President of the Republic
Chief of Staff's Office
Sub-Department of Legal Matters

DECREE No. 9,013 ENACTED 29 MARCH, 2017

This Decree regulates Law no. 1,283, enacted 18 December 1950, and Law no. 7,889, enacted 23 November 1989, which address the industrial and sanitary inspection of animal products.

THE PRESIDENT OF THE REPUBLIC, using the powers invested in him by Article 84, **head provision**, item IV, of the Constitution, and pursuant to what is given in Law no. 1,283, enacted 18 December 1950, and Law no. 7,889, enacted 23 November 1989,

DECREES:

TITLE I

PRELIMINARY PROVISIONS AND SETTING OF OPERATIONS CHAPTER I

PRELIMINARY PROVISIONS

Article 1 This Decree addresses the regulation of the industrial and sanitary inspection of animal products, which governs the supervision and the industrial and sanitary inspection of animal products, brought in by Law no. 1,283, enacted 18 December 1950, and by Law no. 7,889, enacted 23 November 1989.

Paragraph 1 The activities defined in the **head provision**, the competent jurisdiction of the Federal Government, shall be performed by the Ministry of Agriculture, Livestock and Food Supply—MAPA.

Paragraph 2 The activities defined in the **head provision** shall comply with the competent jurisdictions and standards laid down by the SNVS—Brazilian National System for Sanitary Surveillance (*Sistema Nacional de Vigilância Sanitária*).

Paragraph 3 This Decree and the Norms that supplement it shall be guided by the constitutional principles of Federalism, by the promotion of micro- and small companies, of scientific development and technological innovation, by respect for international law, for treaties entered into by the Federative Republic of Brazil and for bilateral and multilateral equivalency agreements, among other constitutional principles, and shall aim to rationalize, simplify and make virtual all processes and procedures.

CHAPTER II

THE SCOPE OF OPERATIONS

Article 2 The inspection and oversight of animal product-producing establishments that engage in interstate (ie domestic) or international trade, addressed by this Decree, are the competent jurisdiction of the Department of Inspection of Animal Products—DIPOA and of the Federal Inspection Service—SIF, which are part of the Ministry of Agriculture, Livestock and Food Supply—MAPA.

Paragraph 1 Inspection and control by the Ministry of Agriculture, Livestock and Food Supply extends to wholesalers that receive activities products, as a supplement to the local sanitary inspection activities as laid down in Law no. 7,889, enacted 1989, and aim to reinspect animal products coming from interstate or international trade.

Paragraph 2 Inspection and control in animal product establishments that engage in interstate and international trade may be exercised by Inspection Services in the States, the Federal District and the Municipalities, provided that equivalency between these services is acknowledged by the Ministry of Agriculture, Livestock and Food Supply, as set forth in specific legislation of SUASA—Unified Animal and Plant Health System (*Sistema Unificado de Atenção à Sanidade Agropecuária*) - , in accordance with Law no. 8,171, enacted 17 January 1991, and in Law no. 9,712, enacted 20 November 1998.

Article 3 Inspection and industrial and sanitary controls performed in animal product establishments engaging in interstate and international trade shall be governed by this Decree whenever the States, the Federal District and municipalities do not possess their own legislation.

Article 4 Only those animal product establishments operating under SIF inspection may engage in international trade.

Article 5 Animals for slaughter, the meat and by-products thereof, seafood and by-products, eggs and egg products, milk and dairy products, the produce and by-products of bees, whether edible or inedible, with or without addition of plant products, are all subject to the inspection and controls set forth in this Decree.

Sole paragraph. The inspection and controls addressed in this article also include—within the industrial and sanitary perspective—ante mortem and post mortem inspection of animals, the reception, handling, treatment, industrial manufacture, fractionation, canning, placement, packaging, labeling, storage, shipping and movements of any animal raw materials and products.

Article 6 The inspection and controls addressed in this Decree shall be performed:

I - on farms supplying raw material for handling or the processing of animal products;

II - at establishments receiving the several animal species for slaughter defined in this Decree;

III - at establishments receiving seafood and seafood-products for handling, distribution or industrial processing;

IV - at establishments that produce and receive eggs and egg products for distribution or industrial processing;

V - at establishments that receive milk and dairy products for treatment and industrial processing;

VI - at establishments that extract bee products or by-products for treatment and industrial processing;

VII - at establishments that receive, handle, store, preserve, pack or ship raw materials and edible or inedible animal products from registered or related establishments; and

VIII - at ports, airports, border posts, special customs facilities and special facilities for customs dispatch for export.

Article 7 When inspection and controls are performed by the Department of Inspection of Animal Products, the establishment shall be exempt from any other kind of Federal industrial or sanitary inspection of animal products.

Article 8 For the purposes of this Decree, a "federally-inspected animal product establishment" is any industrial facility where meat-producing animals are slaughtered or industrially processed and where meat and by-products (including seafood and by-products, eggs and by-products, milk and dairy products, and honey and honey by-products) are obtained, received, handled, treated, industrially processed, fractionated, canned, stored, packed, packaged, labeled or shipped for industrial or commercial purposes, including small-scale agri-industrial animal product establishments as provided for in Law no. 8,171, enacted 1991, and its implementation norms.

Article 9 For the purposes of this Decree, "product" or "by-product" is understood to mean any animal product or raw material.

Article 10. The following definitions are adopted for the purposes of this Decree:

I - self-control analysis - an analysis carried out by the establishment to control its process and to monitor the compliance of raw materials, ingredients, inputs and products;

II - Hazard Analysis and Critical Control Points—HACCP - a system that identifies, evaluates and controls significant risks to the safety of animal products;

III - fiscal analysis - an analysis performed by the National Network of Animal and Plant Laboratories (*Rede Nacional de Laboratórios Agropecuários*) of the Unified Animal and Plant Health System (*Sistema Unificado de Atenção à Sanidade Agropecuária*—SUASA), or other competent health authority on samples taken by staff of the Ministry of Agriculture, Livestock and Food Supply (MAPA);

IV - expert analysis - a laboratory analysis based on an official B sample when one of the parties appeals the result of a fiscal analysis, in order to ensure full right to defense by the interested party, when relevant;

V - exotic animal species - all animals belonging to exotic species of fauna, raised in captivity, the geographic distribution of which does not include the territory of Brazil, species introduced by man, including domestic species, in a wild state, as well as those species introduced outside the territory of Brazil or its territorial waters, but that may have entered Brazilian territory;

VI - wild animals - all animals of native, migratory or other species of aquatic or terrestrial fauna, whose life-cycle takes parts wholly or partially within the limits of the territory of Brazil or Brazilian waters;

VII - game species - those defined by a standard issued by a competent federal public agency;

VIII - Good Manufacturing Practices (GMPs) - systematized hygienic, sanitary and operational conditions and procedures applied throughout the production process to ensure the safety, identity, quality and integrity of animal products;

IX - disinfection - a procedure consisting of the elimination of infectious agents by physical treatments or chemicals;

X - equivalency of inspection services - the condition in which hygiene, sanitary and technical inspection and enforcement measures taken by different inspection services enable the same objectives of inspection, enforcement, product safety and quality to be achieved, as set forth in Law no. 8,171, enacted 1991, and its implementation norms;

~~XI - espécies de açougue - são os bovídeos, equídeos, suídeos, ovinos, caprinos, lagomorfos e aves domésticas, bem como os animais silvestres criados em cativeiro, abatidos em estabelecimentos sob inspeção veterinária;~~

XI - livestock species - bovines, buffaloes, equidae, suidae, ovines, caprines, lagomorphs and domestic birds, as well as wild animals raised in captivity, that are slaughtered in establishments under veterinary inspection; (Wording given by Decree no. 9,069, enacted 2017)

XII - cleaning - a procedure consisting of two distinct steps, washing and sanitization;

XIII - washing - the physical removal of organic, inorganic or otherwise unwanted residues from the surfaces of built structures, equipment and utensils;

XIV - sanitization - the application of chemicals that have been approved by the health regulator, or of physical methods, to the surfaces of built structures, equipment and utensils after cleaning procedures, in order to ensure a microbiologically acceptable level of hygiene;

XV - identity standard - a set of parameters that enables an animal product to be identified according to its nature, its sensory characteristics, its composition, the type of processing and its mode of presentation, which are defined according to a Technical Regulation of Identity and Quality—henceforth "TRIQ";

XVI - SSOP - Sanitation Standard Operating Procedures - procedures that are described, performed, introduced, monitored and verified by the establishment in order to avoid direct or cross-contamination of the product and preserve its quality and integrity by means pre-, peri- and post-operational hygiene;

XVII - self-control programs - programs that are developed, and procedures that are described, developed, implemented, monitored and verified by the establishment in order to ensure that safety, identity, quality and integrity of its products, including - but not limited to - prerequisite programs, GMPs, SSOPs and HACCP, or to equivalent programs recognized by the Ministry of Agriculture, Livestock and Food Supply;

XVIII - quality - a set of parameters that enables the specifications of an animal product to be characterized in regard to a defined desirable standard, concerning intrinsic and extrinsic factors of health, hygiene and technology;

XIX - traceability - the ability to identify the origins and track the movements of an animal product through the stages of production, distribution and sale, as well as those of raw materials, ingredients and inputs used in its production;

XX - Technical Regulation for Identity and Quality (TRIQ) - an act of legislation to determine the identity and minimal quality characteristics that animal products must comply with; and

XXI - technological innovation - novel or significantly enhanced technological products or processes, not included within the state of the technique, and that enable improvement of the objective of the process or of the quality of the animal product, deemed in accordance with the Brazilian standards of industrial property and the applicable international guidelines.

Article 11. There will be permanent federal inspection in those meat and by-product establishments slaughtering different species of livestock and game.

Paragraph 1 In the case of reptiles and amphibians, inspection and oversight will be permanent only during slaughter operations.

Paragraph 2 In the other establishments addressed in this Decree, there will be periodical federal inspection.

Paragraph 3 The frequency of the inspection and oversight mentioned in Paragraph 2 above shall be established in supplementary norms.

Article 12. Industrial and sanitary inspection and oversight of animal products encompass the following procedures, among others:

I - **ante mortem** and **post mortem** inspection of the different animal species;

II - verification of the hygiene and health conditions of the built facilities and equipment, and of the operations of the establishments;

III - verification of hygiene and hygiene habits of the food handlers; IV - verification of the

establishments' self-control programs;

V - verification of labeling and of the technological processes applied to animal products regarding compliance with specific legislation;

VI - sample-taking for fiscal analyses and evaluating the results of physical, microbiological, physical and chemical, molecular biology, histological and other tests that may be necessary in order to verify the production processes or animal product processes, and may also encompass those tests for the consumer markets;

VII - evaluation of the information inherent to primary production that may affect animal health and public health, or information that is part of international agreements with importing countries;

VIII - evaluation of animal welfare among animals for

slaughter; IX - checking supply water;

X - the phases of obtaining, receiving, handling, treatment, industrial production, fractionation, canning, storing, packing, packaging, labeling, shipping and transportation of all edible and inedible products, raw materials, with or without the addition of plants;

XI - grading products and by-products in accordance with standards laid down in specific legislation or in registered formulae;

XII - verification of raw materials and products passing through ports, airports, border posts, special customs facilities and special facilities for customs clearance for export;

XIII - verification of means of transportation of live animals and of products, by-products and raw materials intended for human consumption;

XIV - control of residues and contaminants in animal products;

XV - traceability control for animals, raw materials, inputs, ingredients and products throughout the production chain;

XVI - health certification for animal products; and

XVII - other inspection procedures whenever recommended by the practice and development of the animal product industry.

Article 13. Inspection and oversight procedures may be altered by the Ministry of Agriculture, Livestock and Food Supply, applying hazard analysis, according to the level of technological development involved, whenever applicable, throughout the entire production chain, according to universally applied and established food safety concepts.

Article 14. The inspection and oversight addressed in this Decree are the duty of Federal Agricultural Inspectors who have graduated in Veterinary Medicine, of Sanitary and Industrial Inspection Agents for Animal Products (AISIPOAs, in its Portuguese acronym), and other agricultural inspection officers, duly respecting their several competencies.

Article 15. Officers responsible for carrying out the activities addressed in this Decree must hold a service identification card issued by the Ministry of Agriculture, Livestock and Food Supply.

Paragraph 1 The ministry personnel addressed in this article, when performing their duties, must produce their cards to identify themselves.

Paragraph 2 Personnel of the Ministry of Agriculture, Livestock and Food Supply, duly identified, in the exercise of their duties, shall be allowed unrestricted access to the establishments laid down in Article 2.

Paragraph 3 Ministry personnel may request assistance from law enforcement agencies if their physical safety is in jeopardy, or if the performance of their duties is impeded or hindered.

TITLE II

GENERAL CLASSIFACTION

Article 16. Animal product establishments engaging in interstate (domestic) and international trading, and under federal inspection, are classified as being:

I - meat and by-products;

II - seafood and by-

products; III - eggs and by-

products;

IV - milk and dairy products;

V - bee products and by-products; VI-

storage facilities; and

VII - inedible products.

CHAPTER I

MEAT AND BY-PRODUCT ESTABLISHMENTS

Article 17. Meat and by-product establishments are classified as: I -

slaughterhouses; and

II - meat and meat product processing plants.

Paragraph 1 For the purposes of this Decree, establishments intended for the slaughter of meat-producing animals, the reception, the handling, the packing, the labeling, the storage and the shipping of products from slaughter, and possessing industrial cold facilities, able to receive, handle, industrially process, pack, label, store, and ship edible and inedible products, are defined as slaughterhouses.

Paragraph 2 For the purposes of this Decree, establishments intended for the reception, the handling, the packing, the labeling, the storage and the shipping of meat and meat products, and with the capacity to industrially produce edible products and to receive, handle, industrially process, pack, label, store, and ship inedible products, are defined as meat and meat-product producing units.

Article 18. Gelatin and collagen manufacture shall be performed in establishments categorized as meat and meat-product producing units.

Sole paragraph. Hides may be processed to obtain raw materials to make the products addressed in the **head provision** at the inedible product producing units addressed in Article 24.

CHAPTER II

SEAFOOD AND SEAFOOD-PRODUCT ESTABLISHMENTS

Article 19. Seafood and seafood-product establishments are classified as: I -

factory ships;

II - seafood slaughterhouses;

III - seafood and seafood-product processing units; and

IV - bivalve mollusk depuration stations.

Paragraph 1 For the purposes of this Decree, fishing vessels intended for the capture or reception, washing, handling, the packing, labeling, storage and the shipping of seafood and seafood-products, possessing industrial cold storage capacity, and with the capacity to industrially produce edible products and to receive, handle, industrially process, pack, label, store, and ship inedible products, are defined factory ships.

Paragraph 2 For the purposes of this Decree, establishments intended for the slaughter of seafood, the reception, washing, handling, packing, labeling, storage and shipping of slaughter products, and that can receive, handle, industrially process, pack, label, store and ship edible and inedible products are defined as seafood slaughter facilities.

Paragraph 3 For the purposes of this Decree, establishments intended for the reception and washing of primary production seafood, handling, packing, labeling, storing and shipping seafood and seafood-products, and possessing the capacity to industrially produce seafood products and to receive, handle, industrially process, pack, label, store, and ship inedible products, are defined as seafood and seafood-product processing units.

Paragraph 4 For the purposes of this Decree, establishments intended for the reception, depuration, packing, labeling, storing and shipping of bivalve mollusks are defined as mollusk depuration stations.

CHAPTER III

EGG AND EGG PRODUCT ESTABLISHMENTS

Article 20. Egg and egg product establishments are classified

as: I - bird farms; and

II - egg and egg product treatment plants.

Paragraph 1 For the purposes of this Decree, establishments intended for the production, ovoscopy, classification, packing, labeling, storing and shipping of eggs exclusively from their own production for direct sale are defined as bird farms.

Paragraph 2 Bird farms may sell eggs to the egg and egg product treatment plants.

Paragraph 3 For the purposes of this Decree, establishments intended for the production, reception, ovoscopy, classification, industrial processing, packing, labeling, storing and shipping of eggs or egg products are defined as egg treatment units.

Paragraph 4 Classification of eggs is permitted when egg and egg product treatment units receive eggs that have already been classified.

Paragraph 5 If the egg and egg product treatment unit is dedicated only to the shipping of eggs, the requirement to possess facilities for the industrial processing of eggs may be waived.

CHAPTER IV

MILK AND DAIRY PRODUCT ESTABLISHMENTS

Article 21. Milk and dairy product establishments are classified as: I -

dairy farm;

II - refrigeration station;

III - processing plant; IV -

dairy plant; and

V - cheese-makers.

Paragraph 1 For the purposes of this Decree, establishments intended for the production, pretreatment, treatment, filling, packing, labeling, storing and shipping of milk for direct human consumption, are defined as dairy farms; they may also produce dairy by-products from milk exclusively self-produced

involving the stages of pretreatment, treatment, handling, manufacturing, maturation, grating, fractionating, packing, labeling, storing and shipping.

Paragraph 2 For the purposes of this Decree, establishments that are interposed between farms and treatment plants or dairy plants intended for the selection, reception, weighing and measuring of volume, filtration, refrigeration, packing and shipping of raw milk, including temporary stocking of the milk until shipping, are defined as refrigeration stations.

Paragraph 3 For the purposes of this Decree, establishments intended for receiving, pretreating, filling, packing, labeling, storing and shipping of milk for direct human consumption, and that may also transfer, handle, manufacture, mature, fractionate, grate, pack, label, store, and ship dairy products, and may also ship bulk liquid milk for industrial use, are defined as treatment plants.

Paragraph 4 For the purposes of this Decree, establishments intended for the manufacture of dairy products, involving the stages of reception of milk and milk products, transfer, refrigeration, processing, handling, manufacture, maturation, fractionation, grating, packing, labeling, storing and shipping of dairy products, including the shipping of bulk liquid milk for industrial use, are defined as dairy plants.

Paragraph 5 For the purposes of this Decree, establishments located on farms and intended for the manufacture of traditional cheeses with specific characteristics, made exclusively with milk from the farm itself, involving the stages of manufacture, maturation, packing, labeling, storing and shipping, and that send their product to a dairy plant or processing plant in the event they do not complete the cheese-making process, are defined as cheese-makers.

CHAPTER V

BEE AND BEE PRODUCT ESTABLISHMENTS

Article 22. Bee and bee product establishments are classified as: I - bee-product extraction

and treatment units; and

II - bee and bee product treatment stations.

Paragraph 1 For the purposes of this Decree, establishments intended for receiving raw materials from bee-keepers, extracting, packing, labeling, storing and shipping bee products, and that may also treat and fractionate such products, are defined as extraction and treatment units.

Paragraph 2 For the purposes of this Decree, establishments intended for receiving, classifying, treating, industrially processing, packing, labeling, storing and shipping products and pretreated raw materials from other bee and bee product establishments, and that may extract raw materials from other bee-keepers, are defined as bee and bee product treatment stations.

Paragraph 3 Raw materials extracted previously by bee-keepers may be received provided it complies with this Decree and supplementary norms.

CHAPTER VI

STORAGE ESTABLISHMENTS

Article 23. Storage establishments are classified as: I - storage facilities

for animal products; and

II - wholesalers.

Paragraph 1 Establishments intended exclusively to receive, store and ship edible or inedible animal products, which may or may not need industrial cold facilities, and which have specific facilities for reinspection, are defined as animal product storage facilities.

Paragraph 2 Establishments registered with health agencies that receive animal products from interstate (i.e. domestic) or international trade, ready to sell, packed and labeled for reinspection purposes, are defined as wholesalers.

Paragraph 3 Handling, fractionating or repackaging of product may not be carried out at those establishments defined in Paragraphs 1 and 2.

Paragraph 4 Ports, airports, border posts, special customs facilities or special facilities for customs clearance for export, and container terminals are not classified as animal product storage facilities.

CHAPTER VII

INEDIBLE PRODUCT ESTABLISHMENTS

Article 24. Inedible product establishments are classified as inedible product treatment units.

Sole paragraph. Establishments intended for receiving, handling, and processing raw materials and animal residues for the exclusive preparation of products not used in human foodstuffs as laid down in this Decree or in supplementary norms, are defined as inedible product treatment units.

TITLE III

REGISTRATION AND LISTING OF ESTABLISHMENTS CHAPTER I

REGISTRATION AND LISTING

Article 25. All establishments engaging in interstate (i.e. domestic) or international trade in animal products must be registered with the Department of Inspection of Animal Products or listed in the State-level animal product inspection service, as set forth in Law no. 1,283, enacted 1950, and use the classification addressed in this Decree.

Paragraph 1 In order to engage in international trade in animal products, establishments, in addition to being registered, must meet the specific sanitary requirements of importing countries or blocs of countries.

Paragraph 2 The Department of Inspection of Animal Products may adjust its performance of inspection and oversight activities so as to enable verification of guarantees and controls for health certification in accordance with requirements undersigned by Brazil in international sanitary agreements.

Article 26. Establishments classified as wholesalers in this Decree shall be linked to the Ministry of Agriculture, Livestock and Food Supply by means of a 'listing'.

Article 27. The Ministry of Agriculture, Livestock and Food Supply shall—for the purpose of registration and control—establish the several activities allowed for each establishment-classification set forth in this Decree, including for the small-scale animal product agribusiness companies mentioned in Law no. 8,171, enacted 1991, and in implementation norms.

Article 28. Establishments must present the following documentation when requesting registration or listing:

I - affidavit of commitment in which the establishment agrees to accept the demands of this Decree, without prejudice to others yet to be determined;

II - ground plans of its built facilities;

III - a sanitary specifications sheet for the establishment; and

IV - a document issued by the competent registering authority proving the address for the unit to be registered or enrolled as a Rural Producer or Registry of Natural Person, as applicable.

Sole paragraph. In the case of already built establishments, in addition to the documentation given in the **head provision**, there must be held an inspection to assess the industrial and social facilities, the equipment, flowchart, supply water, and drainage of waste water, with a conclusive technical opinion issued by a Federal Agricultural Inspector who graduated in Veterinary Medicine.

Article 29. The construction of the establishment must comply with other demands set forth in the Federal, State, Federal District and Municipality legislation, as well as that of other technical standardizing agencies, provided that they do not

contradict the sanitary or industrial demands laid down in the present Decree or in supplementary norms issued by the Ministry of Agriculture, Livestock and Food Supply.

Article 30. After the demands established in this Decree and in supplementary norms have been met, the Director of the Department of Inspection of Animal Products, of the Ministry of Agriculture, Livestock and Food Supply, will issue the certificate of registration, which will bear the registration number, the corporate name, and the establishment's classification and location.

Article 31. After the registration certificate has been issued, the establishment will be authorized to operate, once a Federal Inspection Service SIF has been installed, by means of a document issued by the head of the animal product inspection service in the specific State of Brazil.

Article 32. The listing of the establishment shall obey the same criterion laid down for the registration of the establishments, where applicable.

Sole paragraph. After the demands established in this Decree and in supplementary norms have been met, the Director of the Department of Inspection of Animal Products of the specific State of Brazil will issue the certificate of listing, which will bear the listing number, the corporate name, and the establishment's location, and which will authorize the commencement of reinspection activities.

Article 33. All extensions, remodeling, or building work in the registered or listed establishments, either in outbuildings or in essential facilities, which may entail a change in production capacity, flows of raw materials, product or employees, may only be carried out after prior approval of the plans.

~~Article 34. Nos estabelecimentos que realizem atividades em instalações independentes, situadas na mesma área industrial, pertencentes ou não à mesma empresa, poderá ser dispensada a construção isolada de dependências que possam ser comuns.~~

Article 34. Those establishments operating in independent facilities located on the same industrial site, whether or not they belong to a single company, will be spared the isolated construction of social facilities that might otherwise be shared. (In the wording of Decree 9,069/2017)

Paragraph 1 Described by its registration or listing number, each establishment will be held responsible for meeting the demands of this Decree and supplementary norms in the shared facilities that affect its activity either directly or indirectly.

Paragraph 2 Establishments belonging to a single corporate group located in a single industrial area shall be registered or listed under the same number.

Article 35. Any establishment interrupting its operations for a period of time over six months shall only be allowed to resume operations after a prior inspection of its out-buildings, built facilities and equipment, taking into consideration the seasonality of its industrial activities.

Paragraph 1 If an establishment does not engage in interstate or international trade for the period of one year, its registration or listing shall be canceled.

Paragraph 2 If an establishment interrupts its operations for the period of one year, its registration or listing shall be canceled.

Article 36. If registration or listing is canceled, the labeling and all materials pertaining to its SIF, as well as official documentation, seals and stamps, shall be seized.

Article 37. The competent authorities of the State, Federal District or Municipality shall be notified of the cancellation of registration, as shall, if necessary, the Federal Authority, in the person of the Head of the animal product inspection service of the State in which the establishment is located.

Article 38. the Ministry of Agriculture, Livestock and Food Supply shall issue supplementary norms on the procedures of prior approval of plans, remodelings and extensions, and for the procedures of registering and listing establishments.

CHAPTER II

TRANSFER

Article 39. No establishment provided for in this Decree may be sold, rented or leased without concomitantly transferring its registration or listing in the SIF.

Paragraph 1 If the purchaser or lessee refuses to effect this transfer, they must immediately notify the SIF of this fact in writing.

Paragraph 2 Entrepreneurs or corporate groups responsible for these establishments must notify those interested in their purchase, rent or lease of the current situation during all stages of the commercial transaction, pursuant to the demands of this Decree.

Paragraph 3 Until the transfer is completed, those entrepreneurs and corporations in whose name the establishment is either registered or listed shall remain responsible for any irregularities found in the establishment.

Paragraph 4 If the party selling, renting or leasing out the plant has carried out the notification described in Paragraph 1, and the party buying, renting or leasing fails to present the necessary documentation for the transfer within thirty days, the establishment's registration or listing will be canceled.

Paragraph 5 Once the establishment has been purchased, rented or leased, and the registration or listing has been transferred, the new entrepreneur or corporation will be obliged to meet all the demands placed upon the former responsible party, without prejudice to others that may later be determined.

Article 40. The transfer process, as far as is applicable, shall obey the same criteria laid down for registration or listing.

TITLE IV

GENERAL CONDITIONS FOR ESTABLISHMENTS

CHAPTER I

BUILT FACILITIES AND EQUIPMENT

Article 41. No establishment will be allowed to operate until it has been completely installed and equipped for purpose, pursuant to the plans approved by the Department of Inspection of Animal Products.

Sole paragraph. The facilities and equipment addressed in the **head provision** encompass the minimum built facilities, equipment and sundry utensils, in accordance with the production capacity of each establishment and the type of product made.

Article 42. Animal product establishments must possess the following basic and shared conditions, taking into consideration applicable technical specificities, without prejudice to other criteria established in supplementary norms:

I - location in sites sufficiently remote as to prevent foul odors and potential contaminants; II - location on

a site large enough for the movements of people and flow of transport vehicles;

III - the area is to be delimited and large enough to build industrial facilities and other outhouses;

IV - paved yard and thoroughfares and industrial perimeter in good condition and state of cleanliness;

V - buildings and facilities compatible with the purpose of the establishment and suitable for obtaining, receiving, handling, treating, industrially processing, fractionating, canning, packing, packaging, labeling, storing or shipping raw materials and edible or inedible products;

VI - the industrial buildings and facilities for edible product are to be separated by uninterrupted walls from buildings and facilities intended for the preparation of inedible products, and from facilities not related to production;

VII - buildings and facilities for the storage of ingredients, additives, technological adjuvants, packaging, labeling, cleaning materials, chemicals and pest-control substances;

VIII - organization of the buildings, facilities and equipment so as to avoid bottlenecks in the operational flow and prevent cross-contamination;

IX - lined or waterproofed walls and partitions to enable cleaning;

X - ceilings sufficiently high as to enable suitable installation of equipment and meet the specific hygienic, sanitary and technological conditions for the purpose;

XI - false ceilings in settings where reception, handling and preparation of raw material and edible product takes place;

XII - floors waterproofed with sturdy cleanable material and built so as to enable the collection of waste waters and drainage of sanitary and industrial effluents;

XIII - easy-to-clean drains, with traps;

XIV - hand- and boot-washing facilities with specific equipment and utensils at the entrance to production areas and sinks for hand-washing in the production areas;

XV - windows, doors and other openings built and protected so as to prevent vectors and pests from entering and avoid the accumulation of dirt;

XVI - sufficient natural or artificial lighting and ventilation in all buildings;

XVII - corrosion-resistant equipment and utensils that are easy-to-clean, non-toxic and do not allow the accumulation of residues;

XVIII - equipment and instruments to monitor the manufacturing process, calibrated and externally checked, considered needful for technical and sanitary control of production;

XIX - an area for the cleaning of containers used in moving raw material and products; XX - red-colored

equipment and utensils exclusively for inedible products;

XXI - water supply network with facilities for storage and distribution, in sufficient volume to meet the industrial and social needs of the establishment, and when necessary water treatment facilities;

XXII - potable water in the industrial production areas;

XXIII - a separate and distinct network for non-potable water, when used in other applications, in order to avoid a contamination hazard for product;

XXIV - sewerage system designed and built so as to enable cleaning of the residue collection points, possessing devices and equipment intended to prevent contamination in the industrial areas;

XXV - changing-rooms and toilet facilities in quantity sufficient for the number of employees, with suitable internal flow;

XXVI - an area for meals according to the specific legislation of the competent agencies;

XXVII - suitable area and equipment, or an outsourced service, for the cleaning of the uniforms worn by employees making edible product;

XXVIII - a headquarters for the SIF, comprising an administrative area, changing-rooms and toilet facilities;

XXIX - places and equipment enabling sanitary inspection and supervision; XXX - cold and hot water in spaces

where products are handled and prepared;

XXXI - industrial cold chain installations and temperature control devices on chiller and freezer units, in tunnels, in chillers and freezers (i.e. rooms), in carcass holding rooms and in the industrial work spaces;

XXXII - rooms and equipment for receiving, storing and shipping inedible products; XXXIII - space, equipment

and utensils for carrying out laboratory tests;

XXXIV - ice, whether produced by the establishment or bought from third-parties;

XXXV - a specific room with filtered air and positive air-pressure;

XXXVI - suitable equipment for steam production; and

XXXVII - a suitably equipped laboratory, if necessary, to ensure the quality and safety of the product.

Article 43. Meat and meat-product establishments, in addition to the necessary technological specificities, must also possess:

I - built facilities and equipment to receive and house animals in accordance with the precepts of animal welfare, located at a distance that does not jeopardize product safety;

II - specific facilities for examining and segregating sick or suspect animals;

III - a specific facility for necropsy with a cremation oven, autoclave or equivalent device attached, to destroy dead animals and their remains;

IV - facilities and equipment to clean and disinfect animal transport vehicles; and

V - facilities and equipment suitable for receiving, processing, storing and shipping inedible products when necessary.

Sole paragraph. In the case of establishments that slaughter more than one species, the facilities must be built in such a fashion as to meet the specific technical needs of each species, without prejudice to the distinct operational flows.

Article 44. Seafood and seafood-product establishments, in addition to the necessary technological specificities, must also possess:

I - overhead covering to protect the seafood during unloading at establishments that possess their own quay or wharf;

II - a waiting room and washing equipment for seafood at establishments that receive the material directly from primary production;

III - a place for washing and depuration of bivalve mollusks, in the case of mollusk depuration stations; and

IV - specific facilities and equipment for treating and storing clean seawater, when used in seafood processing, in accordance with parameters defined by the competent agency.

Sole paragraph. Factory ships must meet the same conditions demanded for dry-land establishments, where applicable.

Article 45. Egg and egg-product establishments, meeting the suitable technological specificities of each establishment, must also possess facilities and equipment for ovoscopy and egg classification.

Article 46. Milk and dairy product establishments, in addition to the necessary technological specificities, must also possess:

I - facilities and equipment for milking, separated physically from industrial construction, in the case of dairy farms; and

II - in the case of cheese-makers, milking facilities physically separated from the cheese-making facility.

Sole paragraph. Where a cheese-maker does not carry out the entire cheese manufacturing process, the dairy plant or processing plant will be jointly responsible for ensuring the safety of the product by introducing and monitoring herd health programs and self-control programs.

Article 47. Bee and bee-product establishments that have been classified as bee and bee product extraction units may be set up in vehicles possessing equipment and facilities meeting technological, hygienic and sanitary conditions, thus being mobile units.

Article 48. The Department of Inspection of Animal Products may demand changes be made in the industrial plan, the production processes and the operation flow chart, in order to ensure the performance of inspection activities and guarantee the safety of the product and consumer health.

Article 49. Animal product establishments may not exceed the capacity of their facilities and equipment.

Article 50. Different edible animal products may be stored in a single room, provided they are duly identified and that this does not jeopardize the safety and quality of the products, and that the preservation temperatures, the type of packaging and the type of packing are compatible.

Article 51. Facilities and equipment designed for the manufacture of animal products may be used to produce and store products not liable to registration with the Department of Inspection of Animal Products, provided that this does not jeopardize the safety, hygiene and sanitary condition of products that are subject to federal inspection: permission is conditional upon assessment of the risks associated with each product.

Sole paragraph. For these products that are addressed in the **head provision** official SIF stamps may not be used.

Article 52. Demands concerning the physical structure, buildings and equipment of small-scale agribusiness animal product establishments will obey specific supplementary norms, aiming at minimizing the risk of the spread of animal diseases, pests and microbiological, physical and chemical agents that are harmful to public health and consumer interests.

CHAPTER II

HYGIENE CONDITIONS

Article 53. Those responsible for establishments must ensure that all stages of the manufacture of animal products are carried out hygienically in order to obtain products that meet quality standards, and pose no threat to consumers' health, safety or interests.

Article 54. Establishments' built facilities, equipment and utensils must be kept in good hygiene conditions before, during and after the performance of the industrial activities.

Sole paragraph. Cleaning procedures must be carried out regularly and whenever necessary, taking into consideration the specificities of each industrial sector, so as to avoid the contamination of animal product.

Article 55. Establishments must keep a constant and effective pest and vector control program.

Paragraph 1 Chemicals not approved by the health regulator for use in facilities intended for the handling of product and storage of raw material, products and inputs, may not be used.

Paragraph 2 When chemical controls are used they must be performed by specialized companies and trained staff, in accordance with specific legislation, using chemicals approved by the health agency.

Article 56. No animals extraneous to the industrial process of animal product producing establishments may be present.

Article 57. All employees must wear suitable and clean uniforms when performing industrial activities.

Paragraph 1 Employees who work in the handling and in the direct processing of edible products must wear white uniforms, or another light color that enables easy identification of possible contamination.

Paragraph 2 Employees in uniform may not circulate between areas with different sanitary risks, or outside the industrial perimeter.

Paragraph 3 Employees working in other industrial tasks or carrying out jobs that may lead to cross-contamination must wear uniforms differentiated by colors.

Article 58. Employees involved directly or indirectly in all industrial activities must comply with personal and operational hygiene practices that maintain product safety.

Article 59. Separation of areas and distinct flows of employees from different sectors in the common areas such as canteens, changing-rooms or rest areas must be defined so as to prevent cross-contamination, taking into consideration the specificities of different classifications of establishments.

Sole paragraph. Employees working in areas where contaminated material is handled, or where there is an increased risk of contamination, must not pass through areas with a lower risk of contamination in order to avoid cross-contamination.

Article 60. Food may not be kept or consumed, and products, clothing, objects or materials that are foreign to the purposes of the sector in which industrial activities are performed may not be kept.

Article 61. Smoking is banned in spaces where raw materials, animal products and inputs are handled or stored.

Article 62. Whenever necessary the SIF will order improvements and remodeling to the built facilities and equipment so as to keep it in good condition and working order, and minimize the risk of contamination.

Article 63. Reception facilities, live animal housing, and industrial waste deposits, must be cleaned regularly and whenever necessary.

Article 64. Raw materials, inputs and products must be kept so as to prevent contamination at every stage of manufacture from receiving to shipping, including transportation.

Article 65. The use of utensils that owing to their shape or composition may jeopardize the safety of the raw material or product at any stage of the manufacture, from receiving to shipping, including transportation, is forbidden.

Article 66. The plant manager must introduce procedures to ensure that employees working in or passing through handling areas do not carry

food borne diseases.

Paragraph 1 Up-to-date doctors' notes must be presented whenever requested to prove that employees are not carrying diseases that render them unsuitable for food production.

Paragraph 2 If an employee is found or suspected to have an illness or condition that may jeopardize the safety of the product, that employee must be suspended from duties.

Article 67. Water tanks must be protected against external contamination and cleaned both regularly and whenever necessary.

Article 68. Ice makers and silos for storing ice must be regularly cleaned and protected against contamination.

Sole paragraph. Ice used to preserve fish must be made from potable water or clean sea water.

Article 69. No one may reside in those buildings where industrial processes are carried out on animal products.

Article 70. Chillers, freezers, rooms, freezing tunnels and chilling and freezing equipment must be cleaned regularly.

Article 71. Containers, carts and bottles for raw materials and product must be cleaned before being returned.

Article 72. In spaces where there is an immediate risk of contamination of utensils and equipment, there must be devices or mechanisms for sanitizing using water at a minimum of 82.2º C (eighty-two point two degrees Celsius) or some other equivalent method recognized by the Department of Inspection of Animal Products.

CHAPTER III

DUTIES OF ESTABLISHMENTS

Article 73. Establishment managers must: I - obey this Decree and

supplementary norms;

II - deploy personnel, whenever necessary, to assist in the performance of inspection work, in accordance with specific norms laid down by the Ministry of Agriculture, Livestock and Food Supply;

III - provide built facilities, equipment and materials deemed necessary for inspection and oversight;

IV - provide statistical data required by SIF, feeding it into the Ministry of Agriculture, Livestock and Food Supply digitized system by the tenth working day of each month subsequent to the event, and whenever required to;

V - update the registration data required by SIF, in accordance with supplementary norms;

VI - notify SIF at least 72 hours in advance of any slaughter activities or other operations, providing the description, time of commencement and likely completion, and of stoppages - whether partial or total - and resumptions in industrial activities, the replacement or installation of equipment and the shipping of products requiring health certification;

VII - provide material, utensils and specific substances for the taking, storing, packing, protection and shipping of official samples to laboratories;

VIII - shoulder the cost of official analyses to meet specific requirements for the export or import of animal products;

IX - maintain suitable spaces for receiving and storing raw material and products that are subject to reinspection, and for segregating suspected raw materials or products or those intended for conditional use;

X - provide substances to denature and permanently change visually the condemned products, when there are no facilities for immediate alteration;

XI - keep control of temperatures of raw materials, product, environment and technological process, as established in supplementary norms;

XII - keep auditable records of the reception of animals, raw materials and inputs, specifying their origin, quantity and quality, manufacturing process controls, manufactured products, stocks, shipping of products and destination;

XIII - keep a regularly trained and updated team of staff to perform the establishment's activities;

XIV - ensure the access of SIF agents to all areas of the establishment in order to carry out their inspection, oversight, enforcement and state- or federal-level audits, sampling, document verification and other activities related to the industrial and sanitary inspection and oversight activities set forth in this Decree and in supplementary norms;

XV - deploy a recall program for product made and shipped by the establishment when a deviation in the process control is found, or some other non-compliance that may jeopardize consumers' health or interests; and

XVI - keep auditable records of processes either of conditional use or of the rendering unusable of animal products as laid down in this Decree or in supplementary norms issued by the Ministry of Agriculture, Livestock and Food Supply, above all in cases where this conditional use or destruction was not carried out in the presence of the SIF.

Paragraph 1 The materials and equipment needed for inspection activities, provided by the establishments, are the property of the establishments but are available to and under the responsibility of the local SIF.

Paragraph 2 If registration is canceled, the establishment is responsible for rendering unusable the labeling in stock under SIF supervision.

Article 74. Establishments must have self-control programs that have been developed, introduced, maintained, monitored and verified by themselves, containing systemic auditable records proving compliance with the hygiene, health and technological requirements laid down by this Decree and supplementary norms in order to ensure the safety, identity, quality and wholesomeness of their product, from obtaining and receiving raw materials, ingredients and inputs, until product is shipped.

Paragraph 1 Self-control programs must encompass animal welfare, when applicable, GMPs, SSOPs and HACCP or an equivalent program recognized by the Ministry of Agriculture, Livestock and Food Supply.

Paragraph 2 Self-control programs should not be restricted to meeting Paragraph 1.

Paragraph 3 The Ministry of Agriculture, Livestock and Food Supply shall set forth in supplementary norms those official procedures for the verification of self-controls on production processes applied by establishments in order to ensure the safety and standards of products.

Article 75. Establishments must have control mechanisms to ensure the traceability of raw material and products, making information available for the entire production chain, in accordance with this Decree and supplementary norms.

Sole paragraph. For traceability of the origin of the milk, it is forbidden to receive refrigerated raw milk carried in a vehicle belonging to individuals or legal entities that are not formally and provably linked to the bulk collection program of federally-inspected establishments.

Article 76. Establishments must present all documentation required by the SIF, either for enforcement or for analytical reasons, as well as controls of the reception, storage, production, shipping or any other aspect needed for inspection and oversight activities.

Article 77. Establishments must employ an officer in charge of hygiene, health, and technological operations, whose professional training meets that laid down in specific legislation.

Sole paragraph. If the professionals mentioned in the **head provision** are replaced, SIF must be notified.

Article 78. Establishments inspected by SIF cannot receive animal products for human consumption that are not clearly marked as coming from another SIF-inspected establishment.

Paragraph 1 Animal raw material and products may enter from establishments registered in other scopes of inspection, provided that they are recognized by the Ministry of Agriculture, Livestock and Food Supply as equivalent to the receiving service and that the establishment is in the general register of the Brazilian Animal Product Inspection Service.

Paragraph 2 Raw material for making gelatin and other collagen products may enter from other establishments registered in State, Federal District and municipality services provided that it meets the conditions set forth in supplementary services.

Article 79. In SIF-inspected establishments, animal raw materials and products may enter from industrial and wholesale establishments under federal inspection for the purposes of inter-state and

international trade in inedible products, provided that the conditions set forth in supplementary norms are met.

Article 80. Product and raw materials once removed from chillers and freezers may not be returned to them if they have been kept in unsuitable temperature conditions, and if loss of original preservation conditions is found.

Article 81. Establishments may only display and sell product: I - that does not pose

a public health risk;

II - that has not been altered or fraudulently changed; and

III - whose traceability at the steps of obtaining, receiving, manufacturing and shipping is ensured.

Sole paragraph. Establishments shall take all necessary measures to recall lots of product that pose a public health risk or that have been altered or fraudulently changed.

TITLE V

INDUSTRIAL AND SANITARY INSPECTION

Article 82. The Ministry of Agriculture, Livestock and Food Supply shall set forth, in supplementary norms, procedures for the inspection and oversight of animal products, and design official control programs in order to assess the safety, identity, quality and wholesomeness of products and production processes.

Sole paragraph. The programs addressed in the **head provision** encompass sampling for physical, microbiological, physical-chemical, molecular-biological, histological and other testing that may be needed in order to assess the compliance of animal raw material and products.

Article 83. When overseeing the establishment the SIF may perform the analyses laid down in this Decree, in the Technical Regulation of Identity and Quality (TRIQ), in supplementary norms or in specific legislation, in self-control programs and others that may be necessary, or order them to be carried out by the company.

CHAPTER I

INDUSTRIAL AND SANITARY INSPECTION OF MEAT AND MEAT PRODUCTS

~~Article 84. Nos estabelecimentos sob inspeção federal, é permitido o abate de bovídeos, equídeos, suídeos, ovinos, caprinos, aves domésticas e lagomorfos e de animais exóticos, animais silvestres e pescado, atendido o disposto neste Decreto e em normas complementares.~~

Article 84. Federally-inspected establishments may slaughter bovines, buffaloes, equidae, suidae, ovines, caprines, domestic birds, lagomorphs and exotic animals, wild animals and fish, provided they meet the requirements of this Decree and supplementary norms. (In the wording of Decree 9,069/2017)

Paragraph 1 Different species may be slaughtered in one establishment provided specific facilities and equipment are used for these purposes.

Paragraph 2 The slaughter addressed in Paragraph 1 may be carried out provided that complete segregation of the different species and their respective by-products can be proven at all stages of the operation, respecting the specific nature of each species, which includes the cleaning of facilities and equipment.

Section I

Ante-mortem inspection

Article 85. Animals for slaughter may only be received in any area of the establishment with prior notification of the SIF.

Article 86. When the animals are received and unloaded, the establishment must verify the transport documentation defined in specific norms in order to ensure the origin of the animals.

Sole paragraph. Animals may not be transported without their movement documentation.

Article 87. The animals, in accordance with the specificities of each species, must be unloaded and housed in suitable exclusive facilities to await evaluation by the SIF.

Sole paragraph. Animals arriving in sealed vehicles—by sanitary determination—may only be unloaded in the presence of a competent representative of the SIF.

Article 88. The establishment must adopt measures to avoid mistreatment of the animals and take steps to ensure their protection and animal welfare from their unloading to the moment of slaughter.

Article 89. Prior to the slaughter, the establishment must present the slaughter plan and documentation of the identification, handling and origin of the lots as well as other information required in specific legislation in order for the SIF to verify the physical and sanitary conditions of the animals.

Paragraph 1 Where it is suspected that banned substances have been used, or that there is a lack of information about compliance with the withdrawal periods for veterinary products, SIF may seize such lots of animals or products, take samples and adopt such other procedures as to underpin any decision about the disposition.

Paragraph 2 Whenever the SIF deems necessary, documents containing information of interest concerning the lot must be produced at least twenty-four hours beforehand.

Article 90. A competent official of the SIF must perform an **ante mortem** examination of animals intended for slaughter.

Paragraph 1 The examination addressed in the **head provision** includes a document check, a verification of the animal's behavior and overall appearance, and of symptoms of diseases affecting animal and public health, in accordance with this Decree and supplementary norms.

Paragraph 2 Any suspect case will lead to the identification and isolation of the animals involved. When necessary the entire lot will be isolated.

Paragraph 3 Suspect cases will be evaluated by a Federal Agricultural Inspector who graduated in Veterinary Medicine, and may include a clinical examination, necropsy, and other procedures in order to diagnose and determine disposition, applying animal health measures when the case so demands.

Paragraph 4 The **ante mortem** examination must be performed as soon as possible after the animals have arrived at the slaughter establishment.

~~§ 5º Dentre as espécies de abate de pescado, somente os anfíbios e os répteis devem ser submetidos à inspeção **ante mortem**.~~

Paragraph 5 The examination must be repeated if more than twenty-four hours elapse between the first assessment and the moment of slaughter. (In the wording of Decree 9,069/2017)

Paragraph 6 Among seafood species for slaughter, only amphibians and reptiles must undergo **ante mortem inspection**. (Included by Decree 9,069/2017)

Article 91. In the **ante mortem** inspection, whenever animals with suspected zoonoses or infectious-contagious diseases, or animals producing an inconclusive or positive result to diagnostic tests for such diseases are identified, they must be slaughtered separately from the remaining animals after the appropriate prophylactic steps have been taken.

Sole paragraph. If diseases not provided for in this Decree or in supplementary norms are suspected, slaughter must also take place separately, the better to study the lesions and perform supplementary verifications.

Article 92. Whenever notifiable infectious or contagious diseases are identified by the official animal health service, the SIF, in addition to measures already laid down, must:

I - notify the official animal health service, first of all in the immediate competent jurisdiction of the establishment;

II - segregate the suspected animals and keep the lot under observation until the epidemiological measures to be taken have been determined; and

III - order the immediate disinfection of places, equipment and utensils that may have touched animal residues or any other possibly contaminated material, and comply with the recommendations laid down by the official animal health service.

Article 93. If, in the **ante mortem** inspection, isolated cases of non-contagious diseases are found that either allow conditional use or entail total condemnation of the animal, this animal must be slaughtered last, or in facilities specific for this purpose.

Article 94. Suidae presenting acute erysipelas, with diffuse cutaneous erythema, must be slaughtered separately.

Article 95. Sows in advanced pregnancy or those showing signs of recent farrowing, and that are not carrying an infectious-contagious disease, may be removed from the establishment to be better used, in accordance with the procedures

laid down by the animal health service.

Sole paragraph. Sows showing signs of recent farrowing or miscarriage may only be slaughtered after at least ten days, providing they are not carrying an infectious or contagious disease; if they are, they must be assessed in accordance with this Decree and supplementary norms.

Article 96. Animals arriving for slaughter and presenting hypothermia or hyperthermia may be condemned, taking into consideration the weather conditions, transportation conditions and other clinical signs, pursuant to supplementary norms.

Sole paragraph. This **head provision** does not apply to poikilothermic animals.

Article 97. If there are dead animals or animals unable to walk, on transport vehicles that have pulled up at the receiving facility or at any outbuilding of the establishment, the SIF must be notified so that necropsy or emergency slaughter can be performed and the necessary measures taken, in line with the particular nature of each species.

Paragraph 1 If a natural death has been found to occur in any lot of animals, the lot may only be slaughtered after the necropsy result is known.

Paragraph 2 In the case of poultry slaughter, whenever the mortality reported in the sanitary information from the origin of the flock of animals is above limits laid down in the supplementary norms, a necropsy must be carried out, or whenever there is a clinically suspected disease, a necropsy will be at the discretion of the Federal Agricultural Inspector who graduated in Veterinary Medicine.

Article 98. Carcasses of animals that die accidentally within the facilities of the establishment, provided they are bled immediately, may go to conditional use after a **post mortem** examination, at the discretion of the Federal Agricultural Inspector who graduated in Veterinary Medicine.

Article 99. When the SIF authorizes the transportation of dead or dying animals to the site of the necropsy, a suitable vehicle or container must be used, and it must be waterproof and enable disinfection straight after use.

Paragraph 1 In the case of animals that have died from a suspected infectious-contagious disease, their natural orifices must be plugged before transportation in order to avoid the spread of secretions and excreta.

Paragraph 2 If the suspected disease is confirmed, the dead animal and its remains must be incinerated or autoclaved in dedicated equipment that allows the destruction of the infectious agent.

Paragraph 3 After the completion of the necropsy, the vehicle or container used to move the animals, the floor of the room and all equipment and utensils that have touched the animal must be washed and disinfected.

Article 100. Whatever the motivation for them, necropsies must be performed in a specific location and the animals and their remains must be destroyed in accordance with this Decree.

Article 101. The SIF shall inform the official animal health service of the result of the necropsies that demonstrated infectious or contagious diseases, and when necessary shall send material for diagnosis, in accordance with animal health legislation.

Section II

Slaughter of animals

Article 102. No animal may be slaughtered without the

authorization of the SIF.

Article 103. Animals may not be slaughtered if they have not rested, fasted or been watered, in accordance with the particular nature of each species, and emergency situations that compromise animal welfare.

Sole paragraph. The Ministry of Agriculture, Livestock and Food Supply shall lay down parameters for the resting, fasting and watering of animals in supplementary norms.

Article 104. Uncastrated suidae or those showing signs of recent castration may not be slaughtered.

Sole paragraph. Suidae that have been castrated by non-surgical means, provided the process has been approved by the Ministry of Agriculture, Livestock and Food Supply, may be slaughtered.

Sub-Section I

Emergency Slaughter

Article 105. Animals arriving at the establishment in poor health, that cannot walk unaided to the slaughter facility, and those ruled out of normal slaughter after the **ante mortem** examination, must undergo emergency slaughter.

Sole paragraph. The situations addressed in the **head provision** include sick animals showing signs of immediately notifiable infectious or contagious diseases, those that are dying, are injured, bearing fractures, hemorrhaging, suffering from hyper- or hypothermia, or that are downers, animals showing neurological clinical signs, and other conditions laid down in supplementary norms.

Article 106. Emergency slaughter may not be performed in the absence of a Federal Agricultural Inspector who graduated in Veterinary Medicine.

Article 107. The SIF must collect material from animals going to emergency slaughter that show neurological clinical signs, and send them to official laboratories for diagnosis, in accordance with animal health legislation.

Article 108. Animals showing clinical signs of paralysis from metabolic or pathological changes must be sent to emergency slaughter.

Sole paragraph. For paralysis caused by metabolic changes, the animals may be removed from the establishment for treatment, in compliance with procedures defined by the animal health legislation.

Article 109. If a diagnosis of septicemia is in doubt, the SIF must sample material for laboratory analysis, above all whenever there is inflammation of the intestines, udder, uterus, joints, lungs, pleura, peritoneum or if there are suppurating or gangrenous lesions.

Article 110. If animals that have undergone emergency slaughter meet the criteria for condemnation laid down in this Decree or in supplementary norms, they are deemed unfit for human consumption.

Article 111. The carcasses of animals that have undergone emergency slaughter but whose carcasses have not been condemned may go to conditional use, or provided there is no sanitary impediment, may be passed for consumption, in accordance with this Decree or supplementary norms.

Subsection II

Normal

slaughter

Article 112. Animals may only be slaughtered using humane methods, with prior stunning, based on scientific principles, and followed by immediate bleeding.

Paragraph 1 The methods to be applied in each species will be laid down in supplementary norms.

Paragraph 2 Animals may be slaughtered in accordance with religious principles, provided that the by-products from them go wholly or partially for consumption by the religious community that requests them or to international trade with countries that impose this demand.

Article 113. Before reaching the slaughter facility, the animals must pass through a shower using enough water to thoroughly cleanse them and remove dirt, in accordance with the specific nature of each species.

Article 114. Bleeding should be as complete as possible; the animal should be hung by its hind legs or some other method approved by the Department of Inspection of Animal Products.

Sole paragraph. No operations on the carcass may begin until the bleeding has been as thorough as possible, complying with the minimum bleeding period laid down in supplementary norms.

Article 115. Birds may be plucked: I - dry;

II - after scalding in preheated water and with a continuous removal process; or

III - by a process approved by the Department of Inspection of Animal Products.

Article 116. Whenever swine carcasses are delivered for consumption skin-on, complete depilation by prior scalding with hot water is mandatory, or another similar process approved by the Department of Inspection of Animal Products.

Paragraph 1 Depilation may be completed manually or by suitable equipment, and the carcasses must be washed before the operation is carried out.

Paragraph 2 Singeing is banned except after prior scalding and depilation.

Paragraph 3 The water in swine scalding systems must be continually renewed.

Paragraph 4 The use of technological adjuvants in the scald water may be authorized if compliant with criteria laid down by the Department of Inspection of Animal Products.

Article 117. Whenever SIF deems it necessary or whenever deficiencies have been identified in slaughter, it will order interruption of slaughter or a reduction in slaughter speed.

Article 118. Evisceration must be performed in a space that allows speedy examination of the viscera, in order to avoid contamination.

Paragraph 1 If evisceration is delayed, the carcass and viscera will be judged according to supplementary norms.

Paragraph 2 When there is contamination of carcasses and organs at the moment of evisceration, SIF will apply the measures set forth in Section III, Chapter I of Title V.

Article 119. The synchronization of carcasses, carcass parts and viscera must be maintained until SIF has completed the **post mortem** examination, complying with supplementary norms.

Paragraph 1 Trimming operations are banned before the completion of the **post mortem examination.**

Paragraph 2 It is for the establishment to maintain parallelism between the carcass and viscera, and their synchronized passage through the inspection lines.

Article 120. Inflation is allowed as an auxiliary method in the dehiding and deboning of slaughter species, provided that it has been previously been approved by the Department of Inspection of Animal Products.

Paragraph 1 The air used in inflation must be purified so as to ensure its final physical, chemical and microbiological quality.

Paragraph 2 In order to meet the demands of religious slaughter the lungs may be inflated.

Article 121. All carcasses, carcass parts, organs and viscera must first be chilled or frozen, depending on the product specifications, before storing in freezers where other raw materials are already being stored.

Article 122. Carcasses and carcass parts, when chilled in air, must be hung in chillers, in accordance with the specific nature of each species, and arranged in such a way as to ensure sufficient space between all the pieces, and between pieces and walls, pillars and floors.

Sole paragraph. Carcasses and by-products may not be placed directly on the floor.

Article 123. In the event of infectious or contagious diseases, in order to prevent cross-contamination, the SIF must verify the compliance of disinfection procedures for the facilities and equipment.

Article 124. Specific Risk Materials (SRMs) must be removed, segregated and rendered unusable for communicable spongiform encephalopathies of all ruminants for slaughter.

Paragraph 1 The procedures addressed in the **head provision** must be performed by establishments, pursuant to supplementary norms.

Paragraph 2 The animal health legislation will specify the organs, carcass parts, and animal tissues as SRMs.

Paragraph 3 All use of SRMs in human or animal food is forbidden.

Section III

General aspects of post mortem inspection

Article 125. In performing **post mortem**, inspection procedures, the Federal Agricultural Inspector trained in Veterinary Medicine may be assisted by properly trained Inspection Agents (AISIPOAs—Sanitary and Industrial Inspection Agents for Animal Products) and inspection auxiliaries.

Sole paragraph. The inspection team must possess enough staff to perform its activities, as laid down in supplementary norms.

Article 126. **Post mortem** inspection consists of an examination of carcasses, carcass parts, cavities, organs, tissues and lymph nodes, by means of observation, palpation, sense of smell and incisions when necessary, as well as other procedures defined in supplementary norms for each animal species.

Article 127. All organs and carcass parts must be examined in the slaughter facility immediately after they have been removed from the carcasses, and correspondence must always be maintained between them.

Article 128. Carcasses, carcass parts and organs showing lesions or abnormalities that do not affect the carcass or other organs, may be condemned or alternatively authorized to continue on the inspection lines, pursuant to supplementary norms.

Article 129. All carcasses, carcass parts and organs examined on the inspection lines, and presenting lesions or abnormalities that can affect the carcass and other organs, must be railed out to the veterinary Department of Final Inspection to be examined, judged and receive the appropriate disposition.

Paragraph 1 Judgments concerning the disposition of carcasses, carcass parts and organs are the duty of a Federal Agricultural Inspector who graduated in Veterinary Medicine.

Paragraph 2 In the case of infectious and contagious diseases, the disposition of organs will be similar to that given to the carcass itself.

Paragraph 3 Condemned carcasses, carcass parts and organs must be kept by the SIF and will be removed from the Final Inspection Department using specific chutes, carts or other appropriate containers that have been identified for this purpose.

Paragraph 4 Condemned material must be denatured or seized by the SIF when it cannot be processed on slaughter day itself or in cases where it will be transported for transformation in another establishment.

Article 130. Removal, scraping or any other practices to mask lesions on carcasses or organs before examination by the SIF are forbidden.

Article 131. Carcasses deemed fit for consumption must be given the official marks laid down in this Decree, under SIF supervision.

Sole paragraph. Ink-stamping on the carcasses of bovidae and suidae will be dispensed with in establishments that slaughter and debone in the same industrial unit, provided that provisions laid down in supplementary norms are followed.

Article 132. Whenever the animals' owner requires it, the SIF in slaughter establishments will provide a report containing possible diseases or pathologies diagnosed on carcasses during sanitary inspection, and the disposition of the same.

Article 133. During **ante mortem** and **post mortem** inspection procedures, judgment in cases not provided for in this Decree is at the discretion of the SIF, which must seek above all to guarantee product safety, public health and animal health.

Sole paragraph. SIF shall take samples, whenever necessary, for laboratory analysis to confirm diagnoses.

Article 134. Carcasses, carcass parts and organs presenting with multiple or widespread abscesses that affect the overall status of the carcass must be condemned—furthermore:

I - carcasses, carcass parts or organs accidentally contaminated by purulent matter, must be condemned;

II - carcasses presenting general changes such as cachexia, anemia or jaundice resulting from the purulent process, must be condemned;

III - carcasses presenting multiple abscesses in organs or carcass parts, not affecting the overall state, are to be sent for conditional heat treatment after the affected areas have been removed and condemned;

IV - carcasses presenting with multiple abscesses in a single organ or carcass part—except for the case of the lungs—that do not affect the lymph nodes or its overall state, may be approved for further processing after the affected areas have been removed and condemned; and

V - carcasses presenting with localized abscesses may be approved for further processing after the organs and areas affected have been removed and condemned.

Article 135. Carcasses must be condemned when they show widespread or localized actinomycosis or actinobacillosis lesions at typical points, and affect the overall state of the carcass, and furthermore:

I - when the lesions are localized and affect the lungs, but do not affect the overall status of the carcass, the carcass may go to conditional use after sterilization by heat treatment, after the affected organs have been removed and condemned;

II - when the lesion is small and limited to the tongue, possibly affecting the corresponding lymph nodes or otherwise, head meat may go to conditional use after sterilization by heat treatment, and after the tongue and lymph nodes have been removed and condemned;

III - when the lesions are localized, without affecting the lymph nodes and other organs, and the carcass is in good overall condition, then the carcass may be authorized for consumption after the affected areas have been removed and condemned; and

IV - heads with actinomycosis lesions must be condemned except when the bony lesion is small and strictly localized, without suppuration or the paths of fistulae.

Article 136. The carcasses of animals affected by extensive lung tissue diseases, in either acute or chronic, purulent, necrotic, gangrenous, fibrinous condition, or associated (or otherwise) with other complications, and affecting the overall condition of the carcass, must be condemned.

Paragraph 1 The carcasses of animals affected by lung diseases, either in an acute process or in a resolution phase, having involved lung tissue and pleura, with exudate and affecting the regional lymphatic chain, but without affecting the overall condition of the carcass, must be sent to conditional use after heat treatment.

Paragraph 2 In those cases where there is pleural adherence without any kind of exudate, that are the result of resolved pathological processes and without any repercussions for the regional lymphatic chain, the carcass may be authorized for consumption after the affected areas have been removed.

Paragraph 3 Lungs presenting inflammatory, infectious, parasitic, or traumatic lesions or lesions from the dying process, must be condemned, but without prejudice to the examination of the general characteristics of the carcass.

Article 137 The carcasses of animals with septicemia, pyemia, toxemia or signs of viremia, and whose consumption might cause infection or food poisoning, must be condemned.

Sole paragraph. This includes, without being restricted to the diseases addressed in the **head provision**, the

following clinical pictures: I - acute inflammation of the pleura, the peritoneum, pericardium and meninges;

II - gangrene, gastritis and hemorrhagic or chronic

enteritis; III - metritis;

IV - polyarthritis;

V - omphalophlebitis;

VI - hypertrophy of spleen;

VII - generalized hypertrophy of the lymph nodes;

and VIII - diffuse reddening of the hide.

~~Article 138. As carcaças e os órgãos de animais com sorologia positiva para brucelose devem ser condenadas, quando estes estiverem em estado febril no exame **ante mortem**.~~

Article 138. Carcasses and organs of animals testing positive for brucellosis must be condemned when they were in a febrile state at **ante mortem** examination. (In the wording of Decree 9,069/2017)

Paragraph 1 Animals reacting positively to diagnostic tests for brucellosis must be slaughtered separately and their carcasses and organs must be sent to the veterinary Final Inspection Department.

~~§ 2º Os animais reagentes positivos a teste diagnósticos para brucelose que apresentem lesões localizadas devem ter suas carcaças destinadas ao aproveitamento condicional pelo uso do calor, depois de removidas e condenadas as áreas atingidas, incluindo o úbere, o trato genital e o sangue.~~

Paragraph 2 The carcasses of hogs, goats, sheep and buffaloes that either react positively or do not react to brucellosis diagnostic tests, showing a localized lesion, must be sent for conditional use after heat treatment, after the affected areas have been removed and condemned. (In the wording of Decree 9,069/2017)

~~§ 3º Os animais reagentes positivos a teste diagnósticos para brucelose, na ausência de lesões indicativas, podem ter suas carcaças liberadas para consumo em natureza, devendo ser condenados o úbere, o trato genital e o sangue.~~

Paragraph 3 The carcasses of bovines and equines that either react positively or do not react to brucellosis diagnostic tests, showing a localized lesion, may be authorized to be consumed fresh, after the affected areas have been removed and condemned. (In the wording of Decree 9,069/2017)

Paragraph 4 The carcasses of animals testing positive for brucellosis diagnostic tests, without indicative lesions, may be authorized for consumption fresh. (Included by Decree 9,069/2017)

Paragraph 5 The organs, udder, genital tract and blood must be condemned in the events of paragraphs 2, 3, and 4. (Included by Decree 9,069/2017)

Article 139. Carcasses and organs of cachectic animals must be condemned.

Article 140. Carcasses of animals infected with anthrax must be condemned: this includes hides, horns, hooves, hairs, organs, intestinal contents, blood and fat, and the following measures must be executed immediately:

I - the carcasses of animals suspected of carrying anthrax may not be eviscerated;

II - when the condition is recognized after evisceration, all those places that the residues of the animal may have touched, such as bleeding areas, floors, walls, platforms, knives, saws, hooks, equipment in general, employees' uniforms, and any other material that may have been contaminated must all be disinfected;

III - as soon as anthrax is detected, slaughter must be halted and disinfection must commence immediately;

IV - for this disinfection the use of a solution of 5% (five per cent) sodium hydroxide, 1% (one per cent) sodium hypochloride, or any other substance proven effective, is recommended;

V - employees who may have touched the anthrax-carrying material must take all necessary precautions, by applying rules of hygiene and personal antisepsis using products known to be effective, and such employees must be sent to the medical service as a precautionary measure;

VI - all carcasses, and carcass parts, including hides, hooves, horns, organs and the contents thereof that may have touched infectious animals or materials must be condemned; and

VII - the water of the scalding tank through which an anthrax-infected animal may have passed must be disinfected and immediately drained to the industrial effluents system.

Article 141. Carcasses and organs of animals infected with anthrax must be condemned.

Article 142. Animals' carcasses must be condemned when they show marked and widespread muscle changes and when there is degeneration of the myocardium, liver, and kidneys, or reaction of the lymph system accompanied by muscle changes.

Paragraph 1 Carcasses must be condemned if their meat is flaccid, bruised, pale, bloody or exudative.

Paragraph 2 Carcasses with changes owing to stress or fatigue in the animals may, at the discretion of the SIF, be sent for heat treatment, salting, or condemnation.

Article 143. Carcasses, carcass parts and organs with a repugnant appearance, showing congestion, abnormally colored or with degeneration must be condemned.

Sole paragraph. Putrefying carcasses, those reeking of medication, urine, sex hormones, excrement or other abnormalities are also condemned.

Article 144. Bloody or hemorrhagic carcasses and organs resulting from systemic diseases or conditions must be condemned.

Sole paragraph. Carcasses and organs of improperly bled animals must, at the discretion of the SIF, be sent for heat treatment.

Article 145. Livers with atrophic or hypertrophic cirrhosis must be condemned.

Sole paragraph. Carcasses similar to the description in the **head provision**, provided they are not affected, may be released.

Article 146. Organs showing such changes as congestion, infarcts, fatty degeneration, angiectasia, hemorrhages or abnormal color, whether related or otherwise to systemic pathological processes, must be condemned.

Article 147. Carcasses, carcass parts and organs showing an extensive area of contamination by gastrointestinal contents, urine, milk, bile, pus or any other type of contamination, must be condemned when it is impossible to completely remove the contaminated area.

Paragraph 1 When it may be impossible to perfectly delimit the contaminated areas, even after removal, then the carcasses, carcass parts, organs or viscera must be sterilized by heat.

Paragraph 2 When it is possible completely to remove the contamination, the carcasses, carcass parts, organs or viscera may be authorized.

Paragraph 3 As provided for in supplementary norms, it may be allowed to remove the contamination without completely removing the contaminated area.

Article 148. Carcasses of animals with widespread contusions or multiple fractures must be condemned.

Paragraph 1 Carcasses with widespread lesions that have not been totally compromised may go to heat treatment after the affected areas have been removed and condemned.

Paragraph 2 Carcasses presenting localized contusions, fractures or dislocations may be authorized once the affected areas have been removed and condemned.

Article 149. Carcasses showing widespread edema on **post mortem** examination must be condemned.

Sole paragraph. In the case of localized, minor edemas, carcass parts and organs showing edematous infiltrations must be removed and condemned.

Article 150. Carcasses and organs of animals infected with **Oesophagostomum sp** (esophagostomiasis) must be condemned when there is cachexia.

Sole paragraph. Intestines or parts thereof presenting a small number of nodules may be authorized.

Article 151. If the pancreas is infected by parasites of the genus**Eurytrema**, causing eurytrematosis, it must be condemned.

Article 152. Carcasses and organs of animals infected with **Fasciola hepatica** must be condemned when there is cachexia or jaundice.

Sole paragraph. When the lesion is circumscribed or limited to the liver, and has no repercussions on the general status of the carcass, the organ must be condemned while the carcass may be authorized.

Article 153. Fetuses resulting from the slaughter of pregnant females must be

condemned. Article 154. Tongues showing glossitis must be condemned.

Article 155. Carcasses and organs of animals presenting hydatic cysts must be condemned when there is cachexia.

Sole paragraph. Organs presenting with peripheral lesions that are calcified and circumscribed may be authorized after the affected areas have been removed and condemned.

Article 156. Carcasses and organs of animals presenting jaundice must be condemned.

Sole paragraph. Carcasses of animals showing yellow fat owing to nutritional factors or to the breed, may be passed for consumption.

Article 157. Carcasses of animals showing poisoning by medication treatment or accidental ingestion of toxic products must be condemned.

Sole paragraph. When the lesion is restricted to the organs or suggests poisoning by toxic plants, the carcass may go to conditional use or pass for consumption at the discretion of the SIF.

Article 158. Hearts with lesions of myocarditis, endocarditis and pericarditis may be condemned.

Paragraph 1 The carcasses of animals with cardiac lesions may be condemned or sent to heat treatment whenever this affects the overall condition, at the discretion of the SIF.

Paragraph 2 The carcasses of animals with cardiac lesions may be passed for consumption, provided the carcasses have not been affected, at the discretion of the SIF.

Article 159. Kidneys showing signs of nephritis, nephrosis, pyelonephritis, uronephrosis, urinary cysts or other infections must be condemned, and the lesions must be investigated for a possible link to infectious or contagious or parasitic diseases and whether they lead to changes in the carcass.

Sole paragraph. The carcass and kidneys may be passed for consumption when the lesions are not owing to infectious or contagious diseases, depending on the extent of the lesions, after the affected areas of the organ are removed and condemned.

Article 160. Carcasses showing non-specific widespread lesions in the lymph nodes of several regions, affecting the overall state of the carcass, must be condemned.

Paragraph 1 In the case of non-specific progressive lesions in lymph nodes, not affecting the overall state of the carcass, the drainage area of the lymph nodes is condemned, while the carcass is authorized for conditional use after heat sterilization.

Paragraph 2 In the case of limited, circumscribed non-specific lesions in lymph nodes, without an effect on the overall state of the carcass, the drainage area of this lymph node may be condemned, while the rest of the carcass is authorized after the affected areas have been removed and condemned.

Article 161. The carcasses and organs of lean animals that are free of any pathological process may go to conditional use, at the discretion of the SIF.

Article 162. The carcasses and organs of animals presenting with mastitis must go to heat sterilization whenever there is systemic involvement.

Paragraph 1 Carcasses and organs of animals presenting with mastitis, without systemic involvement, may be released after the mammary gland has been removed and condemned.

Paragraph 2 The mammary glands must be removed intact in order to prevent contamination of the carcass by milk, pus or any other contaminant, taking into account the specific nature of each species and the correlation of the glands with the carcass.

Paragraph 3 Mammary glands with mastitis or signs of lactation, and those of brucellosis-positive animals must be condemned.

Paragraph 4 It may be permitted for the mammary gland to be used as a foodstuff, after the carcass has been passed.

Article 163. Carcass parts, organs and viscera infested by larvae (myiasis) must be condemned. Article 164. Livers

showing nodular necrobacillosis must be condemned.

Sole paragraph. When the lesion coexists with other changes leading to carcass compromise, the carcass and organs must be condemned.

Article 165. Carcasses of animals with extensive neoplasms that have repercussions for the overall state, must be condemned.

Paragraph 1 Carcasses and organs of animals with malignant lymphoma must be condemned.

Paragraph 2 Every organ or carcass part affected by a neoplasm must be condemned.

Paragraph 3 In the event of a quantity of neoplasms that are localized and do not affect the overall state, then the carcass and organs may be sent to heat sterilization and the involved parts and organs must be condemned.

Paragraph 4 In the case of discrete localized neoplastic lesions that do not affect the overall state, the carcass may be authorized for consumption after the affected parts and organs have been removed and condemned.

Article 166. Organs and parts showing signs of parasitosis that are not transmitted to humans must be condemned, while the carcass may be passed for consumption, provided it has not been affected.

Article 167. The carcasses of animals showing signs of recent delivery or miscarriage, provided there are no signs of infection, may be sent to conditional use after heat treatment, while the genital tract, udder and blood of these animals are to be condemned.

Article 168. Carcasses with intense infection by **Sarcocystis spp** (sarcocystosis) must be condemned.

Paragraph 1 Intense infection means the presence of cysts in incisions made into several parts of the musculature.

Paragraph 2 Minor infection means the presence of cysts limited to a single point in the carcass or organ, and the carcass must go to cooking after the affected area has been removed.

Article 169. The carcasses of animals with widespread mange infection, compromising their overall state, must be condemned.

Sole paragraph. Carcasses may be authorized when the infestation is minor and still limited after the affected areas have been removed and condemned.

Article 170. Livers showing widespread macular telangiectasia lesions must be condemned.

Sole paragraph. Livers presenting with discrete lesions may be passed for consumption after the affected areas have been removed and condemned.

~~Art.171. As carcaças de animais portadores de tuberculose devem ser condenadas quando:~~

Article 171. The carcasses of animals with tuberculosis must be condemned when: (In the wording of Decree 9,069/2017)

I - the animal is febrile at **ante mortem**

examination; II - there is cachexia;

III - there are tubercular lesions in the muscles, bone, joints or lymph nodes draining the affected parts;

IV - there are concomitant caseous lesions in organs or serosa of the thorax and abdomen; V

- there are miliary or perlaceous lesions in parenchyma or serosa;

VI - there are multiple acute and actively progressing lesions identified by acute inflammation near the lesions, liquefaction necrosis or the presence of young tubercles;

VII - there are hypertrophied, edematous lymph nodes with striped or starry caseification in more than one chosen site; or

VIII - there are widespread caseous or calcified lesions, and whenever there is evidence of the spread of the bacillus to the systemic circulation.

Paragraph 1 The tuberculous lesions are deemed generalized when numerous tubercles are found in addition to those in the respiratory and digestive systems and their corresponding lymph nodes, distributed in both lungs or in the spleen, kidneys, uterus, ovaries, testicles, suprarenal capsules, brain, or the spinal cord or its membranes.

Paragraph 2 After the affected areas have been removed and condemned, the carcasses may go to heat sterilization when:

I - the organs present discrete, localized or encapsulated caseous lesions that are limited to the lymph nodes of one organ;

II - lymph nodes of the carcass or head present discrete, localized or encapsulated caseous lesions; and III -

there are concomitant lesions in lymph nodes and organs of the same cavity.

Paragraph 3 The carcasses of animals reacting positive to the tuberculosis diagnostic test must be sent to heat sterilization, provided they do not meet the conditions laid down in items I to VIII of the **head provision**.

Paragraph 4 Carcasses presenting only one discrete tuberculosis lesion that is localized and completely calcified in a single organ or lymph node, may be passed for consumption, after the affected areas have been condemned.

Paragraph 5 Parts of carcasses and organs contaminated by tubercular material, by accidental or other contact, must be condemned.

Article 172. Products going to conditional use, as laid down in this Decree, must, at the discretion of the SIF, undergo one of the following treatments:

I - cold treatment, at a temperature no higher than -10ºC (minus ten degrees Celsius) for ten days;

II - salting, in brine at no lower than 24ºBe (twenty-four degrees Baumé), for pieces no larger than 3.5cm (three point five centimeters) thick, for at least twenty-one days; or

III - heat treatment by:

a) cooking at a temperature of 76.6ºC (seventy-six point six degrees Celsius) for at least thirty minutes;

b) heat fusion at a minimum temperature of 121ºC (one hundred and twenty-one degrees Celsius); or

c) humid heat sterilization with an F0 value equal to or greater than three minutes or a reduction of twelve log cycles (12 log10) of **Clostridium botulinum**, followed by immediate chilling.

Paragraph 1 The application of any of the conditional treatments given in the **head provision** must ensure inactivation or destruction of the agent involved.

Paragraph 2 Treatments other than those given in the **head provision** may be used, provided that the same guarantees are ensured in the end, and that the technical and scientific basis is approved by the Department of Inspection of Animal Products.

Paragraph 3 If there are no specific equipment or facilities for carrying out the conditional treatment ordered by the SIF, a stricter criterion must always be applied in the establishment itself or at another establishment that has the technological means for this purpose, provided there is real control of traceability and proof of the application of the conditional treatment that was ordered.

Sub-Section I

Post mortem inspection in birds and lagomorphs

Article 173. For the inspection of birds and lagomorphs, as far as is suitable, what is given in Section III of this Chapter will apply, in addition to this particular Sub-Section and in supplementary norms.

Article 174. In cases where at **post mortem** inspection of birds and lagomorphs immediately notifiable infectious and contagious diseases—as determined by the animal health legislation—are found, then in addition to the measures laid down in article 93, the SIF must halt slaughter, isolate the lot of suspect product and keep it segregated until a definition is made of the epidemiological animal health measures to be adopted.

Sole paragraph. For infectious and contagious zoonoses, the appropriate prophylactic measures measures must be taken and applied to the lots involved.

Article 175. Bird carcasses or organs showing signs of an inflammatory process or the characteristic lesions of arthritis, airsacculitis, coligranuloma, dermatosis, dermatitis, cellulitis, pericarditis, enteritis, oophoritis, hepatitis, salpyngitis, ascitic syndrome, myopathies and tibial dyschondroplasia must be assessed in accordance with the following criteria:

I - when the lesions are restricted to one part of the carcass or to one organ only, only the affected areas must be condemned; or

II - when the lesions are extensive, multiple, or there is evidence of a systemic nature, the carcasses and organs must be condemned.

Sole paragraph. For abnormal or pathological conditions not provided for in the **head provision** the final disposition shall be at the discretion of the SIF.

Article 176. In cases of endoparasitosis or ectoparasitosis in birds, when there is no repercussion to the carcass, then the affected organs or areas must be condemned.

Article 177. In the case of lesions arising from cannibalism, that are extensive and affect the overall state of the carcass, then carcasses and organs must be condemned.

Sole paragraph. If there is no systemic involvement, the carcass may be authorized after the affected area has been removed.

Article 178. In the case of birds showing extensive mechanical lesions, including those resulting from excessive scalding, carcasses and organs must be condemned.

Sole paragraph. Superficial lesions will result in partial condemnation with the rest of the carcass and organs being passed for human food.

Article 179. Poultry presenting putrefactive changes, giving off sulfurous or ammoniacal odors, and showing gas crepitation on palpation or changes in color of the musculature shall be condemned.

Article 180. In the case of hemorrhagic disease of rabbits, in addition to tuberculosis, pseudo-tuberculosis, pyosepticemia, toxoplasmosis, spirochetosis, clostridiosis and pasteurelosis, lagomorph carcasses and organs shall be condemned.

Article 181. If there are lesions of necrobacillosis, aspergillosis or dermatophytosis, carcasses of lagomorphs may go for partial use after the removal of affected areas, provided there is no systemic involvement of the carcass.

Article 182. For endoparasitosis and ectoparasitosis in lagomorphs that can be transmitted to man or other animals, or that compromise the carcass, then carcasses and organs must be condemned.

Sole paragraph. Only the affected organs or areas must be condemned when the carcass is not compromised.

~~**Subseção II Da inspeção post mortem de bovídeos**~~

Sub-Section II

Post mortem inspection of bovines and buffaloes
(Wording given by Decree no. 9,069, enacted 2017)

~~Article 183. Na inspeção de bovídeos, além do disposto nesta Subseção e em norma complementar, aplica-se, no que couber, o disposto na Seção III deste Capítulo.~~

Article 183. For the inspection of bovines and buffaloes, as far as is suitable, what is given in Section III of this Chapter will apply, in addition to this particular Sub-Section and in supplementary norms. (In the wording of Decree 9,069/2017)

Article 184. Carcasses and organs of animals with bovine bacillary hemoglobinuria, cowpox, hemorrhagic septicemia and malignant catarrhal fever must be condemned.

Article 185. Carcasses with intense infection by **Cysticercus bovis (bovine cysticercosis)** must be condemned.

Paragraph 1 Intense infection is when at least eight cysts, either viable or calcified, are found, and distributed as follows:

I - two or more cysts located simultaneously in at least two chosen points examined on the inspection line (masticatory muscles, tongue, heart, diaphragm and pillars thereof, esophagus and liver), totaling at least four cysts; and

II - four or more cysts located in the forequarter (neck, chest and shoulder muscles) or in the hindquarter (shank, rump and loin muscles), found in the Final Inspection Department, by means of deep multiple incisions.

Paragraph 2 When more than one cyst—viable or calcified—is found, being less than what has been laid down for intense infection, and taking into consideration examination in sites of choice on the inspection line and in the corresponding carcass, the carcass will be sent for conditional use after heat treatment, after the affected areas have been removed and condemned.

Paragraph 3 When one viable cyst is found, taking into consideration the chosen sites examined on the inspection line, the carcass must be sent for conditional cold or salting treatment, after removal and condemnation of the affected area.

Paragraph 4 When one calcified cyst is found, taking into consideration all the specific sites examined routinely on the inspection line and in the corresponding carcass, the carcass may be sent without restrictions for human consumption after removal and condemnation of the affected area.

Paragraph 5 The diaphragm and its pillars, and the liver, as well as other parts that may be infected, must receive the same disposition as the carcass.

Paragraph 6 Procedures to test for cysticerci in routinely examined sites of choice must comply with supplementary norms.

Sub-Section III

Post mortem inspection for equidae

Article 186. Inspection for equidae: in addition to what is set forth in this Sub-Section and in supplementary norms, Section III of this Chapter applies.

Sole paragraph. Procedures to detect and assess animals infected by **Trichinella spiralis (trichinellosis), addressed in Art. 202, apply to equidae.** (Included by Decree 9,069/2017)

Article 187. Carcasses and organs of equidae affected by: cerebrospinal meningitis, infectious encephalomyelitis, typhoid fever, dourine, *T. evansi*, azoturia, paroxysmal hemoglobinuria, equine distemper and any other diseases and changes with inflammatory lesions or malignant neoplasms must be condemned.

Article 188. Carcasses and organs must be condemned when the typical lesions of equine infectious anemia are found.

Sole paragraph. Carcasses of serologically positive animals may be passed for consumption provided that no systemic lesions are found at **post mortem**.

Article 189. The carcasses and organs of animals in which glanders lesions are found must be condemned, following the procedures given below:

I - slaughter must be halted immediately and all facilities, equipment and utensils that may have touched residues of the animal in question or any other potentially contaminated material must be immediately sanitized when lesions are found on **post mortem** inspection, in compliance with recommendations from the official animal health service;

II - employees who may have touched the contaminated material must take all necessary precautions, by applying rules of hygiene and personal antisepsis using products known to be effective, and such employees must be sent to the medical service as a precautionary measure; and

III - all carcasses, and carcass parts, including hides, hooves, horns, organs and the contents thereof that may have touched infectious animals or materials must be condemned.

Sub-Section IV

Post mortem inspection in ovines and caprines

Article 190. For the inspection of ovines and caprines, as far as is suitable, what is given in Section III of this Chapter will apply, in addition to this particular Sub-Section and in supplementary norms.

~~Article 191. As carcaças de animais portadores de **Coenurus cerebralis** (cenurose) quando acompanhadas de caquexia devem ser condenadas.~~

Article 191. Carcasses of animals infected with **Coenurus cerebralis** (coenurosis) when cachectic, must be condemned. (In the wording of Decree 9,069/2017)

Sole paragraph. The affected organs, the brain or the spinal cord must always be condemned.

Article 192. Carcasses with intense infection by **Cysticercus ovis (ovine cysticercosis)** must be condemned.

Par~~a~~agraph 1 Intense infection means finding five or more cysts in the chosen points and in the carcass musculature.

Par~~a~~agraph 2 When more than one cyst, although fewer than the number that characterizes intense infection, are found, after examination of all chosen points, then the carcasses and other tissues involved must go to conditional use after heat treatment, after the affected areas have been removed and condemned.

Par~~a~~agraph 3 When a single cyst is found, after examination of all points of choice, the carcass may be passed for direct human consumption after the affected area is removed and condemned.

Paragraph 4 Procedures to test for cysticerci in routinely examined sites of choice must comply with supplementary norms.

Article 193. Carcasses of animals showing caseous lymphadenitis lesions in the lymph nodes of several regions, affecting the overall state of the carcass or otherwise, must be condemned.

Paragraph 1 Carcasses with localized, caseous or calcifying lesions must go to heat sterilization provided they allow the removal and condemnation of the drainage area of the affected lymph nodes.

Par~~a~~agraph 2 The carcasses of animals with discrete calcified lesions in the lymph nodes may be passed for human consumption after the drainage area of these lymph nodes has been removed and condemned.

Par~~a~~agraph 3 In all cases where the involvement of organs and viscera is shown, they must be condemned.

Subsection V

Post mortem inspection for suidae

Article 194. Inspection for suidae: in addition to what is set forth in this Sub-Section and in supplementary norms, Section III of this Chapter applies.

Article 195. Carcasses with skin conditions, including erythema, scleroderma, urticaria, cystic hypotrichosis, mange and other types of dermatitis may be passed for human consumption after the affected areas are removed and condemned, provided that the musculature is normal.

Sole paragraph. Carcasses affected by advanced stages of mange and showing signs of cachexia or extensive inflammation of the musculature, must be condemned.

Article 196. Carcasses with arthritis in one or more joints, with reaction in the lymph nodes or hypertrophy of the synovial membrane, accompanied by cachexia, must be condemned.

Paragraph 1 Carcasses with arthritis in one or more joints, reaction in lymph nodes, hypertrophy of the synovial membrane, without repercussions for the overall state, may be sent for conditional use after heat treatment.

Paragraph 2 Carcasses with arthritis, without repercussions for the overall state, may be passed for consumption after the affected part has been removed.

Article 197. Carcasses with intense infection by **Cysticercus cellulosae (swine cysticercosis)** must be condemned.

Paragraph 1 Intense infection means the presence of two or more viable or calcified cysts, located in sites of choice examined on the inspection lines, plus confirmation of the presence of two or more cysts in the carcass muscle masses after testing by multiple deep incisions in the musculature (shoulder, loin and leg).

Paragraph 2 When more than one cyst—viable or calcified—is found, being less than what has been laid down for intense infection, and taking into consideration sites of choice examined on the inspection line and in the corresponding carcass, the carcass will be sent for conditional use after heat treatment, after the affected areas have been removed and condemned .

Paragraph 3 When one viable cyst is found, taking into consideration the chosen sites examined routinely on the inspection line, and in the corresponding carcass, the carcass must be sent for conditional cold or salting treatment, after removal and condemnation of the affected area.

Paragraph 4 When a single calcified cyst is found, after consideration of all points of choice routinely examined in the corresponding carcass, the carcass may be passed for direct human consumption after the affected area is removed and condemned.

Paragraph 5 The tongue, heart, esophagus and fatty tissues, as well as other parts that may be infected, must receive the same disposition as the carcass.

Paragraph 6 Procedures to test for cysticerci in routinely examined sites of choice must comply with supplementary norms.

Paragraph 7 Fatty tissue from intensely infected carcasses may be made use of for the manufacture of lard, after heat fusion, while the other parts are condemned.

Article 198. The carcasses of animals with cryptorchidism or those that have been non-surgically castrated must be condemned when a strong sexual odor is detected using specific tests laid down in supplementary norms.

Sole paragraph. Carcasses with a slight sexual odor may go to the manufacture of cooked meat products.

Article 199. Carcasses of suidae with erysipelas, bearing multiple skin lesions, arthritis aggravated by necrosis or when there are signs of a systemic effect, must be condemned.

Paragraph 1 In localized cases of vegetative endocarditis caused by erysipelas, without systemic changes, or chronic arthritis, the carcass may go to conditional use after heat treatment, after the affected organ or areas have been condemned.

Paragraph 2 In the case of a localized discrete skin lesion without organ or carcass involvement, the carcass may go to conditional use after heat treatment, after the affected area has been removed.

Article 200. Carcasses of hogs presenting localized lesions for granulomatous lymphadenitis, restricted to a primary infection site, such as in the cervical, mesenteric or mediastinal lymph nodes, may be passed for consumption after the affected region or organ has been condemned.

Sole paragraph. Swine carcasses in good condition, with lesions in lymph nodes that drain to two different sites—either the lymph nodes of distinct organs or those with the concomitant presence of lesions in lymph node and one organ—must go to conditional use after heat treatment, after the affected areas have been condemned.

Article 201. Carcasses of animals with swine fever must be condemned.

Paragraph 1 There must be total condemnation when kidneys and lymph nodes show suspect lesions, provided that a characteristic swine fever lesion can be proven in some other organ or tissue.

Paragraph 2 Discrete lesions accompanied by cachexia or any other focal source of suppuration equally entail total condemnation.

Paragraph 3 Carcasses must be sent for heat sterilization after the affected areas have been removed and condemned, in the case of discrete lesions that are circumscribed to a single organ or tissue, including kidneys and lymph nodes.

Article 202. Carcasses affected by **Trichinella spiralis** (Trichinellosis) must go to conditional use through cold treatment.

Paragraph 1 The cold treatment must comply with the following time-temperature pairs: I -

thirty days at -15ºC (minus fifteen degrees Celsius);

II - twenty days at -25ºC (minus twenty-five degrees Celsius); or III -

twelve days at -29ºC (minus twenty-nine degrees Celsius).

Paragraph 2 The Department of Inspection of Animal Products may authorize other treatments for conditional use provided that they are described in a supplementary norm.

Paragraph 3 Procedures to detect **Trichinella spiralis** in susceptible species will be laid down in supplementary norms. (Included by Decree 9,069/2017)

~~Article 203. Todos os suídeos que morrerem asfixiados, seja qual for a causa, bem como os que caírem vivos no tanque de escaldagem, devem ser condenados.~~

Article 203. All suidae that die from asphyxiation of whatever cause, or those scalded alive, must be condemned. (In the wording of Decree 9,069/2017)

Sole paragraph. Deaths from asphyxiation provided for in the **head provision** do not include those from gas stunning, provided that sticking follows immediately.

Subsection VI

Post mortem inspection for fish

Article 204. Inspection for seafood: in addition to what is set forth in this Sub-Section and in supplementary norms, Section III of this Chapter applies.

Sole paragraph. The term **post mortem** does not apply to those species of seafood that are sold alive.

Article 205. Seafood is deemed to include fishes, crustaceans, mollusks, amphibians, reptiles, echinoderms and other aquatic animals exploited for human foods.

Sole paragraph. Seafood from the producing source may not be sold directly to consumers without prior industrial and sanitary inspection.

Article 206. The provisions given in this Decree extend to terrestrial gastropods as far as is applicable.

Sole paragraph. The Ministry of Agriculture, Livestock and Food Supply shall establish inspection procedures for terrestrial gastropods in supplementary norms.

Article 207. The reception and processing of seafood captured or taken without complying with environmental and fisheries legislation is banned.

Article 208. Prior washing of seafood used as raw material for direct human consumption or for industrial processing is mandatory, in order to promote cleanliness, the removal of dirt and superficial microbiota.

Article 209. In addition to Article 10, official controls for seafood and by-products, as far as is applicable, encompasses the following:

I - sensory analyses;

II - freshness indicators;

III - control of histamine, in the forming species;

IV - control of biotoxins or other toxins that are hazardous to human health;

and V - control of parasites.

Article 210. Considering the specific nature of each species of seafood, the assessment of freshness will verify the following sensory characteristics for:

I - fishes:

a) clean body surface, with a relative metallic sheen and multicolored reflections for each species, without any unusual pigmentation;

b) bright, shiny, reflective, convex, transparent eyes, occupying the entire orbit;

c) gills: pink or red, moist and shiny with a natural, mild, characteristic smell;

d) abdomen: normal shape, firm, when pressed, the shape should bounce back;

e) shiny scales, tight to the skin, and the fins should offer resistance to provoked movements;

f) the flesh firm, elastic in consistency, with the natural color of the species;

g) the viscera should be whole, well-differentiated, and the peritoneum should adhere to the wall of the coelomic cavity;

h) closed anus; and

i) the characteristic odor of the species;

II- crustaceans:

a) overall appearance shiny and moist;

b) body holds its natural curvature, is rigid, joints firm and resistant;

c) shell is adherent to the body;

d) no strange colorations—color appropriate to the species;

e) bright protruding eyes;

f) characteristic pleasant odor; and

g) in the case of lobsters and crabs, they should be alive

and vigorous; III - mollusks:

a) bivalves:

1. must be alive, valves shut, retaining clean colorless water in the shells;

2. characteristic pleasant odor; and

3. moist flesh, adhering to the shell, spongy appearance, in the characteristic color for each species;

b) cephalopods:

1. smooth, moist skin;

2. bright eyes that are prominent in their orbits;

3. firm, elastic flesh;

4. absence of any unusual pigmentation for the species; and

5. characteristic odor;

c) gastropods:

1. moist flesh, adhering to the shell, in the characteristic color for each species;

2. characteristic pleasant odor; and

3. alive and vigorous; IV-

amphibians:

a) frog meat:

1. pleasant characteristic odor for the species;

2. pale pink flesh, white and shiny at the extremities near the joints;

3. absence of lesions or extraneous elements; and

4. firm texture, elastic and

tender; and V- reptiles:

a) alligator meat:

1. characteristic odor for the species;

2. pinkish-white color;

3. absence of lesions or extraneous elements; and

4. soft texture with muscle fibers laid out regularly;

b) flesh of Chelonians:

1. characteristic pleasant odor;

2. color characteristic of the species, free of dark blemishes; and

3. firm, elastic, tender texture.

Paragraph 1 The sensory characteristics addressed in this article extend, as fas as is applicable, to other species of seafood used in the human diet.

Paragraph 2 The sensory characteristics addressed in the **head provision** also apply to fresh, chilled or frozen seafood, received as raw material, insofar as is applicable.

Paragraph 3 The several types of seafood addressed in items I to III must be assessed for their sensory characteristics by establishment-trained staff, using a scientifically and technically based classification score sheet, as defined in a supplementary norm by the Ministry of Agriculture, Livestock and Food Supply.

Paragraph 4 Where sensory assessment raises doubt as to the freshness of the seafood, supplementary physical and chemical examinations will be used.

Article 211. Fresh seafood is seafood that meets the following supplementary physical and chemical parameters, without prejudice to the assessment of sensory characteristics:

I - flesh pH below 7.00 (seven exactly) in fishes;

II - flesh pH below 7.85 (seven point eight five) in crustaceans; III - flesh pH below

6.85 (six point eight five) in mollusks; and

IV - total volatile bases below 30 mg (thirty milligrams) of nitrogen/100g (one hundred grams) of muscle tissue.

Paragraph 1 pH and total volatile base scores may be established that are entirely different from those laid down in this article for certain species, to be defined in supplementary norms, when there is scientific evidence that the natural values for the species differ from the values defined.

Paragraph 2 The physical and chemical characteristics addressed in this article also apply to fresh, chilled or frozen seafood, insofar as is applicable.

Article 212. In seafood establishments, visual verification of lesions possibly owing to diseases or infections, as well as the presence of parasites, is mandatory.

Sole paragraph. This procedure must be monitored by trained establishment staff, in compliance with supplementary norms, except for seafood species for slaughter, which will be under permanent inspection.

Article 213. To preserve product safety and quality, the Ministry of Agriculture, Livestock and Food Supply will, in a supplementary norm, define the species of seafood that can be bled, deheaded or eviscerated on board prior to being sent to the establishment, and requirements for receiving the seafood.

Article 214. Conditional use is allowed, in compliance with standards of disposition established in a supplementary norm, for seafood that is injured, mutilated, deformed, with color changes or the presence of localized parasites.

Article 215. Seafood going to conditional use, as laid down in this Sub-Section, must, at the discretion of the SIF, undergo one of the following treatments:

I - freezing; II -

salting; or

III - heat.

Article 216. Seafood and seafood-farming products infected by endoparasites capable of being transmitted to man cannot go to raw consumption without undergoing prior freezing at a temperature of -20ºC (minus twenty degrees Celsius) for twenty-four hours, or -35ºC (minus thirty-five degrees Celsius) for fifteen hours.

Sole paragraph. Treatments other than those proposed may be used, provided that the same guarantees are ensured, with technical and scientific underpinnings approved by the Department of Inspection of Animal Products.

Article 217. Seafood, parts thereof, and organs bearing lesions or abnormalities that may render them unfit for human consumption must be identified and taken to a specific site for inspection, taking into consideration the risk entailed in their use.

CHAPTER II

INDUSTRIAL AND SANITARY INSPECTION OF EGGS AND EGG BY-PRODUCTS

Article 218. For the purposes of this Decree, in the absence of another specification, eggs means hens' eggs in their shells.

Article 219. The inspection of eggs and egg products addressed in this Chapter applies to hens' eggs, and insofar as is appropriate, to other egg-producing species, respecting the differences between them.

Article 220. Eggs may only be displayed for human consumption when previously undergoing inspection and classification as laid down in this Decree and in supplementary norms.

Article 221. For the purposes of this Decree, fresh eggs means those eggs that have not been conserved by any process and that fit the classification laid down in this Decree and in supplementary norms.

Article 222. Eggs received in the egg-processing establishment must come from poultry establishments registered with the official animal health service.

Sole paragraph. Poultry farms must also be registered with the official animal health service.

Article 223. Egg and egg-product establishments must apply the following procedures, which will be verified by the SIF:

I - general appreciation of the state of cleanliness and intactness of

the shell; II - ovoscopy;

III - egg classification; and

IV - verification of cleanliness and wholeness of the packaging.

Article 224. Eggs for human consumption must be classified as categories “A” and “B”, in accordance with their qualitative characteristics.

Sole paragraph. Classification of eggs by weight must comply with the TRIQ.

Article 225. Category “A” eggs must present the following qualitative characteristics: I - normal

shell and cuticle, smooth, clean, intact;

II - immobile air cell no higher than 6mm (six millimeters);

III - yolk visible on ovoscopy, as a shadow, with an apparent outline, moving slightly with the rotation of the egg but coming back to the central position;

IV - the white is limpid and translucid, consistent, without staining or opacity and with intact

chalazae; and V - cicatriculum with imperceptible development.

Article 226. Class “B” eggs must have the following characteristics:

I - be deemed safe even if not fitting into class “A”;

II - present only a few small blood spots in the yolk and white; or

III - come from poultry breeding establishments that did not undergo incubation.

Sole paragraph. Class “B” eggs will go exclusively to industrial processing.

Article 227. Cracked or broken eggs with intact eggshell membranes must go as quickly as possible to industrial processing.

Article 228. Dirty or cracked eggs may not be washed and used in manufacturing egg by-products.

Article 229. Eggs for the production of by-products must be washed before processing.

Article 230. Eggs must be stored and transported in conditions that minimize temperature variations.

Article 231. There must be separate packaging for: I - fresh eggs and eggs undergoing

conservation processes; and

II - eggs of different species.

~~Article 232. Os aviários, as granjas e as outras propriedades avícolas nas quais estejam grassando doenças zoonóticas com informações comprovadas pelo serviço oficial de saúde animal podem destinar sua produção de ovos ao consumo na forma que se apresenta.~~

Article 232. Aviaries, poultry farms and other poultry-breeding establishments where zoonotic diseases are active for which the official animal health service possesses proven information may not send their egg output to consumption in their present form. (In the wording of Decree 9,069/2017)

CHAPTER III

INDUSTRIAL AND SANITARY INSPECTION OF MILK AND DAIRY PRODUCTS

Article 233. Inspection of milk and dairy products, in addition to the demands addressed in this Decree, includes verification:

I - of the health of the herd, the milking process, the packing, preservation and transportation of the milk;

II - of the raw material, the processing, the product, the storage and the shipping; and

III - laboratory facilities, equipment, controls and analyses.

Article 234. The inspection of milk and dairy products addressed in this Chapter applies to cows' milk, and insofar as is appropriate, to other milk-producing species, respecting the differences between them.

Article 235. For the purposes of this Decree, milk, if not otherwise specified, is the product deriving from the complete and uninterrupted milking process, in hygienic conditions, with healthy, well-fed and fully-rested cows.

Paragraph 1 The milk of other animals must be categorized according to the species it comes from.

Paragraph 2 Milk from different animal species may be mixed, provided that the product is so named at sale and that the labeling contains the percentage of milk from each species.

Article 236. For the purposes of this Decree, colostrum is the milking product obtained after birth and while the characteristic elements in it are still present.

Article 237. For the purposes of this Decree, transition milk is obtained in the thirty days before expected calving.

Article 238. For the purposes of this Decree, individual milk is understood as the product resulting from the milking of a single cow, and joint milk is the product resulting from the mixture of individual milks.

Article 239. For the purposes of this Decree, dairy cattle are understood to be the entire herd exploited in order to produce milk.

Sole paragraph. No stimulants of any nature may be given to increase milk secretion with harm to animal and human health.

Article 240. Milk must be produced in hygienic conditions, including the handling of dairy cattle and the processes of milking, preservation and transportation.

Paragraph 1 Immediately after milking, whether manual or mechanical, the milk must be filtered using specific previously washed utensils.

Paragraph 2 Raw milk kept on the farm must be maintained for a period, and at a temperature, defined in a supplementary norm.

Paragraph 3 Containers or equipment to preserve the milk on the farm until collection must be kept in a specific suitable place in hygienic conditions.

Article 241. For the purposes of this Decree, a community vat or tank is a direct-expansion system refrigeration device used exclusively in collective fashion by milk producers to keep raw milk refrigerated on the farm.

Sole paragraph. The community tank must be linked to a federally-inspected establishment and must meet the demands of the supplementary standard.

Article 242. Partial or total skimming of milk is forbidden on the farms.

Article 243. Cows of whatever species may not be sent to any industrial establishment, if:

I - they belong to a banned farm;

II - are not clinically healthy and well-nourished; III - are in the last

month of pregnancy or in the colostral stage;

IV - present a clinical diagnosis or diagnostic test result showing infectious or contagious diseases that can be transmitted to humans through the milk;

V - are undergoing treatment with veterinary products during the withdrawal period recommended by the manufacturer; or

VI - are receiving feed or veterinary products that can impair the quality of the milk.

Article 244. The establishment is responsible for ensuring the identity, quality and traceability of the raw milk, from collection on the farm up until reception at the establishment, including transport.

Sole paragraph. For the purposes of traceability, when the milk is collected by an insulated container truck, a sample of the milk of each farmer or each community vat must be taken before collection, and it must be identified and kept until reception at the industrial establishment.

Article 245. Transfer of raw refrigerated milk between insulated container trucks from the farms to the industrial establishments may include an intermediate facility, controlled by the establishment, provided that the latter can prove that this operation does not negatively affect the quality of the milk.

Paragraph 1 The intermediate facility addressed in the **head provision** must formally be part of the bulk collection program of the industrial establishment to which it is linked.

Paragraph 2 Transfer of raw refrigerated milk between insulated container trucks must be performed within a closed system.

Paragraph 3 It is forbidden to measure or transfer milk in an environment that exposes it to contamination.

Article 246. Establishments receiving raw milk from dairy farmers are responsible for introducing raw material quality improvement programs and for providing farmers with continued education.

Article 247. The taking, packing, and shipping of samples of milk from farms to meet the national milk quality improvement program are the responsibility of the establishment first receiving it from the producers, this responsibility encompasses:

I - somatic cell count - SCC; II - total

bacterial count - TBC;

III - centesimal composition;

IV - detection of veterinary product residues; and

V - other responsibilities that may be determined in a supplementary standard.

Sole paragraph. Sample taking, packing and shipping procedures to be followed are those brought in by the Ministry of Agriculture, Livestock and Food Supply.

Article 248. Milk is deemed as being a product that meets the following

specifications: I - physical-chemical characteristics:

a) normal sensory characteristics (color, odor and appearance);

b) minimum fat content of 3.0g/100g (three grams per hundred grams);

c) minimum protein content 2.9g/100g (two point nine grams per one hundred grams);

d) minimum lactose content 4.3g/100g (four point three grams per hundred grams);

e) minimum non-fatty solids content 8.4g/100g (eight point four grams per hundred grams);

f) minimum total solids content 11.4g/100g (eleven point four grams per hundred grams);

g) titratable acidity between 0.14 (zero point one four) and 0.18 (zero point one eight) expressed as grams of lactic acid/100 mL;

h) relative density at 15ºC (fifteen degrees Celsius) between 1.028 (one point zero two eight) and 1.034 (one point zero three four) expressed as g/mL;

i) cryoscopic rate between -0.530ºH (minus zero point five three zero degrees Hortvet) and -0.555°H (minus zero point five five five degrees Hortvet); and

j) equivalent at -0.512ºC (minus zero point five one two degrees Celsius) and at -0.536ºC (minus zero point five three six degrees Celsius), respectively;

II - it does not present extraneous substances in its composition, such as microbial growth inhibitors, acidity neutralizers, density or cryoscopic rate reconstituters; and

III - it does not present veterinary product residues and contaminants above the maximum levels set forth in supplementary norms.

Sole paragraph. Regions possessing scientific and technical studies of the regional patterns of the characteristics of milk, on approval by the Department of Inspection of Animal Products, may adopt other milk standards.

Article 249. Analysis of milk for selection and reception at the industrial establishment must encompass the specifications laid down in supplementary norms.

Article 250. The industrial establishment is responsible for the control of conditions of reception and selection of milk to be treated or industrially processed, in accordance with specifications laid down in this Decree and in supplementary norms.

Paragraph 1 Only milk meeting the requirements contained in Article 248 may receive treatment.

Paragraph 2 When a non-compliance is detected in analyses supporting the selection of milk, the receiving establishment will be responsible for the disposition of the milk, in accordance with this Decree and with supplementary norms.

Paragraph 3 Disposition of milk that fails to meet specifications set forth in Article 248 and that comes from industrial establishments, provided it has not been internalized, is the responsibility of the supplying establishment, although the receiving establishment decides upon the disposition of the milk.

Paragraph 4 In the hypothesis addressed in Paragraph 3, the receiving establishment will inform the SIF of the occurrence and keep auditable records of analyses performed and controls of traceability and disposition, when this occurs within its facilities.

Article 251. The processing of milk after reception at any establishment includes the following operations, among other processes approved by the Department of Inspection of Animal Products:

I - pretreatment of the milk, including—whether in isolation or in combination—pressure filtration, clarification, bactofugation, microfiltration, standardization of the fat content, thermization (preheating), homogenization and refrigeration; and

II - milk treatment: in addition to item I, this includes the thermal treatments pasteurization, ultra-high temperature (UHT) or sterilization and the filling step.

Paragraph 1 Milk may be frozen for those species in which this procedure is technologically justified, provided that this is established in a specific technical regulation.

Paragraph 2 The use of chemicals to preserve the milk is forbidden.

Paragraph 3 All milk for industrial processing must undergo filtration before any pretreatment or treatment operation.

Article 252. For the purposes of this Decree, filtration is understood to mean the removal of impurities from the milk by a mechanical process, after it has passed under pressure through an appropriate filter material.

Article 253. For the purposes of this Decree, clarification is understood to mean the removal of impurities from the milk by a mechanical process, through centrifugation or another equivalent technological process that has been approved by the Department of Inspection of Animal Products.

Sole paragraph. All milk for direct human consumption must undergo clarification.

Article 254. For the purposes of this Decree, thermization or pretreatment is understood to mean the application of heat to the milk in a specific apparatus in order to reduce is bacterial load without changing the characteristics of the raw milk.

Sole paragraph. Thermized milk must be refrigerated immediately after heating and must maintain the enzyme profile of the raw milk.

Article 255. For the purposes of this Decree, pasteurization is understood to mean heat treatment applied to the milk in order to avoid public health risks resulting from pathogenic micro-organisms that it might contain, and which produces minimal chemical, physical, sensory or nutritional changes.

Paragraph 1 The following milk pasteurization processes are permitted:

I - slow pasteurization, which consists of indirect heating of the milk at between 63ºC (sixty-three degrees Celsius) and 65ºC (sixty-five degrees Celsius) for thirty minutes, slowly mechanically stirring the milk in a specific piece of equipment; and

II - rapid pasteurization, which consists of heating the milk in a laminar layer between 72ºC (seventy-two degrees Celsius) and 75ºC (seventy-five degrees Celsius) for fifteen to twenty seconds, in a specific apparatus.

Paragraph 2 The Department of Inspection of Animal Products may accept other time-temperature binomials provided that their equivalence to the processes laid down in Paragraph 1 is proven. –

Paragraph 3 The technical and sanitary control of the operation demands the use of a suitably installed and perfectly-functioning apparatus that possesses automatic temperature control devices, temperature gages, thermometers and other devices necessary in the process.

Paragraph 4 For the rapid pasteurization system, the apparatus addressed in Paragraph 3 must include an automatic milk flow switching device with a sound alarm.

Paragraph 5 Pasteurized milk for direct human consumption must be refrigerated at no higher than 4ºC (four degrees Celsius) immediately after pasteurization, automatically filled in a closed circuit in the shortest possible time and shipped for consumption or stored in a freezer at a temperature likewise no higher than 4ºC (four degrees Celsius).

Paragraph 6 Pasteurized milk may be stored refrigerated in insulated tanks equipped with thermometers and automatic stirring devices at a temperature between 2ºC (two degrees Celsius) and 4ºC (four degrees Celsius).

Paragraph 7 Pasteurized milk must test negative for alkaline phosphatase and positive for peroxidase.

Paragraph 8 Milk for direct human consumption may not be repasteurized.

Article 256. The Ultra-high temperature process is understood to mean the heat treatment of milk at a temperature between 130ºC (one hundred and thirty degrees Celsius) and 150ºC (one hundred and fifty degrees Celsius), for two to four seconds, in a continuous flow process, after which it is immediately chilled to below 32ºC (thirty-two degrees Celsius) and filled in aseptic conditions in hermetically sealed sterilized containers.

Paragraph 1 The Department of Inspection of Animal Products may accept other time-temperature binomials provided that their equivalency to the processes laid down in the **head provision** is proven.

Paragraph 2 UHT Milk for direct human consumption may not be reprocessed.

Article 257. For the purposes of this Decree, sterilization is understood to mean the heat treatment of milk at a temperature between 110º C (one hundred and ten degrees Celsius) and 130º C (one hundred and thirty degrees Celsius) for twenty to forty minutes in appropriate equipment.

Sole paragraph. The Department of Inspection of Animal Products may accept other time-temperature binomials provided that their equivalence to this process is proven.

Article 258. The following maximum limits of preservation and temperature must be met for preserving milk:

I - preservation and shipping at the refrigeration station: 4º C (four degrees Celsius);

II - preservation in the treatment plant or dairy product plant before pasteurization: 4ºC (four degrees Celsius);

III - refrigeration after pasteurization: 4º C (four degrees Celsius);

IV - storage in the pasteurized milk freezer: 4º C (four degrees Celsius); V - delivery

to the consumption of pasteurized milk: 7º C (seven degrees Celsius); and

VI - storage and delivery to the consumption of sterilized UHT milk: ambient temperature.

Article 259. Milk that is heat treated for direct human consumption can only be displayed for sale when it is filled automatically in a closed circuit, in a tamper-proof container specific for the expected storage conditions.

Paragraph 1 Filling equipment must possess devices to ensure maintenance of aseptic condition for the containers, in accordance with the specificities of the process.

Paragraph 2 Milk for direct human consumption may only undergo filling on dairy farms and in milk treatment plants, as laid down in this Decree

Article 260. Pasteurized milk must be transported in insulated vehicles with installed cold equipment.

Article 261. In order to be displayed for consumption as whole milk, treated milk must present the same requirements as normal milk, except for its indices of non-fatty and total solids, which must comply with the Technical Regulation of Identity and Quality (TRIQ).

~~Article 262. O leite beneficiado, para ser exposto ao consumo como padronizado, semidesnatado ou desnatado, deve satisfazer às exigências do leite normal, com exceção dos teores de gordura, de sólidos não gordurosos e de sólidos totais, que devem atender ao RTIQ.~~

Article 262. Treated milk, in order to be displayed for consumption as semi-skimmed or skimmed milk, must meet the requirements for normal milk, except for its indices of non-fatty and total solids, which must comply with the Technical Regulation of Identity and Quality (TRIQ). (In the wording of Decree 9,069/2017)

Article 263. The microbiological standards for treated milk must comply with the Technical Regulation of Identity and Quality—TRIQ.

CHAPTER IV

INDUSTRIAL AND SANITARY INSPECTION OF BEE AND BEE PRODUCTS

Article 264. Inspection of bee products and by-products, in addition to the demands already laid down in this Decree, must include verification of the extraction, packing, preservation, processing, storage, shipping and transportation of bee products.

Article 265. Analyses of bee products, for the purposes of reception and selection in the processing plant, must include the sensory characteristics and other analyses provided for in supplementary norms, in addition to the necessary indicators of fraud.

Sole paragraph. When a non-compliance is detected in analyses supporting the selection of raw material, the receiving establishment will be responsible for the suitable disposition of the product, in accordance with this Decree and with supplementary norms.

Article 266. Honey, and the honey of stingless bees, when crystallized, pasteurized or dehumidified, must comply with the time and temperature binomial and with supplementary norms.

Article 267. Bee product establishments receiving raw materials from beekeepers must keep an updated registry of such producers, as laid down in supplementary norms.

Sole paragraph. The extraction of raw material by the beekeeper must be performed in a suitable place that enables the tasks of handling and placing the raw materials in hygienic conditions.

Article 268. The products of stingless bees must come from breeding facilities, in the shape of apiaries, authorized by the competent environmental agency.

TITLE VI

STANDARDS OF IDENTITY AND QUALITY CHAPTER I

GENERAL ASPECTS

Article 269. For the purposes of this Decree, an ingredient is understood to mean any substance used in the manufacture or preparation of a product, including food additives, remaining at the end of the process—even if in a modified form—as laid down in specific legislation and in supplementary norms.

Article 270. The use of additives or technological adjuvants must comply with limits laid down by the health agency and by the Ministry of Agriculture, Livestock and Food Supply, as follows:

I - the health regulator will define the additives and technological adjuvants authorized for use in foodstuffs and their maximum limits of addition; and

II - the Department of Inspection of Animal Products will establish, among additives and technological adjuvants authorized for use in foodstuffs, those that may be used in animal products and their maximum limits, when applicable.

Paragraph 1 The use of antiseptics, chemicals, plant extracts and infusions, or tinctures, will depend on prior authorization by the Department of Inspection of Animal Products.

Paragraph 2 Substances that may be prejudicial to or harm the consumer are banned.

Article 271. Salt and its replacements, seasonings and spices used in the preparation of animal products must be free of substances that are extraneous to their composition, and must comply with the specific legislation.

Sole paragraph. Salt may not be reused for edible products after it has been used in salting processes.

Article 272. Turbid, dirty, alkaline, fermented brines may not be used, or those with an odor of ammonia or that are unsuitable for any other reason.

Sole paragraph. Treatment to recover brines is permitted, by means of continuous filtration, pasteurization or the use of chemicals authorized by the competent authority, provided that the original characteristics are not changed.

Article 273. The Ministry of Agriculture, Livestock and Food Supply will establish a TRIQ for animal products provided for in this Decree or otherwise, and will establish specific technical regulations for their respective manufacturing processes.

Sole paragraph. Technical Regulations of Identity and Quality will include the definition of the products, the technology for obtaining them, authorized ingredients, and as far as is applicable, the microbiological, physical and chemical parameters, labeling requirements and other necessary requirements.

Article 274. Animal products must meet microbiological and physical-chemical parameters and limits, limits on veterinary product residues, contaminants and other limits laid down in this Decree, or in the Technical Regulation of Identity and Quality , or in supplementary norms.

Article 275. Animal products may be irradiated in establishments that are in a legally regular situation with the competent agencies.

Sole paragraph. Traceability, registration and labeling procedures, and responsibility for treatment and sale, will be established in supplementary norms.

CHAPTER II

IDENTITY AND QUALITY STANDARDS IN MEAT AND BY-PRODUCTS

Section I

Raw materials

Article 276. For the purposes of this Decree, meats are the muscle masses, and other tissues that accompany them, with or without the corresponding bone base, from different animal species, deemed fit for consumption by official veterinary inspection.

Article 277. For the purposes of this Decree, carcasses are the muscle masses and bones of a slaughtered animal, prepared technically, without heads, organs and thoracic and abdominal viscera, in accordance with the particular characteristics of each species, and:

~~I - nos bovídeos e equídeos a carcaça não inclui pele, patas, rabo, glândula mamária, testículos e vergalho, exceto suas raízes;~~

I - in bovines, buffaloes, and equidae, the carcass does not include the hide, hooves, tail, mammary gland, testicles and pizzle (except the roots); (Wording given by Decree no. 9,069, enacted 2017)

II - in suidae the carcass may include skin, head and feet;

III I - in bovidae and equidae the carcass does not include hide, feet, mammary gland, testicles and pizzle, except its roots, and the tail may or may not be present;

IV - in poultry the carcass must be without feathers—the removal of kidneys, feet, neck, head and reproductive organs in birds not yet sexually mature is optional;

V - in lagomorphs the carcass must be without skin, head and feet;

VI - in ratites the carcass must be without skin and feet, the removal of the neck is optional; VII - in

frogs and alligators the carcasses are without skin and feet; and

VIII - in Chelonians the carcasses are without the shell.

Sole paragraph. The meat around the stick wound must be removed, as it is deemed unfit for consumption, taking into consideration the particularities of each species.

Article 278. For the purposes of this Decree, offals are understood to be the organs and animal parts deemed suitable for human consumption by official veterinary inspection, as specified below:

I - in ruminants: brain, tongue, heart, liver, kidneys, rumen, reticulum, omasum, tail and feet; II - in

suidae: tongue, liver, heart brain, stomach, kidneys, feet, ears, mask and tail; III - in poultry: liver,

heart and gizzard without the inner lining;

IV - in seafood: tongue, heart, gizzard, liver, roes and swim bladder, in accordance with the particularities of each species;

V - in lagomorphs: liver, heart and kidneys; and

VI - in equidae: heart, tongue, kidneys and stomach.

Sole paragraph. In accordance with the regional or traditional habits or the habits of importing countries, lungs, spleen, spinal cord, mammary glands, testicles, lips, cheeks, cartilage and other parts to be defined in supplementary norms may be used for direct consumption, provided they are not specific risk materials.

Article 279. For the purposes of this Decree, the products of the casings room are defined as being the abdominal viscera used as natural casings, such as intestines and bladder, after undergoing the specific technological treatments.

Paragraph 1 Stomachs, the parietal peritoneum, the esophageal serosa, the epiploon and the depilated skin of the hog may all be used as casings.

Paragraph 2 Intestines used as casings must first be scraped and washed, and may be preserved through dessication, salting or some other process approved by the Department of Inspection of Animal Products.

Article 280. Meat and offals used in making meat products must be free of fat, aponeuroses, lymph nodes, glands, the bile ducts, the pericardial sac, papillae, cartilage, bone, major blood vessels, blood clots, tendons and other tissues deemed unfit for human consumption, without prejudice to other criteria defined by the Department of Inspection of Animal Products.

Sole paragraph. One exception to the mandatory removal of bones addressed in the **head provision** is meat used to make bone-in products, where the presence of a bone base is part of its characterization.

Article 281. The use of intestines, tonsils, salivary glands, mammary glands, ovaries, spleen, testicles, lymph nodes, hemal nodes and other glands as raw material for making meat products is forbidden.

Article 282. Blood or blood fractions may be used to prepare meat products, provided it is obtained in specific conditions laid down in supplementary norms.

Paragraph 1 The use of blood or fractions from animals sent for conditional use or deemed unfit for human consumption is forbidden.

Paragraph 2 Manual defibrination of blood is forbidden if it is intended for human consumption.

Section II

Meat products

Article 283. For the purposes of this Decree, meat products are understood as being those obtained from meat, offals and edible parts of different animal species, with the original properties of the raw materials modified by physical, chemical or biological treatment, or by a combination of such methods in processes that may involve the addition of ingredients, additives or technological adjuvants.

Article 284. For the purposes of this Decree, back fat means the fatty panniculus carnosus underlying the skin in hogs, and whose designation and is defined by the technological process applied in its preservation.

Article 285. For the purposes of this Decree, hog's lard is the cavitary fat of pigs, such as the adipose parts of the visceral mesentery, the capsules of the kidneys, and other pressed viscera.

Article 286. For the purposes of this Decree, mechanically separated meat is the product obtained by removing meat from its supporting bones after the deboning process in poultry, bovines, hogs or other species authorized by the Ministry of Agriculture, Livestock and Food Supply, using mechanical means that lead to the loss of modification of muscle fiber structure.

Article 287. For the purposes of this Decree, seasoned meat, followed by a suitable specification, is a meat product obtained from cuts or meats of different animal species, that has been seasoned, with or without the addition of ingredients.

Article 288. For the purposes of this Decree, processed meats are meat products made with meat or edible organs, whether cured or otherwise, seasoned, cooked or otherwise, smoked and dessicated or otherwise, whose casings are the intestines, stomachs or other animal membranes.

Paragraph 1 Animal intestines and membranes used as casings must be thoroughly cleaned and undergo further washing immediately before use.

Paragraph 2 The use of artificial casings is allowed, provided they have previously been approved by the health regulating agency.

Article 289. For the purposes of this Decree, smoked products are those meat products that undergo smoking, after curing, to give them their characteristic smell and flavor, as well as longer shelf life owing to their partial dehydration.

Paragraph 1 Hot or cold smoking are allowed.

Paragraph 2 Smoking must be carried out in ovens built for this purpose and must burn dry, hard, non-resinous woods.

Article 290. For the purposes of this Decree, cooked meat, followed by a suitable specification, is a meat product obtained from the meats of different animal species, deboned or otherwise, with or without the addition of ingredients, and that has undergone a specific heat treatment.

Article 291. For the purposes of this Decree, dehydrated products are meat products obtained by the dehydration of fragmented meat or offals of different animal species, cooked or otherwise, with or without the addition of ingredients, and dessicated by means of a specific technological process.

Article 292. For the purposes of this Decree, sterilized products are meat products obtained from the meat or offals of different animal species, with or without the addition of ingredients, packaged hermetically and subjected to commercial sterilization.

Article 293. For the purposes of this Decree, edible fatty products, according to the animal species from which they come, are products resulting from the processing or use of animal tissues by means of fusion or other

specific technological processes, with or without the addition of ingredients.

Sole paragraph. When fatty products are in a liquid state they must be called oils.

Article 294. For the purposes of this Decree, meat balls are a meat product obtained from the ground meat of one or more animal species, molded into a spherical shape, with or without the addition of ingredients, and having undergone a specific technological process.

Article 295. For the purposes of this Decree, hamburgers are a meat product obtained from ground meat of several animal species, molded into a flattened round or oval shape and having undergone a specific technological process.

Article 296. For the purposes of this Decree, a kibbeh is a meat product obtained from ground beef or lamb, with the addition of cracked wheat, shaped and with added ingredients.

Sole paragraph. Meat of other species may be used in producing kibbehs, but must be declared in the trading description.

Article 297. For the purposes of this Decree, sausages are a meat product obtained from the ground meat of several animal species, seasoned, with or without the addition of ingredients, forced into a natural or artificial casing and having undergone a specific technological process.

Article 298. For the purposes of this Decree, blood sausage (Portuguese *morcela* or Spanish *morcilla*) is a meat product made mainly of blood with or without the addition of ground back fat, then seasoned and cooked.

Article 299. For the purposes of this Decree, mortadella is a meat product obtained from the emulsion of meats from several animal species, with or without the addition of back fat, skin, offals and edible animal parts, specific ingredients and seasonings, placed in a natural or artificial casing with a specific caliber and in different shapes, and undergoing a characteristic thermal process.

Article 300. For the purposes of this Decree, *salsicha* or frankfurter sausage, is a meat product obtained from the emulsion of meats from several animal species, with or without the addition of fat, skin, offals and edible animal parts, specific ingredients and seasonings, placed in a natural or artificial casing with a specific caliber, and undergoing a characteristic thermal process.

Article 301. For the purposes of this Decree, ham is a meat product obtained exclusively from cured pork leg, smoked or otherwise, deboned or otherwise, with or without the addition of ingredients, and having undergone a suitable technological process.

Sole paragraph. It can be made from the meat of the hind leg of other animal species, provided this is acknowledged in its trading description.

Article 302. For the purposes of this Decree, *apresuntado* (a kind of second-class ham) is a meat product obtained from trimmings or cuts of the muscle mass of pigs' fore or hind legs, transformed into a paste, seasoned, with the addition of ingredients, and undergoing a specific thermal process.

Article 303. For the purposes of this Decree, *fiambre* (ham) is a meat product obtained from the meat of one or more animal species, with or without the addition of offals and edible animal parts, transformed into a paste, seasoned, with the addition of ingredients and undergoing a specific thermal process.

Article 304. For the purposes of this Decree, salame is a meat product obtained from pork and back fat, with or without the addition of beef or other ingredients, seasoned, packed in natural or artificial casings, cured, fermented, matured, smoked or otherwise, and dessicated.

Article 305. For the purposes of this Decree, **pepperoni** is a meat product made from ground pork and back fat, with or without addition of beef or other ingredients, seasoned, packed in natural or artificial casings, cured, spiced with pepper, fermented, matured, dessicated, and may or may not be smoked.

Article 306. For the purposes of this Decree, coppa is a meat product obtained from a whole cut of the pork carcass denominated neck or shoulder, seasoned, cured, with or without the addition of ingredients, matured, dessicated, and may or may not be smoked.

Article 307. For the purposes of this Decree, loin is a meat product obtained from a cut of the lumbar region of suidae, ovines or caprines, seasoned, with the addition of ingredients, and may or may not be salted, cured and smoked.

Article 308. For the purposes of this Decree, **bacon** is a meat product obtained from a cut of the thoraco-abdominal wall of hogs, from the sternum to the pubis, with or without a rib, or skin, and with the addition of ingredients, cured and smoked.

Article 309. For the purposes of this Decree, paté is a meat product obtained from meats and offals of several different species of animals or meat products transformed into a paste, with the addition of ingredients and undergoing

a specific thermal process.

Article 310. For the purposes of this Decree, meat stock is a liquid product resulting from the cooking of meats, which is filtered,sterilized and canned or pouched.

Paragraph 1 Concentrated (liquid) meat stock is to be called fluid meat stock.

Paragraph 2 Concentrated meat stock in a soft consistency is to be called meat stock, and when seasoned must be called meat stock with seasoning.

Article 311. For the purposes of this Decree, *charque* (dried salted meat) is a meat product obtained from beef, with the addition of salt and after dessication.

Sole paragraph. Meat of other species may be used in producing charque, but must be declared in the trading description.

Article 312. For the purposes of this Decree, dried cured salted beef or **jerked beef** is a meat product obtained from beef, with added salt and curing agents, and dessicated.

Article 313. For the purposes of this Decree, gelatin is a concentrated dry product obtained by the thermal, chemical or enzymatic (or combined) hydrolysis of collagen protein present in cartilage, tendon, skin, trimmings or bones of several different animal species, followed by purification and filtration.

Paragraph 1 When complete hydrolysis occurs of the collagen protein, so that the product loses its gelling power it will be called hydrolyzed gelatin.

Paragraph 2 In the preparation of gelatin, only raw materials from animals that have passed the official inspection may be used.

Article 314. For the purposes of this Decree, lard is a product obtained from the fusion of fresh pork adipose tissue,with or without the addition of additives and technological adjuvants.

Article 315. Meat products sharing identical characteristics or natures, but manufactured from different compositions, may be classified and differentiated by quality in their respective RTIQs, based on one or more of the following criteria:

I - total protein content, meat protein content, moisture and fat content in the finished product; II -

quantity and quality of the meat raw material used;

III - whether offals or edible parts of several animal species have been added, and their respective quantities; IV -

whether non-meat or plant proteins have been used and their respective quantities; and

V - other parameters laid down in supplementary norms.

Article 316. Within the defined limits, the addition of water or ice to meat products is allowed, in order to facilitate grinding and homogenization of the paste, or for other technological purposes, when provided for in this Decree and in supplementary norms, or after approval from the Ministry of Agriculture, Livestock and Food Supply.

Article 317. Within established limits, the addition of starch or yucca starch, plant ingredients and non-meat protein to meat products is allowed, when provided for in this Decree and in supplementary norms, or after approval by the Department of Inspection of Animal Products.

Article 318. Cooked meat products that need to be stored under refrigeration must be chilled immediately after thermal processing, at a time and temperature that maintains safety.

Sole paragraph. Cooked meat products preserved at room temperature must meet the specifications laid down by the Ministry of Agriculture, Livestock and Food Supply.

Article 319. All sterilized meat products must undergo heat treatment no more than two hours after the sealing of the packaging.

Paragraph 1 After sterilization, if poorly sealed or defective packages are identified, they may, depending on the case, be repaired, and their contents reused, under the following conditions:

I - when the repair and resterilization are carried out within the first six hours after detection of the defect; or

II - when the defect is detected at the end of production and the packages are stored in chillers at no more than 1ºC (one degree Celsius); new filling must take place the following day,

followed by sterilization..

Paragraph 2 When resterilization does not occur, then in compliance with sub-paragraphs I or II of paragraph 1, the contents of the packages must be deemed unfit for consumption.

Article 320. Sterilized meat products will be submitted to process controls including a penetration test and heat distribution test, heat treatment, seal evaluation, and package or recipient resistance tests, incubation and other tests laid down in supplementary orders.

Sole paragraph. The incubation test addressed in the **head provision** will be carried out in accordance with:

I- representative samples of all batches will undergo a ten day incubation test, comprising at least 0.1% (zero point one per cent) of the processed packages, which will be laid out in an oven room with temperature controlled at 35ºC (thirty-five degrees centigrade), and variations of 2.8ºC (two point eight degrees centigrade) will be tolerated above or below;

II- should the incubation temperature fall below 32°C (thirty-two degrees centigrade) or exceed 38°C (thirty-eight degrees centigrade), but not exceed 39.5ºC (thirty-nine point five degrees centigrade), it must be brought back within the range and the incubation time extended by adding the time during which the sample remained in the deviating temperature; and

III- if the incubation temperature remains at a temperature equal to or above 39.5ºC (thirty-nine point five degrees centigrade) for more than two hours, the samples must be discarded, new samples must be taken, and the incubation test must be restarted within the established temperature range.

Article 321. When verifying sterilized meat products, the following aspects must be considered:

I - the overall conditions of the recipient, which must not present defects that jeopardize its tamper-free condition;

II - the presence of signs of swelling;

III - examination of surfaces of containers; IV

- specific smell, taste and coloring;

V - absence of tissues inferior to or different from those indicated in the approved formula when the container is broken down;

VI - for cans, the occurrence of a sound appropriate to the nature of the can in the percussion test; and

VII - non-release of gas, non-projection of liquid and the production of a characteristic sound after the entry of air into the vacuum of the container, which should reduce the concavity of the opposite lid when the can is submitted to a perforation test.

Sole paragraph. Microbiological and physical-chemical tests: those appropriate for each case should be carried out so as to prove the commercial sterility of the product.

Section III

Inedible products

Article 322. For the purposes of this Decree, inedible product is product resulting from the handling and processing of raw material, by-products and residues of animals used in the preparation of commodities not intended for human consumption.

Sole paragraph. Among the inedible products addressed in this Decree, enzymes and enzyme products, opotherapeutic products, pharmo-chemicals and intermediate products, laboratory inputs and products intended for animal feed, with or without a nutritional purpose, obtained from animal tissues, are not included.

Article 323. For the purposes of this Decree, inedible fatty product is product obtained from the fusion of carcasses, carcass parts, bones, organs, and viscera not used in human consumption and anything sent for this disposition by the SIF.

Sole paragraph. Inedible fatty product must be denatured by the use of denaturing substances as determined by criteria defined by the Department of Inspection of Animal Products.

Article 324. All condemned products must be sent to the inedible product section, without passing through sections where edible products are made or handled.

Paragraph 1 Transport of condemned material to its heat denaturing treatment must avoid contamination of the route, equipment and facilities.

Paragraph 2 Condemned materials intended for inedible product treatment units must be previously denatured by denaturing substances, as laid down in regulations by the Department of Inspection of Animal Products of the Ministry of Agriculture, Livestock and Food Supply.

Article 325. When inedible residues are intended for inedible product treatment units, they must be stored and shipped in an exclusive facility and taken in sealed vehicles that can be thoroughly cleaned after each operation.

Article 326. It is mandatory for the carcasses, carcass parts, bones and organs of condemned animals, and the residues of all sections of the establishment to be sent for the preparation of inedible products, with the exception of those materials that require other treatments defined in specific legislation.

Sole paragraph. At the discretion of the SIF, condemned parts may be loaned to teaching institutions and for scientific purposes, upon request by the interested authority, who will declare in the request the intended purpose for the material and assume full responsibility for its disposition.

Article 327. The manufacture of ingredients or inputs for animal feed, such as meat meal, blood meal, meat and bone meal, viscera meal, feather meal, feather and viscera meal, fish meal and other types, may be authorized in facilities attached to the slaughter establishments, intended for the processing of industrial by-products.

Sole paragraph. The identity and quality standards addressed in the **head provision** will be defined by the Ministry of Agriculture, Livestock and Food Supply, as will other inspection and recording procedures, in compliance with specific legislation.

Article 328. Fecal matter from the cleaning of pens and transport vehicles may be made use of, provided that the establishment possesses facilities suitable for this purpose, in compliance with specific legislation.

Sole paragraph. The contents of animals' digestive tracts must receive the same treatment as given in the **head provision**.

Article 329. Preservatives may be added to bile after filtration, when the establishment is not interested in concentrating it.

Sole paragraph. For the purposes of this Decree, concentrated bile is understood to be the product resulting from the partial evaporation of fresh bile.

Article 330. Inedible animal products such as bristles, manes, fur, feathers, horns, hooves, shells and carapaces, must be handled in a section specifically for this purpose.

Article 331. Slaughter establishments may supply animal organs, tissues or parts as raw material for the manufacture of opotherapeutic products, inputs for the pharmo-chemical industry or its intermediates, as laboratory inputs, and for other purposes not subject to supervision by the Ministry of Agriculture, Livestock and Food Supply, provided they possess specific facilities and equipment, and meet the production requirements defined by the competent agency.

CHAPTER III

IDENTITY AND QUALITY STANDARDS IN SEAFOOD AND BY-PRODUCTS

Section I

Seafood products and by-products

Article 332. Edible seafood products are products made from whole or parts of seafood for human consumption.

Paragraph 1 For the product to be considered a seafood product, it must contain over fifty per cent seafood, in compliance with the particularities laid down in specific technical regulations.

Paragraph 2 When the quantity of seafood is below fifty per cent, the product may be deemed a seafood-based product, in compliance with particularities laid down in specific technical regulations.

Article 333. For the purposes of this Decree, fresh seafood is seafood that has not undergone any preservation process except the action of ice or other preservation methods with a similar effect,

and kept at temperatures close to melting ice, except for those seafood products sold alive.

Article 334. For the purposes of this Decree, chilled seafood is seafood packed and kept at refrigeration temperatures.

Article 335. For the purposes of this Decree, frozen seafood is seafood that has undergone quick freezing processes so that the product quickly exceeds the temperature limits for maximum crystallization.

Paragraph 1 The quick freezing process may only be deemed complete when the product reaches -18ºC (minus eighteen degrees Celsius).

Paragraph 2 The use of a brine freezer is allowed when the seafood is intended as raw material for the manufacture of canned product, provided that the concept of quick freezing is met and it reaches a temperature no higher than -9ºC (minus nine degrees Celsius), where this temperature is the maximum limit during transport and storage.

Article 336. During transport the frozen seafood must be kept at a temperature no higher than -18ºC (minus eighteen degrees Celsius).

Sole paragraph. Frozen seafood may not be transported in bulk, except for larger species, in compliance with criteria defined by the Ministry of Agriculture, Livestock and Food Supply.

Article 337. For the purposes of this Decree, thawed seafood is seafood that was initially frozen and underwent a specific temperature-raising process above freezing point and kept at temperatures near that of melting ice.

Sole paragraph. Thawing must always be carried out in suitable equipment and under conditions authorized by the Department of Inspection of Animal Products, so as to ensure the safety and quality of the seafood, and once the product has unfrozen, the seafood must be kept under the same preservation conditions as fresh seafood.

Article 338. For the purposes of this Decree, mechanically separated seafood meat is a frozen product obtained from seafood, involving the deheading, evisceration, cleaning and mechanical separation of the meat of the remaining inherent species-specific structures, such as bones, skeleton and skin.

Article 339. For the purposes of this Decree, **surimi** is a frozen product obtained from mechanically separated fish meat, subjected to repeated washing, draining and refining, with the addition of additives.

Article 340. For the purposes of this Decree, breaded fish is a frozen product made from seafood with or without the addition of ingredients, shaped or otherwise, and coated in a covering that characterizes it, with or without heat treatment.

Article 341. For the purposes of this Decree, canned seafood is seafood with the addition of ingredients, canned in hermetically sealed recipients and undergoing commercial sterilization.

Article 342. For the purposes of this Decree, semi-preserved seafood is seafood obtained through the specific treatment of seafood by salt, with or without the addition of ingredients, canned in hermetically sealed recipients, not heat sterilized, and may or may not be preserved under refrigeration.

Article 343. For the purposes of this Decree, seafood paste or paté, followed by appropriate specifications, is an industrially manufactured product obtained from seafood transformed into paste, with the addition of ingredients, undergoing a specific technological process.

Article 344. For the purposes of this Decree, seafood sausages are a product made from seafood, with the addition of ingredients, which may or may not be cured, cooked, smoked, dessicated, and uses the casings provided for in this Decree.

Article 345. For the purposes of this Decree, cured seafood is made from seafood that has been salt treated with or without additives.

Sole paragraph. Salting may be performed using moist, dry or mixed brines.

Article 346. For the purposes of this Decree, dry or dehydrated seafood is a product obtained from the dessication of seafood at several intensities by means of a natural or artificial process, with or without additives, in order to obtain a product stable at ambient temperature.

Article 347. For the purposes of this Decree, freeze-dried seafood is a product obtained by dehydrating seafood in specific equipment by means of freeze-drying, with or without additives.

Article 348. For the purposes of this Decree, seafood gelatin is a product obtained from natural soluble proteins, coagulated or otherwise, obtained by hydrolysis of the collagen in seafood tissues such as the swim bladder, bones, skins and cartilages.

Article 349. To make edible seafood products the demands for meats provided for in this Decree and in specific legislation must be followed as far as is applicable.

Section II

Inedible seafood products

Article 350. For the purposes of this Decree, inedible seafood products are obtained from whole seafood, parts or any residues that are not fit for human consumption.

Article 351. To make inedible seafood products the demands for inedible products provided for in this Decree and in specific legislation must be followed as far as is applicable.

CHAPTER IV

IDENTITY AND QUALITY STANDARDS IN EGG AND EGG BY-PRODUCTS

Article 352. For the purposes of this Decree, egg by-products are understood to be obtained from eggs, egg components or mixtures, after the shell and membranes have been discarded.

Sole paragraph. Egg by-products may be liquid, concentrated, pasteurized, dehydrated, freeze-dried, crystallized, chilled, frozen, ultrafrozen, coagulated or in other forms used as foodstuffs, in compliance with criteria defined by the Department of Inspection of Animal Products.

Article 353. The Ministry of Agriculture, Livestock and Food Supply will lay down criteria and parameters for eggs and egg products, and their respective manufacturing processes, in a specific technical regulation or supplementary norm.

CHAPTER V

IDENTITY AND QUALITY STANDARDS IN MILK AND DAIRY PRODUCTS

Section

I Milk

Article 354. The following types of liquid milks may be produced: I -

refrigerated raw milk;

II - bulk industrial-use liquid milk; III -

pasteurized milk;

IV - UHT milk; V - sterilized milk; and

VI - reconstituted milk.

Paragraph 1 The production and treatment of other types of milk than those provided for in this Decree is permitted, using new technologies approved in supplementary norms.

Paragraph 2 Only those liquid milks addressed in items III, IV, V and VI of the **head provision**, are considered for human consumption, as well as those that may eventually be approved as per Paragraph 1.

Paragraph 3 Production of reconstituted milk for direct human consumption may only take place with the authorization of the Ministry of Agriculture, Livestock and Food Supply in emergency public shortage situations.

Article 355. For the purposes of this Decree, refrigerated raw milk is milk produced on dairy farms, refrigerated and sent to milk and dairy establishments under official sanitary inspection.

Article 356. For the purposes of this Decree, bulk liquid milk for industrial use is cleaned, refrigerated, optionally thermized (preheated), milk that is pasteurized and has its fat content standardized, transported from one industrial establishment to another for processing and that is not directly intended for the end consumer.

Article 357. Transfer of bulk liquid industrial milk and other raw materials transported in bulk on container trucks between industrial establishments must be carried out using sealed, labeled, insulated vehicles, and go accompanied by reports of analyses, under the responsibility of the originating establishment.

Article 358. For the purposes of this Decree, pasteurized milk is liquid milk subjected to one of the pasteurization processes provided for in this Decree.

Article 359. For the purposes of this Decree, UHT milk is homogenized milk submitted to an ultra-high temperature process as defined in this Decree.

Article 360. For the purposes of this Decree, sterilized milk is liquid milk that has been packaged and subjected to a sterilization process as defined in this Decree.

Article 361. For the purposes of this Decree, reconstituted milk is the product resulting from dissolving powdered or concentrated milk in water, with or without the addition of milk fat to reach the fatty matter content established for this type, followed by homogenization when necessary, and the thermal treatment provided for in this Decree.

Article 362. In making milk and by-products from the milk of goats, buffaloes and other species, the demands set forth in this Decree and in specific legislation must be followed, in accordance with the particularities of each species.

Section II

Classification of dairy products Article

363. Dairy products comprise the following classification:

I - dairy products;

II - compound dairy products;

and III - dairy mixtures.

Article 364. For the purposes of this Decree, dairy products are products obtained from the technological processing of milk, and may contain ingredients, additives and technology adjuvants only when functionally necessary for the processing.

Sole paragraph. For the purposes of this Decree, modified milks, in liquid or in powder form, are dairy products resulting from the modification of the composition of milk by adding or subtracting its constituent parts.

Article 365. For the purposes of this Decree, compound dairy products are products in which milk, dairy products or milk constituents represent more than fifty per cent of the final product, mass/mass, such that it is consumed whenever the non-milk-derived ingredients are not intended totally or partially to replace any of the constituent parts of milk.

Article 366. For the purposes of this Decree, a dairy mixture is a product containing in its final make-up more than fifty per cent of dairy products or compound dairy products, such that they are consumed, and the constituent parts of milk may be replaced provided that the trade name states that it is a “mixture of (name of dairy product or compound dairy product) and (added product)”.

Article 367. The same dairy product, albeit of a different quality, may be added to the mixture, provided that for the purposes of classification and labeling the inferior product prevails.

Sub-Section I

Cream

Article 368. For the purposes of this Decree, fresh cream is a dairy product that is rich in fat removed from the milk by means of a specific technological process, and presents in the form of a fat-in-water emulsion.

Sole paragraph. For display for sale to direct human consumption, cream must undergo a specific heat treatment.

Article 369. For the purposes of this Decree, industrial cream is cream transported in bulk from one industrial establishment to another for processing and is not intended for direct delivery to the final consumer.

Paragraph 1 For the purposes of this Decree, bulk industrial use cream is a product transported in insulated container trucks.

Paragraph 2 For the purposes of this Decree, refrigerated raw cream for industrial use is a product transported in single use packaging.

Paragraph 3 Industrial cream may not be transported in urns.

Article 370. Creams obtained from skimming whey, or buttermilk or other dairy products or obtained as a result of applying destination norms laid down by the Ministry of Agriculture, Livestock and Food Supply, may be used to manufacture other products, provided they meet criteria set forth in the RTIQs for final products.

Sub-Section

II Butter

Article 371. For the purposes of this Decree, butter is understood to be the fatty dairy product obtained exclusively from churning and draining, biologically modifying the cream or otherwise, through a specific technological process.

Sole paragraph. The fat content of butter must be made exclusively of milk fat.

Article 372. For the purposes of this Decree, the traditional Brazilian bottled butters known as *manteiga de garrafa*, *manteiga da terra* or *manteiga do sertão* are the fatty dairy product in liquid or semi-solid states from pasteurized milk, formed by the virtual elimination of water through a specific technological process.

Sub-Section

III Cheeses

Article 373. For the purposes of this Decree, cheese is the fresh or matured dairy product obtained by the partial separation of whey from the milk or reconstituted milk—full fat, or skimmed or semi-skimmed—or from dairy wheys clotted by the action of rennet, of specific enzymes, produced by specific micro-organisms, of organic acids in isolation or combination, all of suitable quality for food use, with or without addition of food substances, spices, seasonings or additives.

Paragraph 1 In cheeses produced from milk or reconstituted milk, the whey protein-casein ratio must not exceed that of milk.

Paragraph 2 For the purposes of this Decree, fresh cheese is ready for consumption immediately after it has been made.

Paragraph 3 For the purposes of this Decree, matured cheese is cheese that has undergone the necessary and characteristic biochemical and physical exchanges for the particular variety.

Paragraph 4 The denomination cheese is reserved for products where the dairy basis does not contain fat or protein of a non-milk origin.

Paragraph 5 The milk used to manufacture cheeses must be mechanically filtered and undergo pasteurization or heat treatment to ensure negative residual phosphatase, combined or otherwise with physical or biological processes that ensure the safety of the product.

Paragraph 6 Milk to manufacture cheeses subjected to maturation at a temperature above 5°C (five degrees Celsius) for at least sixty days does not require pasteurization or any other heat treatment.

Paragraph 7 The minimum period for maturation in the case of the cheeses addressed in Paragraph 6 may be altered after conclusive scientific tests of the safety of the product or in cases laid down in the RTIQ.

Article 374. The date of manufacture of fresh cheeses is deemed to be the last day of cheese-making, and for mature cheeses the day on which that the maturation period ends.

Sole paragraph. Cheeses in the process of maturation must be clearly and accurately identified for their origin and the control of the maturation period.

Article 375. The process of maturation of cheeses must be carried out in an establishment under federal inspection that is different from the establishment that initiated the production, and comply with the technological requirements demanded for the type of cheese and the criteria laid down by the Department of Inspection of Animal Products to guarantee the traceability of the product and to control the maturation time.

Article 376. For the purposes of this Decree, curd cheese (*queijo de coalho*) is a cheese obtained by curdling the pasteurized milk with rennet or other suitable coagulating enzymes, and may be supplemented by the action of specific lactic bacteria, thus obtaining a wheyless mass that is semi-cooked or cooked, pressed and dried.

Article 377. For the purposes of this Decree, 'butter cheese' (*queijo de manteiga* or *queijo do sertão*) is cheese made by coagulating pasteurized milk using organic acids to obtain a wheyless

fused mass, adding to it bottle butter or *manteiga de garrafa*.

Article 378. For the purposes of this Decree, Minas Gerais frescal cheese (*queijo minas frescal*) is a cheese obtained by enzymatic coagulation of pasteurized milk using rennet or other suitable coagulating enzymes, or both, and may be supplemented by the action of specific lactic bacteria, thus obtaining a curdlike, wheyless, unpressed mass that is salted and not matured.

Article 379. For the purposes of this Decree, Minas Gerais standard cheese (*queijo minas padrão*) is a raw or semi-cooked mass cheese obtained by enzymatic coagulation of pasteurized milk using rennet or other suitable coagulating enzymes, or both, and may be supplemented by the action of specific lactic bacteria, thus obtaining a curdlike, wheyless, mechanically pressed mass that is salted and matured.

Article 380. For the purposes of this Decree, fresh ricotta is a cheese obtained by the hot acid precipitation of milk whey proteins, with the addition of milk up to twenty per cent of its volume.

Article 381. For the purposes of this Decree, smoked ricotta is a cheese obtained by the hot acid precipitation of milk whey proteins, with the addition of milk up to twenty per cent of its volume, and subjected to drying and smoking.

Article 382. For the purposes of this Decree, Brazilian Danbo-like cheese (*queijo prato*) is a cheese obtained by coagulating the pasteurized milk with rennet or other suitable coagulating enzymes, and may be supplemented by the action of specific lactic bacteria, thus obtaining a semi-cooked, pressed salted and aged mass.

Article 383. For the purposes of this Decree, provolone is a cheese obtained by coagulating pasteurized milk with rennet or other suitable coagulating enzymes, and may be supplemented by the action of specific lactic bacteria, thus obtaining a stretched-curd, unpressed cheese that may be fresh or matured.

Paragraph 1 Fresh provolone may present a small amount of butter in its mass, in which case it is a variety named *butirro*.

Paragraph 2 The cheese addressed in the **head provision** may be smoked and must meet the sensory characteristics acquired in this process.

Paragraph 3 The cheese addressed in the **head provision** may be named *caccio-cavalo*, fresh or cured, when it is oval or pear-shaped.

Article 384. For the purposes of this Decree, regional northern cheese or tropical cheese is a cheese obtained by coagulating the pasteurized milk with rennet or other suitable coagulating enzymes, or both, and may be supplemented by the action of specific lactic yeasts or by yeast in whey, thus obtaining a wheyless, cooked, pressed salted cheese.

Article 385. Industrially-processed cheeses may be produced in shapes and weights other than those laid down in the TRIQ, provided that the established requirements for each type be maintained.

Sub-Section IV

Fermented milks

Article 386. For the purposes of this Decree, fermented milks are dairy products or compounds obtained by coagulation and reducing the pH of milk or reconstituted milk by fermentation, through the action of specific micro-organism cultures, with or without the addition of other dairy products or food substances.

Paragraph 1 The specific micro-organisms must be viable, active and abundant in the final product during its shelf life, as laid down in supplementary norms.

Paragraph 2 Yogurt, fermented or cultivated milk, acidophilic milk, **kumys**, **kefir** and curds are all considered fermented milks.

Sub-Section V

Concentrated and dehydrated milks

Article 387. For the purposes of this Decree, concentrated milks and dehydrated milks are dairy products resulting from the total or partial dehydration of milk by specific technological processes.

Paragraph 1 For the purposes of this Description, concentrated dairy products include concentrated milk, evaporated milk, condensed milk and other products fitting the description.

Paragraph 2 For the purposes of this Description, dehydrated dairy products include powdered milk, and other products fitting this description.

Paragraph 3 Residues from the manufacture of powdered products may not be used for human consumption or industrial processing.

Article 388. The raw material used to make concentrated and dehydrated milks must meet the conditions set forth in this Decree and in supplementary norms.

Article 389. For the purposes of this Decree, concentrated milk is a product exclusively for industrial use that may not be reconstituted for the purpose of obtaining milk for direct human consumption.

Article 390. For the purposes of this Decree, condensed milk is a product resulting from the partial dehydration of milk with the addition of sugar, or that is obtained by another technological process whose equivalence is recognized by the Department of Inspection of Animal Products, resulting in a product with the same composition and characteristics.

Article 391. For the purposes of this Decree, powdered milk is a product obtained by dehydrating full-fat, skimmed or semi-skimmed milk and fit for human consumption, using a suitable technological process.

Paragraph 1 The product must present a composition such that when reconstituted as shown on the label it meets the standards of the milk for consumption to which it corresponds.

Paragraph 2 For different types of powdered milk, the minimum protein content of thirty-four per cent mass/mass based on the defatted dry extraction has been established.

Sub-Section VI

Other dairy by-products

Article 392. For the purposes of this Decree, flavored milk is a dairy product resulting from a prepared mixture in isolation or combined with milk and cocoa, chocolate, fruit juice and aromas, with the optional addition of sugar and additives that are functionally necessary for the manufacture, and presenting a minimum proportion of eighty-five per cent mass/mass of milk in the finished product, as it is consumed.

~~Article 393. Para os fins deste Decreto, doce de leite é o produto obtido por meio da concentração do leite ou do leite reconstituído sob ação do calor à pressão normal ou reduzida, com adição de sacarose - parcialmente substituída ou não por monossacarídeos, dissacarídeos ou ambos - com ou sem adição de sólidos de origem láctea, de creme e de outras substâncias alimentícias.~~

Article 393. For the purposes of this Decree, caramel (*doce de leite* or dulce de leche) is a product obtained by concentrating milk or reconstituted milk through heat at normal or reduced pressure, with the addition of sucrose—which may be partially replaced by monosaccharides, disaccharides or both—with or without the addition of dairy solids, cream and other food substances. (In the wording of Decree 9,069/2017)

Article 394. For the purposes of this Decree, cream cheese (*requeijão*) is a dairy product or compound dairy product made from a fusion of curds, cooked or otherwise, washed and wheyless, obtained through acidic or enzymatic coagulation or both, with milk, optionally with the addition of cream, butter, anhydrous milk fat or **butter oil**, separately or in combination, with or without the addition of seasonings, spices and other food substances.

Sole paragraph. The name *requeijão* is reserved for products where the dairy base does not contain non-dairy fat or protein.

Article 395. For the purposes of this Decree, a dairy drink is a dairy product or compound dairy product made from milk or reconstituted milk or milk by-products or a combination of the above, with or without the addition of non-dairy ingredients.

Article 396. For the purposes of this Decree, a dairy compound is a powdered dairy product or compound dairy product made from milk or milk by-products or both, with or without the addition of non-dairy ingredients.

Article 397. For the purposes of this Decree, powdered cheese is a dairy product or dairy compound product obtained by fusion and dehydration through a specific technological process, of the mixture of one or more varieties of cheese, with or without the addition of other dairy products, of dairy solids, spices, seasonings or other food substances, in which cheese is the dairy product used as the main raw material in the dairy basis of the product.

Article 398. For the purposes of this Decree, processed or melted cheese is the dairy product or dairy compound obtained by grinding, mixing, melting and emulsifying—through heat and emulsionating agents—of one or more varieties of cheese, with or without the addition of other dairy products, of dairy solids, of

spices, seasonings or other food substances, ion which cheese is the dairy ingredient used as the major raw material in the dairy basis of the product.

Article 399. For the purposes of this Decree, curds are the intermediate dairy product exclusively for industrial use, cooked or otherwise, wheyless and washed, obtained by acidic or enzymatic coagulation of the milk, intended for making *requeijão* or other products, when provided for in a TRIQ.

Article 400. For the purposes of this Decree, milk whey is the liquid dairy product extracted from the coagulation of milk and used in cheese-making and in making casein and similar products.

Sole paragraph. The product addressed in the **head provision** may undergo partial or total dehydration by specific technological processes.

Article 401. For the purposes of this Decree, **butter oil** is the fatty dairy product obtained from cream or butter by virtually total elimination of water and non-fatty solids using suitable technological processes.

Article 402. For the purposes of this Decree, lactose is the sugar of milk obtained by specific technological processes.

Article 403. For the purposes of this Decree, lactalbumin (whey protein) is the milk product resulting from the heat precipitation of soluble albumins from whey resulting from the production of cheeses or casein.

Article 404. For the purposes of this Decree, buttermilk is the milk by-product resulting from churning pasteurized milk during the making of butter, and may present in the form of liquid, concentrate or powder.

Article 405. For the purposes of this Decree, food quality casein is the dairy product resulting from the precipitation of skimmed milk by the enzyme activity or acidification at pH 4.6 to 4.7 (four point six to four point seven), that is washed and then dehydrated by specific technological processes.

Article 406. For the purposes of this Decree, food quality caseinate is the dairy product obtained from the reaction of casein or fresh curd of food quality casein with solutions of hydroxides or alkali or alkali earth salts or food quality ammonia, subsequently washed and dried, using specific technological processes.

Article 407. For the purposes of this Decree, industrial casein is the non-food product obtained by the precipitation of skim milk on application of acid whey, rennet, organic acids or minerals.

Article 408. For the purposes of this Decree, protein dairy products are dairy products obtained from the physical separation of caseins and why protein i a membrane or by means of some other technological process recognized by the Ministry of Agriculture, Livestock and Food Supply.

Article 409. Other constituents of milk may be separated by a membrane or another technological process whose equivalency is recognized by the Ministry of Agriculture Livestock and Food Supply.

Article 410. For the purposes of this Decree, *farinha láctea* ('farine lactée' or milk flour) is a product resulting from the dessication in specific conditions of a mix of cereal or plant flours and milk, in a range of forms and treatments, with or without the addition of other food substances.

Paragraph 1 The starch in the flour must be made soluble by a suitable technique.

Paragraph 2 The milk flour must have at least twenty per cent milk mass/mass in the total quantity of ingredients in the product.

Article 411. For the purposes of this Decree, other products that fit the classification of dairy products, compound dairy product or dairy mixture, are considered milk by-products in compliance with this Decree.

Article 412. Whenever necessary, the Department of Inspection of Animal Products will request documentary proof from the health regulator that governs the registration of products with functional claims, or an indication for infant food or for population groups with specific metabolic or physiological conditions.

CHAPTER VI

IDENTITY AND QUALITY STANDARDS IN BEE AND BEESWAX BY-PRODUCTS

Section I

Bee products

Article 413. For the purposes of this Decree, bee products are understood to be those made by bees, extracted from them or from beehives, without any artificial feeding stimulation to change their original composition, and classifying them as:

I - products of **Apis** bees: honey, bee pollen, royal jelly, propolis, beeswax and apitoxin (honey bee venom); and

II - products of stingless or native bees: honey, bee pollen and propolis from stingless bees.

Sole paragraph. Bee products may undergo freeze-drying, dehydration, maceration or some other specific technological process.

Article 414. For the purposes of this Decree, honey is a food product produced by honey bees from the nectar of flowers or the secretions from living parts of plants or the excretions of plant-sucking insects that live on the living parts of the plants, and which are collected, transformed and combined with specific substances by the bees, stored and allowed to mature in the honeycombs of the hive.

Article 415. For the purposes of this Decree, industrial-use honey is honey outside the specifications for diastase activity, for hydroxymethylfurfural, acidity—or when commencing fermentation shows changes in sensory aspects that do not disqualify it for use in food products.

Article 416. For the purposes of this Decree, bee pollen is a product resulting from the agglutination of the pollen of flowers by worker bees, using nectar and their salivary substances and gathered when returning to the hive.

Article 417. For the purposes of this Decree, royal jelly is the product of the secretion of the hypopharyngeal and mandibular glands in the heads of worker bees, gathered within seventy-two hours.

Article 418. For the purposes of this Decree, propolis is a product made from resinous, gummy and balsamic substances gathered by bees from shoots, flowers and plant exudates, to which the bees add their salivary secretions, wax and pollen to compose the finished product.

Article 419. For the purposes of this Decree, beeswax is a product secreted by bees to make the honeycomb in hives, of a plastic consistency, yellow in color and highly fungible.

Article 420. For the purposes of this Decree, apitoxin is the product of the secretion of abdominal glands or the venom glands of worker bees, stored inside the venom sac.

Article 421. For the purposes of this Decree, stingless bees' honey is a food product produced by stingless bees from the nectar of flowers or the secretions from living parts of plants or the excretions of plant-sucking insects that live on the living parts of the plants, and which they collect, transform and combine with specific substances by the bees, and store and allow to mature in the pots of the hive.

Sole paragraph. Honey may not be mixed with the honey of stingless bees.

Article 422. For the purposes of this Decree, stingless bee pollen is a product resulting from the agglutination of the pollen of flowers by stingless worker bees, using nectar and their salivary substances and which is gathered from the pots of the hive.

Sole paragraph. Bee pollen may not be mixed with the pollen of stingless bees.

Article 423. For the purposes of this Decree, stingless bee propolis is a product made from resinous, gummy and balsamic substances gathered by stingless bees from shoots, flowers and plant exudates, to which the bees add their salivary secretions, wax and pollen to make up the finished product.

Sole paragraph. Propolis may not be mixed with the propolis of stingless bees.

Section II

Bee by-products

Article 424. For the purposes of this Decree, the by-products of bees are those made with bees' products, with or without the addition of permitted ingredients, classified thus:

I - compound of bee products without the addition of ingredients; or II -

compound of bee products with the addition of ingredients.

Article 425. For the purposes of this Decree, a compound of bee products without the addition of ingredients is understood to mean a mixture of two or more bees' products, combined, which must add up to one hundred per cent of the final product.

Article 426. For the purposes of this Decree, a compound of bee products with the addition of ingredients is understood to mean a mixture of two or more bees' products, combined, with the addition of permitted ingredients.

Paragraph 1 The compound of bee products with the addition of ingredients must be made up predominantly in quantitative terms of bee products.

Paragraph 2 The use of sugars of sugary solutions as a vehicle for ingredients of any nature in the formulation of bee products with the addition of other ingredients is forbidden.

TITLE VII

REGISTRATION OF PRODUCTS, PACKAGING, LABELING AND INSPECTION STAMPS CHAPTER I

REGISTRATION OF PRODUCTS

Article 427. All animal products produced in Brazil or imported into the country must be registered at the Department of Inspection of Animal Products.

Paragraph 1 The registration addressed in the **head provision** encompasses the formulation, manufacturing process and the label.

Paragraph 2 The registration must be renewed every ten years.

~~§ 3º Os produtos não previstos neste Decreto ou em normas complementares serão registrados mediante aprovação prévia pelo Departamento de Inspeção de Produtos de Origem Animal.~~

Paragraph 3 Products not regulated will be registered after prior approval from the Department of Inspection of Animal Products. (In the wording of Decree 9,069/2017)

Article 428. The following factors must be present in the registration request process:

I - raw materials and ingredients, broken down by quantities and percentages used;

II - a description of the following stages—reception, handling, treatment, industrial processing, fractionating, preservation, packaging, storing and transportation of the product;

III - a description of the control methods employed by the establishment to ensure the identity, quality and safety of the product; and

IV - a list of the self-control programs carried out by the establishment.

Sole paragraph. Supplementary information or documentation may be demanded for registration, pursuant to criteria established by the Department of Inspection of Animal Products.

Article 429. The manufacture of animal products that have not been set forth in this Decree or in supplementary norms is allowed, provided that the manufacturing process and the composition are approved by the Department of Inspection of Animal Products.

Paragraph 1 In requests for registration of products addressed in the **head provision** of art. 428, the interested party must present the Department of Inspection of Animal Products with:

I - a proposal for the denomination of sale of the product;

II - the specification of physical-chemical and microbiological parameters of the product, its identity and quality requirements and its compliance evaluation methods;

III - information, when existing, about the product's history;

IV - domestic or international legal underpinning, when existing; and V -

technical and scientific literature concerning the manufacture of the product.

Paragraph 2 The Department of Inspection of Animal Products will judge the relevance of the requests for registration, taking into consideration:

I - the safety of the product;

II - the proposed identity and quality standards, in order to preserve the interests of consumers; and III - the

existence of validated assessment methods for the compliance of the final product.

Paragraph 3 In those cases where the proposed technology is similar to existing production processes, the analysis of the request will also consider the traditional technology for obtaining the product and long-standing characteristics valued by consumers.

Article 430. Information contained in the registration of the product must exactly match the procedures carried out by the establishment.

Article 431. All ingredients, additives and technological adjuvants presented in combination must possess clear information about composition and percentages.

Article 432. Labeling of products for international trade printed exclusively in a foreign language must be registered along with the translation into Portuguese.

Article 433. No change to the formulation, to the manufacturing process or to the label may be made without first updating the registration in the Department of Inspection of Animal Products.

Article 434. Procedures for registering the product and canceling it are laid down in a supplementary norm issued by the Ministry of Agriculture, Livestock and Supply.

Paragraph 1 For the purposes of registration, the Ministry of Agriculture, Livestock and Food Supply will make available a specific digitized system.

Paragraph 2 Registration shall be canceled if there is a failure to comply with the legislation.

CHAPTER II

PACKAGING

Article 435. Animal products must be placed or packaged in recipients or containers that provide the necessary protection, meeting the specific characteristics of the product and storage and transport conditions.

Paragraph 1 Material used in making the packaging that directly touches the product must receive prior authorization by the health regulatory agency.

Paragraph 2 When there is sanitary or technological interest, depending on the nature of the product, specific packaging or packing may be demanded.

Article 436. Packaging that is different from the traditional standards for products intended for the international market may be allowed, provided that manufacturer can prove compliance with the legislation of the importing country.

Article 437. The reuse of recipients for bottling or packing products and raw materials used in human food when intact and hygienized may be allowed, at the discretion of the SIF.

Sole paragraph. The reuse of recipients that may have been used to pack product or raw materials used in inedible applications, in order to pack or bottle edible products is forbidden.

CHAPTER III

LABELING

Section I

Labeling in general

Article 438. For the purposes of this Decree, label or labeling is understood to mean all inscriptions, legends, images and all descriptive or graphic matter that is written, printed, stamped, etched, embossed, lithographed or glued to the packaging or containers of the animal product for sale, intended to identify it.

Article 439. Establishments may only ship or sell animal raw materials or products that have been registered by the Department of Inspection of Animal Products and identified by means of labels, placed visibly, when intended directly for consumption or when sent to other establishments that will process them.

Paragraph 1 Labels must withstand the conditions of storage and transportation of the products and when in direct contact with the product, the material used to make them must have prior authorization from the health regulatory agency.

Paragraph 2 Information given on the labels must be visible, in legible characters, in a color that contrasts with the background, and indelible, pursuant to specific legislation.

Paragraph 3 Labels must possess identification that enables product traceability.

Article 440. Products for export must obey the importing country's legislation.

Sole paragraph. Products that have undergone technological processes or have a composition that is allowed by the importing country, but fail to comply with Brazilian legislation, may not be sold in Brazil.

Article 441. The use of ingredients, additives and technological adjuvants in animal products and the way in which this is shown on the label must meet the specific legislation.

Article 442. Labels may only be used on the registered products to which they correspond, and must show the number of the product's registration with the Department of Inspection of Animal Products.

Sole paragraph. Information given on the label must faithfully portray the true nature, composition and characteristics of the product.

Article 443. In addition to other demands laid down in this Decree, in supplementary norms and in specific legislation, the labels must clearly and legibly show:

I - Product name:

II - corporate name and address of producing establishment;

III - corporate name and address of the importer, in the case of an imported animal product; IV -

the official SIF stamp;

V - the corporate (CNPJ) or individual (CPF) taxpayer's number, where applicable;

VI - the brand logo of the product, when there is one;

VII - date of manufacture, use-by date and lot identification; VIII

- list of ingredients and additives;

IX - indication of the registration number for the product in the Department of Inspection of Animal Products; X -

identification of the country of origin;

XI - instructions for preserving the product;

XII - quantity indication, in compliance with the legislation of the

competent agency; and XIII - instructions about the preparation and

use of the product when necessary.

Paragraph 1 The date of manufacture and the use-by date, expressed as day, month and year, and the lot identification, must be printed, etched or given by a stamp, depending on the nature of the container or casing, in compliance with supplementary norms.

Paragraph 2 When the product has been outsourced, the expression "Manufactured by" (“Fabricado por”) must appear, or an equivalent, followed by the identification of the manufacturer, and the expression "on behalf of" (“Para”), or equivalent, followed by the identification of the establishment that has contracted the third party.

Paragraph 3 When only fractionating or packaging of the product has been performed, the expression "Fractionated by" (“Fracionado por”) or "Packaged by" (“Embalado por”), respectively, will replace “manufactured by”.

Paragraph 4 In those cases addressed in Paragraph 3, the date of fractionation or of packaging must appear, and the use-by date must be shorter than or equal to that established by the product manufacturer, except in particular cases, in compliance with criteria defined by the Department of Inspection of Animal Products.

Article 444. Labels may contain allusions to prizes won or honorable mentions obtained, provided these claims are duly proven.

Article 445. In making brands, the use of visuals that refer to them is allowed.

Sole paragraph. The use of brands, wording or visuals that allude to symbols or any indications referring to actions, events or establishments of the Federal Government, the States, the Federal District and the Municipalities must comply with specific legislation.

Article 446. Expressions, logotypes, words, signs, denominations, symbols, emblems, illustrations or other graphical representations that may convey false, inaccurate, insufficient or that may directly or indirectly mislead the consumer, or induce error, confusion or mistake concerning the true nature, composition, yield, origin, type, quality, quantity, shelf life, nutritional characteristics or mode of use of the product, are all banned on the labels of animal products.

Paragraph 1 The labels of animal products may not highlight the presence or absence of components that are intrinsic to or inherent in products of equal nature, except in cases laid down by specific legislation.

Paragraph 2 The labels of animal products may not indicate medicinal or therapeutic properties.

Paragraph 3 The use of claims of functional or health properties in animal products must receive prior approval from the health regulator, and comply with criteria established in specific legislation.

Paragraph 4 Brands that violate this Article will have their use restricted.

Article 447. One label may be used for identical products made in different units of one company, provided that each establishment has been registered for its manufacturing process and composition.

Article 448. Labels must be printed, lithographed, engraved or painted, respecting official spelling rules and the legal system of units and measures.

Article 449. Labels attached to products intended for international trade may be printed in one or more foreign languages, provided they contain the SIF stamp, in addition to an indication that the product comes from Brazil and its registration number with the Department of Inspection of Animal Products.

Paragraph 1 In products to be exported, labeling is allowed to be exclusively in a foreign language, provided that it contains the SIF stamp, in addition to an indication that the product comes from Brazil, highlighted and in uniform lettering.

Paragraph 2 In the case of imported products, labeling that is printed, engraved, lithographed or painted in a foreign language is permitted, with a translation into Portuguese of the mandatory information, provided that this meets provisions given in international trade agreements.

Article 450. No label, sticker or stamp may be applied so as to hide, or totally or partially cover, mandatory wording on the label or the SIF stamp.

Article 451. The SIF labels and stamps must refer to the last establishment at which the product underwent any kind of processing, fractionation or packaging.

Article 452. The labeling of animal products must meet provisions laid down in this Decree, supplementary norms and specific legislation.

Section II

Labeling in particular

Article 453. The product must follow the sales denomination of the respective TRIQ.

Paragraph 1 Seafood must be identified with the common name of the species, and the use of the scientific name may be demanded pursuant to a supplementary norm.

Paragraph 2 Eggs other than hens' eggs must bear the name of the species from which they come.

Paragraph 3 Dairy products made from milk other than cow's milk must bear on the labeling the designation of the species of origin, except in the case of products that are inherently made from the milk of species other than bovines.

Paragraph 4 Cheeses made by filtering through a membrane may use the term 'cheese' in their sales denomination; however, they may not make a reference to any product made using conventional technology.

Paragraph 5 Milk flour must show the percentage of milk that the product contains on the main panel.

Paragraph 6 Designations not provided for in this Decree or in supplementary norms will be submitted to the Department of Inspection of Animal Products for evaluation.

~~Article 454. Carcaças, quartos ou partes de carcaças em natureza de bovídeos, de equídeos, de suídeos, de ovinos, de caprinos e de ratitas, destinados ao comércio varejista ou em trânsito para outros estabelecimentos recebem o carimbo do SIF diretamente em sua superfície e devem possuir, além deste, etiqueta-lacre inviolável.~~

Article 454. Fresh carcasses, quarters, or parts of carcasses of bovines, buffaloes, equidae, suidae, ovines, caprines and ratites, either intended for retail trade or being conveyed to other establishments, will receive the SIF stamp directly on their surface and must in addition receive a tamper-proof health mark (*etiqueta-lacre*). (In the wording of Decree 9,069/2017)

Paragraph 1 Health marks and stamps must contain the demands laid down in this Decree and in supplementary norms.

Paragraph 2 Offals must be identified with a SIF stamp, in compliance with supplementary norms.

Article 455. Meat products containing meat and plant products must show the respective percentages on the labels.

Article 456. Any water added to meat products must have its percentage declared in the list of ingredients for the product.

Sole paragraph. Whenever the quantity of water added is over three per cent, the percentage of water added to the product must be given additionally in the main panel of the labeling.

Article 457. Products that are not milk, dairy products, or compound dairy products, may not use labels or any other form of presentation that declares, implies or suggests that these products are in fact milk, dairy products or compound diary products, or that allude to one or more products of the same type.

Paragraph 1 For the purposes of this Decree, dairy is understood to mean names, denominations, symbols, graphical representations or other forms that suggest or allude directly or indirectly to milk or dairy products.

Paragraph 2 Information about the presence of milk or compound dairy product in the list of ingredients is excluded from the prohibition given in the **head provision**.

Paragraph 3 The denomination of products with a common or normal name that is time-honored in its colloquial use as a suitable descriptive term, is excluded from the prohibition given in the **head provision**, provided that this does not mislead the consumer into a mistake concerning the origin or classification of the product.

Article 458. In the case of fresh seafood, taking into consideration the peculiarities inherent in the species and the ways in which the product may be presented, the use of packaging and application of labels may be dispensed with, in compliance with supplementary norms.

Article 459. In thawed seafood the designation of the product must include the word “descongelado” (thawed, defrosted, unfrozen), and in the main panel of the label, right underneath the denomination of sale, it must highlight in uniform lettering as to size and color, without interrupting these by other wordings or visual images, in bold capitals, the expression “NÃO RECONGELAR” (DO NOT REFREEZE).

Article 460. In labeling for honey, or the honey of stingless bees, and by-products, the warning must be given “Este produto não deve ser consumido por crianças menores de um ano de idade” (this product must not be consumed by children under one year of age), in clear, easily legible highlighted lettering.

Article 461. The label for industrial-use honey, without prejudice to other demands laid down in specific legislation, must meet the following requirements:

I - it may not contain indications or references to its floral or plant origin; and II - it

must contain the expression “Proibida a venda fracionada” (fractionated sale

forbidden).

Article 462. Labeling on packaging of products not intended for human consumption must, in addition to the SIF stamp, contain the statement “NÃO COMESTÍVEL”, (INEDIBLE) in easily visible capital lettering, meeting supplementary norms.

CHAPTER IV

INSPECTION STAMPS

Article 463. The inspection stamp represented the official mark of the SIF and is the guarantee that the product comes from an establishment that is inspected and overseen by the Ministry of Agriculture, Livestock and Food Supply.

Article 464. The establishment's registration number must be identified in the official stamp, the formats, dimensions and uses of which are laid down in this Decree.

Paragraph 1 The stamp must contain:

I - the expression “Ministério da Agricultura” (Ministry of Agriculture), on the upper external rim;

II - the word “Brasil” (Brazil), on the upper

internal part; III - the word “Inspecionado”

(Inspected), inthe center;

IV - the establishment's registration number, below the word “Inspecionado”; and V -

the initials “S.I.F.”, on the lower internal rim.

Paragraph 2 The initials “S.I.F.” stand for “Serviço de Inspeção Federal” (Federal Inspection Service).

Paragraph 3 The establishment's registration number on the inspection stamp is not preceded by the word “número” (number) or its abbreviated form (nº) and it is sited so as to be equidistant from the wording, lettering and lines that represent the form.

Paragraph 4 The expression “Ministério da Agricultura” may be waived on the upper rim of official inspection stamps in those cases where the stamps are engraved in high relief on glassware, cans, heat-molded plastics, seals and signs hung on carcasses.

Article 465. The SIF stamps must exactly obey the description and templates laid down in this Decree and in supplementary norms, in terms of dimensions, shape, wording, language, type and size of lettering, and must be placed prominently on cartons and other packaging, on labels or on products, in a single color, preferably black, when printed, engraved or lithographed.

Sole paragraph. For smaller packages, where the visible surface for labeling is smaller than or equal to 10 cm² (ten square centimeters), the stamp does not need to stand out against the other wording on the label.

Article 466. When flaws are found in the stamps, the SIF must destroy them immediately.

Article 467. The several templates for SIF stamps to be used in establishments that are inspected and overseen by the Department of Inspection of Animal Products must obey the following specifications, in addition to any others laid down in supplementary norms:

I - template 1:

a) dimensions: 7cm x 5cm (seven by five centimeters);

b) shape: elliptical horizontally;

c) wording: the establishment's registration number must stand out, below the word “Inspecionado”, horizontally, and “Brasil”, which follows the upper curve of the ellipse; immediately below the establishment's registration number come the initials “S.I.F.”, following the lower curve; and

d) ~~uso: para carcaça ou quartos de bovídeos, de equídeos e de ratitas em condições de consumo em natureza, aplicado sobre as carcaças ou sobre os quartos das carcaças;~~

d) use: for the carcasses and quarters of bovines, buffaloes, equidae and ratites fit for fresh consumption,applied to the carcasses or quarters; (Wording given by Decree no. 9,069, enacted 2017)

II - template 2:

a) dimensions: 5cm x 3cm (five by three centimeters);

b) shape and wording: identical to template 1; and

c) use: for the carcasses of suidae, ovines and caprines fit for fresh consumption, applied to the carcasses or quarters of the carcasses;

III- template 3:

a) dimensions:

1. 1cm (one centimeter) in diameter, when applied to packages with a visible surface for labeling smaller than or equal to 10cm² (ten square centimeters);

2. 2cm (two centimeters) or 3cm (three centimeters) in diameter, when applied to packages of up to 1kg (one kilogram);

3. 4cm (four centimeters) in diameter, when applied to packages weighing from 1kg (one kilogram) to 10kg (ten kilograms); or

4. 5cm (five centimeters) in diameter, when applied to packages weighing over 10kg (ten kilograms);

b) shape: circular;

c) wording: the establishment's registration number must stand out in isolation below the word “Inspecionado”, horizontally, and “Brasil”, which follows the upper curve of the circle; immediately below the establishment's registration number come the initials “S.I.F.”, following the lower curve; and the expression "Ministério da Agricultura" must follow the upper outside edge; and

d) use: for labels and stickers on animal products used in human food; IV - template 4:

a) dimensions:

1. 3cm (three centimeters) sideways when applied to labels and stickers; or

2. 15cm (fifteen centimeters) sideways when applied to sacks and bags;

b) shape: square;

c) wording: identical and in the same order as those in the preceding stamps, and all arranged horizontally; the expression “Ministério da Agricultura” must lie along the upper outside edge; and

d) use: labels, stickers and bags for inedible product; V - template 5:

a) dimensions: 7cm x 6cm (seven by six centimeters);

b) shape: rectangular horizontally;

c) wording: the word “Brasil” horizontally in the top left-hand corner, followed by the initials “S.I.F.”; and right underneath the word “condenado” (condemned) also horizontally; and

d) use: condemned carcasses or carcass parts; VI -

template 6:

a) dimensions: 7cm x 6cm (seven by six centimeters);

b) shape: rectangular horizontally;

c) wording: the word “Brasil” horizontally in the top left-hand corner; below this the initials “S.I.F.” in the bottom left-hand corner; the letters “E”, “S” or “C” vertically on the right, 5cm (five centimeters) high; or “TF” or “FC” 2.5cm (two point five centimeters) high for each letter; and

d) use: for carcasses or carcass parts intended for heat sterilization (E), salting (S), cooking (C), cold treatment (TF) or heat fusion (FC); and

VII - template 7:

a) dimensions: 15mm (fifteen millimeters) in diameter;

b) shape: circular;

c) wording: the establishment's registration number, alone, above the initials “S.I.F.” placed horizontally, and the word “Brasil” running along the upper internal part of the circle; right below the number, the word “Inspecionado” following the lower rim of the circle; and

d) use: on seals for closing and identifying containers and means of transportation for raw materials and products that require health certification; for official samples; and when enforcement actions are taken to block off equipment, rooms and establishments: can be plastic or metal.

Packaging 1 The stamp may be printed in relief or automatic indelible ink-stamping on the lid or base of packaging when the dimensions of said packaging do not allow the stamp to be printed on the label.

Paragraph 2 For health marks on carcasses and stickers to identify container trucks, the inspection stamp must present the shape and wordings laid down for template 3 which is 4cm (four centimeters) in diameter.

TITLE VIII

LABORATORY ANALYSES

Article 468. Raw materials, animal products and each and every substance going into animal products must undergo the physical, microbiological, physical-chemical, molecular biological, histological and other analyses necessary for assessing compliance.

Sole paragraph. Whenever SIF deems it necessary, it will take samples for laboratory analyses. Article 469. The

analytical methodologies will be standardized and validated by the competent authority of the Ministry of Agriculture, Livestock and Food Supply.

Sole paragraph. In exceptional cases, at the discretion of the competent authority of the Ministry of Agriculture, Livestock and Food Supply, analytical methodologies other than those adopted officially may be accepted, provided that they are recognized internationally or by research institutions, and they must be mentioned in the expert reports on the analyses.

Article 470. A triplicate sample of the raw material, product or any substance going into its production must be taken in order to carry out a fiscal analysis, and the sample must be preserved and kept free of tampering.

Paragraph 1 One of the samples taken will be sent to a laboratory of the National Network of Agricultural Laboratories (LANAGROs) of SUASA—Unified Animal and Plant Health System (*Sistema Unificado de Atenção à Sanidade Agropecuária*) while the other samples are to be kept as B samples. One sample is to be given to the entity owning or responsible for the product, and the other is to be kept by the laboratory or by the local SIF.

Paragraph 2 The owner or entity responsible for the product is responsible for preserving its B sample so as to ensure its physical integrity.

Paragraph 3 Fiscal samples are not to be taken in triplicate when: I -

the amount or nature of the product do not allow this;

II - the product has a short shelf life and there is no available time to carry out analysis of the B sample;

III - they are fiscal analyses carried out as a routine procedure by the official inspection; and

IV - they are taken for microbiological analysis, because in such cases it is deemed irrelevant to perform a B sample analysis.

Article 471. Samples of raw materials, product or of any other substance going into its production, and of supply water for official analysis must be taken by SIF personnel.

Paragraph 1 Whenever possible the sample must be taken in the presence of the product owner or representative, as the case may be.

Paragraph 2 A sample must not be taken of a product whose identity, composition, integrity or preservation is compromised.

Article 472. Samples for analyses must be taken, handled, packed, identified and transported so as to ensure maintenance of physical integrity and to provide suitable preservation to the product.

Sole paragraph. Authenticity of the samples must be guaranteed by the competent authority taking the sample.

Article 473. When the results of official samples do not comply with the legislation, SIF will notify interested parties of the analytical results obtained and take suitable enforcement and administrative measures.

Article 474. Interested parties may request from SIF a specialist analysis of the B sample, where applicable, within forty-eight hours of acknowledgment of the result.

Paragraph 1 When requesting analysis of the B sample, interested parties must give the name of a technical assistant to make up the committee of experts and may appoint a replacement.

Paragraph 2 Interested parties must be informed at least seventy-two hours previously of the date, time and laboratory defined by the competent authority, Ministry of Agriculture, Livestock and Food, when the expert analysis of the B sample will be performed.

Paragraph 3 The expert analysis will use the B sample that is held by the product owner or by the interested party.

Paragraph 4 The same analytical method must be used in the expert analysis of the B sample as was used in the original fiscal analysis, unless the expert committee agrees to employ another method.

Paragraph 5 The expert analysis must not be held if the B sample shows signs of alteration or tampering.

Paragraph 6 If tampering or poor preservation is found in the B sample, the result of the fiscal analysis will stand.

Paragraph 7 In the event of discrepancy with the result of the fiscal analysis or a mismatch between the fiscal and the expert analyses, a new expert analysis will be performed using the B sample held by the laboratory or by the local SIF.

Paragraph 8 Failure to appear by the representative appointed by the interested party on the date and at the time determined, or the nonexistence of a B sample held by the interested party will entail acceptance of the result of the fiscal analysis.

Article 475. The establishment must exercise control over its production process by means of physical, microbiological, physical-chemical, molecular biological, histological and other necessary analyses to assess the compliance of raw materials and animal products as laid down in its self-control programs, in accordance with technically-recognized and scientifically-proven methods, and must keep auditable evidence proving that the above controls have actually been carried out.

Article 476. Taking of samples of animal products registered in the SIF may be performed in retail outlets, in supplementary fashion, in order to meet requirements of programs and specific demands.

Article 477. Procedures for taking samples for fiscal analyses, packing and sending them, as well as the frequency thereof, will be laid down by the Ministry of Agriculture, Livestock and Food Supply in supplementary norms.

Article 478. Establishments may shoulder the cost of fiscal analyses in accredited laboratories to meet national programs, provided they are notified of this at the moment of sampling and expressly communicate their agreement.

TITLE IX

INDUSTRIAL AND SANITARY REINSPECTION

~~Article 479. Os produtos de origem animal podem ser reinspecionados sempre que necessário antes de sua liberação para consumo interno ou para o comércio interestadual ou internacional.~~

Article 479. Animal products may be reinspected whenever necessary before authorization for interstate or international trade. (In the wording of Decree 9,069/2017)

Sole paragraph. Raw materials and animal products undergoing reinspection, sampling criteria and other procedures will be defined in a supplementary norm.

Article 480. Products must be reinspected in a place or environment that preserves their sanitary conditions.

Sole paragraph. The reinspection addressed in the **head provision** encompasses:

I - verification of the integrity of the packaging, casings and recipients; II - labeling, official inspection

marks and dates of manufacture and expiry;

III - assessment when appropriate of sensory characteristics;

IV - taking samples for physical, microbiological, physical-chemical, molecular biological and histological analyses, when appropriate;

V - the health certification for transportation when appropriate;

VI - hygiene and maintenance conditions of the vehicle and the working order of the cold chain equipment, when appropriate; and

VII - the number of the health seal of the origin SIF and whether it has arrived intact, or that of the corresponding official service supervising the establishment of origin, in the case of imported products, when appropriate.

Article 481. When reinspecting raw materials or products showing signs of tampering or fraud, the measures provided for in this Decree and in supplementary norms must be taken.

Paragraph 1 Products deemed on reinspection to be unfit for human consumption must be reused to make inedible product, or rendered unusable; they cannot be sent to other establishments without prior authorization by SIF.

Paragraph 2 Products that on reinspection allow conditional use or retreatment must undergo specific processing authorized and established by SIF and must be reinspected before passing to consumption.

Article 482. Conditional use of raw material and animal products at another federally-inspected establishment is permitted, provided that the SIF authorizes this and that traceability is followed up and proof is provided that it has been received at destination.

TITLE X

MOVEMENT OF ANIMAL PRODUCTS AND HEALTH CERTIFICATION CHAPTER I

MOVEMENT OF ANIMAL PRODUCTS

Article 483. Movements of raw material and animal products must use appropriate means of transport, so as to guarantee maintain product intactness and enable preservation.

Paragraph 1 Vehicles, container or compartments must be cleaned and disinfected before and after transportation.

Paragraph 2 Vehicles, containers and compartments used to transport refrigerated raw material and products must be insulated and when necessary possess cold generating equipment, as well as a temperature control device, to comply with supplementary norms.

Paragraph 3 Frozen seafood may not be transported in bulk, except for larger species, in compliance with criteria defined by the Ministry of Agriculture, Livestock and Food Supply.

Article 484. Raw materials and animal products, when properly labeled and originating from federally-inspected establishments, may move freely and be displayed for sale throughout Brazil, or be traded internationally to countries without specific sanitary requirements, provided they meet demands contained in this Decree and in supplementary norms.

Sole paragraph. Raw materials and animal products may only be traded internationally to countries possessing specific sanitary requirements when they comply with the legislation of the importing country and bilaterally or multilaterally agreed health requirements.

Article 485. Raw materials and animal products originating from domestic establishments, when going through ports, airports, border posts or special customs facilities or special facilities for customs clearance for export, are subject to official control, and may be inspected or reinspected, even if intended for domestic interstate trade, in accordance with supplementary norms, obeying specific competent jurisdiction powers.

Article 486. Import of animal raw materials and animal products may only be authorized when:

I - they come from countries whose health inspection has been assessed or recognized as equivalent by the Department of Inspection of Animal Products;

II - they come from establishments listed for export to Brazil;

III - they have been previously registered by the Department of Inspection of Animal Products; IV -

they are labeled in accordance with the specific legislation; and

V - they are accompanied by health certificates issued by the competent authority of the country of origin, pursuant to bilateral agreements.

Paragraph 1 The Department of Inspection of Animal Products will establish requirements and procedures for the import of samples without commercial value and products for consumption at trade fairs and sporting events, and by diplomatic delegations in Brazil.

Paragraph 2 The Ministry of Agriculture, Livestock and Food Supply, in supplementary norms, will establish procedures for recognizing equivalency with the health inspection services of foreign countries, for the listing and registry changes for overseas establishments and for the import of animal products.

Article 487. Imported animal raw materials and animal products will only be authorized to move in and around Brazil be authorized after:

~~I - fiscalização pela área competente da vigilância agropecuária internacional do Departamento de Inspeção de Produtos de Origem Animal; e~~

I - inspection by the competent area of agricultural surveillance in the Ministry of Agriculture, Livestock and Food Supply; and (Wording given by Decree no. 9,069, enacted 2017)

II - reinspection by the competent agency for international agriculture and livestock surveillance or by SIF.

Paragraph 1 After the inspection procedure, a movement document will be provided on the basis of the elements contained in the health certificate issued in the exporting country, and this will accompany the shipment to the place of reinspection.

Paragraph 2 At the discretion of the Department of Inspection of Animal Products, reinspection of imported animal raw material and products may be waived, and their movement will be authorized after the inspection addressed in item I of the **head provision**.

Article 488. The Ministry of Agriculture, Livestock and Food Supply will define the points at which imported animal products may enter Brazil, where there is a unit in place of the International Agriculture and Livestock Surveillance System, with a place and infrastructure suitable for reinspection of products, complying with the requirements of animal health legislation.

Article 489. The competent authority of the Ministry of Agriculture, Livestock and Food Supply will order any animal products to be returned to the country of origin, or some other destination, whenever there is a violation of this Decree and of supplementary norms.

Paragraph 1 When the products addressed in the **head provision** cannot return to their origin, the shipment must be rendered unusable under the supervision of the official service.

Paragraph 2 Irregularities detected will be notified to the health authorities of the country of origin, so that their causes can be investigated and corrective and preventive actions can be taken in the listed establishments.

Paragraph 3 The Ministry of Agriculture, Livestock and Food Supply will be able to take restrictive actions on the import of animal raw materials or products and totally or partially suspend approval of countries or the listing of their establishments.

CHAPTER II

CERTIFICATION OF ANIMAL PRODUCTS

Article 490. National or international health certificates or movement permits issued for animal products, including those intended for ship supply, must comply with the templates established by the Department of Inspection of Animal Products.

Article 491. Health Certificates for animal products intended for international trade, when drafted in a foreign language, must be translated into Portuguese.

Paragraph 1 Health Certificates for animal products intended for international trade must be signed by a Federal Agriculture Inspector trained in Veterinary Medicine.

Paragraph 2 When requesting that a health certificate be issued for animal products intended for international trade, the establishment must present proof that the certified product meets the demands of the importing country, when such demands exist.

Article 492. Health certification for the movement of animal raw materials or products is mandatory.

Paragraph 1 At the discretion of the Ministry of Agriculture, Livestock and Food Supply, health certification for the movement of animal raw materials or products may be waived, as set forth in this Decree and in supplementary norms, complying with animal health legislation.

Paragraph 2 The procedures for issuing health certification will be defined in supplementary norms.

Article 493. Health certification for the movement of animal raw materials or products intended for conditional use or condemnation is mandatory.

Paragraph 1 In the case of raw materials or products intended for conditional use, proof of reception of the raw material and products from the establishment of origin by the establishment of destination is mandatory.

Paragraph 2 In the case of condemned raw materials or products after denaturation at origin, proof of reception of the raw material and products from the establishment of origin by the establishment of destination is mandatory.

Paragraph 3 The SIF must prevent the shipping of new consignments of raw materials or products until Paragraphs 1 & 2 are met.

TITLE XI

RESPONSIBILITIES, INTERIM MEASURES,

INFRACTIONS, PENALTIES AND ADMINISTRATIVE PROCESSES CHAPTER I

RESPONSIBILITIES AND INTERIM MEASURES

Section I

Those responsible for the infraction

Article 494. The following corporate entities or individuals, for the purposes of applying the penalties provided for in this Decree, will be held accountable for infractions of its provisions:

I - suppliers of animal raw materials or products, from point of origin to reception at the establishments registered or listed in the Ministry of Agriculture, Livestock and Food Supply;

II - owners, lessors or lessees of establishments registered or listed with the Ministry of Agriculture, Livestock and Food Supply at which animal raw materials or products are received, handled, treated, processed, fractionated, industrially processed, canned, packaged, labeled, stored, distributed or shipped;

III - shippers or transporters of animal raw materials or products; and IV - importers

and exporters of animal raw materials or products.

Sole paragraph. The accountability addressed in the **head provision** encompasses infractions committed by any employees and representatives of the individuals or legal entities with industrial or commercial operations involving animal raw materials or products.

Section II

Precautionary measures

Article 495. If there is proof or suspicion that an animal product poses a risk to public health or has been tampered with, adulterated or counterfeited, the Ministry of Agriculture, Livestock and Food Supply will take the following precautionary measures in isolation or cumulatively:

I - seizure of the product;

II - provisional suspension of the manufacturing process or its stages; and

III - take samples of the product for laboratory analysis.

Paragraph 1 Whenever necessary, a review of the establishment's self-control programs may be ordered.

Paragraph 2 Resumption of manufacturing or the authorization for the suspected product to pass to consumption will be authorized if SIF finds that the cause of adoption of the precautionary measure no longer exists or has ceased to be.

Paragraph 3 The provisions of the **head provision** do not cancel the competent jurisdictions of other regulatory agencies as per the legislation.

CHAPTER II

INFRACTIONS

Article 496. The following are violations of this Decree, as are others that have been

I The following are infractions: TO construct, extend or remodel facilities without prior approval from DIPOA— Department of Inspection of Animal Products;

II - fail to transfer accountability or fail to notify the purchaser, lessor or lessee of this legal obligation at sale, renting or leasing;

III - use a label that does not meet the specific relevant legislation;

IV - ship raw materials, ingredients, products or packaging in unsuitable conditions;

V - exceed the maximum slaughter capacity, or the treatment, industrial processing or storage capacities;

VI - make products whose manufacturing and formulation processes and composition are not registered in the Department of Inspection of Animal Products;

VII - ship product without labeling or with labels that have not been registered in the Department of Inspection of Animal Products;

VIII - disobey or fail to comply with precepts of animal welfare provided in this Decree and supplementary norms for animal products;

IX - disobey or fail to comply with health demands for the operations and hygiene of facilities, equipment, utensils and the tasks of handling and preparing raw material and products;

X - omit information about the centesimal composition and technical composition of the manufacturing process;

XI - receive, use, transport, store or ship raw materials, ingredients or products without proof of origin;

XII - use a process, substance, ingredients or additives that fail to comply with specific legislation;

XIII - fail to meet deadlines in the self-control programs and in documentation issued in response to SIF concerning action plans, inspections, warnings of violation, summonses or notifications;

XIV - acquire, handle, ship or distribute animal products from an establishment not registered or listed in the Department of Inspection of Animal Products or that is not in the general register of the Brazilian System of Inspection of Animal Products;

XV - ship or distribute products allegedly but actually not coming from a given establishment;

XVI - make products that do not meet the specific legislation or that fail to comply with manufacturing and formulation processes and composition registered in the Department of Inspection of Animal Products;

XVII - use products with expired validity, attach new dates for after the expiry on such products, or place a date later than the real manufacturing date;

XVIII - give or present false or inaccurate information, statements or documents to the oversight agency about quantity, quality and origin of raw materials, ingredients and products, or withhold information that directly or indirectly interests the Department of Inspection of Animal Products;

XIX - falsify records subject to SIF verification;

XX - to unlawfully provide or use seals, official stamps, labels and packaging; XXI -

alter or fraudulently make any animal raw material, ingredient or product;

XXII - simulate the legality of raw materials, ingredients or products whose origin is unknown;

XXIII - ship product for international trade that has been made without attention to the supplementary norms about the export of animal products; and

XXIV - thwart the actions of a member of staff of the Department of Inspection of Animal Products in the exercise of their duty, in order to hinder, delay, impede, restrict or evade inspection activities;

XXV - disrespect, intimidate, threaten, assault or attempt to bribe a member of staff of the Department of Inspection of Animal Products;

XXVI - produce or ship product representing a public health risk;

XXVII - produce or ship for consumption products unfit for human consumption;

XXVIII - use condemned or uninspected raw materials and products in the preparation of products for human consumption;

XXIX- use, replace, totally or partially remove raw materials, products, labels or packaging seized by the SIF and kept under guard by the establishment;

XXX - falsify official documents;

XXXI - fail to recall products that may pose a threat to consumers' health or interests.

Article 497. Animal raw materials or products are considered unfit for human consumption if they wholly or partially:

I - are altered; II - have been

produced fraudulently;

III - have been damaged by moisture or fermentation, are rancid, show abnormal physical or sensory characteristics, contain dirt, or show sloppy handling in their manufacture, preservation or packing;

IV - contain substances or contaminants without an established limit in the legislation, but that could pose a threat to consumers' health;

V - contain toxic substances or radioactive compounds in levels over those permitted in specific legislation;

VI - fail to meet the standards laid down in this Decree and in supplementary norms;

VII - contain pathogenic micro-organisms at levels over those permitted in this Decree, supplementary norms and in specific legislation;

VIII - are unsuitable for their intended purpose;

IX ~~- contenham contaminantes, resíduos de agrotóxicos, de produtos de uso veterinário acima dos limites estabelecidos em legislação específica do Departamento de Inspeção de Produtos de Origem Animal e do órgão regulador da saúde;~~

IX - contain contaminants, pesticide and herbicide residues, veterinary products above the limits established in specific legislation by the Ministry of Agriculture, Livestock and Food Supply or the health regulator; (Wording given by Decree no. 9,069, enacted 2017)

X - are obtained from animals undergoing treatment with veterinary products during the withdrawal period recommended by the manufacturer;

XI - are obtained from animals receiving feed or veterinary products that can impair the quality of the product;

XII - packaging is bulging;

XIII - packaging is defective, exposing contents to contamination and deterioration; XIV - whose

validity has expired;

XV - whose origin is unknown; or

XVI - are not clearly identified as coming from a federally-inspected establishment.

Sole paragraph. Other situations not laid down in items I to XVI may render raw materials and products unfit for human consumption, as per criteria defined by the Department of Inspection of Animal Products.

Article 498. In addition to cases set forth in Article 497, meats or meat products must be deemed unfit in their present state for human consumption when:

I - they are obtained from animals liable to condemnation as provided for in this Decree and in supplementary norms;

II - they are moldy or mildewed, except for those products where the presence of mold is a natural consequence of their technological processing; or

III - they are infested by parasites or show signs of insect or rodent action.

Sole paragraph. Meat and meat products obtained from animals or raw materials that have not undergone official sanitary inspection are also deemed unfit for human consumption.

Article 499. In addition to cases set forth in Article 497, seafood or seafood products must be deemed unfit in their present state for human consumption when:

I - they are poorly preserved and have a repugnant appearance; II - show

signs of deterioration;

III - carry lesions or diseases;

IV - show widespread muscle infection by parasites;

V - have been treated with antiseptics or preservatives not authorized by the Department of Inspection of Animal Products;

VI - were already dead on capture, except when captured in fishing operations; or VII -

show signs that the wrapping has been holed by parasites.

Article 500. In addition to cases set forth in Article 497, eggs or egg by-products must be deemed unfit in their present state for human consumption when:

I - there are changes in the white and yolk, with the yolk sticking to the shell, yolk ruptured, the presence of dark stains of of blood even discoloring the white, the presence of an embryo with an orbital spot or in an advanced state of development;

II - they are mummified or dry for some other

reason; III - red, black or white rot;

IV - they are contaminated by fungi externally or internally;

V - there is manure externally or they have touched other substances able to transmit strange odors or flavors;

VI - the shells have cracked or are dirty; or

VII - the shells and eggshell membranes have cracked.

Sole paragraph. Incubated eggs are also deemed unfit for human consumption.

Article 501. In addition to cases provided for in Article 497, raw milk is deemed unfit for any type of use when:

I - it comes from a farm that has been banned by the competent animal health authority;

II - in the selection of raw material it shows residues of inhibitors, acidity neutralizers, density or cryoscopic index reconstituters, preservatives, microbial growth inhibitors or other substances that are extraneous to its composition;

III - it shows foreign bodies or impurities that cause repugnance; or IV - it

shows the presence of colostrum.

Sole paragraph. Milk deemed unfit for any type of use, and any product that has been prepared using it or with which it has been mixed, must be discarded and rendered unusable by the establishment.

Article 502. In addition to cases provided for in Articles 497 & 501, raw milk is deemed unfit for the production of milk for human consumption when:

I - it does not meet the specifications laid down in Article 248 and supplementary norms; or

II - fails thermal stability tests contained in supplementary norms.

Article 503. In addition to those cases provided for in Article 497, honey and stingless bees' honey showing advanced fermentation or hydroxymethylfurfural above accepted limits, will be deemed unfit for human consumption, as given in supplementary norms.

Article 504. Raw materials and products may be deemed altered or fraudulent for the purposes of the infractions laid down in this Decree.

Sole paragraph. Raw materials or products showing signs of adulteration or falsification are deemed fraudulent, as follows:

I - adulterations:

a) raw materials or products that have been partially or totally deprived of their characteristic components because these were replaced by inert or extraneous components, thus not meeting what is laid down in specific legislation;

b) raw materials or products with addition of ingredients, additives, technological adjuvants, or substances of any type in order to dissimulate or hide changes and deficiencies in the quality of the raw material, or defects in manufacture or to boost the volume or weight of the product;

c) the use of raw materials or ingredients that are unsuitable or fail to meet the criteria of the TRIQ or the formulation indicated in the product's registration in the handling or the manufacture of products;

d) the use of ingredients,additives or technological adjuvants that are different from those given in the original formulation or have not received prior authorization from the Department of Inspection of Animal Products to make products; or

e) products whose date of manufacture, or date/period of validity have been altered; II -

falsifications:

a) when denominations other than those provided for in this Decree, or in supplementary norms, or in the registry of products in the Department of Inspection of Animal Products have been used;

b) products made, fractionated or repackaged, whether displayed for sale or otherwise, with the overall appearance and characteristics of another product registered with the Department of Inspection of Animal Products and have been misleadingly labeled as the other product;

c) when the product label contains wording, engravings or any other expression that leads the consumer to make a mistake or become confused as to the origin, nature or quality of the product, or attribute to it a therapeutic or medicinal quality;

d) products made from a species other than that declared on the label or diverging from what is in the product registration; or

e) those that have not undergone the processing specified in the registration, whether or not displayed for consumption, and that are indicated as processed products.

Article 505. The Ministry of Agriculture, Livestock and Food Supply will, in supplementary norms, establish criteria for the disposition of raw materials or products deemed unfit as they are for human consumption, including rendering them useless or conditional use when technically viable.

Article 506. In the cases provided for in Article 496, whatever the applicable administrative penalty, the following procedures may be adopted:

I - in cases of sequestration after complete reinspection, the raw materials and products may be condemned or conditional use may be authorized for human consumption, as set forth in supplementary norms; and

II - in cases of condemnation, the raw materials and products may be authorized for inedible uses.

CHAPTER III

PENALTIES

Article 507. The penalties to be applied by the competent authority will be pecuniary in nature, or will consist of the obligation to do or to cease doing something, and the right to defense will always be guaranteed.

Article 508. Without prejudice to the appropriate civil and penal responsibilities, violations of this Decree or supplementary norms concerning animal products, owing to their nature and seriousness, will result, either in isolation or cumulatively, in the following sanctions:

I – a warning, when the offender is a first-time offender and has not acted with intent or in bad faith;

II - a fine, in cases not covered by item I, where the maximum amount corresponds to the amount stipulated in specific legislation, with the following gradations:

~~a) para infrações leves, multa de dez a vinte por cento do valor máximo;~~

a) for minor infractions, a fine from one to fifteen per cent of the maximum amount; (Wording given in Decree no. 9,069, enacted 2017)

b) ~~para infrações moderadas, multa de vinte a quarenta por cento do valor máximo;~~

b) for moderate infractions, a fine from fifteen to forty per cent of the maximum amount; (Wording given in Decree no. 9,069, enacted 2017)

c) for serious infractions, a fine ranging from forty to eighty per cent of the maximum amount; and

d) for the most serious infractions, a fine ranging from eighty to one hundred per cent of the maximum amount;

III - seizure or condemnation of raw material, products, by-products and derivatives of animal origin that do not present hygienic or sanitary conditions suitable for their intended purpose, or that have been adulterated;

IV - suspension of the activity causing a hygiene or health risk or threat, or in the case of hindering inspection actions;

V - total or partial ban of the establishment, when the violation consists of habitual adulteration or falsification of the product, or when a technical inspection carried out by the competent authority detects the absence of suitable hygiene and health standards; and

VI - cancellation of the establishment's registration or listing.

Paragraph 1 The fines set forth in item II of the **head provision** will be increased to their maximum in cases of ruse, subterfuge, simulation, disrespect, hindering or resistance to enforcement action.

Paragraph 2 The ban or suspension may be lifted after the demands that led to it have been met, except in cases provided for in Article 517.

Paragraph 3 If the total or partial ban is not lifted, as per paragraph 2, after twelve months, the establishment's registration or listing will be canceled.

Article 509. For the purposes of applying the fines set forth in item II of Article 508: I - violations covered in

items I to VII of the **head provision** of Art. 496 are deemed minor;

II - violations covered in items VIII to XVI of the **head provision** of Art. 496 are deemed

moderate; III - violations covered in items XVII to XXIII of the **head provision** of Art. 496

are deemed serious; and

IV - violations covered in items XXIV to XXXI of the **head provision** of Art. 496 are deemed extremely serious.

Paragraph 1 Infractions classified as minor, moderate, and serious may receive a higher grading where the violation committed poses a risk to public health or consumer interests, or where there is repeat offending.

~~§ 2º Aos que cometerem outras infrações previstas neste Decreto ou nas normas complementares, será aplicada multa no valor compreendido entre vinte e cem por cento do valor máximo da multa, de acordo com a gravidade da falta e com as circunstâncias atenuantes e agravantes previstas no art. 510.~~

Paragraph 2 Persons committing other infractions of this Decree or of the supplementary norms will face fines ranging from one to one hundred per cent of the maximum amount of the fine, in accordance with the severity of the violation and its impact on public health and animal health, taking into consideration the extenuating and aggravating circumstances provided for in Article
510. (In the wording of Decree 9,069/2017)

Article 510. In order to establish the amounts of the fine addressed in item II of the **head provision** of Article 508, the following will be taken into consideration—the seriousness of the offense, its consequences for public health and consumer interests, the track record of the offender and any extenuating or aggravating circumstances.

Paragraph 1 The following are deemed extenuating

circumstances: I - the offender is a first-time

offender;

II - the action of the offender was not fundamental to the occurrence of the event;

III - the offender spontaneously sought to mitigate or repair the consequences of the harmful act (s)he is

accused of; IV - the offense committed was without malice or not in bad faith;

V - the offense was committed accidentally;

VI - the offense did not result in economic advantage to the

offender; or VII - the offense did not affect the quality of the

product.

Paragraph 2 The following are deemed aggravating

circumstances: I - the offender is a repeat offender;

II - the offender committed the offense in order to obtain an advantage of whatever nature;

III - the offender failed to take steps to avoid the act, despite knowing that it was harmful to public health;

IV - the offender attempted to coerce another party to commit the material execution of the infraction;

V - the offense had harmful consequences for public health or for consumers;

VI - the offender hindered or attempted to thwart the enforcement or inspection act; VII

- the offender acted with malice or in bad faith; or

VIII - the offender failed to comply with the holder's obligations in regard to the keeping of the product.

Paragraph 3 When both extenuating and aggravating circumstances are present, application of the penalty will take into consideration the prevailing circumstances.

Paragraph 4 Recidivism is confirmed when the offender commits another infraction within a period of five years after an unappealable judgment of the enforcement decision that found him/her guilty of the previous offense, whether generic or specific recidivism.

Paragraph 5 Generic recidivism in the offense is characterized by committing some (any) new offense, while specific recidivism is characterized by committing the same offense as before.

Paragraph 6 For the definition of recidivism, the previous condemnation does not prevail if there is, between the date of fulfilling or extinguishing the administrative penalty and the date of the later offense, a period of more than five years; a specific norm may reduce this time.

Paragraph 7 When the same offense falls under more than one provision of this Decree, the more specific provision takes priority over the more generic, for the purposes of punishment.

Article 511. The fines addressed in this Chapter do not exempt the offender from seizure or from the rendering of the product unusable, or from total or partial banning of the facility, suspension of activities, cancellation of registration or listing of the establishment, or even from a criminal lawsuit, when such measure are applicable.

Paragraph 1 The cancellation of listing will be applied by the head of the animal product inspection service in the state to which the establishment is subordinated.

Paragraph 2 Cancellation of the registration of the establishment falls to the Director of the Department of Inspection of Animal Products.

Article 512. If two or more offenses are being investigated in one administrative case file, the penalties will be applied cumulatively for each provision that is breached.

Article 513. For the purposes of applying the sanctions given in item III of the **head provision** of Art. 508, it will be deemed that the animal raw materials and products fail to present suitable hygienic or sanitary conditions for their intended purpose or that they have been adulterated, without prejudice to other provisions in this Decree, when the offender:

I - changes or fraudulently presents some raw material, ingredient or animal product;

II - ships raw materials, ingredients, products or packaging that has been stored in unsuitable conditions;

III - uses products with expired validity, attaches new dates post expiry on such products, or places a date later than the real manufacturing date;

IV - produces or ships product posing a public health risk;

V - produces or ships for edible purpose products unfit for human consumption;

VI - uses condemned or uninspected raw materials and products in the preparation of products for human consumption;

VII - makes products that do not meet the specific legislation or that fail to comply with manufacturing processes, formulation and composition registered in the Department of Inspection of Animal Products;

VIII uses, replaces, totally or partially removes raw materials, products, labels or packaging seized by the SIF and kept under guard by the establishment;

Paragraph 1 It falls to the offender to shoulder the possible costs of removal, transport and destruction of condemned products.

Paragraph 2 It falls to the offender to shoulder possible costs of removal and transport for products seized and lost in favor of the Federal Government that will be sent for use in food security and famine fighting programs, in the terms of Paragraph 4 of article 2 of Law no. 7,889, enacted 1989.

Article 514. For the purposes of applying the sanction addressed in item IV of the **head provision** of art. 508, the following are risky activities or situations that threaten hygiene and health, without prejudice to other provisions of this Decree:

I - to disobey or fail to comply with health demands for the operations and hygiene of facilities, equipment, utensils and the tasks of handling and preparing raw material and products;

II - to omit information about the centesimal and technological composition of the manufacturing process; III -

alteration or fraudulent presentation of any animal raw material, ingredient or product;

IV - to ship raw materials, ingredients, products or packaging that have been stored in unsuitable conditions;

V - to receive, use, transport, store or ship raw materials, ingredients or products without proof of origin;

VI - to simulate the legality of raw materials, ingredients or products whose origin is unknown;

VII - to use products with expired validity, attach new dates post expiry on such products, or place a date later than the real manufacturing date for the product;

VIII - to produce or ship products posing a public health risk;

IX - to produce or ship for edible purposes products unfit for human consumption;

X - to use condemned or uninspected raw materials and products in the preparation of products for human consumption;

XI - to use a process, substance, ingredients or additives that fail to comply with specific legislation;

XII - to use, replace, totally or partially remove raw materials, products, labels or packaging seized by the SIF and kept under guard by the establishment;

XIII - to give or present false or inaccurate information, statements or documents to the oversight agency about quantity, quality and origin of raw materials, ingredients and products, or withhold information that directly or indirectly interests the Ministry of Agriculture, Livestock and Food Supply and the consumer;

XIV - to alter, fraudulently present, adulterate or falsify records liable to SIF verification;

XV - to fail to meet deadlines in the self-control programs and in documentation issued in response to SIF concerning action plans, inspections, warnings of violation, summonses or notifications;

XVI - to exceed the maximum slaughter capacity, or the treatment, industrial processing or storage capacities;

XVII - to fail to produce—in response to a request, summons or notification—for the Ministry of Agriculture, Livestock and Food Supply, the documentation to underpin proof of health of products shipped;

XVIII - to acquire, handle, ship or distribute animal products from an establishment not registered or listed in the Department of Inspection of Animal Products or that is not in the general registry of the Brazilian System of Inspection of Animal Products; or

XIX - to fail to recall products that may pose a threat to consumers' health or interests.

Article 515. For the purposes, without prejudice to other provisions in this Decree, of applying the sanctions addressed in item IV of art. 508, it constitues hindering enforcement actions when the offender:

I - thwarts the actions of a member of staff of the Department of Inspection of Animal Products in the exercise of their duty, seeking to hinder, delay, impede, restrict or evade inspection activities;

II - disrespects, intimidates, threatens, assaults, or attempts to bribe a member of the staff of the Ministry of Agriculture, Livestock and Food Supply;

III - withholds information about the centesimal and technological composition of the manufacturing

process; IV - simulates the legality of raw materials, ingredients or products whose origin is in fact

unknown;

V - constructs, extends or remodels facilities without prior approval from DIPOA—Department of Inspection of Animal Products;

VI - uses, replaces, totally or partially removes raw materials, products, labels or packaging seized by the SIF and kept under guard by the establishment;

VII - gives or presents false or inaccurate information, statements or documents to the oversight agency about quantity, quality and origin of raw materials, ingredients and products, or withholds any information that directly or indirectly interests the Ministry of Agriculture, Livestock and Food Supply and the consumer;

VIII - falsifies official documents;

IX - falsifies records that are subject to SIF verification;

X - fails to meet deadlines in the self-control programs and in documentation issued in response to SIF concerning action plans, inspections, warnings of violation, summonses or notifications;

XI - ships products for international trade that have been made without attention to the supplementary norms about the export of animal products; or

XII - fails to recall products that may pose a threat to consumers' health or interests.

Article 516. For the purposes, without prejudice to other provisions in this Decree, of applying the sanctions addressed in item V of art. 508, the following characterize a lack of suitable hygiene and health conditions:

I - disobeying or failing to comply with health demands for the operations and hygiene of facilities, equipment, utensils and the tasks of handling and preparing raw material and products; or

II - failing to meet deadlines in the self-control programs and in documentation issued in response to SIF concerning action plans, inspections, warnings of violation, summonses or notifications concerning maintenance or hygiene in the facility.

Article 517. Sanctions: a total or partial ban on the establishment shall be applied as a result of habitual adulteration or falsification of the product, or suspension of production activities owing to the hindering of enforcement action, will be applied for a minimum of seven days, to which may be added fifteen, thirty or sixty days depending on the track record of violations, successive repetitions of offense and other aggravating circumstances provided for in Article 510.

Article 518. When an identical offense is found three times, whether consecutively or otherwise, in a twelve-month period, this characterizes a habitual attitude in the adulteration or falsification of products.

Article 519. The establishment's registration or listing will be canceled in cases of:

I - recidivism in the practice of the more serious offenses set forth in this Decree or in supplementary norms;

II - recidivism in the offense for which the penalty was to ban the establishment or suspend activities for the maximum periods allowed in Article 517; or

III - non-lifting of a ban on the establishment after twelve months.

CHAPTER IV

ADMINISTRATIVE PROCESS

Article 520. Infringements of the provisions of this Decree and of supplementary Acts will be investigated in a fully investigated enforcement action, begun by preparing notification of violation.

Article 521. The notice of infraction will be drafted by the Federal Agriculture Inspector who noticed the infraction, at the very place where the irregularity was found, or in the SIF office of the Ministry of Agriculture, Livestock

and Food Supply.

Article 522. The notice of infraction must be clear and concise, without crossings-out or alterations, and must describe the offense committed and the legal provision breached.

Article 523. The notice of infraction will be drafted using a specific template to be established by the Ministry of Agriculture, Livestock and Food Supply.

Article 524. The signature and date given on the notice of infraction by the notified party, on receiving his/her copy, will constitute service of notification for all legal intents and purposes.

Paragraph 1 If an offender refuses to sign a notice of infraction, this fact is to be recorded on the notification itself.

Paragraph 2 Express acknowledgment of the notice of infraction must be given personally, or by sending a notice of receipt (*aviso de recebimento*—AR) through the post, or by telegram or some other means that ensures certainty of the acknowledgment of the interested party.

Article 525. The defense of the party notified must be presented in writing, in Portuguese, and be received with a protocol at the nearest representation of the Ministry of Agriculture, Livestock and Food Supply in the State where the offense took place, within ten days of the date of official acknowledgment.

Article 526. The Service of Inspection of Animal Products in the State where the offense took place, after adding the defense and the default document to the case file, must include a report and the Head of the Service must then go to judgment in the first instance.

Article 527. An appeal as to legality and merit may be lodged regarding the judgment in the first instance, within ten days of the acknowledgment of the decision or of its official disclosure.

Sole paragraph. The timely appeal, at the discretion of the hearing authority, may be able to suspend the penalty applied and must be addressed to the authority that handed down the decision, which, if it does not review its own decision, will forward the administrative case file to the Director of the Department of Inspection of Animal Products, to carry the judgment to the second level.

Article 528. The competent authority to decide on the appeal in the second instance is the Director of the Department of Inspection of Animal Products, within the deadlines and in compliance with the expected procedures for lodging the appeal in the previous instance.

Article 529. Failure to pay the amount of the fine within thirty days, if proven in the records of the case file after it has been decided, will entail forwarding the debt for inclusion in the list of overdue debtors of the Federal Government.

Article 530. Public disclosure will be made of the products and establishments that committed the adulteration or fraud, proven in cases that have been judged administratively.

Sole paragraph. The recall of products that may pose a threat to consumers' health or interests may also be published in the press.

Article 531. Drafting the notice of infraction does not exempt the offender from the demand that motivated it.

TITLE XII FINAL AND

TRANSITORY PROVISIONS

Article 532. The Department of Inspection of Animal Products and the health regulator must work together to define inspection and oversight procedures for foodstuffs containing animal products in varying proportions and do not allow classic categorization as an animal product, so as to ensure the identity and quality and protect the interests of consumers.

Sole paragraph. The procedures addressed in the **head provision** include joint operations in the import or export of foodstuffs and the international health certification of these products.

Article 533. Labels of imported products already registered in a foreign language using stickers with a translation in Portuguese of the mandatory information may be used until the end of the validity of their registration.

Article 534. Within the Ministry of Agriculture, Livestock and Food Supply, technical and scientific committees will be set up to provide consultation, without charge, to address topics inherent in the industrial and sanitary inspection of animal products.

Sole paragraph. The composition of the committee and the appointment of its members will be defined in an act of the Ministry of Agriculture, Livestock and Food Supply.

Article 535. The Ministry of Agriculture, Livestock and Food Supply may adopt supplementary inspection and oversight procedures as a result of the existence or suspicion of:

I - diseases, whether exotic

or otherwise; II - outbreaks;

or

III - any other event that poses a risk to public health and to animal health.

Sole paragraph. When in inspection and oversight activities there is a suspicion of immediately notifiable infectious or contagious diseases, the SIF must notify the official animal health service.

Article 536. Omissions or queries arising from the implementation of this Decree will be solved by the Department of Inspection of Animal Products, based on technical and scientific information.

Article 537. The penalties applied, after unappealable judgment, will be taken into consideration so as to determine repetition of offense concerning acts practiced after this Decree comes into force.

~~Article 538. Os estabelecimentos registrados ou relacionados no Ministério da Agricultura, Pecuária e Abastecimento terão o prazo de um ano, contado da data de entrada em vigor, para se adequarem às disposições deste Decreto.~~

Article 538. Establishments registered or listed in the Ministry of Agriculture, Livestock and Food Supply will have one hundred and eighty days from the coming into force in which to adjust to the new provisions of this Decree concerning the general conditions of facilities and equipment given in Articles 42 to 46 and to update their registration information for the categories of establishment given in Articles 16 to 24. (In the wording of Decree 9,069/2017)

Article 539. The Ministry of Agriculture, Livestock and Food Supply will issue supplementary norms needed for the execution of this Decree.

Article 540. Existing supplementary norms remain in force provided that they do not contradict what is laid down in this Decree.

Article 541. The following acts are revoked:

I - Decree no. 30,691, enacted 29 March 1952;

II - Decree no. 39,093, enacted 30 April 1956; III

- Decree no. 1,255, enacted 25 June 1962; IV -

Decree no. 56,585, enacted 20 July 1965;

V - Decree no. 1,236, enacted 2 September

1994; VI - Decree no. 1,812, enacted 8 February

1996; VII - Decree no. 2,244, enacted 4 June

1997;

VIII - Decree no. 6,385, enacted 27 February 2008;

IX - art. 3 of Decree no. 7,216, enacted 17 June 2010; X

- Decree No. 8,444, enacted 6 May 2015; and

XI - Decree no. 8,681, enacted 23 February 2016.

Article 542. This Decree shall come into force on its publication date.

Brasilia, 29 March, 2017, 196th year of Independence and 129th year of the Republic.

MICHEL TEMER
Blairo Maggi

This text does not replace the one published in the Official Gazette (DOU) on 30.3.2017 and rectified on 1.6.2017

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