

Presidency of the Republic General Secretariat Sub-Department of Legal Matters

DECREE NO. 9,013 ENACTED MARCH 29, 2017

This Decree regulates Law no. 1,283, enacted December 18, 1950; and Law no. 7,889, enacted November 23, 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 the provisions of Law no. 1,283, enacted December 18, 1950, and Law no. 7,889, enacted November 23, 1989,

DECREES that:

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 <u>Law no. 1,283</u>, <u>enacted December 18, 1950</u>, and by <u>Law no. 7,889</u>, <u>enacted November 23, 1989</u>.

Paragraph 1. The activities defined in the **head provision**, which are 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 — the Brazilian National System for Sanitary Surveillance (*Sistema Nacional de Vigilância Sanitária*).

Paragraph 3. This Decree and the standards that supplement it shall be guided by the constitutional principles of Federalism, by the promotion of very small, 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.

Paragraph 3. The present Decree and the standards that supplement it: (In the wording of Decree no. 10,468, enacted in 2020)

- I will be guided: (Included by Decree no. 10,468, enacted in 2020)
- a) among other factors, by the Constitutional principles: (Included by Decree no. 10,468, enacted in 2020)
- 1. of federalism; (Included by Decree no. 10,468, enacted in 2020)
- 2. of fostering very small, and small, enterprises; (Included by Decree no. 10,468, enacted in 2020)
- 3. of scientific development and technological innovation; and (Included by Decree no. 10,468, enacted in 2020)
- 4. of respect for international law, treaties entered into by the Federative Republic of Brazil, and bilateral and multilateral equivalency agreements; and (Included by Decree no. 10,468, enacted in 2020)
 - b) by the principles contained in: (Included by Decree no. 10,468, enacted in 2020)
 - 1. Law no. 8,078, enacted September 11, 1990; (Included by Decree no. 10,468, enacted in 2020)
 - 2. Law no. 13,874, enacted September 20, 2019; and (Included by Decree no. 10,468, enacted in 2020)
- 3. Supplementary Law no. 123, enacted December 14, 2006; and (Included by Decree no. 10,468, enacted in 2020)

II - will aim to rationalize processes and procedures, simplifying them and making them virtual. (<u>Included by Decree no. 10,468</u>, enacted in 2020)

CHAPTER II

THE SCOPE OF OPERATIONS

Article 2. The inspection and oversight of animal product-producing establishments that engage in interstate (i.e., 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. The inspection and oversight performed by the Ministry of Agriculture, Livestock and Food Supply extend to wholesalers that receive and store animal products, as a supplement to the local sanitary inspection activities as laid down in Law no. 7,889, enacted in 1989, and aim to reinspect animal products coming from international trade.

Paragraph 1. The inspection and oversight performed by the Ministry of Agriculture, Livestock and Food Supply extend to wholesalers that receive and store animal products, as a supplement to the local sanitary inspection activities as laid down in <u>Law no.1,283</u>, <a href="enable-ena

Paragraph 2. Inspection and oversight 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 the specific legislation of SUASA — Brazil's Unified Animal and Plant Health System (*Sistema Unificado de Atenção à Sanidade Agropecuária*) in accordance with the provisions of <u>Law no. 8,171, enacted January 17, 1991</u>, and <u>Law no. 9,712</u>, <u>enacted November 20, 1998</u>.

- 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 enforcement controls set forth in this Decree.

Sole paragraph. The inspection and enforcement controls addressed in this article also include — from the industrial and sanitary perspectives — the **ante-mortem** and **post-mortem** inspection of animals, the reception, handling, treatment, industrial manufacture, portioning, canning, placement, packing, 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 intended for the handling or the processing of animal products;
- II at establishments receiving the several animal species for slaughter or industrial processing 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 or industrial processing;
- VI at establishments that extract or receive bee and honey-bee products or by-products for treatment or industrial processing;
- VII at establishments that receive, handle, store, preserve, pack or ship edible or inedible animal raw materials and animal products coming from registered or listed 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, state-level or municipal 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 bees and honey-bee products) are obtained, received, handled, treated, industrially processed, portioned, 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 in 1991, and its enabling standards.
- 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 test a test 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 test a test 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 personnel of the Ministry of Agriculture, Livestock and Food Supply (MAPA);
- IV expert test a laboratory test based on an official B sample when one of the parties appeals against the result of a fiscal test, 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 place wholly or partially within the limits of the territory of Brazil or Brazilian waters;
 - VII game species those defined by a standard issued by the competent federal public agency;
- VIII Good Manufacturing Practices (GMPs) systematized hygienic, sanitary and operational conditions and procedures applied throughout the production process in order 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 chemical agents;
- X equivalency of inspection services the condition in which hygiene, sanitary and technical inspection and enforcement measures taken by different inspection services will enable the same objectives of inspection, enforcement, product safety and quality to be achieved, as set forth in <u>Law no. 8,171, enacted 1991, and its implementation standards;</u>
- XI meat-producing livestock species bovids, equids, suids, ovines, caprines, lagomorphs and domestic birds, as well as wild animals raised in captivity, that are slaughtered in establishments under veterinary inspection;
- XI meat-producing livestock species bovines, buffaloes, equids, suids, 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 sanitation 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 facilities, equipment and utensils;
- XIV sanitization the application of chemicals that have been approved by the health regulatory agency, or of physical methods, to the surfaces of facilities, equipment and utensils after cleaning procedures, in order to ensure a microbiologically acceptable level of hygiene;

- XV identity standard a set of parameters that enable 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 contamination or cross-contamination of the product, and preserve its quality and integrity, by means of 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 enable 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 the 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.
- XX Technical Regulation for Identity and Quality (TRIQ) an act of legislation that aims to determine the characteristics of identity and minimal quality with which animal products must comply; (In the wording of Decree no. 10,468 enacted in 2020)
- 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, and deemed in accordance with the Brazilian standards of industrial property and the applicable international standards and guidelines; (In the wording of Decree no. 10,468 enacted in 2020)
- XXII conditional use a disposition given by the Official Service to raw materials and products that present otherwise than in compliance with the legislation for the manufacture of edible products, by submitting them to specific treatments to ensure their safety; (Included by Decree no. 10,468, enacted in 2020)
- XXIII audit a technical and administrative procedure performed by a Federal Agricultural Inspector/Auditor (AFFA) who has graduated in Veterinary Medicine, in order to: (Included by Decree no. 10,468, enacted in 2020)
- a) examine the performance of the Federal Inspection Service teams working inside permanently-inspected establishments; and (Included by Decree no. 10,468, enacted in 2020)
- b) assess the technical, hygienic and sanitary conditions of the registered establishments; (Included by Decree no. 10,468, enacted in 2020)
- XXIV audit on a decentralized unit a technical and administrative procedure performed by a team that is made up of public servants of the Department of Inspection of Animal Products, of the Secretariat of Animal and Plant Health, of the Ministry of Agriculture, Livestock and Food Supply, and led by a Federal Agricultural Inspector/Auditor (AFFA) who has graduated in Veterinary Medicine, in order to evaluate the performance of the service, and which may include audits on randomly selected registered establishments; (Included by Decree no. 10,468, enacted in 2020)
- XXV certification central a unit of the Ministry of Agriculture, Livestock and Food Supply that is eligible to issue domestic or international health certificates, animal movement permits, and other documents defined by the Department of Inspection of Animal Products of the Secretariat of Animal and Plant Health of the aforementioned ministry, in order to underpin the domestic or international transportation of animal products; (Included by Decree no. 10,468, enacted in 2020)
- XXVI condemnation a disposition given by the Official Service to raw materials and products that present otherwise than in compliance with the legislation for the manufacture of edible products, and, when suitable, ensuring the safety of the final product; (Included by Decree no. 10,468, enacted in 2020)

- XXVII rendering unrecognizable the application, to an animal product or raw material obtained from an animal, of a procedure or process in order to make it visually unfit for human consumption; (Included by Decree no. 10,468, enacted in 2020)
- XXVIII denaturing the application, to an animal product or raw material obtained from an animal, of a procedure or process using a chemical substance in order to make it visually unfit for human consumption; (Included by Decree no. 10,468, enacted in 2020)
- XXIX industrial disposition the disposition given to duly identified raw materials and products that present otherwise than in compliance with legislation, or that fail to meet the specifications laid down in their own self-control programs, in order for such raw materials and products to undergo specific treatments, or to make other edible products, ensuring traceability, identity, safety and quality in the final product; (Included by Decree no. 10,468, enacted in 2020)
- XXX rendering unusable disposition given, by the company or by the official service, to the destruction of raw materials and products that present otherwise than in compliance with the legislation; (<u>Included by Decree no. 10,468, enacted in 2020</u>)
- XXXI international recommendations standards or guidelines edited by the World Organisation for Animal Health or the **Codex Alimentarius** Commission of the United Nations' Food and Agriculture Organisation, concerning animal products; and (<u>Included by Decree no. 10,468, enacted in 2020</u>)
- XXXII Federal Inspection Service (SIF) the technical and administrative unit of the Ministry of Agriculture, Livestock and Food Supply, which constitutes the local representation of the Service of Inspection of Animal Products. (Included by Decree no. 10,468, enacted in 2020)
- Article 11. There will be permanent federal inspection in those meat and by product establishments slaughtering different meat producing 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 standards.
- Article 11. Federal Inspection will be performed in permanent or periodic fashion. (<u>In the wording of Decree no.</u> 10,468, enacted in 2020)
- Paragraph 1. Permanent federal inspection consists of the presence of the official inspection service in order to perform **ante-mortem** and **post-mortem** inspection and oversight, during the slaughter operations for the several meat-producing species, game species, amphibians and reptiles in establishments, as set forth in Article 14. (In the wording of Decree no. 10.468, enacted in 2020)
- Paragraph 2. Periodic federal inspection consists of the presence of the official inspection service in order to perform inspection and oversight procedures on other registered or listed establishments and other industrial facilities belonging to the establishments addressed in Paragraph 1, except for slaughter. (In the wording of Decree no. 10,468, enacted in 2020)
- Article 12. The 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 working of the establishments;
 - III verification of the hygiene practice and the personal 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 tests 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 compliance of 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 intended for slaughter;
 - IX checking the supply water;
- X the phases of obtaining, receiving, handling, treatment, industrial production, portioning, 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 the means of transportation of live animals and of animal products, by-products and raw materials intended for human consumption;
 - XIV control of residues and contaminants in animal products;
- XV traceability controls for animals, raw materials, inputs, ingredients and products throughout the production chain:
- XV verification of traceability controls for animals, raw materials, inputs, ingredients and products throughout the production chain, beginning with the receiving step in the establishments; (In the wording of Decree no. 10,468 enacted in 2020)
 - XVI health certification for animal products; and
- XVII other inspection procedures whenever recommended by the practice and development of the animal product industry.
- Sole paragraph. The Department of Inspection of Animal Products, of the Secretariat of Animal and Plant Health, of the Ministry of Agriculture, Livestock and Food Supply, will perform audits to assess the performance of the Federal Inspection Service in the local units and decentralized units, regarding the execution of the inspection and oversight activities addressed in the **head provision** and in Article 11. (Included by Decree no. 10,468, enacted in 2020)
- 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 Inspector/Auditors (AFFAs) who have graduated in Veterinary Medicine, of Sanitary and Industrial Inspection Agents for Animal Products (Portuguese acronym: AISIPOA), and other agricultural inspection officers, duly respecting their several competencies.
- Article 15. Public servants responsible for carrying out the activities addressed in this Decree must possess a service identification card issued by the Ministry of Agriculture, Livestock and Food Supply.
- Paragraph 1. The MAPA personnel addressed in this article, when performing their duties, must produce their cards to identify themselves.
- Paragraph 2. The 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. Public servants 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 CLASSIFICATION

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

- I meat and meat products;
- II seafood and seafood products;
- III eggs and egg products;
- IV milk and dairy products;
- V bee products and honey bee by-products;
- VI storage facilities; and

VII - inedible products. (Revoked by Decree no. 10,468, enacted in 2020)

CHAPTER I

MEAT AND MEAT-PRODUCT ESTABLISHMENTS

Article 17. Meat and meat-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 that possess industrial cold facilities, and are 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 that have 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.

Paragraph 1. For the purposes of the present Decree, the term 'slaughterhouses' applies to establishments intended for the slaughter of meat-producing animals, for receiving, handling, packing, labeling, storing and shipping products obtained from slaughter, and that possess industrial cold facilities, and are able to receive, handle, industrially process, pack, label, store, and ship edible products. (In the wording of Decree no. 10,468, enacted in 2020)

Paragraph 2. For the purposes of the present Decree, the term 'meat and meat-product producing units' applies to establishments intended for receiving, handling, packing, labeling, storing and shipping meat and meat products, and that have the capacity to industrially produce edible products. (In the wording of Decree no. 10,468, enacted in 2020)

Article 18. Gelatin and collagen-product 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.

Sole paragraph. The establishments addressed in the **head provision** shall ensure that they comply with the requirements laid down in Paragraph 2 of Article 313 that apply to establishments that supply raw materials for use in their activities. (In the wording of Decree no. 10,468, enacted in 2020)

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 as '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 1. For the purposes of the present Decree, the term 'factory ships' applies to fishing vessels intended for capturing or receiving, washing, handling, packing, labeling, storing and shipping seafood and seafood-products, that possess an industrial cold storage capacity, and have the capacity to industrially produce edible products. (In the wording of Decree no. 10,468, enacted in 2020)

Paragraph 2. For the purposes of the present Decree, the term 'seafood slaughterhouses' applies to establishments intended for the slaughter of amphibians and reptiles, and for receiving, washing, handling, packing, labeling, storage and shipping products obtained from slaughter, that possess industrial cold facilities, and are able to receive, handle, industrially process, pack, label, store, and ship edible products. (In the wording of Decree no. 10,468, enacted in 2020)

Paragraph 3. For the purposes of the present Decree, the term 'seafood and seafood-product processing units' applies to establishments intended for receiving and washing seafood obtained from primary production, and for handling, packing, labeling, storing and shipping seafood and seafood-products, and that possess the capacity to industrially produce seafood products. (In the wording of Decree no. 10,468, enacted in 2020)

Paragraph 4. For the purposes of this Decree, the term 'mollusk depuration station' applies to establishments intended for receiving, depuration, packing, labeling, storing and shipping bivalve mollusks.

CHAPTER III

EGG AND EGG-PRODUCT ESTABLISHMENTS

Article 20. Egg and egg-product establishments are classified as:

- I poultry farms; and
- II egg and egg-product treatment plants.

Paragraph 1. For the purposes of this Decree, the term 'poultry farm' applies to establishments intended for the production, ovoscopy, classification, packing, labeling, storing and shipping of eggs, exclusively from their own production, for direct sale.

Paragraph 2. Poultry farms may sell eggs to the egg and egg-product treatment units.

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 and egg-product treatment units'.

Paragraph 3. For the purposes of the present Decree, the term 'egg and egg-product treatment units' applies to establishments intended for producing, receiving, ovoscopy, classifying, industrially-processing, packing, labeling, storing and shipping eggs or egg products. (In the wording of Decree no. 10,468, enacted in 2020)

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.

Paragraph 6. Should the poultry farm possess suitable structure and conditions, it may break eggs on the farm for the exclusive disposition to suitable treatment in an egg and egg-product treatment unit, as provided for in the present Decree and in supplementary standards. (<u>Included by Decree no. 10,468, enacted in 2020</u>)

CHAPTER IV

MILK AND DAIRY-PRODUCT ESTABLISHMENTS

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

- I dairy farms;
- II refrigeration stations;
- II processing plants;
- III milk and dairy-product treatment plants; and (In the wording of Decree no. 10,468 enacted in 2020)
- IV dairy plants; and (Revoked by Decree no. 10,468, enacted in 2020)
- V cheese makers.

Paragraph 1. For the purposes of this Decree, the term 'dairy farm' applies to establishments intended for the production, pretreatment, treatment, filling, packing, labeling, storing and shipping of milk for direct human consumption; they may also produce dairy by-products from milk that has been exclusively self-produced, involving the stages of pretreatment, treatment, handling, manufacturing, maturation, grating, portioning, 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 2. For the purposes of the present Decree, the term 'refrigeration stations' applies to establishments that are interposed between farms and treatment plants or milk and dairy product treatment plants and that are intended for selecting, receiving, measuring weight or volume, filtration, refrigeration, packing and shipping raw refrigerated milk, including the temporary stocking of the milk until shipping. (In the wording of Decree no. 10,468, enacted in 2020)

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

Paragraph 3. For the purposes of the present Decree, the term 'milk and dairy-product treatment units' applies to establishments intended for receiving, pretreating, treating, filling, packing, labeling, storing and shipping milk for direct human consumption, and that may also transfer, handle, manufacture, mature, portion, grate, pack, label, store, and ship dairy products, and may also ship liquid milk in bulk for industrial use. (In the wording of Decree no. 10,468, enacted in 2020)

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, portioning, grating, packing, labeling, storing and shipping of dairy products, including the shipping of bulk liquid milk for industrial use, are defined as 'dairy plants'. (Revoked by Decree no. 10,468, enacted in 2020)

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'.

Paragraph 5. For the purposes of the present Decree, the term 'cheese makers' applies to establishments intended for manufacturing cheeses, involving the stages of manufacture, maturation, packing, labeling, storing and shipping, and that send their product to a milk and dairy-product treatment plant in the event they do not perform the complete cheese-making process. (In the wording of Decree no. 10,468, enacted in 2020)

CHAPTER V

BEE AND HONEY-BEE PRODUCT ESTABLISHMENTS

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

- I bee product extraction and treatment units; and (Revoked by Decree no. 10,468, enacted in 2020)
- II bee and honey-bee product treatment stations.
- I bee-product treatment units. (In the wording of Decree no. 10,468, enacted in 2020)

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, possibly also treating and portioning such products, are defined as 'bee-product extraction and treatment units'. (Revoked by Decree no. 10,468, enacted in 2020)

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 honey bee product establishments, and that may extract raw materials from other bee-keepers, are defined as 'bee and honey bee product treatment stations'.

Paragraph 2. For the purposes of the present Decree, the term 'bee and honey-bee product treatment units' applies to establishments intended for receiving, classifying, treating, industrially processing, packing, labeling, storing and shipping products and pretreated raw materials from other bee and honey-bee product establishments, and that may extract raw materials from other bee-keepers. (In the wording of Decree no. 10,468, enacted in 2020)

Paragraph 3. Raw material extracted previously by bee-keepers may be received, provided that it complies with this Decree and supplementary standards.

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 1. For the purposes of the present Decree, the term 'animal product storage facilities' applies to establishments intended exclusively for receiving, storing and shipping edible animal products, which may or may not need industrial cold facilities, and which have specific facilities for reinspection. (In the wording of Decree no. 10,468, enacted in 2020)

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 2. For the purposes of the present Decree, the term 'wholesalers' applies to establishments registered with health regulatory agencies and that receive and store ready-to-sell, packed and labeled animal products coming from international trade, for reinspection purposes, and that possess the facilities for such activities. (In the wording of Decree no. 10,468, enacted in 2020)

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

Paragraph 3. At those establishments addressed in Paragraphs 1 and 2, the activities of handling, portioning, or the replacing of primary packaging, will not be permitted; the replacement of damaged secondary packaging will be allowed. (In the wording of Decree no. 10,468, enacted in 2020)

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'.

Paragraph 5. In those establishments addressed in Paragraph 1, the bringing together of animal products in order to make up kits or sets, which are not subject to registration, is permitted. (<u>Included by Decree no. 10,468, enacted in 2020</u>)

CHAPTER VII

INEDIBLE PRODUCT ESTABLISHMENTS

(Revoked by Decree no. 10,468, enacted in 2020)

Article 24. Inedible product establishments are classified as 'inedible product treatment units'. (Revoked by Decree no. 10,468, enacted in 2020)

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 standards, are defined as 'inedible product treatment units'. (Revoked by Decree no. 10,468, enacted in 2020)

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 <u>Law no. 1,283</u>, <u>enacted 1950</u>, 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 signed 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, in supplementary standards, for the purpose of the registration and control of activities performed by establishments, 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 <u>Law no. 8,171</u>, <u>enacted in 1991</u>, and in its enabling standards.

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 Persons, 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, flow diagram, supply water, and drainage of wastewater, with a conclusive technical opinion issued by a Federal Agricultural Inspector/Auditor who graduated in Veterinary Medicine. (Revoked by Decree no. 10,468, enacted in 2020)

Article 28. The following steps are to be observed in order for an establishment to obtain registration or listing: (In the wording of Decree no. 10,468, enacted in 2020)

- I the deposition, by the establishment, of the required documentation, in accordance with the provisions contained in supplementary standards; (In the wording of Decree no. 10,468 enacted in 2020)
- II the documentation deposited by the establishment is to be assessed and approved by the inspection service; (In the wording of Decree no. 10,468 enacted in 2020)
- III there will be an on-the-ground inspection of the constructed establishment by a Federal Agricultural Inspector/Auditor (AFFA) who has graduated in veterinary medicine, who will draft a conclusive opinion; and (In the wording of Decree no. 10,468 enacted in 2020)
- IV the establishment's registration or listing will be granted. (In the wording of Decree no. 10,468, enacted in 2020)

Paragraph 1. The steps laid out in the **head provision** will be mandatory for those establishments classified as: (Included by Decree no. 10,468, enacted in 2020)

- I slaughterhouses; (Included by Decree no. 10,468, enacted in 2020)
- II meat and meat-product processing plants; (Included by Decree no. 10,468 enacted in 2020)
- III factory ships; (Included by Decree no. 10,468, enacted in 2020)
- IV seafood slaughterhouses; (Included by Decree no. 10,468, enacted in 2020)
- V seafood and seafood-product processing units; (Included by Decree no. 10,468, enacted in 2020)
- VI bivalve mollusk depuration stations; (Included by Decree no. 10,468, enacted in 2020)
- VII egg and egg-product treatment plants; (Included by Decree no. 10,468, enacted in 2020)
- VIII dairy farms; and (Included by Decree no. 10,468, enacted in 2020)
- IX milk and dairy-product treatment plants. (Included by Decree no. 10,468, enacted in 2020)

Paragraph 2. For all the other establishments addressed in the present Decree, the steps set forth in items I and IV of the **head provision** will be mandatory. (<u>Included by Decree no. 10,468, enacted in 2020</u>)

Paragraph 3. The Ministry of Agriculture, Livestock and Food Supply will set up and maintain a specific computerized system to meet the provisions of the present article. (Included by Decree no. 10,468, enacted in 2020)

Paragraph 4. By a legal act of the Minister of State for Agriculture, Livestock and Food Supply, the simplified registration procedures provided for in Paragraph 2, for those establishments addressed in Paragraph 1, may be brought in, in accordance with the nature of the industrial activities performed. (Included by Decree no. 10,468, enacted in 2020)

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 standards issued by the Ministry of Agriculture, Livestock and Food Supply.

Article 30. After the demands established in this Decree and in supplementary standards 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 30. After the demands set forth in the present decree and in the supplementary standards have been met, the Director of the Department of Inspection of Animal Products, of the Secretariat of Animal and Plant Health, of the Ministry of Agriculture, Livestock and Food Supply will issue the deed of registration, which may be digital in format, on which the following items will appear: (In the wording of Decree no. 10,468, enacted in 2020)

- I the registration number; (Included by Decree no. 10,468, enacted in 2020)
- II the company name; (Included by Decree no. 10,468, enacted in 2020)
- III the classification of the company; and (Included by Decree no. 10,468, enacted in 2020)
- IV the location of the establishment. (Included by Decree no. 10,468, enacted in 2020)

Sole paragraph. The establishment's registration number is unique and identifies the manufacturing unit within the national territory of Brazil. (Included by Decree no. 10,468, enacted in 2020)

Article 31. After the deed of registration 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 31. The deed of registration issued by the Director of the Department of Inspection of Animal Products, of the Secretariat of Animal and Plant Health, of the Ministry of Agriculture, Livestock and Food Supply is the document effectively authorizing the operation of the establishment. (In the wording of Decree no. 10,468, enacted in 2020)

Paragraph 1. In the case of permanently-inspected establishments, the commencement of industrial activities depends not only on possession of the deed of registration addressed in the **head provision**, but also on the appointment, by the Head of the Service of Inspection of Animal Products having jurisdiction over the establishment,

of a team of public servants who are responsible for the activities addressed in item I of the **head provision** of Article 12. (Included by Decree no. 10,468, enacted in 2020)

Paragraph 2. Establishments are to meet the demands or outstanding issues established when the deed of registration is granted, prior to the commencement of their industrial activities. (Included by Decree no. 10,468, enacted in 2020)

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 standards 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 32. The deed of listing of the establishment, issued by the Head of the Service of Inspection of Animal Products having jurisdiction over the establishment, is the document effectively authorizing the commencement of activities of reinspection of imported animal products, and may be issued digitally. (In the wording of Decree no. 10,468, enacted in 2020)

Sole paragraph. The establishment's listing number is to be: (In the wording of Decree no. 10,468, enacted in 2020)

- I unique to each State or to the Federal District; (Included by Decree no. 10,468, enacted in 2020)
- II indicated by the abbreviation for the State or Federal District, and the listing number. (<u>Included by Decree</u> no. 10,468, enacted in 2020)

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 33. Any extension, remodeling, or building work that is carried out within the rooms and facilities of the registered establishments, entailing an increased production capacity or change to the flow of raw materials, products or employees; and changes to the rooms or facilities of locations where reinspection takes place or imported animal products are stored in the case of listed establishments, may only be performed after: (In the wording of Decree no. 10,468, enacted in 2020)

- I the project has received prior approval, in the case of the establishments addressed in Paragraph 1 of Article 28; and (Included by Decree no. 10,468, enacted in 2020)
- II the deposited documentation has been brought up to date, in the case of the establishments addressed in Paragraph 2 of Article 28. (Included by Decree no. 10,468, enacted in 2020)

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 exempt from the isolated construction of buildings that might be shared. 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 exempt from the isolated construction of social facilities that might be shared. (In the wording of Decree no. 9,069, enacted in 2017)

Article 34. In the case of establishments performing activities in independent premises located on the same industrial site, whether belonging to the same company or otherwise, the isolated construction of shared facilities for water storage, wastewater treatment, laboratory, deposit, and spaces for employees to socialize, may be waived. (In the wording of Decree no. 10,468, enacted in 2020)

Paragraph 1. Described by its registration or listing number, each establishment will be held responsible for meeting the provisions of this Decree and supplementary standards 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 longer than six months shall only be allowed to resume operations after a prior inspection of its outbuildings, 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. (Revoked by Decree no. 10,468, enacted in 2020)

- Paragraph 2. If an establishment interrupts its operations for the period of one year, its registration or listing shall be canceled.
- Paragraph 2. If an establishment voluntarily interrupts its operations for the period of one year, its registration shall be canceled. (In the wording of Decree no. 10,468, enacted in 2020)
- 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 37. The competent authorities of the State, Federal District or Municipality shall be officially notified of the cancellation of registration, as shall, if necessary, the Federal Authority, in the person of the Head of the Service of Inspection of Animal Products of the State in which the establishment is located. (In the wording of Decree no. 10,468 enacted in 2020)
- Article 38. The Ministry of Agriculture, Livestock and Food Supply shall issue supplementary standards on the procedures for the prior approval of plans, remodelings and extensions, and for the procedures of registering and listing establishments.
- Article 38. The Ministry of Agriculture, Livestock and Food Supply will publish supplementary standards on the procedures and on the document-based demands for: (In the wording of Decree no. 10,468, enacted in 2020)
- I prior approval of a plan for building, remodeling and extending establishments; (<u>Included by Decree no. 10,468</u>, enacted in 2020)
 - II the registration and listing of establishments; and (Included by Decree no. 10,468, enacted in 2020)
- III the cancellation of the establishment's registration or listing. (<u>Included by Decree no. 10,468, enacted in</u> 2020)

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, tenant or lessee refuses to carry out this transfer, the seller, landlord or lessor 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 purchasing, renting or leasing party 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.
- Paragraph 6. The demands addressed in Paragraph 5 include: (<u>Included by Decree no. 10,468, enacted in 2020</u>)
 - I those regarding meeting deadlines for: (Included by Decree no. 10,468, enacted in 2020)
 - a) action plans; (Included by Decree no. 10,468, enacted in 2020)
 - b) summonses; or (Included by Decree no. 10,468, enacted in 2020)

- c) sanitary orders of any kind; and (Included by Decree no. 10,468, enacted in 2020)
- II those of a pecuniary nature that may be laid down as a result of the administrative evaluation of infractions committed by the predecessor in lawsuits awaiting judgment. (Included by Decree no. 10,468, enacted in 2020)
- Article 40. The transfer process, as far as is applicable, shall obey the same criteria laid down for registration or listing of the established.

TITLE IV THE GENERAL CONDITIONS OF ESTABLISHMENTS

CHAPTER I THE PREMISES 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.
- Article 41. No establishment will be allowed to operate until it has been completely installed and equipped for its intended purpose, pursuant to: (In the wording of Decree no. 10,468, enacted in 2020)
- I the plans as approved by the Department of Inspection of Animal Products, of the Secretariat of Animal and Plant Health, of the Ministry of Agriculture, Livestock and Food Supply, in the case of establishments addressed in Paragraph 1 of Article 28; or (Included by Decree no. 10,468, enacted in 2020)
- II the deposited documentation, for the case of establishments addressed in Paragraph 2 of Article 28. (Included by Decree no. 10,468, enacted in 2020)

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 standards:
 - I location on sites remote from any sources of 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 for the construction of industrial facilities and other outbuildings;
 - IV paved yard and thoroughfares and industrial perimeter in good repair and state of cleanliness;
- V buildings and facilities compatible with the purpose of the establishment and suitable for obtaining, receiving, handling, treating, industrially processing, portioning, conserving, 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 premises built 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, built so as to facilitate sanitation;
- X ceilings sufficiently high as to enable suitable installation of equipment and to meet the specific hygienic, sanitary and technological conditions for the purpose;
- XI false ceilings in rooms where the receiving, 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 wastewater and the 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 wash-basins 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 to avoid the accumulation of dirt;
 - XVI sufficient natural or artificial lighting and ventilation in all rooms;
- XVII corrosion-resistant equipment and utensils that are easy-to-clean, non-toxic and do not allow the accumulation of residues;
- XVIII equipment or instruments to monitor the manufacturing process, calibrated and externally checked, considered as necessary for technical and sanitary control of production;
 - XIX an area for the cleaning of containers used in moving raw material and products;
 - XX equipment and utensils exclusively for inedible products, identified by their red color;
- XXI a 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;
- XXII potable water in the areas where edible products are industrially-produced; (<u>In the wording of Decree no. 10,468 enacted in 2020</u>)
- XXIII a distinct and identified network for non-potable water, when used in other applications, in order to avoid a contamination hazard for product;
- XXIV a sewerage system designed and built so as to enable sanitation 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 taking meals according to the specific legislation of the competent agencies;
- XXVII a 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 Federal Inspection Service (SIF), comprising an administrative area, changing rooms and toilet facilities;
- XXVIII a headquarters for the Federal Inspection Service (SIF), comprising an administrative area, changing-rooms and toilet facilities, in the case of permanently-inspected establishments; (In the wording of Decree no. 10,468 enacted in 2020)
 - XXIX places and equipment enabling sanitary inspection and supervision;
 - XXX cold and hot water in rooms where products are handled and prepared;
- XXXI industrial cold chain installations and temperature control devices on chilling and freezing equipment, in tunnels, in chillers and freezers (i.e., rooms), in anterooms 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 appropriate technological specificities, must also possess:

- I 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 animals or animals suspected of disease;
- 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 a guay or wharf;
- II a waiting room and washing equipment for seafood at establishments that receive the material directly from primary production;
- III a location for the 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 operations, 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 the industrial premises, 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 making 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.

Sole paragraph. When a cheese maker does not carry out the entire cheese-making process, the milk or dairy-product processing unit will be jointly responsible for ensuring the safety of the product by introducing and monitoring herd health programs and self-control programs. (In the wording of Decree no. 10,468, enacted in 2020)

- Article 47. Bee and honey-bee product establishments that have been classified as bee and honey-bee product extraction units may be set up in vehicles possessing equipment and facilities meeting technological, hygienic and sanitary conditions, thus being mobile units. (Revoked by Decree no. 10,468, enacted in 2020)
- Article 48. The Department of Inspection of Animal Products may demand that changes be made in the industrial ground plan, the production processes and the operational 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 (chiller or freezer), 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 subject 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.

Article 51. Facilities and equipment intended for the manufacture or the storage of animal products may be used to produce and store products not liable to the inspection addressed by Law no. 1,283 of 1950, 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. (In the wording of Decree no. 10,468, enacted in 2020)

Sole paragraph. For those products addressed in the head provision official SIF stamps must not be used.

Article 52. Demands concerning the physical structure, buildings and equipment of small-scale agribusiness animal product establishments will obey specific supplementary standards, intended to minimize 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 entities that are 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' buildings, equipment and utensils must be kept in good hygiene conditions before, during and after the performance of the industrial activities.
- Sole paragraph. Sanitation 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. The use in facilities intended for handling and storing raw material, products and inputs of pest-control chemicals that have not been approved by the health-regulating agency, is forbidden.
- 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.
- Paragraph 2. When chemical controls are carried out, they must be performed by specialized companies or by trained staff, in accordance with specific legislation, using chemicals approved by the health agency. (In the wording of Decree no. 10,468 enacted in 2020)
- Article 56. No animals extraneous to the industrial process of animal-product manufacturing establishments may be present.
 - Article 57. All employees must wear suitable, laundered 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 move 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 rooms in the common areas such as canteens, changing-rooms or rest areas must be planned 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 extraneous 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 repair and working order, and minimize the risk of contamination.
- Article 63. The receiving 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 in such conditions 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 entity responsible for the establishment must introduce procedures to ensure that employees working in or passing through product-handling areas are not carriers of foodborne diseases.
- Paragraph 1. Up-to-date doctors' notes must be presented whenever requested in order to prove that employees are not carrying diseases that render them unfit to work in the production of food.
- Paragraph 2. If an employee is found to have, or is suspected of having, an illness or condition that may jeopardize the safety of the product, that employee must be suspended from duties.
- Article 66-A. The Ministry of Agriculture, Livestock and Food Supply will define a procedure to ensure the compliance of public servants working in the inspection and oversight of animal product-manufacturing establishments with the provisions of Paragraph 1 of article 66. (Included by Decree no. 10,468, enacted in 2020)
- 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, anterooms, freezing tunnels and chilling and freezing equipment must be cleaned regularly.
- Article 71. Containers and carts for carrying raw materials and products and bottles must be cleaned before being returned.
- Article 72. In places 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 temperature of 82.2°C (eighty-two point two degrees Celsius) or some other equivalent method recognized by the Department of Inspection of Animal Products.

CHAPTER III

THE DUTIES OF ESTABLISHMENTS

- Article 73. The entities responsible for establishments are required to:
- I obey this Decree and supplementary standards;
- II deploy personnel, whenever necessary, to assist in the performance of inspection work, in accordance with specific standards laid down by the Ministry of Agriculture, Livestock and Food Supply;

- II make available, whenever necessary, in permanently-inspected establishments, the administrative support and the personnel to assist in the performance of **post-mortem** inspection work, in accordance with supplementary standards laid down by the Ministry of Agriculture, Livestock and Food Supply; (In the wording of Decree no. 10,468 enacted in 2020)
 - III provide facilities, equipment and materials deemed essential for inspection and oversight;
- IV provide the 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 following month, and whenever required to;
 - V update the registration data required by SIF, in accordance with supplementary standards;
 - V keep the following up-to-date: (In the wording of Decree no. 10,468, enacted in 2020)
 - a) the registry data of concern to the SIF; and (Included by Decree no. 10,468, enacted in 2020)
- b) the approved plans, in the case of establishments addressed in Paragraph 1 of Article 28, or the deposited documentation in the case of establishments addressed in Paragraph 2 of Article 28; (Included by Decree no. 10,468, enacted in 2020)
- VI notify SIF at least seventy two 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 in the case of an establishment under permanent federal inspection, notify SIF of the performance of slaughter activities and of the time of commencement and likely completion, with advance notice of at least seventy-two hours; (In the wording of Decree no. 10,468 enacted in 2020)
- VII provide material, utensils and specific substances for the taking, storing, packing, protection against tampering and shipping of fiscal samples to laboratories;
- VII provide material, utensils and specific substances for the taking, storing, packing, protection against tampering and shipping of fiscal samples to laboratories; (In the wording of Decree no. 10,468 enacted in 2020)
 - VIII shoulder the cost of fiscal tests 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 visually alter the condemned products, when there are no facilities for immediate transformation:
- X provide substances to denature and permanently visually alter the condemned products, when there are no facilities for its immediate transformation; (In the wording of Decree no. 10,468 enacted in 2020)
- XI keep control of temperatures of raw materials, products, the environment and the technological process that is used, as established in supplementary standards;
- 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, sample-taking, document verification and other activities related to the industrial and sanitary inspection and oversight activities set forth in this Decree and in supplementary standards:
- XV possess a recall program for products made and possibly 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
- XV for the cases listed below, possess a recall program for products produced and possibly shipped by it: (ln the wording of Decree no. 10,468, enacted in 2020)

- a) finding a non-compliance that may pose a health threat; and (<u>Included by Decree no. 10,468, enacted in 2020</u>)
 - b) adulteration; (Included by Decree no. 10,468, enacted in 2020)
- XVI keep auditable records of processes either of conditional use or of the rendering unusable of animal products in accordance with the disposition criteria contained in this Decree or in supplementary standards 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.
- XVI perform, in accordance with the disposition criteria laid down in the present Decree or in supplementary standards published by the Ministry of Agriculture, Livestock and Food Supply, the following treatments of animal products (conditional use, disposition to industrial treatment, rendering unusable) and keep auditable records of the performance of such treatments; (In the wording of Decree no. 10,468 enacted in 2020)
- XVII maintain the facilities, equipment and utensils in an appropriate state of repair for the purpose to which they are intended; (Included by Decree no. 10,468, enacted in 2020)
- XVIII for those establishments inspected periodically, make available a location that is reserved for the use of the Federal Inspection Service (SIF) during inspection activities; (Included by Decree no. 10,468, enacted in 2020)
 - XIX notify the SIF: (Included by Decree no. 10,468, enacted in 2020)
- a) with advance notice of at least five working days of the intention to carry out slaughtering on additional days beyond their regular operations, in order to allow the assessment of authorization, in the case of an establishment under permanent inspection; (Included by Decree no. 10,468, enacted in 2020)
- b) whenever so requested, the establishment's working schedule, which is to contain the nature of the activities to be performed and the times of commencement and likely conclusion, in the case of an establishment under periodical inspection or, in the case of an establishment under permanent inspection, for activities other than slaughter, and (Included by Decree no. 10,468, dated 2020)
- c) halting, or partial or total resumption, of industrial activities; and (<u>Included by Decree no. 10,468, enacted in 2020</u>)
- XX notify the competent unit with at least seventy-two hours' advance notice of the expected arrival of imported animal products that require reinspection. (Included by Decree no. 10,468, enacted in 2020)
- 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 its registration is canceled, the establishment is responsible for rendering unusable the labeling in stock under SIF supervision.
- Paragraph 3. Making personnel available as per item II of the **head provision** will be the responsibility of a legal entity accredited by the Ministry of Agriculture, Livestock and Food Supply. (Included by Decree no. 9,621, enacted in 2018)
- Paragraph 3. The personnel addressed in item II of the **head provision** may be deployed by a legal entity accredited by the Ministry of Agriculture, Livestock and Food Supply, as per the provisions of supplementary standards. (In the wording of Decree no. 10,130, enacted in 2019)
- Paragraph 3. In order to meet the specific demands of importing markets, the personnel addressed in item II of the **head provision** may be deployed by a legal entity accredited by the Ministry of Agriculture, Livestock and Food Supply, as per the provisions of supplementary standards. (In the wording of Decree no. 10,468, enacted in 2020)
- Paragraph 4. The legal entity that has been accredited as per Paragraph 3 is to be remunerated by the establishment that is subject to Federal inspection and oversight. (Included by Decree no. 9,621, enacted in 2018)
- Article 74. Establishments must have self-control programs that have been developed, introduced, maintained, monitored and verified by themselves, containing systematic auditable records proving compliance with the hygiene, health and technological requirements laid down by this Decree and supplementary standards in order to ensure the safety, identity, quality and wholesomeness of their product, from the obtaining and receiving of raw materials, ingredients and inputs, up until the products are shipped.
- Paragraph 1. The self-control programs must include animal welfare, when applicable, GMP, SSOP and HACCP or an equivalent tool recognized by the Ministry of Agriculture, Livestock and Food Supply.

- Paragraph 2. Self-control programs should not be limited to complying with the provisions of Paragraph 1.
- Paragraph 2-A. If computerized systems are used in order to record the data concerning the monitoring and verification of self-control programs, the safety, integrity and availability of the information must be guaranteed by the establishments. (Included by Decree no. 10,468, enacted in 2020)
- Paragraph 3. The Ministry of Agriculture, Livestock and Food Supply shall set forth in supplementary standards those official procedures for the verification of self-controls on production processes applied by establishments in order to ensure the safety and quality 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 standards.
- Sole paragraph. For the traceability of the origin of the milk, it is forbidden to receive refrigerated raw milk transported in a vehicle belonging to individuals or legal entities that either do not have or cannot prove a formal link to the bulk collection program of federally inspected establishments.
- Sole paragraph. For the traceability of the origin of the milk, it is forbidden to receive refrigerated raw milk transported in a vehicle belonging to natural persons or legal entities that either do not have or cannot prove a formal link to the milk-supplier qualification program. (In the wording of Decree no. 10,468 enacted in 2020)
- 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 76. Establishments must present the fiscal and analytical documents and information required by the SIF, as well as records of the controls of the receiving, storage, production, shipping activities or any other records needed for inspection and oversight activities. (In the wording of Decree no. 10,468 enacted in 2020)
- Article 77. Establishments must employ a technically-responsible officer in charge of hygiene, health, and technological operations, whose professional training meets the provisions laid down in specific legislation.
 - Sole paragraph. If the professionals mentioned in the **head provision** are replaced, the 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.
- Article 78. Establishments inspected by the Federal Inspection Service (SIF) cannot receive animal products intended for human consumption that are not clearly marked as manufactured in another SIF-inspected establishment. (In the wording of Decree no. 10,468 enacted in 2020)
- Paragraph 1. Animal raw materials 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 inspection services provided that it meets the conditions set forth in supplementary standards.
- Paragraph 2. The entry of raw materials for producing gelatin and collagen products is permitted when they come from: (In the wording of Decree no. 10,468 enacted in 2020)
- I establishments that are registered with the inspection services of the States, Federal District, and Municipalities; and (Included by Decree no. 10,468, enacted in 2020)
- II hide-processing establishments linked to the competent animal health agency. (Included by Decree no. 10,468/2020)
- Article 79. In SIF-inspected establishments, animal raw materials and residues 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 standards are met. (Revoked by Decree no. 10,468/2020)
- 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 80. If it is found that the original characteristics of preservation have been lost, it is forbidden to recover the cold condition in products and raw materials that have remained at unsuitable temperature conditions. (In the wording of Decree no. 10,468 enacted in 2020)

Sole paragraph. Products and raw materials presenting signs of the loss of their original characteristics of preservation are to be stored in suitable conditions until they are assigned a disposition within the industrial process. (Included by Decree no. 10,468/2020)

- Article 81. Establishments may only display and sell products:
- I that do not pose a public health risk;
- II that have not been altered or fraudulently changed: and
- II that have not been adulterated; (In the wording of Decree no. 10,468 enacted in 2020)
- III whose traceability at the steps of obtaining, receiving, manufacturing and shipping is ensured.
- III whose traceability at the steps of obtaining, receiving, manufacturing and shipping is ensured; and (<u>In the wording of Decree no. 10,468 enacted in 2020</u>)
- IV that meet the applicable specifications set forth in the present decree or in supplementary standards. (Included by Decree no. 10,468, enacted in 2020)

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 produced.

Sole paragraph. Establishments shall take all necessary measures to recall lots of product that pose a public health risk or that have been adulterated. (In the wording of Decree no. 10,468, enacted in 2020)

TITLE V

INDUSTRIAL AND SANITARY INSPECTION

Article 82. The Ministry of Agriculture, Livestock and Food Supply shall, in supplementary standards, set forth procedures for the inspection and oversight of animal products, and shall 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 tests laid down in this Decree, in the Technical Regulation of Identity and Quality (TRIQ), in supplementary standards or in specific legislation, in self-control programs and others that may be necessary, or order such tests to be carried out by the company.

CHAPTER I

INDUSTRIAL AND SANITARY INSPECTION OF MEAT AND MEAT PRODUCTS

Article 84. Federally inspected establishments may slaughter bovids, equids, suids, ovines, caprines, domestic birds, lagomorphs and exotic animals, wild animals and seafood, provided they meet the requirements of this Decree and supplementary standards.

Article 84. Federally inspected establishments may slaughter bevines, buffaloes, equids, suids, evines, caprines, domestic birds, lagomorphs and exetic animals, wild animals and seafood, provided that they meet the requirements of this Decree and supplementary standards. (In the wording of Decree no. 9,069, enacted in 2017)

Article 84. Federally-inspected establishments may slaughter bovines, buffaloes, equids, suids, ovines, caprines, domestic birds, lagomorphs, exotic animals, wild animals, amphibians and reptiles, provided that they meet the requirements of this Decree and supplementary standards. "Article 84. Federally-inspected establishments may slaughter bovines, buffaloes, equids, suids, ovines, caprines, domestic birds, lagomorphs, exotic animals, wild animals, amphibians and reptiles, provided that they meet the requirements of this Decree and supplementary standards. (In the wording of Decree no. 10,468, enacted in 2020)

Paragraph 1. Different species may be slaughtered in one establishment provided that 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, and including the cleaning of facilities and equipment.

Article 84-A. The slaughter establishments are responsible for ensuring the identity, quality and traceability of the products, from the step of obtaining them from primary production up until they are received at the establishment, including transport. (Included by Decree no. 10,468, enacted in 2020)

Paragraph 1. Slaughter establishments receiving animals from primary production must maintain an up-to-date registry of farmers. (Included by Decree no. 10,468, enacted in 2020)

Paragraph 2. Slaughter establishments receiving animals from primary production are responsible for introducing programs to enhance the quality of the raw material, and to provide continuing education for farmers. (Included by Decree no. 10,468, enacted in 2020)

Section I

Ante-mortem inspection

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

Article 85. Animals for slaughter may only be received in any area of the establishment after the SIF has been notified in advance. (In the wording of Decree no. 10,468, enacted in 2020)

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

Sole paragraph. Animals arriving without their transport documentation may not be slaughtered.

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 vehicles that have been sealed by sanitary determination may only be unloaded in the presence of a competent representative of the SIF.

Sole paragraph. Animals arriving in vehicles that have been sealed by sanitary determination as defined by the competent animal health agency, may only be unloaded in the presence of a public servant of the SIF. (In the wording of Decree no. 10,468, enacted in 2020)

Article 88. Establishments are compulsorily to adopt measures to avoid any abuse of animals, and to apply measures to protect the animals and ensure their welfare, from the moment they are loaded at origin, up until 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 where there is a lack of information about compliance with the withdrawal periods for veterinary products, the SIF may seize such lots of animals or products, take samples and adopt such other procedures as will 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 public servant 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-based check, an assessment 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 suspected case will lead to the identification and isolation of the animals involved. When necessary the entire lot will be isolated.

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

Paragraph 3. Suspected cases will be evaluated by a Federal Agricultural Auditor/Inspector who has graduated in Veterinary Medicine, or by a veterinarian who is part of the Federal Inspection Service, and may include a clinical examination, necropsy, and other procedures in order to diagnose and determine the disposition, applying animal health measures when the case so demands. (In the wording of Decree no. 10,419, enacted in 2020)

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

Paragraph 5. Among the species of seafood to be slaughtered, only amphibians and reptiles must undergo ante-mortem inspection.

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 no. 9,069, enacted in 2017)

Paragraph 6. Among the species of seafood to be slaughtered, only amphibians and reptiles must undergo **ante-mortem** inspection. (Included by Decree no. 9,069, enacted in 2017)

Article 91. In the **ante-mortem** inspection, whenever animals with suspected zoonoses, or suspected infectious or 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 standards are suspected, slaughter must also take place separately, in order for the lesions to be examined better, and for supplementary verifications to be performed.

Article 92. Whenever suspected infectious or contagious diseases that are immediately notifiable are identified, as determined 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 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 come into contact with 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 specifically designated for this purpose.

Article 94. Suids presenting acute erysipelas, with diffuse cutaneous erythema, must be slaughtered separately. (Revoked by Decree no. 10,468, enacted in 2020)

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

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

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. The rule set forth in this **head provision** does not apply to poikilothermic animals.

Article 97. If there are dead animals or non-ambulatory animals on transport vehicles that have arrived at the facilities for the receiving or housing of animals, or at any other outbuilding of the establishment, the SIF must be notified immediately 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 the limits laid down in the supplementary standards, 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/Auditor who has graduated in Veterinary Medicine.

Paragraph 2. Necropsies on poultry are to be performed by a Federal Agricultural Inspector/Auditor (AFFA) who has graduated in veterinary medicine, or by a veterinarian who is part of the Federal Inspection Service, should there be a clinical suspicion of disease, and a necropsy is mandatory when laid down in supplementary standards. (In the wording of Decree no. 10,419, enacted in 2020)

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 a Federal Agricultural Inspector/Auditor who has graduated in Veterinary Medicine.

Article 98. Carcasses of animals that die accidentally on the premises of the establishment, provided they are bled immediately, may go to conditional use after a **post-mortem** examination, at the discretion of a Federal Agricultural Inspector/Auditor who has graduated in Veterinary Medicine or a veterinarian who is a member of the Federal Inspection Service team. (In the wording of Decree no. 10,419, enacted in 2020)

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 or 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 2. If the suspected disease is confirmed, the dead animal and its remains are to be: (In the wording of Decree no. 10,468, enacted in 2020)

- I incinerated; (Included by Decree no. 10,468, enacted in 2020)
- II autoclaved in a designated device; or (Included by Decree no. 10,468, enacted in 2020)
- III submitted to an equivalent treatment that ensures the destruction of the agent. (Included by Decree no. 10,468, enacted in 2020)

Paragraph 3. After the completion of the necropsy operations, the vehicle or container that was used in order to move the animals, the floor of the room and all equipment and utensils that have come into contact with the animal must be washed and disinfected.

Article 100. Whatever the reason 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 100. Whatever the reason for conducting them, necropsies must be performed in a specific location and the animals and their remains are to be given a disposition in accordance with this Decree and supplementary standards. (In the wording of Decree no. 10,468, enacted in 2020)

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

Section II

The 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, respecting the particular nature of each species, and in accordance with 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 standards.

Article 104. Uncastrated suids or those showing signs of recent castration may not be slaughtered. (Revoked by Decree no. 10,468, enacted in 2020)

Sole paragraph. Suids that have been castrated by non-surgical means, provided that the process has been approved by the Ministry of Agriculture, Livestock and Food Supply, may be slaughtered. (Revoked by Decree no. 10,468, enacted in 2020)

Sub-section I

Emergency Slaughter

Article 105. Animals arriving at the establishment in poor health, whether they are unable to walk unaided to the slaughter facility or otherwise, 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, hemorrhages, suffering from hyper- or hypothermia, or that are non-ambulatory, animals showing neurological clinical signs, and other conditions laid down in supplementary standards.

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

Article 106. Emergency slaughter is to be carried out in the presence of a Federal Agricultural Inspector/Auditor (AFFA) who has graduated in Veterinary Medicine or of a veterinarian who is a member of the Federal Inspection Service team. (In the wording of Decree no. 10,419, enacted in 2020)

Sole paragraph. If it is impossible for the professional addressed in the **head provision** to accompany the emergency slaughter, the establishment is to slaughter the animal humanely and separate it for subsequent necropsy. (Included by Decree no. 10,419, enacted in 2020)

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 107. The SIF must collect material from animals that have been given the disposition of emergency slaughter and that show neurological clinical signs, and send it to official laboratories for diagnosis; the SIF must also take other measures laid down in the animal health legislation. (In the wording of Decree no. 10,468, enacted in 2020)

Article 108. Animals showing clinical signs of paralysis from metabolic or pathological changes are to undergo emergency slaughter.

Sole paragraph. In the case of 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 there is doubt diagnosing a process of septicemia, 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 standards, they are deemed unfit for human consumption.

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

Sub-section II

Normal Slaughter

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

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

Paragraph 2. Animals may be slaughtered in accordance with religious principles, provided that the by-products obtained 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 113. Before reaching the slaughter facility, the animals must pass through a shower using sufficient water to thoroughly cleanse them and remove dirt, in accordance with the specific nature of each species. (In the wording of Decree no. 10,468, enacted in 2020)

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 standards.

Article 115. Birds may be plucked:

- I dry;
- II after scalding in preheated water that is continuously renewed; or
- III by another process approved by the Department of Inspection of Animal Products.

Article 116. It is mandatory that whenever the carcasses of suids are delivered for consumption skin-on, they be completely dehaired by prior scalding with hot water, or another similar process approved by the Department of Inspection of Animal Products.

- Paragraph 1. Dehairing 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 dehairing.
 - Paragraph 3. The water in hog scalding systems must be continually renewed.
- Paragraph 4. The use of technological adjuvants in the scald water may be authorized if it is 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 117. Whenever deficiencies have been identified during slaughter, the SIF may order the interruption of slaughter or a reduction in the slaughter speed. (In the wording of Decree no. 10,468, enacted in 2020)
- Article 118. Evisceration must be performed in a location 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 standards.
 - Paragraph 1. Trimming operations are not allowed before the completion of the post-mortem examination.
- Paragraph 2. It is the responsibility of the establishment to maintain the 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 previously been approved by the Department of Inspection of Animal Products.

Article 120. Inflation is permitted as an ancillary method to the technological process of dehiding and deboning of slaughter species. (In the wording of Decree no. 10,468, enacted in 2020)

- 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 they are stored in freezers where other raw materials are already being stored.
- Sole paragraph. The chilling or freezing of the products addressed in the **head provision**, prior to their transportation, is mandatory. (<u>Included by Decree no. 10,468, enacted in 2020</u>)
- Article 122. Carcasses and carcass parts, when air-chilled, 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 the pieces and the 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. The Specified Risk Materials (SRMs) for communicable spongiform encephalopathies of all ruminants raised for slaughter must be removed, segregated and rendered unusable.
- Paragraph 1. The procedures addressed in the **head provision** must be performed by establishments, pursuant to supplementary standards.
- Paragraph 2. The animal health legislation will specify the organs, carcass parts, and animal tissues classified as SRM.
 - Paragraph 3. All use of SRM 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/Auditor trained in Veterinary Medicine may be assisted by properly trained Inspection Agents (AISIPOAs—Sanitary and Industrial Inspection Agents for Animal Products) and inspection auxiliaries.
- Article 125. In performing **post-mortem** inspection procedures, a Federal Agricultural Inspector/Auditor who has graduated in Veterinary Medicine, or a veterinarian who is part of the Federal Inspection Service team, may be assisted by properly-trained Inspection Agents (AISIPOAs Sanitary and Industrial Inspection Agents for Animal Products) and inspection auxiliaries. (In the wording of Decree no. 10,419, enacted in 2020)
- Sole paragraph. The inspection team must possess enough staff to perform its activities, as laid down in supplementary standards.
- Article 126. **Post-mortem** inspection consists of the examination of carcasses, carcass parts, cavities, organs, tissues and lymph nodes, by means of observation, palpation, the sense of smell, and incisions, when necessary, as well as other procedures defined in supplementary standards for each animal species.
- Article 127. All organs and carcass parts must be examined in the slaughter rooms immediately after they have been removed from their respective carcasses, and a clear correspondence must always be maintained between the former and the latter.
- 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, cleared to continue on the inspection lines, pursuant to supplementary standards.
- Article 129. All carcasses, carcass parts and organs examined on the inspection lines, and which present lesions or abnormalities that can affect the carcass and other organs, must be railed out to the Department of Final Veterinary Inspection to be examined, judged and receive the appropriate disposition.
- Paragraph 1. The Federal Agricultural Inspector/Auditor (AFFA) who has graduated in Veterinary Medicine will be responsible for evaluating the carcasses, carcass parts, and organs, and providing a disposition for them.

Paragraph 1. The Federal Agricultural Inspector/Auditor (AFFA) who has graduated in Veterinary Medicine, or a veterinarian who is part of the Federal Inspection Service team, will be responsible for evaluating the carcasses, carcass parts, and organs, and providing a disposition for them. (In the wording of Decree no. 10,419, enacted in 2020)

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

Paragraph 3. Condemned carcasses, carcass parts and organs must be held by the SIF and will be removed from the Final Inspection Department using specific piping, 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.

Paragraph 4. The condemned material is to be rendered unrecognizable when: (In the wording of Decree no. 10,419, enacted in 2020)

- I it is not processed on the day of slaughter; or (Included by Decree no. 10,419, enacted in 2020)
- II it is transported for transformation in another establishment. (<u>Included by Decree no. 10,419, enacted in 2020</u>)

Paragraph 5. If it is impossible to render it unrecognizable as addressed in Paragraph 4, the condemned material will be denatured. (Included by Decree no. 10,419, enacted in 2020)

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 quarters of the carcasses of bovids and suids will be dispensed with in establishments that slaughter and debone in the same industrial unit, provided that the provisions laid down in supplementary standards are followed.

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

Article 132. Whenever so requested by the owners of the slaughtered animals, the SIF operating in the slaughter establishment will provide a report which contains possible diseases or pathologies that have been diagnosed in the carcasses, even if presumptively, during sanitary inspection, and the dispositions that were given. (In the wording of Decree no. 10,468, enacted in 2020)

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

Sole paragraph. The SIF shall take samples, whenever necessary, for laboratory testing in order 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 — and additionally:

- 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, yet not affecting the overall condition of the carcass, 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 the overall condition of the carcass, 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 specific points examined routinely on the inspection line, and affect the overall state of the carcass, and additionally:
- 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 by means of sterilization by heat treatment, after the affected organs have been removed and condemned;
- II when the lesion is discrete and limited to the tongue, possibly affecting the corresponding lymph nodes, or otherwise, the head meat may go to conditional use by means of sterilization by heat treatment, 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 tracks of fistulae.
- Article 136. The carcasses of animals affected by extensive diseases of pulmonary tissue, in either an acute or a chronic process, or in a purulent, necrotic, gangrenous, or 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 the phase of resolution, having involvement of the lung tissue and pleura, with exudate, and affecting the regional lymphatic chain, but without affecting the overall condition of the carcass, are to go to conditional use by means of heat treatment.
- Paragraph 2. In those cases where there is pleural adhesion without any kind of exudate, that are the result of resolved pathological processes and without any repercussions in 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 sustained during 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, the consumption of which might cause infection or food poisoning, are to be condemned.

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

Sole paragraph. These include, without being restricted to the diseases addressed in the **head provision**, the following cases: (In the wording of Decree no. 10,468, enacted in 2020)

- 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; (Repealed by Decree no. 10,468, enacted in 2020)
- VII generalized hypertrophy of the lymph nodes; and
- VIII diffuse reddening of the hide.

Article 138. The carcasses and organs of animals testing positive for brucellosis in serology must be condemned if the animals presented with a fever at the **ante-mortem** inspection.

- Article 138. The carcasses and organs of animals testing positive for brucellosis in serology must be condemned if the animals presented with a fever at the **ante-mortem** inspection. (<u>In the wording of Decree no. 9,069, enacted in 2017</u>)
- Paragraph 1. Animals reacting positively to diagnostic tests for brucellosis must be slaughtered separately and their carcasses and organs must be sent to the Final Veterinary Inspection Department.
- Paragraph 1. Animals reacting positive to brucellosis diagnostic tests are to be slaughtered separately. (<u>In the wording of Decree no. 10,468, enacted in 2020</u>)
- Paragraph 2. The carcasses of animals that test positive for brucellosis and that present with localized lesions are to go to conditional use by means of heat treatment after the affected areas including the udders, genital tracts and blood have been removed and condemned.
- Paragraph 2. The carcasses of pigs, goats, sheep and buffaloes that either react positively or do not react to brucellosis diagnostic tests, and presenting a localized lesion, are to go to conditional use by means of heat treatment, after the affected areas have been removed and condemned. (In the wording of Decree no. 9,069 enacted in 2017)
- Paragraph 3. The carcasses of animals testing positive for brucellosis diagnostic tests, without indicative lesions, may be approved for raw consumption but their udders, genital tracts and blood are to be condemned.
- 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 approved to be consumed fresh, after the affected areas have been removed and condemned. (In the wording of Decree no. 9,069, enacted in 2017)
- Paragraph 4. The carcasses of animals testing positive for brucellosis diagnostic tests, without indicative lesions, may be approved for raw consumption. (<u>Included by Decree no. 9,069</u>, <u>enacted in 2017</u>)
- Paragraph 5. The organs, udder, genital tract and blood must be condemned in the events of paragraphs 2, 3, and 4. (Included by Decree no. 9,069, enacted in 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, hair, 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 hypochlorite, 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 hog scalding tank through which an anthrax-infected animal may have passed must be disinfected and immediately drained to the industrial wastewater system.
 - Article 141. Carcasses and organs of animals infected with Blackleg 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 directed to salting, heat treatment, 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, and those reeking of medication, urine, sex hormones, or excrement, or having any 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 poorly-bled animals must, at the discretion of the SIF, be condemned, or go to heat treatment.

Article 145. Livers with atrophic or hypertrophic cirrhosis are to be condemned.

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

Article 146. Organs showing such changes as congestion, infarcts, fatty degeneration, angiectasia, hemorrhages or abnormal color, whether related or otherwise to systemic pathological processes, are to 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, are to be condemned when it is impossible completely to remove the contaminated area.

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

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

Paragraph 3. As provided for in supplementary standards, 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 are to be condemned.

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

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

Article 149. Carcasses showing widespread edema on post-mortem examination are to be condemned.

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

Article 150. The 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 approved for use.

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 approved for use.

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 hydatid cysts must be condemned when there is cachexia.

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

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

Sole paragraph. The carcasses of animals showing yellow fat owing to nutritional factors, or to the breed itself, may be approved for processing.

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

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

Article 158. Hearts with lesions of myocarditis, endocarditis or pericarditis are to be condemned.

Paragraph 1. The carcasses of animals with cardiac lesions are to 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, at the discretion of the SIF, be approved for processing, provided that the carcasses have not been affected.

Article 159. Kidneys showing signs of nephritis, nephrosis, pyelonephritis, uronephrosis, urinary cysts or other infections, are to be condemned, and the lesions must be investigated for a possible link to infectious or contagious, or parasitic diseases, as well as whether they have led 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 have been 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 discrete, circumscribed non-specific lesions in lymph nodes, not affecting the overall state of the carcass, the drainage area of this lymph node may be condemned, while the rest of the carcass is approved for use 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.

Article 162. The carcasses and organs of animals presenting with mastitis are to be condemned whenever there is systemic involvement. (In the wording of Decree no. 10,468, enacted in 2020)

Paragraph 1. The carcasses and organs of animals presenting with mastitis, without systemic involvement, are to be approved for use after the mammary gland has been removed and condemned.

Paragraph 1. The carcasses and organs of animals presenting acute mastitis, when there is no systemic involvement, are to be given the disposition of heat sterilization after the mammary gland has been removed and condemned. (In the wording of Decree no. 10,468, enacted in 2020)

Paragraph 1-A. The carcasses and organs of animals presenting chronic mastitis, without systemic involvement, may be approved for use after the mammary gland has been removed and condemned. (Included by Decree no. 10.468/2020)

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 are to be condemned.

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

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.

Article 165. The carcasses of animals with extensive neoplasms, with or without metastases, and with or without involvement of their overall state, must be condemned. (In the wording of Decree no. 10,468, enacted in 2020)

Paragraph 1. The carcasses and 03 (three) organs of animals with malignant lymphoma must be condemned. (Revoked by Decree no. 10,468, enacted in 2020)

Paragraph 2. Every organ or carcass part affected by a neoplasm must be condemned. (Revoked by Decree no. 10,468, enacted in 2020)

Paragraph 3. In the event of extensive neoplastic lesions that are localized and do not affect the overall state, then the carcass and organs may be sent to heat sterilization after the involved parts and organs have been removed and condemned. (Revoked by Decree no. 10,468, enacted in 2020)

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

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

Article 167. The carcasses of animals showing signs of recent delivery or miscarriage, provided that there are no signs of infection, may go to conditional use after heat treatment, while the genital tracts, udders 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, are to be condemned.

Sole paragraph. Carcasses may be authorized when the infestation is discrete and is 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 processing after the affected areas have been removed and condemned.

Article 171. The carcasses of animals carrying tuberculosis must be condemned when:

Article 171. The carcasses of animals with tuberculosis must be condemned when: (In the wording of Decree no. 9,069, enacted in 2017)

- I the animal is febrile at **ante-mortem** examination;
- II there is cachexia;
- III there are tubercular lesions in the muscles, bones, 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 site chosen for examination; 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 lesions are found 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 the 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 are to go to heat sterilization, provided that 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 approved for processing, 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 intended for conditional use, as laid down in this Decree, must, at the discretion of the SIF, undergo one of the following treatments:
- Article 172. Products intended for conditional use as a result of **ante-mortem** and **post-mortem** inspection decisions, as provided for in the present Decree and in supplementary standards, are, at the discretion of the SIF, to undergo one of the following treatments: (In the wording of Decree no. 10,468, enacted in 2020)
 - I cold treatment, at a temperature no higher than -10°C (minus ten degrees Celsius) for ten days;
- II salting, in brine at no lower than 24°Be (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 76.6°C (seventy-six point six degrees Celsius) for at least thirty minutes;
 - b) heat fusion at a minimum temperature of 121°C (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 ultimately ensured, and that the technical and scientific basis is approved by the Department of Inspection of Animal Products.

Paragraph 3. If there is no specific equipment or there are no specific 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 poultry and lagomorphs

Article 173. For the inspection of poultry and lagomorphs, the provisions of Section III of this Chapter will apply as far as is suitable, in addition to those of this particular Sub-Section and supplementary standards.

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 suspected product and hold it in isolation until a definition is made of the epidemiological animal health measures to be adopted.

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

Article 175. The carcasses or organs of birds 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:

Article 175. The carcasses or organs of birds showing signs of an inflammatory process or the characteristic lesions of arthritis, airsacculitis, coligranuloma, dermatosis, dermatitis, cellulitis, pericarditis, enteritis, oophoritis, hepatitis, salpyngitis, and ascitic syndrome, must be assessed in accordance with the following criteria: (In the wording of Decree no. 10,468, enacted in 2020)

- 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, or 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.

Paragraph 1. For abnormal or pathological conditions not provided for in the **head provision**, the final disposition shall be at the discretion of the SIF. (<u>Included by Decree no. 10,468, enacted in 2020</u>)

Paragraph 2. The disposition criterion addressed in Paragraph 1 does not apply in cases of myopathy and of tibial dyschondroplasia, in which case the carcasses of the birds are to be segregated by the establishment for disposition to industrial processing. (Included by Decree no. 10,468, enacted in 2020)

Article 175-A. When, as a result of an operational or technological flaw during slaughter, fractures and contusions occur, or there are signs of poor bleeding-out, the carcasses of the birds are to be segregated by the establishment for disposition to industrial processing. (Included by Decree no. 10,468, enacted in 2020)

Sole paragraph. The rule laid down in the **head provision** does not apply to extensive or generalized contusions, or to cases of diffuse bloody or hemorrhagic areas, in which case the disposition will be given by the SIF on the inspection lines. (Included by Decree no. 10,468, enacted in 2020)

Article 176. In cases of endoparasitosis or ectoparasitosis in birds, or when the carcass as a whole is not affected, 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 the carcasses and organs must be condemned.

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

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

Sole paragraph. Superficial lesions will result in partial condemnation, with the rest of the carcass and organs being approved for processing.

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. If there are lesions of a hemorrhagic disease of rabbits, in addition to the occurrence of myxomatosis, tuberculosis, pseudo-tuberculosis, pyosepticemia, toxoplasmosis, spirochetosis, clostridiosis and pasteurellosis, the carcasses and organs of the lagomorphs are to be condemned.

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

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

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

Sub-section II Post-mortem inspection of bovids

Sub-section II

Post-mortem inspection of bovines and buffaloes (In the wording of Decree no. 9,069, enacted in 2017)

Article 183. For the inspection of bovids, as far as is suitable, what is given in Section III of this Chapter will apply, in addition to this Sub-Section and in supplementary standards.

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 no. 9,069, enacted in 2017)

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

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

Paragraph 1. Intense infection is understood to be 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
- I four or more cysts at the specific points examined routinely on the inspection line (masticatory muscles, tongue, heart, diaphragm and pillars thereof, esophagus and liver); and (In the wording of Decree no. 10,468 enacted in 2020)
- 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 the examination of all the specific points examined routinely on the inspection line and in the corresponding carcass, the carcass will go to conditional use after heat treatment, after the affected areas have been removed and condemned.

Paragraph 2. In the case of mild or moderate infections, characterized by the detection of viable or calcified cysts found in numbers that do not characterize intense infection, and taking into consideration the examination of all the specific points examined routinely on the inspection line and in the corresponding carcass, this carcass will be sent for conditional use after cold or heat treatment, after the affected areas have been removed and condemned. (In the wording of Decree no. 10,468, enacted in 2020)

Paragraph 3. When one viable cyst is found, taking into consideration the specific points 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. (Revoked by Decree no. 10,468, enacted in 2020)

Paragraph 4. When a single calcified cyst is found, taking into consideration all the specific points examined routinely on the inspection line and in the corresponding carcass, the carcass may be sent without restrictions for direct human consumption after the removal and condemnation of the affected area. (Revoked by Decree no. 10,468, enacted in 2020)

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

Paragraph 6. Procedures to test for cysticerci at the specific points examined routinely on the inspection line are to comply with supplementary standards.

Sub-section III

Post-mortem inspection for equids

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

Sole paragraph. Procedures to detect and assess animals infected by **Trichinella spiralis** (trichinellosis), addressed in Article 202, apply to Equidae. (<u>Included by Decree no. 9,069</u>, enacted in 2017)

Article 187. Carcasses and organs of equids 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 lesions indicative of glanders 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 come into contact with 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 come into contact with 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 come into contact with 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, what is given in Section III of this Chapter will apply, as far as is suitable, in addition to this particular Sub-Section and in supplementary standards.

Article 190-A. Carcasses of ovines with intense infection by **Sarcocystis spp** (sarcocystosis) must be condemned. (Included by Decree no. 10,468, enacted in 2020)

Paragraph 1. Intense infection is characterized by the presence of cysts at more than two points on the carcass or in the organs. (Included by Decree no. 10,468, enacted in 2020)

Paragraph 2. In cases of moderate infection, characterized by the presence of cysts at up to two points on the carcass or in the organs, the carcass is to go to cooking, after the affected area has been removed. (<u>Included by Decree no. 10,468, enacted in 2020</u>)

Paragraph 3. In cases of mild infection, characterized by the presence of cysts at a single point on the carcass or in an organ, the carcass is to go to cooking, after the affected area has been removed. (<u>Included by Decree no. 10,468</u>, <u>enacted in 2020</u>)

- Article 191. The carcasses of animals carrying Coenurus cerebralis (coenurosis) when cachectic, must be condemned.
- Article 191. The carcasses of animals infected with **Coenurus cerebralis** (coenurosis), when cachectic, must be condemned. (In the wording of Decree no. 9,069, enacted in 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.
- Paragraph 1. Intense infection means finding five or more cysts, taking into consideration all the specific points examined routinely, and in the carcass musculature.
- Paragraph 2. When more than one cyst, albeit fewer than the number that characterizes intense infection, are found, after examination of all typically-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.
- Paragraph 3. When a single cyst is found, taking into consideration the examination of all specific routinely-examined points, the carcass may be approved for direct human consumption after the affected area is removed and condemned.
- Paragraph 4. Procedures to test for cysticerci at the specific points examined routinely on the inspection line are to comply with supplementary standards.
- Article 193. Carcasses of animals showing caseous lymphadenitis lesions in the lymph nodes of distinct regions, either affecting the overall state of the carcass or otherwise, must be condemned.
- Paragraph 1. Carcasses with localized caseous or calcifying lesions are to go to heat sterilization provided that they allow the removal and condemnation of the drainage area of the affected lymph nodes.
- Paragraph 2. The carcasses of animals with discrete calcified lesions in the lymph nodes may be approved for human consumption after the drainage area of these lymph nodes has been removed and condemned.
 - Paragraph 3. In all cases where the involvement of organs and viscera is shown, they must be condemned.

Sub-section V

Post-mortem inspection in suids

- Article 194. Inspection for suids: Section III of this Chapter will be applied, as far as is applicable, as well as the provisions of this Sub-Section and supplementary standards.
- Article 195. Carcasses presenting skin conditions such as erythema, scleroderma, urticaria, cystic hypotrichosis, mange and other types of dermatitis, may be approved for consumption after the affected areas have been removed, provided that the musculature is normal.
- Sole paragraph. Carcasses affected by advanced-stage mange, showing signs of cachexia or extensive muscle inflammation, are to be condemned.
- Article 196. Carcasses with arthritis in one or more joints, with a lymph node reaction or hypertrophy of the synovial membrane, accompanied by cachexia, are to be condemned.
- Paragraph 1. Carcasses with arthritis in one or more joints, with a lymph node reaction and hypertrophy of the synovial membrane, without repercussions for the overall status: disposition is to be partial use after heat treatment.
- Paragraph 2. Carcasses with arthritis but without a reaction in the lymph nodes or repercussions for their overall status may be approved 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 at the specific points examined routinely 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, albeit less than what has been laid down to characterize intense infection, and taking into consideration the specific points examined routinely 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 a single viable cyst is found, taking into consideration the specific points examined routinely on the inspection line and in the corresponding carcass, the carcass must be sent for conditional use after cold or salting treatment, and after the affected area has been removed and condemned.

Paragraph 4. When a single calcified cyst is found, taking into consideration all the specific points examined routinely on the inspection line and in the corresponding carcass, the carcass may be approved for direct human consumption after the affected area has been removed and condemned.

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

Paragraph 6. Procedures to test for cysticerci at the specific points examined routinely on the inspection line are to comply with supplementary standards.

Paragraph 7. Fatty tissue from intensely infected carcasses may be made use of for the manufacture of lard, by 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 standards.

Sole paragraph. Carcasses with a milder form of boar taint may go to the manufacture of cooked pork products. (Revoked by Decree no. 10,468, enacted in 2020)

Article 198. The carcasses of suids presenting boar taint are to be segregated by the establishment and given the disposition to go for industrial processing. (In the wording of Decree no. 10,468, enacted in 2020)

Article 199. Carcasses of suids with erysipelas and presenting multiple skin lesions, arthritis aggravated by necrosis, or when there are signs of a systemic effect, are to be condemned.

Paragraph 1. In cases of localized erysipelas-related vegetative endocarditis where there are no systemic changes, or in cases of chronic arthritis, the carcass will go to heat-treatment for conditional use, after the organ or affected areas have been condemned.

Paragraph 2. When a skin lesion is discrete and localized, and there is no involvement of the organ or carcass: the disposition of the carcass is 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 single primary infection site, such as in the cervical, mesenteric or mediastinal lymph nodes, and judged to be fit for consumption, 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 distinct sites — either the lymph nodes of distinct organs or those with the concomitant presence of lesions in lymph node and one organ — are to go to conditional use after heat treatment, after the affected areas have been condemned.

Article 201. The carcasses of pigs with swine fever must be condemned.

Paragraph 1. There must be total condemnation when the 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) are to go to conditional use having undergone cold treatment.

Paragraph 1. The cold treatment must comply with the following time-temperature parameters:

I - thirty days at -15°C (minus fifteen degrees Celsius);

II - twenty days at -25°C (minus twenty-five degrees Celsius); or

III - twelve days at -29°C (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 standard.

Paragraph 3. Procedures to detect **Trichinella spiralis** in susceptible species will be laid down in supplementary standards. (Included by Decree no. 9,069, enacted in 2017)

Article 203. All suids that have died of asphyxiation, whatever the cause, and those that have been scalded having fallen alive into the scalding tank, must be condemned.

Article 203. All Suidae that have died of asphyxiation, whatever the cause, and those that have been scalded alive, must be condemned. (In the wording of Decree no. 9,069, enacted in 2017)

Sole paragraph. The deaths from asphyxiation provided for in the **head provision** exclude those from gas stunning, provided that sticking follows immediately.

Sub-section VI

Post-mortem inspection in seafood

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

Sole paragraph. The term **post-mortem** does not apply to those species of seafood that are sold alive. (Revoked by Decree no. 10,468, enacted in 2020)

Article 204-A. The slaughter and processing of amphibians and reptiles not meeting the provisions of the environmental legislation are forbidden. (<u>Included by Decree no. 10,468, enacted in 2020</u>)

Article 204-B. The carcasses, parts and organs of amphibians and reptiles showing lesions or abnormalities that might make them unfit for consumption are to be identified and taken to a specific location for inspection. (Included by Decree no. 10,468, enacted in 2020)

Sole paragraph. The carcasses, parts and organs of amphibians and reptiles deemed unfit for human consumption will be condemned. (Included by Decree no. 10,468, enacted in 2020)

Article 204-C. In the event of conditional use, the seafood must undergo one of the following treatments: (Included by Decree no. 10,468, enacted in 2020)

- I freezing; (Included by Decree no. 10,468, enacted in 2020)
- I salting; or (Included by Decree no. 10,468, enacted in 2020)
- III heat treatment. (Included by Decree no. 10,468, enacted in 2020)

CHAPTER I-A

THE INDUSTRIAL AND SANITARY INSPECTION OF SEAFOOD AND SEAFOOD PRODUCTS (Included by Decree no. 10,468, enacted in 2020)

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

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 standards.

Article 207. It is forbidden to receive and process seafood captured or taken without complying with environmental and fisheries legislation.

Article 207-A. The establishment is responsible for ensuring the identity, quality and traceability of the seafood, from the step of obtaining it from primary production up until when it is received at the establishment, including transport. (Included by Decree no. 10,468, enacted in 2020)

Paragraph 1. Establishments receiving seafood from primary production must possess an up-to-date registry of suppliers, containing, as the case may be, producers and fishing vessels. (<u>Included by Decree no. 10,468, enacted in 2020</u>)

Paragraph 2. Establishments receiving seafood from primary production are responsible for introducing raw material quality improvement programs as well as programs for providing suppliers with continuing education. (<u>Included by Decree no. 10,468</u>, enacted in 2020)

Article 207-B. When seafood from primary production is not unloaded directly at a SIF-inspected establishment, it must be unloaded at an intermediate location, under the hygiene and sanitary control of the establishment. (<u>Included</u> by Decree no. 10,468, enacted in 2020)

Paragraph 1. The intermediate facility addressed in the **head provision** must be mentioned in the self-control program of the establishment to which it is linked. (Included by Decree no. 10,468, enacted in 2020)

Paragraph 2. The establishment is to ensure: (Included by Decree no. 10,468, enacted in 2020)

- I the traceability of the seafood that it receives; and (Included by Decree no. 10,468, enacted in 2020)
- II that the operations performed at the intermediate facility addressed in the **head provision**: (Included by Decree no. 10,468, enacted in 2020)
 - a) do not compromise the quality of the seafood; and (Included by Decree no. 10,468, enacted in 2020)
- b) are not industrial in nature; washing of the surface of the seafood using potable water, grading, packing into transportation boxes and adding ice, are all allowed, provided that appropriate conditions are made available for such purposes. (Included by Decree no. 10,468, enacted in 2020)

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:

Article 209. Without prejudice to the provisions of the present Chapter, the controls of seafood and seafood products performed by the establishment, as far as is applicable, encompass: (In the wording of Decree no. 10,468, enacted in 2020)

- 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 fish:
- a) clean body surface, with a certain metallic sheen and multicolored reflections appropriate 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: firm and normal in shape, when pressure is exerted by the fingers, the indentation should not be long-lasting;

- e) shiny scales, adhering well to the skin, and the fins should offer resistance to the provoked movements;
- f) flesh: firm, elastic in consistency, with the natural color of the species;
- g) the viscera should be undamaged, well-differentiated, and the peritoneum should adhere to the wall of the coelomic cavity;
 - h) closed anus; and
 - i) distinctive odor, characteristic for the species;
 - II crustaceans:
 - a) the overall appearance is shiny and moist;
 - b) body holds its natural curvature, is rigid, joints firm and resistant;
 - c) the carapace adheres well to the body;
 - d) no strange colorations the color is appropriate to the species;
 - e) bright, protruding eyes;
 - f) characteristic pleasant odor; and
 - g) in the case of lobsters, crabs and **siris** (Portunidae), they should be alive and vigorous;
 - III mollusks:
 - a) bivalves:
 - 1. must be alive, with their valves shut, retaining clean colorless water in the shells;
 - 2. characteristic pleasant odor; and
 - 3. flesh: moist, adhering to the shell, spongy in 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. flesh: moist, adhering to the shell, with the characteristic color for each species;
 - 2. characteristic pleasant odor; and
 - 3. they should be alive and vigorous;
 - IV amphibians:
 - a) frog meat:
 - 1. mild, characteristic odor for the species;
 - 2. pale pink flesh, white and shiny close to the joints;
 - 3. absence of lesions or extraneous elements; and

4. firm, elastic, tender texture; 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) meat of Chelonians:
 - 1. mild characteristic odor;
 - 2. the color is characteristic of the species, free of dark blemishes; and
 - 3. firm, elastic, tender texture.

Paragraph 1. The sensory characteristics addressed in this article extend, insofar 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 standard by the Ministry of Agriculture, Livestock and Food Supply.

Paragraph 3. The several types of seafood addressed in items I to III of the **head provision** must be assessed for their sensory characteristics by establishment-trained staff, using a scientifically and technically-based point-awarding table for classification, pursuant to rules defined in supplementary standards, or if such standards do not exist, in international recommendations. (In the wording of Decree no. 10,468, enacted in 2020)

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 pH of the meat below 7.00 (seven exactly) in fishes;
 - II pH of the meat below 7.85 (seven point eight five) in crustaceans;
 - III pH of the meat 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. Base scores may be established for pH and total volatiles that are different from those laid down in this article for certain species, to be defined in supplementary standards, 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 for the presence of parasites, is mandatory.

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

Sole paragraph. The verification addressed in the **head provision** is to be performed by trained establishment personnel, as provided for in supplementary standards, or if such standards do not exist, in international recommendations. (In the wording of Decree no. 10,468, enacted in 2020)

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 213. The on-board bleeding, gutting and deheading of seafood is authorized. (In the wording of Decree no. 10,468, enacted in 2020)

Paragraph 1. In their technically-based self-control programs, establishments must address: (Included by Decree no. 10,468, enacted in 2020)

- I the type of fishing; (Included by Decree no. 10,468, enacted in 2020)
- II the capture time; (Included by Decree no. 10,468, enacted in 2020)
- III the preservation method; (Included by Decree no. 10,468, enacted in 2020)
- IV the seafood species to be submitted to the activities addressed in the **head provision**; and (<u>Included by</u> Decree no. 10,468, enacted in 2020)
- V the requirements for the vessels that can perform the activities addressed in the **head provision**. (<u>Included by Decree no. 10,468</u>, <u>enacted in 2020</u>)

Paragraph 2. At the receiving step, the establishment is to submit the seafood that is undergoing the activities addressed in the **head provision** to quality control, by means of sensory tests and the assessment of chemical, physical and biological hazards. (Included by Decree no. 10,468, enacted in 2020)

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

Article 214. Seafood displaying injuries, mutilations, deformations, color changes, localized parasites, or other abnormalities that do not make it unfit for human consumption in the form in which it presents, may undergo industrial processing in accordance with supplementary standards, or if such standards do not exist, in accordance with international recommendations. (In the wording of Decree no. 10,468, enacted in 2020)

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: (Revoked by Decree no. 10,468, enacted in 2020)

I - freezing; (Revoked by Decree no. 10,468, enacted in 2020)

II - salting; or (Revoked by Decree no. 10,468, enacted in 2020)

III - heat. (Revoked by Decree no. 10,468, enacted in 2020)

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

Paragraph 1. If seafood is infested by endoparasites of the family **Anisakidae**, the products may only go for consumption in the raw state after they have been submitted to freezing at a temperature of -20°C (minus twenty degrees Celsius) for seven days, or -35°C (minus thirty-five degrees Celsius) for fifteen hours. (Included by Decree no. 10,468, enacted in 2020)

Paragraph 2. In the cases addressed in the **head provision** and Paragraph 1, other processes may be used that ultimately attain the same guarantees, provided that they are technically and scientifically-based and have been approved by the Department of Inspection of Animal Products, of the Secretariat of Animal and Plant Health, of the Ministry of Agriculture, Livestock and Food Supply. (Included by Decree no. 10,468, enacted in 2020)

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.

Article 217. Seafood, and parts and organs thereof, showing lesions or abnormalities that make them unfit for consumption are to be segregated and condemned. (In the wording of Decree no. 10,468, enacted in 2020)

CHAPTER II

THE 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 219-A. The establishments are responsible for ensuring the identity, quality and traceability of the eggs, from the step of obtaining them from primary production up until when they are received at the establishment, including transport. (Included by Decree no. 10,468, enacted in 2020)

Paragraph 1. Establishments receiving eggs from primary production must maintain an up-to-date registry of egg-producers. (<u>Included by Decree no. 10,468, enacted in 2020</u>)

Paragraph 2. Establishments receiving eggs from primary production are responsible for introducing raw material quality improvement programs as well as programs for providing egg-producers with continuing education. (Included by Decree no. 10,468, enacted in 2020)

Article 220. Eggs may only be displayed for human consumption having undergone prior inspection and classification as laid down in this Decree and in supplementary standards.

Article 221. For the purposes of the provisions 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 standards.

Article 222. Eggs received at the egg and egg-product 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:

Article 223. Egg and egg-product establishments must apply the following procedures: (<u>In the wording of Decree</u> no. 10,468, enacted in 2020)

- I general appreciation of the extent to which the shell is clean and intact;
- II ovoscopy;
- III egg classification; and
- IV verification of the extent to which the packaging is hygienic and intact.

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. Class "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 a clear outline, moving slightly when the egg is rotated 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 considered to be 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 at which they did not undergo incubation.
- Sole paragraph. Class "B" eggs will go exclusively to industrial processing.
- Article 227. Clean eggs that are cracked or broken but with intact eggshell membranes must go as quickly as possible to industrial processing.
 - Article 228. Dirty, 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. The following must not be placed in the same, single packaging:
 - I fresh eggs and eggs undergoing conservation processes; and
 - II eggs of different species.
- Article 232. Poultry grower sheds, poultry farms and other poultry raising establishments where zoonotic diseases, for which the official animal health service possesses proven information, are active, may send their egg output to consumption in their present form.
- Article 232. Poultry grower sheds, poultry farms and other poultry-raising establishments where zoonotic diseases, for which the official animal health service possesses proven information, are active, may not send their egg output for consumption in their present form. (In the wording of Decree no. 9,069, enacted in 2017)

CHAPTER III

THE 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 laboratory tests.
- 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, of 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 this fact is declared in the product's denomination of 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, transitional 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 pooled 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 any herd exploited in order to produce milk.
- Sole paragraph. No stimulants of any nature that may cause harm to animal and human health may be given with the purpose of increasing milk secretion.

- 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 utensils that have been previously washed.
- Paragraph 2. Raw milk kept on the farm must be maintained for a period, and at a temperature, defined in a supplementary standard. (Revoked by Decree no. 10,468, enacted in 2020)
- Paragraph 3. Containers or equipment intended for preserving the milk on the farm until collection must be kept in a designated 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. The milk of females of any species may not be sent to any industrial establishment, if these females:
 - I- belong to a blocked farm;
- I belong to a farm that is under a ban ordered by a competent animal health agency; (In the wording of Decree no. 10,468 enacted in 2020)
 - 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
- V- are undergoing treatment with veterinary products during the withdrawal period recommended by the manufacturer; (In the wording of Decree no. 10,468 enacted in 2020)
 - VI are receiving feed or veterinary products that can impair the quality of the milk; or
- VI are receiving feed or veterinary products that can impair the quality of the milk; or (<u>In the wording of Decree</u> no. 10,468 enacted in 2020)
- VII are on a farm that does not meet the demands of the competent animal health agency. (<u>Included by Decree no. 10,468</u>, enacted in 2020)
- 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 1. The intermediate facility addressed in the **head provision** must formally be part of the self-control program of the industrial establishment to which it is linked. (<u>In the wording of Decree no. 10,468, enacted in 2020</u>)

- Paragraph 2. The 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.
- Paragraph 4. The requirement laid down in Paragraph 1 of Article 483 is waived if the other provisions of the article are met. (Included by Decree no. 10,468, enacted in 2020)
- 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;
 - II standard plate count SPC; (In the wording of Decree no. 10,468 enacted in 2020)
 - III centesimal composition;
 - IV detection of veterinary product residues; and
 - V other tests that may be determined in a supplementary standard.

Sole paragraph. The sample-taking, packing and shipping procedures to be followed are those established by the Ministry of Agriculture, Livestock and Food Supply.

Article 248. Milk is deemed to be that product which 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);
- c) minimum protein content 2.9g/100g (two point nine grams per one hundred grams); (In the wording of Decree no. 10,468 enacted in 2020)
 - d) minimum lactose content 4.3g/100g (four point three grams per hundred grams);
- d) minimum anhydrous lactose content 4.3g/100g (four point three grams per hundred grams); (In the wording of Decree no. 10,468 enacted in 2020)
 - 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 15°C (fifteen degrees Celsius) between 1.028 (one point zero two eight) and 1.034 (one point zero three four) expressed as g/mL;
- h) relative density at 15°C/15°C (fifteen degrees Celsius by fifteen degrees Celsius) between 1.028 (one point zero two eight) and 1.034 (one point zero three four); (In the wording of Decree no. 10,468 enacted in 2020)
- i) cryoscopic rate between -0.530°H (minus zero point five three zero degrees Hortvet) and -0.555°H (minus zero point five five five degrees Hortvet); and
- j) equivalent to -0.512°C (minus zero point five one two degrees Celsius) and to -0.536°C (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 standards.

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 standards.

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 standards.

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

Paragraph 1. Only milk meeting the specifications laid down in Article 249 can be processed. (In the wording of Decree no. 10,468, enacted in 2020)

Paragraph 2. When a non-compliance is detected in tests 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 standards.

Paragraph 3. The disposition of milk that fails to meet specifications set forth in Article 248 and that comes from industrial establishments, provided that 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 tests 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 been 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 pre-heating is understood to mean the application of heat to the milk in a specific apparatus in order to reduce its 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 63°C (sixty-three degrees Celsius) and 65°C (sixty-five degrees Celsius) for thirty minutes, slowly stirring the milk mechanically in a specific apparatus; and
- II rapid pasteurization, which consists of heating the milk in a laminar layer between 72°C (seventy-two degrees Celsius) and 75°C (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 combinations 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 an audible alarm.
- Paragraph 5. Pasteurized milk for direct human consumption must be refrigerated at no higher than 4°C (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 4°C (four degrees Celsius).
- Paragraph 5. Pasteurized milk for direct human consumption is to be: (In the wording of Decree no. 10,468, enacted in 2020)
 - I refrigerated immediately after pasteurization; (Included by Decree no. 10,468, enacted in 2020)
- II automatically bottled in a closed circuit as quickly as possible; and (<u>Included by Decree no. 10,468, enacted in 2020</u>)
- III shipped for consumption or stored in a refrigerated room at a temperature no higher than 5°C (five degrees Celsius). (<u>Included by Decree no. 10,468, enacted in 2020</u>)
- Paragraph 6. Pasteurized milk may be stored refrigerated in insulated tanks equipped with thermometers and automatic stirring devices at a temperature between 2°C (two degrees Celsius) and 4°C (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 2°C (two degrees Celsius) and 5°C (five degrees Celsius). (In the wording of Decree no. 10,468, enacted in 2020)
 - 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 (UHT) is understood to mean the heat treatment of milk at a temperature between 130°C (one hundred and thirty degrees Celsius) and 150°C (one hundred and fifty degrees Celsius), for two to four seconds, in a continuous flow process, after which it is immediately chilled to below 32°C (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 combinations 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, in appropriate equipment, at a temperature between 110° C (one hundred and ten degrees Celsius) and 130° C (one hundred and thirty degrees Celsius) for twenty to forty minutes.
- Sole paragraph. The Department of Inspection of Animal Products may accept other time-temperature combinations 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:

Article 258. The following maximum limits of product temperature must be met for preserving milk: (In the wording of Decree no. 10,468, enacted in 2020)

- I preservation and shipping at the refrigeration station: 4°C (four degrees Celsius);
- I preservation and shipping at the refrigeration station: 5°C (five degrees Celsius); (In the wording of Decree no. 10,468 enacted in 2020)
 - II preservation prior to pasteurization in the milk and dairy product treatment unit: 4°C (four degrees Celsius);
- II preservation prior to pasteurization in the milk and dairy product treatment unit: 5°C (five degrees Celsius); (In the wording of Decree no. 10,468 enacted in 2020)
- III refrigeration after pasteurization: 4°C (four degrees Celsius); (Revoked by Decree no. 10,468, enacted in 2020)
 - IV storing the pasteurized milk in a cold room: 4°C (four degrees Celsius);
- IV storing the pasteurized milk in a cold room: 5°C (five degrees Celsius); (In the wording of Decree no. 10,468 enacted in 2020)
 - V the delivery to consumption of pasteurized milk: 7°C (seven degrees Celsius); and
 - VI storage and delivery to the consumption of sterilized UHT milk: room temperature.

Sole paragraph. The preservation temperature of the refrigerated raw milk at the milk and dairy-product processing unit may be up to 7°C (seven degrees Celsius), when the stored milk presents a maximum microbiological count of 300,000 CFU/mL (three hundred thousand colony-forming units per milliliter) prior to processing. (Included by Decree no. 10,468, enacted in 2020)

- 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 that is 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. Treated milk, in order to be displayed for consumption as standardized, 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).
- 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 no. 10,468, enacted in 2020)
- Article 263. The microbiological standards for treated milk must comply with the Technical Regulation of Identity and Quality (TRIQ).

CHAPTER IV

THE INDUSTRIAL AND SANITARY INSPECTION OF BEE AND HONEYBEE PRODUCTS

Article 264. Inspection of bee and honey-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 tests provided for in supplementary standards, in addition to the necessary indicators of fraud.

Sole paragraph. When a non-compliance is detected in tests 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 standards.

Article 266. Honey, and the honey of stingless bees, when decrystallized, pasteurized or dehumidified, must comply with the time and temperature combination, and with supplementary standards.

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

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. (Revoked by Decree no. 10,468, enacted in 2020)

Article 267. The bee and honeybee-product establishments are responsible for ensuring the identity, quality and traceability of the products, from the step of obtaining them from primary production up until they are received at the establishment, including transport. (In the wording of Decree no. 10,468, enacted in 2020)

Paragraph 1. Establishments receiving products from primary production must maintain an up-to-date registry of honey-producers. (Included by Decree no. 10,468, enacted in 2020)

Paragraph 2. Establishments receiving products from primary production are responsible for introducing raw material quality improvement programs as well as programs for providing farmers with continuing education. (<u>Included by Decree no. 10,468</u>, enacted in 2020)

Article 267-A. The extraction of raw material by the bee-keeper must be performed in a suitable place, including mobile units, that enable the tasks of handling and packing the raw materials in hygienic conditions. (Included by Decree no. 10,468, enacted in 2020)

Article 268. The products of stingless bees must come from breeding facilities, in the form 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 standards.

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, from among the 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 approval by the health regulator and 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, or 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, both provided for in this Decree and 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 insofar 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, as well as 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 standards.

Article 275. Animal products may be irradiated in establishments that are legally in good standing with the competent agencies.

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

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, that have been 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 - in bovids and equids the carcass does not include the hide, hooves, tail, mammary gland, testicles and pizzle except for its roots;

- I in bovines, buffaloes, and equids, the carcass does not include the hide, hooves, tail, mammary gland, testicles and pizzle (except the roots); (In the wording of Decree 9,069 enacted in 2017)
 - II in suids the carcass may or may not include skin, head and feet;
- III in ovines and caprines the carcass does not include skin, feet, mammary gland, testicles and pizzle, except for the roots of the pizzle, and the tail may or may not be present;
- IV in poultry the carcass must be without feathers, while the removal of kidneys, feet, neck, head and reproductive organs in birds that are 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, offal is 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 suids: 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 equids: heart, tongue, liver, kidneys and stomach.

Sole paragraph. In accordance with the regional or traditional habits or the habits of importing countries, the lungs, spleens, spinal cords, mammary glands, testicles, lips, cheeks, cartilage and other parts to be defined in supplementary standards 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 dehaired 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 offal used in making meat products must be free of fat, aponeuroses, lymph nodes, glands, the gallbladders, 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 standards.

Paragraph 1. The use of blood or blood fractions from animals approved 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, offal 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 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 or 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 a longer shelf life owing to their partial dehydration.

Paragraph 1. Both hot and 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 the offal 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 the offal of different animal species, with or without the addition of ingredients, packaged hermetically and subjected to commercial sterilization.

Sole paragraph. The humid heat sterilization process must ensure 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. (Included by Decree no. 10,468, enacted in 2020)

Article 293. For the purposes of this Decree, edible fatty products, according to the animal species from which they are obtained, 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, with or without the addition of ingredients, molded into a flattened round or oval shape and having undergone a specific technological process.

Sole paragraph. Hamburgers may be molded into other formats in accordance with specifications in the registration and on the labeling of the product. (Included by Decree no. 10,468, enacted in 2020)

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, encased in 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, offal and edible animal parts, specific ingredients and seasonings, encased 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, offal 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, *presunto* (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 spam) 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 offal 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 comminuted pork and back fat, with or without the addition of beef or other ingredients, seasoned, packed in natural or artificial casings, cured, spiced with pepper, fermented, matured, dessicated, and which 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 which 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 ribs, or skin, and with the addition of ingredients, and is cured and smoked.

Article 308-A. For the purposes of the present decree, 'pururuca' (crackling) is defined as the meat product obtained from the skin of pigs, with or without the addition of ingredients, that has undergone appropriate heat processing, and that may be manufactured with fat or meat adhering to it. (Included by Decree no. 10,468, enacted in 2020)

Article 308-B. For the purposes of the present decree, 'torresmo' (pork rinds) is defined as the meat product obtained from the fat of pigs, with or without the addition of ingredients, that has undergone appropriate heat processing, and that may be manufactured with fat or meat adhering to it. (Included by Decree no. 10,468, enacted in 2020)

Article 309. For the purposes of this Decree, pâté is a meat product obtained from the meats and offal 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 liquid meat stock.

- Paragraph 2. Meat stock that has been concentrated to a paste-like consistency is to be called meat stock paste, and when seasoned must be called meat stock paste 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 animal 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.
- Paragraph 3. For the purposes of document-based control of traceability in order to comply with the provisions of Paragraph 2, the following documents will be accepted: (<u>Included by Decree no. 10,468, enacted in 2020</u>)
- I the sanitary certification or an equivalent document issued or authorized by the competent animal health authority of the States, Federal District and Municipalities; or (Included by Decree no. 10,468, enacted in 2020)
- II the commercial documentation in the case of hide-processing establishments linked to the competent animal health agency. (Included by Decree no. 10,468, enacted in 2020)
- 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 TRIQs, 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 offal 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 standards.
- Article 316. Within the defined limits, the addition of water or ice to meat products is allowed, in order to facilitate the grinding and homogenization of the paste, or for other technological purposes, when provided for in this Decree and in supplementary standards, 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 standards, 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. If, after sterilization, 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 1°C (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 standards.

Sole paragraph. The incubation test addressed in the **head provision** will be carried out in accordance with what follows below:

- 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 arranged in an oven room with the temperature controlled at 35°C (thirty-five degrees centigrade), and variations of 2.8°C (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 39.5°C (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 39.5°C (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 condition of the recipient, which must not present defects that jeopardize its tamper-free condition;
 - II the presence of signs of swelling;
 - III examination of the surfaces of the containers;
 - IV characteristic smell, taste and coloring;
- V the absence of tissues inferior to or different from those indicated in the approved formula when the contents of the container are fragmented;
 - 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, pharmachemicals and intermediate products, laboratory inputs and products intended for animal feed, with or without a nutritional purpose, obtained from animal tissues, are not included. (Revoked by Decree no. 10,468, enacted in 2020)

Article 322. For the purposes of the present Decree, inedible products are defined as being residues of industrial production and other products not fit for human consumption, including those products: (<u>In the wording of Decree no.</u> 10,468, enacted in 2020)

- I deriving from the condemnation of animal products; or (Included by Decree no. 10,468, enacted in 2020)
- II that are obtained in a manner that is inseparable from the slaughter process itself, including hooves, horns, hair, hides, skins, feathers, down, beaks, blood, fetal blood, carapaces, bones, cartilage, the intestinal mucosa, bile, gallstones, glands, animal remnants and any other animal parts. (Included by Decree no. 10,468, enacted in 2020)

Paragraph 1. The provisions of the present Decree do not apply to products manufactured from the later processing of the products addressed in the **head provision**, such as: (<u>Included by Decree no. 10,468, enacted in 2020</u>)

- I enzymes and enzymatic products; (Included by Decree no. 10,468, enacted in 2020)
- II opotherapeutic products; (Included by Decree no. 10,468, enacted in 2020)
- III pharmachemical products or their intermediate products; (Included by Decree no. 10,468, enacted in 2020)
- IV laboratory inputs; (Included by Decree no. 10,468, enacted in 2020)
- V health-related products; (Included by Decree no. 10,468, enacted in 2020)
- VI products intended for animal feed, with or without a nutritional purpose; (<u>Included by Decree no. 10,468, enacted in 2020</u>)
 - VII fatty products; (Included by Decree no. 10,468, enacted in 2020)
 - VIII fertilizers; (Included by Decree no. 10,468, enacted in 2020)
 - IX biofuels; (Included by Decree no. 10,468, enacted in 2020)
 - X sanitizers; (Included by Decree no. 10,468, enacted in 2020)
 - XI hygiene and cleaning compounds; (Included by Decree no. 10,468, enacted in 2020)
 - XII animal glue; (Included by Decree no. 10,468, enacted in 2020)
 - XIII hides and by-products; and (Included by Decree no. 10,468, enacted in 2020)
 - XIV chemicals. (Included by Decree no. 10,468, enacted in 2020)

Paragraph 2. The Ministry of Agriculture, Livestock and Food Supply will create simplified procedures in order to underpin the transport and sanitary certification of the products addressed in the **head provision** and in Paragraph 1, including compliance with export demands. (<u>Included by Decree no. 10,468, enacted in 2020</u>)

Paragraph 3. The Ministry of Agriculture, Livestock and Food Supply will, when appropriate, create simplified procedures for the migration of the registration, or to restore the registration to regular condition before the competent agency, of establishments that manufacture the products addressed in Paragraph 1 that have been registered in the Department of Inspection of Animal Products, of the Secretariat of Animal and Plant Health or the Ministry of Agriculture, Livestock and Food Supply, thus ensuring the continuity of the performance of the economic activity. (Included by Decree no. 10,468, enacted in 2020)

Paragraph 4. Those products addressed in item II of the **head provision** that are approved for human consumption, pursuant to the present Decree or supplementary standards, are not included among the definitions of the **head provision**. (Included by Decree no. 10,468, enacted in 2020)

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 given this disposition by the SIF. (Revoked by Decree no. 10,468, enacted in 2020)

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. (Revoked by Decree no. 10,468, enacted in 2020)

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. The 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.

Paragraph 2. Condemned materials intended for transformation in another establishment must first be rendered unrecognizable, and they may not be sold or used, under any circumstances, for human food, pursuant to the provisions of Article 129 and Article 493. (In the wording of Decree no. 10,468, enacted in 2020)

Paragraph 3. The provisions of Paragraph 2 apply to the condemned products addressed in Article 481. (Included by Decree no. 10,468, enacted in 2020)

Article 325. When inedible residues are intended for inedible product treatment units, they must be stored and shipped in an exclusive location and transported in sealed vehicles that can be thoroughly cleaned after each operation.

Article 325. When inedible products are intended for transformation in another establishment, they are to be: ($\underline{\text{In}}$ the wording of Decree no. 10,468, enacted in 2020)

- I stored and shipped in a location designated exclusively for this purpose; and (<u>Included by Decree no. 10,468, enacted in 2020</u>)
- II transported in sealed vehicles that can be completely cleaned after the operation. (<u>Included by Decree no. 10,468</u>, enacted in 2020)

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 adjoining the slaughter establishments, intended for the processing of industrial by products. (Revoked by Decree no. 10,468, enacted in 2020)

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 record-keeping procedures, in compliance with specific legislation. (Revoked by Decree no. 10,468, enacted in 2020)

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 provided for 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 330. After they have been obtained, the inedible animal products must not be handled in sections where edible products are made. (In the wording of Decree no. 10,468, enacted in 2020)

Article 331. Slaughter establishments may supply animal organs, tissues or parts as raw material for the manufacture of opotherapeutic products, inputs for the pharmachemical 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 that they possess specific facilities and equipment, and meet the production requirements defined by the competent agency. (Revoked by Decree no. 10,468, enacted in 2020)

CHAPTER III

Section I

Seafood products and by-products

Article 332. Edible seafood products are products made from whole seafood 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. (Revoked by Decree no. 10,468, enacted in 2020)

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 333. For the purposes of the present Decree, fresh seafood is seafood that has not undergone any preservation process except the action of ice, and kept at temperatures close to that of melting ice, except for those seafood products sold alive. (In the wording of Decree no. 10,468, enacted in 2020)

Article 334. For the purposes of this Decree, chilled seafood is seafood packed and kept at refrigeration temperature.

Sole paragraph. The maximum storage temperature for chilled seafood must comply with the provisions of supplementary standards, or if such standards do not exist, with the provisions of international recommendations. (Included by Decree no. 10,468, enacted in 2020)

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 -18°C (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 -9°C (minus nine degrees Celsius), where this temperature is the maximum limit during transport and storage.

Paragraph 2. The use of a brine freezer on vessels 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 attains a temperature no higher than -9°C (minus nine degrees Celsius), where this temperature is the maximum limit during transport and storage. (In the wording of Decree no. 10,468, enacted in 2020)

Paragraph 3. The use of brine freezers in land-based industrial premises is allowed, provided that: (<u>Included by Decree no. 10,468</u>, enacted in 2020)

- I there is control, on the equipment itself, over the time and temperature of freezing, and control of salt absorption in the product; and (<u>Included by Decree no. 10,468, enacted in 2020</u>)
- II the freezing is finalized in tunnels until the product attains a temperature of -18°C (minus eighteen degrees Celsius). (Included by Decree no. 10,468, enacted in 2020)

Paragraph 4. The product addressed in Paragraph 2 will be called frozen fish in brine for canning, and the product addressed in Paragraph 3 will be called frozen fish in brine. (Included by Decree no. 10,468, enacted in 2020)

Article 336. During transport, the frozen seafood must be kept at a temperature no higher than -18°C (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 process to raise its temperature 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 from 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 submitted to 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 that may or may not be preserved under refrigeration.

Article 343. For the purposes of this Decree, seafood paste or pâté, 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; they use 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 that is stable at room 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

(Revoked by Decree no. 10,468, enacted in 2020)

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. (Revoked by Decree no. 10,468, enacted in 2020)

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. (Revoked by Decree no. 10,468, enacted in 2020)

CHAPTER IV

IDENTITY AND QUALITY STANDARDS IN EGGS 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 by-products, and their respective manufacturing processes, in a specific technical regulation or supplementary standard.

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 ultra-high temperature (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 standards.

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. The 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 that are under official sanitary inspection.

Article 356. For the purposes of this Decree, bulk liquid milk for industrial use is cleaned, refrigerated, optionally thermized (preheating), 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. The 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 tests, 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 milk 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, as 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 corresponding 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

Fresh 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 suitable single use packaging.

Paragraph 3. Cream for industrial use 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 TRIQs 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 virtually complete 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-dairy origin.
- Paragraph 5. The milk used to manufacture cheeses must be mechanically filtered and undergo pasteurization or heat treatment to ensure negative residual phosphatase, in combination or otherwise with physical or biological processes that ensure the safety of the product.
- Paragraph 6. The milk for manufacturing 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 TRIQ.
- 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 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 may be carried out in an establishment under federal inspection that is different from the establishment that initiated the production, and must 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 bottled 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 379. For the purposes of the present 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, and may be supplemented by the action of specific lactic bacteria, thus obtaining a curdlike, wheyless, mechanically pressed mass that is salted and matured. (In the wording of Decree no. 10,468, enacted in 2020)

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 matured 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 or may not be supplemented by the action of specific lactic bacteria, thus obtaining a stretched curd, unpressed cheese that may be fresh or matured

Article 383. For the purposes of the present Decree, provolone is a cheese obtained by coagulating pasteurized milk with rennet or with 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 (In the wording of Decree no. 10,468, enacted in 2020)

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.

Article 385-A. It is permitted to use and sell, exclusively for industrial purposes, the milky fat extracted from the water used in the extrusion process to make cheeses, provided that the identity and quality of the final product in which they will be used are ensured. (Included by Decree no. 10,468, enacted in 2020)

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 microorganism 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 standards.

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 Decree, concentrated dairy products include concentrated milk, evaporated milk, condensed milk and other products fitting the description.

Paragraph 2. For the purposes of this Decree, 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 standards.

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 that is 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. 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.

Article 393. For the purposes of this Decree, caramel (*doce de leite* or *dulce de leche*) is a dairy product or compound dairy 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. (<u>In the wording of Decree no. 9,069</u>, enacted in 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, of 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-quality 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, in 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, anhydrous milk fat, or 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 liquid, concentrated or powder form.
- 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 after the 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 whey protein by 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, milk flour (*farinha láctea* or 'farine lactée') is a product resulting from the dessication under 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 BEE 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 derived from bee 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 bee 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 bee 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 or 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

THE 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 in the Department of Inspection of Animal Products.

Article 427. All edible animal products either produced in Brazil or imported must be registered in the Department of Inspection of Animal Products, of the Secretariat of Animal and Plant Health, of the Ministry of Agriculture, Livestock and Food Supply. (In the wording of Decree no. 10,468, enacted in 2020)

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. (Revoked by Decree no. 10,468, enacted in 2020)

Paragraph 3. Products not provided for in the present Decree or in supplementary standards will be registered by means of advance approval given by the Department of Inspection of Animal Products.

Paragraph 3. Non-regulated products will be registered after prior approval from the Department of Inspection of Animal Products. (In the wording of Decree no. 9,069 enacted in 2017) (Revoked by Decree no. 10,468, enacted in 2020)

Article 427-A. Products will be registered in a specific computerized system made available by the Ministry of Agriculture, Livestock and Food Supply. (Included by Decree no. 10,468, enacted in 2020)

Paragraph 1. Registration will be granted automatically upon deposition of the documentation required in the system addressed in the **head provision**, in the following cases: (Included by Decree no. 10,468, enacted in 2020)

- I regulated products; (Included by Decree no. 10,468, enacted in 2020)
- II products intended exclusively for export. (Included by Decree no. 10,468, enacted in 2020)
- Paragraph 2. The registration of non-regulated edible products will be granted after prior approval of the formulation of the product and its manufacturing process. (Included by Decree no. 10,468, enacted in 2020)
- Paragraph 3. The sketch of the label will not be subject to prior analysis (<u>Included by Decree no. 10,468, enacted in 2020</u>)
- Article 427-B. The products defined in articles: 308-A; 308-B; 322; 410; 416; 418; 420; 422 and 423 are exempted from registration. (Included by Decree no. 10,468, enacted in 2020)

Paragraph 1. The Ministry of Agriculture, Livestock and Food Supply may waive the registration of other products provided for in the present Decree or in supplementary standards, depending on the risk classification of the products. (Included by Decree no. 10,468, enacted in 2020)

Paragraph 2. The Ministry of Agriculture, Livestock and Food Supply will create simplified procedures in order to underpin the transport and sanitary certification of the products addressed in the present article in order to comply with export demands. (Included by Decree no. 10,468, enacted in 2020)

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 steps receiving, handling, treatment, industrial processing, portioning, 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 (Revoked by Decree no. 10,468, enacted in 2020)
 - IV a list of the self-control programs carried out by the establishment.
 - IV a sketch of the label to be used. (In the wording of Decree no. 10,468, enacted in 2020)

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 standards 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 the registration of the products addressed in the **head provision**, the interested party must, in addition to the requirements laid down in the **head provision** of Article 428, 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;
- II the specification of physical-chemical and microbiological parameters of the product, its identity and quality requirements and its compliance evaluation methods, taking into account the specificities of each product; (In the wording of Decree no. 10,468 enacted in 2020)
 - III information, when such exists, 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 and harmlessness 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. The 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 431. All ingredients and additives presented in combination must possess clear information about composition and percentages in the registration requests. (In the wording of Decree no. 10,468, enacted in 2020)

Sole paragraph. The technological adjuvants used in manufacturing must be listed in the manufacturing process. (<u>Included by Decree no. 10,468, enacted in 2020</u>)

- 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 standard issued by the Ministry of Agriculture, Livestock and Supply.
- Paragraph 3. For the purposes of registration, the Ministry of Agriculture, Livestock and Food Supply will make available a specific digitized system. (Revoked by Decree no. 10,468, enacted in 2020)
 - 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 sanitized, may be allowed, at the discretion of the SIF.
- Article 437. The reuse of recipients for bottling or packing products and raw materials used in human food, when intact and sanitized, may be allowed. (In the wording of Decree no. 10,468, enacted in 2020)

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 graphical 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.

Article 439. Establishments may only ship or sell animal raw materials or products that have been registered by, or that are exempt from registration by, the Department of Inspection of Animal Products, of the Secretariat of Animal and Plant Health, of the Ministry of Agriculture, Livestock and Food Supply, and that are identified by means of labels, placed visibly, when intended directly for consumption or when sent to other establishments that will process them. (In the wording of Decree no. 10,468, enacted in 2020)

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 is to have been given prior authorization from the health regulatory agency.

- Paragraph 2. The information given on the labels must be visible, in legible characters, in a color that contrasts with the background, and is indelible, pursuant to specific legislation.
 - Paragraph 3. Labels must possess identification that enables product traceability.
- Paragraph 4. The attachment of labels to inedible products sold in bulk is waived, when such are transported in vehicles that it is not feasible to seal, or in which the procedure does not provide an additional guarantee that the products are tamperproof. (Included by Decree no. 10,468, enacted in 2020)
 - 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. (Revoked by Decree no. 10,468, enacted in 2020)
- Article 442. The labels may be used only on those registered products or those exempt from registration to which they apply. (In the wording of Decree no. 10,468, enacted in 2020)
- Paragraph 1. The information given on the label must faithfully portray the true nature, composition and characteristics of the product. (Included by Decree no. 10,468, enacted in 2020)
- Paragraph 2. In direct sale to the end consumer, the use of the same label for more than one product is prohibited. (Included by Decree no. 10,468, enacted in 2020)
- Paragraph 3. For the purposes of Paragraph 2, the end consumer is deemed to be a natural person who purchases an animal product for their own consumption. (<u>Included by Decree no. 10,468, enacted in 2020</u>)
- Article 443. In addition to other demands laid down in this Decree, in supplementary standards and in specific legislation, the labels must clearly and legibly show:
 - I the name of the product;
 - II the corporate name and address of producing establishment;
 - III the 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 manufacturing date, expiration date and lot identification;
 - VII expiration date and lot identification; (In the wording of Decree no. 10,468 enacted in 2020)
 - VIII the 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 for the preparation and use of the product, when necessary.

Paragraph 1. The date of manufacture and the date of expiration, 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 standards.

Paragraph 1. The date of expiration and the identification of the lot must be printed, etched or given by a stamp, depending on the nature of the container or casing, in compliance with supplementary standards. (In the wording of Decree no. 10,468, enacted in 2020)

Paragraph 2. When the product has been outsourced, the expression "Manufactured by" ("Fabricado por"), or an equivalent, must appear 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 portioning or packaging of the product has been performed, the expression "Portioned 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 portioning 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.

Paragraph 5. The expression "This Product is Exempt from Registration in the Ministry of Agriculture, Livestock and Food Supply" (*Produto Isento de Registro no Ministério da Agricultura, Pecuária e Abastecimento*), is to appear on the label of products that are exempt from registration, replacing the information addressed in item IX of the **head provision**. (Included by Decree no. 10,468, enacted in 2020)

Article 444. Labels may contain allusions to prizes won or honorable mentions obtained, provided these claims are duly proven.

Article 444. References can be made, on labels, to prizes won or honorable mentions awarded, provided that when requesting registration these awards can be duly proven, and providing that an informational text is included in the labeling for the consumer to clarify the criteria for the award, the entity responsible for it, and the date it was given. (In the wording of Decree no. 10,468, enacted in 2020)

Article 445. In the composition of 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 <u>banned</u> 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 446-A. Information can be attached to the labeling in mention of a specific production system or specific production characteristics within the scope of primary production, provided that the rules laid down by the competent agency are complied with. (Included by Decree no. 10,468, enacted in 2020)

Paragraph 1. Should there be no rules or specific regulations concerning the systems or the production characteristics addressed in the **head provision**, the establishment should attach an explanatory text to the label, in an easily-seen location, informing consumers of the characteristics of the production system. (<u>Included by Decree no. 10,468</u>, enacted in 2020)

Paragraph 2. The establishment is solely responsible for the truthfulness of the information given in the labeling pursuant to the provisions of Paragraph 1 before consumer defense agencies. (<u>Included by Decree no. 10,468, enacted in 2020</u>)

Article 446-B. Expressions of quality may be contained in the labeling when corresponding specifications for a given animal product in a specific technical regulation on identity and quality are established. (<u>Included by Decree no. 10,468</u>, enacted in 2020)

Paragraph 1. Should there be no quality specifications in a specific regulation as addressed in the **head provision**, and in accordance with the provisions contained in Article 446, it is allowed to indicate expressions of quality in the labeling provided that they are followed by an informational text for the benefit of the consumer in order to clarify the criteria used in such definition. (Included by Decree no. 10,468, enacted in 2020)

Paragraph 2. The parameters or criteria used should be based on technical and scientific evidence that is measurable and auditable, and must be described in the request for registration. (<u>Included by Decree no. 10,468, enacted in 2020</u>)

Paragraph 3. The establishment is solely responsible for the truthfulness of the information given in the labeling pursuant to the provisions of Paragraph 1 and Paragraph 2, before consumer defense agencies. (Included by Decree no. 10,468, enacted in 2020)

Article 446-C. The use of information concerning sensory aspects, the type of condiments, references to specific recipes, or other information not related to the quality features, is permitted in the labeling, pursuant to the provisions of item XVIII of the **head provision** of Article 10. (Included by Decree no. 10,468, enacted in 2020)

Sole paragraph. The information addressed in the **head provision** does not fall under the definition of expressions of quality addressed in article 446-B. (<u>Included by Decree no. 10,468, enacted in 2020</u>)

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 447. The same label may be used for identical products made in different units of one company, provided that each establishment has had that product registered. (In the wording of Decree no. 10,468, enacted in 2020)

Paragraph 1. In the assumption contained in the **head provision**, the information addressed in items II, III, IV, V and IX of the **head provision** of Article 443 is to be indicated in the labeling for the manufacturing units that are involved. (Included by Decree no. 10,468, enacted in 2020)

Paragraph 2. The manufacturing unit of the product must be clearly identified on the labeling by an informational text, code, or some other means that ensures the correct information. (Included by Decree no. 10,468, enacted in 2020)

Paragraph 3. As an alternative to the indication of the inspection stamps of the manufacturing units that are involved, the company may choose to place a single inspection stamp referring to the manufacturing unit on the labeling. (Included by Decree no. 10,468, enacted in 2020)

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, portioning or packaging.

Article 452. The labeling of animal products must meet provisions laid down in this Decree, supplementary standards 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 standard.
 - 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 by their identity are 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. "Farine lactée" 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 standards will be submitted to the Department of Inspection of Animal Products for evaluation.
- Article 454. Raw carcasses, quarters, or parts of carcasses of bovids, equids, suids, 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).
- Article 454. Raw carcasses, quarters, or parts of carcasses of bovines, buffaloes, equids, suids, 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 no. 9,069, enacted in 2017)
- Paragraph 1. Health marks and stamps must contain the demands laid down in this Decree and in supplementary standards.
 - Paragraph 2. Offal must be identified with a SIF stamp, in compliance with supplementary standards.
- 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.
- Sole paragraph. The provisions given in the **head provision** do not apply to condiments and spices. (<u>In the wording of Decree no. 10,468, enacted in 2020</u>)
- 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 terms' are 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 standards.

Article 458. In the case of fresh seafood, taking into account the inherent specificities of the species and the ways in which the product is presented, the use of packaging may be waived, provided that the product is identified on the transportation containers. (In the wording of Decree no. 10,468, enacted in 2020)

Sole paragraph. The rules contained in the **head provision** do not apply to seafood received directly from primary production. (<u>Included by Decree no. 10,468, enacted in 2020</u>)

Article 459. In thawed seafood the designation of the product must include the word "descongelado" (thawed), and in the main panel of the label, immediately below 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" (portioned sale forbidden).

Article 462. The labeling on the 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 standards.

CHAPTER IV

INSPECTION STAMPS

Article 463. The inspection stamp represents 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), in the 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 (n°) 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 standards, 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 irregularities 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 standards:

- 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) use: for the carcasses and quarters of bovids, equids and ratites fit for consumption raw, applied to the carcasses or carcass-quarters;
- d) use: for the carcasses and quarters of bovines, buffaloes, Equidae and ratites fit for consumption fresh, applied to the carcasses or quarters; (Wording given by Decree no. 9,069, enacted 2017)
 - II template 2:
 - a) dimensions: 5 cm x 3 cm (five by three centimeters);
 - b) shape and wording: identical to template 1; and
- e) use: for the carcasses of Suidae, ovines and caprines fit for raw consumption, applied to the carcasses or quarters of the carcasses;
- c) use: for the carcasses and quarters of suids, ovines and caprines fit for consumption fresh, applied to the carcasses or quarters; (In the wording of Decree no. 10,468 enacted in 2020)
 - III template 3:
 - a) dimensions:
- 1. 1 cm (one centimeter) in diameter, when applied to packages with a visible surface for labeling smaller than or equal to 10 cm² (ten square centimeters);
- 2. 2 cm (two centimeters) or 3 cm (three centimeters) in diameter, when applied to packages of up to 1 kg (one kilogram);
- 3. 4 cm (four centimeters) in diameter, when applied to packages weighing from 1 kg (one kilogram) to 10 kg (ten kilograms); or
 - 4. 5 cm (five centimeters) in diameter, when applied to packages weighing over 10 kg (ten kilograms);
 - b) shape: circular;
- c) wording: the establishment's registration number must stand out in isolation below the word "Inspecionado", placed 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. 3 cm (three centimeters) sideways when applied to labels and stickers; or
 - 2. 15 cm (fifteen centimeters) sideways when applied to sacks and bags;

- 2. 15 cm (fifteen centimeters) sideways when applied to printed sacks and bags; (In the wording of Decree no. 10,468 enacted in 2020)
 - 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: 7 cm x 6 cm (seven centimeters 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 immediately beneath them the word "condenado" (condemned) also horizontally; and
 - d) use: condemned carcasses or carcass parts;
 - VI template 6:
 - a) dimensions: 7 cm x 6 cm (seven centimeters 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 making products that undergo heat sterilization (E), salting (S), cooking (C), cold treatment (TF) or heat fusion (FC); and
 - VII template 7:
 - a) dimensions: 15 mm (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" (Inspected) 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 made of plastic or metal.
- d) use: on seals for closing and identifying the containers and the means of transportation for raw materials and products that require health certification, and when used in enforcement actions that are taken in order to block off equipment, rooms and establishments; they can be made of plastic or metal. (In the wording of Decree no. 10,468, enacted in 2020)
- Paragraph 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 wording laid down for template 3 which is 4 cm (four centimeters) in diameter.
- Paragraph 3. The application and control of the use of seals and health marks on products, on containers, or on transportation vehicles, when it is necessary to attach them, is the responsibility of the establishments, except in specific situations defined by the competent animal health agency. (<u>Included by Decree no. 10,468, enacted in 2020</u>)

TITLE VIII

LABORATORY TESTING

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 testing necessary for assessing compliance.

Sole paragraph. Whenever the SIF deems it necessary, it will take samples for laboratory testing.

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 respective expert reports on the test.

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 test, and the sample must be preserved and protected against 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 SIF operating in the establishment.

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 does not allow this;
- II the product has a short shelf life and there is insufficient time available to carry out testing of the B sample;
- III they are fiscal tests carried out as a routine procedure by the official inspection; and
- III they are fiscal tests carried out as a routine procedure by the official inspection service; (In the wording of Decree no. 10,468 enacted in 2020)
- IV they are taken for microbiological testing, because in such cases it is deemed irrelevant to perform a B sample test; and
- IV they are taken for microbiological testing, because in such cases it is deemed irrelevant to perform a B sample test; and (In the wording of Decree no. 10,468 enacted in 2020)
- V they are assays to detect analytes that do not remain stable over time. (<u>Included by Decree no. 10,468, enacted in 2020</u>)
- Paragraph 4. For the purposes of item II of Paragraph 3, the product is deemed to present a short shelf life when its remaining shelf life is equal to or less than forty-five days from the sampling date. (<u>Included by Decree no. 10,468</u>, <u>enacted in 2020</u>)
- Article 471. Samples of raw materials, product or of any other substance going into its production, and of supply water for official testing 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 testing must be taken, handled, packed, identified and transported so as to ensure maintenance of physical integrity and suitably to preserve the product.
- Sole paragraph. The authenticity of the samples must be guaranteed by the competent authority taking the sample.
- Article 473. When the results of official tests do not comply with the legislation, SIF will notify the interested parties of the test results obtained and take suitable enforcement and administrative measures.

Article 474. Interested parties may request from the SIF an expert test of the B sample, where applicable, within forty-eight hours of being notified of the result.

Paragraph 1. When requesting a test of the B sample, interested parties must give the name of a technical assistant to make up the committee of experts, and may appoint an alternate.

Paragraph 2. Interested parties must be informed at least seventy-two hours in advance of the date, time and laboratory defined by the competent authority, Ministry of Agriculture, Livestock and Food, when the expert test of the B sample will be performed.

Paragraph 3. The expert test 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 test of the B sample as was used in the original fiscal test, unless the expert committee agrees to employ another method.

Paragraph 5. The expert test must not be performed 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 test is to be adopted.

Paragraph 6. For the case addressed in Paragraph 5, the result of the fiscal test should be adopted. (<u>In the wording of Decree no. 10,468, enacted in 2020</u>)

Paragraph 7. In the event of discrepancy in the result of the fiscal test or a mismatch between the fiscal test and the result of the expert test of the B sample, a new expert test will be performed using the B sample held by the laboratory or by the local SIF.

Paragraph 8. Failure by the representative appointed by the interested party to appear on the date and at the time determined, or if the absence of any B sample being held by the interested party, will entail acceptance of the result of the fiscal test.

Article 474-A. If the party requesting the test appoints a technical assistant or an alternate to be present at the expert tests, they must prove that the designated individuals have the training and the technical ability to accompany the expert test, in accordance with the criteria defined by the Ministry of Agriculture, Livestock and Food Supply. (Included by Decree no. 10,468, enacted in 2020)

Paragraph 1. Should the technical assistant or alternate fail to meet the training and technical ability requirements addressed in the head provision, the request to perform an expert test of the B sample will be deemed dilatory. (Included by Decree no. 10,468, enacted in 2020)

Paragraph 2. In the event addressed in Paragraph 1, the request for the performance of an expert test on the B sample will be refused and the results of the fiscal test will be adopted. (<u>Included by Decree no. 10,468, enacted in 2020</u>)

Article 474-B. The interested party may, within ten days of signing the minute of the expert test of the B sample, put forth an additional statement regarding the results of the expert test of the B sample that is performed during the investigative process for infractions. (Included by Decree no. 10,468, enacted in 2020)

Paragraph 1. The provisions contained in Paragraph 1 and Paragraph 2 of Article 525 will be applied when counting the deadline addressed in the **head provision**, and for this purpose, the date of signature of the minutes of the expert test of the B sample will be assumed to be the date of official notification. (<u>Included by Decree no. 10,468</u>, enacted in 2020)

Paragraph 2. The result of the expert test of the B sample and the additional statement put forth by the interested party concerning the result, if such is the case, will be assessed and taken into consideration as factors in the administrative decision-making process. (Included by Decree no. 10,468, enacted in 2020)

Article 475. The establishment must exercise control over its production process by means of physical, microbiological, physical-chemical, molecular biological, histological and other necessary tests 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. Samples of animal products registered in the SIF may be taken at retail outlets, in supplementary fashion, in order to meet requirements of programs and specific demands.

Article 477. The procedures for taking samples for fiscal tests, and for 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 standards.

Article 478. Establishments may bear the cost of fiscal tests in accredited laboratories to meet national programs, provided that they are notified of this at the moment of sampling and expressly communicate their agreement.

TITLE IX

INDUSTRIAL AND SANITARY REINSPECTION

Article 479. Animal products may be reinspected whenever necessary before authorization for domestic consumption or for interstate or international trade.

Article 479. Animal products may be reinspected whenever necessary before authorization for interstate or international trade. (In the wording of Decree no. 9,069, enacted in 2017)

Sole paragraph. Raw materials and animal products to undergo reinspection, sampling criteria and other procedures will be defined in a supplementary standard.

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 structural integrity of the packaging, wrapping and recipients;
- II labeling, official inspection marks, and dates of manufacture and expiration;
- II labeling, official inspection marks, and expiration dates; (<u>In the wording of Decree no. 10,468 enacted in 2020</u>)
 - III assessment, when appropriate, of sensory characteristics;
- IV taking samples for physical, microbiological, physical-chemical, molecular biology, and histological testing, when appropriate;
 - V the sanitary documentation for transportation when appropriate;
- V the fiscal and sanitary documentation underpinning the transport and sale, when appropriate; (<u>In the wording of Decree no. 10,468 enacted in 2020</u>)
- VI hygiene and maintenance conditions of the vehicle, and the functioning of the cold chain equipment, when appropriate; and
- VII the number and structural integrity of the health seal of the origin SIF 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 standards 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 the SIF.
- Article 481. When reinspecting raw materials or products showing signs of alterations or adulterations, the measures provided for in this Decree and in supplementary standards must be taken. (<u>In the wording of Decree no.</u> 10,468, enacted in 2020)
- Paragraph 1. Upon reinspection, products deemed unfit for human consumption are to be condemned, and it is forbidden to send them to other establishments without prior authorization by the SIF. (In the wording of Decree no. 10,468, enacted in 2020)
- Paragraph 2. Products that on reinspection allow conditional use or retreatment must undergo specific processing authorized and established by the SIF, and must be reinspected before being authorized to pass 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.

Article 482. Animal raw materials and products may be submitted to conditional use or given a disposition to industrial processing in another federally-inspected establishment or in establishments registered in the inspection services of States, Federal District and Municipalities, provided that: (In the wording of Decree no. 10,468, enacted in 2020)

- I the official service of the destination establishment has authorized this in advance; (<u>Included by Decree no.</u> 10,468, enacted in 2020)
- II there is effective control of traceability, covering proof of receiving at destination; and (<u>Included by Decree</u> no. 10,468, enacted in 2020)
 - III item XVI of the head provision of Article 73 is observed. (Included by Decree no. 10,468, enacted in 2020)

Article 482-A. The provisions of Article 481 and Article 482 do not apply to imported animal products that have not yet been internalized, and the disposition of such products will comply with the provisions of Article 489. (Included by Decree no. 10,468, enacted in 2020)

Article 482-B. The reinspection of animal products that were manufactured in Brazil and have been exported and then returned to Brazil by means of a regular import process, is compulsorily to be performed in a SIF-inspected establishment. (Included by Decree no. 10,468, enacted in 2020)

Article 482-C. At the discretion of the Department of Inspection of Animal Products, of the Secretariat of Animal and Plant Health, of the Ministry of Agriculture, Livestock and Food Supply, in the event of a sanitary emergency or of a supply crisis, and for a defined period of time, the reinspection of imported animal raw materials and products may be authorized to be performed in registered or listed establishments, as long as the provisions of Article 487 are complied with. (Included by Decree no. 10,468, enacted in 2020)

TITLE X

THE MOVEMENT AND HEALTH CERTIFICATION OF ANIMAL PRODUCTS

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 the maintenance of product intactness and enable preservation.

Paragraph 1. Vehicles, containers or compartments must be cleaned and disinfected before and after transport takes place.

Paragraph 2. The 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 standards.

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 standards.

Article 484. Animal raw materials and products manufactured in federally-inspected establishments, when duly registered or when exempt from registration: (In the wording of Decree no. 10,468, enacted in 2020)

- I may be sold freely within the national territory of Brazil, provided that they meet: (<u>Included by Decree no.</u> 10,468, enacted in 2020)
- a) the requirements of the animal health agency with regard to the transport of products; and (<u>Included by Decree no. 10,468, enacted in 2020</u>)

- b) the other requirements set forth in the present Decree and in supplementary standards; and (<u>Included by Decree no. 10,468</u>, enacted in 2020)
- II they may be the subject of international trade to countries that do not possess specific sanitary requirements. (Included by Decree no. 10,468, enacted in 2020)

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 Brazilian 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 they are intended for domestic interstate trade, in accordance with supplementary standards, obeying specific competent jurisdiction powers.

Article 486. The import of raw material and products of animal origin may only be authorized when:

- I they come from countries whose health inspection system has been assessed or recognized as equivalent by the Department of Inspection of Animal Products;
 - II they come from establishments eligible to export to Brazil;
 - III they have been registered in advance 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 representations in Brazil.
- Paragraph 2. The Ministry of Agriculture, Livestock and Food Supply, will, in supplementary standards, establish procedures for recognizing equivalency with the health inspection services of foreign countries, for the listing of, and for changes in the registry of, 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 after:
- I inspection by the competent area of international agricultural surveillance within the Department of Inspection of Animal Products; and
- I inspection by the competent area of international agricultural surveillance within the Ministry of Agriculture, Livestock and Food Supply; and (In the wording of Decree 9,069 enacted in 2017)
 - II reinspection by the competent area of the international agricultural surveillance agency or by the SIF.
- II reinspection by the competent area of the international agricultural surveillance area, except in the cases given in Articles 482-B and 482-C. (In the wording of Decree no. 10,468 enacted in 2020)
- Paragraph 1. After the inspection procedure, a transport 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**.
- Paragraph 2. At the discretion of the Department of Inspection of Animal Products, of the Secretariat of Animal and Plant Health, of the Ministry of Agriculture, Livestock and Food Supply, the reinspection of imported animal raw materials and products may be waived, and their movement will be authorized after the inspection addressed in item I of the **head provision** has been performed, and in compliance with the provisions of Article 479. (In the wording of Decree no. 10,468, enacted in 2020)
- 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 location 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 standards.

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 approved 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 the approval of countries or the listing of their establishments.

Paragraph 4. The internalization of products addressed in the **head provision** may be authorized in order to carry out a correction to the data affixed in the labeling, above all with regard to the importer, when technically appropriate, exclusively in a SIF-inspected establishment. (<u>Included by Decree no. 10,468, enacted in 2020</u>)

CHAPTER II

THE 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 490. Domestic or international health certificates, transport permits, declarations of compliance, or declarations of the disposition to industrial processing, or of condemnation, issued for animal products, must comply with the templates established by the Department of Inspection of Animal Products, of the Secretariat of Animal and Plant Health, of the Ministry of Agriculture, Livestock and Food Supply. (In the wording of Decree no. 10,468, enacted in 2020)

Paragraph 1. The procedures for issuing the documents addressed in the **head provision** will be defined in supplementary standards. (<u>Included by Decree no. 10,468, enacted in 2020</u>)

Paragraph 2. In addition, the sanitary certification for inedible products will comply with the provisions of Article 322. (Included by Decree no. 10,468, enacted in 2020)

Paragraph 3. The Ministry of Agriculture, Livestock and Food Supply will make available and maintain a specific computerized system for the issuing, and control of issuing, of the documents addressed in the **head provision**. (Included by Decree no. 10,468, enacted in 2020)

Paragraph 4. The domestic or international health certificates and the product transport permits may be issued: (Included by Decree no. 10,468, enacted in 2020)

- I by the Services for the Inspection of Animal Products; (Included by Decree no. 10,468, enacted in 2020)
- II by the units of the international agricultural surveillance system; and (<u>Included by Decree no. 10,468, enacted</u> in 2020)
- III by the registration centrals defined by the Ministry of Agriculture, Livestock and Food Supply. (<u>Included by</u> Decree no. 10,468, enacted in 2020)
- Article 491. Health Certificates for animal products intended for international trade, when drafted in a foreign language, must be translated into Portuguese.
- Article 491. Health certificates for animal products intended for international trade are to be drafted in Portuguese and in the language accepted by the destination country. (In the wording of Decree no. 10,468, enacted in 2020)

Paragraph 1. The Health Certificates for animal products intended for international trade must be signed by a Federal Agriculture Inspector/Auditor 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.

Paragraph 2. When requesting the issuing of a health certificate for animal products intended for international trade, establishments must present: (In the wording of Decree no. 10,468, enacted in 2020)

- I the declaration of compliance that the product to be certified meets the requirements of the importing country; and (Included by Decree no. 10,468, enacted in 2020)
- II documentary proof to underpin the certification, as laid down in supplementary standards. (<u>Included by Decree no. 10,468, enacted in 2020</u>)

Article 492. Health certification must compulsorily be issued for the movement of animal raw materials or products.

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 standards, complying with the animal health legislation.

Paragraph 2. The procedures for issuing health certification will be defined in supplementary standards. (Revoked by Decree no. 10,468, enacted in 2020)

Article 493. It is mandatory to issue health certification for the movement of animal raw materials or products intended for conditional use or condemnation.

Article 493. It is mandatory to issue sanitary certification for the movement of animal raw materials or products intended for conditional use or condemnation as ordered by the SIF, and to issue the documentation for disposition to industrial processing or condemnation ordered by the establishment. (In the wording of Decree no. 10,468, enacted in 2020)

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 1. In the cases addressed in the **head provision**, the destination establishment must provide the issuer with proof of receipt of the raw materials and products within forty-eight hours of the receipt of the consignment. (In the wording of Decree no. 10,468, enacted in 2020)

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. (Revoked by Decree no. 10,468, enacted in 2020)

Paragraph 3. The SIF must prevent the shipping of new consignments of raw materials or products until the provisions of Paragraphs 1 and 2 are met.

Paragraph 3. New consignments of raw materials or products will not be shipped until the provisions of Paragraph 1 are met. (In the wording of Decree no. 10,468, enacted in 2020)

Paragraph 4. In the case of those slaughter establishments where it is not possible to set apart condemned material coming from the Final Veterinary Reinspection Department (*Departamento de Inspeção Final* — DIF) and from the **post-mortem** inspection lines, from material that has been condemned by the establishment in other industrial operations, the sanitary certification addressed in the **head provision** is waived and the transport of such products will be underpinned by a declaration of condemnation issued by the establishment, as addressed in Article 490. (<u>Included by Decree no. 10,468</u>, enacted in 2020)

TITLE XI

RESPONSIBILITIES, PROVISIONAL REMEDIES,

INFRACTIONS, PENALTIES AND ADMINISTRATIVE PROCESSES

CHAPTER I

RESPONSIBILITIES AND PROVISIONAL REMEDIES

Section I

Those responsible for the infraction

Article 494. The following legal 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, tenants or lessees of establishments registered or listed with the Ministry of Agriculture, Livestock and Food Supply at which animal raw materials, or animal products, are received, handled, treated, processed, portioned, 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 products or raw materials.

Section II

Provisional Remedies

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 provisional remedies individually or jointly:

- I seizure of the product;
- II provisional suspension of the manufacturing process or its stages; and
- III take samples of the product for laboratory testing.

Article 495. If there is proof or suspicion that an animal product poses a risk to public health or has been adulterated, the Ministry of Agriculture, Livestock and Food Supply will take the following provisional remedies individually or jointly: (In the wording of Decree no. 10,468, enacted in 2020)

- I- seizing the product, labels, or packaging; (In the wording of Decree no. 10,468 enacted in 2020)
- II provisionally suspending the manufacturing process or its stages; (<u>In the wording of Decree no. 10,468</u> enacted in 2020)
 - III taking samples for laboratory testing; or (In the wording of Decree no. 10,468 enacted in 2020)
- IV ordering the company to take samples for laboratory testing, either in its own laboratory or at an approved laboratory, in compliance with the provisions of Article 475. (<u>Included by Decree no. 10,468, enacted in 2020</u>)
 - Paragraph 1. Whenever necessary, a review of the establishment's self-control programs may be ordered.
- Paragraph 2. Resumption of manufacturing or the approval for the suspected product to pass to consumption will be authorized if SIF finds that the cause of adoption of the provisional remedy no longer exists or has ceased to be.
- Paragraph 2. The provisional remedies adopted are to be proportional to, and technically related to, the causes warranting them. (In the wording of Decree no. 10,468, enacted in 2020)
- Paragraph 3. What is set forth in the **head provision** does not cancel the competent jurisdictions of other regulatory agencies as per the legislation.
- Paragraph 3. When the seizure of products is motivated by flaws in the control of the production process, the provisional remedies may be extended to other lots of product manufactured under the same conditions. (<u>In the wording</u> of Decree no. 10,468, enacted in 2020)
- Paragraph 4. Those provisional remedies that have been adopted will be lifted if the suspicions that led to their application are not confirmed. (Included by Decree no. 10,468, enacted in 2020)
- Paragraph 5. The manufacturing process will be authorized to resume after the cause of the irregularity has been identified and suitable corrective measures have been taken. (<u>Included by Decree no. 10,468, enacted in 2020</u>)

Paragraph 6. When technically relevant, the seized products may be cleared after laboratory reports showing that there has been no irregularity have been presented. (<u>Included by Decree no. 10,468, enacted in 2020</u>)

Paragraph 7. The provisions of the **head provision** do not cancel the competent jurisdictions of other regulatory agencies as per the legislation. (Included by Decree no. 10,468, enacted in 2020)

Article 495-A. The SIF may order the establishment to develop and apply a sampling plan for laboratory testing, delineated on the basis of scientific criteria, the results of which will underpin the confirmation of the resumption of the manufacturing process, when the reason that caused the provisional remedy to be taken is related to deficiencies in the control of the production process. (Included by Decree no. 10,468, enacted in 2020)

Sole paragraph. The samples addressed in the **head provision** will be taken by the company, and the tests will be performed in its own laboratory or an approved laboratory, in compliance with the provisions of Article 475. (<u>Included by Decree no. 10,468</u>, enacted in 2020)

CHAPTER II

INFRACTIONS

Article 496. The following, pursuant to the provisions of the present Decree, are infractions:

- I constructing, extending or remodeling facilities without prior approval from DIPOA Department of Inspection of Animal Products;
- I constructing, extending or remodeling facilities without previously obtaining approval for the plan, in the case of the establishments addressed in Paragraph 1 of Article 28, or without bringing the deposited documentation up to date, in the case of the establishments addressed in Paragraph 2 of the aforementioned article, when there is an increase in the production capacity or a change in the flows of raw materials, products, or employees; (In the wording of Decree no. 10,468 enacted in 2020)
- II failing to transfer accountability or failing to notify the purchaser, tenant or lessee of this legal obligation at sale, renting or leasing;
 - III using a label that does not meet the specific relevant legislation;
 - IV shipping raw materials, ingredients, products or packaging in unsuitable conditions;
 - V exceeding the maximum capacity of slaughter, or treatment, or industrial processing or storage;
- VI making products whose manufacturing and formulation processes and composition are not registered in the Department of Inspection of Animal Products;
- VII shipping products without labeling or with labels that have not been registered in the Department of Inspection of Animal Products;
- VII shipping products without labeling, or products that have not been registered in the Department of Inspection of Animal Products, of the Secretariat of Animal and Plant Health, of the Ministry of Agriculture, Livestock and Food Supply; (In the wording of Decree no. 10,468 enacted in 2020)
- VIII disobeying or failing to comply with the precepts of animal welfare provided for in this Decree and in supplementary standards for animal products;
- IX 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;
- X omitting information about the centesimal composition and technical composition of the manufacturing process;
- XI receiving, using, transporting, storing or shipping raw materials, ingredients or products without proof of origin;
 - XII using a process, substance, ingredients or additives that fail to comply with specific legislation;
- XIII 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;

- XIII failing to meet deadlines in the documents issued as a response to the SIF concerning action plans, inspections, warnings of violation, summonses or notifications; (In the wording of Decree no. 10,468 enacted in 2020)
- XIV purchasing, handling, shipping or distributing 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;
- XIV purchasing, handling, shipping or distributing animal products manufactured at an establishment not registered or listed in the Department of Inspection of Animal Products, of the Secretariat of Animal and Plant Health, of the Ministry of Agriculture, Livestock and Food Supply, or that is not in the general registry of the Brazilian System of Inspection of Animal Products; (In the wording of Decree no. 10,468 enacted in 2020)
 - XV shipping or distributing products fraudulently purporting to come from a given establishment;
- XV manufacturing, shipping or distributing animal products with counterfeit labeling; (In the wording of Decree no. 10,468 enacted in 2020)
- XVI making 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 using products with expired validity, attaching new dates post-expiration on such products, or placing a date later than the real manufacturing date;
- XVII using products outside their shelf life, going against the criteria laid down in the present Decree or in supplementary standards; (In the wording of Decree no. 10,468 enacted in 2020)
- XVIII giving or presenting false or inaccurate information, statements or documents to the oversight agency about quantity, quality and origin of raw materials, ingredients and products, or withholding information that directly or indirectly interests the Department of Inspection of Animal Products;
- XVIII withholding information of direct or indirect concern to the Department of Inspection of Animal Products, of the Secretariat of Animal and Plant Health, of the Ministry of Agriculture, Livestock and Food Supply and to the consumer; (In the wording of Decree no. 10,468 enacted in 2020)
 - XIX falsifying records that are subject to SIF verification;
 - XX unlawfully providing or using seals, official stamps, labels and packaging;
 - XXI changing or fraudulently presenting any raw material, ingredient or animal product;
- XXI changing any raw material, animal ingredient or animal product; (In the wording of Decree no. 10,468 enacted in 2020)
 - XXII simulating the legality of raw materials, ingredients or products whose origin is unknown;
- XXIII shipping products for international trade that have been made without attention to the supplementary standards concerning the export of animal products;
- XXIII shipping products for international trade that have been made without attention to the supplementary standards concerning the export of animal products; (In the wording of Decree no. 10,468 enacted in 2020)
- XXIV hindering the actions of a public servant of the Department of Inspection of Animal Products in the exercise of their duty, in order to hamper, delay, impede, restrict or evade inspection activities;
- XXV disrespecting, intimidating, threatening, assaulting or attempting to bribe a public servant of the Department of Inspection of Animal Products;
 - XXVI producing or shipping products that pose a risk to public health;
- XXVII producing or shipping for edible purposes products unfit for human consumption; (Revoked by Decree no. 10,468, enacted in 2020)
- XXVIII using condemned or uninspected raw materials and products in the preparation of products for human consumption;

- XXVIII using condemned raw materials and products, or those that have not been inspected, or raw materials and products without a known provenance, in the preparation of products for human consumption; (In the wording of Decree no. 10,468 enacted in 2020)
- XXIX- using, replacing, or totally or partially taking or removing raw materials, products, labels or packaging seized by the SIF and kept under guard by the establishment;
 - XXX falsifying official documents;
 - XXXI failing to recall products that may pose a threat to consumers' health or interests.
- XXXI failing to recall products that may pose a threat to consumers' health or that may have been adulterated; (In the wording of Decree no. 10,468 enacted in 2020)
- XXXII failing to provide the statistical data of concern to the SIF within the regulated deadlines; (Included by Decree no. 10,468, enacted in 2020)
- XXXIII providing or presenting to the Ministry of Agriculture, Livestock and Food Supply, incorrect information or imprecise information on the quantity, quality, and provenance of raw materials, ingredients and products; (<u>Included by Decree no. 10,468</u>, enacted in 2020)
- XXXIV attaching new expiration dates to products after their validity has expired; (<u>Included by Decree no. 10,468</u>, enacted in 2020)
- XXXV importing any adulterated raw material or animal product; (In the wording of Decree no. 10,468 enacted in 2020)
- XXXVI commencing activities without addressing the demands or outstanding issues that were established upon the granting of the deed of registration; (Included by Decree no. 10,468, enacted in 2020)
- XXXVII failing to present animal products that are subject to mandatory reinspection at the authorized reinspection location; (Included by Decree no. 10,468, enacted in 2020)
- XXXVIII making irregular use of false, misleading or imprecise information or documentation, or introducing it into the computer systems of the Ministry of Agriculture, Livestock and Food Supply; (Included by Decree no. 10,468, enacted in 2020)
- XXXIX providing or presenting false information, declarations or documents to the Ministry of Agriculture, Livestock and Food Supply; (Included by Decree no. 10,468, enacted in 2020)
- XL failing to present for reinspection, animal products that are subject to mandatory reinspection; (<u>Included by</u> Decree no. 10,468, enacted in 2020)
- XLI issuing or selling animal products that are subject to mandatory reinspection before such inspection has been performed; (Included by Decree no. 10,468, enacted in 2020)
- XLII receiving, handling, treating, industrially processing, portioning, preserving, storing, packing, packaging, labeling or shipping animal products without possessing registration in the competent inspection agency; (Included by Decree no. 10,468, enacted in 2020)
- XLIII failing to comply with sanitary orders for the total or partial blocking of facilities or equipment, for the suspension of activities, or other orders given as a result of inspection, or notification of violations, including orders given as provisional remedies; and (Included by Decree no. 10,468, enacted in 2020)
- XLIV failing to perform the industrial disposition or conditional use treatments established in the present Decree or in supplementary standards, or failing to provide the correct disposition to condemned products. (<u>Included by Decree</u> no. 10,468, enacted in 2020)
- Article 497. Animal raw materials or products are considered unfit for human consumption if, in the manner in which they are presented, they wholly or partially:
 - I have been altered;
 - II have been produced fraudulently;
 - II have been adulterated; (In the wording of Decree no. 10,468 enacted in 2020)

- III have been damaged by moisture or fermentation, are rancid, show abnormal physical or sensory characteristics, contain dirt, or show careless handling in their manufacture, preservation or packing;
- IV contain substances or contaminants for which a limit has not been established in the legislation, but that could pose a threat to consumers' health;
 - V contain toxic substances or radioactive compounds at levels over those permitted in specific legislation;
- VI fail to meet the standards laid down in this Decree and in supplementary standards; (Revoked by Decree no. 10,468, enacted in 2020)
- VII contain pathogenic micro-organisms at levels over those permitted in this Decree, in supplementary standards, or in specific legislation;
 - VIII prove unsuitable for their intended purpose;
- IX contain contaminants, pesticide and herbicide residues, or residues of veterinary products above the limits established in specific legislation by the Department of Inspection of Animal Products or the health regulator;
- IX contain contaminants, pesticide and herbicide residues, residues of veterinary products above the limits established in specific legislation by the Ministry of Agriculture, Livestock and Food Supply or the health regulator; (In the wording of Decree no. 9,069 enacted in 2017) (Revoked by Decree no. 10,468, enacted in 2020)
- X are obtained from animals undergoing treatment with veterinary products during the withdrawal period recommended by the manufacturer;
- XI have been obtained from animals receiving feed or veterinary products that can impair the quality of the product;
 - XII are contained in packaging that is bulging;
 - XIII have packaging that is defective, exposing contents to contamination and deterioration;
 - XIV are beyond their expiration date;
 - 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 the 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 standards;
- 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 the 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 pierced 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, when the yolk adheres to the shell, or the yolk has been ruptured, or there are dark stains or blood discoloration even of the white, or there is 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 there is red, black or white rot;
 - IV they are contaminated by fungi externally or internally;
- V there is manure dirt externally, or they have touched other substances able to transmit extraneous odors or flavors;
 - VI the shells have cracked or are dirty; or
 - VII the shells and eggshell membranes have cracked.

Sole paragraph. Eggs that have undergone incubation are also deemed unfit for human consumption.

Article 501. In addition to the 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 the cases provided for in Articles 497 & 501, raw milk is deemed unfit for the production of milk for human consumption when it:

- I fails to meet the specifications laid down in Article 248 and supplementary standards; or (Revoked by Decree no. 10,468, enacted in 2020)
 - II fails thermal stability tests contained in supplementary standards.

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 standards.

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: (Revoked by Decree no. 10,468, enacted in 2020)

- I adulterations: (Revoked by Decree no. 10,468, enacted in 2020)
- 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; (Revoked by Decree no. 10,468, enacted in 2020)
- b) raw materials or products with the 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; (Revoked by Decree no. 10,468, enacted in 2020)

- 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; (Revoked by Decree no. 10,468, enacted in 2020)
- 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 (Revoked by Decree no. 10,468, enacted in 2020)
- e) products whose date of manufacture, or date/period of validity have been altered; (Revoked by Decree no. 10,468, enacted in 2020)
 - II counterfeiting: (Revoked by Decree no. 10,468, enacted in 2020)
- a) when denominations other than those provided for in this Decree, or in supplementary standards, or in the registry of products in the Department of Inspection of Animal Products have been used; (Revoked by Decree no. 10,468, enacted in 2020)
- b) products prepared, portioned 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; (Revoked by Decree no. 10,468, enacted in 2020)
- 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; (Revoked by Decree no. 10,468, enacted in 2020)
- d) products made from a species other than that declared on the label or diverging from what is in the product registration; or (Revoked by Decree no. 10,468, enacted in 2020)
- 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. (Revoked by Decree no. 10,468, enacted in 2020)
- Article 504. Raw materials and products may be deemed altered or adulterated, for the purposes of the infractions laid down in this Decree. (In the wording of Decree no. 10,468, enacted in 2020)
- Paragraph 1. Raw materials or products that fail to present suitable hygiene and sanitary conditions for the purpose to which they are intended, and that pose a risk to public health, are deemed altered. (<u>Included by Decree no. 10,468</u>, enacted in 2020)
- Paragraph 2. The following animal raw materials or products are deemed adulterated: (<u>Included by Decree no.</u> 10,468, enacted in 2020)
 - I fraudulently-produced raw materials or products: (Included by Decree no. 10,468, enacted in 2020)
- 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; (Included by Decree no. 10,468, enacted in 2020)
- b) raw materials or products with the addition of ingredients, additives, technological adjuvants, or substances in order to dissimulate or hide changes and deficiencies in the quality of the raw material, or defects in the manufacture of the product; (Included by Decree no. 10,468, enacted in 2020)
- c) raw materials or products manufactured with the addition of ingredients, additives, technological adjuvants, or substances in order to increase the volume or weight of the product; or (<u>Included by Decree no. 10,468, enacted in 2020</u>)
- d) raw materials or products that have been made or sold otherwise than in compliance with the manufacturing technology or process established in supplementary standards, or otherwise than in compliance with the registered manufacturing process by means of the suppression, abbreviation or substitution of steps that are essential to the product's quality or identity; or (Included by Decree no. 10,468, enacted in 2020)
 - II counterfeit raw materials or products: (Included by Decree no. 10,468, enacted in 2020)
- a) raw materials and products that have been given denominations other than those provided for in this Decree, or in supplementary standards, or in the registry of products in the Department of Inspection of Animal Products, of the Secretariat of Animal and Plant Health, of the Ministry of Agriculture, Livestock and Food Supply; (Included by Decree no. 10,468, enacted in 2020)
- b) raw materials and products that may have been prepared, portioned or repackaged, whether or not they have been displayed for sale, with the overall appearance and characteristics of another product registered with the Department of Inspection of Animal Products, of the Secretariat of Animal and Plant Health, of the Ministry of Agriculture, Livestock and Food Supply, and have been labeled as this other product, without being such; (Included by Decree no. 10,468, enacted in 2020)

- c) raw materials and products made from a species other than that declared on the label or diverging from what is in the product registration; (Included by Decree no. 10,468, enacted in 2020)
- d) those raw materials and products that have not undergone the processing specified in their registration, whether or not they have been displayed for consumption, and that are indicated as processed products; (<u>Included by Decree no. 10,468, enacted in 2020</u>)
- e) raw materials or products that have undergone changes to their shelf life; or (<u>Included by Decree no. 10,468, enacted in 2020</u>)
- f) raw materials and products that fail to meet the specifications indicated on the labeling concerning their nature or their origin. (Included by Decree no. 10,468, enacted in 2020)

Article 505. The Ministry of Agriculture, Livestock and Food Supply will, in supplementary standards, 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 505. The Ministry of Agriculture, Livestock and Food Supply will, in supplementary standards, establish criteria for the disposition of raw materials or products deemed unfit for human consumption in the form in which they present, including rendering them useless, conditional use, or industrial processing, when technically viable. (In the wording of Decree no. 10,468, enacted in 2020)

Paragraph 1. Until the standards addressed in the **head provision** have been drafted, the Department of Inspection of Animal Products, of the Secretariat of Animal and Plant Health, of the Ministry of Agriculture, Livestock and Food Supply, may: (Included by Decree no. 10,468, enacted in 2020)

- I authorize products that have been judged unfit for consumption in the form in which they present, to be submitted to the specific conditional use or industrial disposition treatments that ensure the elimination of the causes leading to such judgment, upon technically well-grounded request; or (<u>Included by Decree no. 10,468, enacted in 2020</u>)
 - II order the products referred to in item I to be condemned. (Included by Decree no. 10,468, enacted in 2020)

Paragraph 2. The provisions of the present article do not apply to the cases of conditional use addressed in Article 172 and Article 204-C. (Included by Decree no. 10,468, enacted in 2020)

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 seizure 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 standards; 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 standards 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) in the case of minor infractions, a fine ranging from ten to twenty per cent of the maximum amount;
- a) for minor infractions, a fine from one to fifteen per cent of the maximum amount; (In the wording of Decree 9,069 enacted in 2017)
- a) for minor infractions, a fine from ten to twenty per cent of the maximum amount; (In the wording of Decree no. 10,468 enacted in 2020)
 - b) for moderate infractions, a fine ranging from twenty to forty per cent of the maximum amount;

- b) for moderate infractions, a fine from fifteen to forty per cent of the maximum amount; (In the wording of Decree 9.069 enacted in 2017)
- b) for moderate infractions, a fine from twenty to forty per cent of the maximum amount; (In the wording of Decree no. 10,468 enacted in 2020)
 - 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 the 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 the total or partial banning 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 the 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 2. The suspension of the activities addressed in item IV of the **head provision** and the banning addressed in item V of the **head provision** will be lifted, pursuant to the provisions of Article 517 and Article 517-A. (In the wording of Decree no. 10,468 enacted in 2020)
- 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.
- Paragraph 4. The sanctions addressed in items IV and V of the **head provision** may be applied as provisional remedies, without prejudice to the provisional remedies laid down in Article 495. (<u>Included by Decree no. 10,468, enacted in 2020</u>)
- Article 508-A. Those products seized pursuant to the provisions of item III of the **head provision** of Article 508 and forfeited in favor of the Federal Government, and which despite the adulteration which led to their seizure, present conditions of fitness for human consumption, will receive a priority disposition to food security programs and programs to fight hunger. (Included by Decree no. 10,468, enacted in 2020)

Sole paragraph. The Ministry of Agriculture, Livestock and Food Supply shall, in supplementary standards, lay down procedures for the enforcement of the sanction of forfeiture of products. (<u>Included by Decree no. 10,468, enacted in 2020</u>)

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 Article 496 are deemed minor;
- II violations covered in items VIII to XVI of the head provision of Article 496 are deemed moderate.
- III violations covered in items XVII to XXIII of the head provision of Article 496 are deemed serious; and
- IV violations covered in items XXIV to XXXI of the head provision of Article 496 are deemed extremely serious.
- I those violations covered in items I to VII and item XXXII of the **head provision** of Article 496, are deemed minor; (In the wording of Decree no. 10,468 enacted in 2020)
- II those violations covered in items VIII to XVI, and items XXXIII and XXXIV of the **head provision** of Article 496, are deemed moderate; (In the wording of Decree no. 10,468 enacted in 2020)
- III those violations covered in items XVII to XXIII and items XXXV to XXXVII of the **head provision** of Article 496, are deemed serious; and (In the wording of Decree no. 10,468 enacted in 2020)
- IV those violations covered in items XXIV to XXXI and items XXXVIII to XLIV of the **head provision** of Article 496 are deemed very serious. (In the wording of Decree no. 10,468, enacted in 2020)

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.

Paragraph 2. Persons committing other infractions addressed in the present Decree or in the supplementary standards will face fines ranging from twenty to one hundred per cent of the maximum amount of the fine, in accordance with the severity of the offense and with the extenuating and aggravating circumstances provided for in Article 510.

Paragraph 2. Persons committing other infractions against this Decree or against the supplementary standards 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 no. 9,069, enacted in 2017)

Paragraph 2. Persons committing other infractions against this Decree or against the supplementary standards will face fines ranging from ten 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 no. 10,468, enacted in 2020)

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 history of the offender and any extenuating or aggravating circumstances.

Paragraph 1. The following are deemed extenuating circumstances: if

- I the offender is a first-time offender:
- I the offender is a first-time offender in the same infraction; (In the wording of Decree no. 10,468 enacted in 2020)
 - 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 infraction did not lead to economic advantage for the offender; or
 - VII the infraction did not affect the quality of the product.
- VI the infraction did not lead to economic advantage for the offender; (In the wording of Decree no. 10,468 enacted in 2020)
 - VII the infraction did not affect the quality of the product; (In the wording of Decree no. 10,468 enacted in 2020)
- VIII the offender proved that they had corrected the irregularity that led to the infraction within the time frame for presenting a defense; (Included by Decree no. 10,468, enacted in 2020)
- IX the offender is a small-scale agribusiness establishment producing livestock-based products and falling under the definitions contained in items I or II of the **head provision** of Article 3 or of Paragraph 1 of Article 18-A of Supplementary Law no.123, dated 2006. (Included by Decree no. 10,468, enacted in 2020)

Paragraph 2. The following are deemed aggravating circumstances: $\underline{\textbf{if}}$

- I the offender is a repeat offender;
- I the offender is a specific repeat offender; (In the wording of Decree no. 10,468 enacted in 2020)
- II the offender committed the offense in order to obtain an advantage of some 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 obligations of a depositary in regard to the keeping of the product.
- Paragraph 3. When both extenuating and aggravating circumstances are present, the 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 any kind of new offense, while specific recidivism is characterized by committing the exact 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 standard 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.
- Paragraph 8. The provisions of item IX of Paragraph 1 do not apply to cases of recidivism, fraud, resistance or hindrance to inspection. (Included by Decree no. 10,468, enacted in 2020)
- Article 511. The fines addressed in this Chapter do not exempt the offender from the seizure of, or from the rendering unusable of, the product 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 measures 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 1. The cancellation of listing will be applied by the Head of the Service of Inspection of Animal Products in the state under whose jurisdiction the establishment is located. (In the wording of Decree no. 10,468, enacted in 2020)
- 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 512. Should an administrative process reveal the practice of two or more infractions, the penalties are to be applied cumulatively upon each infraction committed. (In the wording of Decree no. 10,468, enacted in 2020)
- 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; (Revoked by Decree no. 10,468, enacted in 2020)
- II ships raw materials, ingredients, products or packaging that has been stored in unsuitable conditions; (Revoked by Decree no. 10,468, enacted in 2020)
- III uses products with expired validity, attaches new dates post-expiration on such products, or places a date later than the real manufacturing date; (Revoked by Decree no. 10,468, enacted in 2020)
- IV produces or ships products that pose a risk to public health; (Revoked by Decree no. 10,468, enacted in 2020)
- V produces or ships for edible purposes products unfit for human consumption; (Revoked by Decree no. 10,468, enacted in 2020)
- VI uses condemned raw materials and products, or those that have not been inspected, in the preparation of products for human consumption; (Revoked by Decree no. 10,468, enacted in 2020)
- VII makes products that do not meet the specific legislation or that fail to comply with the manufacturing processes, formulation and composition registered in the Department of Inspection of Animal Products; or (Revoked by Decree no. 10,468, enacted in 2020)
- VIII uses, replaces, totally or partially takes or removes raw materials, products, labels or packaging seized by the SIF and kept under guard by the establishment; (Revoked by Decree no. 10,468, enacted in 2020)

Article 513. For the purposes of applying the sanctions given in item III of the head provision of Article 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 tampered with or adulterated, without prejudice to other provisions in this Decree, in the cases defined in Article 504. (In the wording of Decree no. 10,468, enacted in 2020)

Paragraph 1. It falls to the offender to shoulder the possible costs of the removal, transport and destruction of the 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 in 1989.

Article 514. For the purposes of applying the sanction addressed in item IV of the **head provision** of Article 508, the following are risky activities or situations that threaten hygiene and health, without prejudice to other provisions of this Decree:

Article 514. The sanction addressed in item IV of the **head provision** of Article 508 will be applied in the following cases, without prejudice to other provisions of the present Decree, when a risk or threat to hygiene or public health is characterized — such as: (In the wording of Decree no. 10,468, enacted in 2020)

- I breaching, 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;
 - II omitting information about the centesimal and technological composition of the manufacturing process;
 - III changing or falsifying any animal raw material, animal ingredient or animal product;
- III changing any animal raw material, animal ingredient or animal product; (In the wording of Decree no. 10,468 enacted in 2020)
 - IV shipping raw materials, ingredients, products or packaging that have been stored in unsuitable conditions;
- V receiving, using, transporting, storing or shipping raw materials, ingredients or products without proof of origin;
 - VI simulating the legality of raw materials, ingredients or products whose origin is unknown;
- VII using products with elapsed expiry dates, attaching new dates post-expiration on such products, or placing a date later than the real manufacturing date for the product;
- VII using products outside their shelf life, going against the criteria laid down in the present Decree or in supplementary standards, or affixing new expiration dates to products after their shelf life has expired; (In the wording of Decree no. 10,468 enacted in 2020)
 - VIII producing or shipping products posing a public health risk;
- IX producing or shipping for edible purposes products unfit for human consumption; (Revoked by Decree no. 10,468, enacted in 2020)
- X using condemned or uninspected raw materials and products in the preparation of products for human consumption;
- X using condemned raw materials and products, or those that have not been inspected, or raw materials and products without a known provenance, in the preparation of products for human consumption; (In the wording of Decree no. 10,468 enacted in 2020)
 - XI using a process, substance, ingredients or additives that fail to comply with specific legislation;
- XII using, replacing, totally or partially taking or removing raw materials, products, labels or packaging seized by the SIF and kept under guard by the establishment;
- XIII giving or presenting false or inaccurate information, statements or documents to the oversight agency about the quantity, quality and origin of raw materials, ingredients and products, or withholding information that directly or indirectly interests the Ministry of Agriculture, Livestock and Food Supply and the consumer;

- XIII providing or presenting the Ministry of Agriculture, Livestock and Food Supply with inaccurate or imprecise information concerning the quantity, quality and provenance of raw materials, ingredients and products; (In the wording of Decree no. 10,468 enacted in 2020)
 - XIV altering, fraudulently presenting, adulterating or falsifying records liable to SIF verification;
- XIV falsifying records that are subject to SIF verification; and (<u>In the wording of Decree no. 10,468 enacted in 2020</u>)
- XV failing to meet deadlines established in the self-control programs and in documentation issued in response to the SIF concerning action plans, inspections, warnings of violation, summonses or notifications; (Revoked by Decree no. 10,468, enacted in 2020)
 - XVI exceeding the maximum capacity for slaughter, for treatment, for industrial processing or for storage;
- XVII failing 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; (Revoked by Decree no. 10,468, enacted in 2020)
- XVIII acquiring, handling, shipping or distributing animal products from an establishment not registered or listed in the Department of Inspection of Animal Products, or one that is not in the general registry of the Brazilian System of Inspection of Animal Products; or
- XVIII acquiring, handling, shipping or distributing animal products from an establishment not registered or listed in the Department of Inspection of Animal Products, or one that is not in the general registry of the Brazilian System of Inspection of Animal Products; (In the wording of Decree no. 10,468 enacted in 2020)
 - XIX failing to recall products that may pose a threat to consumers' health or interests.
- XIX failing to recall products that may pose a threat to consumers' health or that may have been adulterated; (In the wording of Decree no. 10,468 enacted in 2020)
- XX commencing activities without addressing the demands or outstanding issues that were established upon the granting of the deed of registration; (Included by Decree no. 10,468, enacted in 2020)
- XXI issuing or selling animal products that are subject to mandatory reinspection before such inspection has been performed; (Included by Decree no. 10,468, enacted in 2020)
- XXII receiving, handling, treating, industrially processing, portioning, preserving, storing, packing, packaging, labeling or shipping animal products that do not have a registration in the competent inspection agency; (Included by Decree no. 10,468, enacted in 2020)
- XXIII failing to comply with sanitary orders for the total or partial blocking of facilities or equipment, for the suspension of activities, or other orders given as a result of inspection, or notification of violations, including orders given as provisional remedies; and (Included by Decree no. 10,468, enacted in 2020)
- XXIV failing to perform the industrial disposition or conditional use treatments established in the present Decree or in supplementary standards, or failing to provide the correct disposition to condemned products. (Included by Decree no. 10,468, enacted in 2020)
- 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 constitutes hindering enforcement actions when the offender:
- Article 515. The sanction addressed in item IV of the **head provision** of Article 508 will be applied, pursuant to the provisions of Article 517, when the offender: (In the wording of Decree no. 10,468, enacted in 2020)
- I thwarts the actions of a public servant 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 public servant of the Ministry of Agriculture, Livestock and Food Supply;
 - III omits information about the centesimal composition and technical composition of the manufacturing process;
 - IV simulates the legality of raw materials, ingredients or products whose origin is unknown;

- V constructs, extends or remodels facilities without prior approval from DIPOA Department of Inspection of Animal Products; (Revoked by Decree no. 10,468, enacted in 2020)
- VI uses, replaces, totally or partially takes or 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 the 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; (Revoked by Decree no. 10,468, enacted in 2020)
 - VIII falsifies official documents;
 - IX falsifies records that are subject to SIF verification;
- X fails to meet deadlines established in the self-control programs and in documentation issued in response to the SIF concerning action plans, inspections, warnings of violation, summonses or notifications; (Revoked by Decree no. 10,468, enacted in 2020)
- XI ships products for international trade that have been made without attention to the supplementary standards concerning the export of animal products; or (Revoked by Decree no. 10,468, enacted in 2020)
 - XII fails to recall products that may pose a threat to consumers' health or interests.
- XII fails to comply with sanitary orders for the total or partial blocking of facilities or equipment, for the suspension of activities, or other orders given as a result of inspection, or notification of violations, including orders given as provisional remedies; (In the wording of Decree no. 10,468 enacted in 2020)
- XIII provides or presents the Ministry of Agriculture, Livestock and Food Supply with false information, declarations or documents; (<u>Included by Decree no. 10,468, enacted in 2020</u>)
- XIV fails to present for reinspection, animal products that are subject to mandatory reinspection; and (<u>Included by Decree no. 10,468</u>, enacted in 2020)
- XV issues or sells animal products that are subject to mandatory reinspection before such reinspection has been performed. (Included by Decree no. 10,468, enacted in 2020)

Sole paragraph. The penalty addressed in item IV of the **head provision** of Article 508 shall — pursuant to the provisions of Article 517, without prejudice to other provisions contained in the present decree — when it has been characterized that inspection actions have been hindered, also be applied to the following cases: (Included by Decree no. 10,468, enacted in 2020)

- I deliberately, or repeatedly, failing to meet deadlines established in the documents sent to the SIF regarding compliance with action plans, inspections, warnings of violation, summonses or notifications; (<u>Included by Decree no. 10,468</u>, enacted in 2020)
- II shipping products for international trade that have been made without attention to the supplementary standards concerning the export of animal products; (In the wording of Decree no. 10,468 enacted in 2020)
- III providing or presenting the Ministry of Agriculture, Livestock and Food Supply with inaccurate or imprecise information concerning the quantity, quality and provenance of raw materials, ingredients and products; (<u>Included by Decree no. 10,468, enacted in 2020</u>)
- IV failing to present animal products that are subject to mandatory reinspection at the authorized reinspection location; (Included by Decree no. 10,468, enacted in 2020)
- V making irregular use of false, misleading or imprecise information or documentation, or introducing it into the computer systems of the Ministry of Agriculture, Livestock and Food Supply; and (Included by Decree no. 10,468, enacted in 2020)
- VI giving or presenting false or inaccurate information, statements or documents to the oversight agency about the quantity, quality and origin of raw materials, ingredients and products, or withholding information that directly or indirectly interests the Ministry of Agriculture, Livestock and Food Supply and the consumer. (Included by Decree no. 10,468, enacted in 2020)

Article 516. For the purposes, without prejudice to other provisions in this Decree, of applying the sanctions addressed in item V of the **head provision** of Article 508, the following characterize a lack of suitable hygiene and health conditions: (Revoked by Decree no. 10,468, enacted in 2020)

- 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 (Revoked by Decree no. 10,468, enacted in 2020)
- II failing to meet the deadlines established 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. (Revoked by Decree no. 10,468, enacted in 2020)
- 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 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 period of seven days, to which may be added fifteen, thirty or sixty days depending on the track record of violations, successive repetitions of the offense and other aggravating circumstances provided for in Article 510, regardless of whether the causal irregularities have been corrected. (In the wording of Decree no. 10,468, enacted in 2020)
- Paragraph 1. The time frame for the application of the suspension of activities, caused by the hindering of inspection actions, may be reduced to at least three days, in the case of infractions classified as minor or moderate, or if extenuating circumstances prevail, except in cases of specific repeat offending. (Included by Decree no. 10,468, enacted in 2020)
- Paragraph 2. The effects of the penalties addressed in the **head provision** shall commence within thirty days of the date when the establishment is made aware. (<u>Included by Decree no. 10,468, enacted in 2020</u>)
- Paragraph 3. After the sanctions addressed in the **head provision** have come into effect, the time frame for their application will be counted in the form of consecutive days, except in the cases addressed in Paragraph 1, where the time frame will be counted in the form of subsequent working days. (<u>Included by Decree no. 10,468, enacted in 2020</u>)
- Paragraph 4. The halting of activities as addressed in the **head provision** covers production activities and health certification, and when applicable allows for the completion of the manufacturing process in the case of products that have a prolonged manufacturing process that commenced before the sanction came into effect. (<u>Included by Decree no. 10,468, enacted in 2020</u>)
- Paragraph 5. The blocking that is addressed in the **head provision** will be partially applied to the room in which the adulteration occurred, when it is possible to delimit or identify the location of the occurrence; or will be applied totally when it is not possible to delimit or identify the location of the occurrence, as specified in the document of judgment. (<u>Included by Decree no. 10,468, enacted in 2020</u>)
- Paragraph 6. If the sanctions addressed in the **head provision** have been applied by means of a provisional remedy, the period of duration of the provisional remedy actions, when lasting more than one day, will be deducted from the period of the application of the sanctions at the end of the administrative investigation. (<u>Included by Decree</u> no. 10,468, enacted in 2020)
- Article 517-A. The sanctions of the total or partial blocking of the establishment as a result of the finding that suitable hygiene and sanitary conditions are not present, and the sanction of the suspension of activity, resulting from a risk or threat to hygiene or public health, will be lifted after the demands that caused the sanctions have been met. (Included by Decree no. 10,468, enacted in 2020)
- Paragraph 1. The blocking sanction addressed in the **head provision** will be applied either: (Included by Decree no. 10,468, enacted in 2020)
- I partially in rooms or on equipment failing to present suitable hygienic or sanitary operating conditions; or (Included by Decree no. 10,468, enacted in 2020)
- II totally, if the unsuitable conditions extend throughout the establishment, or if the nature of the identified risk does not allow the room or equipment involved to be cordoned off. (Included by Decree no. 10,468, enacted in 2020)
- Paragraph 2. The suspension of activity addressed in the **head provision** will be applied to any room, item of equipment, or operation that leads to a risk or threat to public health or hygiene. (<u>Included by Decree no. 10,468, enacted in 2020</u>)

Paragraph 3. The sanctions addressed in the present article will cease to be applied upon completion of the investigation process, if they have been applied as a provisional remedy. (<u>Included by Decree no. 10,468, enacted in 2020</u>)

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 518. When an identical offense is found three times, whether consecutively or otherwise, within a twelve-month period, this characterizes a habitual attitude in the adulteration or falsification of products. (In the wording of Decree no. 10,468, enacted in 2020)

Paragraph 1. For the purposes of the present article, an identical infraction is deemed to be one that has the same causal fact, regardless of its legal category, that has been found by the inspection service. (Included by Decree no. 10,468, enacted in 2020)

Paragraph 2. In order to count the number of infractions so as to characterize a habitual nature, the first infraction and two further infractions that are found after the establishment has taken corrective and preventive measures to eliminate the first irregularity, will be taken into consideration. (<u>Included by Decree no. 10,468, enacted in 2020</u>)

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 standards; (Revoked by Decree no. 10,468, enacted in 2020)

- 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 the non-lifting of a ban on the establishment after twelve months.

CHAPTER IV

ENFORCEMENT ACTIONS

Article 520. Infringements of the provisions of this Decree and of supplementary Acts will be examined in a fully investigated enforcement action, begun by preparing notification of violation.

Article 521. The notification of infraction will be drafted by the Federal Agriculture Inspector/Auditor who noticed the infraction, at the very place where the irregularity was found, or in the Ministry of Agriculture, Livestock and Food Supply's inspection agency.

Sole paragraph. For the purpose of the administrative investigation of violations of legislation concerning animal products, and the application of penalties, the commencement date of the inspection activity that enabled detection of the irregularity will be deemed to be the date on which the generating fact of the violation took place, as follows: (Included by Decree no. 10,468, enacted in 2020)

- I the date of inspection, for the case of infractions found during inspection, enforcement or audit activities performed in establishments, or in the analysis of documentation, or in information contained in official electronic systems; or (Included by Decree no. 10,468, enacted in 2020)
- II the date of sample-taking, in the case of products undergoing laboratory testing. (<u>Included by Decree no.</u> 10,468, enacted in 2020)

Article 522. The notification 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 notification of infraction will be drafted using a specific template to be established by the Ministry of Agriculture, Livestock and Food Supply. (Revoked by Decree no. 10,468, enacted in 2020)

Article 524. The signature and date given on the notification 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 notification of infraction, this fact is to be recorded on the notification itself.

Paragraph 2. Express acknowledgment of the notification of infraction must be given personally, or by sending a notice of receipt (AR — *aviso de recebimento*) through the post, or by telegram or some other means that ensures certainty of the acknowledgment of the interested party.

Paragraph 3. In the case of undefined or unknown offenders, or those without a fixed home address, or if it is impossible to notify them officially as addressed in Paragraph 2, notification is performed by means of an official publication. (Included by Decree no. 10,468, enacted in 2020)

Paragraph 4. Notification will be null and void when carried out otherwise than in compliance with legal provisions. (Included by Decree no. 10,468, enacted in 2020)

Paragraph 5. Manifestation by the administered party of their awareness of the content of the notification will offset the lack of, or irregularity of, the notification. (Included by Decree no. 10,468, enacted in 2020)

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 525. The defense and the appeal of the notified party must be presented in writing, in Portuguese, and be received under 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. (In the wording of Decree no. 10,468, enacted in 2020)

Paragraph 1. The deadline addressed in the **head provision** will be counted continuously, and will commence on the first working day after the date of official notification. (Included by Decree no. 10,468, enacted in 2020)

Paragraph 2. The deadline will be extended up until the first subsequent working day should it elapse on a non-working day, or if the working hours are concluded before the normal time. (Included by Decree no. 10,468, enacted in 2020)

Article 525-A. Defenses or appeals lodged in the following situations will not be recognized: (Included by Decree no. 10,468, enacted in 2020)

- I outside the deadline; (Included by Decree no. 10,468, enacted in 2020)
- II to an agency other than the competent agency; (Included by Decree no. 10,468, enacted in 2020)
- III by an individual who has not been legitimated; (Included by Decree no. 10,468, enacted in 2020))
- IV after exhausting the administrative sphere. (Included by Decree no. 10,468, enacted in 2020)

Paragraph 1. In the case of item II of the **head provision**, the notified party will be informed of which is the competent authority and the deadline for defense or appeal will be devolved. (<u>Included by Decree no. 10,468, enacted in 2020</u>)

Paragraph 2. Non-recognition of the appeal does not prevent the public administration from reviewing *ex officio* the illegal act, provided that administrative preclusion has not occurred. (<u>Included by Decree no. 10,468, enacted in 2020</u>)

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 or tier.

Article 526. The Service of Inspection of Animal Products in the State where the offense was detected, after the defense has been included into the case file, must present evidence in the case by including a report, and the Head of the Service must then proceed to judgment in the first instance or tier. (In the wording of Decree no. 10,468, enacted in 2020)

Sole paragraph. If no defense is presented, such information will appear on the fact-finding report. (<u>Included by</u> Decree no. 10,468, enacted in 2020)

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. A 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 instance or tier.

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.

Sole paragraph. The recall of products posing a threat to health, or of products that have been adulterated, may also be disclosed. (In the wording of Decree no. 10,468, enacted in 2020)

Article 531. The drafting the notification of infraction does not exempt the offender from the demand that motivated it.

Article 531-A. For the purposes of the provisions of Article 55 of Supplementary Law no. 123, dated 2006, infractions deemed serious or very serious, pursuant to the terms established in the present Decree, and committed by very small, or small, livestock-product producing companies are deemed to be high-risk activities and situations. (Included by Decree no. 10,468, enacted in 2020)

TITLE XII

FINAL AND TRANSITORY PROVISIONS

Article 532. The Department of Inspection of Animal Products and the health regulatory agency 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 532-A. The Ministry of Agriculture, Livestock and Food Supply is to work jointly with the competent health agency to perform: (Included by Decree no. 10,468, enacted in 2020)

I - animal health and human health actions and programs to mitigate or reduce contagious, infectious or parasitic diseases that can be transmitted between man and animals; and (<u>Included by Decree no. 10,468, enacted in 2020</u>)

II - sanitary education activities. (Included by Decree no. 10,468, enacted in 2020)

Article 532-B. The Ministry of Agriculture, Livestock and Food Supply will, when appropriate, create simplified procedures for the migration of the registration, or to restore the registration to regular condition before the competent agency, of manufacturing establishments for the products addressed in the present Decree, that have been registered in the Department of Inspection of Animal Products, of the Secretariat of Animal and Plant Health or the Ministry of Agriculture, Livestock and Food Supply, thus ensuring the continuity of the performance of the economic activity. (Included by Decree no. 10,468, enacted in 2020)

Article 533. Labels of imported products already registered in a foreign language, and 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 536. Omissions or queries arising from the execution of this Decree will be solved by the Department of Inspection of Animal Products, of the Secretariat of Animal and Plant Health, of the Ministry of Agriculture, Livestock and Food Supply. (In the wording of Decree no. 10,468, enacted in 2020)

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. Establishments registered or listed in the Ministry of Agriculture, Livestock and Food Supply will have one year from the coming into force of this Decree in which to adjust to the provisions laid down in it.

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 no. 9,069, enacted in 2017)

Article 538-A. The Ministry of Agriculture, Livestock and Food Supply and the establishments registered or listed in the Ministry of Agriculture, Livestock and Food Supply, will make adjustments in order to align with the provisions contained in Article 28, Article 84-A, Article 207-A, Article 207-B, Article 219-A, Article 267 and Article 487, within one year, counting from the date of publication of Decree no. 10,468, enacted August 18, 2020. (Included by Decree no. 10,468, enacted in 2020)

Article 539. The Ministry of Agriculture, Livestock and Food Supply will issue supplementary standards needed for the execution of this Decree.

Article 540. Existing supplementary standards 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 March 29, 1952;
- II Decree no. 39,093, enacted April 30, 1956;
- III Decree no. 1,255, enacted June 25, 1962;
- IV Decree no. 56,585, enacted July 20, 1965;
- V Decree no. 1,236, enacted September 2, 1994;
- VI Decree no. 1,812, enacted February 8, 1996;
- VII Decree no. 2,244, enacted June 4, 1997;
- VIII Decree no. 6,385, enacted February 27, 2008;
- IX Article 3 of Decree no. 7,216, enacted June 17, 2010;
- X Decree no. 8,444 enacted May 6, 2015; and
- XI Decree no. 8,681, enacted February 23, 2016.

Article 542. This Decree shall come into force on its publication date.

Brasilia, March 29, 2017, 196th year of Independence and 129th year of the Republic.

MICHEL TEMER Blairo Maggi

This text does not replace the text published in the Official Gazette (DOU) of 30/03/2017 and rectified 01/06/2017

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