats must be obtained from a herd where there has been no demonstration of CAE clinical sings eighty (180) days prior to the event.

Section VI

Specific Requirements for sheep

Art. 15. In the issuance of the Animal Movement Permit (GTA) for goats, for participation of animals in exhibitions, fairs and auctions, the following requirements must be fulfilled:

I – for FMD, coming from establishment where, within 60 days prior to the start of the event, no case of FMD has been found, as well as in the neighborhood within the last 30 days;

II – for brucellosis (B. ovis):

a) breeding males should give negative results of the agar gel immunodiffusion test, conducted up to sixty (6) days before the event;

b) at the discretion of the state veterinary authorities, when the laboratory test cannot be performed, clinical examination for detailed verification of ovine epididymitis.

Section VI

Specific Requirements for Domestic birds

Art. 16. In the issuance of the Animal Movement Permit (GTA) for domestic birds, for participation of animals in exhibitions, fairs and auctions, the following requirements must be fulfilled:

I - for pullorum disease, negative laboratory test performed up to sixty (60) days before the date of event, for growing birds or already adults;

II - vaccination against Newcastle disease, according to the age of the bird.

Section VII

Specific Requirements for Lagomorphs

Art. 17. In the issuance of authorization for transit of rabbits, for participation in exhibitions, fairs, auctions and other livestock agglomerations, the establishment of origin must have had no record of myxomatosis in one hundred eighty (180) days prior the starting date of the event.

Section VIII

Other Requirements

Art. 18. The GTA, the attestations or certificates of laboratory tests, allergy tests and vaccinations must accompany the animals and shall be submitted to the CDSA or the veterinarian responsible for entering the facilities of exhibitions, fairs and auctions.

Art. 19. At the discretion of the state veterinary authorities and taking into consideration the epidemiological situation of the state or region where the event takes place, other sanitary requirements might be complied with, including tests for diagnosis of diseases and vaccinations, for participation of animals in exhibitions, fairs, auctions or other agglomerations.

CHAPTER V

ADMISSION OF ANIMALS IN THE FACILITIES OF EXHIBITIONS, FAIRS AND AUCTIONS

Art. 20. All animals must be examined by a veterinarian, in an appropriate place, before his admission to the venue of the exhibition, fair or auction, being only allowed the entry of animals:

I – identified, individually or in the lot, according to the provisions in this Complementary Norms;

II – accompanied by sanitary documentation regularly issued in the place of origin, identifying the animals and assuring compliance with general and specific sanitary requirements, according to the species;

III – declared healthy and free from ectoparasites, after sanitary inspection.

Art. 21. The entry of animals affected or suspected of contagious disease, animals reagents for laboratory or allergic tests required as well as animals which carry ectoparasites shall not be allowed in the venue of exhibitions, fairs and auctions and other agglomerations.

Sole paragraph. In the case of contagious disease, the prohibition of entry is extended to the susceptible animals that had contact with sick animals.

Art. 22. The animals whose entrance in the venue of the exhibition, fair or auction has not been allowed shall return immediately to the establishment of origin.

Sole paragraph. In the case of animals affected or suspected of contagious disease, at the discretion of the veterinary authority, they shall be kept isolated in appropriated place, with additional measures provided in the relevant federal and state legislation.

CHAPTER VI

ANIMAL IDENTIFICATION

Art. 23. The cattle, buffaloes, pigs, sheep, goats and rabbits, must be individually identified by a permanent number placed the fire, tattoo or other approved.

Sole paragraph. The cattle, buffaloes, pigs, sheep goats and rabbits, for breeding, whose final destination is slaughter, or intended for immediate slaughter may be identified by lot, with a fire mark of the breeder or other, according to the establishment or herd of origin.

Art. 24. Horses must be accompanied by a passport, attestation or certificate regularly issued by competent authority that contains graphic individual review.

Art. 25. Animals of species not mentioned in Articles 24 and 25 shall be identified according to the adopted for the species.

CHAPTER VII

ABOUT VETERINARY CARE

Art. 26. Veterinary care during the events shall be carried out:

I – by a Committee of Animal Health and Inspection (CDSA), previously known, which must include at least one official veterinarian of the animal health and inspection body, in the exhibitions and fairs of any category;

II - in auctions, by a veterinarian, official or independent, previously appointed or hired by the promoters of the event.

Art. 27. It behooves the CDSA and the veterinarian mentioned in item II of Article 26 to:

I - ensure that the facilities have been cleaned and disinfected at least twenty-four (24) hours before the entry of animals;

II - make a health inspection of animals before they enter the precincts of the event;

III - check the sanitary documentation that accompanies the animal and the compliance with general and specific requirements, according to animal species and purpose;

IV - provide medical attention to animals that need, if the owner does not have the veterinarian;

V - authorize the use of medication in animals;

VI - authorize the removal of the animals in the enclosure of the fair, making the health inspection and issuing the appropriate sanitary documentation.

Art. 28. The occurrence or suspicion of any disease in animals during the fair shall be immediately communicated to the CDSA or the veterinarian responsible for adoption of necessary measures according to the nature of the occurrence.

Art. 29. In case of occurrence or suspicion of contagious disease during the event, the veterinary authority shall isolate the sick or suspects animals, in an appropriate place and decide to ban the facilities and surrounding

areas, adopting other measures deemed necessary and provided in the relevant federal and state legislation.

Art. 30. The ban mentioned in the previous article may cover the whole floor or part of the event, including surrounding areas where animals remain susceptible to the disease suspected or diagnosed, preventing the movement of available animals at time required, at the discretion of the local veterinary authority.

Art. 31. In the event of non-contagious disease, treatment of the animal may be conducted under the responsibility of the owner's veterinarian, with prior consent of the CDSA or the veterinarian responsible.

Art. 32. At the end of the exhibition, fair or auction, the CDSA or veterinarian responsible, shall present to the animal health and inspection organ a summary report, containing:

I – number of animals per species, gender, age and origin (city and state);

II – destination of animals traded or not, indicating the establishment, city and state, per species;

III – sanitary occurrences verified during the event, with the adopted measures;

IV – copy of sanitary attestations or certificates received and issued.

CHAPTER VIII

ABOUT THE PARTICIPATION OF ANIMALS FROM OTHER COUNTRIES

Art. 33. The participation of animals from other countries in exhibitions, fairs and auctions, regularly imported under the current rules, will be allowed if they comply with the general and specific sanitary requirements provided for in this Complementary Norms and other to be established according to the country of origin.

Art. 34. To be admitted to the venue of exhibitions, fairs and auctions, the animals from other countries must have entered into the national territory for at least fifteen (15) days, for species susceptible to foot and mouth disease and seven (7) days to the other species, kept under observation in an appropriate place until the beginning of the event, being forbidden the admission to the venue of the event of animals coming directly from outside.

Sole paragraph. the matter provided under the "caput" of this Article shall not apply to animals taken directly from exhibitions held in one of the countries members of MERCOSUR, with animal health documents issued by official veterinarian of the country of origin, complying with the standards set specifically for transit between official exhibitions.

HAMILTON RICARDO FARIAS

NORMATIVE INSTRUCTION Nº. 46 OF SEPTEMBER 2, 2008

Published in the Official Gazette of September 03, 2008 Section 1, Page 3

Approves procedures for importation of genetic material intended for the restitution of poultry stocks of chickens (*Gallus gallus*), guinea fowl (*Numida meleagris*), turkeys (*Meleagris gallopavo*), quails (*Coturnix coturnix*), palmiped birds (ducks, gooses and widgeons), pheasants (*Phasianus colchicus*) and partridges (*genus Alectoris*)

THE STATE MINISTER OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY, using the powers invested in him under art. 87, sole paragraph, item II of the Constitution, in consideration of what is provided for by Decree No. 5.741 of March 30, 2006, in the Regulation of the Animal Sanitary Health and Inspection, approved by Decree No. 24.548 of July 3, 1934 and what is contained in Process No. 21000.004645/2007-76, resolves:

Art. 1. To approve procedures for importation of genetic material intended for the restitution of poultry stocks of chickens (*Gallus gallus*), guinea fowl (*Numida meleagris*),

turkeys (*Meleagris gallopavo*), quails (*Coturnix coturnix*), palmiped birds (ducks, gooses and widgeons), pheasants (*Phasianus colchicus*) and partridges (genus *Alectoris*) described in Annex I, and the zoosanitary requirements for the importation of hatchable eggs and day-old birds, included in Annexes II and III.

Art. 2. Obscure cases and doubts that may arise from the application of this Normative Instruction will be handled by the Animal and Plant Health and Inspection Secretariat.

Art. 3. This Normative Instruction comes into force one hundred and eighty (180) days after its publication.

Art. 4. Normative Instruction No. 14, June 29, 1999 is hereby revoked.

REINHOLD STEPHANES

ANNEX I

ON THE PROCEDURES FOR IMPORTATION OF GENETIC MATERIAL INTENDED FOR THE RESTITUTION OF POULTRY STOCKS OF CHICKENS, GUINEA FOWL, TURKEYS, QUAILS, DUCKS, GOOSES, WIDGEONS, PHEASANTS AND PARTRIDGES

Art. 1. The importation of bird genetic material for restitution of the national poultry stock will occur in the form of hatchable eggs and day-old birds.

Art. 2. The importation of genetic material intended for the restitution of poultry stocks of chickens, guinea fowls, turkeys, quails, ducks, gooses, widgeons, pheasants and partridges will only be allowed from countries licensed by the Brazilian Ministry of Agriculture, Livestock and Food Supply – MAPA, and from breeding facilities licensed by the Official Veterinary Service of the exporting country and by MAPA.

Sole Paragraph. The term genetic material intended for the restitution of poultry stocks comprises hatchable eggs and day-old birds, where hatchable eggs are those intended for incubation, and day-old birds are those whose age is not over seventy two (72) hours after cracking and that have not had access to any external source of food or water.

Art. 3. The veterinary service of the exporting country must submit the following information to MAPA before Brazil authorizes the importation of genetic material:

I – name and full address of the licensed establishment in the country of origin;

II – annual production capacity of the licensed establishment in the country of origin;

and

III – description of sanitary control programs carried out in the rearing establishment licensed for exportation, certified by the veterinary service of the country of origin;

Sole Paragraph. Further information may be required by MAPA, as a means of assessing the sanitary risk involved in the process of importation of the genetic material.

Art. 4. To authorize the importation of genetic material from qualified establishments from the country of origin, the Animal Health Department – DSA may assign technicians to carry out visits to the establishment, with the intention of assessing the sanitary control programs, and verifying the information submitted by the Official Veterinary Service of the exporting country.

Sole Paragraph. To authorize the importation of avian genetic material from producing establishments, the Animal Health Department will observe whether the monitoring program of the breeding farm meets the certification rules of MAPA's National Program for Avian Health, and if it works under the standards described in the Sanitary Safety and Hygiene Procedures set forth by the World Organization for Animal Health – OIE.

Art. 5. The import authorization must be specific to each exporting company and shipping location, and an International Zoosanitary Certificate – CZI must be issued for each establishment of origin.

Art. 6. The authorization to import genetic material will be issued by MAPA for owners of establishments registered in the Federal Agriculture

Superintendences – SFA, as set forth by Normative Instruction No. 56, of December 4, 2007, and for avicultural establishments receiving genetic material which are certified by the sanitary programs of the National Program for Avian Health - PNSA

Paragraph 1. Those interested in importing avian genetic material for breeding must obtain a previous authorization (Import Authorization) from the Animal and Plant Health and Inspection Service – SEDESA of the SFA in the Federation Unit where the avicultural establishment receiving the imported product is located.

Paragraph 2. Those interested in importing avian genetic material for breeding must submit their ordinary monthly import schedule for the forthcoming month to the Avian Health Coordination – CSA of the DSA and to SEDESA / SFA up to the 5th day of the previous month, either directly or through agencies representing their class.

Paragraph 3. SEDESA / SFA must be notified of the arrival confirmation of each imported batch at least twenty (20) days prior to arrival of the cargo, with confirmation of date, place and time, thus allowing the official laboratory to schedule it activities.

Art. 7. Entry points of the genetic material into the Brazilian Territory will be

the International Airport of Viracopos – Campinas / SP, and the International Airport of

São Paulo – Guarulhos / SP.

Sole Paragraph. Authorizations for entry of genetic material from other locations will be issued at DSA/SDA/MAPA's discretion.

Art. 8. The importer of genetic material will be the depository of the goods during the quarantine period, regarding the publication of the results of monitoring activities carried out for the diseases mentioned in this Normative Instruction, and will only be allowed to move the birds within the country after receiving an authorization issued by MAPA.

Art. 9. The genetic material must be mandatorily transported along with a CZI from the moment of its departure from the country of origin.

Sole Paragraph. The CZI must be issued by the Official Veterinary Service of the exporting country, and written in the official language of the country of origin and in Portuguese version.

Art. 10. The sanitary inspection of the imported genetic material upon its arrival will be performed by a Agriculture Livestock Federal Inspector – FFA, who will draw a Collection Record for biologic sample material in three copies (1st copy - laboratory, 2nd copy - importer, 3rd copy - issuing record).

Art. 11. The imported genetic material will be submitted to sample collection for the execution of laboratory tests, during the clearance process for entry into the country. The samples will be sent to the official laboratory in sealed packages.

Paragraph 1. In the case of hatchable eggs, samples will consist of thirty (30) specimens collected from the imported batch, originating from the same grange of origin.

Paragraph 2. In the case of day-old birds, all dead birds must be collected, and twenty living specimens must be slaughtered per grange of origin for collection of blood, swabs and organs, according to the following list:

I – pool of 20 tracheal swabs;

II – pool of 20 cloacal swabs;

III – pool of 20 air sac swabs in Frey broth;

IV – pool of 20 liver, vesicle and spleen swabs;

V – pool of 20 yolk swabs;

VI – pool of 20 caecum swabs;

VII – bottom of box swab in peptonated solution, tamponated at 1%;

VIII – 20 tracheas; and

IX – 20 bottles containing 2 ml of individual serum from the sampled birds.

Paragraph 3. The collected samples must be properly identified, sealed and immediately sent to the official laboratory for execution of the required tests.

Paragraph 4. The following tests will be carried out: serological and bacteriological research for *Salmonella pullorum*, *S. gallinarum*, *S. typhimurium*, *S. enteritidis*, *Mycoplasma synoviae*, *M. gallisepticum*, *M. meleagridis* (turkeys) and serological and virological research for the Newcastle disease and avian influenza viruses.

Paragraph 5. Additional tests may be required by the DSA at any given time, in the event of a change in the epidemiological and sanitary status of the exporting country.

Art. 12. During the quarantine period, in

the event of a suspected occurrence of an officially controlled disease in the batch of imported genetic material, the SEDESA / SFA of the Federation Unit where the importing establishment is located will postpone the quarantine period of the holding until the final results of the laboratory tests are issued. The importer must notify the official service about the identification of clinical signs of officially controlled diseases.

Art. 13 .Test results must be issued in proper forms and published according to the defined flowchart:

I – negative result: LANAGRO must immediately send an official notification to the CSA / DSA and to the SEDESA / SFA of the Federation Unit where the importing poultry establishment is located. SEDESA will determine the end of the quarantine period; or

II – positive result: LANAGRO must immediately send an official report to the CSA / DSA, which will forward it to the SEDESA / SFA of the Federation Unit where the importing avicultural establishment is located. SEDESA will notify the importer of the results and supervise the execution of measures necessary for the elimination of sanitary risks for the national poultry stock.

Paragraph 1. In the event of a positive result in hatchable eggs for Newcastle disease or avian influenza, salmonellas and mycoplasmas, all imported eggs in incubation, and any other eggs from the same incubation machine will be destroyed and have their destination defined by DSA, with the intention of eliminating sanitary risks to the national poultry stock.

Paragraph 2. In the event of existence and execution of traceability procedures in the hatchery that ensure the separate incubation of fertile imported eggs, verified by SEDESA / SFA, uncontaminated avian genetic material may be commercialized after analysis by the DSA.

Paragraph 3. Should day-old birds test positive for Newcastle disease or avian influenza, salmonellas and mycoplasmas, all imported birds, and any other birds from the same quarantining establishment will be destroyed and have their destination defined by DSA, with the intention of eliminating sanitary risks to the national poultry stock. DSA will order the execution of an epidemiological investigation procedure to assess any possible risks to the national poultry stock.

Art. 14. Hatchable eggs must be identified, incubated and hatched in exclusive machines. Birth must occur on a date distinct from the other batches, and must be notified to the SEDESA of the SFA of the Federation Unit where the hatchery is located. Birth and transfer dates must be notified to the avicultural establishment of destination, at least fifteen (15) days in advance.

Art. 15. Clearance for birds born in the National Territory, product of imported hatchable eggs, is subject to negative results of laboratory tests performed by the official collection service.

Art. 16. On the day of birth of chicks originating from imported eggs, an official material collection will be performed for analysis of the diseases listed in the PNSA.

Paragraph 1. Sampling of these tests will follow the same procedure for birds born from fertile eggs produced in National Territory. These tests can be performed in laboratories approved by the General-Coordination for Laboratory Support – CGAL for this purpose, and this General-Coordination will comprise tests performed in pecked eggs, meconium, trachea and drag swabs from the chicks birth room.

Paragraph 2. In addition to the tests described in paragraph 1 of this article, tests for serological and virological research will be performed for detection of Newcastle disease and avian flu viruses in samples of pecked eggs, meconium and trachea collected from thirty birds. The tests will be performed in laboratory approved by CGAL for this purpose.

Art. 17. The imported day-old birds must be sent exclusively to the holding of destination. Transit authorization for these birds will occur after conclusion of quarantine tests with negative results.

Art. 18. During the quarantine period, DSA may require additional material collection and complementary tests.

Art. 19. Boxes used for packaging and transportation of the genetic material to be imported by Brazil must be disinfected and previously unused.

Art. 20. The interior and the exterior of the container used in the transportation of the genetic material to the shipping location of the country of origin of the cargo and in the recep-

tion of the cargo at the airport must be clean, disinfected, and offer biosafety conditions.

Sole Paragraph. Biosafety in transportation is defined as the utilization of a closed, climatized, sanitized and sealed vehicle in the establishment of origin, by the official service or by a veterinarian licensed by the official service, and the seal must be inspected by the Official Veterinary Service of the shipping location.

Art. 21. The importation of genetic material intended for the restitution of the national avian breeding stock may occur in the form of day-old birds, provided that the following specific zoosanitary requirements as provided for by Annex III and the following additional requirements are met:

I – in order to start the importation process of day-old birds, an opinion on the request from the importer will be issued, as established by Ministerial Normative Instruction No. 01, of January 14, 2004, by Ministerial Administrative Ruling No. 548, of August 25, 1995, and by Ministerial Normative Instruction No. 6, of June 2, 2003, justifying the initiative and zootechnical necessity, and this documentation shall be submitted to SFA, whereas DSA shall assess the sanitary risk before continuing with the importation process;

II – the cargo holds of the airplanes that carry out the international transportation of the cargo must be disinfected, using products recommended by OIE active against high pathogenicity avian influenza virus and Newcastle disease.

and

III – should the imported birds originate from different batches, all batches comprising the cargo will be submitted to the same sanitary procedure if a sanitary problem is identified in the imported batch.

Art. 22. If lack of compliance with this Normative Instruction is identified at the time of the official inspection at the point of entry in the country, measures will be taken to seize the imported batch and establish a quarantine as defined by the DSA, whereas the batch will remain under custody and sanitary monitoring by the SEDESA / SFA of the Federation Unit where the quarantine establishment is located. Depending on the sanitary risk, destruction of the entire imported batch may be determined in the point of entry.

Sole Paragraph. Batch maintenance and destruction costs will be under the importer's responsibility.

ANNEX II

ON THE ZOOSANITARY REQUIREMENTS FOR IMPORTATION OF HATCHABLE EGGS OF CHICKENS, GUINEA FOWLS, TURKEYS, QUAILS, DUCKS, GOOSES, WIDGEONS, PHEASANTS AND PARTRIDGES

Art. 1. Hatchable eggs must be accompanied by an International Animal Health Certificate, issued by a veterinarian from the Official Veterinary Service of the country of origin and containing the following information:

I – identification: amount, species, lineage and date of collection of the hatchable eggs;

II – origin: name and address of the establishment of origin and exporter;

III – destination; name and address of the hatchery, grange of destination and importer;

IV – that the hatchable eggs originate from the establishment indicated in item II of this article, where their mothers are born, reared and regularly inspected in an establishment monitored and inspected by a veterinarian of the official service of the country of origin;

V – that the hatchable eggs originate from a country or zone free from Newcastle disease and avian influenza, notifiable under the criteria of the World Organization for Animal Health – OIE;

VI – that the hatchable eggs originate from mothers from stocks where no clinical case of Marek's disease, avian infectious laryngotracheitis, avian infectious bronchitis, infectious bursal disease (Gumboro disease), fowl cholera, infectious avian coryza, psittacosis (avian chlamydiosis), fowl pox, avian encephalomyelitis, reoviral

infection, avian leucosis, reticuloendotheliosis, duck virus hepatitis, chicken infectious anemia and West Nile fever has been detected within thirty (30) days prior to the collection of the hatchable eggs;

VII – that the stock that originated the hatchable eggs received a sanitary inspection performed by a veterinarian from the official service of the country of origin or by a veterinarian qualified by the official service, in the period of thirty (30) days prior to shipping, and was free from any clinical signs of transmissible avian diseases;

VIII – that the hatchable eggs originate from a stock officially declared free from *Salmonella pullorum, Salmonella gallinarum, Salmonella enteritidis, Salmonella typhimurium, Mycoplasma synovia*e and *Mycoplasma gallisepticum*, in accordance with a program under the supervision of the Official Veterinary Service of the country of origin, complying with the PNSA norms, and which works in accordance with the standards described in the Sanitary Hygiene and Safety Procedures set forth by the World Organization for Animal Health;

IX – that the hatchable eggs originate from stocks that were not vaccinated with vaccines containing a modified live virus within sixty (60) days prior to collection of the exported eggs;

X – that the hatchable eggs originate from stocks that were never vaccinated against avian influenza;

XI – that the hatchable eggs were not vaccinated against any type of infectious agent, as well as were not administered antibiotics or chemotherapies;

XII – that the stock that originated the hatchable eggs exported to Brazil was monitored for avian influenza by means of the ELISA (chickens and turkeys) or Agar Gel Immunodiffusion (AGID) in a sample of at least thirty (30) birds, collected by an official veterinarian, or by a veterinarian accredited by the Official Veterinary Service of the country of origin within thirty (30) days prior to shipping, performed in an official laboratory, with all results being negative, and that the establishment was free from any evidence of this disease at the time when the samples were collected, mentioning:

a) antigen batch number;

b) manufacture and expiration date;

c) laboratory and date on which the tests were performed (start and end of the AGID test);

and

d) kit identification (for the ELISA);

XIII – that the hatchable eggs were disinfected in the establishment of origin, by using an active principle that results in the inactivation of vegetative bacteria, fungi, lipophilic and hydrophilic viruses, parasites and *Mycobacterium sp*., mentioning:

a) the active principle;

b) the trade name; and

c) the concentration of the disinfectant used;

XIV – that the hatchable eggs were stowed in new and disinfected packages;

XV – that the transportation vehicle for the hatchable eggs was closed and sealed in the establishment of origin by the official veterinarian or by a veterinarian licensed by the official service, and inspected by the official service at the time of shipping;

XVI – that the eggs and boxes contain the identification of the stock of origin;

XVII – that the hatchable eggs were transported directly from the establishment of origin to the shipping location, avoiding zones under sanitary quarantine, in a previously disinfected vehicle, with a disinfectant that is active against the Newcastle disease and avian influenza viruses, with no contact whatsoever with other birds or products of animal origin;

XVIII – official stamp;

XIX – place and date of issuance of the certificate;

XX – name and signature of the official veterinarian;

Art. 2. Additional information may be required by the DSA, in the event of a change in the epidemiological and sanitary status of the exporting country.

ANNEX III

ON THE ZOOSANITARY REQUIREMENTS FOR IMPORTATION OF DAY-OLD BIRDS OF OF CHICKENS, GUINEA FOWL, TURKEYS, QUAILS, DUCKS, GOOSES, WIDGEONS, PHEASANTS AND PARTRIDGES

Art. 1. Day-old birds must be accompanied by an International Animal Health Certificate, issued by a veterinarian from the Official Veterinary Service of the country of origin and containing the following information:

I – identification: the amount of day-old birds, species, lineage and hatched date;

II – origin: name and address of the establishment of origin, hatchery and exporter;

III – destination; name and address of the quarantine establishment of destination and importer;

IV – that the day-old birds originate from an establishment indicated in item II of this article, where their mothers (genetic material) are born, reared and regularly inspected in establishments monitored and inspected by a veterinarian of the official service of the country of origin;

V – that the day-old birds originate from a country or zone free from Newcastle disease and avian influenza, notifiable under the criteria of the World Organization for Animal Health – OIE;

VI – that the day-old birds originate from progenitresses from stocks where no clinical case of Marek's disease, avian infectious laryngotracheitis, avian infectious bronchitis, infectious bursal disease (Gumboro disease), fowl cholera, infectious avian coryza, psittacosis (avian chlamydiosis), fowl pox, avian encephalomyelitis, reoviral infection, avian leucosis, reticuloendotheliosis, duck virus hepatitis, chicken infectious anemia and West Nile fever has been detected for thirty (30) days prior to the collection of the hatchable eggs;

VII – that the stock of origin received a sanitary inspection performed by a veterinarian from the official service of the country of origin or by a veterinarian qualified by the official service, within thirty (30) days prior to shipping, and was free from any clinical signs of transmissible diseases;

VIII – that the day-old birds originate from mothers from a stock officially declared free from *Salmonella pullorum, Salmonella gallinarum, Salmonella enteritidis, Salmonella typhimurium, Mycoplasma synoviae* and *Mycoplasma gallisepticum,* in accordance with a program under the supervision of the Official Veterinary Service of the country of origin, complying with the PNSA norms, and that originate from a grange that works in accordance with the norms set forth by the World Organization for Animal Health (OIE);

IX – that the day-old birds originate from hatcheries that receive fertile eggs from stocks that have not used vaccines containing a modified live virus within sixty (60) days prior to collection of the eggs;

X – that the eggs and day-old birds did not receive, while in the hatchery of origin, chemotherapy treatment for any infectious agent in the hatchery, neither were they administered antibiotics or chemotherapies;

XI – that the day-old birds were not vaccinated against avian influenza, and that they originate from stocks whose birds have not been vaccinated ahainst this disease;

XII – that the stock that originated the day-old birds exported to Brazil was monitored for avian influenza by means of the ELISA (chickens and turkeys) or Agar Gel Immunodiffusion (AGID) in a sample of at least thirty (30) birds, collected by an official veterinarian, or by a veterinarian licensed by the Official Veterinary Service of the country of origin within thirty (30) days prior to shipping, performed in an official laboratory, with all results being negative, and that the establishment was free from any evidence of this disease at the time when the samples were collected, mentioning:

a) the antigen batch number;

b) the manufacture and expiration date;

c) the laboratory and date on which the tests were performed (start and end of the AGID test);

and

d) kit identification (for the ELISA);

XIII – that the day-old birds were stowed in new and disinfected packages;

XIV – that the transportation vehicle for the day-old birds was closed and sealed in the establishment of origin by the official veterinarian or by a veterinarian licensed by the official service, and inspected by the official service at the time of shipping;

XV – that the boxes contain the identification of the stock of origin;

XVI – that the day-old birds were transported directly from the hatchery of origin to the airport where they were shipped, avoiding zones under sanitary quarantine, in a vehicle with an air intake filtering system, previously disinfected with a disinfectant that is active against Newcastle disease and avian influenza viruses, with no contact whatsoever with other birds or products of animal origin;

XVII – that the cargo holds of the cargo airplanes loaded with the day-old birds were disinfected, using products recommended by OIE and FAO active against high pathogenicity avian influenza virus;

XVIII – official stamp;

XIX – place and date of certificate issuance;

XX – name and signature of the official veterinarian;

Art. 2. Additional information may be required by the DSA, in the event of a change in the epidemiological and sanitary status of the exporting country.

NORMATIVE INSTRUCTION No. 40 OF SEPTEMBER 4, 2007

Published in the Official Gazette of September 05, 2007 Section 1, Page 3

Sets the sanitary requirements for importing bovine and bubaline semen from countries outside Mercosul

The MINISTER OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY, in the use of the attribution granted to him by the Article 2 of the Decree 5,741 of March 30, 2006, and in accordance with the content of the Regulation of the Animal Health and Inspection Service, approved by the Decree 24,548 of July 3, 1934, and that of the Process 21000.006025/2003-48, resolves:

Art. 1. To establish the SANITARY REQUIREMENTS FOR IMPORTING BOVINE AND BUBALINE SEMEN FROM COUNTRIES OUTSIDE MERCOSUL, in the form of the Attached Documents of this Normative Instruction.

Art. 2. Without affecting the determination of this Normative Instruction, and at the discretion of the Ministry of the Agriculture, Livestock and Food Supply (MAPA), all previously established bilateral sanitary agreements concerning the matter remain in full force in what they don't conflict.

Sole Paragraph. New sanitary agreements may be signed, providing they don't contradict what is determined in this Normative Instruction.

Art. 3. This Normative Instruction enters in force the day of its publication.

REINHOLD STEPHANES

ANNEX I

SANITARY REQUIREMENTS FOR IMPORTING OF BOVINE AND BUBALINE SEMEN FROM COUNTRIES OUTSIDE MERCOSUL

CHAPTER I

GENERAL DISPOSITIONS

Art. 1. Brazil will only import semen obtained in Semen Collection and Processing Centres (SCPC), registered and approved by the exporting country's Official Veterinary Service.

Sole Paragraph. To approve the SCPC, the exporting country's Official Veterinary Service will consider the "CONDITIONS APPLICABLE TO ARTIFICIAL INSEMINATION CENTRES" as well as the "CONDITIONS APPLICABLE TO SEMEN LABORATORIES" described in the appendix regarding the "BOVINE SEMEN" of the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE).

Art. 2. All semen to be imported to Brazil must be accompanied of an International Sanitary Certificate, issued both in the exporting country's official language and in Portuguese and signed or endorsed by a veterinarian of the exporting country's Official Veterinary Service, in conformity with the required sanitary measures of the Ministry of the Agriculture, Livestock and Food Supply (MAPA).

Art. 3. The model of the International Sanitary Certificate to be used by countries outside Mercosul to export their bovine and bubaline semen to Brazil must be previously approved by MAPA.

Art. 4. All semen imports must be previously approved by MAPA.

Art. 5. Countries certified as free of a disease are exempted from executing the diagnostic tests and vaccinations against that disease.

Paragraph 1. To achieve the certification of free country, the exporting country should present a consistent work following the recommendations of the Terrestrial Animal Health Code of OIE.

Paragraph 2. The declaration of country free from disease should be included in the document of certification in place of execution of testing and vaccination.

Art. 6. When constituting the importing process at the Federal Superintendence of Agriculture, the interested party must present a copy of the DNA or blood typing test of the donor.

CHAPTER II

SANITARY CONDITIONS OF THE EXPORTING COUNTRY

Art. 7. The exporting country must be free of FMD with or without vaccination, rinderpest, contagious bovine pleuropneumonia (Mycoplasma mycoides mycoides - small colonies) and lumpy skin disease, according to the recommendations of OIE's Terrestrial Animal Health Code.

Sole Paragraph. In case of zoning for the diseases specified in the caput of this article, the exporting country's Official Service must certify that the semen was collected and processed accordingly in a SCPC located in a free area as determined by OIE's Terrestrial Animal Health Code.

CHAPTER III

SEMEN DONORS

Art. 8. Semen donors must be born and raised in the exporting country or have stayed in that country for a minimum of sixty (60) days prior to the semen donation.

Art. 9. Donors must not present any clinical evidence of any semen born disease within 30 (thirty) days prior to collect, at the day of collection, and in 30 (thirty) days following the collection.

CHAPTER IV

DIAGNOSTIC TESTS

Art. 10. The collection of sample for the laboratory tests required by MAPA must be super-

vised by an Official Veterinarian or veterinarian accredited by the Official Veterinary Service of the exporting country.

Art. 11. All diagnostic tests requested by MAPA must be performed at laboratory either official or accredited by the exporting country's Official Veterinary Service.

Art. 12. The semen should be collected in a SCPC facility that fulfills the "CONDITIONS APPLICABLE TO THE TESTING OF BULLS AND TEASER ANIMALS" as established in OIE's Terrestrial Animal Health Code, or in a SPSC that adopts the systematic of testing the animals that enter the Centre and the resident herd, with negative results, as follows:

1. When in pre-quarantine in the herd of origin of the animals:

a) BRUCELOSIS: buffered Brucella antigen test (BBAT), or complement fixation test;

b) TUBERCULOSIS: cervical intradermal tuberculinization with bovine PPD tuberculin, comparative test with bovine and avian PPD or caudal fold test with strong tuberculin.

2. When in quarantine before entering the resident herd:

a) BRUCELOSIS: buffered Brucella antigen test (BBAT), or complement fixation test;

b) TUBERCULOSIS: cervical or scapular intradermal tuberculinization with bovine PPD tuberculin, comparative test with bovine and avian PPD or caudal fold test with strong tuberculin;

c) BOVINE GENITAL CAMPYLOBACTERIOSIS (*Campylobacter foetus subsp. venerealis)*: for animals above six (6) months old: three (3) cultures of prepuce secretion sampled at minimal intervals of seven (7) days; animals below six (6) months old or which were kept up to this age in groups of the same gender: only one culture or immunofluorescence test is required;

d) TRICHOMONOSIS (*Trichomonas foetus*): for animals above six (6) months old: three (3) cultures of prepuce secretion sampled at minimal intervals of seven (7) days; for animals below six (6) months old or kept up to this age in groups of the same gender: only one culture is required;

e) BOVINE VIRAL DIARRHOEA (BVD): negative for isolation and identification of the pathogenic agent by immunofluorescence or immunoperoxidase in whole blood sample, or ELISA for antigen detection or PCR at pre-quarantine or quarantine.

Sole Paragraph. During the stay at the SCPC, the resident herd must be tested every twelve (12) months for the following diseases and present negative results:

1. BRUCELOSIS: buffered Brucella antigen test (BBAT), or complement fixation test;

2. TUBERCULOSIS: cervical or scapular intradermal tuberculinization with bovine PPD tuberculin, comparative test with bovine and avian PPD or caudal fold test with strong tuberculin;

3. BOVINE GENITAL CAMPYLOBACTERIOSIS (*Campylobacter foetus subsp. venerealis)*: one (1) culture of prepuce secretion or immunofluorescence;

4. TRICHOMONOSIS: one (1) culture of prepuce secretion;

5. BOVINE VIRAL DIARRHOEA: negative for isolation and identification of the pathogenic agent by immunofluorescence or immunoperoxidase in whole blood sample, or ELISA for antigen detection or PCR at pre-quarantine or quarantine.

CHAPTER V

COMPLEMENTARY DIGNOSTIC TESTS

Art. 13. In case of exporting semen to Brazil, animals must be submitted to one of the following procedures in relation to the diseases listed below:

1.INFECTIOUS BOVINE RHINOTRACHEITIS (IBR): submit one (1) blood serum sample of each semen donor to be tested by virus neutralization or by ELISA, at least twenty-one (21) days after the last collection of semen; or submit a sample of frozen semen from each batch to be exported to virus isolation test or PCR, with negative result; and

2. BLUE TONGUE: submit one (1) sample of each semen donor's blood serum to be tested by immunodifion in agar gel, or by ELISA with negative results in the day of the first collection of semen, and again between thirty (30) and sixty (60) days after the last collection of semen; or submit

a sample of each semen donor's total blood, collected every 28 days, to the PCR test; or submit a sample of frozen semen from each lot to be exported to the PCR test, with negative result. (NR)

CHAPTER VI

COLLECTION, PROCESSING AND STORAGE OF SEMEN

Art. 14. All semen must be collected in a site that is in conformity with the recommendations included in the "CONDITIONS APPLIED TO THE COLLECTION OF SEMEN" and processed in a site that is in conformity with the "CONDITIONS APPLIED IN THE HANDLING AND PROCESSING OF SEMEN SAMPLES IN LABORATORY" described in OIE's Terrestrial Animal Health Code.

Art. 15. All semen must be placed in individually identified straws in accordance with the recommendations of OIE's Terrestrial Animal Health Code and stored for a minimum of thirty (30) days before being exported to Brazil, under supervision of the official veterinarian in charge of the SCSC.

CHAPTER VII

ADDITION OF ANTIBIOTICS TO SEMEN

Art. 16. For each milliliter of frozen semen, one of the following mixtures of antibiotics must be added

1.Gentamicin (250 Tg), tylosin (50 Tg), lincomycin-espectinomycin (150/300 Tg); or

2.Penicilin (500 UI), estreptomycin (500 UI), lincomycin-espectinomycin (150/300Tg).

Sole Paragraph. New antibiotic combinations may be used once their efficacy has been demonstrated and after being authorized by MAPA.

CHAPTER VIII

TRANSPORTATION

Art. 17. Before shipping, the container with the semen identified in accordance with this Normative Instruction must be sealed with the official seal of the Official Veterinary Service of the exporting country and the number of the seal must be included in the sanitary certificate.

ANNEX II

MINIMAL INFORMATION TO BE POSTED ON INTERNATIONAL SANITARY CERTIFICATES FOR EXPORTING BOVINE AND BUBALINE SEMEN FROM COUNTRIES OUTSIDE MERCOSUL TO BRAZIL

I. IDENTIFICATION:
Product: _____
Import authorization number: _____
Exporting country: _____
II. IDENTIFICATION OF SEMEN FROM INDIVIDUAL DONORS:
Date of collection: _____
Straw number: _____
Total number of straws: _____

III. INFORMATION FROM INDIVIDUAL DONORS:
Registration number: _____
Breed: _____
IV. SOURCE:
Name and address of the exporting party: _____
Name and address of the Semen Collection and Processing Centre (SCPC): _____
_____
_____
_____

V. DESTINATION:
Name and address of the importer party: _____
VI. In addition to the content of incises I to V of this ANNEX, the sanitary information referred to in Articles 7 to 17 must be included.

NORMATIVE INSTRUCTION No. 18 OF JULY 18, 2006

Published in the Official Gazette of July 20, 2006 Section 1, Page 12

Approves the Animal Movement Permit (GTA) model to be used throughout Brazil for the transportation of live animals, fertile eggs and other materials related to animal multiplication

The BRAZILIAN MINISTER OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY, by the powers vested upon him pursuant to Section 87, Sole Paragraph, item II, of the Brazilian Constitution, combined with Section 2 of Decree No. 5741, of March 30, 2006, and taking into consideration Process No. 21000.009775/2005-33, decided to:

Art. 1. Approve the Animal Movement Permit (GTA) model to be used throughout Brazil for the transportation of live animals, fertile eggs and other materials related to animal multiplication pursuant to the laws in effect, in the form of Annex I.

Paragraph 1. The GTA must be printed in ac-

cordance with the following technical specifications:

I – A4 paper, size 21.0 cm x 29.7 cm (trim area), 75-90 g or 53-55 g;

II – text and lines in black ink, 10% gray reticule, with the symbol of the animal health and inspection agency on the background.

III – safety items must be used in the first counterpart, namely: anti-copy security background, numismatic background, margins reading "Brazilian Ministry of Agriculture, Livestock and Food Supply" in micro letters and ultraviolet light-readable invisible ink with the Brazilian National Arms in the form of Annex II. The use of the above safety items is optional for the other counterparts; and

IV – graphical control number of the form using a single numerical sequence for the entire State.

Paragraph 2. The GTAs may only be printed in each State provided the numbering and control by the Brazilian Ministry of Agriculture, Livestock and Food Supply's Federal Superintendence of Agriculture.

Paragraph 3. The use of bar codes on the GTAs is permitted, as long as it meets the requirements and standards set forth by the Animal and Plant Health and Inspection Secretariat– SFA (Federal Superintendence of Agriculture)/MAPA (Ministry of Agriculture, Livestock and Food Supply).

Art. 2. The GTA must be issued based on the information given on the facilities from which the animals are originated and on the fulfillment of the health requirements established for each species.

Sole Paragraph. The people responsible for issuing the GTA must have received training and instructions from the Brazilian Official Veterinary Services, pursuant to the laws in effect.

Art. 3. The transportation of cats and dogs is exempt from the GTA requirements; for this purpose, these animals must be accompanied by a health certificate issued by a veterinarian duly enrolled with the State Veterinary Council of the State from which the animals are originated, certifying the health status of said animals and the fulfillment of the health requirements established by the Official Veterinary Service and by the public health agencies, especially with respect to anti-rabies vaccination.

Art. 4. GTAs issued by employees of an official animal health control agency in any State will be accepted, regardless of previous accreditation by the Ministry of Agriculture, Livestock and Food Supply.

Sole Paragraph. The enforcing animal health control agency in each State must keep a record of the employees responsible for issuing GTAs, including a signature bank, and must provide the Brazilian Federal Superintendence of Agriculture, Livestock and Food Supply (SFA) of the respective State with a list of the people in charge of issuing the GTAs, indicating their full names, animal species for which they are qualified to issue the document and the municipalities in which they are allowed to act.

Art. 5. GTAs issued by Federal Agriculture and Livestock Inspectors must bear the code BR, a six-digit number and the series letter.

Art. 6. GTAs issued by an enforcing animal health and inspection agency must bear the symbol of the enforcing animal health and inspection agency, the two-letter identification of the State, a six-digit number and the series letter.

Art. 7. Each of the GTA's counterparts must bear the identification and the signature of the issuer and the identification of the issuing unit, in the form of Annex III and according to the instructions contained therein.

Art. 8. Only animal transportation documents approved by this Normative Instruction will be valid throughout Brazil.

Art. 9. The form of GTA approved by Administrative Ruling No. 22, of January 13, 1995, will not be valid six (6) months as of the date this Normative Instruction is published.

Art. 10. This Normative Instruction will be effective as of the date it is published.

Art. 11. Administrative Ruling No.39, of November 24, 2006 is revoked.

LUÍS CARLOS GUEDES PINTO

ANEXO I

REPÚBLICA FEDERATIVA DO BRASIL
MINISTÉRIO DA AGRICULTURA, PECUÁRIA E ABASTECIMENTO
SECRETARIA DE DEFESA AGROPECUÁRIA
DEPARTAMENTO DE SAÚDE ANIMAL

Espaço reservado para o símbolo do Órgão Executor de Defesa Sanitária

GUIA DE TRÂNSITO ANIMAL (GTA)

(VÁLIDA EM TODO O TERRITÓRIO NACIONAL)

UF | SÉRIE | NÚMERO

1. BOVÍDEOS ☐ Bovinos ☐ Bubalinos

até 12 meses		13 a 24 meses		25 a 36 meses		+ de 36 meses		total	
M	F	M	F	M	F	M	F	M	F

2. MARCA DO REBANHO (PARA BOVINOS/BUBALINOS)

OP

3. AVES

☐ Galinhas ☐ Perus ☐ Avestruzes
☐ Ovos Férteis ☐ Pintos de 1 dia ☐ Adultos
☐ Bisavós ☐ Avós ☐ Matrizes ☐ Comercial
☐ Corte ☐ Postura

Macho	Fêmea	Total

4. SUÍDEOS ☐ 5. OUTRAS ESPÉCIES ☐ 6. CAPRINOS ☐ 7. OVINOS ☐ 8. EQÜÍDEOS ☐

Macho	Fêmea	Total

☐ Peso (KG) ☐ Unidades

até 6 meses		Acima de 6 meses		TOTAL
M	F	M	F	

☐ Eqüinos ☐ Asininos ☐ Muares

9. ANIMAIS AQUÁTICOS

☐ Peixes ☐ Crustáceos ☐ Moluscos
☐ Adultos ☐ Alevinos ☐ Larvas ☐ Pós-larvas
☐ Ovos Embrionados ☐ Cistos
☐ Peso(KG) ☐ Volumes(n.) ☐ Unidades

Total

As espécies devem ser nominalmente identificadas no campo de observação

10. TOTAL POR EXTENSO :

11. PROCEDÊNCIA	12. DESTINO
CPF/CNPJ:	CPF/CNPJ:
Nome:	Nome:
Estabelecimento:	Estabelecimento:
Código do Estabelecimento:	Código do Estabelecimento:
Município: UF:	Município: UF:

13. FINALIDADE ☐ Abate ☐ Engorda ☐ Reprodução ☐ Exposição ☐ Leilão ☐ Esporte ☐

14. Meio de Transporte ☐ A pé ☐ Rodoviário ☐ Ferroviário ☐ Aéreo ☐ Marítimo/Fluvial | Lacre nº

15. VACINAÇÕES ☐ FEBRE AFTOSA ☐ BRUCELOSE ☐ MAREK ☐

/ / E: / /	/ /	/ /	/ /

16. ATESTADO DE EXAMES ☐ Brucelose ☐ Tuberculose ☐ AIE ☐ | ☐ Certificação nº

17. OBSERVAÇÃO

18. UNIDADE EXPEDIDORA

21. IDENTIFICAÇÃO E ASSINATURA DO EMITENTE

19. EMITENTE:
Médico Veterinário ☐ Federal ☐ Estadual ☐ Habilitado
☐ Funcionário Autorizado

20. EMISSÃO
Local:
Data: Hora:
Validade:
Fone:

* Documento para o trânsito de animais de acordo com o Decreto nº 5.741, de 30 de março de 2006.
** A presente GTA será invalidada nos casos de (1) emenda, rasura ou adulteração; (2) interrupção do trânsito entre a procedência e o destino, com desembarque dos animais.

Nº controle: 00000000

MINISTÉRIO DA AGRICULTURA, PECUÁRIA E ABASTECIMENTO

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ANNEX II

ULTRAVIOLET LAYOUT

ANNEX III

MODELS OF IDENTIFICATION TO BE USED IN THE ANIMAL MOVEMENT PERMITS

1. The identification of the person in charge of issuing the GTA (Animal Movement Permit) must obey the following specifications, according to the status of the issuer, and the data written on the documents must be 6 cm wide x 2.5 cm high, using black ink when the form is filled out through a computer system or blue ink when using stamps:

1.1. Identification of the Agriculture Livestock Federal Inspector:

Name of the Agriculture Livestock Federal Inspector: Arial Narrow 12 pt bold font;

Professional Education: Veterinarian: Arial Narrow 11 pt font;

Inspection Identification Card Number: Arial Narrow 11 pt font;

Number of Enrollment in the State Veterinary Council (CRMV): Arial Narrow 11 pt font.

Full Name Veterinarian Inspection Identification Card Number Number of Enrollment in the State Veterinary Council (CRMV)

1.2. Identification of the Veterinarian with the Agency Responsible for the Animal Health and Inspection in each State:

Name of the Veterinarian: Arial Narrow 12 pt bold font;

Professional Education: Veterinarian: Arial Narrow 11 pt font;

Control number with the official animal health and inspection agency: Arial Narrow 11 pt font;

Number of Enrollment in the State Veterinary Council (CRMV): Arial Narrow 11 pt font.

Full Name Veterinarian Control Number Number of Enrollment in the State Veterinary Council (CRMV)

1.3. Identification of the Accredited Veterinarian:

Name of the Veterinarian: Arial Narrow 12 pt bold font:

Education: Veterinarian: Arial Narrow 11 pt font;

Number of the document proving the Veterinarian is accredited by the animal health and inspection official agency: Arial Narrow 11 pt font;

Number of Enrollment in the State Veterinary Council (CRMV): Arial Narrow 11 pt font.

Full Name Veterinarian Control Number Number of Enrollment in the State Veterinary Council (CRMV)

1.4. Identification of other Authorized Employees from Animal Health and Inspection Agencies:

Name of Authorized Employee: Arial Narrow 12 pt bold font;

Control Number at the Animal Health and Inspection Agency: Arial Narrow 11 pt font;

Duties performed at the Community Office: Arial Narrow 11 pt font.

Full Name Control Number Duties

2. The identification of the unit in charge of issuing the GTA (Animal Movement Permit) must obey the following specifications:

Name of the Issuing Unit: Arial Narrow 12 pt bold font;

Municipality: Arial Narrow 11 pt font;

Phone Number: Arial Narrow 11 pt font;

Electronic Address (when it is the case): Arial Narrow 11 pt font;

Use blue ink when printing manually and black ink when printing electronically.

Name of Issuing Unit Municipality Phone Number Electronic Address

NORMATIVE INSTRUCTION No. 8 OF MARCH 10, 2006

Published in the Official Gazette of March 15, 2006 Section 1, Page 26

Incorporates into the national legislation the Zoosanitary Requirements for the exchange of Bovine and Bubaline Semen among the State Parties.

THE SECRETARY OF AGRICULTURE AND LIVESTOCK HEALTH AND INSPECTION, in the use of the attributes conferred to him by art. 42, Annex I, of Decree No. 5.351, of January 21, 2005 having in mind the resolutions of Ouro Preto's Protocol and Process No. 21000.006933/2005-01, resolves:

Art. 1. To incorporate to national juridical order the zoo-sanitary requirements for the exchange of Bovine and Bubaline Semen, that contains in the annex of the present Normative Instruction, approved by the Resolution GMC - MERCOSUR No. 16, of 2005.

Art. 2. This Normative Instruction come into force on the date of its publication.

Art. 3. Revokes the Normative Instruction No. 18 of April 10, 2003.

GABRIEL ALVES MACIEL

ANNEX I

ZOO-SANITARY REQUIREMENTS FOR THE EXCHANGE OF BOVINE AND BUBALINE SEMEN AMONG STATE PARTIES

CHAPTER I

OF GENERAL CONDITIONS

Art. 1. The Semen Collection and Processing Centre (SCPC) shall be accredited by the Official Veterinary Services of the State Party correspondent, which shall grant a registration number and shall control, at least every six months the health and welfare of animals, as well as the semen collection methods used and the registrations carried out by the SCPC.

Sole paragraph. The accreditation shall be valid for one year.

Art. 2. The Official Veterinary Services of each State Party shall communicate the Official Veterinaries of the others State Parties the roll of SCPC accredited, maintaining updated information in the face of change.

Art. 3. The SCPC shall count with a Veterinary responsible for all the activities performed and registrations carried out.

Art. 4. The Official Veterinary Services of each State Party shall be responsible for granting zoo-sanitary certification to the reproducers and for the certification of semen quality in its hygienic-sanitary aspects, issued by Veterinary responsible for the SCPC, and certify the sanitary situation of the State Party of origin.

Art. 5. The SCPC shall have a logbook of activities, and it shall remain at disposal of the Official Veterinary Services of the respective State Party.

Sole paragraph. The referred registry shall contain, at least, the following data:

I – identification of the resident animals: name, official registry number or other identification, date of birth, when possible, blood type;

II – admission date of the animals at SCPC;

III – vaccinations carried out (date, purpose, laboratory and batch);

IV – diagnostic tests carried out (tests, dates and laboratory name);

V – semen collection dates;

VI – number of prepared doses;

VII – elimination of semen and its causes;

VIII – date and reason for the bull's underside;

IX – number of existing semen doses at the time of the bull's underside; and

X – comments.

Art. 6. For the purposes of the present Normative Instruction it's understood for:

I – Semen Collection and Processing Centre (SCPC): the institutions that have semen donor animals, with permanent or transitory accommodation, and perform procedures of semen collection, processing and storage.

II – installations for the animals' admittance quarantine: area destined to accommodate animals up to the moment they are able to become part of the resident herd;

III – Installations for accommodation of the resident herd: area destined to reassure the health and welfare of the animals while residing at SCPC;

IV – Semen collection installations: area where the collection of semen procedures are carried out under adequate hygiene and safety conditions;

V - laboratory: location adequately equipped and staffed with employees fully trained to perform semen processing and storage;

VI – care centre: isolated area, destined to accommodate and treat ill animals;

VII –changing rooms: placed destined to the changes of work attire for entering the different installments of the SCPC;

VIII – Manure deposit: place to deposit the manure;

IX – Residue deposit: place to eliminate the SCPC residues.

Art. 7. So as to be admitted at SCPC, every animal shall undergo admittance quarantine.

CHAPTER II

OF THE INSTALLATIONS

Art. 8. The SCPC shall be isolated by barriers that guarantee that the resident herd will not get in contact with any other animals, persons and vehicles without the appropriate control.

Art. 9. The SCPC shall count with:

I – permanent ventilation and lighting system wherever necessary;

II – source of drinking water supply, hot and cold, ensuring adequate quantitative and qualitative supply, for the animals' consumption and the performance of the cleaning and disinfection procedures;

III – system of collection and elimination of excrements and residual water, which fulfill the requirements of the State Party where the SCPC is located;

IV – Manure and residues deposit;

V – Insects and rodents control program;

VI – Installations built of materials that allows easy cleaning and disinfection, such as anti-ski flooring, on the whereas where they are necessary;

VII – administration department, isolated from the areas above mentioned.

Art. 10. the admittance quarantine, referred to in art. 7º shall be performed in installations that count with:

I – the accommodation units shall ensure isolation conditions not allowing direct contact between the resident herd and the animals undergoing quarantine;

II – Animal handling and restraint tools for the performance of the clinical observations and testing procedures.

Art. 11. The accommodation units of the resident herd, referred to in art. 10, shall be spacious, hygienic and with easy access to the sector destined for the semen collection.

Art. 12. The semen collection sector shall have protection that withstands hostile climate condition as rain, wind and dust.

Art. 13. the laboratory shall be divided in three sectors conveniently separated and isolated from the other installments and operationally independent.

Sole paragraph. The three sectors mentioned above are:

I – Sector for the preparation, cleaning, disinfection and sterilization of the utensils used in the semen collection and processing: this sector shall be fitted with impervious flooring and minimum walls impervious coating of 2 meters height, drain channels, deep sinks, counters and external openings covered with anti-insect nets;

II – Sector for the preparation, testing and storage of the seminal material: this sector shall

fulfill the construction requirements defined by item I, possess the materials required for the execution specific requested tasks and be isolated from the collection room and only have a communication window between them;

III – Sector for conservation, storage of semen containers, and dispatch of semen: this sector shall meet the same building standards of the laboratory's other sector and have an adequate cataloguing system to ensure the correct identification of the seminal material.

Art. 14. The care centre shall have exclusive and adequate materials for all the procedures performed there.

Art. 15. The changing rooms shall contain shower facilities, adequate work attire sufficient in number for the SCPC.

Art. 16. The manure and residual deposits shall be located at an adequate distance from the other installations so as to avoid sanitary risk.

Art. 17. The SCPC may have with an independent area for the exhibit of the breeding animals, ensuring the maintenance of the sanitary situation. Auctions shall not be performed in the area.

CHAPTER III

OF THE PERSONNEL

Art. 18. All the personnel, when entering SCPC, shall observe the hygiene and safety measures (showers, change of clothes and shoes), as well as not getting in contact with animals which are prone to diseases that may affect the specie.

Art. 19. The personnel shall not perform activities of different sanitary risks within the sectors the SCPC's sector unless the hygiene and safety measures are met (showers, change of clothes and shoes).

Art. 20. Every person that enters SCPC shall meet the hygiene and safety measures required.

CHAPTER IV

OF THE STATE PARTIES OF ORIGIN

Art. 21. The exporting State Party shall be free of Rinderpest, Contagious Bovine Pleuropneumonia, Lumpy Skin Disease and the Rift Valley Fever, in accordance with the resolutions of OIE's Terrestrial Animal Health Code.

Art. 22. The State Party free from Foot and Mouth Disease (FMD) throughout its territory or parts of it, recognized by OIE or by the importer State Party, shall certify this condition; the exporter State Party, that is not free from FMD throughout its territory or part of it, shall agree with the imported State Party additional guarantees that are compatible with the resolutions of the Terrestrial Animals Health Code (OIE).

CHAPTER V

OF THE ANIMALS

Art. 23. Shall only be admitted to the SCPC animals born and reared uninterruptedly in the exporting State Party, or animals that have entered the exporting State Party and have met the norms defined by the MERCOSUR regarding the zoo-sanitary requirements for the cattle and buffalo exchange; in this case they must have remained in the exporting country for at least 60 days prior to the first collection.

Sole paragraph. The animals imported from a third state party must have remained for they must have remained in the State Party for at least 60 days prior to the first collection.

Art. 24. The SCPC must immediately notify all animal casualties to the Veterinary Oficial service of the State Party, stating the reason, the registration number of the animal, the number of existing semen doses and data collection

Sole paragraph. Every animal suspected to be affected by infectious diseases transmissible by semen shall be isolated; the occurrence shall be immediately communicated to Official Veterinarian Services; the animal's semen doses shall not be commercialized until the confirmation of the diagnose, by Official Lab; the destination of the stored semen shall be determined by order from the Official Veterinarian Services.

Art. 25. In case the resident herd, for any

reason, leaves the SCPC premises, they shall undergo admittance quarantine to able to return.

CHAPTER VI

OF THE DIAGNOSTIC TESTING

Art. 26. Further diagnostic testing and procedures, other then those listed in the present Normative Instruction, with the same equivalent guarantees for the exchange of bovine and bubaline semen, may be agreed between and importing and exporting State Parties.

CHAPTER VII

OF THE ZOO-SANITARY PROCEDURES PRIOR TO THE QUARANTINE.

Art. 27. To be admitted at the SCPC, the animals shall be accompanied by a zoo-sanitary certificate, issued by the official veterinary or person responsible for the SCPC, stating that in the establishment of origin there haven't been any occurrences of diseases transmissible by semen that affects the specie for the last 90 days, and that the animals have been tested, with negative results, for the following diseases:

I – Tuberculosis: Delayed hypersensitivity test;

II -Brucellosis: buffered brucella antigen test (BBAT/BPA)/Rose Bengal test; the animals that present tests with positive results shall be undergo the complement fixation or 2-mercaptoethanol Brucella agglutination test or ELISA.

CHAPTER VIII

OF THE QUARANTINE ZOO-SANITARY PROCEDURES

Art. 28. With regards to vesicular estomatitis, the animals that enter centre shall meet the correspondent regulations defined by the OIE's Terrestrial Animal Health Code.

Art. 29. The animals shall be kept in quarantine for a minimum period of 30 days, and shall only become part of the resident herd after being tested, with negative results, for the following diseases:

I - Brucellosis: buffered brucella antigen test (BBAT/BPA)/Rose Bengal test; the animals that present tests with positive results shall be undergo the complement fixation or 2-mercaptoethanol Brucella agglutination test or ELISA;

II - Tuberculosis: Delayed hypersensitivity test

III – Bovine Genital Campylobacteriosis: culture of prepucial smegma or immunofluorescence test;

IV - Trichomonosis: 4 weekly tests of prepucial smegma culture, with negative results;

V – Bovine Viral Diarrhea (BVD): isolation and identification of the causative agent by immunofluorescence or immunoperoxidase in a whole blood or blood serum sample; 2 tests shall be carried out; if the first one presents positive results, the test shall be repeated after a 14 days interval; of the second tests presents negative results, the admittance of the animal shall be authorized.

CHAPTER IX

OF THE ZOO-SANITARY PROCEDURES FOR THE RESIDENT HERD

Art. 30. The resident herd shall be diagnostic tested every 180 days, with negative for the following diseases:

I - Brucellosis: buffered brucella antigen test (BBAT/BPA)/Rose Bengal test; the animals that present tests with positive results shall be undergo the complement fixation or 2-mercaptoethanol Brucella agglutination test or ELISA test;

II - Tuberculosis: Delayed hypersensitivity test

III – Bovine Genital Campylobacteriosis: culture of prepucial smegma or immunofluorescence test;

IV - Trichomonosis: 4 weekly tests of prepucial smegma culture;

Art. 31. The animals of the resident herd, which the semen will be exported, shall be tested, with negative results, for the following diseases:

I – Infectious Bovine Rinotracheitis (IBR): virus neutralization test or ELISA carried out at least 21 days after the last semen collection; or a 0,5ml sample of processed semen of each lot shall be tested by virus isolation or PCR;

II – Blue Tongue: agar-gel immunodiffusion test or ELISA, carried out 40 days after the last semen collection or a sample of whole-blood from the semen donor collected every 14 days submitted to virus isolation test or PCR, or submit a 0,5ml sample of processed semen for each PCR lot;

III – Enzootic Bovine Leukosis (EBL): Agar Gel immunodiffusion test or ELISA on a serum obtained at least 30 days after the last semen collection; or submit a 0,5 ml sample of processed semen from each lot to PCR;

Sole paragraph. A 0,5 ml sample of semen may be used for diagnostic testing for the diseases cited in the items of this article.

Art. 32. The animals belonging to the resident herd with positive results for the diseases listed in this chapter shall be isolated and reevaluated by the Official Veterinarian Services of the respective State Party, which shall determine the destination of the animals.

Art. 33. Diagnostic testing for the diseases mentioned in art. 31 shall not be necessary when the State Party is free of those diseases, throughout its territory or parts of the territory, in face of OIE's or the importer State Party recognition.

Sole paragraph. In this case, the exporter State Party shall certify this condition, and the SCPC shall have official certification of establishment free from diseases, issued by the Official Veterinarian Services of the respective State Party, part of a national eradication program.

CHAPTER X

OF THE SEMEN

Art. 34. The semen shall be collected and processed in accordance with the Terrestrial Animal Health Code (OIE).

Art. 35. The semen shall be stored for a period of 45 days from the collection date, at the SCPC installations.

Art. 36. For the exchange among the State Parties, the bovine and bubaline semen shall be accompanied by the Zoo-sanitary Certificate for Exchange of Bovine and Bubaline Semen among the State Parties, in accordance with the model found in Annex II of the present Normative Instruction.

Paragraph 1. The referred certificate shall be signed by the Veterinary responsible for the SCPC and countersigned by the official veterinary of the exporting State Party.

Paragraph 2. All the certificate sheets shall be sequentially numbered, stamped and signed by the Veterinary of the exporting country Official Services.

ANNEX II

ZOOSANITARY CERTIFICATE FOR THE TRADE IN BOVINE AND BUBALINE SEMEN AMONG STATES PARTIES

Certificate Nº.	
Seal Nº.	
Date issued	
Expiration date	

I. ORIGIN

State Party	
State	
SCPC Registration Nº.	
SCPC name and address	
Exporter's name	
Exporter's address	

II. DESTINATION

State Party	
State	
Importer's name	
Importer's address	

III. TRANSPORTATION

Means of transportation	
Exit point in the State Party	

IV. IDENTIFICATION OF SEMEN DONOR(S)

Donor animal's registration n°.	Breed	Date of entry in the SCPC	Number of doses	Date of semen collection

V. HEALTH INFORMATION

The official veterinary certifies that the SCPC complies with the requirements defined by the Resolution GMC No. 16/05 related to "The Zoo-sanitary Requirements for Exchange of Bovine and Bubaline Semen among the State Parties".

VI. DIAGNOSTIC TESTS OF THE SEMEN DONORS

At every 180 days, the semen donors shall be submitted, with negative results, to the following diagnostic tests:

a. BRUCELLOSIS: buffered brucella antigen test (BBAT/BPA)/Rose Bengal test; the animals that present tests with positive results shall be undergo the complement fixation or 2-mercapto-ethanol Brucella agglutination test or ELISA.

b. TUBERCULOSIS: Delayed hypersensitivity test.

c. BOVINE GENITAL CAMPYLOBACTERIOSIS: culture of prepucial smegma or immunofluorescence test;

d. TRICHOMONOSIS: 4 weekly tests of prepucial smegma culture.

e. INFECTIONS BOVINE RHINOTRACHEITIS (IBR): virus neutralization test or ELISA.

f. BLUE TONGUE: agar-gel immunodiffusion test or ELISA, PCR test or virus isolation test of whole-blood.

g. ENZOOTIC BOVINE LEUKOSIS (EBL): Agar Gel immunodiffusion test or ELISA

VII. DIAGNOSTIC TESTING FOR SEMEN

Three samples of each semen lot, enclosed in this certificate, were submitted, respectively, to diagnostic testing, with negative results, for the following diseases:

One sample of the same lot, enclosed on this certificate, was submitted to three diagnostic tests, with negative results:

a. INFECTIONS BOVINE RHINOTRACHEITIS (IBR):

virus isolation or PCR

Date _____/_____/_____

b. BLUE TONGUE (BT):

PCR

Date _____/_____/_____

c. ENZOOTIC BOVINE LEUKOSIS (EBL):

PCR

Date_____/_____/_____

VIII. DO TRANSPORTE DO SÊMEN

1. The isothermal containers used to store and transport the semen were cleaned and disinfected adequately with products which were officially approved by the exporter State Party.

2. The isothermal containers were sealed by the Official Veterinarian Services of the exporting State Party or by the Veterinary responsible for the SCPC.

PLACE AND DATE

NAME AND SIGNATURE OF THE VETERINARY RESPONSIBLE FOR THE SCPC

NAME AND SIGNATURE OF THE OFFICIAL VETERINARY

NORMATIVE INSTRUCTION No. 80 OF NOVEMBER 11, 2004

Published in the Official Gazette of December 02, 2004 Section 1, Page 7

Incorporates into national legislation "Zoosanitary and Embarkation Certificate Models and Zoosanitary Requisites for the Exchange of Cattle for Rearing and Fattening between Member States of MERCOSUL," approved by MERCOSUL GMC Resolution No. 31/03 that counts as an annex to this Normative Instruction.

THE MINISTRY OF AGRICULTURE, LIFESTOCK AND FOOD SUPPLY'S SECRETARY OF ANIMAL AND PLANT HEALTH AND INSPECTION, through the jurisdiction conferred to it by Article 15, Section II, of Decree No. 4,629 of March 21, 2003 and also taking into consideration terms of the Protocol of Ouro Preto and Process No. 21000.004137/2004-45 resolves:

Art. 1. To incorporate into national law the "Zoo-sanitary and Embarkation Certificate Models and Zoo-sanitary Requisites for the Exchange of Cattle for Rearing and Fattening between Member States of MERCOSUL," approved by MERCOSUL GMC Resolution No. 31/03 that counts as an annex to this Normative Instruction.

Art. 2. This Normative Instruction will enter in vigour on the date of publication.

MAÇAO TADANO

ANNEX 1

ZOO-SANITARY REQUISITS FOR THE EXCHANGE OF CATTLE FOR REARING AND FATTENING BETWEEN MEMBER STATES OF MERCOSUL

CHAPTER I

GENERAL ARRANGEMENTS

All cattle importations destined for rearing and fattening will be accompanied by a Zoo-Sanitary Certificate issued by the Official Veterinary Service pertaining to the Member State of Origin.

Zoo-Sanitary Certificates will be issued by the Official Veterinary Service of each Member State, in accordance with the models shown in Annexes II and III that must be approved by Member States.

1. The issue of the Zoo-Sanitary Certificate will be executed within a period exceeding no longer than 72 (seventy-two) hours before embarkation after the presentation of import authorisation from the importing country.

2. Additional certification will be included at the moment of embarkation, after clinical inspection of the animals to confirm compliance with sanitary rules established by this Resolution.

3. For the purposes of this Resolution, all definitions are those found in the Terrestrial Animal Health Code of the World Animal Health Organisation (OIE), with the addition of the following:

ORIGINATING ESTABLISHMENT: The local where the animals were either born or kept in the twelve months prior to exportation.

DEPARTURE ESTABLISHMENT: The local where the exportation quarantine was carried out.

4. Any MERCOSUL Member State with an official programme of control or eradication for any disease not mentioned in this Annex reserves the right to require addition measures of protection, including tests, in order to prevent the entrance of disease into the country. Where this is the case, the Member State must provide a guarantee of the same standards when exporting animals to other Member States of MERCOSUL.

5. The exporting Member State must provide all information necessary in order to comply with the requirements of the Official Tracking Programme of the importing Member State.

6. In the event of non-compliance with any protection measure included in this Annex, sanctions agreed upon by Member States of MERCOSUL may be adopted.

7. The animals must be quarantined by the Member State of Origin in an officially-approved locale, observing all relevant requirements for a minimum period of 30 (thirty) days. If necessary, samples will be taken under official supervision in order for laboratory tests, treatments and vaccinations to be performed.

8. Laboratory examinations required during the quarantine period will be carried out by official laboratories or those accredited by the Official Veterinary Service of the originating Member State. These examinations will be valid throughout the animal's stay in quarantine for a period not exceeding 60 (sixty) days.

9. The importer has the right to demand additional tests for diseases not mentioned in this Annex but for which it has a particular interest in controlling or preventing. This matter, however, will be agreed upon between the importer and exporter and not subject to an official certificate.

10. The exporting Member State must comply with the laws relating to anabolic substances of the importing Member State.

CHAPTER II

ZOO-SANITARY ARRANGEMENTS

11. The MERCOSUL Member State of Origin must be officially free of Rinderpest, Contagious Bovine Pleuropneumonia, Rift Valley Fever and Lump Skin Disease, in accordance with the Terrestrial Animal Health Code of the OIE.

In the event of the introduction of any disease referred to in this section, Member States will convene to determine the possibility of an exclusion zone and other complementary measures to ensure the continuation of importations and exportations.

12. The animals must have been born and raised in the originating Member State or in any of the other Member States of MERCOSUL. Where animals have been imported from a third-party country, the exportation will only be permitted if the importing country has received prior notification of origin.

13. With respect to:

13.1. BOVINE SPONGIFORM ENCEPHALOPATHY (BSE)

The disease must not have been registered in the Member State of Origin;

The disease must require compulsory notification in the Member State of Origin;

The Member State of Origin has legislation enacted prohibiting the use of proteins obtained from animals that can transmit BSE for the feed of ruminants;

The Member State of Origin must have a system of vigilance in force to detect the eventual occurrence of the disease in the country.

13.2. FOOT-AND-MOUTH DISEASE

The Member State or the zone of the Member State from where the animals originate must be free of Foot-and-Mouth disease without vaccination and this condition must be recognised by the importing Member State; or

The Member State of the zone of the Member State from where the animals originate must be free of Foot-and-Mouth disease with vaccination and this condition must be recognised by the importing Member State (this condition applies to the importing Member State with the same sanitary status or with an inferior sanitary status to the exporting country); or

In the event of non-compliance with the conditions established in this section, the importer and exporter Member States may together establish measures based on the Terrestrial Animal Health Code of the OIE in the Chapter corresponding to Foot-and-Mouth disease aimed at maintaining the exchange of cattle and buffalo for rearing and fattening.

13.3. VESICULAR STOMATITIS

The Member State or the zone of the Member State from where the animals originate must be free of Vesicular Stomatitis and this condition must be recognised by the importing member state; or

The animals must come from an establishment where, within a radius of 15km, there have been no registered cases of Vesicular Stomatitis in the past 30 (thirty) days;

In addition, during the period of quarantine the animals will be submitted to Virus Neutralisation tests (positive > 1.6) or ELISA (positive > 1.3) with negative results for the types of virus known to exist in the Member State of Origin.

13.4. BRUCELLOSIS

The Member States should be free of Brucellosis or contain a zone free of Brucellosis in accordance with rules established by the OIE's Terrestrial Animal Health Code; or

The animals must originate from an establishment free of Brucellosis in accordance with rules established by the OIE's Terrestrial Animal Health Code; or

The animals will be submitted to the BBAT or ELISA or Complement Fixation Test

during the quarantine period.

Females less than 24 (twenty-four) months old vaccinated with the B19 vaccine up until the age of 8 (eight) months are not required to undergo diagnostic tests for Brucellosis. In this case, an additional declaration of vaccination should be included in the certificate.

Young steers are also not required to undergo diagnostic tests for Brucellosis.

13.5.TUBERCULOSIS

The Member State of Origin must be free of Tuberculosis or possess a zone free of Tuberculosis in accordance with rules established by the OIE's Terrestrial Animals Sanitary Code; or

The animals must come from an establishment free of tuberculosis in accordance with rules established in the OIE's Terrestrial Animals Sanitary Code; or

The animals will be submitted to the Intradermal Tuberculin Test with bovine PPD or bovine and avian PPD and receive a negative result during the quarantine period.

14. The animals to be exported must not be subjected of disposal because of a disease control or eradication programme in force in the Member State of Origin.

15. The animals must be submitted treatment against internal and external parasites.

16. The animals must not present any clinical sign of transmissible disease during the quarantine period.

17. The animals must be inspected at the moment of embarkation by an official veterinarian who will issue an additional certificate confirming the conditions of the animals and their method of transportation.

ANNEX II

MODEL OF ZOOSANITARY CERTIFICATE FOR TRADE OF CATTLE FOR REARING AND FATTENING AMONG MERCOSUR STATE PARTIES

Exporting State Party:	
Agency:	
Name of service:	
Province or Municipality, etc:	

I. ANIMALS' IDENTIFICATION

Individual identification	Breed	Gender	Age

II. ANIMALS' ORIGIN

Exporter's name:	
Address:	
Name of the establishment of origin:	
Address:	

III. ANIMALS' DESTINATION

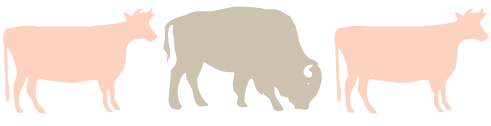
Exporter's name:	
Address:	
Means of transportation:	

IV. SANITARY INFORMATION

Information required under Annex I hereto should be provided.

Official Veterinary Service stamp

Veterinarian's name and seal



ANNEX III

MODEL OF SHIPPING CERTIFICATE FOR CATTLE FOR REARING AND FATTENING DESTINED FOR MERCOSUR STATES PARTIES.

Exporting State Party:	
Agency:	
Name of Service:	

The Exporting State Party's official veterinary hereby testifies that the animals identified in the Zoosanitary Certificate _____ , which are destined for exportation to (Name of the Destination State Party):

1. Were examined at the time of shipping and found to be in sound physical conditions, as well as free of external parasites.

2. Were transported on vehicles that were previously cleaned and disinfected with products registered with the State Party's Official Veterinary Services, so as to prevent direct contact with animals in adverse health conditions, all in accordance with specific transportation requirements.

Shipping place:		Date:	
Means of transportation:			
Transportation vehicles' tag nos.:			
Seal nº.:			

Official Veterinary Service

Official veterinary's signature and seal

NORMATIVE INSTRUCTION No. 69 OF SEPTEMBER 15, 2004

Published in the Official Gazette of September 23, 2004 Section 1, Page 15

Incorporates into national legislation "Zoosanitary and Embarkation Certificate Models and Zoosanitary Requisites for the Exchange of Cattle and Buffalos for Reproduction between Member States of MERCOSUL."

THE MINISTRY OF AGRICULTURE, LIFESTOCK AND FOOD SUPPLY'S SECRETARY OF ANIMAL AND PLANT HEALTH AND INSPECTION, through the jurisdiction conferred to it by Article 15, Section II, of Decree No. 4,629 of March 21, 2003 and also taking into consideration terms of the Protocol of Ouro Preto and Process No. 21000.004136/2004-09 resolves:

Art. 1. To incorporate into national law the "Zoo-Sanitary and Embarkation Certificate Models and Zoo-Sanitary Requisites for the Exchange of Cattle and Buffalo for Reproduction between Member States of MERCOSUL," approved by MERCOSUL GMC Resolution No 30/03, that counts as an annex to this Normative Instruction.

Art. 2. This Normative Instruction will enter in vigour on the day of its publication.

Art. 3. Normative Instruction No.19 of April 10, 2003 is hereby revoked.

MAÇAO TADANO

ANNEX I

ZOO-SANITARY REQUISITES FOR THE EXCHANGE OF CATTLE AND BUFFALO FOR REPRODUCTION BETWEEN MEMBER STATES OF MERCOSUL

CHAPTER I

GENERAL ARRANGEMENTS

1. All cattle and buffalo importations destined for reproduction will be accompanied by a Zoo-Sanitary Certificate issued by the Official Veterinary Service pertaining to the Member State of Origin or Source. Zoo-Sanitary Certificates will be issued by the Official Veterinary Service of each Member State, in accordance with the models shown in Annexes II and III that must be approved by Member States.

2. The issue of the Zoo-Sanitary Certificate will be executed within a period exceeding no longer than 72 (seventy-two) hours before embarkation after the presentation of import authorisation from the importing country.

3. Additional certification will be included at the moment of embarkation, after clinical inspection of the animals to confirm compliance with sanitary rules established by this Resolution.

4. For the purposes of this Resolution, all definitions are those found in the Terrestrial Animal Health Code of the World Animal Health Organisation (OIE), with the addition of the following:

ORIGINATING ESTABLISHMENT: The local where the animals were either born or kept in the twelve months prior to exportation.

DEPARTURE ESTABLISHMENT: The local where the exportation quarantine was carried out.

5. Any MERCOSUL Member State with an official programme of control or eradication for any disease not mentioned in this Annex reserves the right to require addition measures of protection, including tests, in order to prevent the entrance

of disease into the country. Where this is the case, the Member State must provide a guarantee of the same standards when exporting animals to other Member States of MERCOSUL.

6. The exporting Member State must provide all information necessary in order to comply with the requirements of the Official Traceability Programme of the importing Member State.

7. In the event of non-compliance with any protection measure included in this Annex, sanctions agreed upon by Member States of MERCOSUL may be adopted.

8. The animals must be quarantined by the Member State of Origin in an officially-approved locale, observing all relevant requirements for a minimum period of 30 (thirty) days. If necessary, samples will be taken under official supervision in order for laboratory tests, treatments and vaccinations to be performed.

9. Laboratory examinations required during the quarantine period will be carried out by official laboratories or those accredited by the Official Veterinary Service of the originating Member State. These examinations will be valid throughout the animal's stay in quarantine for a period not exceeding 60 (sixty) days.

10. The importer has the right to demand additional tests for diseases not mentioned in this Annex but for which it has a particular interest in controlling or preventing. This matter, however, will be agreed upon between the importer and exporter and not subject to an official certificate.

CHAPTER II

ZOO-SANITARY ARRANGEMENTS

11. The MERCOSUL Member State of Origin must be officially free of Rinderpest, Contagious Bovine Pleuropneumonia, Rift Valley Fever and Lumpy Skin Disease, in accordance with the Terrestrial Animal Health Code of the OIE.

In the event of the introduction of any disease referred to in this section, Member States will convene to determine the possibility of an exclusion zone and other complementary measures to ensure the continuation of importations and exportations.

12. The animals must have been born and raised in the originating Member State or in any of the other Member States of MERCOSUL. Where animals have been imported from a third-party country, the exportation will only be permitted if the importing country has received prior notification of origin.

13. With respect to:

13.1. BOVINE SPONGIFORM ENCEPHALOPATHY (BSE)

The disease must not have been registered in the Member State of Origin;

The disease must require compulsory notification in the Member State of Origin;

The Member State of Origin has legislation enacted prohibiting the use of proteins obtained from animals that can transmit BSE for the feed of ruminants;

The Member State of Origin must have a system of vigilance in force to detect the eventual occurrence of the disease in the country.

13.2. FOOT-AND-MOUTH DISEASE

The Member State or the zone of the Member State from where the animals originate must be free of Foot-and-Mouth disease without vaccination and this condition must be recognised by the importing Member State; or

The Member State of the zone of the Member State from where the animals originate must be free of Foot-and-Mouth disease with vaccination and this condition must be recognised by the importing Member State (this condition applies to the importing Member State with the same sanitary status or with an inferior sanitary status to the exporting country); or

In the event of non-compliance with the conditions established in this section, the importer and exporter Member States may together establish measures based on the Terrestrial Animal Health Code of the OIE in the Chapter corresponding to Foot-and-Mouth disease aimed at maintaining the exchange of cattle and buffalo for reproduction.

13.3 VESICULAR STOMATITIS

The Member State or the zone of the Member State from where the animals originate must be free of Vesicular Stomatitis and this condition must be recognised by the importing member state; or

The animals must come from an establishment where, within a radius of 15km, there have been no registered cases of Vesicular Stomatitis in the past 30 (thirty) days;

In addition, during the period of quarantine the animals will be submitted to Virus Neutralisation tests (positive > 1.6) or ELISA (positive > 1.3) with negative results for the types of virus known to exist in the Member State of Origin.

13.4. BRUCELLOSIS

The Member State of Origin should be free of Brucellosis or contain a zone free of Brucellosis in accordance with rules established by the OIE's Terrestrial Animal Health Code; or

The animals must originate from an establishment free of Brucellosis in accordance with rules established by the OIE's Terrestrial Animal Health Code; or

The animals will be submitted to the BBAT or ELISA or Complement Fixation Test during the quarantine period. Females less than 24 (twenty-four) months old vaccinated with the B19 vaccine up until the age of 8 (eight) months are not required to undergo diagnostic tests for Brucellosis. In this case, an additional declaration of vaccination should be included in the certificate.

13.5.TUBERCULOSIS

The Member State of Origin must be free of Tuberculosis or possess a zone free of Tuberculosis in accordance with rules established by the OIE's Terrestrial Animals Sanitary Code; or

The animals must come from an establishment free of tuberculosis in accordance with rules established in the OIE's Terrestrial Animals Sanitary Code; or

The animals will be submitted to the Intradermal Tuberculin Test with bovine PPD or bovine and avian PPD and receive a negative result during the quarantine period.

13.6. BOVINE VIRAL DIARRHOEA (BVD)

The animals must be subjected to viral isolation tests or ELISA for the detection of viral antigens in total blood samples, the results of which must be negative during the quarantine period. Animals that show positive from the first test must be subjected to a second test with a minimum interval of 14 (fourteen) days. Should the second test prove negative, the animal shall be qualified for exportation.

14. The animals to be exported must not be subjected of disposal because of a disease control or eradication programme in force in the Member State of Origin.

15. The animals must be submitted treatment against internal and external parasites.

16. The animals must not present any clinical sign of transmissible disease during the quarantine period.

17.An official veterinarian who will issue an additional certificate confirming the conditions of the animals and their method of transportation must inspect the animals at the moment of embarkation.

ANNEX II

MODEL OF ZOOSANITARY CERTIFICATE FOR TRADE OF CATTLE AND BUFFALO FOR REPRODUCTION AMONG MERCOSUR STATES PARTIES

Exporting State Party:	
Agency:	
Service:	
Province or Municipality, etc.:	

I. ANIMALS' IDENTIFICATION

Individual identification	Breed	Gender	Age

II. ANIMALS' ORIGIN

Exporter:	
Address:	
Establishment of origin:	
Address:	

III. ANIMALS' DESTINATION

Exporter:	
Address:	
Means of transportation:	

IV. SANITARY INFORMATION

Information specified in Annex I hereto should be provided.

Official Veterinary Service stamp

Veterinarian's name and signature

ANNEX III

MODEL OF SHIPPING CERTIFICATE FOR CATTLE AND BUFFALO FOR REPRODUCTION DESTINED FOR MERCOSUR MEMBER COUNTRIES.

Exporting State Party:	
Agency:	
Service:	

I, Official Veterinarian of the exporting State Party, hereby certify that the animals identified in Zoosanitary certificate No. _____ , destined for exportation to (Name of destination State Party):

1. Have been examined at the time of shipment and on that occasion were in good physical condition as well as free of external parasites.

2. Were being transported in vehicles that had been previously cleaned and disinfected with products approved by the Official Veterinary Services of the State Party of Origin, so as to avoid direct contact with animals in adverse sanitary condition, and in accordance with specific transportation requirements.

Shipping location:		Date:	
Means of transportation:			
Transportation vehicle's tag number:			
Seal's number:			

Official Veterinary Service stamp

Official Veterinarian's name and signature

NORMATIVE INSTRUCTION No. 61 OF AUGUST 30, 2004.

Published in the Official Gazette of September 21, 2004 Section 1, Page 9

Incorporates to the national legislation the "Zoosanitary requirements for the Exchange of Cattle for Immediate Slaughter among the Member States of the Mercosur and the Zoosanitary Certificate and Embarkation Certificate Models."

THE SECRETARY OF ANIMAL AND PLANT HEALTH AND INSPECTION, in the use of the attributes conferred to him by art. 15, item II, of Decree No. 4.629, of March 21, 2003, having in mind the resolutions of Ouro Preto's Protocol and Process No. 21000.004138/2004-90, resolves:

Art. 1. To incorporate to the national juridical order the "Zoo-sanitary requirements for the Exchange of Cattle for Immediate Slaughter among the Member States of the Mercosur and the Model Zoo-sanitary Certificate and Model Embarkation Certificate" approved by the Resolution GMC - MERCOSUR No. 32/03, which is enclosed as annex of the present Normative Instruction.

Art. 2. This Normative Instruction comes into force on the date of its publication.

CEZAR WILSON MARTINS DA ROCHA

ANNEX I

ZOO-SANITARY REQUIREMENTS FOR THE EXCHANGE OF CATTLE AND BUFFALO FOR IMMEDIATE SLAUGHTER AMONG THE MEMBER STATES OF THE MERCORSUR

CHAPTER I

GENERAL COMMENTS

1. Every import of cattle and buffalo for immediate slaughter shall be accompanied by a Zoo-sanitary Certificate issued by the Official Veterinarian Services of State Party origin of the animals.

The zoo-sanitary certificates to be issued the Official Veterinarian Services of each Member State, shall be in accordance with the models present in Annex II and III, and shall be submitted to the approval of the other Member States.

2. The issue of the zoo-sanitary certificate shall be carried out in a period no longer than 72 hours prior to embarkation, through presenting the importation authorization from the importing country.

3. Additional Certification shall be enclosed at the moment of embarkation, after clinical inspection of the animals, attesting the sanitary conditions as defined by the present Resolution.

4. For the purposes of this Resolution, the definitions stated in the Terrestrial Animal Heath Code (OIE) shall be adopted and understood as follows:

ESTABLISHMENT OF ORIGIN: place of birth or where the animals had spent their last 12 months immediately prior to the export date.

ESTABLISHMENT OF PROVENIENCE: where the quarantine for export was carried out.

5. The Member State of the MERCOSUR which adopts an official program of control or eradication of any disease contemplated in the present Annex, reserves the right to request protection measures, including diagnostic tests, so as to prevent the ingress of the disease in its ter-

ritory. In this case, the Member State shall grant the same guarantees when exporting animals to the other MERCOSUR Member States.

6. The exporting Member State shall grant the information necessary to allow the compliance with the requirements of Official Traceability Program of the importing Member State.

7. In case of failure to comply with any protection measure recommended in the present Annex, equivalent measures may be adopted, as long as they have been agreed among the MERCOSUR Member States.

8. The exporting Member State shall comply with the current legislation of the importing Member State with regards to use of anabolic substances.

CHAPTER II

ZOO-SANITARY INFORMATION

9. A MERCOSUR Member State shall be officially free from Rinderpest, Contagious Bovine Pleuropneumonia, Lumpy Skin Disease and the Rift Valley Fever, according to OIE's Terrestrial Animal Health Code.

In the event of the introduction of any disease referred to in this section, Member States will convene to determine the possibility of an exclusion zone and other complementary measures to ensure the continuation of importations and exportations.

10. The animals shall be born and bred in Member State of origin, or in any other MERCOSUR's Member States.

11. With regards to:

11.1. SPONGIFORM ENCEFALOPHATIES (BSE)

The disease mustn't have been registered at the Member State of origin;

The disease shall be of mandatorily notification in the Member State of origin;

The Member State of origin shall have laws which prohibit the use of animal protein, as they may transmit BSE, in all ruminant feeds;

The Member State of Origin shall have a surveillance system to detect the eventual occurrence of the disease in the country.

11.2. FOOT AND MOUTH DISEASE (FMD)

The Member State or part of its territory, where the animals come from, shall be free of FMD without vaccination and this condition shall be recognized by the importing Member State; or

The Member State or part of its territory, where the animals come from, shall be free of FMD with vaccination and this condition shall be recognized by the importing Member State (this condition is applicable to an importing Member State with the same or inferior sanitary status as the exporting Member State); or

In case of non-compliance with the required conditions of this item, the importing and exporting Member States, together, may establish conditions based on the chapter with regards to FMD of the OIE's Terrestrial Animal Health Code, so as to maintain the exchange of bovine and buffalo for immediate slaughter.

11.3. VESICULAR ESTOMATITIS

The Member State, or part of its territory, where the animals come from shall be free from Vesicular Estomatitis, and this condition shall be certified by the importing Member State; or

The animals shall come from an establishment where there haven't been registered occurrences of vesicular estomatitis for the last 30 days within a 15 km radius of the establishment.

12. The animals to be exported shall be subjected of disposal, due to a control and/or eradication of diseases program in execution in the Member State of origin.

13. The animals shall be inspected at the embarkation moment by an official veterinary, who shall issue an additional certification attesting the transport conditions and the animals' clinical condition.

ANNEX II

MODEL OF ZOOSANITARY CERTIFICATE FOR THE EXCHANGE OF CATTLE FOR IMMEDIATE SLAUGHTER AMONG THE MEMBER STATES OF THE MERCORSUR

Exporting State Party:	
Agency:	
Service:	
Province or Municipality, etc.:	

I. ANIMALS' IDENTIFICATION

Individual identification	Breed	Gender	Age

II. ANIMALS' ORIGIN

Exporter:	
Address:	
Establishment of origin:	
Address:	

III. ANIMALS' DESTINATION

Exporter:	
Address:	
Means of transportation:	

IV. SANITARY INFORMATION

Information specified in Annex I hereto should be provided.

Official Veterinary Service stamp

Veterinarian's name and signature

ANNEX III

MODEL OF SHIPPING CERTIFICATE FOR THE IMMEDIATE SLAUGHTER OF CATTLE AMONG THE MEMBER STATES OF THE MERCORSUR.

Exporting State Party:	
Agency:	
Service:	

I, Official Veterinarian of the exporting State Party, hereby certify that the animals identified in Zoo-sanitary certificate No. _____ , destined for exportation to (Name of destination State Party):

1. Have been examined at the time of shipment and on that occasion were in good physical condition as well as free of external parasites.

2. Were being transported in vehicles that had been previously cleaned and disinfected with products approved by the Official Veterinary Services of the State Party of Origin, so as to avoid direct contact with animals in adverse sanitary condition, and in accordance with specific transportation requirements.

Shipping location:		Date:	
Means of transportation:			
Transportation vehicle's tag number:			
Seal's number:			

Official Veterinary Service stamp

Official Veterinarian's name and signature

NORMATIVE INSTRUCTION SDA No. 48 OF JUNE 17, 2003

Published in the Official Gazette of June 20, 2003 Section 1, Page 6

Bovine and bubaline semen may be distributed in Brazil only if collected at Semen Collection and Processing Centers-SCPC registered with the Ministry of Agriculture, Livestock, and Food Supply and which are in compliance with minimum requirements for the production and marketing of bovine and bubaline semen in the country.

THE MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY'S ANIMAL AND PLANT HEALTH AND INSPECTION SECRETARY, by virtue of the powers vested in him under Art. 15, II of Decree No. 4629 of March 21, 2003,

Whereas it is necessary to establish sanitary measures to ensure the quality of semen produced and marketed in Brazil, and

In view of the provisions of Proceeding No. 21000.001909/2002-25,

RESOLVES:

Art. 1. Bovine and bubaline semen may be distributed in Brazil only if collected at Semen Collection and Processing Centers-SCPC registered with the Ministry of Agriculture, Livestock, and Food Supply-MAPA and which are IN COMPLIANCE WITH MINIMUM REQUIREMENTS FOR THE PRODUCTION AND MARKETING OF BOVINE AND BUBALINE SEMEN IN THE COUNTRY, pursuant to the Annexes hereto.

Sole Paragraph. To be registered, SCPC must follow this Ministry's current norms.

Art. 2. To delegate to the Director of the Animal Health and Inspection Department the competence for issuing complementary acts that may be necessary for enforcement of this Normative Instruction.

Art. 3. Noncompliance with the requirements hereunder shall be a crime pursuant to Art. 259 of the Penal Code.

Art. 4. This Normative Instruction shall enter into force on the day of its publication.

MAÇAO TADANO

ANNEX I

MINIMUM REQUIREMENTS FOR THE PRODUCTION AND MARKETING OF BOVINE AND BUBALINE SEMEN IN BRAZIL

CHAPTER I

PRE-QUARANTINE

1. To be admitted to a SCPC, animals must be accompanied by an animal movement permit and must have tested negative in the preceding 60 (sixty) days for the following diseases:

(a) BRUCELLOSIS: Buffered Acidified Antigen test (BAAT) or 2-Mercaptoethanol (2-ME), or Complement Fixation test;

(b) TUBERCULOSIS: intradermal tuberculin test (simple bovine PPD test or bovine PPD and avian PPD comparative test).

Note: Exemption from the performance of brucellosis and tuberculosis tests is allowed for animals from herds certified as free of these diseases, in accordance with the Technical Regulations of the National Program on Control and Eradication of Animal Brucellosis and Tuberculosis.

CHAPTER II

QUARANTINE FOR ADMISSION TO A SEMEN COLLECTION AND PROCESSING CENTER

2. Before being admitted into a SCPC resident herd, all animals shall be subjected to quarantine for a minimum of 28 days, during which time they will be submitted to diagnostic tests for the following diseases:

(a) BRUCELLOSIS: negative BAAT or 2-ME or Complement Fixation tests;

(b) TUBERCULOSIS: negative simple intradermal tuberculin test or bovine PPD and avian PPD comparative test;

(c) BOVINE GENITAL CAMPYLOBACTERIOSIS: three negative culture tests of prepuce material collected at minimum seven-day intervals;

(d) TRICHOMONOSIS: three negative culture tests of prepuce material collected at minimal seven-day intervals;

(e) BOVINE VIRAL DIARRHOEA (BVD): virus isolation negative test and agent identification through immunofluorescence or immunoperoxidase, or viral antigen detection test.

Note: Before being admitted into the resident herd, all animals must be tested so as to eliminate the possibility of persistent BVD infection. Animals tested positive for BVD must be submitted to a second test after a minimum interval of 21 days. If tested negative at the second testing, the animals may be admitted into the SCPC.

CHAPTER III

RESIDENT HERD

3. A SCPC resident herd must be submitted to diagnostic tests at least once a year and test negative for the following diseases:

(a) BRUCELLOSIS: BAAT or 2-ME or Complement Fixation test;

(b) TUBERCULOSIS: simple intradermal tuberculin test or bovine PPD and avian PPD comparative test;

(c) BOVINE GENITAL CAMPYLOBACTERIOSIS: one test of prepuce material;

(d) TRICHOMONOSIS: one culture of prepuce material test.

4. SCPC resident animals tested positive for the abovementioned diseases shall be isolated and reevaluated by the Ministry of Agriculture, Livestock, and Food Supply's Official Veterinary Service.

4.1. Reevaluation will be done through paired tests recommended by the OIE and through epidemiologic survey of the establishment;

4.2. An animal tested positive for any of the abovementioned diseases shall be withdrawn from the SCPC and sanitary health and inspection measures shall be applied, pursuant to MAPA's current legislation.

4.3. Semen from such animal stored in the SCPC must be destroyed.

4.4. Animals that have been in contact with such animal must be also tested again for the disease in question.

CHAPTER IV

ADDITION OF ANTIBIOTICS TO SEMEN PROCESSING

5. To each milliliter of frozen semen will be added bactericide antibiotic mixtures, as follows:

(a) gentamicyn (250 µg), tilosyn (50 µg), lincomicyn (150 µg), and spectinomicyn (300 µg); or

(b) penicillin (500 UI), streptomicyn (500 UI), lincomicyn (150 µg), and spectinomicyn (300 µg).

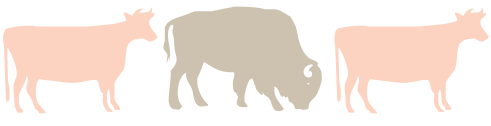
Note: Other antibiotic combinations may be used, provided their efficacy has been proven, and subject to authorization from the Ministry of Agriculture, Livestock, and Food Supply.

CHAPTER V

GENERAL DISPOSITIONS

6. SCPC resident animals must be continuously isolated from animals in different sanitary conditions.

7. Animals may be released from quarantine to join the resident herd after 28 days in isolation and the performance of the sanitary tests.



8. Animals that have left the herd must be subjected to the quarantine procedures before readmission.

9. Laboratory tests must be performed by laboratories recognized or accredited by the Ministry of Agriculture, Livestock, and Food Supply's Animal Health and Inspection Department.

10. Brucellosis testing of animals in quarantine should be done at least 30 days after pre-quarantine testing.

11. Tuberculosis testing should be done pursuant to the requirements under the Technical Regulations of the National Program on Control and Eradication of Animal Brucellosis and Tuberculosis.

12. Tuberculosis tests should be performed only after a minimum of 60 (sixty) days after the last testing.

13. The fast agglutination serum test for brucellosis may be used as long as the National Program on Brucellosis Control and Eradication still permits the use of this technique in the country.

ANNEX II

VETERINARIAN'S STATEMENT

I, _____, a veterinarian registered with the CRMV/CFMV under No. _____, certify that the animal(s) identified below, belonging to Mr. _____, and which are located on the _____ property situated in the Municipality of _____, State of _____, comes/come from a herd certified by the Ministry of Agriculture, Livestock, and Food Supply as free of brucellosis and tuberculosis.

ANIMAL(S) IDENTIFICATION

ANIMALS' NAME OR REGISTRATION Nº.	BREED	AGE (months)

Place and date:

Veterinarian's signature and seal

Please attach proof of the herd's certification as free of brucellosis or tuberculosis.

Delete items that do not apply.

NORMATIVE INSTRUCTION No. 17 OF APRIL 10, 2003

Published in the Official Gazette of April 14, 2003 Section 1, Page 2

Incorporates into the national legislation the "Zoosanitary Requirements and Certificates for Goat Trade among Mercosur State Parties."

THE MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY'S ANIMAL AND PLANT HEALTH AND INSPECTION SECRETARY, by virtue of the powers vested in him under Art. 83, IV of the Office's Internal Regulations approved under Ministerial Administrative Ruling No. 574 of December 8, 1998, having in view the provisions of the Ouro Preto Protocol and Proceeding No. 21000.000629/2003-81,

RESOLVES:

Art. 1. To incorporate into the national legislation the "Zoosanitary Requirements and Certificates for Caprine Animals Trade among Mercosur State Parties" approved under MERCOSUR GMC Resolution No. 42/02 and transcribed in the Annex hereto.

Art. 2. This Normative Instruction shall enter into force on the day of its publication.

MAÇAO TADANO

ANNEX I

ZOOSANITARY REQUIREMENTS AND CERTIFICATES FOR CAPRINE ANIMALS TRADE AMONG MERCOSUR STATE PARTIES

CHAPTER I

GENERAL DISPOSITIONS

Art. 1. All trade in live goats among Mercosur State Parties must be subject to this Resolution and should be accompanied and supported by ZOOSANITARY CERTIFICATES for goats for reproduction, fattening (only castrated animals) or immediate slaughter, as appropriate. Said certificates are issued by the Official Veterinary Service, approved under this Resolution, and transcribed in Annex II.

Art. 2. For the purposes hereunder, the definitions in the International Epizooties Office-OIE's International Zoosanitary Code shall apply, as shall the following definitions:

ESTABLISHMENT OF ORIGIN: establishment where the animals were born or have remained in the 12 (twelve) months prior to being exported; and

ESTABLISHMENT OF PERMANENCE: the establishment where the animals stayed in quarantine prior to exportation.

Art. 3. Animals destined for exportation must be held in isolation for a period of 30 (thirty) days prior to shipment, in facilities approved and under official supervision, pursuant to Mercosur's current norms.

During quarantine and according to their category or purpose, the animals shall be subjected to the diagnostic tests specified under Art. 10.6 hereof, performed in an official laboratory or in a laboratory accredited by the Official Veterinary Services, as a requirement for the issuance of the pertinent official zoosanitary certificate.

Art. 4. The diagnostic test results in support of the caprine zoosanitary certificates shall be valid for 30 (thirty) days as of the collection of samples; this deadline may be extended for 15 (fifteen) days. The zoosanitary certificates shall be valid for 10 (ten) days as of the date on which they were signed.

Art. 5. Animals from countries, regions, or establishments that have been officially declared disease free pursuant to the specifications set forth for each disease under the pertinent chapters of the OIE International Zoosanitary Code shall be exempted from the requirement of diagnostic tests for the diseases of which they have been declared free.

Art. 6. As regards goats from a State Party, which have participated in an international exposition in the same State Party, in compliance with the sanitary requirements for their subsequent exportation, their permanence at the exposition shall be considered as an extension of the exportation quarantine and after the event's closing they may be exported directly to the destination country, provided no case of transmissible disease has occurred during the event.

Art. 7. The direct shipment of goats from one international livestock exposition to another shall be permitted under sanitary conditions agreed between the pertinent Official Veterinary Services.

Art. 8. Animals should be transported in accordance with current Mercosur norms.

CHAPTER II

SANITARY CERTIFICATION

Art. 9. The State Party's Official Veterinary Service must officially certify that the State Party of origin or permanence, or zone thereof, or the animals' country of origin, as applicable, has remained free of the diseases listed below for a period recommended by the OIE in its International Zoosanitary Code for each one:

Foot-and-mouth disease;
Sheep pox;
Pest des petits ruminants
Contagious agalactia;
Rift Valley fever;
Maedi Visna;
Border disease;
Contagious caprine pleuropneumonia; and
Scrapie.

Certification pertaining to these diseases shall be for a minimum of eight years.

As regards transmissible spongiform encephalopathy, the State Party's Official Veterinary Service must certify that the animals were born and raised in said State Party or have stayed in another country enjoying similar sanitary conditions, and the animals' ascendants were born in the State Party or were imported from a country enjoying similar sanitary conditions in the previous eight years.

The Official Veterinary Service of the State Party of origin or permanence should also certify as follows:

1. That the animals were born and raised in the State Party of origin or have stayed in another State Party in a similar sanitary condition as the State Party from which they come;

2. That in the case of animals imported for reproduction from third countries, the animals have remained for the previous 90 (ninety) days in the State Party where they come from, or zone thereof;

3. That at the establishment of origin or quarantine no case of transmissible diseases has occurred in the 90 (ninety) days before shipment;

4. That, as regards foot-and-mouth disease, blue tongue, vesicular stomatitis, and caprine arthritis-encephalitis, the procedures set forth under the pertinent chapter of the OIE International Zoosanitary Code have been adopted;

5. That the animals to be exported have been vaccinated against anthrax and blackleg between 15 (fifteen) and 180 (one hundred eighty) days prior to shipment; and

6. That while in quarantine the animals have been subjected and tested negative to the following diagnostic tests, as provided under Art. 3 hereunder:

6.1. FOOT-AND-MOUTH DISEASE

Tests shall be agreed by the Official Veterinary Services taking into account the sanitary status of the origin or destination region, country, or zone as provided under the OIE International Zoosanitary Code as regards foot-and-mouth disease.

With respect to goats to be exported to an

foot-and-mouth disease free State Party or zone thereof, the destination State Party's Official Veterinary Services will specify the sanitary conditions to be satisfied in accordance with the OIE International Zoosanitary Code.

6.2. BRUCELLOSIS

Brucella abortus: males and females aged over 180 (one hundred eighty) days.

(a) Rose Bengal test

(b) Complement fixation test

6.3. BLUE TONGUE

(a) Agar-gel immunodiffusion, or

(b) ELISA.

6.4. CAPRINE ARTHRITIS/ENCEPHALITIS

(a) Agar-gel immunodiffusion, or

(b) ELISA

7. That the animals have been submitted to treatment against both internal and external parasites within thirty days prior to shipment.

8. That the animals being exported are not discardable animals under any program on disease control and/or eradication under implementation in the State Party from which they are being exported.

9. That the animals did not show any clinical symptom of infectious disease at the time of shipment.

10. That in the animals' State Party of origin it is prohibited to feed ruminants with meat and bone meals and other feed containing proteins of a ruminant origin.

Art. 11. In respect of anabolyzing substances, the importing State Party's national regulations thereon shall prevail.

ANNEX II

ZOOSANITARY CERTIFICATES

ZOOSANITARY CERTIFICATE FOR EXPORTATION OF GOATS FOR REPRODUCTION

Certificate No.:	
Date issued:	
Expiration date:	

I. ORIGIN

State Party:	
State:	
Establishment of origin:	
Establishment adress:	
Exporter:	
Exporter's address:	

II. DESTINATION

State Party:	
State:	
Destination establishment:	
Destination establishment's address:	
Importer:	
Importer's address:	

III. TRANSPORTATION

Means of transportation:	
Point of exit:	

IV. ANIMALS' IDENTIFICATION

Total number of animals					
No. by order	Identification nº. (*)	Breed	Gender	Age (*)	Observations
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					

(*) As applicable

Note: This page may be replaced by a list signed by the Official Veterinarian and attached to the certificate.

V. SANITARY INFORMATION

The undersigned official veterinary certifies that:

1. The State Party is in compliance with the conditions set forth under Art. 9 of Annex I to GMC Resolution No. 42/02 on "Zoosanitary Requirements and Certificates for Caprine Animals Trade among Mercosur State Parties."

2. The animals were born and raised in the State Party of origin or zone thereof or have stayed in another State Party or zone enjoying similar sanitary conditions. That in the case of animals imported from third countries, the latter are in compliance with the pertinent Mercosur sanitary requirements, and that the animals have spent the last 90 (ninety) days in the State Party or zone thereof from where they come.

3. That as regards vesicular stomatitis, procedures were adopted in accordance with the provisions under the pertinent chapter of the OIE International Zoosanitary Code.

4. That as regards blue tongue, procedures were adopted in accordance with the provisions under the pertinent chapter of the OIE International Zoosanitary Code.

5. That as regards foot-and-mouth disease, procedures were adopted in accordance with the provisions under the pertinent chapter of the OIE International Zoosanitary Code.

6. That as regards caprine arthritis-encephalitis, procedures were adopted in accordance with the provisions under the pertinent chapter of the OIE International Zoosanitary Code.

7. That at the establishment of origin and/or quarantine, no case of transmissible diseases occurred in the 90 (ninety) days prior to shipment.

8. That the animals were vaccinated anthrax and blackleg between 15 (fifteen) and 180 (one hundred eighty) days prior to shipment.

9. That the animals were submitted to treatment for internal and external parasites within 30 (thirty) days prior to shipment.

10. That the animals were held in isolation for 30 (thirty) days before being exported, in approved facilities under official supervision, and tested negative for the following diseases:

10.1. BRUCELLOSIS

Brucella abortus: males and females aged over 180 (one hundred eighty) days.

a) Rose Bengal test

b) Complement fixation test

10.2. BLUE TONGUE

a) Agar-gel immunodiffusion, or

b) ELISA.

10.3. CAPRINE ARTHRITIS-ENCEPHALITIS

a) Agar-gel immunodiffusion, or

b) ELISA

11. That the animals being exported are not discardable animals under any program on disease control and/or eradication under implementation in the State Party from which they are being exported.

12. That in respect of anabolyzing substances, the importing State Party's national regulations thereon shall prevail.

13. That animals come from a State party or zone thereof or from an establishment that has been officially declared free of one or more than one disease pursuant to the provisions under the pertinent chapter of OIE International Zoosanitary Code as regards the following diseases:

DISEASE	OFFICIAL DOCUMENT	DATE

OBSERVATIONS:

_____

_____

Place and date _____, _____/_____/_____

Official stamp

_____

Official veterinary's signature and stamp

VI. CERTIFICATION FOR RETURN FROM EXPOSITIONS

The undersigned official veterinary certifies that:

No cases of transmissible diseases susceptible of affecting the species occurred during the event.

Place and date _____ , _____/_____/_____

Official stamp

_____

Official veterinary's signature and stamp

VII. ANIMALS' SHIPMENT

The animals were checked at the time of shipment and showed no clinical signs of infectious diseases and were free of external parasites.

The animals are being transported pursuant to current Mercosur norms.

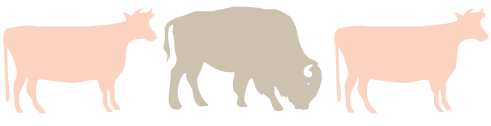
SHIPMENT PLACE:	
SEAL No.	VEHICLE'S TAG No.
SEAL No.	VEHICLE'S TAG No.
SEAL No.	VEHICLE'S TAG No.
SEAL No.	VEHICLE'S TAG No.
SEAL No.	VEHICLE'S TAG No.
SEAL No.	VEHICLE'S TAG No.
SEAL No.	VEHICLE'S TAG No.
SEAL No.	VEHICLE'S TAG No.
SEAL No.	VEHICLE'S TAG No.

Place and date _____ , _____/_____/_____

Official Stamp

_____

Official veterinary's signature and stamp



ZOOSANITARY CERTIFICATE FOR EXPORTATION OF GOATS FOR FATTENING

(Only castrated males)

Certificate No.	
Date issued	
Expiration date	

I. ORIGIN

State Party	
State	
Establishment of origin	
Establishment of origin's address	
Exporter	
Address	

II. DESTINATION

State Party	
State	
Destination establishment	
Destination establishment's address	
Importer	
Importer's address	

III. TRANSPORTATION

Means of transportation	
Point of exit	

IV. ANIMALS' IDENTIFICATION

Total number of animals					
No. by order	Identification nº. (*)	Breed	Gender	Age (*)	Observations
1					
2					

(*) As applicable

Note: This page may be replaced by a list signed by the official veterinary and attached to the certificate.

V. SANITARY INFORMATION

1. The undersigned official veterinary certifies that:

2. The State Party is in compliance with the conditions set forth under Art. 9 of Annex I to GMC Resolution No. 42/02 on "Zoosanitary Requirements and Certificates for Caprine Animals Trade among Mercosur State Parties."

3. The animals were born and raised in the State Party of origin or zone thereof or have stayed in another State Party or zone of similar sanitary status. That in the case of animals imported from third countries, the latter are in compliance with the pertinent Mercosur sanitary requirements, and that the animals have spent the last 90 (ninety) days in the State Party or zone thereof from where they come.

4. That as regards vesicular stomatitis, procedures were adopted in accordance with the provisions under the pertinent chapter of the OIE International Zoosanitary Code.

5. That as regards blue tongue, procedures were adopted in accordance with the provisions under the pertinent chapter of the OIE International Zoosanitary Code.

6. That as regards foot-and-mouth disease, procedures were adopted in accordance with the provisions under the pertinent chapter of the OIE International Zoosanitary Code.

7. That as regards caprine arthritis-encephalitis, procedures were adopted in accordance with the provisions under the pertinent chapter of the OIE International Zoosanitary Code.

8. That at the establishment of origin and/or quarantine, no case of transmissible diseases occurred in the 90 (ninety) days prior to shipment.

9. That the animals were vaccinated against anthrax and blackleg between 15 (fifteen) and 180 (one hundred eighty) days prior to shipment.

10. That the animals were submitted to treatment for internal and external parasites within 30 (thirty) days prior to shipment.

11. That the animals being exported are not discardable animals under any program on disease control and/or eradication under implementation in the State Party from which they are being exported. They are all castrated animals.

12. That in respect of anabolyzing substances, the importing State Party's national regulations thereon shall prevail.

13. That the animals were held in isolation for 30 (thirty) days before being exported, in approved facilities under official supervision, and tested negative for the following diseases:

13.1. BLUE TONGUE

a) Agar-gel immunodiffusion, or

b) ELISA.

13.2. CAPRINE ARTHRITIS/ENCEPHALITIS

a) Agar-gel immunodiffusion, or

b) ELISA

14. That animals come from a State party or zone thereof or from an establishment that has been officially declared free of one or more than one disease pursuant to the provisions under the pertinent chapter of OIE International Zoosanitary Code as regards the following diseases:

DISEASE	OFFICIAL DOCUMENT	DATE

OBSERVATIONS:

_____

_____

Place and date _____ , _____/_____/_____

Official stamp

Official veterinary's signature and stamp

_____

VI. ANIMALS' SHIPMENT

The animals were checked at the time of shipment and showed no clinical signs of infectious diseases and were free of external parasites.
The animals are being transported pursuant to current Mercosur norms.

SHIPMENT PLACE:	
SEAL No.	VEHICLE'S TAG No.
SEAL No.	VEHICLE'S TAG No.

Place and date _____ , _____/_____/_____

Official Stamp

Official veterinary's signature and stamp

_____

ZOOSANITARY CERTIFICATE FOR EXPORTATION OF GOATS FOR IMMEDIATE SLAUGHTERING

Certificate No.	
Date issued	
Expiration date	

I. ORIGIN

State Party	
State	
Establishment of origin	
Establishment of origin's address	
Exporter	
Address	

II. DESTINATION

State Party	
State	
Destination establishment	
Destination establishment's address	
Importer	
Importer's address	

III. TRANSPORTATION

Means of transportation	
Point of exit	

IV. ANIMALS' IDENTIFICATION

Total number of animals					
No. by order	Identification No.	Breed	Gender	Age	Observations
Machos					
Fêmeas					

V- SANITARY INFORMATIONS

The undersigned official veterinary certifies that:

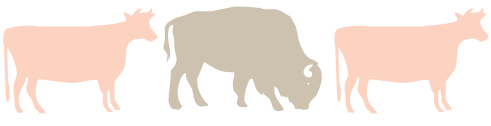
1. The State Party is in compliance with the conditions set forth under Art. 9 of Annex I to GMC Resolution No. 42/02 on "Zoosanitary Requirements and Certificates for Caprine Animals Trade among Mercosur State Parties."

2. The animals were born and raised in the State Party of origin or zone thereof or have stayed in another State Party or zone of similar sanitary status.

3. That as regards vesicular stomatitis, procedures were adopted in accordance with the provisions under the pertinent chapter of the OIE International Zoosanitary Code.

4. That as regards blue tongue, procedures were adopted in accordance with the provisions under the pertinent chapter of the OIE International Zoosanitary Code.

5. That as regards foot-and-mouth disease,



procedures were adopted in accordance with the provisions under the pertinent chapter of the OIE International Zoosanitary Code.

6. That as regards caprine arthritis-encephalitis, procedures were adopted in accordance with the provisions under the pertinent chapter of the OIE International Zoosanitary Code.

7. That at the establishment of origin and/or quarantine, no case of transmissible diseases occurred in the 90 (ninety) days prior to shipment.

8. That the animals being exported are not discardable animals under any program on disease control and/or eradication under implementation in the State Party from which they are being exported.

9. That in respect of anabolyzing substances, the importing State Party's national regulations thereon shall prevail.

OBSERVATIONS:

_____

_____

Place and date _____ , _____/_____/_____

Official Stamp

Official veterinary's signature and stamp

_____

VI. ANIMALS' SHIPMENT

The animals were checked at the time of shipment and showed no clinical signs of infectious diseases and were free of external parasites.
The animals are being transported pursuant to current Mercosur norms.

SHIPMENT PLACE:	
SEAL No.	VEHICLE'S TAG No.
SEAL No.	VEHICLE'S TAG No.
SEAL No.	VEHICLE'S TAG No.
SEAL No.	VEHICLE'S TAG No.
SEAL No.	VEHICLE'S TAG No.
SEAL No.	VEHICLE'S TAG No.
SEAL No.	VEHICLE'S TAG No.
SEAL No.	VEHICLE'S TAG No.
SEAL No.	VEHICLE'S TAG No.

Place and date _____ , _____/_____/_____

Official Stamp

Official veterinary's signature and stamp

_____

SDA NORMATIVE INSTRUCTION No. 54 OF SEPTEMBER 17, 2002

Published in the Official Gazette of September 19, 2002 Section 1, Page 8

Approves zoosanitary requirements for the importation of swine semen. Not applicable to Mercosur States Parties.

THE SECRETARY OF AGRICULTURE AND LIVESTOCK HEALTH AND INSPECTION OF THE MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY, proceeding from his attributions established by Article 38, Item IV, of the Secretary's Internal Regulation, approved by Ministerial Decree No. 574 of December 8, 1998, considering process No. 21000.008028/2001-54, decides:

Art. 1. Approve animal health requirements for importation of swine semen, as described in the Annex which is part of this Normative Instruction.

Sole paragraph This Normative Instruction shall not apply to Member States of MERCOSUL.

Art. 2. The Animal Health and Inspection Department (DDA – Departamento de Defesa Animal), where necessary, shall edit additional rules for this Normative Instruction.

Art. 3. This Normative Instruction shall come into effect from the date of its publication.

LUIZ CARLOS DE OLIVEIRA

ANNEX

BRAZIL'S ANIMAL HEALTH REQUIREMENTS FOR IMPORTATION OF SWINE SEMEN OF COUNTRIES WHICH ARE NOT MEMBERS OF MERCOSUL

I. GENERAL CONDITIONS

1. Requirements of this Normative Instruction shall be complied by countries recognized by the Brazilian Ministry of Agriculture, Livestock and Food Supply (MAPA – *Ministério da Agricultura, Pecuária e Abastecimento*) as free of African swine fever, swine vesicular disease, rinderpest and foot-and-mouth disease (FMD).

2. The semen for export to Brazil shall be collected in a Center for Semen Collection and Processing (CSCP) that:

2.1. is registered with the Veterinary Control Service of the exporting country;

2.2. operates under the surveillance of the official veterinary Control Service of the exporting country to control periodically animal's health and welfare conditions, as well as the methods used for collection, processing and storage of semen, records made and sanitary control of the CSCP;

2.3. has technical staff, including at least one veterinarian accredited by the official veterinary control service of the exporting country;

2.4. keeps animals related to production of sperm only;

2.5. is isolated from establishments that rearing or slaughter pigs;

2.6. has strict entrance control for visitors;

2.7. provides protective clothing and boots for employees engaged in semen gathering, processing and storage;

2.8. has appropriate facilities to accommodate the semen donors at collection;

2.9. has separate facilities to perform semen collection, processing and storage.

3. Every import of swine semen shall be previously authorized by the Ministry of Agriculture, Livestock and Food Supply.

4. Every import of swine semen shall be accompanied by Animal Health Certificate, described as follow:

4.1. The certificate shall be issued in the of-

ficial language of the exporting country and in Portuguese;

4.2. The certificate shall be signed or endorsed by the Official veterinary Control Service of the exporting country;

4.3. The certificate shall be numbered and stamped on each page with the Official veterinary Control Service's stamp;

4.4. The certificate form of the exporting country shall be submitted prior to approval of the Animal Health and Inspection Department (DDA) of the Ministry of Agriculture, Livestock and Food Supply (MAPA).

5. Every collection of donor material for tests required by MAPA shall be supervised by an official veterinarian of the exporting country or by the veterinarian responsible for the collection center.

6. Laboratory tests required by MAPA shall be performed only in a laboratory approved by the Official veterinary Control Service of the exporting country.

7. Straws or ampoules of semen shall be identified with the registration number, breed of donor animal, date of collection and name of the CSCP.

II. ANIMAL HEALTH CERTIFICATE

The animal health certificate accompanying the Brazilian imports shall be in accordance with the model recommended by the International Animal Health Code of the World Organization for Animal Health (OIE), plus the following health information:

A – CONCERNING THE EXPORTING COUNTRY

1. From the period of collection until the embarkation of the semen, the country must be free from African swine fever, swine vesicular disease, rinderpest and foot-and-mouth disease, according to recommendations of International Animal Health Code of the OIE.

B – CONCERNING THE CENTER FOR SEMEN COLLECTION AND PROCESSING (CSCP)

2. The Center for Semen Collection and Processing (CSCP), where the to-be-exported semen was collected, complies with item I.2, Appendix of SDA Normative Instruction No. ....., ... 2002.

3. The CSCP, where the to-be-exported semen was collected, is located in a zone free from classical swine fever (CSF-free), recognized as such by MAPA.

C – CONCERNING SEMEN DONORS

4. The donor animals shall remain in the exporting country for at least sixty (60) days prior to semen collection.

5. The donor animals must come from facilities located in a non-infected zone of classical swine fever (CSF-free) in accordance with the International Animal Health Code of the OIE.

6. The donor animals must come from facilities free from brucellosis, tuberculosis, Aujeszky's disease, in accordance with the International Animal Health Code of the OIE.

7. The donor animals must come from facilities where vesicular stomatitis, transmissible gastroenteritis (TGE), and Teschen disease had not been reported during the ninety (90) days prior to semen collection.

8. The donor animals must come from facilities free from porcine reproductive and respiratory syndrome (PRRS).

9. The donors and other animals living in the collection center must not present any clinical signs of disease during the thirty (30) days prior to collection, at the time of collection and during the thirty (30) days after collection of the semen.

D – CONCERNING DIAGNOSTIC TESTS

10. The donor animals shall be tested and have negative results for the following diseases:

10.1. Brucellosis – BBAT, ELISA or complement fixation test, on entry into CSCP and every six months thereafter while resident at the center.

10.2. Aujeszky's disease (pseudorabies) – Virus neutralization or ELISA, on entry into CSCP and every six (6) months thereafter while resident at the center.

10.3. Porcine reproductive and respiratory syndrome (PRRS) – ELISA, at least thirty (30) days prior to collection of the semen and then between fifteen (15) and sixty (60) days after collection.

E – CONCERNING THE SEMEN

11. The semen must be collected, processed and stored in a manner consistent with recommendations of the International Animal Health Code.

12. Appropriate antibiotic mixes (such as penicillin, dihydrostreptomycin and polymyxin) at effective levels must be used in frozen semen

to prevent the presence of contaminating bacterial agents.

13. The semen must be stored in semen tanks previously cleaned and disinfected for a period of at least thirty (30) days prior to embarkation in a locked room under the direct control of the veterinarian responsible for the collection center.

Note: If the country has achieved free status for any of the diseases listed in D.10, tests would not be necessary for the disease agent. In this case, the exporting country must obtain recognition from MAPA for this certification.

NORMATIVE INSTRUCTION SDA No. 39 OF JUNE 17, 2002

Published in the Official Gazette of June 24, 2002 Section 1, Page 15

Adopts Mercosur GMC Resolution No. 51/01, which approves the "Zoosanitary Requirements for Sheep Trading among Mercosur State Parties."

THE MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY'S ANIMAL AND PLANT HAELTH AND INSPECTION SECRETARY, by virtue of the powers vested in him under Art. 83, IV of the Office's Internal Regulations approved under Ministerial Administrative Ruling No. 574 of December 8, 1998, having in view the provisions of the Ouro Preto Protocol and Proceeding No. 21000.000313/2002-99,

RESOLVES:

Art. 1. Adopt Mercosur GMC Resolution No. 51/01, which approves the "Requirements and Certificated for Ovine Trade among Mercosur State Parties" as well as the Resolution's annexes.

Art. 2. This Normative Instruction shall enter into force on the day of its publication.

LUIZ CARLOS DE OLIVEIRA

MERCOSUR/GMC/RES.NO.51/01

"REQUIREMENTS AND CERTIFICATED FOR OVINE ANIMALS TRADE AMONG MERCOSUR STATE PARTIES."

(REVOKES GMC RES Nº. 66/94)

HAVING IN VIEW the Treaty of Asunción, the Ouro Preto Protocol, Common Market Council Decision No. 6/96, and Common Market Group Resolution No. 66/94;

WHEREAS there is a need to update the sanitary requirements and the certificates called for under GMC Resolution No. 66/94 for ovine trade in Mercosur, as well as the pertinent zoosanitary certificates,

THE COMMON MARKET GROUP RESOLVES:

Art. 1. To approve the "Requirements and Certificated for Ovine Animals Trade among Mercosur State Parties," pursuant to Annex I hereto, which form part hereof. Said requirements are the only requirements to be enforced in trade among the States Parties.

Art. 2. For the purposes hereunder, the Zoosanitary Certificates listed below, pursuant to Annex II, are hereby approved and form part hereof.

- "Zoosanitary Certificate for exportation of sheep for reproduction;"
- "Zoosanitary Certificate for exportation of sheep for fattening (Only castrated males.)"
- "Zoosanitary Certificate for exportation of sheep for immediate slaughtering,"

Art. 3. The States Parties shall enforce the legal, regulation, and administrative provisions for implementation of this Resolution through the following bodies:

Argentina: Department of Agriculture, Livestock, Fisheries, and Food Supply-SAGPyA-National Agriculture and Food Health and Quality Service-SENASA;

Brazil: Ministry of Agriculture, Livestock, and Food Supply-MAPA-Agriculture, Animal and

Plant Health and Inspection Secretariat -SDA;

Paraguay: Ministry of Agriculture and Livestock-MAG-State Livestock Department-SSEG-National Animal Health Service-SENACSA; and

Uruguay: Ministry of Livestock, Agriculture, and Fisheries-MGAP-Livestock Services Office-DGSG.

Art. 4. GMC Resolution no. 66/94 is hereby revoked.

Art. 5. The Mercosur States Parties shall incorporate this Resolution into their national legislation by March 31, 2002.

XLIV GMC, Montevideo, December 5, 2001.

ANNEX I

REQUIREMENTS AND CERTIFICATED FOR OVINE ANIMALS TRADE AMONG MERCOSUR STATE PARTIES.

CHAPTER I

GENERAL DISPOSITIONS

Art. 1. All live sheep trade among Mercosur State Parties must comply with this Resolution and must be accompanied and supported by the pertinent ZOOSANITARY CERTIFICATES approved under this Resolution and forming part of Annex II, pertaining to sheep for reproduction, fattening (only castrated males), or immediate slaughtering.

Art. 2. For the purposes hereunder, the definitions in the World Organisation for Animal Health-OIE's International Zoosanitary Code shall apply, as well as the following definitions:

Establishment of Origin: establishment where the animals were born or have remained during the 12 (twelve) months prior to being exported;

Permanence Establishment: location where the animals were held in quarantine prior to being exported.

Art. 3. Animals destined for exportation must be held in isolation for 30 (thirty) days prior to shipment, in facilities officially approved and supervised pursuant to current Mercosur norms. During this quarantine period, the animals must be subjected, in accordance with their category or destination, to the diagnostic tests referred to under Art. 10.6, performed at an official laboratory or at a laboratory accredited by the Official Veterinary Services, so that the pertinent zoosanitary certificate may be issued.

Art. 4. The laboratory test results that support an ovine zoosanitary certificate issued by the Official Veterinary Services of Mercosur States Parties shall be valid for 30 (thirty) days as of the date samples are collected and may be extended for another 15 (fifteen) days, while the zoosanitary certificates shall be valid for 10 (ten) days as of the day they are signed.

Art. 5. Animals from countries, regions, or establishments officially declared free according to the specifications pertaining to each disease pursuant to the pertinent chapters of the OIE International Zoosanitary Code are exempted from diagnostic testing for the diseases of which they have been declared free.

Art. 6. As regards sheeps from a State Party, which are participating in an international exposition in said State Party in compliance with the sanitary requirements for subsequent exportation, their stay at the exposition shall be considered as an extension of quarantine, and they may, at the close of the event, be exported directly to the destination country, provided no case of transmissible disease has occurred during the event.

Art. 7. The direct transfer of sheeps between international livestock expositions shall be permitted under sanitary conditions agreed between the respective Official Veterinary Services.

Art. 8. The animals must be transported as provided under current Mercosur norms.

CHAPTER II

SANITARY CERTIFICATION

Art. 9. The Mercosur State Party's Official Veterinary Service should officially certify that

the State Party or zone of the State Party of origin or permanence and the animals' country of origin, if applicable, have remained free of the diseases listed below for the period recommended by the OIE International Zoosanitary Code:

- foot-and-mouth disease
- sheep pox
- pest des petits ruminants
- contagious agalactia
- Maedi-Visna;
- Rift Valley fever
- Ovine pulmonary adenomatosis
- Border disease
- Scrapie.

Certification must be for a minimum of eight years.

As regards transmissible spongiform encephalopathy, the State Party's Official Veterinary Service must certify that the animals were born and raised in said State Party or have stayed in another country enjoying similar sanitary conditions, and the animals' ascendants were born in the State Party or were imported from a country enjoying similar sanitary conditions in the previous eight years.

Art. 10. The Official Veterinary Service of the State Party of origin or permanence should also certify as follows:

1. That the animals were born and raised in the State Party of origin or have stayed in another State Party in a similar sanitary condition as the State Party from which they come;

2. That in the case of animals imported for reproduction from third countries, the animals have remained for the previous 90 (ninety) days in the State Party where they come from, or zone thereof;

3. That at the establishment of origin or quarantine no case of transmissible diseases has occurred in the 90 (ninety) days before shipment;

4. That, as regards foot-and-mouth disease, blue tongue, vesicular stomatitis, and caprine arthritis-encephalitis, the procedures set forth under the pertinent chapter of the OIE International Zoosanitary Code have been adopted;

5. That the animals to be exported have been vaccinated against anthrax and blackleg between 15 (fifteen) and 180 (one hundred eighty) days prior to shipment; and

6. That while in quarantine the animals have been subjected to and tested negative for the following diagnostic tests, as provided under Art. 3 hereunder:

6.1. FOOT-AND-MOUTH DISEASE

Tests shall be agreed by the Official Veterinary Services taking into account the sanitary status of the origin or destination region, country, or zone as provided under the OIE International Zoosanitary Code as regards foot-and-mouth disease.

With respect to sheep to be exported to a foot-and-mouth disease free State Party or zone thereof, the destination State Party's Official Veterinary Services will specify the sanitary conditions to be satisfied in accordance with the OIE International Zoosanitary Code.

6.2. BRUCELLOSIS

Brucella ovis: males aged over 180 (one hundred eighty) days.

a) Agar-gel immunodiffusion, or

b) Complement fixation test, or

c) ELISA.

Brucella abortus: males and females aged over 180 (one hundred eighty) days.

a) Rose Bengal test

b) Complement fixation test

6.3. BLUE TONGUE

a) Agar-gel immunodiffusion, or

b) ELISA.

6.4. CAPRINE ARTHRITIS/ENCEPHALITIS

a) Agar-gel immunodiffusion, or

b) ELISA

7. That the animals have been submitted to treatment against both internal and external parasites within thirty days prior to shipment.

8. That the animals being exported are not discardable animals under any program on disease control and/or eradication under implementation in the State Party from which they are being exported.

9. That the animals did not show any clinical symptom of infectious disease at the time of shipment.

10. That in the animals' State Party of ori-

gin it is prohibited to feed ruminants with meat and bone meals and other feed containing proteins of ruminant origin.

Art. 11. In respect of anabolyzing substances, the importing State Party's national regulations thereon shall prevail.

ANNEX II

ZOOSANITARY CERTIFICATE FOR SHEEP EXPORTATION

FOR REPRODUCTION

Certificate No. _____

Date issued _____

Expiration date _____

I – ORIGIN

State Party _____

Province, State, Department _____

Establishment of origin _____

Address _____

Exporter

Address _____

II – DESTINATION

State Party _____

Province, State, Department _____

Establishment of origin _____

Address _____

Importer _____

Address _____

III – TRANSPORTATION

Means of transportation _____

Exit point _____

IV – ANIMALS' IDENTIFICATION

Nº. of animals Breed Age Observations _____

Males _____

Females _____

Total No. of animals _____

No. by order _____

Identification No. (*) _____

Breed _____

Gender _____

Age (*) _____

Note: This page may be replaced by a list signed by the Official Veterinarian and attached to the certificate.

V – SANITARY INFORMATION

The undersigned official veterinary certifies that:

1. The State Party is in compliance with the conditions set forth under Art. 9 of Annex I to GMC Resolution No. 42/02 on "Zoosanitary Requirements and Certificates for Ovine Animals Trade among Mercosur States Parties."

2. The animals were born and raised in the State Party of origin or zone thereof or have stayed in another State Party or zone enjoying similar sanitary conditions. That in the case of animals imported from third countries, they are in compliance with the pertinent Mercosur sanitary requirements, and that the animals have spent the last 90 (ninety) days in the State Party or zone thereof from where they are being exported.

3. That as regards vesicular stomatitis, procedures were adopted in accordance with the provisions under the pertinent chapter of the OIE International Zoosanitary Code.

4. That as regards blue tongue, procedures were adopted in accordance with the provisions under the pertinent chapter of the OIE International Zoosanitary Code.

5. That as regards foot-and-mouth disease, procedures were adopted in accordance with the provisions under the pertinent chapter of the OIE International Zoosanitary Code.

6. That as regards caprine arthritis-encephalitis, procedures were adopted in accordance with the provisions under the pertinent chapter of the OIE International Zoosanitary Code.

7. That at the establishment of origin and/or quarantine, no case of transmissible diseases occurred in the 90 (ninety) days prior to shipment.

8. That the animals were vaccinated against anthrax and blackleg between 15 (fifteen) and 180 (one hundred eighty) days prior to shipment.

9. That the animals were submitted to treatment for internal and external parasites within 30 (thirty) days prior to shipment.

10. That the animals were held in isolation for 30 (thirty) days before being exported, in approved facilities under official supervision, and tested negative for the following diseases:

10.1. BRUCELLOSIS

Brucella ovis: males aged over (180 one hundred eighty) days.

a) Agar-gel immunodiffusion, or

b) Complement fixation test

c) ELISA.

Brucella abortus: males and females aged over 180 (one hundred eighty) days.

a) Rose Bengal test

b) Complement fixation test

10.2 BLUE TONGUE

a) Agar-gel immunodiffusion, or

b) ELISA.

10.3 CAPRINE ARTHRITIS-ENCEPHALITIS

a) Agar-gel immunodiffusion, or

b) ELISA

11. That the animals being exported are not discardable animals under any program on disease control and/or eradication under implementation in the State Party from which

they are being exported.

12. That in respect of anabolyzing substances, the importing State Party's national regulations thereon shall prevail.

13. That animals come from a State party or zone thereof or from an establishment that has been officially declared free of one or more than one disease pursuant to the provisions under the pertinent chapter of OIE International Zoosanitary Code as regards the following diseases:

Official Date

OBSERVAÇÕES:

Place and date _____ , _____/_____/_____

Official Stamp

Official veterinary's signature and stamp

VI. CERTIFICATION FOR RETURN FROM EXPOSITIONS

The undersigned official veterinary certifies that:

No cases of transmissible diseases susceptible of affecting the species occurred during the event.

Place and date _____ , _____/_____/_____

Official Stamp

Official veterinary's signature and stamp

VI. ANIMALS' SHIPMENT

The identified animals were checked at the time of shipment and showed no clinical signs of infectious diseases and were free of external parasites. The animals are being transported pursuant to current Mercosur norms.

SHIPMENT POINT _____

SEAL No. : _____ VEHICLE'S TAG No. _____

SEAL No. : _____ VEHICLE'S TAG No. _____

SEAL No. : _____ VEHICLE'S TAG No. _____

SEAL No. : _____ VEHICLE'S TAG No. _____

Place and date _____ , _____/_____/_____

Official Stamp

Official veterinary's signature and stamp

_____

ZOOSANITARY CERTIFICATE FOR EXPORTATION OF SHEEP FOR FATTENING

(Only castrated males)

Certificate No. _____

Date issued _____

Expiration date _____

I – ORIGIN

State Party _____

Province, State, Department _____

Establishment of origin _____

Address _____

Exporter _____

Address _____

II – DESTINATION

State Party _____

Province, State, Department _____

Establishment of origin _____

Address _____

Importer _____

Address _____

III – TRANSPORTATION

Means of transportation _____

Exit point _____

IV – ANIMALS' IDENTIFICATION

No. of animals Breed Age Observations _____

Males _____

Females _____

IV – ANIMALS' IDENTIFICATION

Total of animals _____

No. by order _____

Identification No. (*) _____

Breed _____

Gender _____

Age (*) _____

OBSERVATIONS _____

1 _____

2 _____

3 _____

4 _____

5 _____

6 _____

7 _____

8 _____

9 _____

10 _____

11 _____

12 _____

13 _____

14 _____

(*) As applicable

Note: This page may be replaced by a list signed by the official veterinary and attached to the certificate.

V. SANITARY INFORMATION

The undersigned official veterinary certifies that:

1. The State Party is in compliance with the conditions set forth under Art. 9 of Annex I to GMC Resolution No. 51/021on "Zoosanitary Requirements and Certificates for Ovine Trade among Mercosur State Parties."

2. The animals were born and raised in the State Party of origin or zone thereof or have stayed in another State Party or zone of similar sanitary status.

3. That as regards vesicular stomatitis, procedures were adopted in accordance with the provisions under the pertinent chapter of the OIE International Zoosanitary Code.

4. That as regards blue tongue, procedures were adopted in accordance with the provisions under the pertinent chapter of the OIE International Zoosanitary Code.

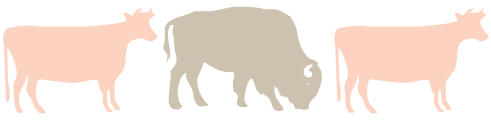
5. That as regards foot-and-mouth disease, procedures were adopted in accordance with the provisions under the pertinent chapter of the OIE International Zoosanitary Code.

6. That as regards caprine arthritis-encephalitis, procedures were adopted in accordance with the provisions under the pertinent chapter of the OIE International Zoosanitary Code.

7. That at the establishment of origin and/or quarantine, no case of transmissible diseases occurred in the 90 (ninety) days prior to shipment.

8. That the animals were vaccinated against anthrax and blackleg between 15 (fifteen) and 180 (one hundred eighty) days prior to shipment.

9. That the animals were submitted to treatment for internal and external parasites within



30 (thirty) days prior to shipment.

10. That the animals being exported are not discardable animals under any program on disease control and/or eradication under implementation in the State Party from which they are being exported. They are all castrated animals.

11. That in respect of anabolyzing substances, the importing State Party's national regulations thereon shall prevail.

12. That the animals were held in isolation for 30 (thirty) days before being exported, in approved facilities under official supervision, and tested negative for the following diseases:

12.1 BLUE TONGUE

a) Agar-gel immunodiffusion, or

b) ELISA.

12.2 CAPRINE ARTHRITIS AND ENCEPHALITIS

a) Agar-gel immunodiffusion, or

b) ELISA

13. That animals come from a State party or zone thereof or from an establishment that has been officially declared free of one or more than one disease pursuant to the provisions under the pertinent chapter of OIE International Zoosanitary Code as regards the following diseases: Disease – Document

Oficial Data

OBSERVAÇÕES:

Place and date _____ , _____/_____/_____

Official Stamp

Official veterinary's signature and stamp

_____

VI. ANIMALS' SHIPMENT

The animals were checked at the time of shipment and showed no clinical signs of infectious diseases and were free of external parasites. The animals are being transported pursuant to current Mercosur norms.

SHIPMENT POINT _____

SEAL No.:_____ VEHICLE'S TAG No. _____

SEAL No.:_____ VEHICLE'S TAG No. _____

SEAL No.:_____ VEHICLE'S TAG No. _____

SEAL No.:_____ VEHICLE'S TAG No. _____

SEAL No.:_____ VEHICLE'S TAG No. _____

SEAL No.:_____ VEHICLE'S TAG No. _____

SEAL No.:_____ VEHICLE'S TAG No. _____

SEAL No.:_____ VEHICLE'S TAG No. _____

Place and date _____ , _____/_____/_____

Official Stamp

Official veterinary's signature and stamp

_____

ZOOSANITARY CERTIFICATE FOR EXPORTATION OF SHEEP FOR IMMEDIATE SLAUGHTERING

Certificate No._____

Date issued _____

Expiration date _____

I – ORIGIN

State Party _____

Province, State, Department _____

Establishment of origin _____

Address _____

Exporter _____

Address _____

II – DESTINATION

State Party _____

Province, State, Department _____

Establishment of origin _____

Address _____

Importer _____

Address _____

III – TRANSPORTATION

Means of transportation _____

Exit point _____

IV – ANIMALS' IDENTIFICATION

No. of animals Breed Age Observations _____

Males _____

Females _____

V – ANIMALS' IDENTIFICATION

Total No. of animals _____

No. by order _____

Identification Nº. (*) _____

Breed _____

Gender _____

Age (*) _____

OBSERVATIONS

1 _____

2 _____

3 _____

4 _____

5 _____

6 _____

7 _____

8 _____

9 _____

10 _____

11 _____

12 _____

13 _____

14 _____

15 _____

16 _____

17 _____

18 _____

(*) As applicable

Note: This page may be replaced by a list signed by the official veterinary and attached to the certificate.

VI – SANITARY INFORMATION

The undersigned official veterinary certifies that:

1. The State Party is in compliance with the conditions set forth under Art. 9 of Annex I to GMC Resolution No. 51/01 on "Zoosanitary Requirements and Certificates for Ovine Animals Trade among Mercosur State Parties."

2. The animals were born and raised in the State Party of origin or zone thereof or have stayed in another State Party or zone of similar sanitary status.

3. That as regards vesicular stomatitis, procedures were adopted in accordance with the provisions under the pertinent chapter of the OIE International Zoosanitary Code.

4. That as regards blue tongue, procedures were adopted in accordance with the provisions under the pertinent chapter of the OIE International Zoosanitary Code.

5. That as regards foot-and-mouth disease, procedures were adopted in accordance with the provisions under the pertinent chapter of the OIE International Zoosanitary Code.

6. That as regards caprine arthritis-encephalitis, procedures were adopted in accordance with the provisions under the pertinent chapter of the OIE International Zoosanitary Code.

7. That at the establishment of origin and/or quarantine, no case of transmissible diseases occurred in the 90 (ninety) days prior to shipment.

8. That the animals being exported are not discardable animals under any program on disease control and/or eradication under implementation in the State Party from which they are being exported.

9. That in respect of anabolyzing substances, the importing State Party's national regulations thereon shall prevail.

Oficial Data

OBSERVATIONS

Place and date _____ , _____/_____/_____

Official Stamp

Official veterinary's signature and stamp

VII. ANIMALS' SHIPMENT

The animals were checked at the time of shipment and showed no clinical signs of infectious diseases and were free of external parasites. The animals are being transported pursuant to current Mercosur norms.

SHIPMENT POINT _____

SEAL No.: _____ VEHICLE'S TAG No. _____

SEAL No.: _____ VEHICLE'S TAG No. _____

SEAL No.: _____ VEHICLE'S TAG No. _____

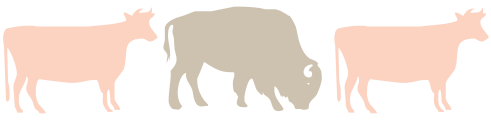
SEAL No.: _____ VEHICLE'S TAG No. _____

SEAL No.: _____ VEHICLE'S TAG No. _____

SEAL No.: _____ VEHICLE'S TAG No. _____

SEAL No.: _____ VEHICLE'S TAG No. _____

SEAL No.: _____ VEHICLE'S TAG No. _____



Place and date _____ , _____/_____/_____

Official Stamp

Official veterinary's signature and stamp

_____

NORMATIVE INSTRUCTION No. 31 OF MAY 10, 2002

Published in the Official Gazette of May 13, 2002 Section 1, Page 8

All pigs imported must be accompanied by a Zoosanitary Certificate warranting the compliance with the conditions required by the Ministry of Agriculture, Livestock and Food Supply of Brazil.

The SECRETARY OF ANIMAL AND PLANT HEALTH AND INSPECTION OF THE MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY, in the use of the powers given to him by the Article 83, incise IV of the Internal Rules of Procedure approved by the Ministerial Administrative Ruling 574 of December 8, 1998 and in view of the Ministerial Administrative Ruling 49 of March 11, 1987 and considering the need to harmonize the norms for importing pigs for reproduction from foreign countries, and also considering the content of the Process 21000.008029/2001-07, resolves:

Art. 1. All imported pigs must be accompanied by a Sanitary Certificate warranting the compliance with the conditions required by the Ministry of Agriculture, Livestock and Food Supply of Brazil.

Paragraph 1. The Sanitary Certificate must be issued in both the exporting country's official language and in Portuguese.

Paragraph 2. The exporting country must submit the certificate to the Ministry of Agriculture, Livestock and Food Supply of Brazil for previous approval.

Paragraph 3. The Sanitary Certificate of the imported animals to be supplied by the exporting party must contain the signature of an official veterinarian.

Paragraph 4. The Sanitary Certificate must contain the official seal and signature of the local Brazilian consulate excepting when, in accordance with existing bilateral agreement established by presidential decree, the exporting is free of this requirement.

Art. 2. A previous authorization from the Ministry of Agriculture, Livestock and Food Supply of Brazil is necessary for each import of pigs.

Sole Paragraph. The imported animals can only be transported by the route indicated by the above mentioned importing authorization.

Art. 3. All pigs to be exported to Brazil must be submitted to two quarantines: the first at their country of origin and the second when entering Brazil.

Paragraph 1. The quarantine at the country of origin is to take place under the supervision of the local Official Veterinary Service, on a site approved by that Service and will last no less than twenty-eight (28) days.

Paragraph 2. The quarantine at destination will take place under supervision of the Ministry of Agriculture, Livestock and Food Supply of Brazil on a site approved by the mentioned Ministry and will last no less than twenty eight (28) days.

Paragraph 3. The importing party will act as trustee of the heads of pigs during the quarantine in Brazil and it will be subject to the terms

of the Article 1265 and followers from the Brazil's Civil Code of Procedures.

Paragraph 4. The quarantine will only end and the animals will only be allowed to be taken away through an official authorization from the Ministry of Agriculture, Livestock and Food Supply of Brazil.

Art. 4. All pigs to be exported to Brazil will be submitted to all the diagnostic tests required by the Ministry of the Agriculture, Livestock and Food Supply of Brazil and these tests will take place during the origin and destination quarantines.

Paragraph 1. In case of any animal presenting a positive required diagnostic test at the country of origin quarantine, the entire lot in quarantine will have denied its export to Brazil.

Paragraph 2. In case of any animal presenting a positive required diagnostic test at the destination quarantine, the Ministry of the Agriculture, Livestock and Food Supply will act in agreement with the established in the Regulation of Animal Sanitary Health and Inspection and with all other complementary legislation.

Art. 5. The sampling for the diagnostic tests during the quarantine at the country of origin will be supervised by the Official Veterinarian Service of that country and, at the destination, by the Ministry of Agriculture, Livestock and Food Supply of Brazil.

Art. 6. The diagnostic tests required during quarantine at the country of origin will take place at a laboratory belonging to or accredited by the Official Veterinary Service of the exporting country and, on destination, at a laboratory belonging to or accredited by the Ministry of Agriculture, Livestock and Food Supply of Brazil.

Art. 7. The certification of country, zone or establishment free of a specific disease will be given in accordance with the International Animal Health Code from the World Organisation for Animal Health (OIE) or with criteria set by the Ministry of Agriculture, Livestock and Food Supply of Brazil.

Art. 8. The means for transporting the pigs must be clean and disinfected with products approved by the Official Veterinary Service of the exporting country.

Art. 9. A model of the health certificate for exporting pigs to Brazil is enclosed as Annex I of this Normative Instruction.

Art 10. The norms for the approval and functioning of the quarantine conditions for exporting pigs to Brazil are enclosed as Annex II of this Normative Instruction.

Art. 11. When necessary, the Animal Health and Inspection Department of the Ministry of Agriculture, Livestock and Food Supply of Brazil will issue complementary instructions to this Normative Instruction.

Art. 12. This Normative Instruction will be in force on its publication date.

LUIZ CARLOS DE OLIVEIRA

ANNEX 1

HEALTH CERTIFICATE FOR EXPORTING BREEDING PIGS TO BRAZIL

I. ANIMAL INDIVIDUAL IDENTIFICATION:

Animal number, breed, gender, age

II. ORIGIN:

Name and address of the source farm

Name and address of the exporting party

III. DESTINATION:

Name and address of the destination farm

Name and address of the importing party

IV. SANITARY INFORMATION

The Official Veterinary Service of the exporting country certifies that the swine above identified:

1. They are from a farm registered in the Official Veterinary Service of the exporting country and under the responsibility of a veterinarian accredited by the mentioned service.

2. They are from a country free of mouth-and-foot disease, swine vesicular disease, African

swine fever and rinderpest as determined by the International Animal Health Code of the OIE.

*** In case of foot-and-mouth disease, it is also accepted the certification of Free Zone as determined by the OIE or by the Ministry of Agriculture, Livestock and Food Supply of Brazil.

3. They are from a zone free of classical swine fever as determined by the International Animal Health Code of the OIE and recognized by the Ministry of Agriculture, Livestock and Food Supply of Brazil.

4. They are from farms free of brucellosis, tuberculosis and Aujeszky's disease as determined by the International Animal Health Code of the OIE and recognized by the Ministry of Agriculture, Livestock and Food Supply of Brazil.

5. They are from farms with no known clinical occurrence of vesicular stomatitis, theschovirus encephalomyelitis, transmissible gastroenteritis, swine influenza, porcine respiratory coronavirus, porcine epidemic diarrhea, atrophic rhinitis of swine, swine enzootic pneumonia (*Mycoplasma hyopneumoniae*), swine dysentery (*Brachyspira hyodysenteriae*) and pig reproductive and respiratory syndrome (PRRS), for at least 12 months before shipping.

*** If the exporting country is free from the diseases listed on items 3, 4, 5 and 6 or if it has zones free from diseases listed on items 4, 5 and 6, the mentioned country must obtain the pertinent accreditation from the Ministry of Agriculture, Livestock and Food Supply of Brazil.

6. They were, under official supervision, placed apart in a place approved by the Official Veterinary Service of the exporting country for a minimum period of twenty eight (28) days. In this occasion all animals were submitted to diagnostic tests with negative results for the diseases bellow mentioned:

6.1 Brucellosis – BBAT, ELISA or Complement Fixation Test;

6.2 Tuberculosis – Comparative Intradermal test with bovine and avian PPD and read 48 hours after inoculation;

6.3 Classical Swine Fever – ELISA;

6.4 Aujeszky's Disease – Virus Neutralization Test or ELISA;

6.5 Porcine Reproductive and Respiratory Syndrome (PRRS) – two ELISAs with a 21-day minimum interval;

6.6 Transmissible Gastroenteritis – Virus Neutralization Test or ELISA;

6.7 Theschovirus Encephalomyelitis – Virus Neutralization Test;

6.8 Leptospirosis – 1:100 microagglutination for *L. pomona, L. hardjo, L.wolfi, L. icterohaemorrhagiae, L. canicola, L. grippotyphosa, L. tarassovi, L. bratislava* e *L. ballum*

Or

They were submitted to two treatments with dihydrostreptomycin (25 mg/kg of live weight) fourteen (14) days apart within the twenty eight (28) days prior to shipping.

*** The condition of country, zone or farm free of a specific disease waives the making tests for that disease during the quarantine at the origin. In this case, the exporting country must obtain the recognition of that condition from the Ministry of Agriculture, Livestock and Food Supply of Brazil.

7. They were treated against internal and external parasites with products approved by the Official Veterinary Service of the exporting country within a minimum of five (5) days before shipment.

*** The name of the product and the treatment date are to be informed.

8. They were free of clinical signs of any transmissible diseases and of external parasites on the shipping day.

9. They were taken directly from the source farm to the shipping place in a vehicle cleaned and disinfected with products approved by the Official Veterinary Service of the exporting country and had no contact whatsoever with animals in adverse sanitary condition.

- Official Stamp
- Site and date.
- Name and signature of the accredited veterinarian.

ANNEX II

NORMS FOR APPROVING AND OPERATING A QUARANTINE SITE FOR PIGS IN BRAZIL

ON THE CONSTRUCTION DESIGN

1. The design for a quarantine site must be submitted to the Ministry of Agriculture, Livestock and Food Supply;

1.1 Submit the blueprint of the site on a 1:200 minimum scale.

1.2 Submit a detailed description of all included facilities.

1.3 Submit the official technical opinion on the construction site from the party responsible for the applicable environmental policy

ON THE QUARANTINE SITE LOCATION

2. It must be located on an isolated area, far from the urban perimeter and respecting the following distances:

2.1. Eight hundred (800) meters away from commercial or subsistence swine farms;

2.2. Eight hundred (800) meters away from farms with other species of animals that may represent sanitary risks to domestic pigs;

2.3. Eight hundred (800) meters away from any public road and/or highway;

2.4. Two (2) kilometers away from swine slaughterhouses or any other species that may present diseases common to swine.

ON THE LEGAL ASPECTS

3. The sites for quarantining imported pigs must be registered at Brazil's National Inventory of Business Companies (CNPJ);

ON THE CONSTRUCTION

4. The quarantine site must be divided into physically apart different working areas and it must be provided of:

4.1 External fences around the quarantine specific facility with a distance between them of not less than ten (10) meters;

4.2 Only one gate for controlling the ins and outs of people and animals;

4.3 Shallow pools with disinfectant for shoes and tires at the main entrance;

4.4 An administrative office physically apart from any quarantine facility;

4.5 A canteen for the meals of the employees;

4.6 Restrooms away from the quarantine facility;

4.7 Dressing rooms with a room for the incoming employees to leave their belongings; another for them to dress for work and a rest room between the two.

4.8 A laundry for washing the clothes of the employees working in the quarantine area;

4.9 Bays with enough capacity to accommodate the pigs;

4.10 A deposit of swine feed;

4.11 A cesspool within the specifications of the pertinent environmental authorities;

ON THE WATER QUALITY

5. The water to be used in the quarantine site must come from known source, not from natural courses; its tank must be kept protected and be clean and disinfected at least every six months.

ON THE EFFLUENT TREATMENT

6. It must be done in accordance with all applicable environmental and sanitary norms;

ON THE TECHNICAL RESPONSIBILITY

7. All swine quarantine sites must have a dully accredited veterinarian as its technical responsible;

7.1 The veterinarian in charge is liable for all activities carried out in the quarantine site;

7.2 One (1) veterinarian can only be responsible for one (1) approved swine quarantine site;

7.3 During the quarantine time, the responsible veterinarian will work full time in the quarantine site, no other job being allowed.

ON THE TESTS PERFORMED DURING QUARANTINE

8. During their quarantine, the animals will be tested for the following diseases:

8.1 Brucellosis: BBAT, ELISA or Complement Fixation Test;

8.2 Tuberculosis: Comparative Intradermal test with bovine and avian PPD and read forty-eight (48) hours after inoculation;

8.3 Classical Swine Fever: ELISA;

8.4 Aujeszky's Disease: Virus neutralization test or ELISA;

8.5 Porcine Reproductive and Respiratory Syndrome (PRRS): ELISA;

8.6 Transmissible Gastroenteritis: Virus neutralization test or ELISA;

8.7 Theschovirus Encephalomyelitis: Virus neutralization test;

8.8 Leptospirosis: 1:100 microagglutination for *L. pomona, L. hardjo, L.wolfi, L. icterohaemorrhagiae, L. canicola, L. grippotyphosa, L. tarassovi, L. bratislava e L. ballum.*

9. The imported animals destined to farms certified by the Ministry of Agriculture, Livestock and Food Supply of Brazil as free of atrophic rhinitis of swine, enzootic pneumonia (*Mycoplasma hyopneumoniae*), swine contagious pleuropneumonia (*Actinobacillus pleuropneumoniae*) and swine dysentery (*Brachyspira hyodysenteriae*), will be submitted to diagnostic tests for these diseases during their quarantine in accordance with the SDA Normative Instruction 19 of February 15, 2002.

ON THE SAMPLING AND SENDING MATERIAL FOR LABORATORY

10. The official veterinarian is responsible for supervising the sampling and shipping of material to the laboratory for diagnosing the diseases as required by the Ministry of Agriculture, Livestock and Food Supply.

ON CONTROLLING PERSONNEL AND VISITS

11. All movements of personnel in the quarantine area will obey the bio-safety criteria; visits of people foreign to the site are absolutely prohibited without previous authorization from the Ministry of Agriculture, Livestock and Food Supply of Brazil.

ON DISCARDING MATERIAL

12. The death of any animal during quarantine must be immediately communicated to the Ministry of Agriculture, Livestock and Food Supply, which will supervise the appropriate necropsy and sample material for lab work. The dead animals will be incinerated or submitted to any other method of sanitary discard as decided by the Official Service.

ON CONTROLLING RODENTS AND INSECTS

13. The quarantine area must have an efficient system for controlling insects and rodents.

ON THE RELEASE OF PIGS TO THE FARM

14. The pigs will be released from quarantine only after authorization from the Ministry of Agriculture, Livestock and Food Supply.

OF THE DOWNTIME

15. After the exit of the animals, the quarantine site will be submitted to downtime for a period of ten (10) days, counted from the date of the disinfecting measures.

COMPLEMENTARY LEGISLATION

NORMATIVE INSTRUCTION No. 12 OF APRIL 18, 2007

Published in the Official Gazette of April 20, 2007 Section 1, Page 15

Approves sanitary requirements pertaining to females receiving bovine embryos collected in vivo in and regularly imported from the Republic of India, as well as quarantine conditions prior to transfer.

NORMATIVE INSTRUCTION No. 32 OF JULY 11, 2007

Published in the Official Gazette of July 12, 2007 Section 1, Page 8

Modifies Normative Instruction No. 6 of February 13, 2006.

NORMATIVE INSTRUCTION No. 6 OF FEBRUARY 13, 2006

Published in the Official Gazette of February 14, 2007 Section 1, Page 14

Modified by Normative Instruction No. 32 of July 11, 2007.

Approves sanitary requirements and technological procedures for the importation – and for the transfer to receiving females on the national territory – of bovine embryos collected in vivo in and imported from the Republic of India.

NORMATIVE INSTRUCTION No. 60 OF NOVEMBER 6, 2002

Published in the Official Gazette of November 17, 2002 Section 1, Page 7

Permits the importation of fertile ostrich eggs only from countries qualified by Brazil's Ministry of Agriculture, Livestock, and Food Supply-MAPA and from raising establishments recognized by the exporting country's Official Veterinary Services and by MAPA.

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Pan-American Foot-and-Mouth Disease Center-PANAFTOSA
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Fax: ++ 55 (21) 3661-9001
http://www.panaftosa.org.br

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Animal and Plant Health and Inspection Secretariat

Ministry of Agriculture, Livestock and Food Supply

BRASIL UM PAÍS DE TODOS GOVERNO FEDERAL

Pan-American Health Organization
Regional Office of the World Health Organization
Veterinary Public Health
PANAFTOSA - PAHO/WHO