

Presidency of the Republic
Chief of Staff's Office
Sub-Office for Legal Matters

DECREE Nº 5,741 ENACTED MARCH 30, 2006.

Regulates articles 27-A, 28-A and 29-A of Law 8,171 of January 17, 1991, that organizes the Unified Animal and Plant Health System, among other provisions.

THE PRESIDENT OF THE REPUBLIC, exercising the powers conferred upon him by Article 84, paragraphs IV and VI, line "a", of the Constitution, and pursuant to what is set forth in articles 27-A, 28-A and 29-A of Law 8,171 of January 17, 1991,

DECREES:

Article 1. In the Appendix to this Decree, the Regulation of the following Articles is approved: 27-A, 28-A and 29-A of Law 8,171 of January 17, 1991.

Article 2. The Minister for Agriculture, Livestock and Food Supply will draft the supplementary acts and norms provided for in the herein approved Regulation.

Article 2. The Minister for Agriculture, Livestock and Food Supply will draft the supplementary acts and norms provided for in the herein approved Regulation. (In the wording of Decree 6,348/2008)

Article. 3 This Decree shall come into force as of the date of its publication.

Brasília, March 30, 2006, 185th year of Independence and 118th year of the Republic.

LUIZ INÁCIO LULA DA SILVA

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This text does not replace the text published in the Official Gazette (DOU) of 31.3.2006.

APPENDIX

REGULATION OF ARTICLES 27-A, 28-A and 29-A of Law 8,171 of January 17, 1991.

CHAPTER I
PRELIMINARY PROVISIONS

Article 1. These Regulations establish the Unified Animal and Plant Health System.

Paragraph 1 – The following parties will participate in the Unified Animal And Plant Health System:

I – Official services and institutions;

II – farmers and rural workers, their respective associations and professionals who assist them;

III – inspection agencies of the professional categories directly linked to animal and plant health; and

IV – entities managing the funds organized by the private sector in order to supplement public action in the field of animal and plant health.

Paragraph 2. The Unified Animal and Plant Health System works according to the principles and definitions of animal and plant health; this includes health, inspection, auditing, and education activities; and animal, plant, input and animal and plant product surveillance.

§ 3 The Unified Animal and Plant Health System shall permanently carry out the following activities:

I – Plant health surveillance;

II – Animal health surveillance;

- III – Inspection and classification of plant products and byproducts, including residues of economic value;
- IV – Inspection and classification of animal products and byproducts, including residues of economic value; and
- V – Inspection of inputs and services used in agricultural activities.

§ 4 The Unified Animal and Plant Health System shall liaise with the Single Health System (Sistema Único de Saúde) whenever and wherever relevant to public health.

Section I Principles and General Obligations

Article 2. The rules and processes of the Unified Animal and Plant Health System contain principles to be followed in animal and plant health, above all those principles concerning the responsibilities of growers, manufacturers and the competent authorities, with the structural and operational requirements of animal and plant health.

Paragraph 1. The general and specific rules of the Unified Animal and Plant Health System aim to assure the protection of the health of animals and plant, the suitability of the inputs and services used in agriculture and animal raising, and the identity, quality and technological, hygienic and sanitary security of the final animal and plant products for consumption.

Paragraph 2. The Unified Animal and Plant Health System operates in an integrated fashion to assure animal and plant health from the primary production location to the placement of the final product on the domestic market or the export market.

Paragraph 3. Producers—both rural and industrial; and the suppliers of inputs, distributors, cooperative and associations—both industrial and agri-industrial; wholesalers and retailers, importers and exporters, entrepreneurs and any other agribusiness operator, throughout the production chain, must assure the health and quality of animal and plant products, and guarantee that the quality and health of agricultural and animal raising inputs should not be compromised.

Paragraph 4. The performance of official controls as set forth in the Regulation does not exempt parties of the production chain from their legal and moral responsibility to assure the health of animals and plants, the security, quality and identity of animal and plant products, and of inputs; nor does it prevent the performance of further controls or exempt them from civil or penal liability resulting from the failure to comply with their responsibilities.

§ 5 Farmers and other participants in the production chain shall cooperate with the competent authorities to assure greater effectiveness of official controls and enhance animal and plant health.

§ 6 Health control processes will include the traceability of animal and plant products, and of agricultural and animal-raising inputs and their respective ingredients and raw materials, throughout the production chain.

§ 7 Supplementary animal and plant health norms deriving from this Regulation shall be based upon scientific knowledge.

§ 8 The import and export of animal and plants, and animal and plant products, of agricultural and animal-raising inputs and their respective ingredients and raw materials, shall comply with the provisions of this Regulation.

Paragraph 9. The Unified Animal and Plant Health System shall respect the regional specificities of products and different scales of production, including small-scale rural agribusiness. (Included by Decree 7,216/2010)

Art 3 The municipality is the basic geographical unit for organizing the Unified Animal and Plant Health System and for the operation of the official animal and plant health services.

Art 4 This Regulation applies to all phases of production, processing, distribution and of agricultural and animal-raising services, without affecting specific requisites to assure agricultural and animal-raising health and the quality, origin and identity of farming produce and inputs.

Art 5 Participants in the production chain are obliged to inform the competent authority, as the authority demands, concerning:

I – the names and characteristics of the establishments under their control, engaged in any of the phases of production, processing, distribution and farming services;

II – up-to-date information on the establishments, by notifying the authority of any significant change in activities, or of closure; and

III – any change in sanitary or phytosanitary conditions occurring on their establishment, production unit or property.

Article 6. The present Regulation defines the rules for participants in the Unified Animal and Plant Health System, and the norms for carrying out official controls to enforce farming health legislation and farming inputs and services legislation, taking the following factors into consideration:

I – guaranteed animal and plant health;

II – guaranteed health, quality and safety of animal and plant products throughout the production chain, beginning with primary production;

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

IV - the overall application of procedures based on the Hazard Analysis and Critical Control Points system (HACCP) and on risk analyses;

V – meeting microbiological criteria;

VI – ensuring that imported animals, plants, farming inputs and animal and plant products meet the same sanitary and quality standards as those demanded by Brazil, or equivalent standards;

VII – prevention, elimination or reduction of risks to acceptable levels;

VIII – compliance with animal and plant health norms;

IX – compliance with official sampling and analytical methods; and

X –meeting all other requirements laid down by agricultural and animal-raising health legislation.

Paragraph 1. The official sampling and analytical methods used as benchmarks shall be established by a specific norm.

§ 2 Until official sampling and analytical methods are specified, scientifically validated methods in line with recognized international rules and protocols may be used

Article 7. The Ministry of Agriculture, Livestock and Food Supply shall establish specific standards regarding animal and plant health to be observed: (In the wording of Decree 8,471/2015)

I - Rural production for the domestic preparation, handling or storage of farm produce for family consumption does not require registration, oversight and inspection; (In the wording of Decree 8,471 of 2015)

II – retail or bulk sale or supply of small quantities of primary production direct to the end consumer by the family farmer or small grower who produces the goods; and (In the wording of Decree 8,471 of 2015)

III - the agroindustrial processing performed by family agriculture or equivalent and their organizations, including the structural conditions and process control. (In the wording of Decree 8,471/2015)

Paragraph 1. The specific standards mentioned in the heading shall be edited within: (Included by Decree 8,471/2015)

I - Ninety days, in the case of item II of the heading; and (Added by Decree 8,471/2015)

II - one hundred and eighty days, in the case of item III of the heading. (Included by Decree 8,471/2015)

Paragraph 2. The specific standards set forth in this Article must observe the minimum risk of the spread of animal diseases, pests and microbiological and chemical agents that are harmful to public health and consumer interests. (Included by Decree 8,471/2015)

Article 7-A. The Ministry of Agriculture, Livestock and Food Supply may classify the agroindustrial establishments for beverages or animal products as an artisanal agroindustrial establishment, considering the traditional uses, habits and knowledge in order to value food diversity and culture of the people, traditional communities and family farmers. (Included by Decree 8,471/2015)

Article 8. This Regulation does not exempt citizens from meeting whatsoever official specific provisions unrelated to animal and plant health brought in by the Federal Government, State governments, the Federal District government, or municipalities

Sole paragraph. Among the Federal Government official controls mentioned in the heading are those concerning sanitary-hygiene controls laid down by the Single Health System—SUS.

CHAPTER II

UNIFIED ANIMAL AND PLANT HEALTH SYSTEM

Section I

Levels of Government

Article 9. Actions of the Unified Animal and Plant Health System shall be carried out at three Levels of Government: the Central and Higher Level; the Intermediate Level; and the Local Level

Paragraph 1. The Central and Higher Level of Government includes exclusive activities of the Federal Government: political, strategic, normative, coordinating, supervisory, auditing, and inspection activities, as well as operational activities if national or regional interest so determines.

Paragraph 2. Intermediate Level Agencies carry out activities furthering the strategic, normative, regulatory, coordinating and operational interests of the Federal Government, as well as those that pertain to the States of Brazil and the Federal district, within their respective fields of action, and pursuant to the terms of relevant federal, state or municipal regulations.

Paragraph 3. Local Level Agencies carry out activities that further the interests of the Federal Government, States, the Federal District or the Municipalities, within their fields of action, pursuant to the terms of relevant federal, state or municipal regulations.

Paragraph 4. Participants in the Unified Animal and Plant Health System shall strive to comply fully with specific legislation in effect, regulating animal and plant health actions, and the duties and commitments undertaken within international agreements.

§ 5 Control measures taken by the competent authorities are deemed to be direct measures of the Public Power

§ 6 Competent authorities within the three Levels of Government shall assure

I – the effectiveness and suitability of official controls at all stages of production chains;

II – that professionals carrying out official control activities shall be hired after taking part in public competitive exams;

III – that professionals carrying out official control activities shall have no conflicts of interest;

IV – that there are laboratories with a suitable capacity to carry out tests, employing sufficient numbers of suitably trained staff, and that there is access to such laboratories, thus enabling official controls to be carried out efficiently and effectively;

V – the availability, suitability and due maintenance of premises and equipment, so as to assure that staff can carry out official controls effectively and safely;

VI – that the necessary legal powers exist to carry out official controls and take the measures set forth in this Regulation; and

VII - that there are emergency and contingency plans, and that teams be trained to carry out these plans.

§ 7 The competent authorities at all three Levels of Government shall assure the impartiality, quality and coherence of the official controls

Article 10. The three Levels of Government shall ensure that official controls be carried out regularly, because of actual or potential animal and plant health risks, with sufficient frequency to achieve the goals of this Regulation, above all:

- I – Identified or related risks;
- II – the past history of those responsible for production or processing;
- III – Reliability of the self-controls carried out; and
- IV – signs of non-compliance with this Regulation or with specific legislation.

Article 11. At the discretion of the competent authority, official controls may be carried out at any stage in production, processing, storing, transport and distribution and shall encompass the whole domestic market as well as imports and exports.

Paragraph 1. The competent authorities of each Level shall verify compliance with the legislation by means of non-discriminating controls.

§ 2 In order to organize the official controls, the competent authorities of each Level shall request additional documents and information from producers about their products

§ 3 If any non-compliance is found during an official control carried out at the final destination, or during storage or transport, the competent authorities of each Level of Government shall take suitable measures

§ 4 Audits, inspections and supervisions shall be carried out without prior warning, except in specific cases where prior notification of the person responsible for the establishment or the services is mandatory

Article 12. Adjustment, formulation and amendments to animal and plant health norms shall comply with the provisions of this Regulation, to assure the continuous enhancement of the Unified Animal And Plant Health System.

Section II

The Central and Higher Level of Government

Article 13. The actions of the Central and Higher Level of Government are carried out by the Ministry of Agriculture, Livestock and Food Supply and its collegiate bodies, which are set up and disciplined by the National Council for Agricultural Policy, pursuant to the terms of Article 5 of Law no 8,171, of January 17, 1991

Paragraph 1. The National Council for Agricultural Policy shall assure that collegiate bodies include representatives of governments and civil society, making sure that they operate democratically and harmonize the interests of the federation and of all participants in the system, and approving the internal rules of the collegiate bodies.

§ 2 The Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level of Government, shall institutionalize the collegiate bodies within ninety days maximum after they have been set up by the National Council for Agricultural Policy

Paragraph 3. The Decentralized Units of the Ministry of Agriculture, Livestock and Food Supply—Federal Superintendencies of Agriculture, Livestock and Food Supply and the National Animal and Plant Laboratories—are part of the Central and Higher Level of Government.

§ 4 The Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level of Government, shall, within the deadline defined in § 2, set up Executive Committees to support the management of animal and plant health that is the responsibility of the Central and Higher Level of Government.

Article 14. The Central and Upper Jurisdiction of the Unified Animal And Plant Health System shall:

- I – Agricultural surveillance in ports, airports and international border inspection posts and special customs;
- II – establish norms for campaigns to control and eradicate plant pests and animal diseases;
- III – approve diagnostic methods and veterinary and agronomical products;
- IV – maintain the epidemiological information system;

V - regulate, regularize, introduce, implement, coordinate and assess health education activities for animal and plant health in the three Levels of Government of the Unified System;

VI - audit, supervise, assess and coordinate activities carried out at intermediate and local government levels;

VII – represent Brazil in international forums concerning animal and plant health;

VIII – carry out epidemiological studies to support the development of the Unified Animal And Plant Health System;

IX – Improvement of the Unified Animal And Plant Health System;

X – Technical cooperation with other levels within the Unified Animal And Plant Health System;

XI – maintenance of supplementary norms for animal and plant health; and

XII – performance and enablement of animal and plant health certification and surveillance activities, within the areas of its competence.

Article 15. The Ministry of Agriculture, Livestock and Food Supply, as the Central and Upper Jurisdiction of the Unified Animal And Plant Health System shall:

I – draft animal and plant health regulations governing the import and export of animals and plants, their parts, products and by-products, and organic materials, biological organisms and other articles that are regulated owing to the risk they represent for the introduction and spread of pests and diseases;

II - organize, conduct, draw up and ratify the risk analysis for pests and diseases pertaining to the import and export of products and raw materials;

III – promote the accreditation of collaborating centers;

IV – participate in the development of international standards to meet animal and plant health requirements, and develop risk analysis for pests and diseases;

V - manage, compile and systematize information about pest and disease risks; and

VI – carry out training activities focusing on pest and disease risks.

Article 16. The Ministry of Agriculture, Livestock and Food Supply, as the Central and Upper Jurisdiction of the Unified Animal And Plant Health System shall establish the operating standards including the detailed activities of the Unified Animal And Plant Health System under its authority.

Article 17. The States, the Federal District and Municipalities shall provide all information requested by the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level of Government.

Article 18. In order to operate and control the Unified Animal And Plant Health System, the Ministry of Agriculture, Livestock and Food Supply, as the Central and Upper Jurisdiction, shall:

I – Organize and define the relationship among the authorities of the Unified Animal And Plant Health System;

II – Establish the objectives and goals to be met;

III – Define the roles, responsibilities and duties of the staff;

IV – define sampling procedures; and define methods and techniques of control, interpretation of results, and decision-making stemming from this;

V – develop programs to follow up official controls and control by animal and plant health surveillance;

VI – provide mutual support when official controls demand intervention by more than one intermediate government level agency;

VII – cooperate with other services and departments that may have responsibilities in this sphere;

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

IX – carry out or encourage other activities and generate information that is necessary for the effective working of official controls.

Section III

The Intermediate Level of Government

Article 19. In every State of Brazil, the activities of the intermediate Level of government will be carried out by the Agency with a mandate or with a duty to carry out animal and plant health activities.

Paragraph 1. The activities of the Intermediate level agencies may be carried out by institutions appointed by the State Governments or by the Federal District, and may represent:

- I – Geographical regions;
- II – Groups of States or individual States or the Federal District;
- III – production hubs; and
- IV – a specific geographical region.

§ 2 The Intermediate Level shall appoint the competent authorities responsible for achieving the official objectives and controls set forth in this Regulation

Paragraph 3. When one of the Intermediate level agencies empowers an authority, or authorities, of another Intermediate Level Agency, or another institution, the Agency that delegated such power shall assure efficient and effective coordination among all the authorities involved.

Article 20. The Intermediate Jurisdictions of the Unified Animal And Plant Health System shall carry out the following activities:

- I – animal and plant surveillance for the interstate transport of animals and plants;
- II – coordination and carrying out of programs and campaigns to control and eradicate plant pests and animal diseases;
- III – updating of nosographic information;
- IV – coordination and execution of epidemiological activities;
- V - coordination and carrying out of health education programs, projects and activities in their field of action; and
- VI – control of the diagnostic network and the network of accredited health professionals.

Article 21. The Intermediate Level shall take necessary measures to guarantee that control processes be carried out in similar fashion in all Municipalities and Local Levels.

Paragraph 1. The competent authority of the destination State shall enforce compliance with legislation through non-discriminatory controls.

§ 2 If any non-compliance is discovered during a control being carried out at the destination, or during storage or transport, the Intermediate Level Agency shall take suitable action.

Article 22. The Intermediate Level shall coordinate and compile information on animal and plant health activities within its field of action.

Section IV

The Local Level of government

Article 23. The activities of the Local Level shall be performed by the local animal and plant health unit, which is linked to the Intermediate Level, as will be defined by the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level; this may encompass one or more basic geographical units, Municipalities, microregions, territory, association of Municipalities, consortium of Municipalities or other forms of association between Municipalities.

Paragraph 1. The Local Level shall devote its full attention, in its own jurisdiction, to animal and plant health, with participation by organized society; this involves the following activities:

- I - registry of farms;
- II – inventory of animal and plant populations;
- III – control of animal and plant movements;
- IV – registry of health professionals;
- V – performance of animal and plant health education programs, projects and activities within its sphere of action;
- VI – registry of establishments selling products for agronomical and veterinary use;

VII – registry of laboratories for the diagnosis of diseases;

VIII – inventory of diagnosed diseases and pests;

IX – execution of disease and pest control campaigns;

X – health education and surveillance;

XI – participation in disease and pest eradication projects; and

XII – participation in disease and pest eradication programs.

§ 2 The Local Level Agencies shall appoint the competent authorities that shall be responsible for achieving the official objectives and controls set forth in this Regulation

Article 24. The Local Level may have more than one unit to serve the community and farmers with regard to animal and plant health.

Article 25. The Local level agencies, represented by their offices in the community and by the local units for animal and plant health, are the agencies that are to be notified of events pertaining to animal and plant health.

CHAPTER III

PROCEDURES OF THE LEVELS OF GOVERNMENT OF THE UNIFIED ANIMAL AND PLANT HEALTH SYSTEM

Section I

Eradication and Control of Pests and Diseases

Article 26. Policies and strategies to promote animal and plant health and surveillance shall be ecosystem-wide and decentralized by health problem in order to encompass pest- and disease-free areas, as provided for in international agreements and treaties to which Brazil is a signatory.

Paragraph 1. Whenever epidemiologically necessary, the eradication of diseases and pests is a priority in a free-area strategy.

Paragraph 2. If it proves impossible to carry out eradication, programs shall be carried out for prevention, control and animal and plant health surveillance to contain the disease or pest in order to obtain recognition as a low-prevalence area, or in order to set up a risk-mitigation system.

Article 27. A contingency or emergency plan, suitable to the role of every Level of Government within the System, shall be adopted in all relevant cases.

Article 28. National or regional campaigns for prevention, control and eradication shall be compatible with the goal of recognition as an area, compartment, zone or location that is free or with low prevalence of the pest or disease.

Article 29. The Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall set up and keep up-to-date the animal and plant health requirements for domestic and international transport of animals and plants, their parts, animal or plant products and by-products, economically valuable residues, biological organisms and other regulated products and articles that could serve as a substrate, culture medium, vector or vehicle for the spread of pests or diseases.

Article 30. The Intermediate and Local Levels shall introduce a detection system to give warning of direct or indirect risks to animal and plant health, and for the exchange of information that will enable rapid and accurate risk assessment and management by the members of the Unified Animal and Plant Health System.

Article 31. The Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall control mechanisms to enable the participation of consortia of public and private agencies, institutions and funds to implement shared animal and plant health policy so as to assure greater integration of a micro-region into regional, domestic, and international markets.

Article 32. The three Levels of Government in the Unified Animal and Plant Health System shall develop mechanisms to mobilize, articulate and organize the local community in formulating, implementing and assessing animal and plant health policies.

Article 33. The Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall draw up contingency, control and emergency plans for major pests and diseases, and set up National Animal and Plant Health Emergency Groups as institutions.

Paragraph 1. These contingency, control and emergency plans for major pests and diseases shall be drawn up preventively and are a priority for the three Levels.

Paragraph 2. The Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall coordinate the National Animal and Plant Health Emergency Groups and shall define norms in order to establish and run them, as well as their capacity-building programs, training programs, hierarchies and specific competencies.

§ 3 The National Animal and Plant Health Emergency Groups shall be set up preferentially by type of animal or plant health problem

Paragraph 4. To enable the National Animal and Plant Health Emergency Groups to work properly, the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall guarantee the existence of minimally-staffed teams that are permanently trained, with the capacity to work in animal and plant health emergency actions.

§ 5 The National Animal and Plant Health Emergency Groups can receive help from specialized technical teams as defined by the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level

Article 34. The Intermediate Level Agencies shall set up and coordinate State or Regional Animal and Plant Health Emergency Groups.

Sole paragraph. For the State or Regional Animal and Plant Health Emergency Groups to work properly, they must be recognized by the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level.

Article 35. The National, State or Regional Animal and Plant Health Emergency Groups shall work as operational and auxiliary agencies aiding the competent authorities in their activities, with the support of the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, and shall work as task forces.

Paragraph 1. The National, State or Regional Animal and Plant Health Emergency Groups shall begin field operations upon the declaration of a state of animal or plant health alert or emergency, as defined by the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level.

Paragraph 2. The National, State or Regional Animal and Plant Health Emergency Groups shall permanently stand by and keep themselves in a state of readiness, regardless of whether or not a state of emergency is declared, and shall be able to carry out the recommended preventive and corrective actions to contain the animal or plant health. incident

Article 36. Training and capacity-building programs for the National, State or Regional Animal and Plant Health Emergency Groups shall be coordinated by the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, taking into consideration the contingency, control and emergency plans.

Section II Animal Health

Article 37. The Unified Animal and Plant Health System shall maintain animal health promotion services as well as services to prevent, control and eradicate diseases that harm animal production, hurt the economy and affect animal and plant health; and will carry out the following activities, in accordance with the legislation currently in force, and respecting the duties of each level of agency within the System.

I – risk evaluation and transport controls for animals, animal products and by-products, and merchandise that can be a substrate, culture medium, vector or vehicle for diseases;

II – draft policies, norms and guidelines for disease prevention, control and eradication programs, in order to establish a free or a controlled area;

III – schedule, coordinate and implement animal health actions, particularly in order to define the sanitary requirements to be observed in the transportation of animals, animal products, by-products and derivatives;

IV – draft contingency, control and emergency plans for diseases of impact, defining which authorities will intervene, their respective powers and duties, and the channels and procedures involved in the exchange of information between them;

V – plan, coordinate and implement an animal health information system and corresponding database, in order to facilitate the coordination of activities, the exchange of information, and the drafting and execution of shared projects;

VI - plan, coordinate and carry out epidemiological studies for diseases of interest in animal health;

VII – conduct studies and analyses of animal health data and the corresponding epidemiological investigations, in order to inform the planning, assessment and control activities pertaining to health programs and the strategies for the development of national animal health policy;

VIII – schedule, coordinate and execute the inspection of the transportation of animals, veterinary products, animal breeding materials, products for animal feeding, products and by-products of animal origin, as well as enforce the health requirements to be observed in importing and exporting;

IX – plan, coordinate and carry out actions concerning animal quarantine and the respective quarantine establishments;

X - plan, coordinate and carry out actions concerning the staging of exhibitions, fairs, auctions and other gatherings of animals;

XI – establish control procedures, including audits, at any jurisdictional Level of the Unified Animal and Plant Health System, to help animal health management, the supervision of activities and planning reviews;

XII – in tandem with the international animal and plant surveillance system, select and prepare specific points of entry to Brazil of imported animals and animal products that require notification before arrival, given their associated risks; assure access to control premises, storage places, suitable places for quarantine and the presence of a support laboratory;

XIII – liaise with the network of approved, official, and accredited laboratories in activities related to animal health so as to raise the quality and consistency of results; and

XIV – coordinate the animal health warning system to give warning of risks to animal health and to provide information facilitating rapid and suitable action to manage the risks.

Sole paragraph. The import of animals; animal products and by-products and economically valuable residues; material for animal breeding; animal organs, tissues and cells; shall all comply with principles defined through risk analysis and with procedures laid down by the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level

Section III

Plant Health

Article 38. The Unified Animal and Plant Health System shall maintain plant health promotion services as well as services to prevent, control and eradicate pests that harm plant production, hurt the economy and affect animal and plant health; and will carry out the following activities, in accordance with the legislation currently in force, and respecting the duties of each Agency at all Levels of the System:

I - risk evaluation and transport controls for plants, plant products and by-products, residues, organic material and biological organisms, and any other products, inputs or merchandise that can serve as a substrate, culture medium, vector or vehicle for pests;

II – draft policies, norms and guidelines for the prevention, control and eradication of pests in order to eradicate them or establish a free area, free location, low-prevalence area or risk mitigation system for regulated pests;

III – schedule, coordinate and implement phytosanitary surveillance actions, particularly in order to define requirements to be observed in the transportation of plants, products, by-products, residues, organic material and biological organisms, and any other products, inputs or merchandise that can serve as a substrate, culture medium, vector or vehicle for pests;

IV - draft contingency, control and emergency plans for regulated pests, defining which administrative authorities will intervene, their respective powers and duties, and the channels and procedures involved in the exchange of information between them;

V – plan, coordinate and implement an animal health information system and corresponding database, in order to facilitate the coordination of activities, the exchange of information, and the drafting and execution of shared projects;

VI – establish phytosanitary requirements for authorizing the import and export of plants, plant products and by-products and any other item regulated for commercial, scientific, cultural and diplomatic purposes;

VII - conduct studies and analyses of phytosanitary data and the corresponding epidemiological investigations, in order to inform planning, assessment and control activities pertaining to health programs and the strategies for the development of national plant health policy;

VIII - schedule, coordinate and execute the inspection of the transportation of plants, plant products and by-products, residues, organic material, material for propagation and multiplication, biological organisms and any other products, inputs or merchandise that can serve as a substrate, culture medium, vector or vehicle for pests, as well as enforce the phytosanitary requirements to be observed in importing and exporting;

IX - plan, coordinate and carry out actions concerning plant quarantine and the respective plant quarantine establishments;

X - establish control procedures, including audits, in any Agency of the Unified Animal and Plant Health System, to help plant health management, the supervision of activities and planning reviews;

XI - in tandem with the international animal and plant surveillance system to select and train specific points of entry to Brazil of imported plants and plant products that require notification before arrival, given their associated risks; access to control premises, storage places, the suitable places for quarantine and the presence of a support laboratory;

XII - liaise with the network of approved, official, and accredited laboratories in activities related to plant health so as to raise the quality and consistency of results;

XIII – regulate criteria and guidelines for rendering services relating to phytosanitary treatments and quarantine by approved companies, collaborating centers and quarantine stations, pursuant to current legislation; and

XIV - coordinate the plant health warning system to give warning of risks to plant health and the environment, and to provide information facilitating rapid and suitable action to manage the risks.

Sole paragraph. The import of plants, plant products and derivatives, by-products and economically valuable residues, and of organic material, biological material, and plant reproduction material, will comply with principles defined through risk analysis and with procedures laid down by the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level

Section IV

Health Education

Article 39. Health education is a strategic action and an instrument of animal and plant health in the Unified Animal and Plant Health System, to assure the commitment of participants all along the farm production chain and of society as a whole to meeting the objectives of this Regulation.

Paragraph 1. For the purposes of this Regulation, health education for animal and plant health is understood to be an active on-going process using means, methods and techniques to educate and develop a critical awareness in the target audience.

The three Levels of Government of the Unified Animal and Plant Health System shall have an organized structure for their animal and plant health activities

§ 3 The three Levels will be able to support health education activities carried out by public and private services, institutions and organizations

Article 40. The Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, will continuously, and in tandem with the other Levels and with the Brazilian Agricultural Produce and Inputs Inspection Systems, manage health education plans, programs and activities for animal and plant health.

Paragraph 1. The Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall bring in, regulate, coordinate and periodically assess the National Animal and Plant Health Education Program.

§ 2 The National Program shall have the following guidelines, among others

I – to promote the understanding and enforcement of the animal and plant health legislation;

II – to promote health education courses;

III – to train disseminators of knowledge;

IV – to promote the exchange of experience; and

V – to use means of communication as an instrument of information and education.

Article 41. The Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall support health education for animal and plant health given by public and private participants in the animal and plant production chain and by society at large, and by teaching and research institutions, provided that they are in line with what the National Animal and Plant Health Education Program sets forth.

Section V

Laboratory Management

Article 42. The competent authorities within each Level of the Unified Animal and Plant Health System shall appoint accredited laboratories for the analysis of official control samples, in the manner defined by the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level.

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

Paragraph 2. The National Animal and Plant Laboratories and accredited public and private laboratories make up the National Network of Animal and Plant Laboratories of the Unified Animal and Plant Health System, coordinated by the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level.

§ 3 The Laboratories shall be organized in a network with a regionalized hierarchy; the structure shall be based upon

I – the level of complexity of the laboratory facilities;

II – the epidemiological, health, demographic and geographical criteria that guide the demarcation of their territorial catchment areas; and

III – activities within their respective jurisdictions.

Paragraph 4. Accreditation of laboratories shall meet the demand for analyses or tests, groups of analyses of specific specimens, as per criteria defined by the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level.

Paragraph 5. Any competent authority of the three Levels of the Unified Animal and Plant Health System that has accredited a given laboratory may, at any moment, cancel the accreditation when it fails to meet criteria laid down in the accreditation system.

Paragraph 6. Any laboratory, whether public or private, once accredited by one of the three Levels of the Unified Animal and Plant Health System, may be designated a reference laboratory, in one or more scopes, if it meets the necessary requirements.

Paragraph 7. The Intermediate Level, when designating a laboratory to be a reference laboratory, for a specific scope, to operate in its sphere of competence, shall follow a documented procedure to verify compliance with the criteria defined by this Level, in order to formally acknowledge and accept the analytical competence of this laboratory.

§ 8 The Intermediate and Local Levels of Government may institute technical cooperation agreements with reference laboratories in other States of Brazil

Article 43. No hazardous pathogenic organism may be handled without the existence of a laboratory with the requisite level of biosecurity or without the prior authorization of the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level.

Section VI

Agricultural Transportation

Article 44. Animals and plants, and their products and by-products as well as any other derived matter, and farm implements and equipment, when transported in Brazil or internationally, by whatsoever means of transport, must be inspected to assess animal and plant health conditions and the accompanying transport documentation.

Paragraph 1. All Levels of the Unified Animal and Plant Health System Uniform shall apply uniform procedures for inspection and health controls in the domestic and international transportation of animals, plants, inputs, animal feed, and animal and plant products, and farm implements and equipment, under the terms of this Regulation.

Paragraph 2. Authorities responsible for domestic and international air transportation, international shipping and Brazilian coastal shipping, railroads, waterways, and highways, are to guarantee animal and plant health inspection teams of access to passenger embarkation and disembarkation areas and to cargo receiving and dispatch areas.

Paragraph 3. The Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall define the norms for, and coordinate the inspection of, domestic and international transportation by whatever means of animals and plants, animal and plant products and by-products or any other material deriving from animals and plants.

Paragraph 4. The Intermediate Levels of the Unified Animal and Plant Health System shall work in the inspection of interstate transportation of animals and plants as per norms laid down by the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level.

§ 5 The Intermediate level agencies shall regulate and coordinate animal and plant health inspection of transportation between and within municipalities, based on norms laid down by the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level

§ 6 Local level agencies of the Unified Animal and Plant Health System shall work in animal and plant health inspections within their spheres of operation.

Paragraph 7. Local level agencies of the Unified Animal and Plant Health System shall regulate and coordinate transportation within municipalities, based on norms laid down by the Intermediate Level agencies and by the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level.

Article 45. Among other measures, inspection of domestic and international transportation shall include the demand to be shown official animal and plant health documentation issued by the corresponding service, and which shall contain an indication of the origin and destination, the purpose, and any further legal demands.

Section VII

Surveillance of the Interstate Transportation of Agricultural Products

Article 46. Technical criteria classifying or categorizing the risk of spread and introduction of regulated pests and diseases, by Brazilian State or geographical region, to guide the inspection of interstate transportation, shall be defined by the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, based on the following factors

- I – specific epidemiological characteristics of pests and diseases;
- II – record of the occurrence of cases or outbreaks of these pests or diseases;
- III - record of non-conformities found in transportation inspections;
- IV – definition of the geographical area in the program, to which the classification or categorization applies;
- V – assessment of animal or plant health status of the geographical areas to be classified or categorized, and their borders;
- VI – the structure, working and performance of programs for prevention, eradication and control of pests and diseases;
- VII – the organization of the animal and plant health surveillance system;
- VIII – the condition and efficiency of animal and plant transportation inspection; and
- IX – the degree of interconnection of institutional support structures including the laboratory network.

Article 47. The planning of actions and the carrying out of animal and plant health measures for each disease or pest, and the definition of transportation control norms for plants and animals and their products, as well as for any other product or merchandise, shall be based upon the risk classification or category defined by the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level.

Article 48. At the discretion of the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, transportation routes and specific entry and exit points shall be defined for animals, plants, basic products and other regulated articles that may serve as a vector or vehicle for the spread or dispersion of a given pest or disease.

Paragraph 1. The Intermediate level Agencies, in close collaboration with other institutions whenever necessary, shall set up fixed or mobile interstate or inter-regional animal and plant health inspection posts in order to inspect transportation; this includes measures such as mechanisms for the interception and exclusion of diseases and pests, and the destruction of seized material.

Paragraph 2. When pests and diseases, or vectors or vehicles for pests or diseases with a high risk of spreading are detected, the infested material shall be immediately destroyed or eliminated, as laid down in a specific norm.

Paragraph 3. The Agencies responsible for transportation control, within their field of operation, shall identify and notify the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, of places and premises intended for inspection, disinfection, disinfestation, destruction or elimination of seized material.

Article 49. The competent authorities of Local and Intermediate Levels of Government, when controlling animal and plant transportation, shall verify compliance with the requirements laid down in this Regulation and in other relevant normative acts.

Paragraph 1. The competent authority of the Intermediate level shall organize its operations and those of the Local level of government, based on the pluriannual plans drafted under the terms of this Regulation and based on the hazard categorization or classification.

§ 2 Controls shall encompass all aspects of health legislation for animals, plants, inputs, including animal feed, and animal and plant products

Paragraph 3. Controls shall be carried out on all routes for the transportation of plants, animals, their products and any other products, merchandise, agricultural implements and equipment that may act as a vector or vehicle for the spread of pests or diseases.

§ 4 Civil servants employed by Intermediate level Agencies, in accordance with what is laid down in § 6 of Article 9 of this Regulation, shall be the competent authorities for the inspection of the transportation of plants, animals, their products and any other products, merchandise, agricultural implements and equipment that may act as a vector or vehicle for the spread of pests or diseases, when circulating between States of Brazil.

Article 50. Official animal and plant health controls include, at the discretion of the competent authority, control of documentation, control of origin, physical control, as per the norm defined by the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level.

Paragraph 1. The frequency and nature of these controls will be defined through specific norms brought in by the three levels of government.

§ 2 The frequency of physical controls will depend on:

I – the hazards posed by the animals, plants, inputs including animal feed, and the animal and plant products;

II – the preceding record of compliance with the requirements applicable to the product in question; and

III – controls carried out by the producers of the animals, plants, inputs including animal feed, and the animal and plant products.

§ 3 Samples collected by transport inspection shall be handled in such a way as to guarantee analytical validity

Article 51. The Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level of Government, shall define and disseminate a list of animal and plant products that are at risk for pests and diseases, and that require control measures and prior notification of transportation between the Agency of origin and the Agency of destination.

Sole paragraph. Agencies responsible for the administration of animal and plant health inspection barriers shall assure minimum operating standards for animal and plant health surveillance of transportation between States of Brazil, between municipalities, and within municipalities.

Article 52. When there are signs of non-compliance with the legislation or queries as to the identity or destination of the load, consignment or production batch, or about the match between the load, consignment or production batch and their respective certified guarantees, the competent authority at the animal and plant health inspection barriers may hold the consignment or batch until queries or signs have been eliminated.

Paragraph 1. The competent authority shall officially detain all transported animals, plants, inputs including animal feed, and animal and plant products that fail to comply with the requirements of the legislation.

§ 2 The competent authority shall officially notify those responsible for the consignment of the non-conformity that has been found; appeal may be made, as per the specific norm for such case

§ 3 The competent authority, at its discretion, shall take the following measures

I – order the animals, plants, inputs including animal feed, animal and plant products to be subjected to special treatment or to be quarantined, returned, slaughtered or destroyed; and

II – direct the animals, plants, inputs including animal feed, and animal and plant products to other purposes than those for which they were originally intended, depending on the specific associated risk.

§ 4 in the case of agricultural equipment and implements that could spread diseases and pests, the competent authority shall make their release dependent upon disinfection or disinfestation

Paragraph 5. When non-conformities are found, the competent authority shall notify the other Agencies involved and provide information that is defined by specific norms issued by the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level.

§ 6 The competent authority shall assure that special treatment and quarantine are carried out in conformity with the conditions laid down in this Regulation and in the specific applicable norms

§ 7 The maximum period during which a load or consignment may be detained for animal and plant health inspection reasons shall be fifteen (15) days

§ 8 The period referred to in § 7 may be extended at the discretion of the competent authority, in cases provided for in specific norms

§ 9 Upon completion of the fifteen-day period, if re-consignment has not occurred, unless there is a justified delay, the consignment shall be returned, slaughtered or destroyed

Article 53. The competent authority shall notify the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, of its decisions, preferably by means of the official electronic service.

Article 54. Those responsible for hiring the transportation services, as well as the transporter of animals, plants, inputs including animal feed, animal and plant products, agricultural equipment and implements, shall be liable for expenses incurred as a result of the decisions of the competent authorities.

Section VIII

Surveillance of the International Transportation of Agricultural Products

Article 55. Animal and plant health surveillance of animals, plants, inputs including animal feed, animal and plant products, packaging and wooden casing, whether imported, in transit through Brazil, or exported, falls exclusively to 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 of international animal and plant health surveillance.

Paragraph 2. The Ministry of Agriculture, Livestock and Food Supply shall set up the management committee of the international animal and plant health surveillance system and the sub-committees of the international animal and plant health surveillance system in international airports, organized ports, border posts and special customs posts, and these shall act as advisory bodies alongside the competent authorities.

Paragraph 3. The Federal Agricultural Inspectors (Official Veterinarians) are the competent authorities working in the field of animal and plant health inspection for import, export and customs clearance of animals, plants, inputs including animal feed, and animal and plant products.

Paragraph 4. The general norms of international animal and plant health surveillance laid down in this Regulation and in specific legislation are applicable to official controls of imported and exported animals, plants, inputs including animal feed, and animal and plant products.

§ 5 Official controls shall encompass all aspects of animal and plant health legislation for animals, plants, inputs including animal feed, and animal and plant products

Paragraph 6. Official controls shall be carried out in places defined by the Ministry of Agriculture, Livestock and Food Supply, including points of merchandise entry to, and exit from, Brazil; cold stores; production facilities; under customs regimes or as free zones, special cold stores; special re-export facilities; or other points along the production-distribution chain, including re-embarkation points.

Article 56. The Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall define the primary zones for animal and plant health, and establish import and export corridors for animals, plants, inputs including animal feed, animal and plant products, based on risk-analyses, health requirements and controls, animal and plant health status, geographical position and availability of infrastructure and human resources.

Article 57. Official animal and plant health controls for the export and import of animals, plants, inputs including animal feed, and animal and plant products, shall include, at the discretion of the competent authority, control of documentation, control of identity and physical control, as per the norm defined by the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level.

Paragraph 1. The frequency and nature of these controls shall be defined by the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, and will depend on:

I – the hazards posed by the animals, plants, inputs including animal feed, and the animal and plant products;

II – controls carried out by producers or importers; and

III – guarantees provided by the competent authority of the exporting country.

§ 2 Samples must be handled so as to assure their analytical validity

Paragraph 3. In order to organize official controls of international animal and plant health surveillance, the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, may require of importers or those responsible for the import of animals, plants, inputs including animal feed, animal and plant products, that they give prior notification of the arrival and the nature of the products, pursuant to a specific norm.

Article 58. Those responsible for the administration of customs areas shall assure basic suitable conditions for activities of international agricultural surveillance, for the operation of entry and exit points into and out of Brazil, in ports, airports, special customs posts, border inspection posts and other points that are eligible or that are under customs inspection, as defined by the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level

Article 59. If there are signs of non-compliance or there are queries as to the identity, quality, destination or the purpose of imported products, or a mismatch between the import and the respective certified guarantees, then the competent authority at the units for international agricultural surveillance may detain the load or consignment until such signs or queries are eliminated.

Paragraph 1. The competent authority shall officially notify those responsible for the shipment of the non-conformity that has been found; appeal may be made, as per the specific norm for this case.

§ 2 The competent authority may, at its discretion and under the relevant legislation:

I - order the animals, plants, inputs including animal feed, animal and plant products, to be slaughtered or destroyed, given special treatment or quarantine, returned or re-exported;

II - order the animals, plants, inputs including animal feed, and animal and plant products to be given a different purpose than their original purpose, depending on the associated risk; and

III – notify other customs services of their reasons for refusal and provide information about the final purpose of the import, when non-conformities are detected or when authorization for the introduction of these animals, plants, inputs including animal feed, and animal and plant products is withheld.

§ 3 The measures described in section I of § 2, at the discretion of the competent authority and according to relevant legislation, shall be

I – treatment or transformation that will bring the animals, plants, inputs including animal feed, animal and plant products into line with the requirements of Brazilian legislation, or with the requirements of a re-consignment export country, including if necessary decontamination, but not including dilution; and

II – transformation by any other suitable means toward other purposes than animal or human consumption, providing it meets relevant legislation.

§ 4 The competent authority shall make sure that the special treatment or quarantine be carried out at official or accredited establishments and in compliance with conditions laid down in this Regulation and in specific approved norms

§ 5 The competent authority of the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall allow re-export of a consignment, provided that:

I – the new destination has been defined by the person responsible for the consignment; and

II – the country of destination has received prior notification of the reasons and circumstances preventing the entry of these animals, plants, inputs including animal feed, and animal and plant products to Brazil.

§ 6 The maximum period during which a load or consignment may be detained for animal and plant health inspection reasons shall be fifteen (15) days

§ 7 The period referred to in §6 may be extended at the discretion of the competent authority, in cases provided for in specific norms

§ 8 At the end of the fifteen day period, if re-export has not taken place, except where there is justified delay, the load or consignment shall be destroyed

§ 9 The competent authority of the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall notify the customs services of its decisions, preferably by means of information technology.

Paragraph 10. The Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall take necessary steps to prevent the entry into Brazil of rejected or refused consignments, as defined in legislation

Paragraph 11. Those responsible for the import of animals, plants, inputs including animal feed, and animal and plant products shall pay for the costs incurred owing to the decisions of the competent authorities

Article 60. The competent authorities for animal and plant health surveillance of the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, and other public and private customs services, shall work in close cooperation in organizing the official controls referred to in this Regulation.

Paragraph 1. Customs services shall not allow the entry or handling in primary zones, free zones, or special customs areas, of consignments of animals, plants, inputs including animal feed, animal and plant products, unless the competent authority for international animal and plant health surveillance of the Ministry of Agriculture, Livestock and Food Supply has so agreed.

Paragraph 2. The competent authority of the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall, by means of the documents defined in its own specific norms, inform the customs services and the importers whether the consignments may or may not be allowed to enter Brazil.

Paragraph 3. The competent authority of the Ministry of Agriculture, Livestock and Food Supply shall, by means of the documents defined in its own specific norms, inform the customs services and the importers to indicate whether the merchandise may or may not be brought into Brazil before the results of the analyses are available, provided that the traceability of the imports is guaranteed.

Article 61. Measures shall be defined within the terms of this Regulation, to assure uniform enforcement of the official controls for the introduction of animals, plants, inputs including animal feed, and animal and plant products.

Section IX

Certificates

Article 62. The three Levels of the Unified Animal and Plant Health System and the Brazilian Systems for the Inspection of Agricultural Products and Inputs, within their fields of competence, shall introduce, monitor and manage procedures of animal and plant health certification, and identity and quality certification processes intended to guarantee the origin, quality and identity of certified products and make the traceability process credible.

Paragraph 1. The control processes shall make it possible to identify and verify the supplier of the certified material at the origin and destination of the products, which will be identified by means of codes enabling traceability all along the production chain, as provided for in a specific norm.

§ 2 It is, in law, for the Agricultural Inspectors to issue official agricultural certificates demanded by international trade

Article 63. The Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall set up and coordinate a database concerning certification.

Sole paragraph. Animal and plant health requirements for the inter-municipal, interstate and international transportation of animals and plants, animal or plant products and by-products, other products that could serve as a substrate, culture medium, vector or vehicle for the spread of regulated pests or diseases, shall be defined in specific norms containing certification information

Article 64. A national register shall be set up of responsible professionals entitled to issue animal and plant health certification as to origin, identity and quality, and movement permits for plants and animals as defined by the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, and by relevant legislation.

Article 65. Without over-ruling any general requirements adopted for animal and plant health or Brazilian and international norms, the certification process shall observe:

I – templates for certification laid down in norms currently in force;

II – animal health and plant health requirements and the legal underpinning for the Certification;

III – qualifications of those responsible for the certification;

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

V – procedures for issuing certificates; following them; creating further certificates based on one original; canceling, rectifying and replacing certificates; and

VI – documentation accompanying the consignment, load or batch after official controls have been carried out.

Article 66. When certification is demanded, the following conditions must be met:

I – there is a link and traceability is possible between the certificate and the shipment, batch, item, or load;

II – the information on the certificate is accurate and true; and

III – the specific requirements for certification been met.

Section X

Records and Registrations

Article 67. The Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, in manner it has defined, shall promote the articulation, coordination and management of a database to interlink the three Levels of the Unified Animal and Plant Health System for the purposes of the single unified record and register, based on uniform identification.

Article 68. The Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall define procedures to be observed for the registration of establishments or organizations..

Paragraph 1. Registration is mandatory and shall be carried out by official services within the competent sphere of the Unified Animal and Plant Health System, as defined by the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level.

§ 2 The register shall contain unique individual identification in the Unified Animal and Plant Health System, identifying the interested party in all processes of its interest

Paragraph 3. Whenever there are official registers for other purposes, the information and databases existing for those purposes shall be used preferentially to feed the single register and the information of the Unified Animal and Plant Health System, for the normatized purposes of this Regulation.

Paragraph 4. The competent authorities, at the three Levels of the Unified Animal and Plant Health System, shall keep up-to-date the register of holdings and producers of animals, plants, agricultural inputs including animal feed, and animal and plant products, whether individuals or legal entities, corporations, service providers or organizations.

Article 69. The Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall define procedures to be followed for registering establishments, organizations or products, as laid down in this Regulation.

Paragraph 1. The granting of registration by the Unified Animal and Plant Health System shall involve inspection and official auditing, to verify whether the legal requirements and requirements of this Regulation have been met.

§ 2 The register shall be used exclusively for the purpose to which it was intended, and transfer or use in other units or establishments shall be forbidden

§ 3 Registered establishments shall be obliged to acquire only material that meets the demands of the legislation in force

§ 4 The registered establishment shall be obliged to cooperate and guarantee access to its premises for people who are qualified to carry out inspection, auditing, sample collection and document verification

Section XI

Accreditation of Technical and Operational Service Providers

Article 70. The Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall define procedures to be followed in the accreditation of companies or organizations that are interested in providing technical or operational services, as per the legislation in force.

Paragraph 1. Whenever it receives a request for accreditation, the competent authority shall visit the location and issue an inspection report and other relevant reports as per regulations.

§ 2 The competent authority shall accredit the service provider only if it can be demonstrated that the service provider meets the relevant requirements of animal and plant health legislation and other legal requirements

Paragraph 3. It is for the competent authority to assess whether the service provider meets the requirements of procedures, personnel, infrastructure, equipment, technical know-how and other legal requirements as defined in this Regulation and in specific animal and plant health legislation.

Article 71. The competent authority, as defined by the Ministry of Agriculture, Livestock and Food Supply as the Central and Higher Level, shall audit and inspect, at its discretion, the activities of the service provider.

Paragraph 1. If shortcomings or non-conformities are detected, the competent authority shall take the corrective actions laid down in a specific norm, and may, at its discretion, suspend the accredited services that were being provided until the shortcomings are made good within a defined period of time.

§ 2 After the period defined in § 1 has elapsed, and if the shortcomings and non-conformities continue, the process to disaccredit the corporation or organization shall begin; however, there is the right of appeal, although this does not exempt the corporation or organization from the penalties defined in the relevant legislation

Paragraph 3. If the shortcomings and non-conformities are repeated, or if serious shortcomings and non-conformities are found, as is defined in a specific norm, the competent authority shall immediately suspend the accreditation and begin the process of disaccreditation.

Article 72. The competent authorities shall keep an up-to-date register, preferably in an electronic medium, of accredited service providers, and make it available to all the Agencies of the Unified Animal and Plant Health System and to the public at large, where appropriate.

Article 73. Accredited service providers must:

I – meet the criteria, guidelines, parameters and specifications in services, materials and products, facilities, equipment components and modalities of application of treatments and procedures, and security measures, as per specific norms;

II – make documentation available to the agricultural health inspection agencies of all three Levels, whenever requested, to prove accreditation, the lists of products and equipment used, and the past records of activities and services carried out;

III – enable access to their premises so that the competent authority can visit the facility and publish a report on inspection, and other relevant reports, as regulated, at the time that accreditation is requested or at any moment;

IV – communicate to the corresponding government agency any changes to the information presented in their accreditation, this information being submitted to analysis for approval and authorization;

V – keep records and controls of processes and services offered and carried out, for a minimum period of five years; and

VI – guarantee supervision by a responsible professional, in observance of current animal and plant health legislation in force.

Article 74. A specific norm published by the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, will define the accreditation processes, and the services whose accreditation will mandatorily be homologated and the specific rules for homologation, following sectoral legislation.

Section XII

The Training of Professionals and Qualifications

Article 75. The three Levels of the Unified Animal and Plant Health System will be able to train professionals to provide services and issue documents, as per current legislation, as defined by the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level.

Paragraph 1. The respective Levels shall promote and oversee the execution of the activities of trained professionals.

Paragraph 2. Trained private professionals will in special cases regulated by the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, be allowed to render service and issue certificates, obeying other specific legislation.

Section XIII Meeting International Commitments

Article 76. The three Levels of the Unified Animal and Plant Health System are responsible for meeting the commitments and obligations stemming from international agreements signed by the Federal Government, in the field of animal and plant health.

Paragraph 1. The Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall coordinate and oversee the introduction of decisions concerning the interests of Brazil's agricultural industry, brought in by international organizations and agreements with foreign governments.

§ 2 The Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, without relinquishing any of its rights and duties in international forums, shall:

I – contribute toward the consistent formulation of international technical norms for agricultural products and feed for animals, and animal and plant health norms;

II – promote the coordination of work on norms put forward by international animal and plant health organizations, when justified;

III – whenever relevant and suitable, contribute toward the drafting of agreements on the recognition of the equivalence of specific measures related to animal and plant products and to animal feeds;

IV – pay special attention to the specific developmental needs and the financial and economic necessities of the States of Brazil, in order to ensure that international norms do not pose obstacles to these States' exports; and

V – promote coherence between international technical norms and the animal and plant health legislation, ensuring at the same time that the level of protection is not lowered.

Section XIV

Staff Training

Article 77. The three Levels of the Unified Animal and Plant Health System shall be responsible for the capacity-building of its staff of professionals.

Paragraph 1. Capacity-building actions shall be used in order to develop a harmonious approach by the official controls in the three Levels of the Unified Animal and Plant Health System.

§ 2 The capacity-building and training program shall address the following topics, among others

I – Brazilian and international legislation on animal and plant health;

II – the methods and techniques of controls, such as the audit systems conceived by operators in order to obey animal and plant health legislation;

III – methods and techniques for the production and trading of inputs, including animal feeds, and animal and plant products;

IV – pedagogical and communication means, methods and techniques so that professionals can carry out sanitary education training activities with components of the production chain and with society at large; and

V – other specific actions that are the competence of each level of government, to be defined by the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level.

§ 3 Capacity-building events may be open to participants from other countries

Article 78. The Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall put forward the capacity-building program, after consultation with the Local and Intermediate levels of government.

Article 79. The competent authority of the three Levels of the Unified Animal and Plant Health System shall guarantee that all personnel with official control responsibilities:

I – shall have received the professional training required for animal and plant health activities;

II – be given, in their respective fields of work, suitable capacity-building and mandates to do their job with competence, independence and fairness;

III – keep up-to-date in their field of competence, and if necessary be given regular supplementary training; and

IV – be prepared to work in multidisciplinary cooperation.

CHAPTER IV

METHODOLOGY AND SPECIAL PROCEDURES

Section I

Risk Analysis

Article 80. Risk analysis shall be the basic method used in defining procedures to be adopted for animal and plant health.

Paragraph 1. Risk analyses shall be performed using references and concepts that have been internationally harmonized and approved of in agreements signed by Brazil.

Paragraph 2. To achieve the general objectives of a high level of animal and plant health protection, and the guarantee of safety of animal and plant products, the animal and plant health measures shall be based on risk analysis, except whenever this is not suitable to the circumstances or the nature of the measure.

Paragraph 3. In carrying out risk analyses, the following factors shall be taken into consideration: the available scientific information; relevant production processes and methods; relevant testing, sampling and inspection methods; the prevalence of specific pests and diseases; the existence of areas free of pests and diseases; environmental and ecological conditions; and quarantine regimes.

Paragraph 4. Definition of the measures to be taken to reach the suitable level of animal and plant health protection for a given risk, should consider the potential hazard to animal and plant health, economic losses in the event of introduction, taking root and dissemination of a pest or disease, the cost of control and eradication in Brazil, and the cost-benefit relationship of alternative approaches to limit the risk.

Article 81. The competent authorities of the three Levels of the Unified Animal and Plant Health System shall establish procedures to identify risks within their areas of competence.

Article 82. Whenever an authority suspects that there is an animal or plant health hazard, it shall request information from the other Agencies of the Unified Animal and Plant Health System, which should transmit urgently all the relevant information at their disposal.

Article 83. The corrective measures necessary to determine the suitable level of animal and plant health protection for a place, Municipality, region or State, with regard to an identified risk, shall be compatible with the goal of minimizing the negative effects for the Unified Animal and Plant Health System and for trade between the areas and places involved.

Paragraph 1. In cases where scientific evidence is insufficient for risk analyses, at the discretion of the competent authority, protective animal or plant health measures may be taken provisionally, based on other available information, including information from benchmark international organizations, as well as animal and plant health measures put in place by other countries.

Paragraph 2. Risk analysis shall be carried out in order to authorize the import of animals, plants and products, whenever the sanitary or phytosanitary status of the country of origin or its neighbouring countries warrants this, or when there is non-compliance with the animal and plant health conditions that have been established.

Paragraph 3. The Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall analyze the regions of Brazil and formulate diagnoses and propose lines of action as a strategy to boost the development of local, regional or national agribusiness, based on risk analysis studies.

Section II

Hazard Analysis and Critical Control Points (HACCP)

Article 84. Producers of animals, plants, agricultural inputs including animal feed, and animal and plant products shall observe the principles of the Hazard Analysis and Critical Control Points (HACCP) system, as per specific norms.

Paragraph 1. Producers of animals, plants, agricultural inputs and animal and plant products, as per specific norms, must:

I – provide the competent authority with proof of compliance with the established requirement, in the way demanded by the competent authority, given the nature and size of their activity;

II – ensure that all documents describing the processes followed are always kept up to date; and

III – keep any other documents and records for the period of time defined by the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level.

§ 2 Special conditions shall be defined for small producers of animals and plants, establishing the use of the processes mentioned in the guidelines, for the application of HACCP principles or those of equivalent systems

§ 3 The conditions must specify the period in which the animal and plant producers must keep documents and records

Paragraph 4. Programs and projects introduced in order to enhance the control activities related to the HACCP system will be recognized in the Unified Animal and Plant Health System, in specific acts of the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level.

CHAPTER V

SUPPLEMENTARY ANIMAL AND PLANT HEALTH STANDARDS

Section I

Commitment to Consumers and Producers

Article 85. Supplementary national and state animal and plant health norms shall be drafted on the basis of the guidelines of this Regulation, seeking to protect the interests of consumers, agricultural production and producers, with regard to the quality of raw materials, inputs, protection against fraud, adulteration of products, and against practices that may mislead the consumer, aiming to guarantee animal and plant health and the safety of animal and plant products.

Sole paragraph. In the supplementary norms cited in the heading, the responsibilities of the producer shall be defined and emphasized, in terms of placing safe and secure products and practices on the market, self-control in production and the critical control points for every approved process.

Section II

Drafting Supplementary Norms of Best Practices

Article 86. The three Levels of the Unified Animal and Plant Health System shall draft supplementary Best Practices norms for animal and plant health, including sanitation standard operating procedures (SSOPs) to enable the application of risk analysis principles for pests and diseases, and Hazard Analysis And Critical Control Points, in compliance with this Regulation.

Paragraph 1. The National Council for Agricultural Policy shall approve the supplementary national and state norms and determine periodic reviews thereof.

§ 2 The goal of such review is to assure that the supplementary norms continue to be applied and incorporate scientific and technological developments

§ 3 Titles and references for the national supplementary norms shall be published and disseminated throughout Brazil

Paragraph 4. The national Best Practices supplementary norms shall be drafted by the production chain with the participation of producers and other participants in the chain, also considering the relevant supplementary Practices norms of benchmark international organizations.

Article 87. The Intermediate Level Agencies may, at their own discretion, and to cater to specific interests, draft their own supplementary Best Practices norms, which they shall send for appreciation to the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, and to the other Intermediate Agencies.

CHAPTER VI

OPERATION AND CONTROL

Section I

Laboratory Control

Article 88. Methods of analysis must obey the following criteria:

I - accuracy;

II - applicability (matrix and range of concentrations);

III - limit of detection;

IV - limit of determination;

V - precision;

VI - recuperation;

VII - selectivity;

VIII - sensitivity;

IX - linearity;

X - uncertainty of measurements; and

XI - other criteria that may yet be selected, depending on necessity.

Paragraph 1. The values that characterize the precision mentioned in point V above must be obtained from the collective assay, carried out in accordance with nationally or internationally recognized protocols and, when performance criteria have been established for the analytical methods, precision must be based on conformity assessment.

§ 2 The results of the collective assay shall be published or accessible without restrictions

§ 3 Analytical methods that are uniformly applicable to several groups of products shall be preferred to methods that are only applicable to specific products

§ 4 Specific norms and guidelines shall be defined in order to produce harmonization in situations where

I – the analytical methods can only be validated in accredited or reference laboratories; and

II – the performance criteria for the analytical methods are based on conformity assessment.

Article 89. The analytical methods adopted within the terms of this Regulation shall be formulated in accordance with specifications and methods of analysis that are recommended nationally or internationally.

Section II

Samples

Article 90. Sampling and analysis methods used in official controls must respect the applicable Brazilian standards.

Paragraph 1. The analytical methods shall be validated in the laboratory, in observance of the recommended national or international protocol.

Paragraph 2. In the absence of national norms, or internationally recognized norms or protocols, the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall approve norms or instructions to define suitable methods to achieve the intended objective.

§ 3 The analytical methods shall be characterized by the criteria defined by this Regulation

Article 91. The competent authorities of the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall regulate procedures for B samples and shall establish suitable procedures to assure the right of producers of animals, plants, inputs including animal feed, animal and plant products, whose products have been submitted to sampling and analysis, to request an opinion from another accredited expert, in a regulated manner, without affecting the duty of the competent authorities to take rapid action in the case of an emergency.

Sole paragraph. The procedures of a B sample and the opinion of a second expert do not apply in the case of risks to animals, plants and perishable agricultural products

Article 92. The samples shall be taken, handled, packaged, identified and transported in a suitable form so as to guarantee their analytical validity.

Section III

Controls of the Unified Animal And Plant Health System

Article 93. The Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall carry out both general and specific audits on other level agencies to assess conformity of the controls and activities performed on the basis of the national pluriannual control plans.

Paragraph 1. The Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, may appoint experts from the Local or Intermediate level Agencies, if necessary, to execute or support general and specific audits on the other Agencies.

§ 2 General and specific audits shall be organized in coordination and cooperation with the competent authorities of the Intermediate and Local level Agencies

§ 3 General audits shall be carried out regularly based on the pluriannual control plans

Paragraph 4. At the discretion of the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, up-to-date information may be requested concerning animal and plant health controls generated by the Intermediate and Local level agencies prior to general audits.

Article 94. General audits shall be supplemented by specific audits and inspections on one or more given areas.

Paragraph 1. Specific audits and inspections aim to:

I – assess the execution of the national pluriannual plan, and the legislation concerning animals, plants, inputs including animal feed, animal and plant products, and the legislation concerning animal and plant health; these audits and inspections may, if needed, include inspection in situ of official services and of the production chain premises being audited;

II – assess operating conditions and the organization of the work of the Intermediate and locations;

III – identify, assess and put forward contingency or emergency plans for relevant, critical or recurrent problems occurring in the Intermediate or Local Levels; and

IV – investigate emergency situations, emerging problems, the solutions to contingency plans or enhancements adopted by the Intermediate and Local Levels.

§ 2 The Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall draft a report on the results of each audit in which it participates.

§ 3 These reports shall contain, if suitable, recommendations to the Intermediate and Local level agencies, to enhance compliance with animal and plant health legislation

Paragraph 4. The Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall provide the competent authority with the draft of the report so that the audited agency may, within a thirty day period, formulate its own opinion and observations.

§ 5 The comments of the Intermediate and Local Levels shall be part of the final report, provided they are forwarded within the period defined in § 4

§ 6 The reports shall be disseminated in observance of the form regulated by the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level

Article 95. The Intermediate and Local Levels shall:

I – participate in general and specific audits performed by the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level;

II – carry out their own general and specific audits;

III – take corrective measures to comply with the recommendations stemming from the audits;

IV – provide all necessary assistance and supply all documentation and whatsoever other technical support requested by the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level; and

V – assure the auditors of the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, of access to all premises or areas of premises and to information, including information systems, that are important to the audit.

Article 96. The Ministry of Agriculture, Livestock and Supply, as the Central and Higher Level, shall at any moment assess the animal or plant health status, or the equivalence of agricultural health systems adopted by Intermediate and Local Level Agencies. (In the wording of Decree 7,216/2010)

Section IV

Import and Export Control

Article 97. Importers of animals, plants, agricultural inputs including animal feed, animal and plant products, and other products that may pose a risk of the introduction and spread of diseases and pests, must obey the requirements of this Regulation and of norms defined by the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level.

Article 98. The Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall draft a list and keep it up-to-date, of pests and diseases, animals, plants, inputs including animal feed, animal and plant products, based on risk analysis and which are subject to official controls at points of entry to Brazil, at the discretion of the authorities.

Article 99. The competent authorities of the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall conduct official controls to check conformity with regard to aspects of the legislation concerning import and export, and which are defined in this Regulation.

Article 100. The Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall define special controls per country, by means of specific norms, prior to the export by these countries to Brazil of animals, plants, inputs including animal feed, animal and plant products, to check compliance with requirements and other demands of this Regulation.

Paragraph 1. Approval shall be applicable to animals, plants, inputs including animal feed, and animal and plant products from any country, provided it has a sanitary agreement with Brazil, and shall be granted to one or more products.

§ 2 Whenever the approval mentioned in § 1 has been granted, the import controls for animals, plants, inputs including animal feed, and animal and plant products shall be simplified and streamlined in conformity with the associated risk and with the specific rules defined by the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level

Paragraph 3. The controls performed in the country of origin prior to export remain effective, but the competent authority may, at its discretion, request new official controls to certify animal health, plant health and quality of imported animals, plants, inputs including animal feed, and animal and plant products.

§ 4 The approval referred to in § 1 shall be granted provided that

I - official audits or procedures, based on specification provided by the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, prove that the animals, plants, inputs including animal feed, animal and plant products exported to Brazil meet the requirements of this Regulation or equivalent requirements; and

II – the controls performed in the country of origin prior to export be deemed sufficiently efficient and effective to replace or reduce the controls of documentation, identity and physical controls provided for in this Regulation.

§ 5 Approval shall identify the competent authority of the country of origin, under whose responsibility the controls prior to export are carried out

§ 6 The competent authority or control body specified in the approval granted to the exporting country is responsible for contact with the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level

§ 7 The competent authority or control body of the exporting country shall assure official certification of each controlled consignment prior to its respective entry to Brazil

§ 8 Approval shall specify a model for the certificates

Paragraph 9. When the official import controls subjected to the above-mentioned procedures show any non-compliance with this Regulation, the authorities of the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall extend their verifications and controls, in line with the severity of the non-compliance, carrying out further risk analyses and immediately notifying the exporting countries, in accordance with the animal and plant health agreements.

Paragraph 10. If the non-compliance referred to in § 9 persists, or if it is found that the non-compliance jeopardizes the objectives of this Regulation, including animal and plant health, the simplified or streamlined control regime immediately shall cease to be applicable

Article 101. With regard to export or re-export of animals, plants, inputs including animal feed, animal and plant products, the requirements of this Regulation and also of the animal and plant health legislation in force are to be followed, as well as the legal requirements of the importing countries.

Article 102. The Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall establish specific norms for carrying out import controls for:

I – animals and plants of no economic value, when international transport is used;

II – specific exemptions or conditions applicable to given procedures for processing, industrial processing or immediate re-export

III – animal and plant products for supplying the passengers and crew of international means of transport;

IV - inputs including animal feeds, and animal and plant products, ordered postally, over the telephone or over the worldwide computer network, and delivered to the consumer;

V – animal feeds and animal and plant products carried by passengers or crew of international means of transport;

VI – consignments originating in Brazil but returned by importing countries; and

VII - documents that should accompany the consignments when samples have been collected from them.

Article 103. The Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, may at any moment assess the animal or plant health conditions, or the equivalence of legislation and of animal and plant health systems adopted by exporting and importing countries, in comparison with Brazil's animal and plant health legislation.

Paragraph 1. The Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, may at its discretion appoint experts or specialists for specific tasks that are defined in the heading of this article..

§ 2 Assessments shall include, among others

I – the consistency and coherence of the animal and plant health legislation of the exporting country;

II – the organization and workings of the official services and the competent authorities of the exporting country, their competencies and degree of independence;

III – the training of personnel and of the team that carries out official controls;

IV – the available infrastructure including laboratories and diagnostic facilities;

V – the existence of, and working of, control procedures;

VI – the situation with regard to animal health, animal diseases, and plant health, and procedures for the notification of outbreaks and events of animal and plant disease; and

VII – guarantees given that Brazilian requirements or animal and plant health equivalences will be met.

§ 3 The frequency of assessments of the animal and plant health situation existing in countries exporting to Brazil will be determined on the following basis

I - Risk analysis for exported products;

II - provisions of Brazilian legislation;

III - volume and nature of imports from the country in question;

IV - results of earlier assessments carried out by the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level;

V - results of import controls;

VI - information received from other agencies;

VII - information received from internationally recognized agencies such as the World Health Organization, the Codex Alimentarius, the International Plant Protection Convention and the OIE;

VIII - the detection of pests and diseases in the exporting country;

IX - the identification of risks associated with animals, plants and perishable agricultural products; and

X - the need to investigate emergency situations in an exporting country.

Article 104. When, in the risk analysis, risks are identified in the case of animals, plants and perishable agricultural products, the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall immediately take the emergency measures set forth in this Regulation or in the relevant animal and plant health legislation in force.

Article 105. The Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall draft a report on the results of every assessment carried out, including relevant recommendations.

Article 106. The Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, may request information from exporting countries about the organization and management of their animal and plant health control systems.

Paragraph 1. This information shall be related to the results of the controls of the exporting country.

Paragraph 2. If an exporting country fails to produce this information or if the information is incorrect, Brazil may immediately, and unilaterally, apply full import controls without any concessions.

§ 3 The Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall establish the way in which information shall be collected, prepared, organized and presented, and the transition measures intended to give exporting countries time to prepare such information.

Article 107. Equivalence agreements recognize that the measures applied in exporting country offer equivalent guarantees equivalent to those given in Brazil.

Paragraph 1. In order to assess equivalence, the following aspects shall be evaluated:

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

II – the specific requirements applicable to export to Brazil; and

III – the results of audits.

Paragraph 2. The Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall draw up, and keep up-to-date, lists of regions or establishments from which import by Brazil is allowed, in observance of the equivalence system.

§ 3 Recognition of equivalence shall be immediately and unilaterally revoked whenever failure to comply with any of the established conditions occurs

Article 108. The Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, is authorized to carry out joint action and support neighbouring countries with regard to the health of animals, plants, inputs including animal feed, animal and plant products, in order to develop the institutional capacity required to comply with the conditions referred to in this Regulation.

CHAPTER VII

COOPERATION AND ASSISTANCE

Article 109. At the request of the competent authorities of the Local level Agencies and in cooperation with them, the Intermediate Level shall provide cooperation and assistance to the Local level agencies.

Article 110. At the request of the competent authorities of the Intermediate level agencies and in cooperation with them, the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall provide cooperation and assistance to the Intermediate Level.

Sole paragraph. The cooperation and assistance provided by the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall include, above all:

I – clarification as to national animal and plant health legislation;

II – information and data available at a national level that might be useful for the controls of the Intermediate and Local Levels to ensure the universal application, harmonization, equity and effectiveness of animal and plant health measures; and

III – operational support necessary for controls that are the responsibility of the Intermediate and Local Levels in the Unified Animal and Plant Health System.

Article 111. The Intermediate Level shall take temporary emergency assistance measures if the Local level agencies fail to comply with obligations laid down in the animal and plant health legislation and in this Regulation, and when this failure compromises the objectives of the Unified Animal and Plant Health System.

Article 112. The Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall take temporary emergency assistance measures if the Intermediate level agencies fail to comply with obligations laid down in the animal and plant health legislation and in this Regulation, and when this failure compromises the objectives of the Unified Animal and Plant Health System.

Paragraph 1. Whenever the competent authority of the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, identifies non-compliance, it shall take measures to guarantee that the Intermediate or Local Level can solve the situation.

§ 2 When opting to provide assistance, owing to a temporary or operational difficulty of the Intermediate level agencies in complying with what § 1 lays down, the competent authority of the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall take into consideration the prior record and the nature of the non-compliance

§ 3 The assistance referred to in the heading may include one or more of the following measures

I – the adoption of health procedures or any other measures deemed necessary to assure the security of animals, plants, inputs including animal feed, animal and plant products, and of the norms concerning animal health;

II – a restriction or ban on the placement of products on the market;

III – follow-up and, if needed, the recall, removal or destruction of products;

IV – authorization of the use of inputs including animal feed and animal and plant products for purposes other than those to which they were originally intended;

V – suspension of operations or closure of all or part of the production activities or of companies;

VI – suspension or cancellation of accreditation that has been granted; and

VII – any other measures deemed suitable by the competent authority of the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level.

§ 4 The financial burden resulting from the actions established in § 3 shall be borne by the producers of animals, plants, inputs including animal feed, animal and plant products; appeal can be lodged, in the form regulated by the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level

Article 113. Sanctions against infractions relating to animal and plant health shall be applied in the form defined in specific legislation, in the federal, state and municipal spheres.

Article 114. All procedures of the Unified Animal and Plant Health System must be documented.

Article 115. In the case of a failure to comply with the norms of animal and plant health, the producers of animals, plants, inputs including animal feed, animal and plant products, shall be formally notified by the competent authority.

Section I

Crisis Management

Article 116. The Unified Animal and Plant Health System shall have a Manual of Procedures for Managing Crises, and Special Emergency Action Groups for Animal and Plant Health, which shall obey specific norms defined by the Ministry of Agriculture, Livestock and Food Supply.

Article 117. To implement the guidelines contained in the Manual of Procedures for Managing Crises, the three Levels of the Unified Animal and Plant Health System shall proactively draft contingency and emergency plans to define the measures that are immediately applicable whenever a risk to animal and plant health is identified, whether directly or through the environment.

Paragraph 1. The emergency and contingency plans shall specify those administrative authorities that must intervene, their respective powers and duties, and the channels and procedures for exchanging information among the several intervening agents.

§ 2 The Intermediate level agencies, in their fields of operation, shall review and adjust the contingency and emergency plans to the specific conditions

Article 118. The Intermediate level agencies shall afford each other mutual assistance, either on request or under their own initiative, whenever the results of official controls require the adoption of emergency measures in more than one Intermediate level agency.

Sole paragraph. The mutual assistance of the Intermediate level agencies may include, if necessary, participation in controls in situ, carried out by the competent authority of other Intermediate level Agencies.

Article 119. Whenever a competent authority of the three Levels becomes aware of a case of non-compliance and this case may have implications for the Unified Animal and Plant Health System and for another Intermediate level agency, it shall immediately transmit this information to the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, and to the other Intermediate level agency, without any need for a prior request.

Paragraph 1. The Agencies that receive the above-mentioned information shall carry out investigations and inform the Agency that gave them the information of the results of investigations and if necessary of measures taken, especially the assistance without prior request.

§ 2 If the competent authorities of the Levels involved have reason to believe that these measures are insufficient, they should together try to find ways and means to solve the non-compliance

§ 3 The Intermediate level Agencies shall inform the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, if they are unable to reach agreement on suitable measures and if the non-conformity affects the Unified Animal and Plant Health System as a whole

Paragraph 4. If found that the non-conformity can affect animal and plant health on a regional or national scale, the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall provide assistance without prior request in the area identified.

Article 120. The Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall suspend the application of unjustified animal or plant health measures, or measures that go against the animal and plant health legislation, between agencies of the Unified Animal and Plant Health System, taking appropriate steps.

CHAPTER VIII

PLANNING

Article 121. The Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall bring in strategic and executive Pluriannual Animal and Plant Health Plans linking the three Levels of the Unified Animal and Plant Health System; these plans shall be:

I – drafted every five years, with the participation of sectors of society and the governments involved, and brought up to date annually;

II – benchmarks for the drafting of the Federal Government Pluriannual Plan, equivalent plans for the State governments and the Federal District government, Municipal governments and their respective action plans; and

III – organized and put into action on the basis of the risks identified concerning animals, plants, inputs including animal feed, and animal and plant products.

Paragraph 1. The Pluriannual Animal and Plant Health Plans shall define the goals, responsibilities of each Level, the resources needed, including financial counterparties, and sources of funding.

§ 2 The Ministry of Agriculture, Livestock and Food Supply shall define the way in which the resources of the Federal Government are applied, in accordance with relevant legislation

§ 3 The three Levels shall assume responsibility for applying the resources and for full compliance with the Pluriannual Animal and Plant Health Plans, which are jointly agreed

Article 122. The Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, shall establish a schedule for the drafting and updating of the Pluriannual Animal and Plant Health Plans, so as to contribute to the drafting of the Federal Government Pluriannual Plan.

Paragraph 1. The Pluriannual Animal and Plant Health Plan must contain general information on:

I – the strategic goals of the plan and the way in which these are reflected in the attribution of priorities and resources;

II – the risk category or classification for the activities;

III – the designation of competent authorities and their respective duties, at all levels of operation, and the resources they have available;

IV – the organization and management of the official controls, including official controls in the different establishments;

V – the control systems applied and coordination among the competent authorities that are responsible for the official controls;

VI – possible delegation of tasks;

VII – methods to assure respect for operational criteria;

VIII – the training of the personnel entrusted with carrying out official controls;

IX – documented procedures;

X – the organization and operation of contingency and emergency plans, in the case of diseases and pests that cause an impact, and in the case of other risks;

XI – the organization of mutual cooperation and assistance;

XII – mechanisms for liaison between institutions; and

XIII – collegiate bodies and cooperation and assistance bodies, as with rural extension.

§ 2 The Pluriannual Animal and Plant Health Plans may be altered during their application

§ 3 Alterations shall be carried out taking into consideration the following factors, among others

I – the emergence of new diseases and pests causing an impact, or of other risks;

II – new legislation and adjustments defined by the Central and Higher Level;

III – significant alterations in the structure, management or working of the competent authorities;

IV – results of the official controls carried out within the Unified Animal and Plant Health System;

V - scientific discoveries;

VI – the suggestions made by the three Levels or by international technical missions; and

VII – the result of audits conducted by the Central and Higher Level.

§ 4 The Pluriannual Animal and Plant Health Plans shall provide for

I – a coherent, global and integrated approach to legislation;

II – priorities by risk;

III – criteria for categorizing or classifying the risks of activities;

IV – control and correction procedures;

V – international, multilateral or bilateral commitments relating to animal and plant health;

VI – indicators in the phases of the production chain that supply representative information of compliance with animal and plant health legislation;

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

VIII – traceability control systems;

IX – systems to assess the performance and the outcomes of control actions, with performance indicators;

X - norms and recommendations of the international reference agencies;

XI – criteria for performing audits; and

XII – a structure for annual reports and the information to be contained in such reports.

Article 123. One year after the start-up of enforcement of the Pluriannual Animal and Plant Health Plans and subsequently each year, reports are to be drafted and published on the progress of the work by the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, containing the following indications:

I – alterations proposed or introduced into the Pluriannual Animal and Plant Health Plans;

II – the results of controls and audits carried out in the preceding year, as provided for by the Pluriannual Animal and Plant Health Plans;

III – the type and the number of cases of non-compliance that are found, and the geographical location of the major events, preferably using electronic maps; and

IV – recommendations for enhancing the execution of the work provided for in subsequent Pluriannual Animal and Plant Health Plans.

Article 124. The report shall be submitted to the National Council for Agricultural Policy, which shall forward it, with its recommendations, to the Minister of State for Agriculture, Livestock and Food Supply, who shall publish it for the population at large.

CHAPTER IX

RESOURCES AND FINANCING

Article 125. It is the responsibility of the three Levels to guarantee the necessary resources for the activities of the Unified Animal and Plant Health System, in their respective jurisdictions, in compliance with the relevant legislation.

Paragraph 1. The Levels of the Unified Animal and Plant Health System may collect fees or charges, as per their respective relevant legislation, to cover expenses incurred by official controls; however, it is forbidden to charge twice for the services rendered.

§ 2 Whenever several official controls are being conducted simultaneously in the same establishment, the competent authority shall consider them a single activity and charge a single fee

§ 3 Whenever any fee relating to the Unified Animal and Plant Health System is paid, proof of payment shall mandatorily be issued, in the regulated manner

Article 126. Agencies of the Unified Animal and Plant Health System may, based on their own legislation, establish differentiated fees for the services they provide or waive these fees in specific situations.

Article 127. The Levels of the Unified Animal and Plant Health System must make public the table of fees charged for services or activities.

Article 128. The Levels of the Unified Animal and Plant Health System may charge for expenses stemming from additional controls, whenever the detection of a non-conformity gives rise to official controls or corrective measures that go beyond the normal activities of the competent authority, in compliance with the relevant legislation.

Sole paragraph. Activities that go beyond the normal control activities include corrective measures and other additional controls to assess the dimensions and the solution of a problem

Article 129. The Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, may suspend distribution of resources to the Intermediate and Local Levels in the following cases:

I – non-compliance with this Regulation and other specific norms for animal and plant health;

II – failure to carry out the activities and goals provided for in the Pluriannual Animal and Plant Health Plans, and in specific projects, when the justification put forward by the authority in the Intermediate or Local level is rejected;

III – lack of proof of the corresponding counterparty for resources;

IV – irregular employment of transferred financial resources;

V – lack of proof of regular and timely input to and feedback from the epidemiological information systems; and

VI – lack of timely response to formal requests for information.

Sole paragraph. After analysis of the justification put forward by the Intermediate and Local Levels giving rise to suspension of distribution of resources, the Ministry of Agriculture, Livestock and Food Supply, as the Central and Higher Level, based on a well-founded technical opinion, may re-establish distribution of financial resources, provide unsolicited assistance, maintain the suspension of the distribution of resources, or cancel recognition of the defaulting jurisdiction.

Article 129-A. For the purposes of Article 26 of Law 10,522, of July 19, 2002, the activities mentioned in Paragraph 3 of Article 1 of this Regulation, regarding the inspection and oversight of food, water and beverages for human consumption, inputs, products and substances that are part of the production chain, comprise social actions for the protection of health and food safety. (Included by Decree 8,613/2015)

CHAPTER X

INSPECTION OF AGRICULTURAL PRODUCTS AND INPUTS

Article 130. As part of the Unified Animal and Plant Health System and with the objective of inspecting and controlling animal and plant products and agricultural inputs, the Brazilian Systems for the Inspection of Agricultural Products and Inputs are hereby constituted thus:

I – The Brazilian System for the Inspection of Plant Products;

II - The Brazilian System for the Inspection of Animal Products; and

III - The Brazilian Systems for the Inspection of Agricultural Inputs.

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

I - audits, controls, inspections, certification and classification of plant products, by-products and economically valuable residues;

II - audits, controls, inspections, certification and classification of animal products, by-products and economically valuable residues; and

III – audits, controls, inspections and certification of inputs and services employed in agricultural activities.

§ 2 The activities of the Brazilian Systems for the Inspection of Agricultural Products and Inputs shall be pursued in compliance with the current legislation for animal and plant health and international agreements to which the Brazilian government is a signatory

§ 3 Audits, controls and inspections shall be carried out without prior warning, except in specific cases where prior notification of the professional responsible for production is mandatory

§ 4 Audits, controls and inspections shall be carried out on any stage of production, processing, storage or distribution

Paragraph 5. The above does not include audits, controls and inspections provided for in § 4 relating to foodstuffs, beverages and water for human consumption, which are the responsibility of the health surveillance institutions that make up the Single Health System—*Sistema Único de Saúde* (SUS).

§ 6 At the discretion of the competent authority, a Hazard Analysis and Critical Control Points methodology may be adopted during the inspection

§ 7 Audits, controls and inspections encompass all animal and plant products and agricultural inputs, whether imported or produced in Brazil, whether for export or otherwise

§ 8 At the discretion of the competent authorities, inspections may be carried out on a permanent basis, on the industrial or agri-industrial facilities

Article 131. The Ministry of Agriculture, Livestock and Food Supply shall coordinate the Brazilian Systems for the Inspection of Agricultural Products and Inputs.

Paragraph 1. The State and the Federal District may apply to become part of the Brazilian Systems for the Inspection of Agricultural Products and Inputs.

§ 2 Municipalities may apply to become part of the Brazilian System for the Inspection of Animal Products and the Brazilian System for the Inspection of Plant Products

Paragraph 3. The Ministry of Agriculture, Livestock and Food Supply shall establish, within ninety days of the publication of this Regulation, requirements and other necessary procedures for application to become part of the Brazilian Systems for the Inspection of Agricultural Products and Inputs. (In the wording of Decree 5,830/2006)

§ 4 To become part of the Brazilian Systems for the Inspection of Agricultural Products and Inputs, the States of Brazil must adapt their control and inspection processes and procedures

Article 132. The inspections and controls of animal and plant products and agricultural inputs carried out by States, the Federal District and those Municipalities that have not yet become part of, or that chose not to join the Brazilian Systems for the Inspection of Agricultural Products and Inputs, shall be recognized only within the scope of their jurisdiction.

Paragraph 1. Provided that there is a formal request, the Federal Government may cooperate technically with States and the Federal District in the same way that the States may cooperate with the Municipalities.

§ 2 The Ministry of Agriculture, Livestock and Food Supply shall conduct annual audits of the inspection services of the States, the Federal District, Territories and Municipalities.

§ 3 The States shall carry out annual audits in the Municipalities within their jurisdiction

Article 133. The Ministry of Agriculture, Livestock and Food Supply, and the States, Federal District and Municipalities acceding to the Brazilian Systems for the Inspection of Agricultural Products and Inputs shall ensure:

I – the effectiveness and suitability of inspections and controls at all stages of the production chain;

II – that the technical and ancillary personnel carrying out controls and inspections shall be hired through public competitive examinations;

III - that the technical and ancillary personnel carrying out controls and inspections have no conflicts of interest;

IV – the existence of, or access to, official or accredited laboratories with suitable capacity for the conduct of tests, with sufficient qualified and experience personnel to perform the official controls efficiently and effectively;

V – the existence of suitable facilities and equipment and the maintenance of the same so as to ensure that the personnel can carry out controls and inspections safely and effectively;

VI – the institution of the necessary legal powers to carry out controls and inspections, and adopt the measures provided for in this Regulation;

VII – the conduct of controls and health education actions;

VIII – that no industrial facility or cold storage plant may operate in Brazil without prior registration with the competent Agency, so that its activities can be inspected;

IX – effective combat of clandestine operations; and

X – that rural and industrial producers, and the suppliers of inputs, distributors, cooperatives, associations (both industrial and agri-industrial), wholesalers and retailers, importers, exporters, entrepreneurs and any other operators in the production chain, shall submit to any control or inspection carried out within the terms of this Regulation and that they shall support the personnel of the competent authority in the performance of their mission.

Sole paragraph. In order to be part of the Brazilian Systems for the Inspection of Agricultural Products and Inputs, the States and Municipalities must follow the federal legislation or have equivalent Regulations for the inspection of animal and plant products, and inputs, approved in the way defined by this Regulation and by specific norms.

Article 134. The Brazilian Systems for the Inspection of Agricultural Products and Inputs shall ensure that procedures and the organization of the inspection of animal and plant products, and of agricultural inputs, be conducted by universal methods that are applied equitably in all inspected establishments.

Article 135. Audits and technical assessments shall be conducted in order to suitably organize, structure and systematize the control and inspection actions throughout Brazil and to seek to enhance the Brazilian Systems for the Inspection of Agricultural Products and Inputs; these procedures shall be followed:

I – the public inspection services of the States and of the Federal District shall be assessed by the Ministry of Agriculture, Livestock and Food Supply; and

II – the public inspection services of the Municipalities shall be observed by the States, taking into consideration their geographic areas of operations.

Paragraph 1. The Ministry of Agriculture, Livestock and Food Supply shall guide the public inspection services of the States, of the Federal District and of the Municipalities as to compliance with the legal provisions of this Regulation.

§ 2 Correction measures possibly taken shall be communicated to the representative organizations of society, of the region, or of the industries affected

Article 136. The activities of the Brazilian Systems for the Inspection of Agricultural Products and Inputs that fall to the responsibility of the States, of the Federal District and of the Municipalities, shall be performed by public institutions recognized by the Ministry of Agriculture, Livestock and Food Supply.

Article 137. The States, the Federal District and the Municipalities shall appoint civil servants to make up the teams to be the authorities responsible for the controls and inspections laid down in this Regulation.

Article 138. The competent authority of the States, the Federal District and the Municipalities may delegate duties related to controlling and inspection to one or more public institutions.

Article 139. The competent authorities of the Brazilian Systems for the Inspection of Agricultural Products and Inputs shall ensure the impartiality, quality and coherence of the official controls.

Article 140. Whenever functions related to official controls are entrusted to different public institutions, the competent authority that delegated the functions shall ensure coordination and cooperation among the institutions.

Article 141. Mechanisms shall be created for the inter-relationships among the Brazilian Systems for the Inspection of Agricultural Products and Inputs, and teaching and research institutions, so that the professionals in the Systems can receive on-going training, capacity-building and education.

Section I Inspection and Oversight of of Animal Products

Article 142. Hygiene, health, technological and industrial inspection of animal products are the competence of the Federal Government, the States, the Federal District and the Municipalities.

Paragraph 1. Inspection is hereby established as mandatory, from a health and industrial point of view, for all animal products whether edible or otherwise, and whether plant products are added to them or otherwise.

Paragraph 2. Inspection encompasses ante- and post-mortem inspection of animals, and the reception, handling, transformation, making, preparation, preservation, packing, packaging, deposit, labeling, transport and consumption of all products, by-products and economically valuable residues, whether plants products are added to them or otherwise, and whether intended for human consumption or not.

Article 143. No industrial establishment or cold storage plant for animal products may operate in Brazil without prior registration with the competent agency, so that its activities can be inspected.

Article 143-A. The States, the Federal District and the Municipalities may introduce specific standards for the general conditions of premises, equipment and operational practices of small-scale rural agribusinesses, in accordance with basic principles of food hygiene, aiming to guarantee the safety of animal products, and in accordance with Article 7. (In the wording of Decree 8,471/2015)

Sole paragraph. Small agroindustrial establishment of animal products is the establishment that cumulatively presents the following: (In the wording of Decree 8,471/2015)

I - it belongs to family farmers or rural producers, or equivalent, either individually or collectively; (Wording given by Decree 8,471/2015)

II - it is aimed exclusively at the processing of animal products; (Added by Decree 8,471/2015)

III - it has facilities for: (In the wording of Decree 8,471/2015)

- a) the slaughter or industrial processing of meat-producing animals; (Added by Decree 8,471/2015)
- b) the processing of fish or fish products; (Added by Decree 8,471/2015)
- c) the processing of milk or dairy products; (Added by Decree 8,471/2015)
- d) the processing of eggs or egg products; (Added by Decree 8,471/2015)
- e) the processing of beekeeping products and by-products; and (Added by Decree 8,471/2015)

IV - It has a built area no larger than two hundred and fifty square meters. (In the wording of Decree 8,471/2015)

Article 143-B. Sets up, within the scope of the Ministry of Agriculture Livestock and Food Supply, the Consultative Technical Committee of the Brazilian Animal Product Inspection System. (Included by Decree 7,216/2010)

Article 143-C. It is for the Consultative Technical Committee of the Brazilian Animal Product Inspection System to: (Included by Decree 7,216/2010)

I - periodically assess guidelines and the technical and operational conditions of the Brazilian Animal Product Inspection System; (Added by Decree 7,216/2010)

II - appreciate and propose changes to the standards regulating the Brazilian Animal Product Inspection System; and (Added by Decree 7,216/2010)

III - issue technical opinions to underpin the decision-making behind the rules and procedures of the Brazilian Animal Product Inspection System. (Included by Decree 7,216/2010)

Article 143-C. The Consultative Technical Committee of the Brazilian Animal Product Inspection System will be made up of the following members: (Included by Decree 7,216/2010)

I - two representatives of the Ministry of Agriculture Livestock and Food Supply's Department of Inspection of Animal Products; (Added by Decree 7,216/2010)

II - two representatives of the Ministry of Agrarian Development; (Added by Decree 7,216/2010)

III - one representative of the Ministry of Agriculture Livestock and Food Supply's Secretariat for Animal and Plant Health (SDA—*Secretaria de Defesa Agropecuária*); and (Added by Decree 7,216/2010)

IV - representatives of civil society, appointed by a specific act of the Ministry of Agriculture Livestock and Food Supply. (Included by Decree 7,216/2010)

Paragraph 1. Committee Members may appoint technical specialists of the Official Inspection Services and representatives of similar entities to take part in meetings. (Included by Decree 7,216/2010)

Paragraph 2. The Committee will be coordinated by the Department of Inspection of Animal Products, which will organize two ordinary meetings per year. (Included by Decree 7,216/2010)

Paragraph 3. Committee members and their respective alternates will be nominated by the heads of the agencies they represent and appointed by the Secretary for Animal and Plant Health. (Included by Decree 7,216/2010)

Section II

Inspection and Oversight of of Plant Products

Article 144. The performance of hygiene, health, technological and industrial inspections of animal products is the competence of the Federal Government, the States, the Federal District and the Municipalities.

Article 144-A. The Ministry of Agriculture, Livestock and Food Supply will define the small beverage agroindustrial establishment, that must belong to family farmers or rural producers, or equivalent, individually or collectively, and have facilities for the production of beverages. (Included by Decree 8,471/2015)

Sole paragraph. The definition mentioned in the heading shall consider the scale of production and the built-up area. (Included by Decree 8,471/2015)

Article 145. The Brazilian System for the Inspection of Plant Products aims to ensure the identity, quality, conformity, suitability and the hygiene, health and industrial safety of plant products, by-products, derivatives and economically valuable residues through control, inspection and classification of the products, systems, or the production chain, as the case may be.

Section III

Inspection and Oversight of Agricultural Inputs

Article 146. Inspection and control of agricultural inputs are the competence of the Federal Government, the States, the Federal District, in compliance with the duties laid down in a specific Act.

Article 147. The Brazilian System for the Inspection of Agricultural Inputs and the Brazilian System for the Inspection of Livestock Inputs are hereby instituted; they shall be structured and organized under the coordination of the Ministry of Agriculture, Livestock and Food Supply, and responsible for inspecting and controlling agricultural and livestock inputs.

Article 148. The Brazilian System for the Inspection of Agricultural Inputs and the Brazilian System for the Inspection of Livestock Inputs aim to ensure the identity, quality, conformity, suitability and the hygiene, health and industrial safety of agricultural and livestock inputs through control, inspection and classification of the products, systems, or the production chain, as the case may be.

Section IV

Equivalence of Services

Article 149. The Ministry of Agriculture, Livestock and Food Supply, the States of Brazil, the Federal District and the Municipalities shall take necessary measures to ensure that control and inspection of animal and plant products and of inputs shall be carried out throughout all States and Municipalities in a way that is uniform, harmonious and equivalent.

Sole paragraph. For the purposes of this Regulation, equivalence of inspection services means a situation in which the hygiene, health and technological inspection measures taken by different inspection services enable the same inspection, enforcement, safety and product quality goals to be attained. (Included by Decree 7,216/2010)

Article 150. The Ministry of Agriculture, Livestock and Food Supply shall ensure that controls and inspections be carried out in line with rules and criteria for controls that are pre-defined in the Brazilian Systems for the Inspection of Agricultural Products and Inputs.

Article 151. Public inspection services linked to the States of Brazil, the Federal District and the Municipalities and consortia of Municipalities shall ask the Ministry of Agriculture, Livestock and Food Supply to verify and recognize their equivalence for inter-state trade purposes, as defined by the procedures for applying to join the Brazilian Systems for the Inspection of Agricultural Products and Inputs. (In the wording of Decree 8,445/2015) (Effectiveness)

Sole paragraph. After analysis and approval of the standard documentation, documentary and operational audits of the state, district or municipal inspection services shall be carried out by the competent authorities of the Ministry of Agriculture, Livestock and Food Supply in order to recognize accession to the System

Article 152. The inspection services of the States, Federal District and the Municipalities that join the Brazilian Systems for the Inspection of Agricultural Products and Inputs shall be recognized as equivalent, for their activities and competencies, provided that they follow Federal norms and Regulations and that they meet the requirements established by the Unified Animal and Plant Health System introduced by the Ministry of Agriculture, Livestock and Food Supply, keeping their original administrative characteristics.

Paragraph 1. The States, Federal District and Municipalities shall guarantee that all products, whether intended for the local, regional or national market, shall be inspected and controlled with the same rigor.

§ 2 The competent authorities at the destinations must verify compliance with the legislation for animal and plant products, through non-discriminatory controls

§ 3 The States, Federal District and Municipalities may request specific technical information from the official services that delivered merchandise from other States or Municipalities, or the Federal District

Paragraph 4. The States, Federal District or Municipalities that in compliance with the terms of their legislation approve establishments within their territory, must inform the Ministry of Agriculture, Livestock and Food Supply and the other States and Municipalities.

Article 153. The following are conditions for recognition of equivalence and for licensing the product inspection services in the Brazilian Systems for the Inspection of Agricultural Products and Inputs:

I - a formal request based on the prerequisites and criteria defined by the Unified Animal and Plant Health System; (Wording given by Decree 8,445/2015) (Effectiveness)

II - presentation of the law that defined the inspection service and its regulation; (Added by Decree 8,445/2015) (Effectiveness)

II - presentation of the work plan for the inspection service; (In the wording of Decree 8,445/2015) (Effectiveness)

IV - proof of structure and a team that are compatible with the duties. (Added by Decree 8,445/2015) (Effectiveness)

V - submittal of a complete list of the establishments that are already registered and inspected by the inspection services. (Included by Decree 8,445/2015) (Effectiveness)

Paragraph 1. The public inspection services of the States and of the Federal District shall request the Ministry of Agriculture, Livestock and Food Supply to analyze and approve the documentation to recognize equivalence. (In the wording of Decree 8,445/2015) (Effectiveness)

Paragraph 2. The public inspection services in the States that became members of the Brazilian Systems for the Inspection of Agricultural Products and Inputs shall analyze the documentation and perform technical and administrative audits to verify the equivalence of the inspection public services linked to the Municipalities and the consortia of Municipalities within its jurisdiction, before the final approval by the Ministry of Agriculture, Livestock and Food Supply. (In the wording of Decree 8,445/2015) (Effectiveness)

Paragraph 3. If the public inspection services in the States did not become members of the Brazilian Systems for the Inspection of Agricultural Products and Inputs, the public inspection services in the Municipalities and the consortia of Municipalities within its jurisdiction shall directly request the Ministry of Agriculture, Livestock and Food Supply to analyze and approve the documentation and perform technical and administrative audits to recognize the equivalence. (In the wording of Decree 8,445/2015) (Effectiveness)

Paragraph 4. Public inspection services linked to the States of Brazil, the Federal District and the Municipalities and consortia of Municipalities that became members of the Brazilian System for the Inspection of Animal Products shall periodically undergo technical and administrative audits by the Ministry of Agriculture, Livestock and Food Supply in order for the System to be improved and for the membership to be maintained. (In the wording of Decree 8,445/2015) (Effectiveness)

Paragraph 5. Public inspection services linked to the States of Brazil, the Federal District and the Municipalities and consortia of Municipalities that became members of the Brazilian System for the Inspection of Animal Products shall submit the updated list, mentioned in item V, with the identification number of the establishments, to the Ministry of Agriculture, Livestock and Food Supply in the frequency and form defined by the Ministry of Agriculture. (In the wording of Decree 8,445/2015) (Effectiveness)

Paragraph 6. The establishments identified on the lists mentioned in item V of the heading and Paragraph 5 shall be integrated to the Brazilian System for the Inspection of Animal Products. (Included by Decree 8,445/2015) (Effectiveness)

Paragraph 7. The Ministry of Agriculture, Livestock and Supply and the competent state agencies will have a ninety-day deadline, from when the request for equivalence and eligibility of the inspection service is formally delivered, to analyze the documentation submitted, carry out the technical and administrative audits and issue an opinion on whether the request should be granted to the inspection services of Municipalities and consortia of Municipalities. (Included by Decree 8,445/2015) (Effectiveness)

Paragraph 8. According to Paragraph 2, the Ministry of Agriculture, Livestock and Food Supply will have thirty days to issue its final opinion regarding the approval of the request to recognize the equivalence and eligibility of the inspection services of the Municipalities and consortia of Municipalities as of the date when the documentation has been received from the State competent agency. (Included by Decree 8,445/2015) (Effectiveness)

Paragraph 9. The Ministry of Agriculture Livestock and Food Supply and the competent State authorities may ask for internal investigations to be conducted, which will interrupt the deadline described in Paragraphs 7 and 8, the latter to be resumed after a protocol for the documentation proving performance of the investigation is formally delivered. (Included by Decree 8,445/2015) (Effectiveness)

Article 154. The public inspection services of the Brazilian Systems for the Inspection of Agricultural Products and Inputs shall be delisted if the following cases are found:

I – non-compliance with the norms and the activities and goals listed and approved in the program of work, when this jeopardizes the objectives of the Unified Animal and Plant Health System;

II – failure to feed in data and maintain up-to-date the information system; and

III – lack of timely response to formal requests for information.

Article 155. To meet the goals of the Brazilian Systems for the Inspection of Agricultural Products and Inputs, the Ministry of Agriculture, Livestock and Food Supply shall continuously conduct planning and produce a management plan for the programs, actions, audits and other activities essential for the inspection of animals, plants and inputs.

CHAPTER XI

FINAL PROVISIONS

Article 156. The competent authorities of the three Levels of the Unified Animal and Plant Health System and of the public services linked to the Brazilian Systems for the Inspection of Agricultural Products and Inputs shall ensure that their activities are carried out with transparency, and to this end must give the population at large access to relevant information kept by the systems, above all the control activities.

Sole paragraph. The three Levels of the Unified Animal and Plant Health System and the authorities responsible for public services linked to the Brazilian Systems for the Inspection of Agricultural Products and Inputs shall have a mechanism to prevent confidential information, to which they have had access in the performance of official controls, and which by its nature is covered by professional secrecy, being divulged

Article 157. The Ministry of Agriculture, Livestock and Food Supply, under the law and within its area of operations, is authorized to sign agreements with public agencies to provide subsidiary support for actions in the field of animal and plant health.

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