PROPOSAL

MEAT AND MEAT PRODUCTS SANITARY INSPECTION REGULATIONS

IN THE DOMINICAN REPUBLIC

MEAT AND MEAT PRODUCTS SANITARY INSPECTION REGULATIONS

CONSIDERING: That it is an essential function of the Dominican Government to safeguard human health by adopting and enforcing adequate sanitary measures. It also has the essential function to regulate and inspect the processing and sale of bovine, ovine, porcine and goat meats, including products derived from these meats destined for human consumption for national and export sales, with the purpose of assuring that they are apt for export.

CONSIDERING: That, due to the country's development, the national meat production industries has incorporated technological advances, making it necessary to update current regulations to complement existing world markets regulations.

CONSIDERING: That, to facilitate the international trade of meats and meat products, it is advisable to grant the sanitary legislation of our country a legal instrument in accord with the exigencies required in foreign markets.

CONSIDERING: That the meat, carcasses, viscera and their processed products can be a source of diseases that affect public and animal health, as well as the economy if their origin and zoo-sanitary quality if not verified, under this circumstances should be guaranteed optimum quality health and hygiene, in order to provide quality and safety for consumers and national livestock production.

THEREFORE:

AGREES to emit the following:

MEAT AND MEAT PRODUCTS INSPECTION REGULATIONS
TITLE I
GENERAL REGULATIONS
CHAPTER I
OBJECTIVE AND SCOPES OF THE REGULATIONS

Article 1 These regulations have the objective to extend the legal, technical and administrative norm referring to the inspection of products and meat byproducts.

Article 2 These regulations establish the sanitary specifications that establishments dedicated to animal slaughter and processing, and transformation and storage of products and byproducts of animal origin must comply to guarantee food safety for national consumption or export.

CHAPTER II
REGULATION ADMINISTRATION INSTANCES

Article 3 SESPAS, through the General Directorate of Environmental Health and its Food and Beverage Risk Control Department, by means of the Meat and Meat Products Inspection Program, will be responsible for the application of these regulations.

Article 4 These regulations shall apply to all establishments dedicated to slaughter, packing, process, and storage of meat products of national and foreign origin.

CHAPTER III
OFFICIAL ADMINISTRATIVE SYSTEM

SESPAS: State Secretariat of Public Health and Social Assistance, administered or directed by the office of the Secretary of State.

GENERAL DIRECTION OF ENVIRONMENTAL HEALTH.
The General Director represents it, and his function is to enforce the Law and sanitary regulations, as well as to coordinate the functions of those responsible of the different departments, among them, the Food and Beverage Risk Control Department.

FOOD AND BEVERAGE RISK CONTROL DEPARTMENT. Its representative carries out the functions of the Inspection System of the Country for all types of food and beverages of national production and imports.

MEAT AND MEAT PRODUCTS INSPECTION PROGRAM. The Program Representative will have the functions of National Veterinary Supervisor and will carry out general coordination of the inspection services of the authorized establishments.

OFFICIAL EMPLOYEE. The employee of the General Directorate of Environmental Health conducts the inspection of animal origin products and byproducts.

VETERINARY DOCTOR INSPECTOR OFFICER. Professional Veterinary functionary from the General Directorate of Environmental Health assigned to an establishment to make inspection functions. This professional must fulfill the obligations anticipated in these regulations.

OFFICIAL INSPECTION ASSISTANT. Personnel trained and certified by the Food and Beverage Risk Control Department to assist the Veterinary Doctor Inspector Officer's tasks. These personnel must fulfill with estimated obligations in these regulations.

PROGRAM EMPLOYEE. All Environmental Workers or another person employed by SESPAS that authorized to carry out any activity or task related to the program.

INSPECTION. Set of actions and applied procedures of physical and anatomo-pathological nature the Veterinary Doctor or the program's personnel uses to examine

with the sense of smell, vision and tact, the conditions and organoleptic properties of animal origin foods or its raw materials.

ANTE-MORTEM INSPECTION. It is the procedure where the Official Veterinary Doctor verifies the animals within the corrals to decide if they are clinically healthy to slaughter.

POST-MORTEM INSPECTION. Name given to the procedure where the Official Inspection Service checks the animals within the establishment during the slaughter process making its observation in carcasses and viscera to decide if they are edible for human.

INSPECTED AND APPROVED. The words sealed in the meats, food products and others to indicate that the actions of control have been fulfilled fixed by these regulations.

CHAPTER IV
THE AUTHORIZED TECHNICAL DEFINITIONS

Article 5 For aims of these regulations, the definitions constitute the official interpretation of the following terms:

POTABLE WATER. Water approved by the corresponding sanitary authority or another qualified governmental organism, which certifies the national legislation for use in food product processing facilities.

EDIBLE FOOD. Food produced in sanitary conditions inspected and approved by the Inspection Service, and innocuous for human consumption without any restriction.

HEAT TREATED FEED FOR ANIMALS. All products, byproducts or derivatives of animal origin destined for feeding animal excluding ruminants, that have received a direct and indirect heat process, or another procedure approved by the General Directorate of Environmental Health. In no case, it could be destined for human consumption.

ANIMAL. For these regulations, the animal is the live unit of any species approved by the General Directorate of Environmental Health for its industrialization destined to human or animal consumption.

FALLEN ANIMAL. Animal or animals, those by fractures or some other injury are unable to enter by themselves to the sacrifice room.

HAZARD ANALYSIS AND CRITICAL CONTROL POINTS SYSTEM AUDITS (HACCP). Confirmation by systematic evaluation of the practical compliance established in the documentation of the HACCP system and their results adjust to anticipated objectives.

MEAT. The part of the muscle and soft tissues that surround the skeleton of the sacrificed animal, including their cover of fat, sinews, vessels, nerves, aponeurosis and other tissues separated during the slaughter operation, with exception of the skin in the porcine specie.

FRESH MEAT. Meat that besides being refrigerated has not received its conservation effects, another treatment besides the protective package, and that conserves its natural characteristic.

DEBONED MEAT. Product obtained from separating the meat of the bones that sustains it.

TRIMMED MEAT. Deboned meat reduced to fragments.

CARCASS. The acceptable elaborate animal in authorized establishment, after sacrificed, bled, skinned, beheaded, removing extremities at the carpus and tarsus level, tail, breasts and eviscerated. This excludes the porcine specie with regard to skinning and removing the head and legs.

STORING CENTER. Place or building used for receiving, storage and distribution of foods of animal origin.

CLASSIFICATION OF THE SLAUGHTERHOUSES. The slaughterhouses classify in the following categories:

Slaughter House Class "1": Establishment or industrial plant authorized to export meat and meat byproducts or their commercialization within the national territory. Furthermore, they are named processing plants.

Slaughter House Class "2": Establishment or industrial plant authorized to slaughter bovine, goats, ovine and porcine only for commercialization within the national territory.

Slaughter House Class "3": Establishment authorized to slaughter bovine, goats, ovine and porcine only for local commercialization.

CONSCIOUSNESS. Responsiveness of the brain to the impressions received through the senses.

ARTIFICIAL Coloring. Dye or pigment manufactured by synthetic procedure or analogous process.

CONDITIONS OR REQUIREMENTS. Requirements to which establishments shall adjust in order to be authorized by the General Directorate of Environmental Health.

CONDEMNED. All products, byproducts or derivatives from animal origin, that been inspected are declared improper for human consumption and must be eliminated by the use of a render or incinerator. Include in this definition the standing animals.

CONTAMINATION. It is the direct or indirect transmission of microorganisms, chemical substances and strange material to meat products and meat byproducts.

CUT. It is the part of the animal of easy anatomical identification.

RECORD BOOK. Control pages written and authorized by the Representative of the Food and Beverage Risk Control Department in which the Program Supervisor and the Veterinary Doctor Inspector brief the total movement of activities made in the establishment; this is the main communication media between the Inspection Service and the proprietors or persons responsible of the establishment.

SCRAPS. Parts of the animal considered as inedible.

DISINFECTION. The application, after a complete cleaning, of procedures destined to destroy infectious agents.

RENDER OR YIELD PLANT. An area provided with appropriate equipment for industrialization of dead animals in corrals, carcasses, viscera, bones and blood seized for being inedible for human consumption and the result of this industrialization is destined to the non-ruminant animals.

IMMEDIATE PACKAGE. Container or another cover in which the product is directly contained total or partial.

PACKING. The outer cover (box, bag, barrel, basket or another container or cover) that contains any previously packed product in one or more immediate packages total or partially.

SHIPMENT. They are the products or byproducts that enter or leave an authorized establishment protected by an Official Certificate of Inspection.

MEAT PRODUCT ESTABLISHMENT. All establishments with the following operations: prepare, elaborate, process, packaging, storage, distribution, handling and meat products sale.

SLAUGHTER. Work made from the sacrifice of the animals to its entrance to the refrigerating chambers or its delivery destined to the consumption or industrialization of the carcasses, half carcasses or quarters.

CATTLE. It means all animals from the bovine, ovine, goat and porcine species.

HYGIENE. The set of actions needed during elaboration, treatment, storage, transport and commercialization of foods, to guarantee its security and innocuousness.

INDUSTRIALIZATION. The manufacturing process to which animals slaughtered, their parts, fluids and raw materials submit to obtain foods.

CLEANING. The process of elimination of strange material, residues or impurities forms the surfaces of the facilities, equipment, utensils or others.

FOOD LOT. Set of foods made in an authorized industrial establishment under the same processing conditions during a determined period and identified under the same number.

LOT OF ANIMALS. Set of animals that belong to a same proprietor and have the same origin that will enter the establishment protected by the same documentation and marks.

CORROSION RESISTANT MATERIAL. It is the non-toxic impermeable product, resistant to the seawater, ice, substances released by the product or other corrosive substances, with which it can make contact. Its surface must be smooth and resistant to the repeated action of cleaners approved by The General Directorate of Environmental Health.

TRANSPORT MEANS. The system used to transfer animals, meats, products, byproducts and their derivatives, inside or outside the establishment. The General Directorate of Environmental Health will approve transport means for their use, for which they must gather the established hygienic and sanitary conditions in these regulations.

INEDIBLE. Product checked by the Inspection Service and determined as not appropriate for human consumption.

HAZARD. Biological, chemical or physical agent that with a reasonable probability can cause disease or injury to the person.

SANITATION OPERATION PROCEDURES STANDARDS (SOPS). Documented system that guarantees the hygiene of personnel, cleaning of the facilities, equipment and instruments and their disinfection to reach levels specified before the operations and in their course.

HACCP PLAN. Written document based on principles of Hazard Analysis and Critical Control Points (HACCP), which defines the formal procedures that must follow according to the general principles, to guarantee food safety.

MEAT PRODUCTS. Those prepared with meat, blood, viscera, or other byproducts of animal origin authorized for human consumption adding or not additives and approved species. These products will be denominated according to their species.

REJECTED. No product, byproduct, derivative, container or vehicle by its sanitary conditions agrees with what it establishes these regulations.

CHEMICAL RESIDUES. Residues from veterinary medicines and pesticides that can be present in meat products and detected by chemical analyses.

RETAIN, DETAIN, OR INTERVENE. All product, byproduct, derivative, containers or vehicles that do not agree with that established in these regulations due to their sanitary conditions, without giving rise to be rejected or condemned.

ARTIFICIAL FLAVOR. The flavor or an agent that contains or offers a synthetic flavor, or other analogous media.

BRINE. Food grade sodium chloride solution, prepared with potable water and other ingredients allowed for human, used for the conservation or treatment of animal origin products or its raw materials.

FOOD SAFETY SYSTEM. Set of procedures that processors, slaughterhouses, storing centers and all other establishments authorized by The General Directorate of Environmental Health must define, adopt, update and comply with to manipulate animal origin foods with the purpose of guaranteeing food safety.

ANIMAL ORIGIN BYPRODUCTS. Any part suitable to be used as food that is not meat, processed or not byproducts, edibles when destine for human consumption and inedible for animal consumption.

EXPOSITION TIME. Period an animal exposes to an anesthetic concentration.

HACCP SYSTEM VERIFICATION. The periodic proof conducted by the Food and Beverage Risk Control Department to the HACCP System by audit.

VISCERA. The organs contained in the main cavities of the body of animals.

TITLE II
OF THE INSPECTION, APPROVAL, AND CERTIFICATION OF THE PROCEDURES RELATED WITH FOOD SAFETY

Article 6 It corresponds to SESPAS through the General Directorate of Environmental Health to emit procedures and to coordinate with the participation of the private sector and other institutions of the public sector the actions to ensure the quality and safety of the meats and meat products.

Article 7 The General Directorate of Environmental Health through the Food and Beverage Risk Control Department, will elaborate technical and hygienic-

sanitary manuals, statistical sampling plan for product re-inspection, will establish tolerance levels for chemical and microbiological residues and other programs that will be in agreement to the national and international norms, and with Codex Alimentarius.

Article 8 SESPAS through The General Directorate of Environmental Health jointly with the productive sectors, processors, cattle trading sector and superior education centers, nationals and internationals and related ones, will promote and coordinated the information, education, communication, training and agreements related to the quality, health and meats and meat products safety.

Article 9 The establishments authorized and approved for export will undergo immediate changes in the process of Sanitary Inspection according to the innovations or requests of the meat products importing countries, that must be taken care of immediately, previous approval of the Responsible of the Food and Beverage Risk Control Department.

Article 10 The norms and international agreements ratified by the country will be applied as a complement to these regulations, in the specifications not contemplated in it.

TITLE III
OFFICIAL PERSONNEL OF THE INSPECTION SERVICE

Article 11 The Veterinary professionals and competent assistants, trained and certified by The General Directorate of Environmental Health will carry out the hygienic-sanitary inspection of the establishments and their products. In the establishments, where a permanent inspection is needed and required more than one veterinary inspector, the Food and Beverage Risk Control Department will assign an Official Veterinary Doctor Chief of Inspection in the facility.

Article 12 The following are obligations of the Veterinary Doctor Inspector in the Establishment:

1. Control the services in order to maintain the discipline and responsibility in the personnel necessary to obtain an efficient inspection.

2. Comply and enforce the Law and dispositions of these regulations.

3. Distribute personnel under its orders and give account to the superiors of the faults or omissions in which the employees incurred, applying at the same time the disciplinary measures according to the Law established for such aim.

4. Supervise and control the Assistant Officers or Accredited Assistants.

5. Maintain sanitary control in all the departments of the establishment responsible of, being responsible for all deficiencies for which it does not take the corrective actions, by itself, if it belongs to its faculty, or putting him in awareness of whom it concerns.

6. Decide on the destiny of meats observed by personnel of Inspection.

7. Have to its position and updated the record book, the books, seals and forms obligatory to take in each establishment. He is responsible for the safekeeping and signs of the certificates.

8. Send to superiors in the precise date the forms, reports and all other documentation with that destiny.

9. Submit monthly to the Food and Beverage Risk Control Department, a report in the first 5 days of the subsequent month of the work done during the previous month, as well as the improvements that considers necessary for good service of the inspection.

10. Receive and give signed the documentation and Inspection seals under inventory, maintaining updated, and be responsible for the conservation of the Inventory Book and other elements assigned to the inspection under its safekeeping.

11. In case of necessity shall take responsibility part of the Inspection Service without damage of the assigned direct functions.

12. Sample and deliver to the laboratory the samples of the processed products to analyses, as well as raw materials that enter their processing.

13. Perform every 6 months as minimum the chemical physical analysis and every thirty (30) days the bacteriological of the water used by the establishment in all its operative stages having them done in an Official or accredited Laboratory destined for that aim. The personnel of the Inspection Service located in the establishment must obtain the samples.

14. Perform sampling and shipment to the Official or accredited Laboratory of samples from suspicious animals having diseases whose macroscopic diagnosis raises doubts or difficulties.

15. Enforce effective dispositions on labeling or tagging on packages and weights declared before granting the sanitary documentation.

16. Establish surveillance in the load transportations and product handling under its control, as well as the storage of products destined to the commerce.

17. Maintain in direct form relations with superiors and the establishment management that controls.

18. Serve in the establishment in the assigned schedule.

19. Attend the establishment according to the daily schedule established.

20. Carry out the ante-mortem inspection previous revision of the sanitary documentation of the animals, to verify the corresponding amounts, coincidence of marks, origin of the lots and all other verification.

21. Be responsible of the necropsies and study material collection, taking all pertinent measures for isolation and disinfection in cases of infected-contagious diseases giving immediate notification when occurring to the National Supervisor for its respective intervention.

22. Be responsible for the slaughter for all animal or lot of animals destined to human consumption.

23. Proceed to the post-mortem examination of the sacrificed animals in the establishment, investigating in the site where the inspection performs the sanitary condition of the head of cattle and take part in the destiny of them, solving in doubtful cases.

24. Carry out along with Assistants the examination of viscera and lymphatic ganglia, visually, by palpation or through incisions not more, neither more extended than what is required; the Veterinary Doctors Inspectors Officers are responsible of the procedure.

26. Issue the respective Official Inspection Certificate when technical and legal requirements have met.

Article 13 The Assistants to the Veterinary Doctors Inspectors Officials or Credited will have obligations as follows:

1. Fulfill its specific work in the site and schedule assigned by the Responsible of the Service or the Veterinary Inspector.
2. When the work at the office requires it, perform administrative functions.

3. They are required in all the cases of verifying some abnormality in any area or process made inside the establishment and outside the plant, to stop the deviation in the process and communicate it to their superiors.

Article 14 The obligations of the National Veterinary Doctor Supervisor are:

1. Verify compliance of the Law and its regulations in all the authorized establishments by the General Directorate of Environmental Health.

2. Verify sanitary control in all departments of the establishments, being responsible for deficiencies communicated to him by the Plant Inspection Official Veterinary Doctors and for which does not arbitrate means within reach to correct them, by himself if it enters its faculty or putting it knowledge to whom corresponds.

3. Verify the normal attendance of personnel of the Inspection Service to establishments where they are assigned, according to their dates and estimated times.

4. Inform to the person Responsible of the Food and Beverage Risk Control Department of the abnormalities verified in the establishments where he is responsible.

5. Inform to Responsible of the Food and Beverage Risk Control Department of the existence of non-authorized establishments by the General Directorate of Environmental Health, and develops industrial activities contemplated in the Law and its regulation.

6. Monthly present to Responsible of the Food and Beverage Risk Control Department reports requested opportunely.
7. Carry out audits corresponding to food safety procedures by means of self-control plans that the establishments place in operation, under the HACCP System.

Article 15 The following are responsibilities of the Responsible of the Food and Beverage Risk Control Department as Veterinary Doctor in charge of the National Inspection Service:

1. Comply and enforce the Law and dispositions of these regulations.
2. Verify the sanitary control in all the departments of the establishments under Official Inspection. Is responsible for the deficiencies communicated to him by the Official Inspection Veterinary Doctors of the Plant, or by the National Official Veterinary Doctor Supervisor responsible, and for which does not arbitrate means to its reach to correct them, or by him, if it enters its faculties or putting it into knowledge of whom corresponds.

3. Control the services in order to keep discipline and responsibility in the personnel necessary to obtain an efficient inspection.
4. Distribute the personnel under his orders and inform superiors of any faults or omissions which employees incurred, applying at the same time disciplinary actions according to the Law established for such aim.
5. Prepare and send reports on the inherent activities to its area in time and availability that require the superior authorities.
6. All activity the superior authorities consider convenient bonded to their area.

Article 16 All members of the Official Inspection Service assigned to an establishment, as well as their superiors in direct line, will have free access to all departments of the establishment authorized by The General Directorate of Environmental Health, at any hour of the day or at night.

TITLE IV
OF THE REQUIREMENTS RELATED TO THE HYGIENIC-SANITARY CONSTRUCTION FOR THE MEAT PRODUCT PROCESSING ESTABLISHMENTS

Article 17 For the authorization of the establishments that produce or process meat, they shall comply with the following requirements for construction and sanitary engineering, without damage of other specific conditions that for their activity consider these regulations:

1. They shall be located on firm ground, in a non-flooding area.
2. They shall be far apart from industries that produce odor or detrimental emanations.
3. They shall be 4 kilometers minimum distant from residential zones.
4. They shall count on with abundant supplying of potable water and power services.
5. They shall be located in places with suitable access to paved and transit routes.
6. The location shall be in addition subject to favorable report of the corresponding organism, with respect to the industrial drainage.
7. Other constructions, industries or houses other to this activity cannot be present within the contour framed by the perimeter fence of the establishment.

Article 18 All internal roads of the establishment shall be paved or have an impermeable layer. The adjacent spaces must be waterproofed or in defect lay with lawn.

Article 19 A fence will be surrounding the establishments and will enclose all the departments in their perimeter area. This will be constructed with approved materials. When it is not totally of concrete block or reinforced brick, it shall have a wall with this material at least fifty (50) centimeters over the floor level to avoid the entrance of animals or noxious animals. Its

height shall have a minimum of two (2) meters. The doors for vehicles or people shall have the same height as the fence.

Article 20 The perimeter of the establishment shall have artificial illumination.

Article 21 The establishments authorized must be constructed with materials that will facilitate their cleaning and disinfection.

Article 22 Arrangements of the establishments, their design, construction and measures shall obey fundamentally to the following:

1. Allow cleaning and disinfection of areas and equipment, avoiding the accumulation or deposit of dirtiness on foods or surfaces that contact them.
2. Avoid the formation of condensation or undesirable moulds on surfaces of equipments or foods.
3. Provide food sanitation practice and prevention of crossed contamination due to equipment, utensils, foods, personnel, materials, water, raw materials or external sources of contamination caused by insects or rodents.
4. Assure the adequate temperature conditions for manipulation or storage of the products and raw materials.
5. Have devices or installations for monitoring the adequate conditions of the environmental temperature, located in accessible and visible places.

Article 23 The places or premises for the reception of raw materials shall be separated from the manufacturing rooms, personnel circulation, materials and equipment, in such form to avoid crossed contamination.

Article 24 The processing and manufacturing rooms shall be located and arranged in such a way to avoid the contamination.

Article 25 The establishments shall have a sufficient number of individual hand washers properly distributed and marked, with the following characteristics:

1. They shall be stainless steel constructed or with another material resistant to corrosion and be designed to facilitate their cleaning.
2. They shall have cold and warm water. The Inspection Service can authorize the omission of hot water in those premises that for production reasons justifies it and as long as it does not represent a detriment of hygienic aspects.
3. The water exit shall be approximately thirty (30) centimeters over the superior edge of the hand washer. Having to be driven to pedal or by automatic system.
4. Provide with liquid soap, or soap-powder and paper towel.

5. The discharge of these hand-washers shall go straight to the water-drainage system through siphon closure.
6. According to the needs of the sector shall have attached a sterilizer to sanitize, disinfect utensils and tools. The Inspection Service shall authorize the omission of this clause in those premises that for production reasons justify it whenever they do not represent a detriment of hygienic-sanitizing aspects.
7. The disinfection equipment shall consist of a container that contains an antiseptic approved by the Inspection Service or a water source at 82º C or 180º F as minimum.
8. In addition to hand washers and disinfection equipment of utensils for general use, mentioned before, in each operative zone of the Inspection Service shall count with hand washer and disinfection equipment.
9. The equipment destined to the hand washing shall not be used for washing raw materials or food.

Article 26 The floors shall be constructed with impermeable, washable, nonabsorbent and nontoxic materials, properly authorized by The Food and Beverage Risk Control Department. They shall not have filtrations to natural ground or inferior floors according to if the premises are in ground floor or superior floors. Shall be nonskid and shall stay in good state of conservation, without cracks, holes, nor deteriorations that allow the stagnation of liquids. It shall have an inclination slope of fall not less than two (2) percent towards the entrance or water-drainage channels. Its design must facilitate cleaning and disinfection. Each fifty (50) square meters, at least, will exist a water discharge with pipe not less than fifteen (15) centimeters of diameter.

Article 27 The served water conduits will discharge to the main conduct (s) with interposition of a siphon with a hydraulic closing.

Article 28 The walls of the establishments shall be constructed with impermeable, washable, nonabsorbent and nontoxic materials. The surface shall be smooth up to an adequate height for the activity they are made for, never smaller than two (2) meters, and shall stay in good state of conservation, without deteriorations that allow deposit of dirtiness. Its design shall facilitate the cleaning and disinfection. They shall be white or clear color. The superior part of the walls, from the smooth zone to the union with the ceiling, will be of polished cement of clear color.

Article 50 In the union of the walls with the floors, ceilings and walls to each other, the angle formed shall be rounded in concave form to facilitate the cleaning, disinfection and avoid deposit of dirtiness.

Article 29 When projections are present on walls caused by columns, moldings, etc., all union angles and corners shall be rounded.

Article 30 Roofs, ceilings and other installations suspended shall be designed, constructed and finished to prevent the entrance and accumulation of dirtiness, reduce or prevent condensation and the formation of undesirable molds and particles detachment.

Article 31 Construct the surfaces, including the tables and equipment, in contact with food with impermeable materials, washable, nonabsorbent and nontoxic. They shall be smooth or continuous without cracks in unions to facilitate its cleaning, disinfection and stay in good state of conservation.

Article 32 Rooms shall count on appropriate and sufficient means of mechanical or natural ventilation. Avoid all airflow from a contaminated zone to another clean. The design and construction of the ventilation systems shall allow easy access to their mechanisms for hygiene and maintenance. Provide mechanical air extractors with blinds of automatic locking.

Article 33 The metallic doors shall have smooth surfaces, nonabsorbent, easy to clean and disinfect. Openings to the outside, as doors, windows, extractors and others, shall count on with anti-insects protection systems, such as stainless metallic meshes of 1/16 of inch, air curtains and other devices approved by the Food and Beverage Risk Control Department. The systems shall prevent access of insects even when the equipment is not in operation. The windows and other holes shall be constructed to prevent accumulation of dirtiness.

Article 34 Shall count on white color artificial light. The intensity shall be three hundred fifty (350) lux units as minimum in working positions, five hundred fifty (550) lux units in places where activities of inspection and classification are made, and a level equivalent to two hundred twenty (220) units lux as minimum in all other points. The type of light for the inspection sectors shall be localized. The lamps shall be covered with a protective system that avoids the glass dispersion in case of breakage.

Article 35 The electrical systems for lights and equipment shall be designed with approved materials and respecting the corresponding industrial safety measures. All working equipments, as well as machines and tools driven electrically, shall polarize to earth.

Article 36 All facilities must stay in good state of cleaning and operation so they do not constitute a contamination focus.

Article 37 The equipment, utensils and accessory installations used to industrialize foods, particularly those that enter in direct contact with products or their

raw materials, shall be constructed with stainless steel or another resistant material to corrosion and of easy cleaning.

Article 38 The design and installation of machines and equipment shall facilitate cleaning and disinfection of all its parts and the surrounding zones where installed and shall avoid the contamination of food products or its raw materials.

Article 39 Wood is prohibited in rooms where foods or raw materials without packaging are processed or manipulated.

Article 40 The equipment that enters in direct contact with food shall count with a special device, manual or mechanical, so the previous to a new use shall be perfectly sanitized (cleaning and disinfection).

Article 41 The equipment or sinks destined for washing food shall be provided with cold and hot potable water, if necessary. Shall be constructed with stainless steel or another approved material and shall be cleaned with frequency necessary to avoid the deposit of dirtiness or stagnation of water or liquids. The discharge of these sinks could be direct to the water-drainages system, through siphon closure.

Article 42 The working platforms in which workers operate shall be constructed:

1. As inclined plane, steps or elevated to facilitate a good performance in the activity to carry out.
2. Shall be construct with rustproof authorized materials.
3. Its design shall facilitate cleaning and disinfection of all parts.
4. The floor shall be nonskid and all along the front, it shall be equipped with a border as a baseboard of ten (10) centimeters of height made with the same materials used for it.
5. The access stairs cannot be wood made. They shall have their nonskid type support surface and a metallic security railing of galvanized tube.

Article 43 The trays, containers and cart destined to contain or transport food products shall be stainless steel or another authorized material and shall respond to the following requirements:

1. Its design shall facilitate its cleaning and disinfection.
2. All their inner angles shall be round to avoid the dirt deposit.
3. They will not be placed directly in the ground, but shall have to do it in platforms destined that only aim, and at a height not less than fifteen (15) centimeters from the ground.
4. They shall always be clean and shall avoid the deposit of liquid or solid residues in its interior.

Article 44 The materials and construction of carts for condemned products or byproducts will be similar to those of general use ought to count with, in addition, with lid, hinge and a special and well visible identification with the word “CONDENADO S.P.” (CONDEMN), painted in red color.

Article 45 When the equipment or machineries perform a heat treatment by cold or heat on the food, they shall count on the installations or devices that allow surveillance of the conditions, treatment, temperature and time, located in accessible and visible places.

Article 46 All equipment and machineries shall stay in good state of cleaning and operation so it does not constitute a contamination focus for the products.

Article 47 The equipment and utensils of reserve shall keep in a storehouse on shelves or pallets.

Article 48 The dressers for the personnel shall be designed based on a sufficient capacity of (1) a square meter per person as minimum and shall comply with the following construction requirements:

1. They shall be located on well accessing places separated from the industrialization or manufacturing departments and accesses shall be paved.
2. They shall be constructed with approved materials.
3. Floors shall be constructed with impermeable materials with a slope 2% towards the water-drainages entrances, having to drain the effluents by closed pipe provided with siphon closing, directly to the general system. They shall not have filtrations to the natural ground or inferior floors. They shall be nonskid and stay in good state of conservation, without cracks, holes, nor deteriorations that allow the stagnation of liquids.
4. Walls shall be covered with a material of smooth, impermeable surface up to two (2) meters of height from the level of the floor and when not covered by tiles shall be covered with polished plaster.
5. When the baseboard does not reach the ceiling that sector of the wall shall be concave. The union between the walls, floor, and ceiling shall be rounded.
6. Ceilings shall be constructed of impermeable and insulating material.
7. Doors and windows or any other kind of opening shall be protected with screens 1/16 inch size and provided with automatic locking.
8. To facilitate ventilation, every sixty (60) cubic meters shall have large windows with a minimum of two (2) square meters. If this takes place by mechanic means, shall assure the air renovation ten (10) times per hour as minimum.
9. Artificial illumination shall have a minimum of one hundred fifty (150) lux units.

10. Dressers shall have enough seats to sit simultaneously up to 20% of users of this department.

Article 49 The baths shall be next to the dressers, which, in addition to the mentioned requirements of construction for the dressers, they shall be:

1. Provided with cold and warm water.
2. In direct communication with the dressers but shall be independent of toilets.
3. In the restrooms shall be located hand washers that could be individual or straight sinks, which shall have a dimension not less than forty (40) centimeters wide and twenty (20) centimeters depth.
4. This sinks shall be provided with cold and hot water with or without mixers.
5. The faucets shall be at least twelve (12) millimeters and placed with their discharging opening not less than thirty (30) centimeters over the superior edge of the sink or hand washer. The drive of the faucets shall be automatic or pedal. They are not to be operated with hands.
6. Next to the hand washers, will locate devices with liquid or powder soap, nailbrush and towels for a single use and containers to deposit discarded paper towel.
7. The hand washers or sinks, shall be cleaned next close to every shift.
8. The discharge of these sinks shall be direct to the effluents system of the establishment by siphon closing. In no case shall discharge through the cleaning channels that exist in the floors of the establishment.

Article 50 The sanitary services shall meet the following conditions:

1. The restrooms for men, shall count with a urinal per every thirty (30) workers or fraction, (1) a toilet per every fifteen (15) workers or fraction, (1) hand washer per every fifteen (15) employees or fraction and one (1) shower per every eighteen (18) employees or fraction.
2. For the feminine personnel shall be installed (1) one toilet per every fifteen (15) workers or fraction and equal amount of hand washers and showers that for men.
3. In both cases the restrooms shall form separated installations from the others by walls with minimum average of one and a half (1.50) meters that shall not reach the ceiling. The toilet rooms shall not have their own ceiling but the superior part shall be a free opening up to the roof of the building.
4. All sanitary installations for baths, toilets and hand washers shall perform in accordance with the norms of Sanitation Engineering.
5. To the entrance of the premises, where they are manipulated or processed edible products, and where the personnel obligatorily

must pass, shall install sanitary hygienic filters. Their components are located in the following order: boot washer, hand washer with faucets auctioned by pedal, knee or another approved method, with a pressure device for liquid soap, towel dispenser with disposable towels, footbath with ten (10) centimeters depth, with an antiseptic solution approved, current and permanently renovating.

6. All the facilities shall stay in good state of cleaning and operation so it does not constitute a focus of infection.

Article 51 It establishes the following color code and those that the Food and Beverage Risk Control Department adds in the future, for identification of pipes, accessories and working elements:

1. **For the Pipes**:
   Blue: Compressed air.
   Gray with orange strips: Ammonia; it is recommended to label word “Ammonia”.
   Orange: Steam Water.
   Black: Electricity
   Red: Fire hydrant for fire control.
   Red: Elements to fight against fires (fire extinguishers, etc.).
   Orange: Hot water
   Green: Cold water
2. **For others:**
   Fuels (liquid and gases): Yellow
   Edible products: Green
   Non-edible products: Black
   Dangerous products or condemned: Red
   Sewer: Gray with violet strips.

Article 52 The establishment shall place visible posters or signboards to identify the use of allowed colors; shall be for pipes and other equipment, distributed in all areas and rooms of the establishment.

Article 53 If the establishment requires modifying the use of the colors established in these regulations, it shall request it in writing to the Responsible of the Food and Beverage Risk Control Department for approval.

Article 54 The norms for the evacuation of waters served and waste products in the establishments shall obey:

1. The Law and regulations must adjust permanently to that on elimination of effluent liquids, solids or gaseous that prevails in the country. To this end shall present every time required the permissions emitted by the relevant organism.
2. It will be responsibility of the companies or competent national or municipal authorities, to enforce effluent evacuation norms in agreement with the legislation in force.

3. Every time the application authority indicates to the Inspection Service, the non-compliance of an authorized establishment of some of the norms that regulate evacuation of effluents or residues will have the suspension of the Inspection Service, or the total or partial closing of the establishment involved. Until the authorities manifest the facts have regularized, shall allow the partial or total renewal of the activities.
4. The evacuation of residual waters shall agree with established in this Title, without damage of the compliance of other complementary regulations in matter of environmental protection.
5. The establishments authorized for animal sacrifice or their industrialization, when the tasks developed require it, shall have septic chambers or wastewater purifying plants.
6. The location of all new establishments is subject to possibilities of the receiving body of its wastewaters. The authorization request of all new establishments shall accompany with favorable opinion of the competent organism in this matter.
7. The General Directorate of Environmental Health shall make sure that the establishment counts on the permissions from the competent authority for the liquids' pre-treatments. These liquids originate from drainages on the reception and animal slaughter of any species and its industrialization shall be subject, without detriment of treatments that can be necessary to comply with the conditions, they demand, in each case, the organisms responsible of the control of receiving water bodies or canalization of the drainages.
8. The Food and Beverage Risk Control Department shall determine the conditions in which the separation of the canalization drainages must take place, within the establishments.
9. In all the cases, separate the blood coming from the slaughter, and will not be admitted its discharge to drainage under any concept.

Article 55 The Food and Beverage Risk Control Department will determine the terms within which the exigencies of these regulations must comply, in the establishments already authorized.

Article 56 The Food and Beverage Risk Control Department, shall demand the presentation of prints of sanitary works, with the purpose to recognize the route of pipes and drainages in all areas of the establishment.

Article 57 The drainages of corrals, slaughter and industrialization shall separate in three independent systems of canalization, which shall meet underneath waters from the respective pre-treatment systems:

1. Drainages of corrals and their corridors where the standing cattle transits.
2. Fat drainages.
3. Non-fat drainages.

Article 58 The waters coming from the drainages referred at the previous article shall be subject to the following pre-treatments:

1. Stated in clause 1 shall be pre-treated by physical means, such as sieves, sedimentation or by another approved system, to obtain the separation of the manure.
2. Stated in clause 2 shall be pre-treated to obtain separation and recovery of fatty substances.
3. Stated in clause 3 shall be pre-treated sifted and sedimentation or any approved system to obtain the separation of solids.

Article 59 The pluvial drainages from all ceilings and patios not used for circulation of standing cattle of the establishment shall meet fully separated canalization of the industrial drainages and sewers. The meeting of the pluvial water-drainages with the rest is accepted after the treatment of the later, and whenever it is feasible, in agreement with the conditions established by the organization responsible for the control of the water body or receiving canalization of the water-drainages.

Article 60 The water to be use in the establishments with exception of the employed for mechanical services and sanitary services shall be potable, free of organisms or chemical elements that can produce in food products contaminations or alterations of any nature, that affect their condition of human food without restriction.

Article 61 The establishments shall install equipment for the automatic water chlorination when thereby established by the Inspection Service. The free residual chlorine concentration shall be minimum the demanded for the potable water of human consumption, according to the effective norm in the country. The Inspection Service shall control in special situations the specific necessities covered with each establishment. The company shall provide the Inspection Service equipment to determine the free chlorine concentration.

Article 62 Every six (6) months like minimum, the establishment shall make chemical analysis and every thirty (30) days a bacteriological that allows The Food and Beverage Risk Control Department appreciate the characteristics of the water in use with respect to its potability.

Article 63 Potable water shall meet microbiological and chemical conditions established in The Dominican Norm NORDOM 1, Water for Domestic Use.

Article 64 Chemical and microbiological analyses shall be made in official laboratories or those the Food and Beverage Risk Control Department accredits officially for such effect.

Article 65 When using non-potable water for purposes authorized by these regulations, the deposits will separate totally and the distribution will be different and performed in ways that not even accidentally be mixed with the potable.

Article 66 Shall not allow the passage of non-potable or residual water pipes through industrialization environments where edible products are processed or handled, whatever type of industry that process them.

Article 67 Total water availability of an establishment shall be calculated by the sum of capacity of deposits plus the provision capacity per hour of the source of origin, multiplied this last one by the normal number of working hours. The estimate calculation to consider for establishments shall be:

1. When other bovine or ruminants are slaughtered and industrialized, it shall be estimated one thousand five hundred (1500) liters per animal and five hundred (500) liters per porcine.
2. When meat and meat products are processed, packed, the potable water availability for establishment necessities shall be twenty-five (25) liters per kg of finished product.
3. In both cases, these figures are basic and will be suitable by The Food and Beverage Risk Control Department, according to working conditions.

Article 68 Potable water conductive pipes, nonpotable and served, shall be identified with the colors established in these regulations.

Article 69 Ice and steam used in direct contact with food products, shall not contain any substance that represents danger for health or can contaminate the product. In all cases, they shall be produced from potable water.

Article 70 Establishments shall adopt and document an insect and rodent control system, which shall be approved by the Inspection Service.

Article 71 The respective documentation to this system, as well as the methodology, surveillance form, shall be at disposition of the Inspection Service.

Article 72 The competent official authority in the country must approve and register chemicals such as rodent baits, insecticides and others.

Article 73 Rodenticides, insecticides, disinfectants and other potentially toxic substances shall be stored in rooms or closets closed with key; they shall be used in such a way the risk of product contamination does not exist.

Article 74 Establishments shall count with an independent local, or an adequate system, to store the residues. Its design shall avoid odor emanation, liquid leaks and access of insects or rodents.

Article 75 The disposal of solid, semisolid or liquid residues of the places where they are deposited or stored, must process continuously using chlorinated water and utensils needed, to keep clean the places and reduce danger of contamination.

Article 76 It is prohibited to deposit the materials and cleaning utensils in the processing rooms or refrigerating chambers.

Article 77 The cleaning materials must be manufactured with approved stainless materials. It is prohibited the use of wood for that aim.

Article 78 The refrigerator chambers are premises constructed with thermal insulating material, destined to conservation of perishable products by means of the cold.

Article 79 The capacity of the refrigerating chambers as far as volume, shall be established by The Food and Beverage Risk Control Department according to the product to store, cool or freeze and according to the temperature conditions that shall obtain for each product.

Article 80 The refrigerating chambers shall comply with the following sanitary hygienic and construction requirements.

1. The floor shall be constructed with impermeable, nonskid and non-attackable material by fatty acids. The union angles on walls and columns shall be rounded, and the floor shall be at the same level or superior to the outer floors.
2. The interior walls of the refrigerating chambers, shall be covered with materials of easy cleaning, smooth, impermeable, corrosion resistant and clear colors; all angles shall be rounded and unions of impermeable materials.
3. The roof shall be of similar construction to the one of the walls. The ceiling shall be impermeable and fireproof material and easy cleaning.
4. Any thermal insulating material utilized shall be placed in a way that allows compliance with the specified for walls, ceilings and have no contact with the internal or external environment of the refrigerating chamber.
5. The doors will be full sheet, provided with thermal insulating material. The wood covered in its totality by noncorrosive and rustproof metallic material or another element is admitted in its construction whenever odorless, little hygroscopic and waterproofed properly authorized by The Food and Beverage Risk Control Department. The height and width of the doors in the chambers and pre chambers will be in agreement with the aims to that this is destined.
6. The columns shall meet the same requirements demanded for the walls.

7. When the refrigerating chambers include pre-chambers, these shall meet all requirements demanded for those.
8. All chambers shall be provided with artificial illumination, with a on and off switch in the inside and outside. Its luminance capacity shall be forty (40) to sixty (60) lux units.
9. When using shelves, these shall be metallic or impermeable material of easy washing and respond to the specifications determined for each case in these regulations.
10. The ventilation in the refrigerating chambers and air renewal shall be to avoid the alteration of the merchandise stored.

Article 81 Enforce the following standards for the storage of carcasses, half carcasses or quarters:

1. For porks, the distance between rails shall not be smaller than fifty (50) centimeters and the height shall allow them to suspend not less than thirty (30) centimeters from the ground.
2. For bovines, shall be a minimum distance between each other of eighty (80) centimeters and shall be not less than sixty (60) centimeters from the walls, cooling equipment or any other construction element within the chambers. Rails shall be placed not less than thirty (30) centimeters from the ceiling and the suspended animals shall be not less than thirty (30) centimeters from the ground.

Article 82 The refrigerating chambers shall have an alarm system driven from the interior and count with double bolt for personnel safety.

Article 83 Any refrigerating or freezing system, fast or slow, dry or humid, is allowed whenever its application does not alter the organoleptic characteristics of products to cool.

Article 84 The characteristics and complete engineering specifications of these systems, indicating types of equipment, cold power, regimen and principles of the system, shall be approved by The Food and Beverage Risk Control Department, for those interested shall provide a complete technical memory, accompanied by the operation prints and specifications.

Article 85 When the cooling or freezing system is based on liquid circulation and its devices are located in the superior part of the walls, next to the ceiling, they shall be protected by devices that prevent dripping of condensation water towards the ground or on stored products.

Article 86 The working capacity of the chambers for the processes of cooling, freezing and deposit, shall be evaluated by The Food and Beverage Risk Control Department, taking care of specifications indicated in the previous

sections and considering in addition the power of electromotive generation of the establishment.

Article 87 For the storage of food of animal origin, its raw materials and byproducts in the refrigerating chambers, shall comply with the following:

1. Will not allow the storage of any product on the floor, It is to realize it on grids, platforms or shelves, constructed with materials authorized that facilitate the ventilation.
2. The chambers destined to the frozen product storage shall have, anywhere, controls where it is possible to determine that the demanded freezing temperature is the indicated.
3. Without the authorization of the Inspection Service it will not be allowed deposit simultaneously in a same refrigerating chamber, meat, products, byproducts or derivative coming from different animal species,. The meat, meat products and meat byproducts frozen in packages closed hermetically, suitable for human consumption according to the norms established in these regulations, are excluded from this exigency. It can be deposited simultaneously meats cooled from different species, when they constitute the material for the product process that implies their mixture.
4. The Food and Beverage Risk Control Department shall grant previous authorization to use, all refrigerating chamber new or refurnished and reject those that present construction or sanitary problems.
5. While cooling and not been frozen, meats shall not touch each other and the half carcasses shall be arranged in rails displayed “bone with bone and meat with meat”.

Article 88 Chambers shall be permanently clean, without deteriorations and disinfected with antiseptic solutions or other approved. Cleaning and disinfection shall take place whenever is determined by the Inspection Service and in the course of any of these operations, chambers shall be empty.

Article 89 Refrigerating chambers shall be provided with minimum and maximum thermometers to control the environmental temperature. When the Inspection Service considers it necessary can ask the establishment on the incorporation of automatic devices for continuous temperature record of the chambers. The records shall be at disposition of the Inspection Service and filed by the period The Food and Beverage Risk Control Department opportunely indicates.

Article 90 For the refrigeration of different food products, the refrigerating chambers shall be ruled by the following general procedures:

1. Refrigerating chambers destined to air the bovine meat, shall have the capacity to obtain a temperature of 2º C or 36^0F in the deepest part of the animal before forty eight hours (48 hours). This temperature shall

be obtained with a maximum of two (2) half carcasses by meter of rail and up to a maximum of four hundred (400) kilograms.

2. The head of cattle cooled to 0ºC or 32^0F shall be conserved in the chambers at the rate of a maximum of six hundred (600) kilograms per meter of rail and not more than three (3) carcasses for the same length.
3. Shall have a chamber or otherwise a space (retention cage) within the general chambers, isolated, with door and key to place animals that need observation for exclusive use of the Inspection Service.
4. The cooling capacity of the refrigerating chambers shall be such to obtain in the deepest part of the channels a temperature of 0ºC or 32ºF in a period of time not more than forty eight (48) hours at its entry to the chamber. In that time, the surface temperature cannot be less than -2ºC or 28ºF.
5. The cooling capacity of the conservation chambers for cooled products shall not surpass at any moment -1ºC or 30ºF.
6. The cooling capacity of the freezing chambers destined for the carcasses, shall be such that meats introduced in them with a maximum temperature of 3ºC or 37ºF, shall reach at least a temperature of -18ºC or 0.5ºF in a period of time no more than forty eight (48) hours for the meat with bone. Measure the temperatures in all cases at the midpoint of the greater muscular piece of the front or back quart.
7. The cooling capacity of the conservation chambers for frozen products cannot be inferior to maintain the product frozen to the temperatures they were set.
8. In case of modifying the cooling capacity by mechanical problems or other causes, all product movement or transfer, shall be notified to the Inspection Service with the purpose to adopt the measures estimated for that case.
9. It is prohibited to return frozen meats and other products to conserve them in refrigerating chambers, once defrosted and placed under room temperature.
10. The meats exposed for a certain period of time to the environmental temperature, shall not return to the cold action again to extend their conservation, except for when exposition to the environmental temperature has taken place by a brief lapse and an essential need of transportation.

Article 91 Establishments shall count with auxiliary departments that without affecting in a direct form the process or conservation of raw material, are necessary to complete their specific activity.

Article 92 The following areas are considered as auxiliary departments:

1. Machines room.
2. Boilers room.

3. Warehouses.
4. Mechanic Shop.
6. Covers and boxes assembly.
7. Deposit for primary and secondary containers.
8. Deposit for packaged merchandise.
9. Deposit for salt.
10. Deposit for additives and species.
11. Deposit for inedible byproduct
12. Water treatment Room
13. Deposit and treatment of skins
14. Render
15. Laundry
16. Cafeteria or dining room
17. Administrative Offices and those for the Inspection Service

Article 93 All establishments that receive external power provision shall have its own electric generator; the generator shall be located far from the departments where handling edible products.

Article 94 The total availability of energy expressed in kilowatts hour, shall be enough to guarantee basic needs of the establishment.

Article 95 The machine room must be constructed isolated from the departments where edible products are handled, having to comply the following:

1. Construction of the premises for the machine room or boilers will be fireproof material, with concrete floors or another impermeable and washable material.
2. Shall count on enough natural or artificial illumination.
3. Ventilation shall be guaranteed by windows or air extractors.
4. Shall have running water and be equipped with devices against fire.

Article 96 The boilers room shall provide hot water and steam to all departments. In addition shall count on an alternating system that guarantees basic consumption needs of the establishment.

Article 97 The establishment shall count with adequate storage spaces:

1. The place for storage of equipment and other elements shall be isolated from other departments. Containers of edible products are exempt to be used in the process of raw material.
2. Spaces for storage of packing and chemical agents shall be isolated from the manufacturing rooms. In these places, the products shall be placed on platforms, not less than ten (10) centimeters from the ground and in a form that allows an adequate ventilation and illumination.
3. The place or shop for repairs and maintenance of equipment shall have fireproof materials and impermeable floor, and shall have devices against fire.

4. The establishments shall count with a place where packages, bags, boxes or any other material of packing are fabricated using a department destined exclusively to that purpose.
5. The space used to deposit empty packages, whatever its nature, is an obligatory section in all the establishments where edible meat products are processed and packaged.

Article 98 Packaged merchandises, ready for sale, shall not be stored outdoors, and shall be in refrigerated chambers. Maintain the locals destined to deposit fat products at a maximum temperature of twenty-five degrees Celsius (25ºC or 77ºF).

Article 99 In places for depositing packages, the floors, walls and ceilings shall be constructed totality of impermeable material. Doors shall have automatic locking and windows or other openings shall be protected with screens 1/16 inch.

Article 100 When using salt in a massive form, use a special local for its deposit, which shall have the following characteristics:

1. It shall be constructed with materials authorized by The Food and Beverage Risk Control Department.
2. It shall have floor, walls and ceilings covered with impermeable and unalterable material by salt.
3. Doors shall have automatic locks and be constructed with anticorrosive material to the sodium chloride action.
4. The salt, whatever its destiny, shall not be deposited in bulk in the ground.

Article 101 Additive deposits shall be installed in an independent local away from all departments of the factory. The room of additives shall have shelves with drawers or rustproof containers of easy cleaning, for classification and deposit of the additives.

Article 102 Do not deposit packages destined to edible products in a space smaller than fifteen (15) centimeters high from the ground, permanently in a clean area, free of insects and rodents. It is prohibited to deposit edible and non-edible products simultaneously in the same environment.

Article 103 The local destined for the personnel’s breaking room, shall meet general characteristics of construction, illumination and ventilation demanded by these regulations. If the access to this local is close to the processing room, a “hygienic filter” shall be installed, besides having trash deposits with lids and its capacity shall be according to the amount of employees and working shifts.

Article 104 The Food and Beverage Risk Control Department can approve the establishments with the Inspection Service, when considering convenient, a qualified Laboratory to carry out the microbiological exams that judged necessary to guarantee innocuousness of the products.

Article 105 The Food and Beverage Risk Control Department, shall look for the necessary agreement with the competent governmental offices to establish controls that shall regulate conditions that laboratories of the companies shall meet, make previous inspection, issue final decisions for authorization and carry out periodic audits for the verification of its operation and controls.

TITLE V
OF THE SPECIAL CONDITIONS OF CONSTRUCTION

Article 106 The establishments where livestock industrialization operations take place, shall comply with the construction and sanitation engineering norms mentioned in Title IV of these regulations and the special conditions of construction, detailed below, without detriment of other dispositions contemplated in these regulations:

1. The perimeter wall of the area will enclose the entire establishment departments, including corrals and places used for unloading, handling and lodging animals destined to slaughter, the facilities destined to the inedible byproducts processing for human consumption and installations for sewage control.
2. All facilities destined to lodging animals before their slaughter shall have natural or artificial illumination in a minimum intensity between one hundred (100) and one hundred and fifty (150) lux units. In the inspection facilities, the intensity shall be five hundred fifty (550) lux units.
3. Outside the peripheral wall of the area and to a minimum separation distance of fifty (50) meters, there must be another wire peripheral wall, or another approved material that borders the total area destined to the establishment. Between both peripheral walls it is prohibited the installation of any type of construction.

Article 107 All establishments that receive animals transported by mechanic means shall have as minimum a ramp for unloading, which shall have the following characteristics:

1. They can be stationary or mobile, according to the needs of service given, the stationary ramps shall be made of impermeable material and nonskid and mobile ramps shall be made of metal with the same floor as the stationary.
2. Both stationary and mobile ramps shall have railings, doors and any other annex that allow safe and easy access to the animals.

3. The maximum inclination of the ramp shall be twenty-five (25) percent; shall have a free width of eighty (80) centimeters and a height of a meter with eighty centimeters (1.80).
4. All materials used in their construction shall be apt for such purpose and approved. Its design shall facilitate its washing and disinfection and shall not have projections that can produce injuries to the animals.

Article 108 All processing establishment shall have within the limits of the perimeter wall, holding corrals / pens with corridors for movement to allow the handling and enclosing of the animals destined to sacrifice. The corrals must be identified and have cardholders. The fields used for deposit shall be outside the area demarcated by the perimeter wall.

Article 109 The capacity of the holding corrals shall be defined according to:

1. The capacity of the corrals calculates at the rate not less than two (2) meters with fifty (50) square centimeters per head of bovine and one meter with fifty (50) square centimeters per head of goat, ovine or porcine.
2. When the surface of the corrals surpasses the one hundred twenty-five (125) square meters they shall make use as many sections of corrals as necessary, and be numbered.
3. Cattle, goats, sheep and porks shall have to stay in separated corrals.

Article 110 Corrals and corridors of services shall obey the following characteristics:

1. The floors will be impermeable, resistant to wear and corrosion and shall support as minimum three thousand (3000) pounds by square inch, nonskid, of easy cleaning and disinfection and shall have a minimum slope of two (2%) percent towards the canalization or respective drainage.
2. They shall not present splits, holes or deteriorations that allow the accumulation and stagnation of liquids, there shall be no projections and sharp objects that can injure the animals.
3. Channels, drains, wastepipes and pipes, which shall never meet in the surface of the animals' passageway, will provide the drainage. The discharge shall be to the general system of effluents evacuation of the establishment. The net formed by channels or pipes of corrals and corridors, its opening in the general canalization, shall have a siphon device to avoid the reflux of liquids.
4. It is prohibited that liquids from the floor of the corrals pass towards the floors of the corridors and corrals annexes.
5. The mouth of drainages located in the corrals or corridors shall have covers and grids, whose design prevents the animals to injure.
6. They shall have ceilings in its totality, for whose construction shall use thermal material, inedible for animals; the height of ceilings shall not be inferior to three (3) meters.

7. There shall be located ventilation openings with a minimum surface equivalent to twenty (20) percent of the total surface, when for reasons of construction the space that occupies each section of corrals is surrounded by walls more than one meter with seventy (70) centimeters of height.

Article 111 The walls of the corrals shall be constructed with approved materials. When constructed with concrete blocks or similar material, the walls shall be completely plastered and polished and the angles of encounter of the walls to each other and with the floor shall be rounded. The minimum altitude of the walls shall be of one meter with eighty (80) centimeters for bovines and of a meter for porks.

Article 112 Each corral shall have its own water troughs that shall comply with the following requirements:

1. They shall be fed with pipes constructed especially with that intention; the water will not be spilled on the floor of the corrals, counting on with an automatic system for filling and overflowing by pipe with direct discharge to the water-drainage system.
2. The length of the water troughs cannot be less than (1) a meter per each fifty (50) square meters of corral and fifty (50) centimeters wide not concerning the surface of the corral; the height of the floor to the edge of the water through shall be fifty (50) centimeters.

Article 113 Shall count on with an isolation corral for suspicious animals. They shall contain ten (10) percent of the maximum authorized daily slaughter and that, besides the enumerated characteristics for the confinement corrals the following conditions are considered:

1. The perimeter of this corral shall be surrounded by a wall of reinforced concrete blocks or similar material and shall have a minimum altitude of two (2) meters to be measured from the highest point of the floor. This wall shall be completely coated with impermeable material and the union between wall and floor and in between the walls shall be rounded.
2. The access door shall be metal and have a device to place a padlock or security system.
3. The water-drainage shall be independent and proper for this corral and constituted by a drain executed along the door and under, equipped with a grid over and in such way that no liquid of the corral can leave to the floor from the access corridor itself. This mouth of water-drainage or drain shall unload through pipe not less than fifteen (15) centimeters of diameter to the main net of evacuation of effluents of the establishment and in its encounter with the same one having siphon closing. The liquids shall be treated before their entrance to this net and during its evacuation, by means of approved antiseptics of bactericidal action. As a variant the drain and mouth of water-

drainage could be located internally in the floor of the corral, if the referred floor in its more elevated point will be five (5) centimeters below the level of the floor of the corridor.

4. The illumination of this corral will be three hundred (300) lux units.

Article 114 The sanitary hygiene of the corrals shall be carried out every twenty-four (24) hours, recollecting the existing dung in the corrals and corridors and immediately shall effectuate a general cleaning with pressure water as much in the floors as in the walls. To this last effect shall count with a net of water distribution that assures an exit to this liquid, at the rate of sixty (60) pounds per inch of pressure. After washing the corrals, they shall be disinfected with a disinfectant approved by the Food and Beverage Risk Control Department.

Article 115 Every time a case of contagious infected disease has taken place, the corresponding corral and corridors by which they passed the/or the affected animals shall be washed immediately and disinfected with some of following disinfectants:

1. Calcium Hypochlorite: Impure with twenty-nine (29%) percent of active chlorine (calcium chloride or bleaching powder), prepared in water solution from two point five (2.5) to seven (7%) percent.
2. Sodium Hypochlorite: In concentrated water solution with ninety (90) grams of active chlorine per liter. Use diluting with water the concentrated solution in the proportion of two point five (2.5) to twelve (12%) percent, equivalent to two thousand (2000) and ten thousand (10,000) parts per million of active chlorine respectively.
3. Phenol: Gross Phenol, is used in water solution at three (3%) percent.
4. Phenol: used in water solution at one (1%) percent.
5. Sodium Hydroxide: With ninety four (94%) percent purity. It is used in water solution recently prepared, in the proportion of five (5%) percent.
6. Other disinfectants previously approved by the Food and Beverage Risk Control Department shall be used.

Article 116 There shall have a dung deposit, that shall be an enclosure to deposit the dung coming from the cleaning of corrals and trucks, which shall meet the following minimum conditions:

1. Impermeable cement walls with polished surface.
2. Impermeable floor with water-drainage.
3. Prepared in such form that avoids the entrance of vectors.
4. Gates with devices to prevent the exit of the liquids.
5. The dung cannot remain more than forty eight (48) hours within this enclosure.

Article 117 In the proximity of the corrals, there shall be constructed an enclosed space for washing the trucks for animal transporting which shall have the following characteristics:

1. Waterproofed walls and floors.
2. Minimum length of twelve (12) meters and wide not smaller than four (4) meters.
3. The walls shall have a minimum altitude of three (3) meters.
4. The pressure of the water coming out from the hose shall not be smaller than forty (40) pounds per square inch.
5. The water-drainages shall respond to the specifications described for the corrals.

Article 118 The Inspection Service assigned to the establishment will verify that the transport for animals is washed and disinfected after unloading.

Article 119 Next to the corral of suspicious animal isolation shall be constructed the necropsy room that shall have the following characteristics:

1. The minimum dimension of this local shall be three (3) meters wide, by five (5) meters in length.
2. Floors, walls and ceilings shall be made of impermeable material and all their angles of union shall be rounded.
3. The access door shall be of impermeable material, drive to guillotine or sliding system. The windows shall be metallic.
4. All the windows shall be equipped with metallic meshes of 1/16 inch of stainless material.
5. These rooms shall have a system of water-drainage and treatment similar to the isolation corral for suspicious animals, being able to be interconnected both by means of interposition of siphon closing.
6. The room shall have abundant cold and hot water with an exit service not less than sixty (60) pounds of pressure per square inch.
7. The illumination of the working places shall not be inferior to three hundred (300) lux units.
8. The ventilation shall be obtained by mechanic means that assures a minimum air renovation of fifteen (15) times per hour.
9. For the accomplishment of necropsies shall count with at least one bed completely metallic, stainless and with a minimum altitude of fifty (50) centimeters, considered from the bars to the floor.
10. The room shall count on with a manual or electrical pulley for dead animal manipulation.

Article 120 The room shall be equipped with the necessary instruments for the specific tasks and the development of the preliminary laboratory techniques, as also having a stainless steel table, a sink of same material, medicine kit and closets for instruments, in addition:

1. The materials and instruments shall remain constantly in the necropsy room, not being able to be retired without previous knowledge of the Veterinary Inspection.
2. The necropsy room shall have permanent disposition of the personnel from inspection or from the establishment, who works there, antiseptics approved by the Food and Beverage Risk Control Department.
3. The necropsy room shall have a sanitary filter equipped with all the elements for washing and disinfection of boots and hands.
4. The necropsy room shall have its own dressers and toilets, constructed according to the conditions and characteristics stipulated in these regulations.

Article 121 When the Inspection Service determines, the animal or animals originating from the isolating room for suspicious animals, from the necropsy room, including corpses of the animals fallen in corrals or in the transport shall be transferred to the render of the establishment. This transfer will assure not to contaminate any area of the establishment anticipating the provisions in these regulations for that aim.

Article 122 The animals shall have to remain in these corrals by a minimum time of 6 hours before the slaughter, to allow the ante-mortem inspection. If the cattle remain by any circumstance by a lapse over 24 hours, they shall be fed. In no case, the animals shall remain without slaughter over a period of 48 hours.

Article 123 The animals shall arrive up to the sacrifice compartment or tramp by their own feet previous passing by an aspersion bath after approved in the ante-mortem inspection.

Article 124 Non-ambulatory animals that cannot move by themselves, that cannot rise by themselves, or fallen animals included but not limited to these, those that have fractures on their extremities, torn of tendons and ligaments, paralysis, fractures of the spine or metabolic conditions, shall be inspected by the Official Veterinary Doctor. Those animals considered suspicious of Bovine Spongiform Encephalopathy (BSE), will be condemned and not allowed to enter to the processing room. In other cases not described previously, the Official Veterinary Doctor shall consider if this animal is suitable for slaughter at that moment or not.

Article 125 The animals for slaughter shall have to be clean enough, in such a manner that will not put in danger the hygiene during the sacrifice and slaughter, reason why they shall be bath before entering the slaughter area. This bath shall be with an automatic aspersion system in a corridor that shall have the following characteristics:

1. Walls shall be made of reinforced concrete blocks or another material approved by the Food and Beverage Risk Control Department.
2. The floor shall be impermeable and nonskid.
3. The corridor can vary according to the capacity of slaughter of the establishment.
4. The minimum altitude of its walls in the cases of major cattle shall be a meter with eighty (80) centimeters.
5. The bath shall have cross-sectional sections with water spraying nozzles approximately every seventy (70) centimeters in all its length.
6. The minimum pressure of the water shall be sixty (60) pounds per square inch.
7. The porks bath shall respond to characteristics similar to the ones described, setting a minimum altitude of 1.30 meters (a meter with thirty centimeters) for walls.
8. The illumination shall be 150 lux units.

Article 126 The slaughter area for bovines and porks shall be independent one from the other. When the Food and Beverage Risk Control Department authorizes the use of a same area to kill different species, the work shall perform in different schedules, having previously clean and a total disinfection between both slaughters. The slaughter area shall be divided in two defined zones:

1. Dirty or septic zone and clean zone.
2. The floors of the dirty zone shall be minimum ten (10) centimeters under the level of the clean zone, having the adequate animal elevation devices.
3. The water-drainages of the clean and dirty zones shall obey to those described in these regulations.
4. During the bovine sacrifice, the entrance of the stunning compartment (trap) will have a permanent water curtain.
5. After stunning and previous to bleed, the floor from zone where the animal is hoisted shall be constructed in such way to become a receiver, to receive waters originating from the showers and the regurgitation, with its own water-drainage and service pipe with a diameter not less than fifteen (15) centimeters.
6. A collecting device shall be in the floor in the site where the animal is cut, avoiding eliminating blood by the common drainage with the regurgitation or water from the showers. Bleeding shall be as complete as possible. If the blood is to be used for feeding purposes, it shall be gathered and handled in a hygienic form.
7. In the place where washing under pressure the half carcasses, the floor shall be conformed in such way to become a receiver or sink that gathers water originated from the washing, avoiding expanding to the rest of the slaughter area. This sink shall as well have a drainage mouth of fifteen (15) centimeters of diameter connected

directly to the net of effluents by means of interposition of siphon closing.

8. Sterilizers for knives, hooks, sharpeners, saws and other utensils with water at a temperature of 82ºC or 180 ºF or another system that allow the sterilization of these implements during the process.
9. Sterilizers and hand washers in sufficient amounts in sites that allow the operators an opportune and expeditious access.

TITLE VI
OF THE BASIC CONDITIONS FOR THE ESTABLISHMENTS

Article 127 Slaughterhouses Class “1” and “2” shall count with a minimum of two (2) refrigerating chambers, one of them for head of cattle and the other for giblets. The first shall have a minimum capacity for allowing the deposit of the head of cattle slaughtered during a working day and the second to admit the giblets coming from the same ones.

Article 128 Slaughterhouses Class “2” and “3” that do not have refrigerating chambers for the airing shall have an airing area independent of sales, which shall meet the following characteristics:

1. Its size shall allow accumulating not less than seventy percent (70%) of the slaughter capacity for which they are authorized.
2. The temperature shall not exceed 10ºC or 50ºF.

Article 129 Slaughterhouses Class “3” shall meet the following minimum conditions:

1. The perimeter wall shall fulfill the established exigencies in these regulations, with exception what refers to illumination.
2. They shall have corrals or pens to lodge separately each animal species. The corrals shall meet the conditions established in these regulations, particularly in relation to cleaning facilities and disinfection.
3. The capacity of the corrals shall be sufficient to lodge the animals to slaughter in the lapse of twenty-four (24) hours.
4. A closed local or room, with walls and cemented floors, shall contain the area for slaughter. The roof, floor, walls and ceiling, shall meet the conditions specified in these regulations. Drainages shall prevent the water accumulation or liquids in the premises. They shall end by conduits in covered holes or distant filtering surfaces at a minimum of one hundred (100) meters from the slaughter plant and of all housing.
5. The slaughter area shall count on with a minimum of two (2) sectors, separated by a physical mean that could be a wall, metallic stainless division or nonabsorbent material that allows the passage of the cattle. The dirty zone shall be for the stunning and bleeding, and the rest for the slaughter. They shall have bed to skin, rails for the evisceration and aeration.
6. There shall count with scalders when sacrificing pigs.

7. The bovines and porks shall consecutively be slaughter in the same facilities having previous cleaning between species.
8. The viscera can be set on specifically prepared tables in the slaughter area. Remove the intestines, with exception of the duodenum, from the slaughter area immediately after inspected. The stomachs can be used, but they shall have an adequate space to evacuate their content and to carry out their cleaning, and this will be constructed with cement and the same construction conditions as the slaughter area.
9. The washing, drying and seal of the head of cattle shall take place in agreement with the norms of these regulations with the addition of a seal that expresses “Class 3” with the same seal specifications for this aim indicated in these regulations.
10. Windows or mechanical devices shall assure the ventilation of the slaughter area. The opening to the outside, as doors, windows, ventilation tubes, etc., shall count on with protection of a mesh 1/16 of inch of stainless metallic material.
11. Shall be installed the necessary hand washers in the slaughter area and other working places to assure the personnel hygiene.
12. The slaughter house must count on potable water provided by permanent pipes, allowing using hoses only when the main valve is at a distance not less than eight (8) meters. It is obligatory to maintain reserves of potable water not less than five thousand (5000) liters, in a closed permanently clean tank, placed at a minimum altitude of five (5) meters or otherwise a cistern with hydro pneumatic equipment.
13. There shall be a local for a dresser annexed to a bathroom with shower and toilet. In the bathroom shall be installed a hand washer and shall have liquid soap and single use towel. For the calculation of the necessities and the requirements for construction will have to comply with these regulations.
14. The slaughterhouse shall count on an area in form of a corridor with walls, ceiling and floor of masonry, with its corresponding aerial rails to deposit the head of cattle slaughtered until its expedition that shall only be able after the animal heat has dissipated. This area shall protect the head of cattle from insect attacks and dust impregnation.

Article 130 Slaughterhouses that do not process the blood of the slaughtered animals shall eliminate it by some of the following procedures:

1. Drying it, using mechanic means.
2. Cooking for animal consumption that in no case shall penetrate in the slaughter plant.
3. Collecting it in deposits with lids to avoid the proliferation of insects and rodents.
4. Other systems proposed by the officials of the establishments and approved by the Food and Beverage Risk Control Department.

Article 131 The slaughterhouses that process edible fat shall count on with an isolated area from any other section of the establishment. The minimum equipment for the fat processing shall be the following:

1. Sinks or tanks made from unalterable material.
2. Autoclave to melt the fat.
3. Decantation and refinement tank or another system that fulfills the same objective.
4. A special place for the packing of melted fats.
5. Refrigerating chambers for the storage of products.

TITLE VII
OF THE CONDITIONS AND CHARACTERISTICS OF SLAUGHTER EQUIPMENT

Article 132 The conditions and characteristics that shall have the equipment destined to slaughter bovines shall be the following ones:

1. The stunning or insensibilization compartment shall be constructed with iron, concrete or by the combination of those materials, with a design that allows its easy cleaning and disinfection.
2. In the entrance to the stunning compartment, a persistent water shower shall exist like a curtain or an air curtain that shall avoid the entrance of flies or other insects.
3. The floor shall be over level at forty (40) centimeters as minimum from the floor of the premises and shall have a small inclination towards the interior of the slaughter area.
4. The wall of the stunning compartment that faces to the slaughter area shall be gyratory, for unloading the insensible animal.
5. At the exit of the stunning compartment, the animal shall fall on a stainless metallic grid.

Article 133 Equipment for transporting viscera shall fulfill the following conditions:

1. Be designed and equipped so the viscera does not make contact with the ground.
2. They shall be constructed with a movable compartment system, that when passing under or laterally from the head of cattle in the evisceration zone will allow accommodating the viscera in the respective compartments. In the inferior part will be for the stomachs and intestines, and the rest of the viscera in the superior part, having them arrive up to the Inspection point.
3. Its design shall avoid the liquids of the viscera drip from a compartment to another one.
4. It shall not cross the dirty zone or area where they are located edible products and their circulation shall avoid cross contamination.
5. After inspection and unloading the viscera, the equipment shall be washed with hot water before a new use.
6. A mechanical system can be used for the reception, transport, and inspection, and unloading of the viscera, which shall respect the

previous statements on the hygiene of this process, the characteristics of design and construction contemplated in these regulations.

Article 134 Washing of the tables or viscera carts shall take place first with cold water, then with hot water not less than 82ºC or 180ºF.

Article 135 If trays, hooks and other sets of tools used by the Inspection Service, or other workers contaminates with infectious material, they shall be washed with soap and water or an approved detergent, completing hygiene with the application of an approved antiseptic.

Article 136 The supports and the metallic structure of all the rail system shall respect the following special conditions:

1. They shall not be painted, and if any import country admits the painting, this shall be done with materials that do not alter, emit scents or will shell.
2. The rails shall be completely metallic, rust free, preserved perfectly clean. Fat dripping shall be avoided on the head of cattle.
3. The rail in the dirty zone shall have for bovine species a minimum altitude of four meters with eighty (4.80) centimeters and in the intermediate zones and clean the distance between the floor and the inferior part of the head of cattle will not be less than thirty (30) centimeters, for all species. In the inspection position, the distance between the head of cattle and the ground shall be in agreement with the tasks made there.
4. The rails for the bovines bleeding shall be distanced (1) to a meter from any wall or column.
5. The rails in general, shall be installed with a minimum separation of sixty (60) centimeters from any wall.
6. The rails for bovines shall be at a distance from the working platforms with respect to their vertical, not less than thirty (30) centimeters from their edge.

Article 137 The equipment destined to saw the head of cattle shall respect the following special conditions:

1. The saws destined to divide the head of cattle shall be motorized type, with the exception of special authorization,
2. The platform where the worker acts shall be inclined, staircase or raised to facilitate a good cut and presentation.
3. The floor there will be a container tray shaped or basin constructed with impermeable material, to gather the bone sawdust originated from this task.
4. In the place next to the task, there shall place a sterilizer for cleaning and disinfecting saw blades, manual or mechanic.

Article 138 Stations or platforms for the Inspection Service shall have the following special characteristics:

1. They shall be constructed with an adequate height that allows carrying out the examination of the lymph nodes from the hind quarters.
2. The front shall be free, without obstacles to the inspection work, or that the head of cattle can rub against them as they pass in front of the inspection area. The installation of security railings shall be the only fixed accessory element allowed.

Article 139 Carts destined to the non-edible product transport shall be identified with the word "**Non edible**", painted in black color. The materials and construction of the carts for condemned products shall be similar to general use, having to count on with, in addition, a lid and security system so it cannot be opened and a visible special identification with the word "Condemned S.P.", painted in the color red.

Article 140 In those establishments where the slaughter area is located in an elevated floor, tubes or conduits shall be installed for evacuation of condemned products and byproducts; these shall be constructed in stainless material or waterproof approved materials, have an automatic locking system that prevents the passage of scents and insects, and stay in perfect hygiene conditions.

Article 141 The equipment and tools, such as hooks, knives, knife sharpeners, etc., that are in contact with the head of cattle, shall comply the conditions required in these regulations and shall be washed meticulously before being used again.

Article 142 The scalding tank and the peeling machine shall present the following special characteristics:

1. Can be constructed of iron or another material approved by the Food and Beverage Risk Control Department.
2. Shall have an exit mouth for used water, connected to the effluent net.
3. The room where they are installed shall be provided with extractors that allow a renovation of the air mass in a permanent and effective form for the environment in which the work is developed, avoiding the steam condensation.

TITLE VIII
OF THE CONTROL SYSTEM FOR FOOD SAFETY

Article 143 The establishments, where processing, elaborating or handling meat products or meat byproducts, are responsible to guarantee the hygiene of foods they produce or commercialize, having to poses automatic control systems that guarantee and demonstrate that each product or meat byproduct has been processed complying with the dispositions of

these regulation. By such a reason they must define, to put in practice, comply and update the adequate security procedures, in each of the industrialization processes, they carry out, according to with the principles of the HACCP system (Hazard Analysis and Critical Control Points) detailed below.

1. Identification of the hazards, risk analysis and determination of the measures needed for its control.
2. Location, within the processes mentioned before, of critical points and identification of those whose control is critical for food safety (critical control points).
3. Establishment of critical limits for each critical point.
4. Definition and application of effective surveillance procedures, monitoring and control in each critical point.
5. Establishment of corrective measures shall be taken if necessary.
6. Establishment of the verification procedures or periodic verification of the system.
7. Establishment of the documentation corresponding to all procedures and records.

Article 144 To determine the critical point for food safety contemplated in the previous section it shall be consider the nature of the product, the form in which is manipulated, packaged, and any other operation submitted before given to the consumer. Also shall consider the possible uses submitted by the consumer and the groups of consumers to whom the product is destined.

Article 145 Each establishment shall have, in addition, define, put in practice, and comply with Standard Sanitation Operational Procedures (SSOP) and Good Manufacturing Practices (GMP) that assure effective cleaning and disinfection of all facilities and equipment used in the process of meat products and meat byproducts. The set of the standardized sanitation procedures of the company shall constitute its manual and shall have to be updated in permanent form, describing the procedures to achieve, frequency, products to use, the person responsible for its execution, the methodology of verification of its efficiency and the measures to adopt in case of an unfavorable result.

Article 146 The Company shall reevaluate the operation of its self-control Plan HACCP, SSOP and GMP annually, making pertinent or necessary changes to demonstrate the process is under control and that changes have been made in those recurrent deviations.

Article 147 The Company shall present to The Food and Beverage Risk Control Department for its approval, validation and annual certification of the manuals or plans of the HACCP, SSOP and GMP and a copy of the documentation where it exposes the set of referring data to the

accomplishment of self-controls and its verification according to the following detail:

1. Description of the product (composition, structure and physical-chemical characteristics, treatments, packaging and packing, storage conditions and distribution, duration or life utility of the product, instructions of use, authorized microbiological or chemical criteria that can be applied, etc.).
2. Description of the expected use (normal or anticipated use the consumer shall do with the product, specific groups of consumers the product is destined, indicating sensible groups).
3. Description of the process procedure indicating critical points, from the arrival of raw materials to the commercialization of finished product (waiting times between the stages of the process, preparations, processing treatments, packaging, storage and distribution, specifying the concrete technical data).
4. For each critical point, the probable dangers shall be indicated (biological, chemical and physical), evaluate the risks and indicate the projected measures to control those, expressing detailed mention of procedures and specifications to guarantee its effective application.
5. Description of the surveillance methods, monitoring and control each critical point, indicating clearly who is responsible to perform, the methods used, observation frequencies, record procedure, critical limits of each parameter that shall control and the anticipated corrective measures in case of loss of the control.
6. Methodology of Verification or confirmation of the self-control system, where it clearly exposes verification procedures to fulfill (operations inspection, validation of critical limits, examination of deviations, applied corrective measures, the dispositions taken with affected products, audit the self control system, examination of records, etc.) and the periodicity at which shall be done.
7. Manual of Standard Sanitation Operational Procedures (SSOP) where clearly specify technical data of the procedures to carry out, the frequency, products to use, responsible of its execution, methodology of verification of its efficiency and measures to adopt in case of an unfavorable result.

Article 148 When the self/auto control system (HACCP) belongs to a company authorized for its operation, and therefore is in operation, there shall attach in addition the:

1. Registry of the observations or measures corresponding to surveillance and control of the critical points.
2. Results of the verification operations that demonstrate that automatic control system responds effectively according to which anticipated.
3. Report of corrective measures applied and destiny of the batches of processed product while the production system was outside control.

4. Description of the document management system, that assures finding easily the registries of a lot or batch.

Artículo149 All the documentation shall be available, in the establishment, verifiable by the Inspection Service or authorities of the Food and Beverage Risk Control Department that request it, and shall keep at least two (2) years, all documents properly signed and dated.

Article 150 The self-control Plan for HACCP, SSOP and GMP shall be signed and dated by the person with all authority in the establishment, or by a high level representative. Shall sign and date at the beginning of its implementation, annual validations and when any modification is made.

Article 151 The Food and Beverage Risk Control Department through the Inspection Service shall carry out daily revisions and audits of good operation of the self-control systems. For these revisions, the system shall count with a manual of procedures applied to evaluate HACCP, SSOP and GMP Plans.

Article 152 The General Directorate of Environmental Health through the Food and Beverage Risk Control Department is the responsible to annually approve and validate the auto control Plans of HACCP, SSOP and GMP of approved establishments and those that require its approval.

Article 153 The persons responsible of the establishments shall assure adequate training of all personnel who participates in the self-control system.

Article 154 The establishments Class “3” can only count on with one SSOP and GMP plan, establishing correct implementation of hygienic-sanitary measures of the process.

Article 155 The establishment, shall count on a tracking system of the animals and products, which shall be perfectly documented with the data provided by the animals producer and from the establishment to establish a relation between production activity and process up to their final distribution through the company that officially carries it out.

Article 156 Suspension of the Inspection Service shall be performing immediately by the Food and Beverage Risk Control Department, adopting the conducing measures to prevent the operation of the establishment by the following situations:

1. The noncompliance with the implementation of HACCP, SSOP and GMP Plans in these regulations as mandatory.
2. The personnel of the establishment fails in detection of deviations of critical points without making effective corrective actions putting in risk the processed product.

3. Any transgression to the legal precepts, or norms, agreements, regulations or dispositions, dictated by the competent sanitary authority, that occurs.

TITLE IX
OF THE APPROVALS OF THE ESTABLISHMENTS

Article 157 All establishments where slaughter and process animals, or process products, byproducts or derivatives of animal origin shall not work without the official approval of the State Secretariat of Public Health and Social Assistance through the General Directorate of Environmental Health.

Article 158 The applications for their approval shall be in writing and addressed to The General Directorate of Environmental Health, which shall include the following information:

1. Name of the people or company that presents the application, attach data corresponding to their identity and real address or photocopy of company constitution or certification.
2. Effective Environmental license emitted by the Environment and Natural Resources State Secretariat.
3. Activity for which it is requested the approval and the Inspection Service.
4. Landscape permit for construction of the establishment, granted by the Municipal Authority that corresponds.
5. Description of the establishment, detailing the facilities and the equipment.
6. Description of the general flow chart.
7. A set of plans of the establishment in a scale 1:100, approved by an Engineer or Architect from their board, with the set of land, place that occupies the establishment, access routes, near water routes, water wells of the establishment, main neighboring buildings, indicating clearly geographic location with respect to easily identifiable points.
8. The plans will show each one of the plants of the building. Will be indicated the openings, main branches of served water evacuation, internal sanitary installation, and dispositions assigned for the final evacuation of effluents. Also will indicate the rail paths for the head of cattle or products, the location and characteristics of construction of the corrals / pens, the location of the equipment, the location and measures of hot and cold water pipes, the sanitary comforts for the personnel; distribution of the departments for different operations; the premises assigned for the Inspection Service. The intensity of the illumination in the different working places shall be expressed in Lux Units.
9. The plans must also show transversal cuts of the building showing characteristics of construction of floors, walls and ceilings, vertical clearance of environments, height of rails in slaughter rooms, working

environments, refrigerating chambers and profile of the effluents evacuation channels.

10. Description of the storage system and the elimination of solid residues.
11. Dictum issued by an official laboratory, or credited by the General Directorate of Environmental Health, on the physical, chemical and bacteriological examination of potable water used in the establishment, dated no more than fifteen (15) days of emitted.

Article 159 All mentioned documentation, shall count on the applicant signature or its legal representative and the one professional members of the board responsible of the projection and calculations, having the legal representative accredited for such purpose.

Article 160 The Public Health and Social Assistance State Secretariat, through the Food and Beverage Risk Control Department, will approve or reject total or partial the documents presented on the physical and operative aspects, or by equipment, every time they do not adjust to the hygienic-sanitary and operation aspects in the opinion of the authority, and they will be given an opportunity to present their point of view.

Article 161 The establishment shall operate only after the inspection and approval for operation and when receiving the number that credits it as an authorized establishment. Shall not be assigned more than one number to each establishment and numbers already used shall not be repeated.

Article 162 The number assigned to the establishment shall be used to identify all products inspected and approved, and could not be lend, transferred or granted to any other.

Article 163 The adjustment of the establishments already approved to dispositions of these regulations, shall be done within the times The General Directorate of Environmental Health decides for each case individually, having to present the documentation the same one demands.

Article 164 The transference of the authorization of an establishment will be in agreement under jointly request of the holder himself and the new owner or only under request of this last one, when duly credited the legal trespassing act of the establishment. As long as the transference has not been granted, all the obligations and responsibilities in charge of the holder of the authorization subsist.

Article 165 When an approved establishment modifies or transfers the facilities, they shall require authorization of The General Directorate of Environmental Health previous to:

1. Transfer of an approved establishment, section or activities to the new premises. Shall be required the previous approval of the new premises.
2. The modifications or extensions in the establishments shall fulfill the established in these regulations.
3. The construction or modification of the annexed or independent premises of the approved establishments shall form a single unit.

Article 166 The approval of an establishment takes place when The State Secretariat of Public Health and Social Assistance through the General Directorate of Environmental Health consider it.

Article 167 The approval of an establishment shall expire automatically any time by:
1. Request of the Owners or Administrators of the establishment.
2. Withdrawal of the Inspection Service.
3. Inactivity of the establishment by an uninterrupted period of two years.
4. Disposition of the competent Authority to noncompliance of legal technical norms of operation.

Article 168 The annual renovation of the Sanitary Permit is an indispensable requirement for the function of the establishment

Article 169 The approval of the Slaughterhouses Class “3” will be exceptional, having to consider the following conditions:
1. The plant does not cause damages to environment and surrounding areas.
2. That the Inspection Service is assured by a Veterinary professional, or by a trained Environmental Worker, according to the norms established in these regulations.
3. The population of the place cannot be supplied in a normal and appropriate form in the opinion of competent authority by establishments of superior category.

Article 170 For not anticipated cases and those presenting special conditions by characteristics of the zones, authorizes The Food and Beverage Risk Control Department to regulate by request and in agreement with communal authorities on the requirements and hygienic-sanitary exigencies establishments must comply for authorization.

TITLE X
OF THE OBLIGATIONS OF THE ESTABLISHMENTS

Article 171 The establishments are required to:
1. Comply or make comply in which it concerns them, the exigencies and dispositions contained in these regulations.

2. Obligatorily establish the implementation of the Hazard Analysis of Critical Control Points (HACCP), Standard Sanitation Operational Procedures (SSOP) and Good Manufacturing Practices (GMP).
3. Provide to Inspection Service assigned in the establishment, within five (5) first working days of the following month to expiration, the statistical data required on production, industrialization, storage, transport or commercialization of meat products, meat byproducts and derivatives.
4. Notify the Inspection Service twenty four (24) hours in advance as minimum on accomplishment any activity specifying its nature, hour beginning and probable duration of the work.
5. Notify the Inspection Service with sufficient advance, the arrival of animals, products or byproducts and provide all referring data requested.
6. Adopt measures so no person alien or not to the establishment, interferes in any way with the work of the Inspection Service.

Article 172 When the establishment counts on a permanent inspection and is far away from the urban perimeter, or is located in isolated places, or does not have regular means of communication, it will be on behalf of the company to provide suitable transport and food to personnel of the Inspection Service.

Article 173 The establishments shall cover expenses that imply the Inspection Service personnel must work extra hours, non-workable days or holidays or visits outside their standard times of work are required. The establishment must sign an agreement with SESPAS.

Article 174 Provide with the appropriate material, such as utensils for reception, conservation and shipment of samples that shall be sent for analysis and study to the Official Laboratories, when competent authority determines it.

Article 175 Provide the Inspection Service for its exclusive use, an office with its own sanitary services. This office shall count with the following elements: closets, desks, chairs, wardrobes, hangers, file, computer, printer, office material, telephone and other necessary material for the performance of function, of the Inspection Service, in conformity it establishes in each case The Food and Beverage Risk Control Department.

Article 176 Provide adequate locals, in opinion of the Inspection Service, for reception and deposit of raw materials coming from other establishments that must be re-inspected.

Article 177 Provide appropriate substances for denaturation of condemned products and therefore destine to inedible use.

Article 178 Maintain updated the documentation for reception of animals or raw materials specifying its origin, quality, as well as processed products, delivery and their destiny.

Article 179 Put immediately in knowledge the Inspection Service, the presence of dead animals in transport or corrals of the establishment.

Article 180 Provide the Inspection Service personnel appropriate garments and footwear for Inspection.

TITLE XI
SEALS, MARKS AND OFFICIAL CERTIFICATES

Article 181 It is SESPAS responsibility through the General Directorate of Environmental Health to make sure all emitted seals and marks are used solely in the establishments and their products authorized by this institution.

Article 182 These seals shall contain abbreviations for identification being previously approved by SESPAS and shall have the same use and vigor that the approved seal of inspection.

Article 183 All seals of Inspection must have a diameter not smaller than two (2) inches up to the mark of their outer circle.

Article 184 All official seals, trailer cable seals or cargo lock seals used in the sacrifice and meat process shall be under the supervision and exclusive use of the Inspection Service, shall be properly inventoried and with a binnacle of its use and shall stay locked all times while not in use.

Article 185 The establishments shall provide the Inspection Service all the elements and materials necessary to mark inspected products such as seals, trailer cable seals or cargo lock seals having them manual, mechanical or electrical.

Article 186 The establishments shall provide the Inspection Service the dye needed for seals application, this dye shall be without ingredients that damage or alter the meat and be inoffensive for human consumption.

1. The dye shall be previously approved by SESPAS.
2. Shall not allow the use of dye that contains F. D. & C violet No.1.
3. The use of green dye shall not be allowed in the carcasses or fresh meat.
4. Any other color shall be used whenever it is previously approved by SESPAS.

5. Shall assure that the dye used and the color approved allows the applied seal to be visible and legible and contrasts with the color of the product where it is applied.

Article 188 The seals to be used shall be the following:

1. Seal of Slaughterhouse “CLASS 1”, shall have the following legend: “INSPECTED AND APPROVED” by The State Secretariat of Public Health and Social Assistance of the Dominican Republic in its abbreviations SESPAS R.D. It shall be contained in a circle that shall include the assigned number to the authorized establishment with an anterior prefix code with the letter C that shall be assigned to the establishments that process bovine, ovine, goat and pork meat. This shall be placed or printed on a safe form in the product, in the immediate product container and in the packing.
2. Seal of Slaughterhouse “CLASS 2 “, shall be circular with the legend of Slaughterhouse Class 2 or abbreviation “MC 2” in center, and under shall be placed the number of the establishment with its prefix, above in the superior part of the circle the legend “INSPECTED AND APPROVED”, and under and throughout the circle the legend “SESPAS R.D.”.
3. Seal of Slaughterhouse “CLASS 3”, shall be circular with the legend of Slaughterhouse Class 3 or the abbreviation “MC 3” in the center, under shall be placed the number of the establishment with its prefix and above in the superior part of the circle the legend “INSPECTED AND APPROVED”, and under and throughout the circle the legend “SESPAS R.D.”.
4. The seal for the mark “CONDEMNED”, shall be rectangle with the word condemned in the superior part and under this the legend “S.P.” centered.
5. The seal for the mark “R. D. REJECTED” shall be rectangle that shall measure not less than 4 inches wide and 6 inches long with the legend R.D. REJECTED in the superior part in a centered form and under this centered the legend “S.P.”.
6. The Food and Beverage Risk Control Department shall create other seals or marks considered necessary in the sacrifice and process of meats.

Article 189 The establishments shall place in all packing and bags the seal of Approved and Inspected by SESPAS, which contains their assigned number.

Article 190 The Inspection Service shall use in necessary cases the Inspection cards, according to findings in the establishment:

1. When the inspector finds any equipment, utensil, room or compartment in conditions that must be corrected shall place a card with the legend

of “RETAINED S.P.”, the date and a description of the reason for retention.

2. When the inspector finds a product or byproduct adulterated and therefore, improper for human consumption, shall use a card with the legend “REJECTED S.P”, as the date and a description of the reason for rejection.
3. The Inspection Service is the only authority that shall use and remove the Inspection cards in the establishments and shall maintain a record of the use of Inspection cards.

Article 191 The seals, metallic seals, or other approved material used to seal containers or meat product containers must have written a series number and identification with official abbreviations approved by SESPAS, can be use only once. The Inspection Service is the only authorized to place it when loading meat products loading in the establishment where produced.

Article 192 The marks and labels used in the immediate containers or in packing and the seals of the carcasses or parts of these shall change according to the requirements of a country where desired to export the product and shall be approved before their use by The Food and Beverage Risk Control Department.

Article 193 The establishments will use boxes, bags or other packing material previously approved by The Food and Beverage Risk Control Department.

Article 194 All meat products and meat byproducts must be labeled in a visible place and contain the following information:

1. Commercial name of the company or establishment.
2. Commercial address of the establishment.
3. Authorization number granted by The Food and Beverage Risk Control Department to the establishment.
4. Name of the product.
5. Raw materials and ingredients used to process the product, in its qualitative composition.
7. Net weight.
8. Lot number of products; and in case the product or products are processed for another company must say “manufactured by…; for….”
9. Product code if it applies.
10. The official seal of “INSPECTED AND APPROVED” by The State Secretariat of Public Health and Social Assistance of the Dominican Republic.
11. Instructions for the consumer of its conservation and use.
12. Expiration date.

Article 195 All products, byproducts and derivatives of animal origin processed or used in authorized establishments shall count on with corresponding

Sanitary Registry of The State Secretariat of Public Health and Social Assistance.

Article 196 The primary products not subjected to any transformation, or have experienced only the processing effects such as deboning, evisceration, conservation by the cold, and are not added with any kind of substance, shall only require the approval of its use, packages and legends.

Article 197 Meat products and meat byproducts that leave the establishment must do it accompanied by its corresponding Official Inspection Certificate. This must be authorized, signed and sealed by The Responsible of the Food and Beverage Risk Control Department and by the Official Veterinary Inspector of the establishment, which shall be numbered in a consecutive order and shall remain under the safekeeping of the Inspection Service the entire time before being used.

Article 198 The Official Inspection Certificate shall contain the following information:

1. Place (city and country)
2. Date
3. Name and number of the establishment
4. Address
5. Destiny (name of the company, address and country)
6. Marks of shipment or packing
7. Number of invoice
8. Number of shipment
9. Number of the container
10. Signature and seal of the Official Veterinary Inspector
11. Signature and seal of the Responsible of the Food and Beverage Risk Control Department
12. Product
13. Origin
14. Number of pieces or bulks
15. Lots
16. Codes
17. Weight

Article 199 The Official Inspection Certificate issued for products and byproducts destined for export will be process considering the requirements of the country of destiny.

The General Directorate of Environmental Health through Food and Beverage Risk Control Department will be responsible of the certification of meat product processing establishments, as much as national level as international.

Article 200 The personnel of the Inspection Service shall carry an official identification that credits so all the time to enter the establishments, and shall be clearly identified when present in the processing room using the white color in the working helmet and an official monogram.

TITLE XII
OF THE REQUIREMENTS THAT MUST OBSERVE THE PERSONNEL WHO WORKS OR ENTERS THE PLANT

Article 201 By requirement of the General Directorate of Environmental Health, the workers and employees must provide themselves a Card of Health where states they do not suffer infected-contagious and parasitic diseases, it must be extended by official authority and shall have a maximum validity of six (6) months.

Article 202 Shall not work with tasks that imply contact with edible products in any stage of their process, people that suffer infected-contagious diseases, parasitic or skin affections. In cases suspected existence of an infected-contagious, parasitic or skin disease, a Medical Certification of the state of health of the questioned worker shall be requested.

Article 203 All personnel who works in direct relation with food products or acts in working environments of the establishments, refrigerating chambers, processing rooms, transport or loading places, must be dress with smock or another garment adequate to its specific tasks, that cover all clothes parts which can make contact with food products. These shall be white fabric, or another authorized color by the Food and Beverage Risk Control Department and in the cases in the nature of work requires it, they shall take over this article and not in substitution of the same one, another garment of impermeable protection or coat.

Article 204 The working clothes, must be clean and in good state at the beginning of everyday tasks, being the Official Inspector enough authority for the rejection and obligation to change clothing that are not in these conditions. When the clothing has been in contact with any part of an affected infected-contagious disease animal must change to clean clothes.

Article 205 The personnel who works in contact with meats, edible products or edible byproducts of the same in any area or stage of the process, must cover their head with caps/hair covers or helmets, according to gender, which shall cover the hair totality. These clothing shall be white fabric and shall be subject under the same cleaning regime and eventually disinfection of the aprons.

Article 206 It is mandatory to use rubber boots or other impermeable material authorized by The Food and Beverage Risk Control Department. Before beginning daily tasks, footwear must be perfectly clean.

Article 207 Any person present as normal or transitorily in any place or area of the establishments where process or deposit products, officials or not and whatever their position or condition, it is prohibited to use tobacco in any forms. Also, remain in areas where edible products are processed or deposited, must be equipped with the regulated clothing.

Article 208 Before beginning the daily or shift tasks the workers obligatorily must wash their hands, arms and forearms with hot water and soap and done every time whenever by physiological exigencies they attend to the sanitary dependencies.

Article 209 All personnel destined to the tasks of cut, pieces or debone of meat, as well as the product manufacturing, are forced to wash their hands and nails with brush. Feminine and masculine personnel shall trim nails to finger tips, carry no jewels of any type and feminine personnel assigned to these tasks cannot have painted nails or acrylic during work.

Article 210 The labor personnel of the establishments must count with dressers and appropriate baths, separated by sexes, and constructed according with the norms established in these regulations.

Article 211 All personnel, independently its position or function, will have prohibited smoking, spitting, drink and eat in the working and storage premises of food products or its raw materials.

TITLE XIII
OF THE HUMANITARIAN SACRIFICE OF THE ANIMALS

Article 212 The Inspection Service shall assure that transporting animals in vehicles to slaughter shall comply with the norms for them established in NORDOM 199.

Article 213 The Inspection Service shall make sure that corrals, ramps and corridors be in good conditions:

1. They shall be free of sharps or sharpened pieces that in the Inspector's opinion could cause a wound or pain to the animal. Loose planks or those with broken pieces or openings where the size allows the head, legs or hooves of the animal to enter and cause wounds or pain, must be repaired by the establishment.
2. The floors in the corrals, corridors and ramps must be constructed and maintained in good conditions so the animals do not slide when walking at any moment, although they are humid or with rainwater.

3. Corrals must provide enough space for the number of animals in them, avoiding overpopulation.
4. The corrals will be covered, including the isolation corral for suspicious animals.
5. All corrals shall have no sharpened corners, and diminish the inverse direction of the animals in the corridors.
6. Animal handling from one corral to another and to the stunning area must have the minimum excitation and annoyance possible. The animals shall not be forced to move fast beyond their own walking step.
7. Cattle prods, sticks or other instruments used to move animals, must cause the least excitation possible. When exceeding, the inspector must prohibit their use.
8. Cattle prods must be regulated to have an effective voltage but not exceeding 50 volts AC.
9. Pipes, sharpened sheets or pointed objects that in opinion of the inspector can cause injuries or unnecessary pain, shall not be allowed.
10. Separate the normal walking animals from fallen or those that cannot move, and take them to another corral.
11. Dragging the fallen animals or those that cannot move, shall not be allowed, only if they are stunned.
12. Mobilization of fallen animals or those that cannot walk shall be done with equipment for that intention.
13. Corrals shall have water available 24 hours.
14. When the animals must remain more than 24 hours and spend the night in the corrals, they must have enough space to lie down.
15. Animals remaining in the corrals more time than stipulated or more than 24 hours shall be fed.

Article 214 The methods approved by the Food and Beverage Risk Control Department for stunning animals shall be effective in a form to avoid them suffering after this process.

Article 215 When the Inspector observes at any time that animals are treated inadequately against the stipulated in these regulations, shall inform the responsible of the establishment the incident and assure what is necessary to avoid recurrence.

Article 216 When the establishment does not take appropriate steps, the Inspection Service shall take them to ensure that corrective actions carried out:

1. If non-human handling of the animals is due to malfunction of equipment or flaw, the Inspector shall consider the equipment retained and shall not use it until it works adequately.
2. If non-human handling of the sacrifice is due to inadequate procedures from personnel of the establishment to lead the animals towards the stunning compartment, the Inspector shall suspend the entrance of the

animals to that area until he makes sure the procedures of handling the animals accomplish correctly.

3. If non-human handling of the sacrifice is due to inadequate stunning, an inspector shall suspend the animal entrance to the stunning compartment until the establishment assures that the procedure shall accomplish correctly.

TITLE XIV
OF THE PROCEDURE FOR THE ANIMAL SACRIFICE

Article 217 The slaughter conditions in the dirty zone shall be made in the following forms:

1. In bovine species: introduction to the stunning compartment or knockout drawer, stunning, hoist the head of cattle in the rail, cut the throat, bleeding, dehorn, skinning, cut of the head and legs or front extremities.
2. For porks: mechanism or device for stunning, cut the throat, bleeding, scalding and remove hair.
3. From this zone, shall not have liquid drains towards the clean zone.
4. In case using the blood for human consumption or animal feeding, must count on a collecting system that prevents its contamination.

Article 218 Will perform in the clean zone in all species operations included after the bleeding to the exit of the head of cattle of the slaughter area.

Article 219 Stunning the animals shall be in the stunning compartment or knockout drawer destined for such purpose. Must be equipped with a system that assures fastening the animal, and allows expeditious and a non violent exit once unconscious. The stunning will base on methods that attenuate the suffering of animals allowing for their commotion electricity, inert gases, cerebral struck with or without captive bolt pistol. The Food and Beverage Risk Control Department shall authorize the animal sacrifice in a different form from the ones stipulated in these regulations.

Article 220 When slaughter relates to certain religious groups recognized or constituted in conformity with Law, may use the ritual methods accepted by such groups.

Article 221 The following will be the operations corresponding to cut the throat:

1. After stunning, the animal will be hoisted and suspended in the rail where the bleeding will carry out; operation which shall be done in all cases with the animal hanging.
2. Once the animal is in the bleeding site, shall make a deep incise at the entrance to the chest, in such way that sections the great blood vessels in the proximity of the heart. For this procedure, the operator must use two (2) knives, one exclusively to cut the skin and the other

to section the great blood vessels. Both tools must be properly washed and sterilized between operations.

3. The animal will bleed in approximately two (2) minutes. This shall perform immediately after stunning, at most one minute.

Article 222 Completed the bleeding continue dehorning, cut the distal part of the front extremities, skin and cut the head, and immediately shall proceed to tie the esophagus; these operations shall perform in the dirty zone.

Article 223 With the animal hoisted or in the bed shall proceed to enucleate the anus and tie the rectum.

Article 224 The head of cattle can be skinned by the platform system or by the “aerial rail” or a combination of both.

1. The head of cattle shall descend in the bed system with a pulley to the movable beds, proceeding to skin in dorsal decubitus position.
2. Whichever the skin or skinning system, shall practice first an incision in the median line and shall skin from the belly, flanks, and sectioning only the skin.
3. Simultaneously, skin the distal part of the hind legs disarticulating them by the tarsometatarsal joint.
4. Once completed these operations and if skin is performed in the bed, the head of cattle is hoisted by a balance beam (hanger) carrying sheaves (pulleys) with hooks, which hold the head of cattle by the Achilles tendon. With the head of cattle partially elevated, skin the hindquarters. The operator who skins the hindquarters and the anus enucleation shall work in a platform at an appropriate height, when skinning in the aerial rail.
5. The penis or mammary glands will be removed immediately after skinning the abdominal zone.
6. Detaching the skin from the tail and spine shall be manually or mechanically. When using a mechanical system shall adopt measures to avoid splashing the neighbor head of cattle when skinning.
7. The skin must be removed from the slaughter area by tubes, canals, floodgates or other special means in such way not producing contamination of the slaughter area when dragging.
8. Once finalized the skin and the head of cattle placed in the aerial rail proceed to separate the trachea from the esophagus using a tool with blunt edges.
9. Immediately, saw the median plane longitudinally to the breastbone.
10. Proceed to remove the testicles and next carry out the evisceration of the head of cattle incising longitudinally the median plane of the abdominal muscles extracting the rectum, intestinal mass, stomach, spleen, liver, bladder, kidneys and uterus in females.
11. Previous to the separation of the gastric mass from the intestines, carry out a double tie in the duodenum, one at a level close to the

pylori and another one to the ileum, previous compression of the intestine towards the abomasum.

12. These viscera must be placed in the viscera cart or in trays. Removing the gallbladder will be performed in the slaughter area after the inspection and before the liver is sent to the giblets room.
13. Next, extract the heart, lung and trachea together with esophagus from the head of cattle.
14. Transport of the viscera within the slaughter area through the system of trays or carts.
15. Once produced the total evisceration, the head of cattle, viscera and head shall have a correlative relation in the inspection process, made in the slaughter area.
16. Once practiced the final inspection, transport the viscera in the same carts or trays to the respective unloading area. The transport equipment shall not leave the environment of the slaughter area. In those cases when transporting confiscated viscera, shall count with an area or local with a washing device and immediate disinfection of the respective cart.
17. Shower the head shall to eliminate rests of blood and gastric regurgitation in an appropriate cabinet for such aim. They shall identify to which head of cattle belongs and pass to the head inspection zone.

Article 225 Eviscerated the head of cattle, proceed to saw throughout the spine in the median plane to divide in half carcasses and immediately to its cleaning.

Article 226 Finalized the previous operation, the half carcasses shall be inspected finally to set out their destiny. This inspection area shall count on:

1. A container where all condemned products shall be deposited immediately. From this container these products must go directly to the render or incineration, avoiding dripping during their route. If using the rail to transport the hoisted meat, must have an exclusive corridor for this service.
2. For the inspection of the viscera, must separate and identify the corresponding ones to each head of cattle, At this moment the personnel of the Inspection Service will proceed to check lymph glands by vision, palpation and incision.
3. The head of cattle suitable for human consumption shall be sealed as inspected and approved with the official seal of the Inspection Service.

Article 227 Finished the inspection and considered suitable for consumption, the half carcasses shall pass through the tunnel or washing hall, and shall be washed through waterspouts or sprayers. The water pressure shall be 40 pounds per square inch. It is prohibited the use of rags or papers to dry the head of cattle, as well as air pressure; it shall be allowed to drain off, previous approval of the Food and Beverage Risk Control Department, stainless metallic spatulas to which shall be applied an adequate washing

and sterilization routine. The half carcasses will continue to the airing room or refrigerating cameras.

Article 228 Porks that arrive to the slaughter area shall be subject to the stunning procedure, similar to bovines and following the next:

1. For the specie, the knockout drawer or stunning compartment can be utilized or not, performing this operation with special equipment destined to fasten and drag the porks.
2. Once bled the animal if not skinned immediately, must proceed to scald in water at an adequate temperature.
3. Finalized the scalding shall carry out the hair removal manually or mechanically.
4. Once removing the hair and before entering the clean zone, shall shower the carcass with cold water.
5. Other operations not described in this Article shall be done in a similar form to those of the bovine specie.
6. For commercial reasons, the longitudinal saw of the pork shall be carried out in an incomplete form up to the neck zone and leaving the head attached to the carcass.

Article 229 During all the operations conducted in the slaughter area, the carcasses and half carcasses, with skin or skinned, shall be handled in such way to avoid contact between them, with the equipment or with the facilities. In the same manner, the half carcasses or quarters must be placed within the refrigeration chambers.

TITLE XV
OF THE ANTE-MORTEM INSPECTION

Article 230 The ante-mortem inspection will perform in the pens of the establishment, where will be examined animals presented for slaughter day.

Article 231 Shall not slaughter any animal without previous authorization of the Inspection Service, reason why the ante-mortem examination of all animals destined to the sacrifice is obligatory. This examination shall be done when the lot arrives to the establishment; repeating periodically and having the last one carry out immediately before the sacrifice.

Article 232 The ante-mortem inspection shall be done in the corrals of the establishment or the accessing corridors, with natural light or in defect with a luminance source not less than five hundred fifty (550) lux units.

Article 233 All lots of animals that not inspected when arriving to the establishment by any circumstance, the authority of the establishment must notify such fact to the Inspection Service.

Article 234 The resting period in the resting places shall be a minimum of twenty-four (24) hours and a maximum of seventy two (72) hours, for the bovines. The porks must remain not less than twelve (12) hours and no more than twenty-four (24) hours. The resting time could be reduced to half the minimum time indicated, when cattle comes from fairs or distant markets no more than fifty (50) kilometers and the transport is through mechanic means. The Inspection Service can also prolong the resting time, when sanitary conditions of cattle require it.

Article 235 When a lot of cattle comes from remote sites more than fifty (50) kilometers, the resting period can be shorten with a written order from the establishment, and can exempt having reasons founded in opinion of the Inspection Service that justifies it, and when their sanitary state allows it, whenever the establishment takes care of any emergent contingency. In no case, the resting will be inferior to six (6) hours.

Article 236 The animals during the confinement in corrals must have plenty of water to drink.

Article 237 In the inspection of the cattle in the corrals, first the animals altogether within each corral shall be examined, later shall make them walk back and forth in the corridors outside the corral, to appreciate possible claudication, skin lesions, secretion through the natural openings and any other suspicious symptom, also:

1. The animals shall be walked returning to the same corral where removed, observing them again.
2. If necessary, the rectal temperature may be taken.
3. The Veterinary Doctor Inspector shall have a flashlight and thermometer for clinical use during this task.
4. Carried out the inspection of the animals in each corral shall place in their card his observations and will leave writing of its conformity in reference to its health, indicating the day and hour of its act.

Article 238 During the ante-mortem examination, the Veterinary Doctor Inspector who suspects the presence of any infectious or contagious disease, and for whose diagnosis it is essential the collaboration of the official diagnose laboratory or those credited, will isolate the lot, disinfect places where it had transited, communicate the news to its immediate superior, and send material samples to the laboratory marking the suspicious animals.

Article 239 Once received the answer of the laboratory shall proceed in the following form:

1. When the result is negative, the animal or animals shall be killed separately from other animals, arriving to the slaughter area with the indication of “suspect”.

2. When the result is positive, shall adopt the measures anticipated in these regulations.

Article 240 When detecting animals that suffer diseases during the ante-mortem inspection, and whose cause must be condemned and destined to render, shall not be slaughter in the sacrifice area, having to do it in the necropsy room.

Article 241 For the females that abort in corrals, as a result of an infection, will be chosen by one of the following actions:

1. Remove it from the establishment with written authorization of the Inspection Service for treatment purposes.
2. Sacrifice it in the necropsy room and destine to render.

Article 242 For the animals born in the corrals, consider the following conditions:

1. Remove it from the establishment with written authorization of the Service of Inspection.
2. If the animal is dead, shall condemn and send to the render.
3. Raise it within the establishment by a minimum period of 30 days.

Article 243 Animals with generalized traumatisms shall be sacrificed in the necropsy room and all their parts shall be sent to the render.

Article 244 Animals that present evident signs of vesicular diseases in mouth, hooves or udder, shall be separated and taken to the isolation corral for suspicious animals, shall sample and send to the State Secretariat Laboratory of Agriculture. The animal shall not be sacrificed until obtaining a diagnosis from the laboratory and all symptoms have disappeared.

Article 245 Animals that present evident symptoms of any non-contagious disease in the ante-mortem inspection shall be sent to the suspicious animal corral and shall be sacrificed at the end, identifying them as such or allowing their exit from the establishment for their respective treatment.

Article 246 Animals that present symptoms of infectious or contagious diseases, exotic diseases, or of sanitary and economic importance for the country, must be sacrificed in the necropsy room and be sent to the render or incinerator.

Article 247 When during the ante-mortem examination verifies or suspects diseases such as: anthrax, hog cholera, salmonellosis, parturient paresis, transport tetany or other susceptible disease to therapeutic treatment, with the possibilities of success, shall proceed to the following:

1. If the animal is diagnosed with anthrax or carbuncle, it shall be sent immediately to the necropsy room for sacrifice without bled and sent to the render with skin, without allowing to be cut in pieces.

2. In the corrals, all utensils and containers, as well as the place where the animal or the affected lot of carbuncle had passed, shall be disinfected as indicated in these regulations.
3. In the lot or lots where a case of anthrax had taken place shall be located in the isolation corral and shall be slaughter only after forty eight (48) hours past the last death. If in this lapse a new case took place, the lot shall remain isolated and shall communicate the establishment that must apply to all animals surviving serum, antibiotics or any specific medication accepted by the Inspection Service, being prohibited the use of live vaccines.
4. Once applying the medicine to the animal or animals, they can remain in the isolation corral in observation during ten (10) days minimum, if no new cases take place they shall be released for sacrifice.

Article 248 When the porks in the ante-mortem inspection show clear symptoms of hog cholera shall proceed to the following:

1. They shall be condemned and sent to the necropsy room for sacrifice and later destined to the render or incinerator.
2. The rest of the animals in the same lot shall be sacrificed at the end of the slaughter.
3. Proceed to the disinfection of all corrals and utensils as established in these regulations.

Article 249 The animals in which suspects Salmonellosis by presenting enteritis, vaginal secretions, arthritis or skin suppuration processes, shall sacrifice in the necropsy room and sent to the render and later to the inedible byproduct process.

Article 250 When animals appear with symptoms of parturient paresis, transport tetany or other susceptible disease of therapeutic treatment with the possibilities of success, the establishment shall decide on its immediate sacrifice in the necropsy room and destine them to inedible byproducts or treatment until healing outside the establishment.

Article 251 The establishment shall notify the Inspection Service the existence of all dead or fallen animals in the transport or in the corrals of the establishment, immediately.

Article 252 The Inspection Service shall dispose the fallen animals immediately, determining in each case if they shall be sent to the necropsy room for their sacrifice and later destruction, following the related with BEE suspicious animals that refers in these regulations.

Article 253 When the Inspection Service authorizes the transfer of dead or dying animals to the necropsy room, they shall be transported in an exclusive vehicle for that purpose. This vehicle shall be covered with stainless metal

and easily clean. After each use, the vehicle shall be washed and disinfected, according to what is indicated in these regulations for that purpose.

Article 254 In the case of those animals suspicious of having died of infected-contagious diseases, shall be lead to the necropsy room, with obturation of their natural openings. If during the necropsy is proved an infectious or contagious disease, the Inspection Service shall send material to the official laboratory or that credited by the Food and Beverage Risk Control Department to confirm the diagnosis. The animal or its offal will be destined to the render or incinerator.

Article 255 Pork entering the establishment with a corporal temperature of 41^0 C or 106^0 F, or above, as the cattle, goats or sheep with a greater temperature of 40^0 C or 105^0 F shall be marked as suspects. If any doubt on the cause the Official Inspector shall retain the cattle by a reasonable period to determine the cause. Any animal retained by this cause shall be reevaluated its temperature on its slaughter day. If continues having the temperature over the previously described it shall be rejected and shall determine their destiny.

Article 256 All animals affected by epithelioma of the eye, actinomycosis or actinobacillosis or benign injuries in certain parts of the body shall be marked as suspicious for sacrifice even though the injuries are visible.

Article 257 All animals considered suspicious by the Inspection Service shall be marked with a tag, emblem or marks visible for their identification in the corrals or if they have been allowed to enter the slaughter room at the end of the day.

Article 258 The Inspection Service along with the representative of the State Secretariat of Agriculture shall maintain the documentation on the received animals in the establishment and the emitted in the ante-mortem inspection, having in files complete information of suspicious or rejected animals.

TITLE XVI
OF THE POST MORTEM INSPECTION

Article 259 After slaughter, all animals shall immediately be subject to a macroscopic examination of its organs and tissues, completing with a microscopic and bacteriological examination when necessary. This post-mortem inspection will show if the carcass or part of the carcass is not affected by any disease or condition that makes it non-suitable for human consumption, in addition it will be demanded that:

1. The Inspection must be made only by the personnel of the Official Inspection Service.
2. The Official Inspection shall be made in 3 specific points: head, viscera and carcass, being this last one exposed to the inspection before the final washing and after any cleaning or final cut.
3. The evisceration shall take place in a non-smaller lapse of 30 minutes from the moment in which the animal has been sacrificed. If by causes of force majeure, this lapse extended, all head of cattle must be under bacteriological examination.
4. The head and all the organs, shall accompany the carcass, until the final opinion of the Inspection Service. Reason why the 3 parts shall be clearly identified until approve releasing.
5. All carcasses that observe some injury before divided into half carcasses shall be identified, whichever the anatomical region where present and places in danger the health of the personnel or hygiene of the working instruments. The head of cattle with its viscera shall be removed from the working line, and examined by the Veterinary Inspector, not allowing be washing or cutting before the final dictum.
6. When injuries of difficult immediate macroscopic diagnosis appear, the carcasses and their viscera will be deposited in the retention cage at the orders of the Inspection Service, until the laboratory exams allow to orient the criteria to follow.
7. When observing abnormal conditions in the carcass or its viscera and make suspect the presence of some injury that can determine that the carcass or part of it is inedible or of conditional consumption, shall remove them from the common rail and taken to the retention rail for reinspection and final dictum.
8. It is prohibited all kind of manipulation that tends to mask or disappear the injuries. Such conduct will be cause of condemning the carcass or its parts destined for render.

Article 260 Animals post-mortem inspection includes macroscopic visual observation, palpation, organ cutting and lymph glands, viscera and parietals muscles cuts. In addition:

1. Shall macroscopic visualize, the state of nutrition of the carcasses, contusions, hemorrhages, color alteration, bleed efficacy, abnormalities such as bony tumefactions, bone deformations, joints, muscular, or any tissue, organ or cavity.
2. Shall be examined visually and by palpation, the serous membranes, the soft tissues to verify their consistency and when possible the lymph glands located in the deep muscles.
3. Shall examine previous incision, the visceral, superficial parietal lymph glands and the parenchyma of the organs considered necessary, two incisions in each masseter muscle (internal and external) for the Cysticercosis investigation, or what specifically indicates these regulations.

4. The blood destined for human food, or as byproduct with that same purpose, or for the process of biological products, shall be collected having extreme hygienic precautions that SESPAS determines, in containers that meet the conditions established in these regulations where the blood of not more than ten (10) animals be collected per container. In all the cases, the animals will be individualized. If any is affected by infectious or contagious disease, the total of the content of the container will be declared non-suitable for human consumption.
5. The blood not obtained according to the previous clause, must be collected in deposits with a lid and obligatorily dehydrated in totally, dried by mechanical means or partially by heat, for animal feed, operations to achieve at the same slaughter plant. When cooking, SESPAS will authorize the systems that guarantee the treatment of the blood at 70º C or 158º F during thirty (30) minutes.
6. Blood withdrawal is forbidden from the slaughter establishments in conditions different from the ones stipulated previously. Only when technological reasons of the blood industrialization plants make it necessary, like the use of the “spray” system or another dehydration method approved by SESPAS, the blood donating establishments can give it in a liquid state, previous authorization of SESPAS. In cases in which the blood has not been collected in the conditions indicated in this article must adjust to the norms that on the matter are established for these special cases; it is also prohibited to introduce the hand in the container for blood defibrination.
7. The examination of the head will take place after its cleaning and washing with high-pressure water, will incise with foliar incision the retropharynx, submaxillary and parotid lymph glands and extirpate tonsils.
8. Incise the masseter and pterygoid muscles to investigate the presence of Cysticercus, neoplasia, xanthosis and other pigmentary alterations.
9. The eyes, nasal cavities, gums, lips and velum palatinum will be examined through visualization and palpation, to investigate abnormal pigmentations, neoplasia, erosions, ulcers, abscesses and necrotic tissues.
10. Once removing the tongue from the oral cavity, inspect through visualization and palpation to investigate aphthae, abnormal ulcers, abscesses, abnormal tissues, and abnormal pigmentations and actinobacillosis injuries.
11. The larynx will be incised longitudinally at the median plane and inspected through visualization and palpation, to determine ulcerous, neoplastic or parasitic injuries.
12. For the examination of the pharynx shall proceed in analogous form to that of the larynx.
13. The lungs shall be examined by visualization and palpation; cut the parenchyma, and foliar incision of the bronchial, mediastinal and apical lymph glands. The great bronchi shall be incised longitudinally and the

parenchyma shall be incised in its terminal third, perpendicularly to its great axis.

14. The esophagus shall be examined by visualization and palpation, to determine the presence of neoplasia, abscesses and parasitic injuries.
15. The stomach shall be examined by visualization and palpation. Incisions will be done to inspect the mucosa if needed. The gastric and gastrosplenic lymph glands shall be incised by foliar incisions.
16. The intestines shall be examined by visualization and palpation. The mesenteric, cranial and caudal lymph glands shall be incised by means of foliar incision, after extended the mesentery.
17. The examination of the liver will be through visualization and palpation, incision of the parenchyma and foliar incision of the retro - hepatic and portal lymph glands. The incision of parenchyma will be practiced on the stomach face of the liver in such a form that it sections the biliary canaliculus. In the base of the Spigelius lobe will be performed a deep incision.
18. The examination of the pancreas will be through visualization and palpation, and incisions of the parenchyma, when considered necessary.
19. The spleen examination will be through visualization and palpation. When considered necessary the capsule will be open to observe the parenchyma.
20. The pericardium examination will be through visualization and palpation after incising.
21. The heart examination will be through visualization, palpation and incision of the myocardium and endocardium for the elimination of clots and visualization of the atrioventricular activities. The cut of the myocardium will be longitudinal from the base to the vertex through the left auricle and ventricle and the interventricular septum and interatrial septum.
22. The kidneys and adrenal glands will be examined lacking of their adipose cover, as well as of its fibrous capsule, the renal lymph gland will be incised in foliar cuts and in case of doubt the parenchyma of the kidney also.
23. The bladder will be through visualization and palpation.
24. The uterus will be through visualization and palpation, having to open the organ in all the cases by means of a longitudinal cut for the examination of its mucosa.
25. The udder examination will be through visualization and palpation and by deep a longitudinal cut, which reaches up to the galactophorous sinuses. The incision of mammary lymph gland will complete the examination.
26. The testicles examination will be through visualization and palpation. The inspection must assure the removal of these and the spermatic cord.

27. The central nervous system (brain and spinal marrow), will be examined by visualization and palpation once opened the cranium and sawed the spine longitudinally.
28. The pleura and peritoneum examination will be through visualization and palpation.
29. The examination of the bones will be through visualization in the surfaces of cut that by the manipulation have been uncover.
30. The examination of the joints will be through visualization and palpation and in case of suspecting the presence of injuries by incision of the articular capsule.
31. The lymph glands that obligatorily must incise through foliar cuts in each half carcass are the following ones: preescapular, prepectoral, presternal, precrural or pre femoral, superficial sciatic-inguinal or retromammary according to sex, iliac external and internal, in case of doubt will incise popliteal, axillary and supra sternal lymph glands.

Article 261 The animals inspected and in agreement with the result of the conducted inspection, may be destined to:

1. Human consumption or meat product process.
2. Incineration or processing in the render: in case of injuries that cause the carcasses to be inappropriate for human consumption. After applying this process, the material can be destined to the inedible byproduct process.
3. The viscera will be destined according to the defined in the previous numerals.
4. When the carcasses, half carcasses, quarters or organs were destined to the render, and introduced directly from the slaughter area, will be denatured with odorless products approved by the Food and Beverage Risk Control Department.

Article 262 The Inspection Service, will mark in each case, the carcass, half carcass or quarters of carcass, in the following way:

1. For human consumption the carcass, half carcass or quarters of carcass will be identified with the official Inspection seal of: Inspected and approved.
2. The carcass, half carcass, quarters and organs will be marked with the condemned seal when condemned and sent to the render or incineration.

Article 263 Those companies qualified by the Competent Authority will remove the organs, part of organs or its secretions used by the pharmaceutical industry, from the establishment. The person properly authorized through sealed containers, accompanied by the sanitary documentation issued, will make their removal.

Article 264 The carcasses, half carcasses, and quarters inspected and approved for human consumption, will be sealed according to the following specifications:

1. Seals will be placed on the external face of the carcass, in the hind and in the front quarter of sacrificed animals.
2. The Food and Beverage Risk Control Department shall authorize the change of the location of the seals when considers it proper.
3. Meats declared suitable for human consumption must be sealed and transported accompanied with the sanitary documentation emitted by the Inspection Service.
4. The customs and border authorities, as well as the transport companies, will demand as previous condition for the acceptance of the load, the test of fulfillment of the previous clause.

Article 265 The destiny of the animals inspected according to the injuries or diseases will follow the specific procedures detailed below:

1. In the cases of multiple injuries of Actinobacillosis in most of the organs and lymph nodes, must proceed to condemn totally the animal. When the disease is located in the tongue, sublingual nodes or in any region or organ, the organs or affected regions will be condemned, whenever the general state of the animal is not affected.
2. When verifying generalized Actinomycosis, the animal must be totally seized. In the located actinomycosis, shall proceed to the partial condemn.
3. When the animal appears in good nutritional condition and located injuries are verified, shall be given to the consumption after extracting the affected organs.
4. The affected head with Actinomycosis shall be confiscated, excepting the cases in which the maxillary injury is a minor lesion, strictly located and without suppurations or fistulous regions.
5. Shall condemn and destined to the render, the animal that presents Anaplasmosis or Piroplasmosis in the acute form.
6. The animal shall be condemned and destined to the render when, by the action of Anaplasma or Piroplasmosis, presents edematous filtration of muscles or a cachexia state. When the head of cattle presents an acceptable nutritional state, condemn shall not take place, although some findings are observed.
7. When suspecting Brucellosis in the udder, the organ shall be condemned, as the retromammary, iliac and sciatic lymph nodes.
8. The porks that present injuries produced by brucella in bones, joints, testicles, matrix, spleen or other organs shall be condemned and destine to the render, in case of doubt, shall destine to the render.
9. When suspect Bacterial Anthrax in the slaughter area, proceed to the immediate detention of the activities developed in the establishment and if confirmed, proceed to condemn and destine the animal to the render totality, including the skin and all its organs and tissues.

10. When the verification of the disease takes place during the viscera inspection, proceed as indicated in number 9 with the infected carcass, the previous carcass and the three (3) carcasses following the ill carcass.
11. All the bled animals, later to the sick, shall be washed by aspersion, without brush, with a watery solution of hypochlorite with a concentration not smaller than two thousand (2000) parts per million of active chlorine.
12. Hands and arms of the personnel who has been in contact with the infected animal, shall wash with the same solution mentioned in number 11 or one watery solution of formaldehyde at one (1) by a thousand (1000).
13. The facilities, equipment and working tools shall be washed tediously with water at a temperature not less than 82ºC or 180 ºF or water vapor and then shall be disinfected with a solution approved by SESPAS for this purpose.
14. The waterproofed aprons and the footwear of the personnel must disinfect with a disinfectant solution approved by SESPAS for this purpose.
15. When the Acute Bacterial Anthrax is confirmed in a pork, proceed as in other species, disinfecting the dehairing machine, previous drainage of the water tank for scalding.
16. If the Bacterial Anthrax has been verified like a chronic process, shall be sent only the affected pork to the render and shall disinfect with a solution of hypochlorite at two thousand (2000) parts per million of active chlorine the five (5) later porks, letting the solution work for thirty (30) minutes and washing it later with common water.

Article 266 When Cysticercosis is verified in a bovine, proceed as following:

1. If verified that a head of cattle is affected by cysts of Cysticercus bovis and the meat is watery or faded, condemn will be total and destined to the render.
2. If it verifies that, a head of cattle is infested in massive form with Cysticercus bovis it shall be confiscated and destined to the render. When the head of cattle presents one or more cysts by anatomical region and in several regions simultaneously with a maximum of five (5) cysticercus per head of cattle, it is considered massive infestation with the purpose of setting up the condemn criterion.
3. If a cyst in a superficial muscle is verified, shall investigate in the entire carcass by means of deep cuts and if the expressed in number 2 is not observed, the criteria of number 4 shall be applied.
4. When a cyst of Cysticercus bovis verifies, found in any state in masseter muscles or heart, carcass, previous extirpation of the piece of muscle with parasite, it shall be subject to cold during 20 days, without increasing the temperature during that period, measured in the

deepest part of the muscle from -10º C or 15º F. After this process, the carcass can be released for consumption.

5. The fat of the head of cattle with parasites shall be condemned and destined to the render.
6. The organs of the head of cattle with parasites shall be condemned and destined to the render.

Article 267 For the bovine inspection in the research of Cysticercus bovis, proceed as follow:

1. Head: Shall practice parallel cuts in the muscle surface in masseter and pterygoid.
2. Tongue: Will be observed and palpated making cuts in the lateral base region.
3. Heart: the external surface will be examined and a longitudinal cut will be done from the base to the vertex through the left auricle and ventricle and the interventricular septum and interatrial septum
4. The diaphragm, neck and intercostals muscles as other superficial muscles examination will be through observation and through serial cuts.

Article 268 When proved the presence of Cysticercus cellulosae in porks, the carcass, organs and parts will be condemn and destine to the render.

Article 269 When verified the presence of Distoma in liver, the viscera shall be condemn. If present in icteric o cachectic form, the carcass shall be condemn and destine to the render.

Article 270 For the parasitic diseases not mentioned in these regulations and transmit to human, proceed as following:

1. If the lesions are located and allow the extraction of the parasites or the lesions caused by them, these parts will be condemn and the rest to the human consumption will be destined.
2. If the parasitic disease generalizes in such manner it makes impracticable extracting the lesions, the carcass will be condemn totally and destined to the render.
3. Intestines that present oesophagostomum nodes, in a quantity greater than 5 per meter, will be condemn. When the amount is smaller, the extirpation will be allowed. When the animal presents cachexia, concomitant with oesophagostomiasis will be condemn and destine to the render.
4. When the presence of Stephanurus dentatus verifies in the peri-renal fat or kidneys, these parts will be condemn.
5. If exists concomitant with the Stephanurus, hydronephrosis with uremia or cachexia, the animal will be condemned and destine to the render.

6. The livers shall be condemned and destine to the render when they present nodular necrosis. When the injury coexists with other alterations, the carcass must also be condemn and destined to the render.
7. The organs and parts of the animals parasited by hydatic cysts will be condemned.

Article 271 The affected animals with acute Leptospirosis shall be condemned and destined the render. When finding injuries located in an organ like kidney, liver, brain and others and does not exists other pathological alterations, shall condemn only the affected organ.

Article 272 When necrosis appears in the bovines' cattle hooves without complications, only the affected parts will be condemned. However, if appears septicemia or cachexia with the necrosis of the hooves, the carcass shall be condemn and destined to the render.

Article 273 When hog cholera appears in the porks in acute or chronic form, with added suppurative infections such as infectious enteritis of the porks, porcine contagious pleuropneumonia, swinepox, the Veterinary Inspector will proceed in the following way:

1. If acute and characteristic injuries of hog cholera appear, in organs or tissues, besides the kidneys, nodes and skin, condemn will be total.
2. If the carcass presents doubtful lesions in kidneys or lymph nodes or in both simultaneously and at the same time verifies characteristic lesion of Hog Cholera in an organ or tissue, all the lesions of the same origin must be considered to these last and its condemn will be total.
3. If it presents acute lesions in organs or nodes, concomitant with an advanced cachexia or if verifies centers of lymphoid suppuration, condemn will be total.
4. The porks with chronic Hog Cholera or lesions of smallpox in skin that at the same time presents necrotic centers in arm, kidneys and other organs that indicate the existence of Salmonella will be condemned and destined to the render.
5. The porks that present in the skin lesions of smallpox shall be used for human consumption when the acute period has passed and whenever they are free from Salmonella. If the Smallpox appears in the acute period, the porks will be condemn and destined to the render.
6. The presence of some petechia in the kidneys of the pork or lymph nodes without concomitance with other lesions, will not give rise to condemn.
7. If during the slaughter they had been accidentally contaminated with gastrointestinal content, the tissues impregnated of this content will be extracted and latter will be washed tediously with chlorinated potable water in the proportion of 3 parts per million of residual active chlorine.

Article 274 When Sarcosporidia attacks the carcass, proceed in the following form:

1. Shall condemn and destine to the render when a generalized infestation with modification of the muscular tissue verifies.
2. If no modification is present on the muscular tissue, but the Sarcosporidia is in great amount, the carcass will be condemned and destine to the render.
3. When eliminating Sarcosporidia, the head of cattle can be used for human consumption.

Article 275 The animals in which undernourishment verifies, for being affected of scabies or whose meats present inflammatory or edematous characteristics, shall be condemned and destined to the render. If the scabies is benign, the animal shall be admitted for human consumption.

Article 276 Animals affected by the following diseases, must be condemn totally:

1. Shipping fever.
2. Pyemia.
3. Anthrax.
4. Black leg
5. Malign Edema.

Article 277 All animals, whose consumption can cause food toxic-infections in humans, shall be condemned and destined to the render. The Veterinary Inspector shall consider the inflammatory processes to judge these animals, concomitance with infectious diseases and in necessary case the result of the bacteriological analysis.

Article 278 The animals that present acute toxoplasmosis, shall be condemned and destined to the render.

Article 279 Carcasses of animals affected with Tuberculosis must be totally condemned and shall be destined to the render when:

1. Concomitant with tuberculous lesions the animal has presented fever immediately before its sacrifice.
2. The tuberculosis is concomitant with a cachectic state.
3. When verified tuberculous origin alterations in muscles or intramuscular tissues or bones, joints or lymph nodes as result of the passage of the bacillus through muscles, bones or joints.
4. Present simultaneous miliary tuberculous lesions in two (2) parenchyma or in (1) parenchyma and one (1) of the splenic serosa or in one (1) tumefaction of the lymph node whatever they were the locations of the miliary lesions.
5. They present verified caseous tuberculous lesions on organs of the great visceral cavities with alterations of its serosa.
6. There is generalization, having to consider the tuberculous lesions located in the respiratory or digestive apparatus, including their

ganglia, and verifies in one of the following organs: spleen, kidneys, uterus, udder, ovaries, testicles, renal capsule, brain and spinal marrow or its membranes.

7. Present numerous tubercles uniformly distributed in both lungs, and tuberculous lesions that indicate recent collapse of the organic defenses, like the generalized tuberculosis of the lungs, bronchopneumonia with sarcomatous aspect, massive caseous tuberculosis of organ, exudative tuberculosis of pleura, peritoneum, pericardium or meninges, caseous hypertrophic tuberculosis.
8. The lymph nodes present semi-caseous, congestive, edematous processes, with hemorrhagic focus in the marginal zones or hypertrophic alterations resulting from a generalized acute tuberculous infection.
9. When observing fibrous or calcified lesions in the organs of the two great splenic cavities with alterations of the corresponding serosa.
10. Two or more affected lymph nodes appear, corresponding to different quarters, without generalization.

Article 280 When the animal presents Tuberculosis in circumscribed areas shall perform a partial condemn as in the following cases:

1. When the lesions are slight, located, the lymph nodes can be extracted without practicing condemn.
2. When affected the sub scapular or axillary, subdorsal, popliteal and cervical lymph nodes, will extirpate only them, having or not those of the head affected.
3. When the preescapular, prepectoral, pre-sternal or the sternal lymph nodes are affected, the quarter of the carcass will be condemned.
4. When present tuberculous lesions of an organ of a single splenic cavity with alterations of the corresponding serosa as a result of a process originated by infections by antiquity, condemn the quarter of the carcass and the diaphragm.
5. When the heads present tuberculous lesion they shall be condemned.
6. In porks that have affected one or two nodes of the head and do not present another tuberculous lesion, the nodes will be extirpated without carrying out condemn.
7. All affected organ with tuberculosis shall be condemned or only when the corresponding lymph node.
8. To establish the existence of acute tuberculosis, the lung shall be examined in the pork, through a deep, longitudinal cut, starting with the dorsal surface.
9. All carcass or organ in contact with the knife or other working tools, infected with tuberculous material, will be condemned. Knives and equipment shall disinfect according to the article of these regulations referring to disinfection by contamination of infectious contagious disease.

Article 281 When different diseases appear, the procedure shall take place according to them and shall perform as follows:

1. Icteric animals shall be condemned and destined to the render. When having doubts in the diagnosis, the animal shall be taken to the cage of retention in the refrigerator chamber at a temperature that assures its conservation and shall practice the investigation of biliary pigments.
2. Carcasses, affected by pigmentation due to the use of medicine shall be condemned and destined to the render.
3. When a carcass is affected with a condition of melanotic pigmentation, (melanosis, and similar) and this is slight extended and tissues are excisable, the affected parts shall be condemned and the rest of the carcass shall destine to human consumption, if the melanosis embraces great amount of tissues, the carcass shall be condemned and destined to the render.
4. When a carcass with brown yellowish coloration appears, affecting cartilages, tendons and joints and these parts can be excised, the carcass shall be used for human consumption. If the pigmentation appears more extended, proceed as in the melanosis case.
5. When the muscular rigidity is located in the front quarters resulting from bleeding, there will be no place to condemn.
6. The cachectic carcasses shall be condemned and destined to the render. The undernourished animals, free of any pathological process shall be destined to the cooked product process.
7. Carcasses that present edematous infiltrations of parenchyma or connective tissue shall be condemned and destined to the render.
8. Carcasses that present marked and diffuse muscular alterations because of the febrile state shall be condemned and destine to render.
9. Carcasses that present putrefaction processes, even though these are in circumscribed zones shall be condemned and destine to render.
10. Meats will be considered as repugnant, when they present bad aspect or abnormal coloration, or that they release disagreeable odors or others considered abnormal. They shall be condemned and destined to render if there are not lesions and diseases specified in these regulations and that they have another destiny. Shall not be accepted for slaughter the non-castrated porks or with clear evidences of recent castrations.
11. When bloody meats appear, because of lesions in the digestive apparatus, shall be condemned to the render.
12. If the hemorrhagic or congestive lesions take place due to traumatisms, the affected regions shall be extirpated and the rest released for human consumption.
13. Animals that present signs of intoxication as a result of the ingestion or application of toxic products, shall be condemned and destined to the render.
14. All animal that dies accidentally in the premises of the slaughter establishment and not bled and eviscerated in immediate form,

whatever the appearance of the animal, shall be condemned to the render, except the skin.

15. Animals that come from females killed in advanced gestation state shall destine to process inedible byproduct.
16. When a hepatic process has caused alterations in the animal, like anemia, jaundice, lose weight or the liver presents an extended suppurative process, the animal shall be condemned and destined to the render.
17. When lesions appear in a liver, produced by the passage of parasites or the presence of their larvae, the liver shall be condemned and it will be destined to the render.
18. The presence of nephric lesions such as nephritis, necrosis, or pyelonephritis, implies to establish their concomitance with infectious contagious diseases and the presence of uremia. In all the cases, the affected kidneys will be condemned.
19. The cystic kidneys will be condemned and destined to the render.
20. When animals appear affected with ocular neoplasia, in the orbital region or in the corresponding lymph nodes, if the affection has damaged the bony structures of the head with an extended infection that has suppuration and necrosis, or if metastasis exists from the eye towards the orbital region or to another organs, muscles, skeleton and other tissues, or if the affection is associated with cachexia or secondary alterations, they will be condemned and destined to the render.
21. When the neoplastic affection of the eye or orbital region is located and the animal presents an acceptable general state, the head will be condemned, including the tongue.
22. Animals affected by malignant tumors will be condemned and destined to the render.
23. Porks with benign melanotic tumors, will have them excise and the adjacent tissues. In cases where the lymph nodes are invaded, the quarter of the carcass corresponding to the affected ganglion will be condemned and destined to the render.
24. The porks affected by urticaria, scabies demodecica, erythema or scleroderma can be used for human consumption, after excising the affected parts and provided that the musculature presents a normal aspect.

Article 282 The Inspection Service shall condemn the risk material from Bovine Spongiform Encephalopathy (BSE), and must ensure:

1. To condemn the tonsils or amygdala and the distal ileum removing the small intestine completely from all the sacrificed bovines
2. To mark or identify animals older than 30 months to which condemn the parts indicated in the previous number, in addition with the encephala, bones of the head, eyes, ganglia, trigeminal nodes, the root of the dorsal ganglion, spinal cord or spinal marrow, spine (exception

for the vertebrae of the tail, transverse wings of the thoracic and lumbar vertebrae and the wings of sacrum).

3. Equipment used for the removal or segregation of the risk material of the carcass shall be disinfected routinely during the process.
4. That the sacrifice shall be set in such a way, in which those animals younger than 30 months be slaughter separately or before the older animals.
5. That the material shall have to be collected in special containers clearly identified and sent to the render or to incineration.
6. That the procedures implemented by the establishment to achieve this work under the supervision of the Inspection Service are written and inserted in HACCP Plan or in the SSOP or any other program.
7. That during the process the establishment makes effective corrective actions for the control of the risk material.
8. That the establishment maintains control for the adequate removal, segregation and condemn of the risk material according to the written procedures.
9. That the establishment assures that meat byproducts that contain these risk materials shall not be use for human diet or ruminants.
10. That shall count with records and documents that will give faith of the implementation and fulfillment of the procedures of handling of risk materials. These shall remain available for 2 years for audit by the health authorities.

TITLE XVII
OF THE PROCESS
OF DEBONED MEAT AND ITS PRODUCTS

Article 283 All establishments that elaborate and process debone meat will comply with the requirements for special construction and the sanitary-hygienic norms of the meat product establishments. In addition to the general conditions in Title VII, meet the following specific conditions, without damaging the compliance of another construction exigency and sanitary-hygienic requirements that in relation with the work to develop consigns in these regulations:

1. Establishments shall be separated from all other section or establishment where other activities of industrialization or storage are performed.
2. Meats that enter an establishment shall be lead to the place of their manipulation by means of rails, containers or other means that in opinion of the Inspection Service are appropriate. The meat shall not contact the outer environment at any moment.
3. During work in the deboning room, shall stay at an environmental temperature not over 10ºC or 50ºF while the temperature of the

refrigerated meat does not have to surpass the seven degrees 7ºC or 45ºF.

4. Accumulation of bones is not admitted, which shall be removed in a continuous form during the task.
5. It is not allowed to throw or to deposit wastes or bones in the ground. Transport shall be through trays, carts or containers destined to such aim, which shall meet the requirements established for this type of equipment in Title VII of these regulations.
6. When carcasses, half carcasses and quarters do not come from the same establishment, but from another establishment approved by SESPAS, shall arrive cooled with a maximum temperature of 5ºC or 41ºF.
7. Refrigerating chambers destined to deposit carcasses for their later debone, must be independent of the refrigerating chambers destined to deposit of the deboned meat. The capacity of the chambers should be, as minimum, equal to the maximum production capacity. The construction characteristics must respond to the established in Title IV of these regulations.
8. Thawing of carcasses, pieces or meat cuts, shall not be done by means of hot airflow.
9. Containers and packages used to cover the meat cuts shall be authorized by SESPAS. They will be of first use and shall be stored so in order to assure its hygiene before and during its use.
10. The area destined to the secondary packing must be separated from the deboning meat zone.
11. Accesses within the establishments shall be paved and with adequate areas for loading and unloading, which shall be covered to enable the means of transport be well protected during these operations, by eaves not smaller than five (5) meters.
12. Unloading carcasses, half carcasses or quarters shall be done with aerial rails or other mechanic mean. Meat cuts shall be transported in carts. In no case, will allow transport in shoulders.
13. Meat processing establishments shall have the following areas/departments, according with the industrial activities they perform:
    a. Office destined to the Inspection Service.
    b. Deboning room.
    c. Processing room.
    d. Refrigerating chambers.
    e. Dryers.
    f. General depot for dry ingredients or additives.
    g. Local for washing utensils.
    h. Local for labeling, package and shipping.
    i. Deposits for residues of cleaning, wastes and condemn.
    j. Restrooms.
    k. Dressers.

14. When the nature of production is not required to have any of the above units, it will be exempted when the Food and Beverage Risk Control Department authorizes it.
15. All the areas enumerated in clause No.13 shall be separated to each other, with their doors and outer windows protected with stainless screens 1/16 of inch or air curtains.
16. The facilities shall be consistent in size and capacity to the production, estimated to be in pounds or kilograms per day.
17. The premises destined to debone shall meet the conditions established in this title for that activity without damage of others demanded in these regulations.
18. The rooms destined to debone and process can be common when the Food and Beverage Risk Control Department authorizes it.
19. Illumination in the processing room will be natural or artificial, allowing a correct development of activities in all environments of the premises. The intensity of the light will be as established in Title IV in these regulations, demanding a minimum of two hundred twenty (220) lux units in the working places. In no case, the light must modify the colors of the raw material.
20. In the processing room, water faucets shall be available in sufficient quantity to carry out their cleaning and located not less than thirty (30) centimeters and not more than fifty (50) centimeters from the ground.
21. The working personnel shall sanitize their equipment and utensils regularly.
22. The Inspection Service shall inspect the hygienic conditions of the facilities, equipment and instruments before beginning each working shift.
23. It is prohibited the permanence of non-authorized persons in the places where meats are processed in the establishment.

Article 284 The equipment to be used in the integral process of raw materials, are:

1. Aerial rails, pulleys, carts, trays, molds, tables and machines, must be of easy cleaning and disinfection and shall not release strange substances to the raw material.
2. Machines destined to the tasks of cutting, tender, chopping, mixing, grinding and kneading meat products in process, shall have stainless steel all the pieces exposed to edible products.
3. Metals or other materials in contact with foods and their raw material, must not contain more than one (1%) percent of lead, antimony, zinc or other impurities, nor more than zero point zero one (0,01%) percent of arsenic or other harmful substance.
4. The use of synthetic material in the construction of the machines shall be admitted whenever it is resistant to abrasion, hot water, not fragile and responds to the prescriptions of the previous number.

5. Sinks shall be constructed with impermeable materials and smooth surface, according to the established in Title IV of these regulations. Their drains must connect to the general net.

Article 285 The local for the general storeroom for dry ingredients or additives must comply with the following special requirements:

1. Shall be an independent local from other units of the factory.
2. Shall have shelves for classification and deposit of additives. These containers must be easy to wash and clearly identified.
3. All the packages shall be enclosed in their original packing; containers are not allowed to be opened in this storeroom.
4. The storeroom shall be conditioned according to the required by the products stored there.
5. The utensils used in handling the additives must be limited to the specific use to which they are intended. The building material of the utensils shall be stainless steel or plastic and their design will make them easy to clean.
6. Within this storeroom, there will be an area where products of restricted use are deposited, which will be closed with key and under the control or custody of the Inspection Service. The Inspector shall have to count on of an inventory of existence or entrances and exits of these substances daily to the establishment.

Article 286 During the process of non-stuffing products, the temperature in the working environment shall not exceed 10ºC or 50ºF and the refrigerating chambers shall adjust to the requirements established in Title IV of these regulations.

Article 287 Non-stuffing meat products shall comply with the following norms:

1. **Ground Meat:** Processing of the chilled or frozen beef without additives, whose percentage of fat shall not be greater than 30% and shall not contain added water or any other extenders of volume. When using cheek meat shall not be allowed more than 25% and it must be declared in the label.
2. **Hamburger**: Product processed with chopped beef with the addition of salt, sodium glutamate and ascorbic acid. Its fat content shall not exceed 30%. In addition, shall not be added water to the mixture.
3. **Preformed cakes of chopped or ground meat (beef patties)**: Processed product of chopped or ground beef without addition of fat or flavoring additives or others. Water will not be added or only the necessary for the preformed of the pattie.
4. **Fabricated Steak**: Chopped or ground meat used to process formed in steak form with additives like hydrolyzed protein and flavorings. Could be added or not fat that will not exceed 30%. The addition of transglutaminase enzyme at levels of up to 65 ppm will be added like binders.

5. **Breaded Steak**: Product consisting of a slice or a fillet of meat breaded.
6. **Product Prepared by Breaded Steak**: All meat food obtained from specific lines of technology such as the chopping, flaking, compacting and that responds for its physical or dimensional characters which they own of the breaded beefsteak and that it is breaded.
7. **Meat for Breaded Steak**: Slice or fillet of meat without bread.
8. **Special Meat Cuts:** Slices, strips, cubes or any form of cut of clean meat without bread.
9. **Skin or Pork Rims**: Byproduct from the pork skin defatted exposed to cook to a temperature of not less than 49^0C or 120^0F.

Article 288 The local destined for the labeling, packaging and shipment must meet the demanded general requirements for the rest of the units.

Article 289 The area destined for washing utensils and other items used in the product processing must count on a sink according with the necessities for which it is destined and abundant water provision.

Article 290 All products introduced in the waste room must be denatured according to the direction of the Inspection Service.

Article 291 The deboned meat and the non stuffed meat products when stored already packed must be found at a temperature of maintenance for fresh cuts of 0^0 C or 32 ^{0} F and for frozen product of -28 ^{0} C or -18^0 F.

TITLE XVIII
OF THE METHODOLOGY OF SAMPLING FOR THE CONTROL OF PATHOGENS

CHAPTER I
METHODOLOGY OF SAMPLING FOR Escherichia Coli (E.coli)

Article 292 Each establishment shall perform the analysis for E. coli, for which shall:

1. Collect the samples according to the sampling techniques, methodology and frequency requested in these regulations.
2. Count on a manual for the procedures of sampling, where it is assigned who shall perform the sampling, how shall be done the random selection of the sample(s), their handling and transport. This manual shall be reviewed and approved by the Food and Beverage Risk Control Department and shall always be available for its revision.
3. Sample considering all the carcasses that are in refrigeration.
4. Sample through sponge or cuts of the flank, rump and brisket.
5. Establish the frequency of the sampling that shall be according to the volume of slaughter, having this 1 sample per every 300 slaughtered animals, but, a minimum of one sample during each week of operation.

6. In the case of porks take one sample per every 1,000 slaughtered animals but a minimum of one sample during each week of operation.
7. Analyze the sample by means of an approved quantitative method for E. coli. As an official method, shall adopt the developed one by the recognized Association of Official Analytical Chemists (AOAC).
8. Interpret the analysis through the NMP method (more probable number), having a confidence level of 95%.
9. Have audited, if counts on with its own laboratory, its procedures, and validation by the official competent authority or by the official laboratory of reference, having records of an Inter-laboratorial checking program of their approved techniques.
10. Have a regular training program for the technicians of their laboratory.
11. Evaluate the results using process control techniques in statistical form when sampling by the sponge method.
12. Have the procedures of the moving window of 13 samples to evaluate the results.
13. Maintain the records and data of the results of the samplings in the terms of CFU/cm2 (Colony Forming Units by square centimeter), which will stay in a table of data containing the 13 more recent results. The establishment will maintain the records by two years for its revision and audit.
14. Comply with the conditions in these regulations when sending the samples out of the establishment.

Article 293 The criteria for the evaluation of the results of E. coli will be the following ones:

Type of Livestock Specie	Lower limit of marginal range (m)	Upper limit of marginal range (M)	Number of samples tested (n)	Maximum number permitted in marginal range (c)
Bovine	Negative	Over 100 CFU/cm^2	13	Less than 3
Swine	10 CFU/cm^2	Over 10,000 CFU/cm^2	13	Less than 3

Article 294 When the sampling results do not comply with the evaluation criteria it indicates that the establishment is not controlling the fecal contamination. The Inspection Service must take actions to enforce the provisions of these regulations, from the written notification of the deviations to the suspension of the Inspection Service.

CHAPTER II
METHODOLOGY OF SAMPLING FOR Escherichia Coli 0157:H7 (E. coli 0157:H7)

Article 295 Meats destined to special cuts, stuffings not cooked, prepared meats, base for ground meat and ground meat, shall be sampled for detection of E. coli 0157:H7; the methodology will be the following:

1. The official Inspector shall be the responsible to sample or collect the sample, prepare it and send it to the official laboratory.
2. Shall be requested the establishment to add to the annual reassessment the changes that correspond to its HACCP Plan and SSOP to comply with this requirement.
3. Samples shall be only from the product processed in the establishment.
4. The sample shall be before the final packing of the product and sent to the laboratory before the establishment completes the pre-shipment revision.
5. Samples shall be taken to each lot of product that applies (the establishment will determine what will be the consideration for lot) to which it already has been made all the process.
6. The Inspection Service will retain the lots until it receives the results before shipping the product.
7. Handling and transport of the samples described in these regulations.
8. The laboratory will have to inform to the Inspection Service of the results for releasing the lots.
9. A manual of procedures will be prepared for sampling, handling and transporting the samples and definition of lot for each establishment.
10. The official personnel responsible of taking the samples shall have a specific training for it, having to make it the competent authority.
11. Samples will be aseptically been taken in an appropriate number of pieces per lot.

Article 296 When the establishment obtains positive or presumably positive results, the actions taken with the product will be the following:

1. The Inspection Service will request the establishment to arrange that the product be sent to the render or heat treatment for its immediate destruction under the official supervision and must notify immediately in writing to the Responsible of the Food and Beverage Risk Control Department.
2. If the product leaves the establishment in order to be sent to a render of another establishment or to be applied another process of denaturation it must have the approval and supervision of the Inspection Service.
3. The establishment and the Inspection Service must maintain a record of the destruction or elimination of the lot of products with their respective results.
4. The Inspection Service must make sure that the establishment has established the precise respective corrective measures, as well as the changes in its HACCP plan and the programs that are required.

5. If the establishment does not apply any or some of the previous measures the Inspection Service shall notify it to the Food and Beverage Risk Control Department and apply the sanctions that will result from a written notification to the withdraw of the Inspection Service.

CHAPTER III
METHODOLOGY OF SAMPLING FOR SALMONELLA

Article 297 The random sampling procedure will be used to select the half-bovine carcass, which must have remained 12 hours or more in the refrigeration chamber. The sampling procedure shall be through groups of consecutive samples of minimum annual operation observed in these regulations that applies to the species.

Article 298 The methodology shall be the same for the three places of the half-bovine carcass, where investigating contamination by Salmonella; they are flank, brisket, and rump. Shall count on with a manual as a guide to locate these areas and for this procedure:

1. Make sure labeling all the tubes and that all the materials are at hand.
2. If using reusable template be sure to submerge it from 1-2 minutes in a disinfectant solution before taking the first sample and repeat this passage between each sampling. When taking apart the template from the disinfectant solution shake to remove excess of liquid.
3. Locate the flank, brisket, and rump of the half-bovine carcass, according to the instructions for this analysis.
4. Locate the stairs near the half carcass to sample.
5. Use sterile gloves when sampling.
6. Remove the cap of the test tube containing sterile buffered peptone water and avoid touching the tube opening.
7. Proceed to damp a sponge in the sterile buffered peptone water.
8. Wipe the humid sponge first in horizontal form and then vertically through the delimited area of the temple of 100 cm^2 for the head of cattle and 50 cm^2 for porks. The pressure applied to the sponge, is similar to that needed to remove dried blood from the carcass surface. Introduce again the sponge in a sterile bag and add 10 ml of sterile buffered peptone water, in such way that it is impregnated totally with the solution.
9. This procedure will be done in the same form in the 3 selected places, (flank, brisket, and rump), with the purpose of obtaining a complete sample.
10. Place bags with sponges as soon as possible in the cooler or refrigerator and must be transported to the laboratory.
11. Shall not pass more than 24 hours from the moment of sampling to the moment in which the analysis in the laboratory begins, making sure for maintaining the cold chain all the time.

Article 299 The sampling for Salmonella in ground meat and packed product shall be random after the grinding process and before the addition of spices or another ingredient if it is possible and before the packing.

1. Aseptically take 25 grams of ground product, put the sample in a sterile bag and send it to the laboratory. Select several portions of the meat so that the sample is representative of the lot of the product.

Article 300 Shall select randomly the carcasses to analyze from all the carcasses available. Both parts of the half carcass (front and hind) must have equal opportunity to be select with the frequency of the sampling. Each establishment must count on with its procedure:

1. The frequency will be one sample per three hundred (300) carcasses.
2. Any method can be use to determine the random number.
3. Keep a written record of the random numbers selected and the procedures used for this purpose.

Article 301 Handling of the samples shall be as follows:

1. Refrigerate immediately and remain so until analysis.
2. If analyzed outside the establishment, must do as soon as possible, after the sampling. Pack these samples with sufficient cooling material to maintain a temperature of 0^0 C–10^0 C or 32^0–50^0 F and transport immediately to the laboratory.
3. Send them to the laboratory the same sampling day and shall analyze in a period no longer than 24 hours after sampling.
4. Place them in position to avoid leakage of liquids, if needed it can be used newspaper to absorb shocks and to assure its vertical position.
5. Place a cardboard on top of the samples and then put on top of the cardboard packages of dry ice, this way prevents that the dry ice comes in direct contact with the samples. Use enough dry ice to maintain the samples at refrigeration temperature.

Article 302 For the analysis of samples of Salmonella and their reports:

1. If samples of the carcasses cannot be analyzed after the day they were taken, then the carcasses shall be kept refrigerated until it is possible the analysis.
2. The analysis procedure shall be an officially validated method.
3. Results of the report of Salmonella analysis will be positive or negative.

Article 303 In establishments that process bovine meat requires a standard of efficiency for the detection of Salmonella, reason why the establishment shall have implemented the HACCP system in which the positive deviations in the analyses of Salmonella shall not exceed:

1. For adult cattle, 2.7% of a sampled population that represents 58 analyzed samples, the maximum number of positive shall not exceed 2.

2. For young cattle (young bulls or calves) 1.0% of a sampled population that represents 82 analyzed samples, the maximum number of positive shall not exceed 1.
3. For ground meat, it shall not exceed the 7.5% of positive deviations in a number of 53 samples of and a maximum of 5 positives.
4. For porks it shall not exceed the 8.7% of positive deviations in a number of 55 samples and a maximum of 6 positives.

Article 304 The procedures to follow according to the results of the analysis for Salmonella:

1. If the results of the first set of samples are deviated from the permitted limit, the establishments must take immediate corrective action and then make a second set of samples of equal numbers at random, to verify that there are no deviations.
2. If the second set of samples taken randomly to verify the efficiency fail, must revise the HACCP system and later a third sampling will be done.
3. If the third standard sampling of efficiency is random and this deviates from the established limit, the Food and Beverage Risk Control Department will suspend the Inspection Service to the establishment until verifies satisfactorily and notifies in writing to the Responsible of the Food and Beverage Risk Control Department that deficiencies have been corrected.

CHAPTER IV
SAMPLING METHODOLOGY FOR Listeria monocytogenes

Article 305 Sampling will be mandatory for all processed ready-to-eat (RTE) products; the establishment will identify the sampling areas where the processing products are exposed such as storage, cooling or freezing chamber, packing and internal transport.

Article 306 The establishment must establish 2 sampling sites:

1. None direct contact surfaces: As drains, floors, walls, refrigeration units, lights, etc., considering those with potential contact with the product such as borders of the equipment, legs of tables, etc.
2. Direct contact surfaces: as conveyor bands, tables, containers, equipment surfaces, baskets, etc.

Article 307 May conduct these samplings during the operations of cleaning pre-operational and operational. The establishment will develop procedures for this task.

Article 308 Samplings in surfaces shall be:

1. Not less than two per month in pre-operational in indirect and direct surfaces.
2. Not less than 3 per month in operational in direct contact surfaces.

Article 309 The Food and Beverage Risk Control Department shall be able to modify these samplings based on historical antecedents of the establishments and the conditions of process or by requirements of a country where the products export.

Article 310 The sampling Method shall be the following one:

1. The sampling system shall be by sponge or gauze, not by swab, using aseptic techniques with sterile equipment and gloves. The area to cover shall be approximately one square inch, but shall depend on the equipment used.
2. For operational samplings or those made during the production process of the establishment shall be taken from 2 to 3 hours after having started.
3. After sampling, refrigerate the samples for their analysis, which shall be no more than 24 to 48 hours after.
4. Methods used for the analysis of Listeria spp. will be those recognized by the AOAC.
5. The results of the analysis will be positive or negative.

Article 311 The procedure before the finding of positive results:

1. Sampling must be clearly documented and the origin of the data from where the results come.
2. Document corrective and preventive actions taken with respect to the result.
3. Perform a revision of the programs and procedures of cleaning and disinfection.
4. The affected area shall be object of a thorough cleaning and disinfection and verify its effectiveness and should document the corrective actions.
5. Shall sample again in the same form and place where the sample was found positive and if negative will be able to return to the program established.
6. If there is a positive result in the place, again the process shall stop until the investigation of cause.

Article 312 The investigation of cause in an indirect contact area in an establishment occurs when this has given positive in a second round of samples and will be the following one:

1. Swabbing will be done by 3 consecutive days in the pre-operational.
2. If these turn out to be negative, it will go back to the normal sampling frequency.
3. If one of the swabs is positive, additional corrective actions must be taken and return to make 3 consecutive samplings.
4. If in the third sampling of 3 consecutive samplings the result is positive the equipment shall be removed from the process or the area shall be

retained for its evaluation until the source of contamination is identified and eliminated.

Article 313 The Investigation of cause in an area of direct contact in an establishment occurs when appears positive in a second round of samples, and will be the following one:

1. Swabbing will be done by 3 consecutive days in the pre-operational.
2. If in this sampling one of the swabs gives a positive result, continue with a cleaning and deep disinfection.
3. If in the third sampling of 3 consecutive samplings the result is positive the equipment or the area must be retained for its evaluation until the source of contamination is identified and eliminated.
4. In order to use the equipment again it shall be sampled by 3 consecutive days in the pre-operational and its use shall be allowed if these results are negative.
5. Shall maintain a procedure of control of sampling of the product from the equipment that was affected and that has been released, sampling by 3 consecutive days of process, one piece of the product of the line per hour of production, the samples could be composed to be sent to the laboratory. All products under this sampling shall be kept as retain until the results of the analysis.
6. If these occur as a negative result, the product will be released and it will return to the normal sampling frequency.
7. Reprocess or destroy the products if they are positive samples to Listeria monocytogenes, and remove the equipment from the processing area until making sure that the contamination source has been eliminated.

Article 314 All these studies and the control of the procedure achieved will be under the supervision and control of the Inspection Service.

Article 315 When a third sampling results positive the establishment will be forced to make a revision of its HACCP plan to determine if an additional PCC for the control of the Listeria is required.

Article 316 The Inspection Service must be informed and will have under control all the procedures, handling of samples, corrective actions, and what the entire establishment makes with respect to these procedures, described or not in this chapter.

Article 317 For establishments that are in remodeling stages and operation should do the following:

1. The establishment will set up a more aggressive sampling program than normal to assure the integrity of the product.

2. Shall include environment samples of the areas in construction and the place where part of the process happens or sharing the same environment.
3. Sample the indirect surfaces (floors, walls and drains) adjacent to the remodeling area from its beginning.
4. The establishment shall create clear procedures of corrective actions for its approval by the Inspection Service before starting remodeling works and the effectiveness of the sampling of the program that shall establish for this purpose.
5. Workers contracted for remodeling shall count on an initial training of good practices to avoid poor procedures.

Article 318 Use samples for Listeria monocytogenes taken from products only for this analysis.

Article 319 The official personnel or those trained by the establishment under the surveillance of the Inspection Service shall be the only ones able to make this sampling.

Article 320 The sampling will be aseptically following the next method:
1. The person that samples will do it with their hands washed, disinfected, and will put on sterile disposable gloves.
2. Will sample by duplicate from the final area of the packing and place them in a bag or sterile box.
3. Unwrapped samples can be done with sterile plastic polyethylene film.
4. Clearly identify all the samples indicating all the data on the lot, product, process, date, etc.
5. Place the samples in refrigeration immediately and prepare them to be sent to the laboratory. The duplicate of the samples will stay until the results have been received from the laboratory and the lot of product is released.

Article 321 Will accept the results of analysis of all the samples of Listeria that the Inspection Service made in the official laboratory or officially recognized laboratories. Will not recognize as official the results emitted in the laboratory of the establishment.

Article 322 Receive the product samples in the laboratory not more than 24 hours after sampling and keep them through all their transfer in refrigeration and in aseptic form.

Article 323 Retain the lots of sampled products until obtaining the results of the analyses and these results will be included in all the pre-shipment documents.

Article 324 If the results are negative, release the lots for their commercialization.

Article 325 If the results are positive the establishment will have to perform the following:

1 Destruction of the product.
2. Post- lethality treatment for microbial elimination.

Article 326 For the post-lethality treatment, shall understand the following:

1. **Antimicrobial agent**: The substance added in the stuffing product that has the effect to reduce or eliminating microorganisms such as L. monocytogenes that limits or prevents its growth during the shelf life of the product such as potassium lactate and the sodium diacetate.
2. **Antimicrobial process:** An operation such as freezing the product, which has the effect of suppressing or limiting the growth of microorganisms such as Listeria monocytogenes during their shelf life.
3. **Lethality treatment**: Process that includes the application of an antimicrobial agent, which will eliminate or reduce the number of pathogenic microorganisms in the product, making the product safe for human consumption. Examples: cooking or the application of antimicrobial agents.
4. **Post-Lethality treatment for microbial elimination**: Treatment for the microbial elimination applied to the final product or packed in order to reduce or eliminate the level of pathogens found in the product.
5. **Post-lethality processing environment for the microbial elimination**: The area of an establishment where the product is taken after being subjected to an initial lethality treatment. The product will expose in this area to slicing, peeling, re-packing, cooling with a brine solution, or other processes.

Article 327 For a product to maintain sanitary conditions required to comply with the procedure of the post-lethality treatment the establishment shall use:

Alternative 1: A system of post-lethality treatment for the microbial elimination AND an antimicrobial agent or a process that limits the growth of the L. monocytogenes to consider in this case:

1. Include the procedure in its HACCP plan or in the SSOP.
2. Validate the effectiveness of the procedure that wants to carry out and document it.

Alternative 2: A system of post-lethality treatment for the microbial elimination OR an antimicrobial agent or a process that limits the growth of the L. monocytogenes to consider in this case:

1. Include the procedure in its HACCP plan or in the SSOP.
2. Validate the effectiveness of the procedure that wants to carry out and document it.
3. Carry out reliable samplings of the agent or treatment used.

4. Identify the conditions under which the tests were conducted, including the considered areas.
5. Include an explanation about why the tests conducted assure or are sufficient for their effectiveness.

Alternative 3: The use of sanitation measures only, in this case will add to stipulated in the previous alternative the following:

1. Provide results with analysis of tests of food contact surfaces in the post-lethality processing environment to ensure that they are hygienic and free of L. monocytogenes.
2. Identify the conditions under which the establishment will implement hold-and-test procedures following a positive test of a food-contact surface for L. monocytogenes.
3. Identify the size and location of the area where the tests will conduct.

Article 328 When using alternatives 2 and 3 establishments will apply samplings with a greater frequency than in 1 and with the use of alternative 3 they will be greater than 1y 2.

Article 329 For any of the alternatives used may use verification testing for the L. monocytogenes and Listeria spp. to guarantee the effectiveness of the procedure used.

Article 330 For any of the alternatives used should carry out specific sanitary measures to control L. monocytogenes, with agents or growing suppressors. They may be incorporated in the HACCP plan or SSOP of the establishment, determining in the hazard analysis that by this procedure contamination with L. monocytogenes is less probable to happen.

Article 331 The establishment that uses these reconditioning procedures of product by contamination of L. monocytogenes must declare it on their labels.

CHAPTER V
SAMPLING METHODOLOGY FOR THE MEAT RAW MATERIAL AND PROCESSED MEAT PRODUCTS

Article 332 Conduct microbiological examinations to the raw material and processed products to verify their sanitary conditions according to the following criteria:

1. Carry out daily microbiological examinations of chopped and grounded meat or comminute originating from bovine and swine species or the mixtures of them or other species.
2. Shall conduct weekly microbiological examinations from processed products.

4. Examinations shall be conducted in an Official Laboratory or in an officially recognized Laboratory by the Competent Authority.
5. Collected samples will be formed by five (5) units and will be representative of the daily production.
6. Analysis methods shall be according with the standards recognized by HACCP.

Article 333 The microbiological criteria for the grounded or chopped meat will be the following:

1. Listeria monocytogenes: Negative
2. Escherichia coli; n=5, c=2, M=5x10$^{2\ UFC}$/gram, m=50 UFC/grams.
3. Mesophilic aerobic germs: n=5, c=2, M=5x10 ^{UFC} /gram, m=5x105$^{5\ UFC}$ /gram.
4. Salmonella: n=5, c=0, absence in 25 grams
5. Staphylococcus aureus: n=5, c=2, M=10^{3UFC}/gram, m=10$^{2\ UFC}$/gram.

Article 334 For Salmonella results will be negative or positive.

Article 335 The microbiological criteria for other pathogens in carcasses, equipment and facilities will be the following:

1. Listeria monocytogenes: Negative.
1. Staphylococcus aureus: n=5, c=1, M=5x10^{3UFC}/gram, m=5x10^{2UFC}/gram.

Article 336 The Interpretation of the expressed microbiological criteria in this chapter will be:

M= is the limit of acceptability over which the results are considered satisfactory.
m = is the limit under which all the results are considered satisfactory.
n = is the number of units that compose the sample.
c = is the number of units of the sample that show values located between “m” and “M”.

Article 337 For the mesophilic aerobic germs, Escherichia coli and Staphylococcus aureus, a plan of three classes will be performed: an inferior class or equal to limit “m”, a class between limit “m” and limit “M” and one class superior to limit “M”. The results will be satisfactory when all the values observe inferior to limit “m”; acceptable when, in meat products c/n equal to 2/5 (or 1/5) for Staphylococcus aureus the observed values are included between the established limit “m” and “M”, and will result unsatisfactory when at least one of the observed values surpasses limit “M”, or c/n is superior to the relation mentioned before.

Article 338 Samples taken in carcasses for analysis of Salmonella, and E.coli 0157: H7, in addition to the officials of Listeria monocytogenes and E. coli and other therefore considered according to the Food and Beverage Risk

Control Department shall be taken by Official Inspectors in the authorized establishments and be analyzed in the Official Laboratory.

Article 339 The Official or recognized laboratories shall have the obligation to receive the samples and grant the results in the required time. Will cooperate in training the personnel of the Inspection Service and the establishment that requires it, conduct control programs and certification to the laboratories of the establishments, Inter-laboratorial tests and audit, as to conduct all the documentation on the samples and keep them at least for two years in their files.

TITLE XIX
OF THE SAMPLING OF CHEMICAL RESIDUES FOR MEATS AND MEAT PRODUCTS

Article 340 The Food and Beverage Risk Control Department together with the Official or credited laboratory responsible of making the analyses of residues, will have to develop a National Program of Control of Chemical Residues for all the meats and meat products that are processed in the country and imports. Review this program annually and will contain the results of the analyses of the previous year. The deadline for the preparation for subsequent years will be the first 15 days of January.

Article 341 The levels of tolerance of the chemical residues in the meats will be conducted for organ chlorinated, organ-phosphorated, antibiotics, sulfas, chemical pollutants, dewormers, anabolics, pyrethroids and heavy metals, identifying their maximum level of tolerance and the tissue from where the sample will proceed from.

Article 342 The prohibited chemical substances for their use are:

1. Chloramphenicol
2. Clembuterol
3. Diethylstilbestrol (DES)
4. Dimetridazole
5. Ipronidazole
6. Nitromidazole
7. Furazolidone (except for topical use)
8. Nitrofurazone (except for topical use)
9. Fluoroquinolones
10. Glycopeptides

TITLE XX
OF THE REINSPECTION OF DEBONED MEAT

Article 343 The Inspection Service will conduct a reinspection of the carcasses immediately after they exit the chiller and directed to the deboning process.

Article 344 The re-inspection station shall have the same conditions that the inspection stations established for post-mortem in these regulations; these will count on with a platform, hand washer, sterilizer, illumination and an inedible product container. Install one or two reinspection stations that must comply with the verification of the front and hindquarters in their external and internal parts.

Article 345 Re-inspection of deboned meat is a mandatory procedure conducted by the Inspection Service. Sample the meat randomly to guarantee the quality and health of the products obtained in the deboning room and meat process. It does not apply to big cuts.

Article 346 Shall designate an area to use for reinspection within the deboning room with a table and equipment for that purpose and will be near to a hand washer and sterilizer to sanitize the equipment and instruments to use.

Article 347 Re-inspection areas will have at least an illumination of 550 Lux units.

Article 348 Conduct the selection form of the sample as considered appropriate, it can be random between the packages of the lots that are processed or randomly taking packages every hour or two of the process and from different processed cuts. Take not less than 12 pounds per sample or 30 pounds 4 times per shift.

Article 349 The inspector will examine the product meticulously, shall classify its defects and determine the acceptance or rejection of the lots or processing hours according to the criteria of established defects. The defects can be classified in minors, majors and critical. Consider the presence of fecal matter or ingesta always as a critical defect.

Article 350 Describe all procedures, forms, classifications and evaluation of criteria for the determination of results in a manual of procedures, where clearly details the inspector how to conduct the reinspection.

Article 351 The Inspection Service will maintain the reinspection records not less than two years for its review, and will send every month the data to the offices of the Food and Beverage Risk Control Department.

TITLE XXI
OF THE TRANSPORT OF MEAT AND MEAT PRODUCTS

Article 352 In relation to animal transport and those transporting meats and meat byproducts destined to human consumption, the establishment will only

allow the entrance of these vehicles if the same count on the authorization of SESPAS that qualifies them for that activity.

Article 353 The means of transport will have an official document granted by SESPAS, which will credit their authorization and must be presented by the carrier's driver whenever required by the competent authority.

Article 354 All vehicles that concur to an authorized establishment by SESPAS for loading or unloading meat products and meat byproducts must be in good conditions of hygiene and disinfection.

Article 355 The personnel assigned to the tasks of loading and unloading meat products, meat byproducts and meat derivatives, must comply with the articles on the personnel general hygiene described in these regulations.

Article 356 The utensils and other instruments used in transport will respond to the exigencies mentioned in these regulations. Do not place the auxiliary elements for the mechanical maintenance and cleaning of the vehicle in the cargo box.

Article 357 All vehicles that transport meat products and that have been loaded in an authorized establishment by SESPAS, must leave the place with a band metal seal or any other material (pre-sealed) and with the corresponding health documentation.

Article 358 Do not remove the seals from the vehicles without the presence and authorization of the Inspection Service at destiny. Any other national or municipal authority, that in exercise of its functions removes the seal, must brief this situation to the back of the health documentation, indicating the new number of seal placed, signature, an explanation of the motive and the position that occupies in the operating institution.

Article 359 Do not transport meats of different species simultaneously when some of them can transmit odor to the rest. Transport packaged finished products together with the same or approximate temperature of conservation.

Article 360 Vehicles or containers that arrive to ports, airports or border passages with meat products and meat byproducts shall be accompany with the health documentation and will require the inspection of SESPAS located in the place, which shall notify with a minimum anticipation of 24 hours.

Article 361 In order to transport meat products and meat byproducts that drain liquids, the vehicles must have receptor tanks for them.

Article 362 During the transportation of the meat and meat products the interior of the box of the vehicle must maintain a temperature not exceeding 10ºC or

50^0F and the temperature of the chilled meat should not exceed 7ºC or 45^0F.

Article 363 When using ice for refrigeration, this will respond to the exigencies that Dominican Norm NORDOM 447 establishes and it will be transported prepared in drawers or plastic bags that must fulfill the exigencies established for that purpose.

Article 364 When transporting meat products, meat byproducts and meat derivatives it shall observe the following general requirements:

1. No edible product will make direct contact with the floor from the transport, except the cases where this has a secondary container/pack.
2. Products placed on racks in transports equipped with refrigeration units will have better air circulation.
3. Will not be transported simultaneously in the same environment, chilled products with frozen products, packed products with products without packing, products of different species, unless they are perfectly bottled, with the exception of fish, which is permitted only in those cases involving frozen products.
4. Do not transport viscera and refrigerated meats together, unless they are packed.
5. The half carcasses that by their size can contact the floor of the vehicle, they shall be hoisted in such way that will not happen.
6. The viscera such as lungs, heart and liver, tripe and ground meat and the fresh or cooled meat products without packing, they must be placed in stainless containers. If they are packed, place them on platforms or shelves.
7. Transport in vehicles that meet the established conditions in these regulations, the viscera and non-processed tripe, sent to other plants for their later preparation, properly prepared in impermeable and stainless containers.
8. Transport cooked or semi-cooked tripe, in natural state, within containers of approved materials that meet the conditions demanded by these regulations.
9. Transport the salty viscera arranged in containers that meet the conditions demanded by these regulations.

Article 365 When transporting meat byproducts and meat derivatives of animal origin, it shall proceed as follows:

1. Fat in pieces or lard, will be transported in closed vehicles, within containers that meet the conditions specified in these regulations.
2. Liquid fat will be transported in containers will meet the requirements specified in these regulations.
3. Transport blood in containers approved by SESPAS.

4. Meat byproducts processed or not will transport in vehicles that prevent the lost of liquids, solids and the access to insects.

TITLE XXII
OF THE STORING CENTERS

Article 366 All establishments used to deposit and distribute meat products and meat byproducts must count on with the authorization of SESPAS and shall meet the following conditions:

1. The accessing roads, perimeter wall, internal roads and areas for deposit, operations and load, must adjust to the established in Title IV of these regulations.
2. The illumination of the establishments will be in accordance with Title IV of these regulations. The Inspection Service will be able to modify this value according to the needs of each establishment.
3. They must have a suitable room for the office of inspection.
4. Loading and unloading products is prohibited under climatic conditions considered harmful for them by the Inspection Service.

TITLE XXIII
OF THE CONDITIONS OF CONSTRUCTION AND SANITATION FOR PROCESSED PRODUCTS

Article 367 Construction characteristics included for walls, floors, drainages, illumination, ventilation, hand washers, sterilizers must comply with those stipulated in these regulations.

Article 368 The illumination, drainages, ventilation and entrances of hot and cold water, shall be located in such a way that guarantees the innocuousness/safety of products processed there.

Article 369 Establishments must count on a positive flow of personnel and raw material to avoid cross contamination that affects the hygiene of the processes.

Article 370 The electrical system shall be located in such form to prevent its condensation and electrical alterations occurring in the room.

Article 371 All areas shall count with sufficient hand washers and disinfectants to guarantee the hygiene of the hands of the workers. These must wear mask, hair net and apron.

Article 372 Personnel that work in the stuffing area (cutter) or where the noise is considerable shall count with ear protectors.

Article 373 It is required to place close to each equipment a hand washer with disinfectant to maintain the hygiene between resting breaks as well as water connections for the cleaning the machine and have drainages with direct connection to the net of drainages.

Article 374 Establishments can install connectors for air compressed in those areas that require it, to clean motors and internal coils of the machinery.

Article 375 Construct ceilings of cooking areas to a greater height than those of the other areas and there must be an efficient system to eliminate fumes, smoke and the hot air produced there.

Article 376 Floors of the cooking area must have greater slopes than the other areas in order to eliminate quickly the water and solids.

Article 377 The cooling chambers for cooked products shall comply with the construction requirements for cold chambers described in Title IV of these regulations. Regulate the illumination to prevent discoloration of finished products.

TITLE XXIV
OF THE GENERAL CONDITIONS OF THE RAW MATERIAL FOR THE MEAT PRODUCTS ELABORATION
CHAPTER I

Article 378 Accompany the meat used as raw material when coming from another authorized establishment or country, with the corresponding official documents that guarantees its origin. The reception area will have to be adapted for that purpose and guarantee the safety of the product.

Article 379 All raw materials that enter an establishment will have to pass through the following procedure:

1. Visual inspection of the transport.
2. Visual inspection of the transported product.
3. Inspection of the organoleptic characters of the product (color, scent, texture and freshness that will have to be sui generis) this must appear free of strange matter and with the conditions of quality that is required.
4. The temperature of the fresh meat must be from 0^0 C or 32^0 F or as maximum from 4^0C or 39^0F and a pH that oscillates between 5.8 and 6.2.
5. Samples will be taken from frozen or fresh meat for its microbiological analysis and in the case of imported can be taken for chemical residues.

Article 380 Once inspected the meat, it will have 3 possible destinies:

1. Accepted: Will be identified at its entrance and shall allow the storage according to the principle of first-in-first-out (FIFO) and shall stay to the temperature of conservation according to its condition.
2. Retained: If the meat is suspicious, a label of RETAINED S.P will be placed to make the related examinations and to assure the product final destiny.
3. Rejected: When the meat does not meet the specific sanitary conditions for process, the label of REJECTED S.P will be placed, and determine its final destiny, which could be incineration or denaturation for the process of products for animals or return to the country of origin if imported.

Article 381 The retained or rejected meat, may be maintained in the same storage chamber whenever is provided with a specific area for this, that will delimit clearly and visibly. It must make sure that it does not represent a contamination risk to other products stored there.

CHAPTER II
DRY RAW MATERIAL

Article 382 The dry raw material shall arrive free from dust, humidity and with the corresponding documentation that guarantees its origin, the supporting ones as technical specifications, physical-chemical, microbiological analyses certificates, and the documentation required by the competent authority according to the product.

Article 383 All ingredients must arrive in sealed containers from their origin, perfectly identified, with the information of composition, lot, and expiring date, handling recommendations, origin, storage conditions and recommended dose.

Article 384 All dry ingredients must be in an air-conditioned area between 15 and 20 ^{0} C and with a humidity control from 70 to 75% for the place where the synthetic casings and packing material are stored.

Article 385 Once inspected the dry raw material, shall apply the same destiny prescribed for meat in Article 379.

Article 386 The storage will be done in a specific area for it, which will be closed, dry and of easy cleaning, the containers will remain closed, free of dust and humidity, well identified and stored by compatibility.

Article 387 The completion of the mixing and dosing by weight will be in a specific area physically separated from the storing room, where opening the bags or packages, and those not used in its entirety, must be stored in containers secured and identified.

CHAPTER III
APPROVAL AND USE OF CHEMICAL INGREDIENTS FOR THE PROCESS

Article 388 For the approval of substances to be used in the preparation of products shall consider:

1. No product may contain any substance that adulterates or is not approved by the Food and Beverage Risk Control Department.
2. When the substance is new or has a new usage level, even though is already approved, the Food and Beverage Risk Control Department will give its approval if the substance complies the requirements of compatible regulations like those of the FDA (Foods and Drugs Administration of the United States) and the Codex Alimentarius having them as references.
3. The use of controlled products considered as high risk, and that have predetermined levels as in sodium nitrate between 40 to 80 ppm, potassium nitrate between 49 to 99 ppm, sodium ascorbate or erythorbate that is 550 ppm, or another fermentable carbohydrate, or effective bacteria to control fermentation to be approved by the Food and Beverage Risk Control Department, will be subject to enforcing conditions.
4. Substances that are already approved to be added to products are: common salt, sugar (sucrose, sugar cane or beets, maple sugar, dextrose, inverted sugar, honey, corn syrup solids, corn syrup and glucose syrup), wood smoke, vinegar, safe flavorings and spices.
5. When applying materials or color substances or dyes to the pack, they shall not cause color penetration to the product.
6. Pack the product in conventional containers for its use, when added any color or dye with artificial flavor to the fat.

Article 389 The substances specified in the following charts are approved for product preparation as long as they are used for the purposes indicated:

Substances	Purpose	Products	Amount
ANTICOAGULANTS:			
Citric Acid Sodium Citrate	Prevent clotting	Fresh Blood of livestock	0.2% with or without water. When water is used to make a solution of citric acid or sodium citrate not more than 2 parts of water to 1 part of citric acid or sodium citrate.

Substances	Purpose	Products	Amount
ANTIFOAMING AGENT:			
Methyl polysilicone	Retard foaming	Soups and rendered fats	10 ppm
ANTIOXIDANTS AND OXYGEN INTERCEPTORS			
Ascorbyl stearate. BHA (butylate hidroxyanisole) BHT (butylated hydroxytoluene) Propyl gallate TBHQ (tertiary butylhydroquinone)	Retard rancidity	Dry sausage Rendered animal fat or a combination of such fat and vegetable fat. Fresh pork chops and sausage, Italian sausage, precooked fried beef and fresh sausages made with beef or pork. Dry meat, margarine, oleo-margarine	0.003% based on total weight 0.006% in combination with other anti-oxidants for use in meats 0.01 % of the total fat. 0.02 % in combination with other anti-oxidants 0.01% based on total weight or in combination with other antioxidants 0.02 % (by wt. of the finished product) individually or in combination with other antioxidants. For TBHQ in combination with BHA and/or BHT.
Ascorbyl palmitate	Retard rancidity	Margarine or oleomargarine	0.02 % (by wt. of finished product) individually or combined with other antioxidants
Tocopherols	Retard rancidity	Rendered animal fat or combination of such fat and vegetable fat.	0.03%. A 30% concentration of tocopherols in vegetable oils shall be used when

Substances	Purpose	Products	Amount
			added as an antioxidant to products designated a “lard” or “rendered pork fat”.
		Dry sausage, semidry sausage, dried meats, uncooked or cooked fresh sausage made with beef and/or pork, uncooked or cooked Italian sausage products, uncooked or cooked meatballs, uncooked or cooked meat pizza toppings, brown and serve sausages, pregrilled beef patties, and restructured meats.	Not to exceed 0.03 % based on fat content. Not used in combination with other antioxidants.
BLEACHING AGENTS			
Hydrogen peroxide	To remove color	Tripe (substance shall be removed from product rinsing with clear water)	Sufficient for purpose.
CATALYSTS **(substances must be eliminated during process)**			
Nickel	To accelerate chemical reaction	Rendered animal fats or a combination of such fats and vegetable fats.	Sufficient for purpose.
Sodium amide	Rearrangement of fatty acids radicals	Rendered animal fats or a combination of such fats and vegetable fats.	Sufficient for purpose.
Sodium Methoxide	Rearrangement of fatty acids	Rendered animal fats or a combination of	Sufficient for purpose.

Substances	Purpose	Products	Amount
	radicals	such fats and vegetable fats.	
ARTIFICIAL SWEETENERS			
Saccharin	To sweeten product	Bacon	0.01 %
BINDERS AND EXTENDERS			
Algin	To extend and stabilize product	Breading mix; sauces	Sufficient for purpose.
Carrageenan	To extend and stabilize product and prevent purging of brine solution	Breading mix; sauces	Sufficient for purpose.
Carrageenan, Locust bean gum, and Xantan gum blend.	To extend and stabilize product and prevent purging of brine solution	Breading mix; sauces	In combination, not to exceed 0.5 % of formulation: not permitted in combination with other binders approved for use in cured pork products.
Carboxymethyl cellulose (cellulose gum)	To extend and stabilize product	Baked pies (meat)	Sufficient for purpose.
Enzyme (rennet), treated with calcium reduced dried skim milk and calcium lactate.	To bind and extend product.	Sausages as provided in these regulations.	3.5% total finished product (calcium lactate required at 10% of binder.)
		Imitation sausages; nonspecific loaves; soups, stews	Sufficient for purpose. (Calcium lactate required at 10% of binder.)
Enzyme (rennet), treated with sodium caseinate and calcium lactate.	To bind and extend product.	Imitation sausages; nonspecific loaves; soups, stews.	Sufficient for purpose. (Calcium lactate required at 25% of binder).
Gums, vegetables,	To bind and extend product.	Egg rolls (meat only)	Sufficient for purpose.
Methyl cellulosae	To bind and extend product (also carrier).	Meat and vegetable patties	0.15%
Sodium caseinate	To bind and extend product.	Sausages as provided in these regulations Imitation sausages; nonspecific loaves;	2 % Sufficient for purpose.

Substances	Purpose	Products	Amount
		soups, stews. Chili con carne, chili con carne with beans Spaghetti with meatballs and sauce and similar products.	 8% individually or collectively with other binders. 12 % individually or collectively with other binders.
Soy protein concentrate	To bind and extend product.	Sausages	2 %
Agar-agar	To extend and stabilize product.	Thermally processed canned and jellied meat food products.	0.25 % of finished product.
Whey, Dry or dried Whey, Reduced lactose Whey, Reduced minerals Whey, protein concentrate	To bind or thicken	Sausage Imitation sausages, nonspecific loaves soups, stews, chili con carne or with beans, beef with barbecue sauce.	3.5 % individually or collectively with other binders or extenders. 8 % individually or collectively with other binders and extenders.
Whey, protein concentrate	To bind meat pieces	Restructured meat food products, whole muscle meat cuts	3.5 % individually or collectively with other binders and extenders.
Xantan Gum	To maintain: uniform viscosity, suspension of particulate matter, emulsion stability; freeze-thaw stability.	Meat sauces, gravies or sauces and meats, canned or frozen and/or refrigerated meat salads, canned or frozen meat stews, canned chili or chili with beans, pizza topping mixes and batter or breading mixes.	Sufficient for purpose.
Bread	To bind and extend product.	Bockwurst	3.5 % individually or collectively with other

Substances	Purpose	Products	Amount
			binders.
		Chili con carne, chili con carne with beans	8 % individually or collectively with other binders.
		Spaghetti with meatballs and sauce and similar	12 % individually or collectively with other binders.
Cereal	To bind and extend product.	Sausages and bockwurst	3.5 % individually or collectively with other binders or extenders.
		Chili con carne and with beans	8 % individually or collectively with other binders.
Dried milk or dehydrated	To bind and extend product.	Sausages	3.5 % individually or collectively with other binders
Dried skim milk, calcium reduced.	To bind and extend product.	Sausages	3.5 % individually or collectively with other binders.
		Chili con carne and with beans	8 % individually or collectively with other binders
Soy flour Soy protein concentrated Vegetable starch Tapioca dextrin Wheat gluten	To bind and extend product	Sausages	3.5 % individually or collectively with other binders and extenders.
		Chili con carne and with beans	8 % individually or collectively with other binders and extenders

Substances	Purpose	Products	Amount
		Spaghetti with meatballs and sauce, spaghetti with meat and sauce and similar products.	12 % individually or collectively with other binders and extenders
COLORING AGENTS (NATURAL)			
Alkanet, annatto, carotene, cochineal, chlorophyll, saffron and turmeric.	To color casings or rendered fats; marking and branding product.	Sausage casings, oleomargarine, shortening, marking or branding ink on product.	Sufficient for purpose (may be mixed with approved artificial dyes or harmless inert material such as common salt and sugar).
COLORING AGENTS (ARTIFICIAL).			
Approved dyes derived from coal tar (Must have certification that dye can be used in food)	To color casings or rendered fats; marking and branding product.	Sausage casings, oleomargarine, shortening, marking or branding ink on product.	Sufficient for purpose (may be mixed with approved natural coloring matters or harmless inert material such as common salt and sugar).
Titanium oxide	To color casings or rendered fats; marking and branding product.	Canned ham salad spread and creamed-type canned products.	0.5 %
CURING ACCELERATORS (must be used only in combination with curing agents)			
Ascorbic acid Erythorbic acid	To accelerate color fixing or preserve color during storage.	Cured pork and beef cuts, and cured meat food product.	87.5 oz to 100 gal pickle at 10 % pump level; 7/8 oz to 100 lb meat, meat byproduct, 10 % solution to surfaces of cured cuts prior to packing.
Glucono delta lactona.	To accelerate color fixing or	Cured meat products, cured comminuted	8 oz to each 100 lb of meat or meat

Substances	Purpose	Products	Amount
	preserve color during storage.	meat food products. Genoa salami	byproduct. 16 oz to 100 lb of meat.
Sodium acid pyrophosphate	To accelerate color fixing or preserve color during storage.	Frankfurters, wieners, vienna, bologna, garlic bologna, knockwurst and similar.	Not to exceed alone or in combination with other curing accelerators: 8 oz in 100 lb of meat, or meat byproduct; nor 0.5% in the finished product.
Sodium ascorbate Sodium Erythorbate	To accelerate color fixing or preserve color during storage.	Cured pork and beef cuts, and cured comminuted meat food product	87.5 oz to 100 gal pickle at 10% pump level; 7/8 oz to 100 lb meat, or meat byproduct; 10% solution to surfaces of cured meat cuts prior to packaging.
Citric acid or sodium citrate	To accelerate color fixing or preserve color during storage.	Cured pork and beef cuts, and cured comminuted meat food product	May be used in cured meat products in 10% solution used to spray surfaces of cured meat cuts prior to packaging to replace up to 50 % of the ascorbic acid, erythorbic acid, sodium ascorbate, or sodium erythorbate that is used.
CURING AGENTS			
Sodium or potassium nitrate	Source of nitrite	Cured meat products other than bacon. Nitrates may not be used in baby, junior, and toddler foods.	7 lb to 100 gal pickle; 3.5 oz to 100 lb meat (dry cured); 2.75 oz to 100 lb chopped meat.
Sodium or potassium	To fix color	Cured products.	2 lb to 100 gal

Substances	Purpose	Products	Amount
nitrite (must be kept under the care of a responsible employee of the establishment. The specific nitrite content of such supplies must be known and clearly marked accordingly).		Nitrites may not be used in baby, junior, or toddler foods.	pickle at 10 % pump level; 1 oz to 100 lb meat (dry cure); 0.25 oz to 100 lb chopped meat and meat byproduct. The use of nitrites, nitrates or combination shall not result in more than 200 ppm of nitrite, calculated as sodium nitrite in finished product, except that nitrites may be used in bacon.
DENUDING AGENTS (May be used in combination. Must be removed from tripe by rinsing with potable water)			
Lime (calcium oxide, calcium hydroxide)	To denude mucous membranes.	Tripe	Sufficient for purpose.
Sodium carbonate	To denude mucous membranes.	Tripe	Sufficient for purpose.
Sodium gluconate	To denude mucous membranes.	Tripe	Sufficient for purpose.
Sodium hydroxide	To denude mucous membranes.	Tripe	Sufficient for purpose.
Sodium citrate	To denude mucous membranes.	Tripe	Sufficient for purpose.
Sodium silicates (Roth, meta y sesqui)	To denude mucous membranes.	Tripe	Sufficient for purpose.
Sodium persulfate	To denude mucous membranes.	Tripe	Sufficient for purpose.
Trisodium phosphate	To denude mucous	Tripe	Sufficient for purpose.

Substances	Purpose	Products	Amount
	membranes.		
EMULSIFYING AGENTS			
Actylated monoglycerides	To emulsify product	Shortening	Sufficient for purpose.
Diacetyl tartaric acid esters of mono- and diglycerides.	To emulsify product	Shortening	Sufficient for purpose.
Glycerol-lacto stearate, oleate, or palmitate	To emulsify product	Shortening	Sufficient for purpose.
Lecithin	To emulsify product (also as an antioxidant)	Oleomargarine, shortening, various meat products.	0.5 % in oleomargarine, use in other products-sufficient amount for emulsification.
Mono and diglycerides (glycerol palmitate, etc)	To emulsify product	Rendered animal fat or a combination of such fat with vegetable fat; oleomargarine.	Sufficient for purpose in lard and shortening; 0.5% in oleomargarine.
Polysorbate 80 (polyoxyethylene (20) sorbitan monooleate).	To emulsify product	Shortening for use in non-standardized baked goods, baking mixes, icings, fillings, and toppings and in the frying of foods.	1% when used alone. If used with polysorbate 60 the combined total shall not exceed 1%.
Polyglycerol esters of fatty acids (are restricted to those up to and including the decaglicerol esters and others known).	To emulsify product	Rendered animal fat or a combination with vegetable fat when use is not precluded by standards of identity of composition; oleomargarine.	Sufficient for purpose for rendered animal fat or combination with vegetable fat; 0.5% for oleomargarine.
Propylene glycol mono and diesters of fats and fatty acids.	To emulsify product	Rendered animal fat or a combination with vegetable fat.	Sufficient for purpose.
Polysorbate 60 (polyoxyethylene (20)	To emulsify	Shortening for use in non-standardized	1% when used alone. If used with

Substances	Purpose	Products	Amount
sorbitan monooleate).	product	baked goods, baking mixes, icings, fillings, and toppings and in the frying of foods.	polysorbate 80 the combined total shall not exceed 1%.
Stearyl-2-lactylic acid	To emulsify product	Shortening to be used for cake icings and fillings (meat only).	3 %
Stearyl monoglyceridyl citrate.	To emulsify product	Shortening	Sufficient for purpose.
Mono and diglycerides of fatty acids esterified with any of the following acids: acetic acetyltartaric, citric, lactic, tartaric, and their sodium and calcium salts; the sodium sulfoacetate derivatives of these mono and diglycerides.	To emulsify product	Margarine and oleomargarine	0.5%
FLAVORING AGENTS Protectors and developers			
Artificial smoke flavoring Autolyzed yeast extract.	To flavor product	Various meat products	Sufficient for the purpose
Harmless bacteria starters of the acidophilus type, lactic acid starter or culture of Pediococcus cerevisiae	To develop flavor	Dry sausage, pork roll, thuringer, Lebanon bologna, cervelat, and salami.	0.5 %
Benzoic acid (sodium, potassium and calcium salts)	Retard flavor reversion	Margarine and oleomargarine	0.1% individually and 0.2 % in combination with other flavoring agents or with sorbic acid and its salts.
Citric acid	Flavoring	Chili con carne	Sufficient for the purpose.

Substances	Purpose	Products	Amount
Corn syrup solids; corn syrup; glucose syrup.	To flavor product.	Chili con carne, sausage, hamburger, meat loaf, luncheon meat, chopped or pressed ham.	Sufficient for the purpose,
Dextrose	To flavor product.	Sausage, ham and cured products.	Sufficient for the purpose
Diacetyl	To flavor product.	Oleomargarine	Sufficient for the purpose
Disodium guanylate Disodium inosinate Hydrolyzed plant protein Milk protein hydrolysate. Monosodium glutamate	To flavor product.	Various meat products	Sufficient for the purpose
Malt syrup	To flavor product.	Cured meat products	2. 5 %
Sodium sulfoacetate derivative of mono and diglycerids.	To flavor product.	Various meat products	0.5 %
Sodium tripolyphosphate Sodium tripolyphosphate and mixes of sodium metaphosphate insoluble and sodium polyphosphate, glassy.	To help protect flavor	Fresh beef, beef for further cooking, cooked beef, beef patties, meat loaves, meat toppings, and similar products derived from pork lamb, veal, mutton, and goat meat which are cooked or frozen after processing.	0.5 %
Sorbitol	To flavor, to facilitate the removal of casings from product, and to	Cooke sausages labeled “frankfurter", "frank", "furter", "wiener",	Not to exceed 2% of the weight of the formula excluding the formula weight of water or ice.

Substances	Purpose	Products	Amount
	reduce caramelization and charring.	"knockwurst", cured pork and pork products.	
Starter distillate	To help protect flavor	Oleomargarine	Sufficient for the purpose
Stearil citrate	To help protect flavor	Oleomargarine	0.15 %
Sugars (dextrose and sucrose)	To flavor product.	Various meat products	Sufficient for the purpose
Calcium lactate	To protect flavor	Cooked semi-dry and dry products including sausage, imitation sausage, and nonspecific meat food sticks.	0.6 % in product formulation.
Harmless lactic acid producing bacteria	To prevent the growth of Clostridium botulinum	Bacon	Sufficient for purpose.
Potassium lactate Sodium lactate	To flavor product	Various meat and meat food products except infant formula and infant food.	Not to exceed 2 % of formulation
Sodium acetate Sodium diacetate	To flavor product	Various meat products	Not to exceed 0.25 % of formulation
GASES			
Carbon dioxide solid (dry ice)	To cool product	Chopping of meat, packing of product.	Sufficient for purpose.
Carbon dioxide liquid Nitrogen, liquid	Contact freezing	Various meat products	Sufficient for purpose.
Nitrogen	To exclude oxygen from sealed containers	Various meat products	Sufficient for purpose.
HOG SCALD AGENTS (must be removed by subsequent cleaning operations).			
Caustic soda	To remove hair	Hog carcasses	Sufficient for

Substances	Purpose	Products	Amount
Dicotyl sodium sulfosuccinate Lime (calcium oxide, calcium hydroxide) Dimethylpolysiloxane Sodium carbonate Sodium dodecylbenzene sulfonate Sodium hexametaphosphate Sodium lauryl sulfate Sodium silicates (ortho, meta, sesqui) Sodium n-alkylbenzene sulfonate (alkyl group predominantly C12 and C13 and not less than 95% C10 and C16)			purpose.
Sodium sulfate Sodium tripolyphosphate Potassium hydroxide Propylene glycol Soap (prepared by the reaction of calcium, potassium, or sodium with rosin or fatty acids of natural fats and oils) Sodium acid pyrophosphate Sodium mono and dimethylnaphtalene sulfonate (molecular	To remove hair	Hog carcasses	Sufficient for purpose.

Substances	Purpose	Products	Amount
weight 245-260). Trisodium phosphate Sucrose Sodium dodecylbenzene sulphonate Triethanolamine			
RENDERING AGENTS			
Tricalcium phosphate Trisodium phosphate	To aid rendering	Animal fats	Sufficient for purpose
SYNERGISTS (Used in combination with antioxidants)			
Citric acid	To increase effectiveness of antioxidants	Any meat product permitted to contain antioxidants.	Not to exceed 0.01 % based on fat content.
Malic acid Phosphoric acid	To increase effectiveness of antioxidants	Lard and shortening	0.01 % based on total weight in combination with antioxidants. 0.01 %
Monoisopropyl citrate Monoglyceride citrate	To increase effectiveness of antioxidants	Lard, shortening, fresh pork sausage, dried meats.	0.02 %
REFINING AGENTS (must be eliminated during process of manufacturing)			
Acetic acid	To separate fatty acids and	Rendered fats (meat only)	Sufficient for purpose

Substances	Purpose	Products	Amount
Bicarbonate of soda	glycerol		
Carbon (purified charcoal)	To aid in refining of animal fats	Rendered fats (meat only)	Sufficient for purpose
Caustic soda (sodium hydroxide) Diatomaceaus earth; Fullers earth. Sodium carbonate Tannic acid	To refine fats	Rendered fats (meat only)	Sufficient for purpose
ACIDIFIERS			
Acetic acid Citric acid Glucono delta-lactone Lactic acid Phosphoric acid Tartaric acid	To adjust acidity	Various meat products	Sufficient for purpose
ANTIMICROBIAL AGENTS			
Potassium lactate Sodium lactate	To inhibit microbial growth.	Various meat products except infant formulas and infant food.	4.8 % by weight of total formulation.
Sodium diacetate	To inhibit microbial growth.	Various meat products except infant formulas and infant food.	0.25 % by weight of total formulation.
FILM FORMING AGENTS			
A mixture consisting of water, sodium alginate, calcium chloride, sodium carboxymethylcellulose, and corn syrup solids.	To reduce cooler shrinkage and help protect surface	Freshly dressed meat carcasses, identified, containing this mix.	Formulation may not exceed 1.5% of hot carcass weight when applied. Chilled weight may not exceed hot weight.

Substances	Purpose	Products	Amount
MISCELLANEOUS			
Potassium sorbate	To retard mold growth	Dry sausage	10% in water solution may be applied to casings after stuffing or casings may be dipped in solution prior to stuffing.
Calcium disodium, EDTA (calcium disodium ethylenediaminetetra acetate)	To preserve product and to protect flavor.	Margarine or oleomargarine	75 ppm by weight of the finished oleomargarine or margarine.
Propyl paraben (propyl p-hydroxy-benzoate)	To retard mold growth.	Dry sausage	3.5% in water solution may be applied to casings after stuffing or casings may be dipped in solution prior to stuffing.
Sodium bicarbonate Sodium carbonate	To neutralize excess acidity, cleaning vegetables	Rendered fats, soups, curing pickle.	Sufficient for purpose
Calcium propionate Sodium propionate	To retard mold growth.	Pizza crust.	0.32% alone or in combination based on weight of the flour brace used.
Adipic acid Citric acid (sodium and potassium salts). Hydrochloric acid Lactic acid (sodium and potassium salts). L-tartaric acid (sodium and sodium potassium	To acidify	Margarine or oleomargarine	Sufficient for purpose

Substances	Purpose	Products	Amount
salts). Phosphoric acid			
Ascorbic acid, erythorbic acid, citric acid, sodium ascorbate and sodium citrate, single or in combination.	To delay discoloration.	Fresh beef cuts, fresh lamb cuts, and fresh pork cuts.	Not to exceed, single or in combination, 500 ppm or 1.8 mg/sq inch of product surface of ascorbic acid, erythorbic acid, or sodium ascorbate; not to exceed, single or in combination, 250 ppm or 0.9 mg /sq inch of product surface of citric acid, or sodium citrate.
Citric acid	To preserve cured color during storage.	Cured pork cuts.	Not to exceed 30 % in water solution used to spray surfaces of cured cuts, prior to packaging. (The use of such solution shall not result in the addition of a significant amount of moisture to the product and shall be applied only once to product).
d –di-alpha -tocopherol	To inhibit nitrosamine formation.	Pump cured bacon.	500 ppm; by injection or surface application.
Potassium carbonate. Potassium bicarbonate.	To alkalize.	Margarine or oleomargarine	Sufficient for purpose.
Dipotassium phosphate Disodium phosphate	To reduce the amount of cooked out	Only in allowed meat food products.	For meat food products, 5 % of phosphate in pickle

Substances	Purpose	Products	Amount
Monopotassium phosphate Monosodium phosphate Potassium tripolyphosphate Sodium acid pyrophosphate Sodium hydroxide Sodium metaphosphate, insoluble. Sodium pyrophosphate Sodium tripolyphosphate.	juices.		at 10% pump level; 0.5% of phosphate in neat food product (only clear solution may be injected into meat food product).
Glycerine	Humectant	Shelf stable meat snacks.	Not to exceed 2 % of the formulation weight of the product.
Silicon dioxide	Processing aid/dispersant	Tocopherol containing bacon curing mixes.	At level not to exceed 4 % in the dry mix.
Sodium hydroxide	To alkalize	Margarine or oleomargarine	Sufficient for purpose.
Sorbic acid (sodium, potassium, and calcium salts)	To preserve product and to retard mold growth.	Margarine and oleomargarine	0.1% individually, or if used in combination or with benzoic acid or its salts, 0.2 % (expressed as the acids in the wt. of the finished foods).
AGENTS TO TREAT WATER FOR COOLING AND RETORTS			
Calcium Chloride	Prevent stains	Any product.	Sufficient for

Substances	Purpose	Products	Amount
Citric acid Calcium disodium ethylenediaminetetra-acetate. Disodium ethylenediaminetetra-acetate. Disodium phosphate Ethylenediaminetetra-acetic acid. Potassium pyrophosphate Propylene glycol Sodium bicarbonate Sodium gluconate Sodium hexametaphosphate Sodium metasilicate	on the outside of canned foods.		purpose.
Sodium dodecilbenzene Sodium lauryl sulfate. Sodium alkylbenzene sulfonate (alkyl group predominantly C12 and C13 and not less than 95% C10 and C16). Sodium pyrophosphate Sodium tripolyphosphate	Prevent stains on the outside of canned foods.	Any	0.05%
Zinc oxide Zinc sulfate	Prevent stains on the outside of canned foods.	Any	0.001 %

Substances	Purpose	Products	Amount
Dioctyl sodium	Prevent stains on the outside of canned foods.	Any	0.5 %
Sodium bisulfate	Prevent corrosion on the outside of canned foods.	Any	0.001%
Sodium nitrate (this should be de-characterize with 0.05 % powdered vegetal charcoal or 0.03 % of nigrosine and will be identified)	Prevent corrosion on the outside of canned foods.	Any	600 ppm

TITLE XXV
OF THE CONDITIONS AND HYGIENE OF THE EQUIPMENT FOR PROCESSED PRODUCTS

CHAPTER I
HAM TUMBLING AND MEAT CURING

Article 390 The process of tumbling meat for ham and curing shall be under refrigeration to guarantee product quality and reduce possible bacterial contamination.

Article 391 The product processors are required to have separated the areas dedicated for tumbling, injecting, softening and brine deposit tanks. Allow common areas in small or medium establishments with previous authorization of the Food and Beverage Risk Control Department.

Article 392 When using equipment for tumbling (denominated tumblers) must have special care in the hygiene of the machine and temperature of the meat in the process to be sufficiently low to avoid contamination not exceeding 50^0 F or 10^0 C.

Article 393 When tumbling meat for the ham production without the addition of starches and proteins, can work to a maximum temperature of 8^0 C or 46^0 F; using starches and proteins will work at less temperature up to 5^0 C or 41^0 F, to avoid the gas formation and to improve the conditions of final yield on the hams.

Article 394 Condition the stuffing manufacturing room to a temperature of 10^0 C or 50^0 F to avoid the bacterial contamination and fermentation of meat pastes or the instability of the emulsions.

CHAPTER II

COOKING ZONE AND COOKING FURNACES

Article 395 The cooking zone must be separated from other areas and the finished products cannot enter back into the production areas where raw materials or in process. These finished products shall go to the packaging zone.

Article 396 The cooking furnaces must be located in line to facilitate the flow of products. In the back part of the furnaces, recommends letting a space of at least 1.50 meters to facilitate the operations of feeding the smokers and maintenance.

Article 397 In front of the doors of the cooking furnaces is permitted the installation of a pipeline system, which must be operated by a mechanical form for the extraction of the steam and the smoke coming out when opening the doors.

Article 398 The floor of the furnaces must be of resistant material or concrete and be installed in front of them a canal with a resistant grid, to eliminate water and particles as well as spills by cleaning.

CHAPTER III

SHOWERS FOR COOLING STUFFING

Article 399 The showers facilities for cooling the stuffings will be close to the cooking furnaces respecting the process flow. Can consist of a coil with water sprinklers properly distributed so that it falls uniformly on all the carts; this can be continuous or at intervals. The Food and Beverage Risk Control Department shall approve the system used to guarantee product safety.

CHAPTER IV
CARTS FOR SMOKING AND COOKING PRODUCTS

Article 400 The carts used for the smoking and cooking products must be stored in a specific area for them within the facilities and respecting the process flow. Provide this area with cold water, hot water and/or steam to wash them and shall avoid contamination between clean and dirty carts. Do not allow leaving empty carts in other areas.

CHAPTER V

AREA FOR COOKING HAMS

Article 401 The area for cooking hams shall have an efficient system for steam and water disposal used to cook them and the pipe by where this eliminates must connect to the served water drainage avoiding to spill on floors.

Article 402 There are several systems to cook hams allowing stainless steel for those cooking in water tanks. These tanks must have hermetic lids, with thermoregulatory valves or thermostats, steam solenoid valves, guaranteeing therefore the adequate control of the temperature for cooking.

Article 403 Molds used for cooking hams must be stainless steel.

Article 404 The bottom of the cooking tank must have a stainless steel grid so that inferior molds will not be less than 15 cms from the floor.

Article 405 To help uniformity of the internal temperature of the tanks, will allow compressed air coils continuously or at intervals, or hot water circulating pumps.

CHAPTER VI

ROOM FOR COOLING HAMS

Article 406 Cooling hams must be as fast as possible after cooking, allowing showers, cooling by water immersion or transporting them in stainless steel cages through a rail to a cooling system using water circulation.

Article 407 Due to cooling the internal temperature of hams must reach below 35^0 C or 95^0 F, and then take them to a cold chamber to lower it quickly between 2 to 5^0 C or 36 to 41^0 F. Release hams from their molds 24 hours after cooking.

CHAPTER VII

HAM UNMOLDING AREA

Article 408 Condition this area at 10^0 C or 50^0 F to guarantee no bacterial growth in the finished product.

Article 409 The unmolding can be done with manual pressure or air pressure against the bottom of the mold.

Article 410 Wash each mold before using it; this procedure shall perform in a specific area where the product shall not be contaminated, and the clean molds shall maintain separated from the dirty. Washing can be done with hot water, detergents and an alkaline degreaser.

CHAPTER VIII

PACKING AND COOLING CHAMBERS

Article 411 It is allowed to use a bag or polyethylene film for vacuum packing. In case needed, before the vacuum packing procedure can be authorized washing the ham surface with a solution of ascorbic acid with salt or other substances as color stabilizers.

Article 412 Hang free products in the cooling chambers in transporting carts or perforated plastic baskets. They shall stand there not less than 12 hours.

Article 413 The temperature products shall reach in the refrigerating chamber is 1 to 3 ^{0} C or 34 to 41^{0} F avoiding freezing and keeping humidity between 70 and 75%.

CHAPTER IX

ROOMS FOR SALAMI MATURATION AND DRYING

Article 414 In the salami maturation and drying rooms, the temperature, humidity and airflow must be under control as critical factors for maturation and drying of raw stuffing products.

Article 415 The use of transporting aerial carts or with wheels, manufactured with galvanized, aluminum or stainless steel material is allowed. The use of firm wooden shelves or any other absorbent material is prohibited.

CHAPTER X

WASHING FINISHED SALAMIS

Article 416 The local designed for finished salamis must be separated from the maturation and drying rooms to avoid the humid environment in the drying areas.

Article 417 Washing the salamis allows removing unwanted fungi (greens, black and yellow), first brushing dry each salami individually, then wet them with a hard flush of water and rub the surface with a brush or rough sponge. Later take the salamis again to the dryer to eliminate the superficial humidity.

Article 418 When the establishments slice the pieces of salami, it is recommended to remove the casing a day before and put salami in the cold chambers to eliminate the superficial flora (fungi of the genus Aspergillus) that is detrimental for the sliced product.

CHAPTER XI

PACKING ROOM FOR FINISHED PRODUCT

Article 419 The floors of the packing room for finished product must be kept dry during labor, the doors shall be closed and the temperature of the area shall be conditioned between 10 to 15 ^{0} C or 50 to 59^{0} F.

CHAPTER XII

CHAMBERS FOR FINISHED PRODUCTS PACKED

Article 420 In the finished product packed chambers a strict control on them shall maintain with clear identification of its production and storing dates (standardized) in boxes, cardboards, and plastic trays easy to handle and account, as well as to implement the methodology of first in first out (PEPS).

Article 421 All finished product shall be stacked in shelves (stands) or in plastic or metallic platforms of anticorrosive material.

Article 422 Within this chamber, shall be enabled an area for product retention, which will be locked up and shall be exclusively used by the Inspection Service. The area must have enough space to keep the retained 10% of the daily production of the establishment, having this as the place where the Inspection Service will identify the lots for the official sampling.

CHAPTER XIII

TRIPES AND ZONES OF SOAKING

Article 423 In the case of natural casings (tripes), they shall come from authorized establishments and under official inspection of SESPAS, guaranteeing its hygienic condition.

Article 424 Natural casings must come in brine or salted in closed containers and kept in refrigeration not more than 10^{0} C or 50^{0} F during their storage.

Article 425 The casing soaking area will be separated from the one for process and will soak only those to be used the production day.

CHAPTER XIV

ROOM FOR MILLING SPICES

Article 426 The spices that enter the milling room come from the main supply warehouse of dry ingredients and additives of the establishment, whose conditions were described on Title V of these regulations. Direct entrance is not allowed from the exterior to the room of spices without having previously been stored in the main warehouse.

Article 427 The room for milling spices shall be an independent and dry area, which has mills, and an appropriate extraction system for dust and odors.

Article 428 The grinded spices shall be stored in sealed bags or containers and properly identified.

Article 429 All products shall be stacked on pallets, shelves or tables avoiding placing the containers directly on the floor.

CHAPTER XV

ROOM FOR WEIGHING AND PREMIXTURES OF SPICES AND ADDITIVES

Article 430 Move the milled spices to the weighing room in sealed bags and be properly identified.

Article 431 Shall count on with the necessary equipment to carry out the weighing and the premixtures of the spices and additives used in the formulas of the products to elaborate.

Article 432 The milled spices and the additives already weighted and premixed shall be packed in new polyethylene bags where shall be visibly identified their usage or destiny and the manufacturing date.

Article 433 Must count on with a hygienic system for storage and transport these bags of spices and additives premixed for their entry to the processing area.

Article 434 All products shall be stacked on pallets, shelves or tables avoiding placing the containers directly on the floor.

Article 435 The weighing room shall be located in an annexed area, directly or internal to the processing place and conditioned at a temperature between 10 to 15^0 C or 50 to 59^0 F**.**

CHAPTER XVI

MACHINERY FOR STUFFING ELABORATION

Article 436 The machinery used for the stuffing elaboration shall be approved for that purpose by the Food and Beverage Risk Control Department and that their manufacturers certify their use in food processing establishments.

Article 437 The equipment allowed for elaboration/ processing stuffing is the following, but not limited to:

1. Frozen meat cutters: guillotines, band saw, block cutters or flakers.
2. Meat mincer: grinder or chopper for fresh or frozen meat.
3. Emulsifying mill: bowl cutter, dual speed knife, vacuum, and micro cutter closed with lid. The lid can be stainless steel or acrylic.
4. Grinder emulsifier or mix master: with knife system or discs (blades) with knives.
5. Mixers: tumbling, continuous, vacuum, chopper.
6. Meat and fat dice cutters: continuous and manual.
7. Stuffers: manuals, driven by compressed air or water pressure, semiautomatic and continuous automatic.
8. Staplers or clip machine: simple manual, double, continuous, and automatic.
9. Portioning with torsion: semiautomatic or automatic with natural or synthetic casings.
10. Linkers or continuous tying: standardize the product to same size. Some allow ties or hangers.

11. Cookers and smokers: manuals, automatic, continuous vertical or horizontal. The heat source can be wood, gas and smoke with saw dust, and cooled with water.

12. Tanks for cooking in water: with compressed air or circulated steam pump. Heat source can be generated by gas or vapor.

13. Cooking chamber for hams: indirect steam process handling the product by carts or baskets manually on rolls or rails.

14. Cooking tunnel: based on steam.

15. Autoclave/retort: sterilizers for casing products supporting 120^0 C or 248^0 F, thermal process that achieves a commercial sterility ensuring conservation at room temperature.

16. Sausage peeler: eliminates the cellulosic casing manually or automatic. The automatic are auctioned by steam or air compressed.

17. Sausage cutter: cut regulators for sausages unpeeled.

18. Saws for cutting pork and beef: circular saws for cutting fresh or frozen with or without bone.

19. Skinning machine: separates the fat from the pork skin. They are manual and semiautomatic in band/conveyor.

20. Membrane separators: similar to the skinning machine but eliminates the membranes of connective tissue and fat attached to the muscles.

21. Brine injection and tenderizers: they are manual and automatic with special filters with single or double head of needles.

22 Ham massagers: tanks where the meat for ham rests, which can be whole or in pieces, and previously injected and tenderized for a uniform process. They are open horizontal, tumblers or drums.

23. Brine mixer: stainless steel cylindrical tanks that stirs, disperse or solubilize chilled brine.

24. Brine recovery filters: stainless steel tank with internal cylinder, which separates the fat and foam from the brine.

25. Whole ham molds.

26. Pre-vacuum chambers: the air is extracted gradually from the stuffing.

27. Vacuum chambers and sealing, vacuum chamber and thermal seal: vertical vacuum chamber that extracts air and staple.

28. Press for cooked ham molds: Use air pressure.

Article 438 All the equipment mentioned in the previous article shall be stainless steel or a material approved and certified for that purpose by the competent authority.

CHAPTER XVII

CLEANING EQUIPMENT

Article 439 For cleaning the tumblers will recommend:

1. Use of high pressure equipment with cold and hot water, detergents and degreasers that emulsion fats and all shall be approved by SESPAS for such aim.
2. Rotate them in two directions assuring the complete washing.
3. Be sure to wash the removable parts and maintain a program of cleaning that it is not done daily.
4. Avoid incrustations in the welds since they retain polluting agents.
5. The water of the last rinsing has to be not less than 75^0 C or 167^0 F.
6. That the disinfectants used are not corrosive, avoiding sodium hypochlorite.
7. That the mineral oil used is approved by the competent authority for use in food process.

Article 440 To clean the tenderizers, brine tanks and injectors shall recommend to:

1. Disassemble them for a careful cleaning.
2. Avoid leaving incrustations and obstructions inside the needles.
3. After emptying the brine, let water flow through the hoses and needles, soak with warm water and use detergents and degreasers approved for this purpose.

Article 441 Cleaning carts, trays and others:

1. Shall be done at a central location easily accessible from all production areas, but respecting the process flow.

2. Shall have hot and cold water, or mechanical equipment for washing.

3. Shall count on with closed containers for solid wastes.

4. The dirty equipment area shall be well defined from the clean equipment area.

5. The clean area shall have a disinfection system for the equipment.

TITLE XXVI

OF THE CLASSIFICATION OF MEAT PROCESSED PRODUCTS

Article 442 Processed meat products classify in:

1. **Stuffings**: when independently of the operations used in the manufacturing process, they have been introduced to pressure in a bottom of a sac of organic or inorganic origin (natural or synthetic casings) approved for such purpose, even though at the sale or consumption they lack the casing.

2. **Non stuffings:** when it does not meet the definition of the preceding paragraph.

3. **Salted:** When organs, pieces of meat or tissue have undergone a process of preservation by salt, added in bulk and according to the technology of the product to process. The addition of sodium chloride can be wet or dry and the completion of the elaboration ends with smoking.

Article 443 **Cooked stuffing:** Products with a non-defined form of processing that undergoes a process of cooking in dry or in water.

The cooked stuffings are detailed below:

1. Blood sausage: cooked stuffing processed based on blood, obtained from animals authorized for consumption, defibrinated and filtered, adding or not bacon, prick pork skin, salt and spices and other substances found in the monograph approved.

2. Beef liver sausage: cooked stuffing processed based on blood, obtained from animals authorized for consumption and pork meat triturate, pork and bovine liver and bacon, adding or not salt, saltpeter, grounded white pepper, oregano, clove, coriander, onion and cornstarch.

3. Blood sausage with tongue: cooked stuffing processed with bovine or pork blood, obtained from animals authorized for consumption, pork skin and molded tongue, adding or not salt, grounded black pepper, grounded clove, grounded oregano, grounded thyme, coriander, marjoram and onion.

4. Bologna: cooked stuffing processed based on pork and bovine meat, adding bacon, sugar, saltpeter, amylase products, powdered milk and spices. The mixture can be stuffed in plastic bags approved for this purpose, dry cooked viscera, bladders and esophagus cooked. When other than bladders, shall place in molds according to the form wanted.

5. Salami: stuffing cooked, smoked or cured processed based on pork, bovine and poultry meat, or pork and bovine meat, with bovine fat and bacon, adding or not salt, saltpeter, grounded garlic, nutmeg, clove, coriander and cornstarch.

6. Frankfurter and Vienna sausages: cooked stuffing processed based on pork meat or pork and bovine meat adding bacon, salt, and spices. At the end of the process, scald and smoke until obtaining a clear brown color.

7. Botifarra: cooked stuffing processed based on pork or bovine meat, adding bacon, salt and spices, which have a proper cooking temperature.

Article 444 For the validity of fresh sausages shall consider the following conditions of storage and packaging:

1. Keep fresh sausages at temperatures between -2º C or 28º F and 5º C or 41º F and the expiration date in agreement with the technical criteria of the processer cannot exceed seven (7) days.

2. When sausages packed in vacuum or in controlled atmosphere and maintained at the temperature above mentioned, shall provide an expiration date according to the technical criteria of the processor, not exceeding fifteen (15) days.

3. When stuffings have been frozen immediately after their process at a temperature not exceeding -18° C or 0º F, it shall be provided an expiration date according to the technical criteria of the producer, not exceeding one hundred eighty (180) days.

Article 445 Place in the labels of these products their conservation temperature and all information stipulated in the actual Labeling Norms NORDOM 53.

Article 446 The Food and Beverage Risk Control Department can authorize the inclusion of the classification of other products that do not deviate entirely from the requirements established in this Title. To this effect shall present a document describing the product, processing form and components used.

Article 447 Requirements for raw materials and ingredients used in the preparation of stuffings are:

1. Mixtures or meat pastes not used in their preparation day may be used the following day, provided they are conserved in cold chambers at a temperature of 4ºC or 39º F or 5ºC or 41º F in the interior of their mass.

2. Can use mixtures and pastes of meats coming from wrap ruptures of meat products in process to prepare other products processed that same day. In case of not using them that same day may do so the next day, provided they be subject to cooking and stored in cold chambers.

3. Natural viscera can be treated by immersion in fresh pineapple juice or extract of papain, of bromelin, ficin or pancreatic juice to allow the enzymes act on the viscera achieving to be soften, shall in all cases, after this treatment, undergo to a profuse wash to remove any of the substances used.

4. Sausages prepared in oil must undergo previously to a temperature not less than 72ºC or 162ºF for a minimum period of thirty (30) minutes.

Article 448 Requirements for the materials used in the stuffing elaboration, are:

1. In stuffings, the bath of purified and deodorized paraffin, wax, varnish or other product approved by the Food and Beverage Risk Control Department is allowed.

2. The tin or lead papers and the colored ones with anilines considered harmful that do not yield their color easily, can be used as wrappers whenever is placed between them an intermediate paper of impermeable material.

3. In the stuffing casings, the aluminum or tin foil can be replaced by films or pure cellulose, cellophane, plastic materials, their resins and their compounds and other materials approved by the Food and Beverage Risk Control Department.

4. The use of animal wrappings is prohibited such as intestine, esophagus and other infested with parasite nodes.

Article 449 Declarations of components and prohibitions in the stuffing elaboration:

1. When using dyes in the preparation of meat products, shall be disclosed on the label the words "artificially colored" and followed the dye used.
2. Meat products shall not be processed using inferior quality raw materials or with different proportion from that declared in the monograph whereupon was approved the product.
3. Do not add water or ice over the authorized in these regulations.
4. No tissues or organs will be added to inferior quality, or aponeurosis, intestines, spleen, mammary glands, uterus or internal secretion glands, with exception of the liver.
5. When using cheek meat or other, with abundant aponeurotic tissue or tendons, shall be stripped of excess tissue.

Article 450 Considered as stuffings not suitable for consumption:

1. When the surface is humid, sticky or seeps.
2. When to the palpation flaccid zones are verified or abnormal consistency.
3. When there were indications of putrid fermentation.
4. When the mixture or mass present abnormal colors.
5. When verifies rancidity in fats.
6. When the wrapping of the stuffing was found perforated by parasites.
7. When verifies existence of pathogenic germs.

Article 451 The stuffing establishments shall not process fats if they are not qualified for such purpose.

Article 452 Additions of nutritional amylaceous substances are allowed in processed products. What it is established in these regulations will not go in contradiction with those found in Dominican Technical Norms (NORDOM) for this aim, it is recommended to use the following proportions:

1. Fresh stuffings up to a 5% of the gross weight of the finished product.
2. Dry stuffings up to a 3%.

3. Cooked stuffings are admitted up to 10%.

Article 453 Stuffings shall not contain derivatives of sulfurous acid.

Article 454 Possession or use of wood sawdust is prohibited in establishments except for that destined to be burned in the smokers. Also is prohibited the possession or use of rice hulls or similar products.

Article 455 Stuffings can be fresh, dry or cooked.

1 **Fresh Stuffing**. Those produced with meat and raw meat byproducts, with the addition of salt, spices and allowed additives that have not been under thermal or smoking processes. Fresh sausages are categorized as the following:

a) Fresh Sausage. Fresh stuffing made with meat of pork, bovine or a mixture thereof, with the addition of bacon and the aggregate or not of additives allowed to be used.

b) Pork Sausage (Longaniza barbecue). Fresh stuffing made on the base of meat of pork, bacon, hot chili, oregano, wine, anise or fennel and other additives allowed to be used, being able to add bovine meat.

c) Fresh Sausage. Fresh stuffing made based on pork and bovine, with the addition of bacon, salt, saltpeter and spices.

Article 456 **Dry Stuffings.** Those raw products that have been subjected to dehydration process naturally or artificially and partly to encourage them for a prolonged period.

The following are considered as dry stuffings:

1. Spanish Sausage. The stuffing made based on pork meat or bovine and pork, with the addition or not of bacon, salt, saltpeter and spices, in particular sweet pepper, the product can be smoked.

2. Longaniza (sausage). Dry stuffing prepared based on pork meat and bovine with or without addition of bacon, salt, saltpeter and spices.

3. Spanish Longaniza. Dry stuffing made based on meat of pork, bovine meat and bacon with the addition or not of salt, saltpeter, sugar, clove, sweet pepper, nutmeg, oregano, garlic and red wine.

4. Neapolitan Style Longaniza. Dry stuffing made on the base of meat of pork, bovine meat and bacon, with the addition or not of salt, saltpeter, nutmeg, hot chili, garlic, fennel in grain and red wine.

5. Salami. Dry stuffing made on the base of pork meat, or meat of pork and bovine, with bacon added, salt, saltpeter, sugar, spices and white wine.

Article 457 Non-stuffing meat products shall fulfill the following norms:

1. **Rolled piglet.** Non-stuffing meat product, made with deboned piglet, cured, marinated, rolled, tied with matambre (Stuffed Flank Steak) and put under cooking.

2. **Rolled thin beef flank steak**. Non-stuffing meat product, made with the plane non skeletal muscle from bovine, cured, marinated, rolled, tied and put to cook.

3. **Ground Beef with Ham.** Non-stuffing meat product prepared with ham, bacon, bovine meat with the addition or not of salt, white pepper, hot chili, ground mint, chopped dry peas, white wine and wheat flour. The mass prepared in minces taken to the molds previously covered internally with omentum and cooked under an appropriate temperature and time.

4. **Ham Ground Beef**. Meat product processed in similar form to the Ground Beef with Ham, but made exclusively with ham.

5. **Pork cheese**. Non-stuffing meat product processed with meat of head of pork, cheek and bovine tongue with the addition or not of salt, saltpeter, pepper, nutmeg, clove, cinnamon, peas, ground hot chili, garlic, pinions, white wine and wheat flour. The mixture wrapped in bovine omentum placed in molds and subject to cooking at appropriate temperature and time.

Article 458 Meat products considered as salted stuffings are those prepared using each one of the designated anatomical parts detailed next:

1. Salted pork head, salted pork rib, tail or salted pork tail, salted pork skin, salted pork muzzle, salted pork ear, salted pork leg.

2. **Cecina dried meat**. It is prepared with pork lean salted meat and dried to the air, the sun, the smoke or another approved means.

3. **Charque, charqui or salted meat.** Lean meat of those species allowed for consumption, dried to the air, the sun, with artificial heat or to the smoke, with addition of salt. Meat not salted is excluded from salted meats.

4. **Uncooked ham**. Salted meat prepared with the pork leg, with or without bone that must undergo a maturation process.

5. **Cooked ham**. Salted meat prepared with pork leg, with or without bone and undergone to cooking.

6. **Uncooked Pork shoulder**. Salted meat prepared with the front/thoracic pork limb with his own muscles and part of the ones that join it to the trunk up to the carpal joint, subject to a similar process to the raw ham.

7. **Cooked Pork shoulder**. Salted meat prepared with the described anatomical piece in the previous numeral subject to a process similar to the one for cooked ham.

8. **Salted Bacon belly**. Salted meat prepared with muscular tissue pieces of the abdominal region of the pork.

9. **Salted bacon**. Salted meat prepared with tissue pieces of the lumbar and jowl regions of the pork, put under the action of the salt in dry.

10. **Capocollo.** Boneless pork shoulder butt, dry-cured with salt or brine.

11. **Coppa**. Boneless pork shoulder butt, dry-cured with salt or brine.

Article 459 These definitions on stuffings, object of these regulations will be without prejudice to that described in the Dominican Technical Standards, criteria that will prevail over these regulations.

TITLE XXVII

OF STANDARDS OF IDENTITY OR COMPOSITION

OF PROCESSED PRODUCTS

Article 460 The General Directorate of Norms and Quality Systems (DIGENOR) is the national government organization authorized to establish definitions and standards of identity or composition through norms. They cover the main constituents of the products over their specific name or other labeling terminology that used. This action is necessary to prevent the sale of the product under false or misleading labeling and that it is necessary to protect the public.

Article 461 All the standards of identity and composition of processed products contained in these regulations are made without prejudice to that described in the Dominican Technical Norms (NORDOM) criteria that will prevail over these regulations.

Article 462 These regulations consign the standards of identity or composition of processed products that require an internationally recognized composition or the necessary for its export.

Article 463 All the standards of identity and composition of the processed products not described under the norms of DIGENOR or in these regulations can be based on the ones established by the Codex Alimentarius.

Article 464 The packs must show the correct name of the product, a statement of ingredients and any other information in the labeling according to the special provisions.

Article 465 Products that require the addition of nitrite or nitrate or that allow their use in them, can be prepared without these ingredients, as long as in its label is used the non-curing term preceded with the same size and style of the letters used for the standardized name.

Article 466 Mechanically separated deboned meat. Final products (comminuted), resulting from the process of almost complete removal of the bones of the skeletal muscle in mechanical form. At least 89% of the bone particles present shall not exceed 0.5 mm in size and not more than 0.85 in length.

Article 467 The general composition of the boneless meat mechanically separated must ensure that calcium should not exceed 0.75% of total solids of bones, and these as well must not exceed 3%. The protein must not be less than 14% and fat not more than 30%. If the product does not comply with these requirements, it shall use to produce animal fat. The P.E.R. must be 25% (protein-efficiency ratio).

Article 468 In mixtures of processed meats, the content of essential amino acids must be 33% of the total amino acids. The essential amino acids referred here are isoleucine, leucine, lysine, methionine, phenylalanine, threonine, valine, tyrosine, arginine, hystidine, alanine, aspartic acid, glutamic acid, glycine, proline, serine and hydroxyproline.

CHAPTER I

COOKED MEATS

Article 469 Meats for barbecue marked "Beef Barbecue" or “Barbecue pork" shall be prepared by the direct action of the resulting dry heat from the hard wood burning fire or the mineral coal, for a sufficient period to assume the usual characteristics including the brown crust of the surface. During the process, the product shall be coated with

sauce. The final product shall not exceed 70% of the weight of the fresh uncooked product, excluding salt and seasonings.

Article 470 The head meat, cheek meat, and heart once removed glandular and connective tissues can be use individually or together, not to exceed 5% of the total meat. When used they shall appear on the label.

CHAPTER II

CURED MEATS, SMOKED AND UNSMOKED

Article 471 Pressed Beef or Corned Beef, can be prepared from beef briskets, ribs, rounds, rumps, or similar cuts, using one or a combination of curing ingredients. The final product shall not exceed 70% of the fresh product excluding salt and flavorings. If the product is not canned, the pieces shall not weigh less than a pound. If cooked, the product must not exceed the original weight of the fresh product. Cheek, head and heart meat may be used, and the application of brine for curing meat cuts intended for “bulk” and the final product shall not exceed 10% of the weight of fresh.

Article 472 Pressed meat. Can be parts of round and other cuts, that shall not weigh less than a pound and such application of the curing solution shall not result in an increase of more than 10% the weight of the product in relation to fresh product; if it is cooked shall not exceed the weight of the fresh uncured product.

Article 473 Cured beef tongue. The application of the curing solution shall not increase in the weight of the cured beef tongue by more than 10% of the weight of the fresh uncured product.

Article 474 Cured pork products, including ham, shoulders, picnics, butts and loins, shall comply with the minimum protein fat free (PFF) percentage.

Type of Cured Pork Product	Minimum Meat PFF Percentage	Product Name Qualifying Statements
Cooked ham, loin	20.5	Common and usual
	18.5	Common and usual with natural juices
	17.0	Common and usual, water added
	< 17.0	Common and usual, water product –X% of weight is added ingredients.
Cooked shoulder, butt,	20.0	Common and usual

Type of Cured Pork Product	Minimum Meat PFF Percentage	Product Name Qualifying Statements
picnic		
	18.0	Common and usual with natural juices
	16.5	Common and usual, water added
	<16.5	Common and usual, water product –X% of weight is added ingredients.
Uncooked cured ham, loin	18.0	Uncooked, Common and usual
	<18.0	Uncooked, Common and usual, and water product – X% of weight is added ingredients
Uncooked cured shoulder, butt, picnic	17.5	Uncooked, Common and usual.
	<17.5	Uncooked, Common and usual, and water product – X% of weight is added ingredients

Article 475 The minimum PFF is the minimum protein content of the unprocessed fresh pork, expressed as a percent of the nonfat portion of the finished product.

Article 476 Products such as ham patties, chopped ham, pressed ham, spiced ham and related products shall comply with the minimum meat protein fat free (PFF) percentage requirements:

Type of Cured Pork Product	Minimum Meat PFF Percentage	Product Name Qualifying Statements
Ham Patties Chopped Ham Pressed Ham Spiced Ham	19.5	Common and usual.
Ham Patties Chopped Ham Pressed Ham Spiced Ham	17.5	Common and usual, with natural juices.
Ham Patties Chopped Ham Pressed Ham Spiced Ham	16.0	Common and usual, water added.
Ham Patties	<16.0	Common and usual, and

Chopped Ham Pressed Ham Spiced Ham		water product–X% of weight is added ingredients

Article 477 Cured pork products prepared under this Title, except Ham patties may contain finely chopped ham shank meat to the extent of 25% over that normally present in boneless ham. In addition to other requirements of this Title, chopped ham can contain more than 2% of a sweetener like corn syrup. Ham patties may not contain more than 35% fat.

Article 478 The products: “Country Ham”, “Country Style Ham”, “Dry Cured Ham”, “Country Pork Shoulder”, “Country Style Pork Shoulder”, or “Dry Cured Pork Shoulder” are the uncooked, cured, dried, smoked or not smoked, meat food products made respectively from a single piece of meat conforming to the definition of "Ham". They may not be injected or placed in brine to cure them. These products must be treated to destroy the possible presence of Trichinae in accordance with the approved methods.

Article 479 The entire exterior of the ham or pork shoulder shall be coated by the dry application of salt or in combination with other permitted ingredients.

Article 480 Additional salt or salt mixed with other permitted ingredients may be reapplied to the product as necessary to insure complete penetration in the product.

Article 481 When applying nitrite or nitrate or their combination, the salt shall be in sufficient quantity to insure that the finished product has an internal salt content of at least 4%.

Article 482 When nitrites or nitrates, or both are not used, the application of salt shall be in sufficient quantity to assure that the finished product has a brine concentration of not less than 10% or a water activity of not more than 0.92.

Article 483 For hams or pork shoulders labeled as "country" or "country style”, the combination period for curing and salt equalization shall not be less than 45 days for hams. For pork shoulders shall not be less than 25 days. The total time for curing salt equalization and drying shall not be less than 70 days for hams and shall not be less than 50 days for pork shoulders. During the drying and smoking period, the internal temperature of the product must not exceed 35^0 C or 95°F. This does not apply when it is under natural climatic conditions.

Article 484 When hams or pork shoulders labeled "dry cured", the combined period for curing and salt equalization shall not be less than: minimum 45 days for hams and not less than 25 days for pork shoulders. The total time for curing, salt equalization, and drying shall not be less than 55 days for hams and shall not be less than 40 days for pork shoulders. The weight of the finished products shall not be less than 18% of the fresh uncured weight of the product.

Article 485 When preparing bacon (pork bellies), the weight of the cured pork bellies ready for slicing and label as "bacon" shall not exceed the weight of the fresh uncured pork bellies.

CHAPTER III
FRESH SAUSAGE

Article 486 This product can be prepared from one or more kinds of meat or meat and meat byproducts, containing various amounts of water, usually seasoned with spices and frequently cured. May contain binders and extenders e.g.: Cereals, vegetable starch, soy flour, soy protein concentrate, soy protein, isolated soy protein, dehydrated milk, calcium lactate, etc.

Article 487 The final product shall not contain more than 3.5% of these additives individually or collectively. Two percent of isolated soy protein considers equivalent to 3.5% of one or more of these additives. The sausages may not contain phosphates, except those previously approved by the competent authority.

Article 488 To facilitate chopping or mixing, or dissolving the ingredients, can use water or ice in the preparation of non-cooked sausages. The amount cannot exceed 3% of the total ingredients in the formula.

Article 489 Cooked Sausage such as Polish sausage, cotto salami, Braunschweiger, liver sausage and similar, shall not exceed 10% of water added to the finished product. Sausage may contain mechanically separated boneless meat.

Article 490 Fresh pork sausage. Can be prepared with pork, fresh or frozen, or both. It shall not include pork byproducts. May contain mechanically separated deboned meat and seasonings as stipulated in these regulations. The finished product shall not contain more than 50% fat. To facilitate chopping or mixing, can use water or ice in amounts not exceeding 3% of the total ingredients.

Article 491 Fresh beef sausage. Sausage prepared with fresh or frozen beef or both. It can also use the mechanically separated deboned meat and

seasonings, but it is not allowed beef byproducts. The finished product shall not contain more than 30% fat. It can use water and ice in amounts not exceeding 3% of the total ingredients.

Article 492 Sausages for breakfast (Breakfast sausage). Sausage prepared with fresh and / or frozen meat, and / or meat byproducts, and may contain mechanically separated deboned meat and seasoned with condimental substances. The final product shall not contain more than 50% fat. To facilitate chopping and mixing, can use water or ice in amount not to exceed 3% of the total ingredients used. Can use approved binders and extenders up to 3.5% of the finished sausage.

Article 493 Whole hog sausage. Sausage prepared with fresh and/or frozen swine meat in the proportions that are a normal to a single animal, may include mechanically separated deboned meat and seasoned with condimental substances. The finished product shall not contain more than 50% fat. To facilitate chopping and mixing, can use water or ice in an amount not exceeding 3% of the ingredients.

Article 494 Italian Sausage Products. Sausages cured or uncured, containing at least 85% meat. They can combine with fat not more than 35% of the finished product. They shall contain salt, pepper, anise or fennel or both combined. Shall be prepared with fresh or frozen pork and pork fat may be added. It is allowed the use mechanically separated boneless meat. Italian sausage with veal or Italian sausage with both meats shall be prepared with fresh or frozen pork. Pork constitutes the major percentage of the total content.

Article 495 Italian sausage from Kosher beef. Shall be prepared with fresh or frozen beef and can be used beef fat. The Italian veal sausage or kosher Italian veal sausage shall be prepared with fresh or frozen veal and veal fat. These Italian products may contain sodium nitrite or potassium nitrite in amounts not exceeding those allowed in these regulations and will label with the legend "Cured Italian Sausage" and the word "cured" will be the same size and style of the other words in the product name.

Article 496 Optional ingredients allowed in Italian sausage (sausages):

1) Spices (including paprika and flavorings).
2) Water or ice, not more than 3%.
3) Red or green peppers or both.
4) Dehydrated of fresh onions, garlic and parsley.
5) Sugar, dextrose, corn syrup, corn syrup solids and glucose syrup.
6) Monosodium glutamate and antioxidants as provided in these regulations.

Article 497 Italian sausage products are cooked or smoked and/or before cooked or smoked, shall not have more than 3% of water and must use the word "cooked" or "smoking" on the label and the letters in the same shape and size of those used in the product name.

CHAPTER IV
UNCOOKED SMOKED SAUSAGE

Article 498 Smoked pork sausages. Pork sausage that is smoked with hardwood or other approved nonresinous materials. It may season with condimental substances as permitted in these regulations. The finished product shall not contain more than 50% fat. To facilitate chopping or mixing, may use water or ice in amounts not exceeding 3% of the total ingredients used.

CHAPTER V
COOKED SAUSAGE

Article 499 The cooked sausages are: Frankfurter, frank, furter, hot dog (sausage), wiener, vienna, bologna (mortadella), garlic bologna, knockwurst and similar cooked products.

Article 500 The cooked sausages are comminuted, semisolid, prepared with fresh meat, one or more kinds of meat cuts, and can be used fresh or cooked meat chicken, also can be used one or more seasonings and curing agents permitted by these regulations. They may or may not be smoked. Fat shall not exceed 30% on the finished product, and may use water or ice, or both to facilitate chopping and mixing but the sausage shall not contain more than 40% of a combination of fat and added water. Phosphates approved by these regulations may be used. The fresh or cooked poultry meat shall not exceed 15% of the total ingredients excluding water and boneless meat of any specie mechanically separated and shall be designated in the ingredient statement on the label.

Article 501 Frankfurter, frank, furter, hot dog, wiener, vienna, bologna (mortadella) etc., that are labeled with the phrase "with byproducts" or with "variety of meats" in the product name are comminuted semi-solid sausages consisting in not less than 15% of raw byproducts. May use raw or cooked poultry products, can be seasoned, cured or smoked, and may be added pork or beef fat or a combination of both not exceeding 30% of the finished product. The water shall not exceed 10% and phosphates shall be used adequately according to these regulations. Poultry products shall not contain kidneys or sexual glands and the amount of poultry skin must not exceed the natural proportion of skin

present on each carcass. The content of the chicken meat must be declared in the label of the product. The mechanically separated deboned meat can be used.

Article 502 Designate individually meat byproducts used in these sausages in the ingredient statement on the label.

Article 503 Cooked sausages as defined in this Chapter shall be labeled by their generic name, e.g., frankfurter, frank, furter, hot dog, wiener, vienna bologna, garlic bologna, or knockwurst. When such products are prepared with meat from a single species of cattle, swine, sheep or goat, they shall be labeled with the term that refers to the particular species with the generic, and when such products are prepared from deboned meat mechanically separated.

Article 504 The appropriate label for products with other ingredients such as "frankfurter with dried skim milk low in calcium or Bologna with byproducts (or with variety meats), with the addition of soybean meal," one or more of the binders can be used in the cooked sausage. May be added dried milk, enzyme (rennet) treated calcium reduced dried skim milk, calcium lactate, nonfat dried milk, dried whey powdered, lactose reduced whey, minerals reduced whey, whey protein concentrate, cereal, vegetable starch, flour vegetable starch, soy flour, soy protein concentrate and isolated soy protein, provided that such ingredients do not exceed 3.5% of one or more of the binders.

Article 505 The cooked meats shall not be labeled with terms such as "all meat" or "all of (species)" or in other form to indicate that they do not contain meat ingredients or that are prepared only with meat.

Article 506 Poultry meat means deboned chicken or turkey or both, without skin or fat added, poultry meat products means chicken or turkey or chicken or turkey meat, or poultry byproducts as defined by these regulations. Meat byproduct (or varied meats) means stewed tripe and pork snout, beef tripe, beef, veil, lamb or goat, heart, tongue, fat, snouts and esophagus, and beef or pork fat tissues partly defatted.

Article 507 The Cheesefurters and similar products (cheese products). They are products in casings, which resemble frankfurters, except that they contain sufficient cheese to give well-defined characteristics to the final product. They can contain cereal, vegetable starch, vegetable flour starched, soy protein concentrated flour and isolated soy protein, soy, skim milk, etc. The final product shall not contain more than 3.5% of these additives. (See list of permitted additives). The soy protein shall not exceed 2%. When the product is added with any of these ingredients, shall appear prominently in the label, next to the name of

the product will be the name of the added ingredient, such as "cereal added", “potato flour added," etc. The products shall not contain more than 10% of water; fat should not exceed 30%.

Article 508 Braunschweiger and liver sausage or liverwurst. It is a cooked sausage made with fresh, cured and/or frozen pork, beef, and / or veil and at least 30% pork, beef and / or veil livers, computed on the weight of fresh livers; it may also contain pork and / or beef fat, mechanically separated boneless beef, binders and extenders permitted in these regulations. The product may have smoke taste characteristics, originating of smoked meats, smoke flavoring or smoking of the product. If the product is prepared with ingredients from a single species it shall be mentioned on the label, e.g.: beef braunschweiger or pork liver.

CHAPTER VI
LUNCHEON MEAT, LOAVES AND JELLIED PRODUCTS

Article 509 Meat for lunch (luncheon meat). This product is cured, cooked, made of comminuted meat and can use mechanically separated boneless meat. To facilitate chopping or mixing can add water or ice in an amount not to exceed 3% of the total ingredients.

Article 510 Meat Loaf. Prepared the same as the meat for lunch but giving the form of a roll of bread.

CHAPTER VII
MEAT SPECIALTIES

Article 511 Scrapple. Shall contain not less than 40% meat or meat byproducts computed based on the fresh weight excluding the bones, allowing the use of mechanically separated deboned meat. The flour used may be derived from grains and / or soybeans.

TITLE XXVIII
OF THE TECHNICAL DEFINITIONS OF THE PROCESS OF CANNED MEAT PRODUCTS

Article 512 For the purposes that the canning process entails, the technical definitions constitute the official interpretation of the following terms:

WATER ACTIVITY. Ratio between water vapor pressures of the product to the vapor pressure of pure water at the same temperature.

PROCESSING AUTHORITY. The person or organization with technical knowledge on thermal processing requirements related with canned foods and appointed by the establishment to perform certain functions as indicated in this title.

AUTOCLAVE OR RETORT. Pressure vessel designed for thermal processing of product packaged in hermetically sealed containers.

CODE LOT. All productions of a particular product, with a specific size, which containers are marked with a specific code.

VENTING. Removal of air from a retort before beginning the "time of processing."

HEADSPACE. The portion of the container not occupied by the product.

1) Gross headspace: is the vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the top edge of the container (e.g. Flange of an unsealed can, or the top edge of an unsealed jar.

2) Net headspace: the vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the inside surface of a lid.

SHELVES STABILITY. Condition achieved by the application of heat alone or in combination with other treatments, to render the product free of microorganisms capable of growing at a temperature above 50°F or 10°C at non-refrigerated conditions at which the product is intended to be held by distribution and storage. The product stability at shelf level is synonymous with commercial sterility.

CRITICAL FACTOR. Any characteristic, condition or aspect of a product, container or procedure, that affects the adequacy of the process schedule. The processing authorities determine the critical factors.

THERMAL PROCESSING. Heat treatment necessary to achieve commercial sterility as determined by the authority responsible of the process. It quantifies as:

1) Time and temperature
2) Minimum product temperature

PROCESSING SCHEDULE. The thermal process and any specific critical factor for a canned product required to achieve shelf stability.

ACIDIFIED LOW ACID PRODUCT. It is the canned product that has been formulated so as to achieve in the finished product a pH of 4.6 or less within 24 hours after the completion of the thermal process and keeps it until the expiring date and more.

LOW ACIDITY PRODUCT. A canned product in which any component has a pH above 4.6.

CANNED PRODUCT. Meat food product with a water activity above 0.85, which receives a thermal process before or after packed in a hermetically sealed container.

The term "product" used in this Chapter shall mean "Canned Product" unless otherwise specified.

INCUBATION TEST. Test in which the thermally processed product keeps at an specific temperature for a specific period, in order to determine if outgrowth of microorganisms occurs.

ABNORMAL CONTAINER. Container with signs of swelling, bad sealing or any evidence, which can spoil the contents of the unopened container.

HERMETICALLY SEALED CONTAINERS. Airtight containers designed and destined to protect the contents against the entry of microorganisms during and after thermal processing.

1) Rigid container: Container that when filled and sealed its shape and contour is not affected by the product or deformed by external mechanical pressure of up to 10 pounds per sq inch (0.7 kg/cm2) (e.i., normal firm finger pressure).

2) Semirigid container: Container that when filled and sealed its shape and contour is not significantly affected by the enclosed product under normal atmospheric temperature and pressure, but can be deformed by external mechanical pressure less than 10 lbs per sq inch (0.7 kg/cm^2) (e.i., normal firm finger pressure).

3) Flexible container: Container that when filled and sealed, its shape and contour suffer significantly changes affected by the enclosed product.

BLEEDERS. They are small orifices in the sterilizer or retort through which steam and other gases, are emitted from the retort throughout the entire thermal process.

SEAL. Those parts of a semi-rigid container and lid or of a flexible container, which are fused together in order to hermetically close the container.

CLOSURE TECHNICIAN. An individual designated by the establishment, trained to examine the integrity of the “sealing” of the container as provided in this title.

INITIAL TEMPERATURE. The temperature determined at the initiation of a thermal process cycle, of the contents of the coldest container to be processed.

PROCESS TEMPERATURE. The average minimum temperature of the heating to be maintained as specified in the indictment.

PROCESSING TIME. The minimum temperature of the heating medium maintained as specified in the process schedule.

COME-UP TIME. The elapsed time, including venting time (if applicable) between the introduction of the heating medium into a closed retort (closed autoclave) and the start of the process timing.

TITLE XXIX

OF THE CONTAINERS AND CLOSURES FOR CANNED MEAT PRODUCTS

Article 513 Inspection and cleaning of empty containers:

1. Empty containers, closures and flexible pouch roll stock, that shall evaluate the establishment to ensure their cleanliness and free of structural defects and damage that may affect the product or container integrity.

2. The exam shall base upon an established sampling.

3. Empty containers, closures and flexible pouch roll stock shall be handled to prevent contamination or damage that could affect the hermetic condition of the sealed container.

4. Before cleaning, rigid containers shall be cleaned to prevent incorporation of foreign matter into the finished product. Closures, semi rigid containers, preformed flexible pouches and flexible pouch roll stock contained in original wrappings do not need to be cleaned before use.

Article 514 Closure examinations for rigid containers (cans).

1. Visual examination. A closure technician shall visually examine the double seams formed by each closing machine head. When seam defects such as cutovers, sharpness, knocked down flanges, false seams, droops, must take corrective actions. Adjust or repair the closing machine, additionally, examine the entire container to prevent product leakage or other defects. Examine frequently, at least every 30 minutes; should be done at the beginning of the operation and after any adjustment or machine repair. Record any irregularity in the process.

2. Teardown examinations. The examinations shall be performed as often the case, should not spend more than four hours interval for each machine in operation. Examine at least one container from each closing head the end of the packaging line. The technician shall record any abnormality. The establishment shall have container specification guidelines for double seam integrity on file and available for review by authorized Program employees.

3. At the beginning of each shift or when the machine is set to proceed to the examination.

Article 515 The following procedures can be used to measure the dimensions of the double seams:

1. With micrometer: for cylindrical containers shall consider four points:

   a. Double seam length (W)

   b. Thickness (S)

   c. Body hook length (BH)

   d. Cover hook length (CH)

   The maximum and minimum values shall be recorded.

2. Seam scope or seam projector.

   a. Required measurements of the seam include thickness, body hook, and overlap. Measure the thinner parts with a micrometer. Cylindrical containers, at least two locations, excluding the side seam juncture, shall be used to obtain the required measurements.

   b. Seam tightness. Regardless the former, the seam examined shall be stripped to assess the degree of wrinkling.

   c. Side seam juncture rating. The cover hook shall be stripped o examine the cover hook droop at the juncture for containers having side seams.

   d. Examination of noncylindrical containers. Rectangular, square, D shaped or any other, will be examined as described in b) I), II) and III) except that the required dimensional measurements shall be made on the double seam according with the establishment's container specification guidelines.

3. Closure examinations for glass containers.

   a. Visual examinations. A closure technician shall visually observe no defects in the closures (loose or lost caps, fractured or cracked containers and low vacuum jars); take corrective actions if any of these defects. Conduct the examinations at least every 30 minutes over the production line. They shall be done at the beginning of each operation and after a closing machine adjustment.

   b. Closure examinations and tests. Depending on the type of container and closure, qualified personnel shall perform tests before or after processing at intervals of not more than four

hours. Examine at least one container from each closing machine during each regular examination period. Take immediately and record any corrective action. The technical guidelines for closure shall be available to the program employees.

4. Closure examinations for semirigid and flexible containers:

   a. The examination of each sealing machine shall be done as frequent as necessary observing well the type of sealing. The examinations shall obey a statistical sampling to ensure the seal integrity.

   b. Physical tests: perform after the processing and at least every two hours of continuous production. The establishment's acceptance guidelines for each test procedure shall be on file and available for the inspectors. Double seams for these containers shall be examined and the results recorded as provided in b) of this article.

5. Container coding: they shall be marked with a permanent, legible, identifying code mark. The mark shall identify the product, day and year of packing, as minimum.

6. Handling of containers after closure.

   a. Shall be handled so as to prevent damage that may affect the hermetic condition of the containers.

   b. The maximum time lapse between closing and thermal processing shall be two hours. The Director of the DIGESA can indicate shorter periods to ensure the integrity of the product. Periods longer than two hours shall need the permission of the Director.

TITLE XXX

OF THE CANNING PROCESS

Article 516 Thermal processing. Prior to the processing of any canned product for distribution in commerce, an establishment shall have the respective methodology as specified in these regulations for each meat product to be processed and packed. Source of process methodology:

1. This shall be developed by a processing authority.

2. The processing authority of the establishment shall evaluate any change in the formulation or in the thermal treatments

that may adversely affect the product heat penetration profile or sterilization value requirements. If it is determined that such changes adversely affects over the processing program, the respective authority shall adequate the process program.

3. All records, including any associated incubation tests, shall be available to the Inspector.

Article 517 Records processing and other information such as operating procedures for increasing the temperature of the autoclaves will be provided to the Inspector.

1. Prior to the processing of canned product for distribution in commerce, the establishment shall provide the inspector with all processing protocols. If critical factors are identified in the process program, the establishment shall provide the inspector with a copy of the procedures for measuring, controlling, and recording other factors related with the frequency of such measurements.

2. The processing authority shall make written communication to the establishment recommending all process schedules and these recommendations shall be filed and be at disposition to the Inspection Service for revision or copies thereof.

3. If identified critical factors in the process schedule the establishment shall provide the inspector with a copy of the procedures for measuring, controlling, and recording these factors, with the aim to keep them within the usual limits of the process.

4. The process schedules and associated critical factors, and the measuring procedures (including the frequency), controlling and recording, shall not be changed without prior review and written communication to the Director of DIGESA, and include written documents that approve the changes.

Article 518 The critical points and the application of the process methodology are:

1. General

    a) Maximum fill-in weight or drained weight;
    b) Arrangement of pieces in the container;
    c) Container orientation during thermal processing;
    d) Product formulation;
    e) Particle size;

f) Maximum thickness for flexible, and to some extent semirigid containers during thermal processing;
g) Maximum pH;
h) Percent salt;
i) Ingoing (or formulated) nitrite level (ppm);
j) Maximum water activity; and
k) Product consistency or viscosity

2) Continuous rotary and batch agitating retorts.

a) Minimum headspace; and
b) Reel speed.

3. Hydrostatic retorts.
a) Chain or conveyor speed.

4. Steam/air retorts.
a) Steam/air ratio; and
b) Heating medium flow rate.

Article 519 The operations in the area of thermal processing:

1. Process schedule/protocols for daily production including minimum initial temperatures and operating procedures for thermal processing equipment, shall be posted in visible places near to the equipment, such information shall be available to the operator and the inspector.

2. Process indicators and retort traffic control. To prevent a product from bypassing the retort a system shall be design for that aim. All the baskets or vehicles containing unprocessed products or at least one visible container in each vehicle shall be marked clearly and visibly with a temperature indicator that will indicate whether such unit has been thermally processed. Remove the indicators before such vehicles are refilled with unprocessed product.

3. Initial temperature. To assure that the minimum initial temperature of the contents of cold containers where the unprocessed products maintains when the cycle begins is not lower than the specified in the process schedule, shall record the temperature of the content of the coldest cans. When the product requires process in sealed containers shall verify the water to use in order that its temperature will not be less than the minimum temperature of the product.

4. Timing devices. Markers used in the records of the main thermal process events such as come-up time, retort venting, etc., shall be well calibrated for such functions. Wristwatches are not considered acceptable timing devices. Analog and digital clocks are considered acceptable. If the clock does not display seconds, a minute shall be considered a safety factor over the specified time for the process. Temperature/time recording devices shall correspond within 15 minutes to the time of the day recorded on written records required.

5. Measurement of pH. An electronic potentiometer shall be used to measure the maximum pH when is considered a critical point in the work method. The Inspection Service can review and approve other acceptable methods.

TITLE XXXI
OF THE EQUIPMENT AND PROCEDURES FOR THERMAL PROCESSING SYSTEMS

CHAPTER I
EQUIPMENT

Article 520 The instruments and common controls to different systems for thermal processing are:

1. Temperature indicator. Each retort shall be equipped with at least one indicating internal temperature device that measures the actual temperature within the retort and this can be used as a reference for indicating the process temperature and not to confuse with temperature/time records.

    a) Mercury-in-glass thermometers. A mercury-in-glass thermometer shall have divisions of 1^{o} F or 0.5° C, and the graduated scale shall not contain more than 17°F/inches or 4.0°C /cm. The thermometer shall be calibrated once installed and at least once a year against a known accurate standard to ensure its accuracy. The establishment shall record and maintained on file the following data: date, standard thermometer used, method, and the person that performed the calibration and shall maintain on file available for the Program employees. A mercury-in-glass thermometer that has a divided mercury column or that cannot be adjusted to the standard shall be repaired and calibrated to guarantee a good functioning before further use or replaced.

b) If using other devices instead of the mercury-in-glass thermometer (after approval by the Inspection Service) the operator can use another temperature indicator such as resistance detectors to measure temperature that shall be tested or calibrated once a year.

2. Temperature/time recording devices. Each thermal processing system shall be equipped with at least one temperature/time recording device and can be combined with the steam controller and constitute a recording/controlling instrument that provides a permanent record of the temperature within the thermal process system. When the temperature indicator is acquired, the recording accuracy shall be equal to or better than 1°F or 0.5°C over the process temperature stipulated. The recording chart should be adjusted according with the required temperature but shall never be higher than the known accurate indicating temperature device. In order to prevent unauthorized changes in temperature adjustments, a lock or a note can be posted, warning that only authorized persons are permitted to make adjustments. Air-operated temperature controllers shall have adequate filters to ensure a supply of clean and dry air. The recorder timing mechanism shall be accurate.

3. Chart type devices. Each device shall use a graphic chart. The working scale shall not exceed 12° C per centimeter or 55° F per inch within a range of 11°C or 20°F of the process temperature. Chart graduations shall not exceed 1°C or 2°F within a range of 5°C or 10°F. The record intervals shall not exceed one minute.

4. Steam controllers. Each retort or autoclave shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording/controlling instrument when combined with a temperature/time recording device.

5. Air valves. All air lines connected to a retort shall be equipped with a globe valve or other equivalent valve or piping arrangement that will prevent leakage of air into the retort during the process.

6. Water valve. All retort water lines intended to be closed during the process shall be equipped with a globe valve or other equivalent type to prevent water leakage into the retort during the process.

CHAPTER II
PRESSURE PROCESSING WITH STEAM

Article 521 Pressure processing with steam in batch still retorts.

1. Bulb sheaths or probes of indicating temperature devices shall be installed within the retort shell, or in external wells, which shall be connected to the retort through at least ¾ inch (1.9 cm) diameter opening, equipped with a 1/16 inch (1.6 mm) bleeder opening so located as to provide a constant flow of steam past the length of the bulb thermometer or probe.

2. The bleeder shall emit steam continuously during the entire process period of the autoclave and requires the use of a manometer as steam pressure control.

3. Horizontal retorts shall be equipped with steam spreaders extended through the full length of the retort.

4. Steam inlet. Steam shall be provided through an inlet large enough to maintain the pressure in line for a proper operation of the retort, and shall enter at a point to facilitate air removal during venting.

5. Crate supports. Vertical still retorts with bottom steam entry shall employ appropriate retort crate supports that allow the free steam circulation.

6. Baffle plates shall not be used in the bottom of the retorts.

7. Steam spreader. Shall ensure they are not blocked and be functioning, these do not have to be greater than the entrance of the steam line. In horizontal retorts, the perforated steam spreaders shall extend all along of the bottom and throughout the retort. Any other system must be authorized.

8. Bleeders and condensate removal. Bleeders except those for external wells of temperature devices shall be wide open during the entire process including the come-up time for temperature. For horizontal still retorts, bleeders shall be located within approximately 30 centimeters (one foot) of the outermost locations of containers at each end along the top of the retort. An additional bleeder shall be located no more than 2.4 m from the top.

9. The condensate removal system shall be equipped with an alarm system that shall be revised at the beginning of each process for its proper functioning.

10. An additional bleeder shall be located not more than 8 feet (2.4 m.) from the top.

11. Other bleeders may be installed, specifying in the procedures used that they comply with the removal of air and steam circulation. Vertical retorts shall have at least one bleeder opening located opposite the steam inlet.

12. All bleeders including those for the removal of air condensate shall be in such position that the operator can observe they are functioning properly.

13. Observations shall be done at 15 minutes intervals and the results recorded.

14. Still equipment:

    a. The bottom of each tray, gondola, crates, etc., shall have perforations at least one inch (2.5 cm.) in diameter and 2 inches (5 cm.) from the center of the perforation to the center of the perforation of the next line.

    b. The equipment for holding or stacking containers in retorts. Crates, trays, gondolas, carts, and other vehicles destined for holding or stacking product containers in the retorts shall be so constructed to ensure a proper steam circulation during the venting, come-up and processing.

    c. The establishment shall have daily records showing that the air has been removed from the pipe before starting every thermal process. This information shall be available to the official inspector for review.

15. Bleeders and vent mufflers.

    a. The establishment shall have truthful information from the mufflers manufacturer or from the heat distribution procedures that they do not impede the removal of air. Any other documentation from the manufacturer shall file, and presented in the work methodology.

    b. Vents shall be located in that portion of the retort opposite the steam inlet and shall be design, installed and operated in such a way that air will be removed from the retort before starting every thermal process. A gate, cap valve or other full flow valve, which shall be full open, shall control vents and permit rapid removal of air from retorts during the venting period.

c. The safety valve shall be wider than the steam inlet pipe and satisfy the safety conditions and norms for non-fire pressure containers.

d. Vents shall not connect to a closed drain system without an atmospheric break in the line. Where a multiple interconnection of retorts with several pipes connected to a manifold (multiple collector) the air vent shall be controlled by a gate or a cap valve or other full-flow valve and the manifold shall be of a size such that the cross sectional area is greater than the total cross-sectional area of all interconnecting tubes or vents.

e. A manifold header connecting vents or manifolds from several still retorts shall lead to the atmosphere.

f. Some typical installations and operating procedures describe later. Other retort installations, vent piping arrangements, operating procedures or auxiliary equipment, such as dividing plates, may be used provided written documents that air is removed from the retort before starting the process. Such documentation shall have in their formats heat distribution data or other documentation from the equipment manufacturer or processing authority, and the establishment shall file the information and make available to the Inspection Service.

g. For crateless retort installations, the establishment shall have heat distribution data or other documentation from the equipment manufacturer or from the processing authority that demonstrates that the venting procedure used accomplishes the removal of air and condensate and the establishment shall file the information and make available to the Inspection Service.

Article 522 Some typical installations that comply with the requirements of this article are the following:

1. Venting horizontal retorts.

2. Agitating retorts.

3. Continuous rotary retorts.

4. Hydrostatic retorts.

CHAPTER III
PROCESS CONDITIONS IN RETORTS

Article 523 Bulbs or probes of indicating temperature devices shall be located in such position to be close/beneath to the water surface through the process. In horizontal retorts, insert bulb or probes directly into the retort shell. In vertical and horizontal retorts, the indicating temperature device bulb or probe shall extend directly into the water a minimum of 2 inches (5 cm) without a separate well or sleeve. In vertical retorts equipped with a recorder/controller, the controller probe shall be located at the bottom of the retort below the lowest crate rest in such a position that the steam does not strike it directly. In horizontal retorts so equipped, the controller probe shall be located between the water surface and the horizontal plane passing through the center of the retort so that there is no opportunity for direct impingement on the controller probe. Air operated temperature controllers shall have filter systems to ensure a supply of clean, dry air.

Article 524 Pressure recording device. Each retort shall be equipped with a pressure-recording device, which may combine with a pressure controller.

Article 525 Heat distribution. Heat distribution data or other documentation from the equipment manufacturer or a processing authority demonstrating uniform heat distribution within the retort, shall be kept on file at the establishment and made available to the Inspection Service.

Article 526 Crate supports. A crate support must be at the bottom of the vertical retorts. Shall not be used baffle plates in the bottom of the retort.

Article 527 Stacking equipment. For filled flexible containers and when using semirigid containers, stacking equipment shall be designed to ensure that the thickness of the filled containers does not exceed that specified in the process schedule and that the containers do not become displaced and overlap or rest on another during the thermal process.

Article 528 Drain valve. Use a nonclogging, watertight drain valve. Install screens over all drain openings.

Article 529 Water level. There shall be a means of determining the water level in the retort during operation, i.e., by using a gauge, electronic sensor or sight glass indicator. For retorts requiring complete immersion of containers, water shall cover the top layer of containers during the entire come up time and the thermal processing periods and should cover the top layer of containers during cooling. For retorts using

cascading water or water sprays, shall maintain the water level within the range specified by the manufacturer or processing authority during the entire come-up, thermal processing, and cooling periods. Provide the means to ensure water circulation during these three steps. The retort operator shall check and record the water level with enough frequency to ensure it meets the specified processing parameters.

Article 530 Air supply and controls. In both still retorts, an automatic pressure control unit and a non-return valve in the air supply line to prevent water from entering the system shall control vertical and horizontal, introducing compressed air or steam. The air or steam pressure shall be continuously during the come-up, thermal processing, and cooling periods. If using air to promote circulation, introduce the steam line to a point between the retort and the steam control valve at the bottom of the retort. The adequacy of the air circulation for maintaining uniform heat distribution within the retort shall be documented, kept in file, and available to the Inspection Service.

Article 531 Water circulation. When using water circulation system for heat distribution, water shall drain from the bottom of the retort through a suction manifold, and discharged through a spreader that extends its length or circumference of the retort lid and the holes in the spreader shall distribute uniformly. Protect the suction outlets with screens to keep debris from entering the recirculation system. The pump shall be equipped with a pilot light or a similar device to warn the operator when it is not running, and with a bleeder to remove air when starting operations. An alternative alarm system can be used (flow meter) to ensure proper water circulation. The adequacy of water circulation for maintaining uniform heat distribution within the retort shall be documented by heat distribution data or other documentation from the processing authority and such data shall be maintained on file by the establishment and be available to the Inspection Service for review. Any alternative method must comply with the previously exposed.

Article 532 Cooling water entry. In retorts for processing product packed in glass jars, the incoming cooling water should not directly strike the jars, in order to minimize glass breakage by thermal shock.

Article 533 Insert bulb sheaths or probes for indicating temperature devices and temperature/time recording devices or controller probes, directly into the retort shell in such manner that steam will not strike them directly.

Article 534 Provide a means for the circulation of the steam/air mixture to prevent formation of low-temperature pockets. Document the efficiency of the circulation system by heat distribution data or other documentation from a processing authority, and maintain such data on file by the

establishment and made available to Inspection service for review. The circulation system shall have an alarm system that alerts to warn the operator when it is not functioning, additional, shall revise in order to guarantee its adequate functioning. Due to a broad variety of designs, must request references to the equipment manufacturer for installation, operation and control details.

CHAPTER IV
ATMOSPHERIC COOKERS

Article 535 Each of these equipments (e.i., hot water bath) shall be equipped with at least one temperature/time recording device in accordance with the basic requirements described in these regulations.

Article 536 The atmospheric cookers shall be equipped and operated in such manner to ensure uniform heat distribution throughout the processing system during the thermal process. Heat distribution data or other documentation from the manufacturer or a processing authority demonstrating uniform heat distribution within the cooker shall be kept filed by the establishment and available to the Inspection Service.

Article 537 Any other system used in the thermal processing or canned, shall be subject to evaluation by DIGESA based on the one by one case by the Director.

Article 538 Equipment maintenance:

1. The establishment to guarantee proper functioning and calibration shall check all equipment and instruments.

2. At least once a year an individual not involved with the establishment in order to guarantee its proper functioning shall examine each thermal processing system.

3. Air and water valves that must be closed during thermal processing shall be checked by the establishment. Repair or replace defective valves as required.

4. To prevent failures in the vent or bleeding efficiency, check, maintain or replace by the establishment vents and bleeder mufflers.

5. When using water spreaders for venting, a maintenance program shall be developed and implemented to assure that the holes maintain at their original seize.

6. Keep maintenance records on all points that can affect the adequate thermal process. Records shall include the date and type of maintenance performed and the person who conducts it.

CHAPTER V
CONTAINER COOLING AND COOLING WATER

Article 539. Use potable water for cooling. The water of the cooling canal shall be chlorinated or treated with a chemical approved having a bactericidal effect equivalent to chlorination. Clean and fill with potable water the cooling channels to prevent microorganisms, organic matter, and other materials.

Article 540 Handle container cooling waters that are recycled or reused in systems designed, operated, and maintained for that purpose, so there is no buildup of microorganisms, organic matter or other materials.

Article 541. System equipment such as pipelines, holding tanks and cooling towers, shall be constructed and installed in such way that can be cleaned and inspected. In addition, the establishment shall maintain and make available to Program employees for review, information on the following:

1. System design and construction.

2. System operation, including the rates of renewal with fresh potable water and the water treating, so that there is a measurable residual at the point where the water exits the container cooling vessel.

3. System maintenance shall include procedures for the cleaning and sanitizing procedures of the entire system.

4. Water quality standards such as microbiological, physical and chemical, monitoring procedures, including the frequency and sites of sampling and the corrective actions taken when water does not reunite these standards of quality.

CHAPTER VI
POST PROCESS HANDLING OF CONTAINERS (CANS)

Article 542 Handle containers in a manner that will prevent damages especially in the hermetic sealing area.

Article 543 Conveyors for transporting containers shall be from non-porous materials and built in such a manner that shall not retard, hit or

damage containers. Minimize abrasions particularly in the seal area. Containers should not remain stationary on moving conveyors.

Article 544 Keep clean all post-processed container handling equipment so there is no buildup of microorganisms on surfaces in contact with the containers.

CHAPTER VII
PROCESSING AND PRODUCTION RECORDS FOR CANNED

Article 545 The establishment shall record the following information related to process and production:

1. Date of production
2. Product name and style
3. Container code
4. Container size and type
5. Process schedule including the minimum initial temperature

Article 546 Record critical factors. In addition, when applicable shall record the following information:

1. Steam process

2. For each retort batch shall record:

    a. Retort number or other designation
    b. Approximate number of containers, or
    c. Number of retort crates per retort load
    d. Product initial temperature
    e. Start time steam entered on
    f. Start processing time

Article 547 Read the thermometer and the temperature recorder at the same time, at least once during process timing and record observed temperatures. For each retort and lot shall record:

1. The retort number or other designation
2. Approximate number of containers
3. Number of crates per batch of retort load
4. Product initial temperature
5. Time steam on
6. Start process timing

Article 548 Record all critical factors of the process schedule such as: initial temperature, cooking speed and final internal product temperature.

Article 549 Identify process records by production date, container code, processing vessel number or other designation and other data that correlates. Make annotations at the time the specific event occurs and the recording individual shall sign each record form and date it. The establishment shall review the programmed against the achieved to ensure that product received adequate treatment within one working day.

Article 550 An automatic system can be authorized individually or in combination with the manual form of monitoring and record previous request to the Food and Beverage Risk Control Department.

Article 551 Records can be kept of every examinations done to container closures, specifying the can code, date and hour of closures examinations, closure dimensions and any corrective action done. Records shall be signed by specialized technician not more than one day after the production date to ensure the operation control.

Article 552 Records shall be maintained identifying the initial distribution of the finished product to facilitate if necessary the segregation of adulterate products.

Article 553 The HACCP plan and the quality control systems shall be approved and be available for the Inspection Service and all records shall be kept for two years in the establishment.

CHAPTER VIII
DEVIATIONS IN THE CANNING PROCESS

Article 554 Whenever the process is less than the process schedule or when a critical factor does not comply with the requirements specified for this factor, it is considered that there is a deviation in the processing. When this occurs, manage the deviations under an establishment's control program for such purpose.

Article 555 If identifying a deviation in the process, the establishment shall:

1. Reprocess immediately the product, following the process schedule.

2. Hold the product and be advised by a processing authority to determine the safety and stability of the product. Upon completion of the product evaluation, the establishment shall provide the inspection Service the following:

a. A complete description of the deviation along with the basic documentation needed.
b. A copy of the evaluation report.
c. A description of actions taken with the product.

3. Product handled under the conditions of this article shall not be shipped until the Inspection Service has reviewed and approved all information submitted.

4. If an alternate process schedule is not recorded and approved by the Inspection Service, the product shall be set aside for further evaluation.

Article 556 When a deviation occurs in a continuous rotary retort, the product shall be handled in accordance with paragraph 1, 3 and 4 of the previous article or in accordance with the following procedures:

1. Emergency stops. When retort jams or breakdowns and the process has not completed, all the affected containers shall be removed, reprocessed or destroyed.

2. When the timer of the retort reel stopped and the retort is used for an emergency process, shall note the temperature/time on the recording card and entered on other production records.

3. When the retort temperature drops below the specified in the process schedule the transportation reel shall be stopped and the following actions shall be taken:

4. When drops 5.5^{o} C or 10^{o} F or less:

   a. Shall be given an emergency process before connecting the new reel to enter new containers.

   b. Containers entered to the retort shall be applied an emergency agitating process before entry of new containers.

   c. Or prevent containers entry and the reel restarted to empty the retort.

5. When temperature drops 5.5^{o} C or 10^{o} F or more shall proceed in the same form.

Article 557 The establishment shall maintain a complete file with all the information regarding appropriate processing, corrective actions, production record, process assessment and results.

TITLE XXXII
OF THE INCUBATION CONDITIONS

Article 558 Incubation of canned product to be stored. The establishment shall provide incubation facilities that include temperature/time recording device, calibrators, air circulation system inside the incubator to prevent temperature variations, and means to prevent unauthorized entry. The Inspection Service is responsible for the security of the incubator.

Article 559 The incubation temperature shall maintain at 35 + 2.8^{o}C or 95+ 5^{o}F.

Article 560 If the temperature falls below 32^{o} C or 90^{o} F or exceeds 38^{o} C or 100^{o} F but does not reach 39.5^{0} C or 103^{0} F the incubator shall be adjusted to the required temperature and the product shall maintained in incubation for the time it was held out of the established range.

Article 561 Terminate the test if temperature is above 39.5^{0} C or 103^{0} F for more than two hours. Adjust the range and incubate new samples.

Article 562 Products requiring incubation:
1. Low acid products
2. Acidified low acid products

Article 563 Incubation samples: From each load of product processed in a batch type thermal processing system (still or agitation), shall select at least one container for incubation. For continuous rotary retorts hydrostatic retorts or other continuous type thermal processing systems, shall select per system one container per 1,000 for incubation.

Article 564 Incubation time. Shall not be less than 10 days (240 hours) under the specified conditions in this Title.

Article 565 The establishment shall designate qualified personnel to daily check containers under incubation and notify the inspector when observing abnormal containers. They shall cool before a final decision. Maintain records for every incubation test, with the minimum data that will identify the lot.

Article 566 All records shall be available to the Inspection Service and maintain the data for two years in the establishment.

Article 567 When finding abnormal containers. The finding of these causes official retention of the lot involved.

Article 568 Ship no product until the incubation test has finished. Ship only normal appearing containers.

Article 569 Retain containers with abnormal appearance. They can be released if the inspector determines that the product is safe and stable.

Article 570 All personnel shall be under direct supervision of a person who has completed studies in canning operations.

Article 571 Establishments shall prepare and maintain an agile and effective procedure for the recall of all canned product under the conditions of these regulations, if any. The procedure shall be available for review by the Inspection Service.

TITLE XXXIII
OF THE COMPOSITION OF CANNED MEAT PRODUCTS

Article 572 **Chili con Carne**. Shall contain not less than 40% of meat computed on the weight of the fresh meat. Head meat, cheek meat, and heart meat may be used to the extent of 25% of the meat ingredients, under specific declaration on the label. The mixture may not contain more than 8%, either individual or collectively, cereal, vegetable starch, vegetable starch flour, soy flour, soy protein concentrate, isolated soy protein, dried milk, nonfat dry milk, whey nonfat dry, dry whey powder, whey reduced lactose, whey reduced minerals, whey protein concentrate milk, dried skim milk low in calcium.

Article 573 **Chile con carne with beans.** Shall contain not less than 25% of meat computed on the weight of the fresh meat. Mechanically Separated deboned meat may be used and head, cheek, or heart meat may be used to the extent of 25% of the meat ingredients and the presence of these meats shall be reflected in the statement of declaration of the label.

Article 574 **Hash.** Shall contain not less than 35% of meat computed on the weight of the cooked and trimmed meat. The weight of the cooked meat used in this calculation shall not exceed 70% of the weight of the uncooked fresh meat. Mechanically Separated deboned meat may be used.

Article 575 **Corned Beef Hash.** Semisolid food product in the form of a compact mass that is prepared with beef, potatoes, curing agents and seasonings.

1. Either fresh beef, cured beef, or canned corned beef or a mixture of two or more of these ingredients may be used, and the finished product shall contain not less than 35% of beef computed on the weight of the cooked and trimmed bef. The weight of the cooked meat used in this calculation shall not exceed 70% of the weight of the uncooked fresh meat.
2. “Potatoes” refers to fresh potatoes, dehydrated potatoes, cooked dehydrated potatoes, or a mixture of two or more of these ingredients.

3. The curing agents that may be used are salt, sodium nitrate, sodium nitrite, potassium nitrate, or potassium nitrite, or a combination of two or more of these ingredients. When sodium nitrate, or sodium nitrite, potassium nitrate, or potassium nitrite is used, it shall be in amounts not exceeding those specified in these regulations.
4. The seasonings that may be used singly or in combination are salt, sugar (sucrose or dextrose), spice, and flavoring, including essential oils, oleoresins, and other extractives.
5. It can contain one or more of the following optional ingredients:
    a. Beef cheek meat and beef head meat from which the overlaying glandular and connective tissues have been removed, and beef heart meat, exclusive of the heart cap. These meats may be used individually or collectively to the extent of 5% of the meat ingredients.
    b. Onions, including fresh onions, dehydrated onions, or onion powder.
    c. Garlic, including fresh garlic, dehydrated or powder.
    d. Water
    e. Beef broth or beef stock
    f. Monosodium glutamate
    g. Hydrolyzed plant protein
    h. Beef fat
    i. Mechanically Separated deboned meat from authorized establishments may be used.
6. The finished product shall not contain more than 15% fat, or not more than 72% moisture.
7. When any ingredient specified in this article, the label shall bear the following applicable statement: “Beef cheek meat constitutes 5% of the meat ingredient” or “Beef heart meat constitutes 5% of the meat ingredient”. When two or more meat ingredients are used, the words “constitutes 5% of meat ingredient” need to appear only once.
8. Shall appear in the label visibly and remarkable, without being brought any other written, printed or painted matter the words “corned beef hash” to identify the contents.

Article 576 **Meat stews**. Meat stews such as “Beef stew” shall contain not less than 25% of meat of the specie named on the label and computed on the weight of the fresh meat. Mechanically Separated may be used if provided from authorized establishments for it.

Article 577 **Tamales**. They shall be prepared with at least 25% meat of the specie named on the label and computed on the weight of the uncooked fresh meat in relation to all ingredients of the tamales. When packed in sauce or gravy, the name of the product shall include a prominent reference, for example: “Tamales with Sauce”, etc. Products labeled

this way shall contain not less than 20% computed meat of the weight of the uncooked fresh meat in relation of the total ingredients making up the tamales and sauce or gravy. Can use mechanically separated deboned meat if provided by establishments authorized for it.

Article 578 **Spaghetti meatballs and sauce, Spaghetti with meat and sauce, and similar products.** These shall contain not less than 12% of meat computed on the weight of the fresh meat. May use mechanically Separated deboned meat if provided from authorized establishments. The presence of the sauce or gravy shall be on the label prominently as part of the name of the product. Meatballs may be prepared with not more than 12% individual or collectively of farinaceous materials, soy flour, soy protein concentrate, isolated soy protein, nonfat dry milk, dried skim milk low in calcium and similar substances.

Article 579 **Spaghetti sauce with meat**: Spaghetti sauce with meat shall contain not less than 6% of meat computed on the weight of the uncooked fresh meat. Can use mechanically separated deboned meat if provided from authorized establishments.

Article 580 **Beans with frankfurters in sauce, sauerkraut with wieners and juice, and similar products.** They shall contain not less than 20% frankfurters or wieners computed on the weight of the smoked and cooked sausage prior to its inclusion with beans and sauerkraut.

Article 581 **Lima beans with ham in sauce, beans with ham in sauce, beans with bacon in sauce, and similar products.** They shall contain not less than 12% of ham or bacon computed on the weight of the smoked ham or bacon prior to its inclusion with the beans and sauce.

Article 582 **Chow mein vegetables with meat, and chop suey vegetables with meat.** They shall contain not less than 12% meat computed on the weight of the uncooked fresh meat prior to its inclusion with other ingredients. Can use mechanically separated deboned meat if provided from authorized establishments.

Article 583 **Meat pies.** Shall contain meat of the species specified on the label, in an amount not less than 25% of all ingredients including crust and shall be computed on the basis of the fresh uncooked meat.

Article 584 **Meat extract or soup mixtures.** Shall contain no more than 25% humidity.

Article 585 **Deviled ham and similar products or Meat salads.** Product made with fine shredded cured meat that contains seasonings. Can use mechanically separated deboned meat if provided from authorized establishments. Deviled ham may contain added fat, if the total fat content shall not exceed 30% of the finished product and the moisture content of deviled ham shall not exceed that of the fresh unprocessed

meat. It shall not contain cereal, vegetal flour, nonfat dry milk, or similar substances. The amount of water added to the canned food should be limited to that necessary to replace the moisture lost during the process.

Article 586 **Ham spread and similar products.** They shall contain not less than 50% of the meat ingredient mentioned above computed on the weight of the fresh. Can use other meat and fat to give the desired spreading consistency, if do not detracts the nature of the spreads named. Can use mechanically separated deboned meat from approved establishments.

Article 587 Food products characterized and labeled as liver products such as liver loaf, liver cheese, liver spread, liver mush, liver paste, and liver pudding shall contain not less than 30% of pork, beef, sheep, or goat livers.

TITLE XXXIV
OF THE SPECIAL CONDITIONS FOR PACKAGE OF PROCESSED PRODUCTS

CHAPTER I
LABELS OR TAGS CONDITIONS

Article 588 The placement of labels or tags on containers of all products shall appear on the main display panel as:

1. In the case of rectangular package, a complete side, the area, this is at least height by the width of that side.
2. In the case of a cylindrical or almost cylindrical container: an area that is 40% of the height of the container of the product by the circumference of the container or a box, that its width is one third of the circumference and height, or if immediately to the right or left of the main display box there was a box with a width not greater than 20% of the circumference.
3. In the case of a container with any other form, 40% of the total surface of the container.

Article 589 To determine the area of the main display box, shall exclude the lids, funds, flanks of the lids and bottoms of the cans, or bottlenecks.

Article 590 Label all products in a way that precisely describes their identity and composition. The product name shall specify the identity of the product (e.g., emulsified, finely chopped, etc.), and the name of the species. If the product is cooked, it shall be labeled as it.

Article 591 Declare in the label of any product when using Mechanically Separated boneless meat with the phrase: "(Species) deboned mechanically separated." The appropriate terminology on the label indicates if the heat treatment has been used in the preparation of the product.

Article 592 Labels on natural casings of stuffed products shall identify the casing specie of origin, the identity of the casing or tripe, if required, shall be placed on the principal display panel or declaration of ingredients. The establishments that produce, process or use natural casings shall keep notes where documented the source of these casings. In the case of stuffing products in synthetic casings may ignore this fact in the product label.

CHAPTER II
DECLARATION OF INGREDIENTS

Article 593 The label shall show a declaration of the ingredients of the product if it is made of two or more ingredients and these shall be listed by their common or usual names in descending order of their proportions.

Article 594 All the ingredients present in individual amounts of 2% or less by weight may be listed in the declaration of ingredients in descending order of predominance.

Article 595 These ingredients can be adjusted in the formulation of the product without a change in the statement of ingredients on the label, provided that the adjusted amount does not exceed the amount shown on the statement of quantification. Any adjustment to the formulation must be provided to the Inspection Service.

Article 596 The terms spice, natural flavor, natural flavoring, taste or flavor can be used in the following manner:

1. The term "spice" means any aromatic vegetable substance in whole, ground or cut, with the exceptions of onions, garlic and celery, whose primary function in food is seasoning rather than nutritional and from which any portion of any volatile oil or other flavoring principle has been removed.
2. The term "natural flavor", “natural flavoring," "flavor" or "flavoring" means the essential oil, oleoresin, essence or extract, distillate or any product containing the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, yolk, root, leaf or any edible portion of a plant, meat, seafood, poultry, eggs, dairy products, or fermenting products whose primary role in the food is as flavoring rather than nutritional. Natural flavors include the natural essence or extracts

obtained from plants. The term natural flavor, natural flavoring, taste and flavor can also be used to designate spices, onion powder, garlic powder and celery powder.

3. Any ingredient not mentioned in numbers (1) and (2) of this article, and whose function is to provide flavor, in whole or in part, must be noted on the label by their common or usual name.

Article 597 When adding artificial flavorings and colorings it shall appear on the label in prominent letters and contiguous to the product name a statement such as "artificial smoke flavor added" or "smoke flavor added," as applicable and declaration of ingredients will identify any artificial flavor or color.

Article 598 When adding antioxidants, chemical preservatives and other additives, it shall appear on the label in prominent letters and contiguous to the product name, a statement showing the name of the antioxidant and the purpose for which it is added. For example, "BHA added to help protect the taste", do the same with chemical additives, naming the additive and the purpose of its use. Any other approved substance that can be used in the product must be included in the statement.

CHAPTER III
AMOUNT OF CONTENT

Article 599 The label shall carry accurate information of the net amount of content in terms of weight or measure. It must not be false or misleading.

Article 600 The net weight marked on the containers of the products shall be the net weight of products without the weight of materials of wet or dry packaging materials and wrapping materials.

Article 601 The declaration of the contents net quantity shall appear on the principal display panel of all containers to be sold intact to detail, printed in black letters that shall stand out and easy to read in distinctive contrast to other matters on the package.

CHAPTER IV
CONDITIONS OF WEIGHING EQUIPMENT

Article 602 All equipment used in the establishments to weigh ingredients and products to be sold or otherwise distributed in commerce shall be installed, maintained and operated to ensure accurate weights.

Article 603 The establishment shall conduct reliable tests of its weighing system on a regular basis and may include a certification of a commercial firm recognized or authorized to do so.

Article 604 The establishment shall keep all records relating to adjustments and deviations found.

CHAPTER V
CODES OF PACKING

Article 606 Mark permanently and clearly with a code or other defined system all canned products. This shall have the content identity information and the canning date. Products bottled in glass jars do not require to be marked with the date of filling, if such information appears on the packing.

Article 607 All trademarks used as a code or other systems used shall be sent to the Inspection Service containing their meaning.

Article 608 All national processed products destined for export require the approval of the label for printing which may be in the language required by the country of destiny.

CHAPTER VI
RELABELING

Article 609 When an establishment requires relabeling a product, due to mutilated or damaged tags, or for any other reason need be relabeling, shall make a written request to the Food and Beverage Risk Control Department with the reasons for its request and the number of labels required. Labels for such products shall not be removed from the approved establishment until it receives permission from the Department. An Official Inspector will supervise the relabeling.

TITLE XXXV
NUTRITIONAL INFORMATION

Article 610 All processed products shall have the nutrition information on the label, except for those that contain only meat as an ingredient, which may be placed on a voluntary form.

Article 611. Place nutritional information on an exclusive chart for it on the label and shall be visible and legible. It can be permitted to place in small labels, a special one for this information on the product container.

Article 612 All the nutrients and components shall be declared in this section, such as protein, fat, calories, saturated fatty acids, polyunsaturated and monounsaturated, and trans cholesterol, total carbohydrates, fiber, sugar, and vitamins and minerals included. This list is not limited to

these; the information can be considered to what the establishment wants to express.

Article 613 All information on nutrients shall be determined based on the product packed or product consumed, expressed in weight proportion or quantity per service.

Article 614 Express all nutrient values, measured by weight and / or percentages based on nutritional value of the units recognized internationally.

Article 615 The nutritional information declared will base on analysis of products in recognized laboratories nationally or internationally, and previously approved by SESPAS. These shall be available to the Inspection Service for at least two years or until the product has a new formulation.

Article 616 All products of national or foreign process shall have on its label the nutrition information in Spanish.

Article 617 Express all details of the nutritional information clearly and in detail in the monograph of the application for product approval provided to SESPAS.

TITLE XXXVI
OF THE TREATMENT OF PORK MEAT WITH TRICHINAE AND PRODUCTS CONTAINING PORK MEAT

Article 618 All products containing pork muscle tissue shall make a treatment for the elimination of trichinae except those that suffer a cooking process enough to ensure their destruction, carried out by the consumer or in their elaboration.

Article 619 All products that contain pork muscle tissue, must pass through an effective process of heating, cooling or curing to destroy any possible trichinae alive. Such as: dried or smoked sausage, ground meat mixture seasoned, mortadella, cured sausages, cooked meat roll, grilled ham, baked ham, boiled ham, smoked cured pork tips or boneless, coppa, capocollo, and similar cuts with pork meat in natural or synthetic casings, breaded, bacon, meat mixtures containing pork. SESPAS shall approve all process methods to ensure the destruction of any presence of the parasite in the raw pork meat.

CHAPTER I
HEATING

Article 620 All parts of the pork muscle tissue shall be heated according to one of the time and temperature combinations established in the following table:

Minimum Internal Temperature In ^{0} Celsius	Minimum Internal Temperature In ^{0} Fahrenheit	Minimum time of exposition
49	120	21 hours
50	122	9.5 hours
51.1	124	4.5 hours
52.2	126	2 hours
53.4	128	1 hour
54.5	130	30 minutes
55.6	132	15 minutes
56.7	134	6 minutes
57.8	136	3 minutes
58.9	138	2 minutes
60	140	1 minute
61.1	142	1 minute
62.2	144	instantaneous

Article 621 The time and temperature shall be monitored and recorded by a calibrated instrument.

Article 622 During the treatment, the time to raise product temperature from 15.6^0 C or 60^0 F to 49^0 C or 120^0 F shall not exceed two hours unless the product is cured or fermented.

Article 623 Treatments above 58.9^0 C or 138^0 F with their respective times need not be monitored if the thickness of the product does not exceed two inches and the refrigeration of the product does not begin within 5 minutes before having reached the temperature.

Article 624 All procedures that ensure proper heating of all parts of the product shall be applied; it is important that each piece of the product treated with hot water is maintained entirely submerged throughout the heating period, considering all the pieces that have been placed in the coolest parts of the heating compartment.

CHAPTER II
REFRIGERATION

Article 625 Pork meat used for the preparation of the products must be kept refrigerated all time to not above 4.4^0C or 40^0F frozen and all products produced with it are subject to a specific temperature depending on the

thickness of the meat or the size of the product or container for treatment.

Article 626 Required period of freezing at temperature indicated.

Temperature in ^{0} Celsius	Temperature in ^{0} Fahrenheit	Group 1 (days)	Group 2 (days)
-15	5	20	30
-23.3	-10	10	20
-28.9	-20	6	12

Article 627 Group 1 includes product in separate pieces not exceeding 6 inches in thickness or arranged on separated racks with the layers not exceeding 6 inches in depth, or stored in crates or boxes not exceeding 6 inches in depth, or stored as solidly frozen blocks not exceeding 6 inches in thickness.

Article 628 Group 2 includes product in pieces, layers or within containers in which the thickness exceeds 6 inches but not 27 inches, as well as products in containers including tierces, barrels, kegs and cartons that have a thickness not exceeding 27 inches.

Article 629 The products submitted to treatment temperatures or their containers shall be spaced in the freezer to enable the free circulation of air between the pieces of meat, layers, blocks, boxes, barrels and drums so that the temperature of the meat throughout will be promptly reduced to not higher than the temperature for treatment above mentioned.

Article 630 There are alternate periods of freezing, dry and vacuum; these temperatures shall be reached in the center of the pieces of meat:

Maximum Internal Temperature in ^{0}Celsius	Maximum Internal Temperature in ^{0}Fahrenheit	Minimum Time (hours)
-17.8	0	106
-20.6	-5	82
-23.3	-10	63
-26.1	-15	48
-28.9	-20	35
-31.7	-25	22
-34.5	-30	8
-37.2	-35	1/2

Article 631 During the treatment period the product shall be kept in custody by the Inspection Service, and separated from other products in a safe form with seals, marks or lock to comply with the temperature and time required.

Article 632 The equipment to measure the temperature of the refrigerating chambers shall be accurate and be placed at or above the highest level at which the products are stored and away from the coils or refrigerating equipment.

Article 633 Pork meat or its products may be used or commercialized after having fulfilled their treatment.

CHAPTER III
CURING

Article 634 The sausage can be stuffed in synthetic casings or cloth bags, in any case to treat the destruction of trichina; these casings shall not be coated in paraffin or any similar substance, nor shall any sausage be washed during any prescribed period of drying. In the preparation of sausage, any of the following methods may be used:

Method 1. The meat shall be ground or chopped into pieces not exceeding three fourths of an inch in diameter. Mix thoroughly with a curing mixture containing not less than 3.33 pounds of salt per 100 pounds of unstuffed sausage. After stuffed, sausages shall not exceed 3.5 inches in diameter and shall maintain in a drying room for a period not less than 20 days, at a temperature not less than 7.2^0 C or 45^0 F. Except for sausages known as pepperoni, if the casings do not exceed 1 3/8 inches in diameter measured at the time of stuffing, the drying period may be 15 days. In no case, however, the sausages shall be released from the drying room in less than 25 days from the time the curing materials are added, except pepperoni. Sausages exceeding 3.5 inches in diameter, but not 4 inches shall remain in the drying room at least 35 days at a temperature not less than 7.2^0 C or 45^0 F, and in no case the sausage shall be released from the drying room in less than 40 days from the date of curing.

Method 2. The meat for sausage shall be prepared and stuffed in the same way that in method 1. Sausages with a diameter not exceeding 3.5 inches stuffed, shall be smoked at least 40 hours at a temperature not less than 26.6^0 C or 80^0 F. Finally held in a drying room not less than 10 days at a

temperature not less than 7.2^0 C or 45^0 F. Sausages shall not be removed less than 18 days from the time the curing materials are added to the meat. Those exceeding 3.5 inches, but not 4 in diameter will be smoked in the same way as above indicated; drying at least 25 days, but in no case shall be released from drying room in less than 33 days from the time the curing materials are added to the meat.

Method 3. The sausage meat shall be prepared in the same way that in method 1, after being mixed with salt and other curing materials and before stuffing the mixture shall be kept at a temperature not less than 1^0 C or 34^0 F at least 36 hours. After being stuffed, sausages shall be held at a temperature not less than 1^0 C or 34^0 F for a sufficient period to make a total of not less than 144 hours from the time of curing. Shall held for a specific time in brine for at least 50^0 strength (salometer reading) at a temperature not lower than 6.6^0 C or 44^0 F. Sausages not exceeding 3.5 inches in diameter shall be smoked at least 12 hours. The temperature at the smokehouse during this period shall never be lower than 32.2^0 C or 90^0 F. For 4 consecutive hours during this period the smokehouse shall be maintained at a temperature not lower than 53.3^0 C or 128^0 F. Sausages exceeding 3.5 inches in diameter, but not exceeding 4 will be smoked for not less than 15 hours, and shall never be lower than 32.2^0 C or 90^0 F. For 7 consecutive hours the smokehouse shall be maintained at a temperature not lower than 53.3^0 C or 128^0 F, having this temperature being attained gradually during a period not less than 4 hours.

Method 4. The meat shall be ground or chopped into pieces not exceeding one fourth of an inch in diameter. This meat shall be mixed with a dry-curing mixture with not less than 2.5 pounds of salt per 100 pounds of sausage not stuffed. This mixture before stuffing will remain as a compact mass not more than 6 inches in depth at a temperature not lower than 2.2^0 C or 36^0 F for at least 10 days. At the termination of the holding period shall be stuffed in casings not exceeding 3.5 inches in diameter. After stuffed, hold in a drying room at a temperature not lower than 7.2^0 C or 45^0 F for a 35-day period measured from the time of curing. If deemed appropriate by the establishment, the product may be heated in a water bath not exceeding 3 hours, at a temperature over 29.4^0 C or

85^0 F, or subject to smoke at a temperature not less than 26.6^0 C or 80^0 F. All the former shall be additional to the period of 35 days specified in the method.

Method 5. The meat for sausage shall be prepared, cured and stuffed the same way that in method 1. After stuffed, shall be held not less than 65 days at a temperature not lower than 7.2^0 C o 45^0 F. Sausages prepared with this method may be coated at any stage of the preparation before or during the holding period with paraffin or other substance approved.

Method 6. The meat shall be ground or chopped into pieces not exceeding three-fourths of an inch in diameter; this meat will be mixed with a dry-cured mixture with not less than 3.33 pounds of salt per 100 pounds of unstuffed sausage, excluding the weight of dry ingredients. After mixture, sausage shall be held for two steps: holding and drying. Holding period shall be maintained for a minimum of 48 hours with a temperature of not less than 1.7^0 C or 35^0 F, may be fulfilled before or after the drying period. During the drying period the sausage shall be held in a drying room at a temperature not lower than -12.2^0 C or 10^0 F for the period of time established in the following table:

Diameter of product at time of packing (in inches) Up to:	**Days of drying in drying room**
1	14
1.5	15
2	16
2.5	18
3	20
3.5	23
4	25
4.5	30
5	35
5.5	43
6	50

Reducing the time while hanging; sausage may be smoked or fermented. If the temperature increases to 21.1^0 C or 70^0 F or higher, while the sausage hangs, subsequent drying times may reduce according to the following chart:

Minimum time (hours)	21.1^{0}C or 70^0 F	23.9^{0}C or 75^0 F	26.6^{0}C or 80^0 F	29.4^0 C or 85^0 F	32.2^0 C or 90^0 F
24	4*	5	8	10	15
48	9	12	18	25	35
72	14	19	28	39	55
96	19	26	38	53	75
120	24	33	48	67	95

Minimum time (hours)	35^{0}C or 95^0 F	37.9^{0}C or 100^0 F	40.6^{0}C or 105^0 F	43.3^0 C or 110^0 F	48.9^0 C or 120^0 F
24	23	37	57	90	100
48	49	88	100	100	100
72	74	100	100	100	100
96	98	100	100	100	100
120	100	100	100	100	100

* Results from the above table are expressed in percentage of time reduction.

The trichina is destroyed during fermentation or smoking at the temperature and time indicated. Reason why no drying period is required in the room for products thus treated.

Article 635. A reduced salt content of less than 3.33 pounds per 100 pounds of mix for sausage including the dry ingredients may be permitted if the drying time is increased according to the following table:

Minimum pounds of salt added	Increase in drying time (%)
3.2	4
3.1	7
3	10
2.9	13
2.8	16
2.7	19
2.6	22
2.5	25
2.4	28
2.3	31
2.2	34
2.1	37

Minimum pounds of salt added	Increase in drying time (%)
2	40

Article 636 Capocollo (capacola). Boneless pork butts shall be cured in a dry-curing mixture containing not less than 4.5 pounds of salt per 100 pounds of meat, for a period not less than 25 days and a temperature not less than 2.2^0 C or 36^0 F. During or after curing, meat shall not be subject to any treatment with the purpose of removing the salt, except superficial washing. After being stuffed, the product shall smoke for a period not less than 30 hours at a temperature not lower than 26.6^0 C or 80^0 F, and shall finally be held in a drying room not less than 20 days at a temperature not lower than 7.2^0 C or 45^0 F.

Article 637 Coppa. Boneless pork butts shall cure in a dry-curing mixture containing not less than 4.5 pounds of salt per 100 pounds of meat, for a period not less than 18 days, at a temperature not less than 2.2^0 C or 36^0 F. During or after curing, meat shall not be subject to any treatment with the purpose of removing the salt, except superficial washing. After being stuffed, the product shall hold in a drying room not less than 35 days at a temperature not lower than 7.2^0 C or 45^0 F.

Article 638 Hams and pork shoulder picnics. One of the methods below shall be used:

Method 1. Hams and shoulder picnics shall cure in a dry-cured mixture not less than 40 days at a temperature no lower than 2.2^0 C or 36^0 F. These cuts shall be laid down in salt, using not less than 4 pounds per 100 pounds of meat, the salt being applied in a thorough manner to the product and can be washed with brine. At least once the product shall apply additional salt to be completely covered. After removal from curing, the products may be soaked in water at a temperature not higher than 21.1^0 C or 70^0 F for not more than 15 hours, the water at this point may be changed once, but shall not be subjected to any treatment with the purpose of removing the salt, except that superficial washing may be allowed. The products shall finally be dried or smoked not less than 10 days and at a temperature not lower than 35^0 C or 95^0 F.

Method 2. The products shall cure by a dry-curing process at a temperature not less than 2.2^0 C or 36^0 F for a period not less than 3 days per pound of raw product. The curing time is calculated based on the weight of the heavier product. Before placed in curing they shall be covered in

brine of less than 100 degrees of concentration injecting 4 ounces of the solution in the leg and an equal amount along the lateral side of the bone (femur). The products shall be placed in the salt at a concentration and applications equal to method 1 only that soak shall be no longer than 4 hours. The products will be dried and smoked at least 48 hours at a temperature not less than 26.6^0 C or 80^0 F and finally held in a drying area not less than 20 days at a temperature not lower than 7.2^0 C or 45^0 F.

Method 3. Products weighing 20 pounds shall be cured by dry-salt process at a temperature not lower than 1.7^0 C or 35^0 F for 45 days covered with salt. For every pound weigh over 20 pounds shall add two days. The time required for the equalization shall be replaced by the time the product is covered with salt. Equalization time is the process salt diffusion in the meat once the excess salt is removed. The product shall be overhauled at least once during the curing and shall be covered with fresh salt again. Wash with brine not less than 100^0 of concentration or strength. Excess salt must be removed by washing or air pressure, not allowing any other treatment. After cured, must be dried and smoked, or both, as provided in the table below:

Minimum temperature in the drying room in ^{0}Celsius	**Minimum temperature in the drying room in ^{0}Fahrenheit**	**Minimum days after curing**
54.4	130	1.5
51.7	125	2
48.9	120	3
46.1	115	4
43.3	110	5
40.6	105	6
37.8	100	7
35	95	9
32.2	90	11
29.4	85	18
26.7	80	25
23.9	75	35

Article 639 Loins and loin ends. In lieu of heating or refrigeration to destroy possible trichina, curing may be done for a period not less than 25 days at a temperature not lower than 2.2^0 C o 36^0 F, by the use of one of the following methods:

Method 1. Application of a dry-salt curing mixture, containing not less than 5 pounds of salt per 100 pounds of meat.

Method 2. Application of a brine solution with not less than 80^0 concentration on the basis of not less than 60 pounds of pickle per 100 pounds of meat.

Method 3. Application of a solution of brine added to the dry-salt cure approved, provided the brine solution is not less than 80^0 in concentration. After removal from cure, the loins may be soaked in water for no more than one hour, at a temperature not higher than 21.1^0 C or 70^0 F or washed under spraying, but during or after the curing process shall not be submitted to any other treatment to remove the salt. After curing loins are smoked for at least 12 hours, the temperature of the smokehouse at no time shall be lower than 37.8^0 C or 100^0 F, and for 4 consecutive hours of this period the smokehouse shall be maintained at a temperature not lower than 51.7^0 C or 125^0 F. The final product shall be held in the drying room for a period not less than 12 days at a temperature not lower than 7.2^0 C or 45^0 F.

Paragraph 1. SESPAS may consider any procedure or additional process that establishments may submit and may be approved once they are reviewed and determined to provide treatment security and that can be monitored and properly documented. This new procedure for approval must count on with an experimental protocol described in detail. The establishment must have the necessary measuring equipment for all areas.

Article 640 The Inspection Service may approve or not the equipment used by the establishing to measure temperature, salt concentration, time or others in any of the methods used and may reject them or request their replacement, with the result of suspending or reject the treatment being conducted according to the allowed.

Article 641 For the procedure on the analysis of trichinae using the digestion technique for a pool of samples, it shall consider the following:

1. Identify each sample correctly, as the backing samples, and separate them from others.

2. Shall use SESPAS official laboratory for analysis of samples, or a laboratory officially accredited for this purpose.

3. The samples shall be not less than 5 grams of diaphragm muscle or tongue of each carcass and not less than 10 grams of other muscles. The pool should not exceed 100 grams. Personnel of the establishment under official supervision can take these samples.

4. All carcasses or products sampled, or those lots within the pool shall not be released until the result of the analysis is negative to trichina.

TITLE XXXVII
OF OTHER PROCESSED PRODUCTS

Article 642 **Pizzas with meat or stuffing.** It is a product of meat on a base of bread with tomato sauce and cheese. Shall contain cooked meat prepared with not less than 15% of raw meat or 12% of cooked stuffing or 10% of dry stuffing. It is allowed the use of mechanically separated deboned meat.

Article 643 **Margarine and oleomargarine**. This can be found in a plastic form or liquid emulsion, containing not less than 80% fat, of vegetable or animal from beef, lamb or pork. It may contain:

1. Water, milk, dairy products such as liquid, condensed or dry form of whey, reduced lactose whey, reduced minerals whey, whey protein concentrate, non-lactose-containing whey components, casein, or caseinate; or other suitable edible protein including albumin, or soy protein isolated, or mixture of them. These shall be pasteurized and may be subjected to the action of harmless bacterial starters to form a solidified or liquid emulsion with the fat or oil ingredients.

2. Vitamin A, in such quantity that the finished margarine contains not less than 15,000 IU (international units) per pound, or 33,000 IU per kilogram of product.

3. Vitamin D, in such quantity that the finished margarine will contain not less than 1500 IU per pound or 3,300 IU per kilogram of product.

4. Salt as sodium chloride or potassium chloride for dietary margarine or oleomargarine.

5. Nutritive carbohydrate sweeteners, emulsifiers, antioxidants, coloring agents, flavors, acidulants, alkalizes permitted in quantities sufficient for this purpose

Article 644 **Mixed fat shortening**. Mixture of pork fat and vegetable oils. Depending on the predominance of fat and oils used, the product can be labeled "Shortening made from…" and may contain other ingredients that are listed in descending order of their predominance.

Article 645 **Lard, leaf lard**. Lard is the fat rendered from clean and sound edible tissues from swine; they may be fresh, frozen, cooked, or prepared by other processes approved in specific cases that shall not result in the adulteration of the lard. The tissues shall be reasonable free from blood, and shall not include stomachs, livers, spleens, kidneys, and brains, or settlings and skimmings. Leaf lard is lard prepared from fresh abdominal fat. Lard may be hardened using lard stearin or hydrogenated lard or both and may contained refined or deodorized lard. The characteristics of the products shall be:

1. White color when solid
2. Free from foreign odors and flavors
3. Moisture 0.2% maximum
4. Maximum of 0.05% insoluble impurities

The process of obtaining lard shall be by clarification through cooking with approved equipment but ensuring it reaches a temperature of 76.7^0 C or 170^0 F for a period not less than 30 minutes.

Article 646 **Rendered animal fat or mixed.** It shall contain no added water, except that puff pastry shortening that may contain no more than 10% of water.

Article 647. **Fluid extract of meats**. Shall contain no more than 50% of moisture.

TITLE XXXVIII
PACKING MATERIAL

Article 648. Packing material used for food products shall not contain any substance in its composition or other poisonous substance that appears and causes a disturbance or an issue to consumer health.

Article 649. Packing material shall be accompanied by a certification or safety declaration in writing from supplier that matches the name or commercial signature that distributes it when entering an approved establishment. The guarantee is limited to each shipment and for each product particularly.

Article 650. The certification or safety declaration of packaging materials that are received in an approved establishment shall contain the information required by the competent authority for it usage in food.

Article 651. The information required from the packaging material supplier shall be, but not limited to:

1. Name of the manufacturer
2. Product trade name and product code
3. Chemical composition of packaging materials
4. The recommended use of the product
5. Specific conditions of storage

Article 652 The establishment will grant a reasonable time not exceeding 30 days after receiving the shipment of packing material, so that the supplier delivers all the information required. The Inspection Service shall ensure the retention of the lots of products received until the information has been received and indicate that the lots are suitable to be use.

Article 653 If the establishment uses packing material without guarantee from the supplier or without the necessary information for its use, the Inspection Service may retain or reject the lot of packing material that corresponds or product where packed, since it represents a threat to consumer health.

Article 654 Shall ensure that the packing material comes free from dust, moisture, and is essential to arrive in its original packing, free of ruptures.

Article 655 The storage of packing materials shall be done in a specific area for it and separated from any other area, which shall be closed, dry and easy to clean, and be clearly identified. They shall be stacked according to the specifications of the manufacturer.

TITLE XXXIX
OF THE ADMISSIBILITY OF THE SYSTEM OF INSPECTION AND IMPORTS

Article 656 The entry or admission of meat products and meat byproducts into the country will be through SESPAS and the Secretary of State of Agriculture, which are the authorities responsible for establishing the procedures and for which they have their respective attributions.

Article 657 Countries wishing to export their meat products to the Dominican Republic, shall apply by written communication to both Secretaries of State. Secretary of State for Agriculture shall control the health status,

evaluation of the veterinary services in animal health, their animal health programs and disease control. SESPAS shall control the Inspection Services, all the controls to establish within the slaughter establishments and the meat products process, their laboratories and analysis of chemical and microbiological residues. For first time applications shall require to conduct out a verification of the operation system in origin and this shall be done by personnel of both Secretaries of State. To extend an authorization or renewal of slaughter establishments or meat products process when deemed appropriate shall be through SESPAS only. The countries will be informed if they require more information.

Article 658. Countries wishing to export to the Dominican Republic meat products and byproducts shall have an equivalent system according to the terms of these regulations.

Article 659. All the required documents shall be written in Spanish.

Article 660. No product or byproduct shall be allowed to enter into the country if the approval of their country of origin and establishments has not been completed in accordance with this Title.

Article 661. SESPAS will emit an answer as equivalent or not, in a reasonable time when completed the study of documentation and verification of origin, referring to the appropriate authorities of the requesting country and previous approval of the application by the Secretary of State of Agriculture. SESPAS shall emit a certificate with the list of establishments and products approved for import.

Article 662. When a country changes their health status or has any modification in their systems that affect the equivalence, the competent authorities will have the authorization at any time to stop temporarily imports of products from that country until it is proven that there is no health risk and that the new measures are still equivalent.

Article 663. All product considered in these regulations shall be inspected when entering the customs office of the country by SESPAS Inspection Service in order to allow their entry and trading in the country.

1. The inspector shall conduct a visual inspection of products, inspecting appearance and general condition.

2. There shall be an observation on seals and tags located in containers and product packaging, ensuring that match those in the certificate of entry of the product and that comply with the required by laws and regulations of the country for that purpose.

3. The inspector is empowered to sample the product at no cost, for their laboratory analysis, when considers necessary to determine their sanitary status.

4. No product that requires inspection under these regulations shall be authorized to mobilize or leave the port and the customs office where it entered into the country without permission and approval of the personnel of SESPAS.

5. The consignee or his agent shall provide all facilities and assistance for the handling and marking of products that may require during the inspection, and shall pay the costs involving the procedures applied for their products during this inspection.

Article 664 The inspection personnel of SESPAS is empowered to reject entry of any meat product that is considered non-suitable for human consumption or which constitutes a health risk to the country. In this case, the Inspector of SESPAS shall place to the packaging of the products a stamp with a legend that says "R.D.Rejected". Shall inform by written communication to the Representative of the Custom Office that the shipment must be returned to their country of origin within a period not exceeding 45 days, or may request their destruction or denaturation immediately according to the sanitary risk that represents. Considering the following:

1. Shall allow voluntary destruction of the product by the owner or consignee if decides for commercial purposes, and may allow its transformation into animal feed; this procedure shall be carried out under the control of SESPAS, as their transfer to the authorized establishment that shall process it.

2. Expenses involving the product devolution to the country of origin, sampling and process of destruction or denaturation shall be borne by the owner or consignee.

3. Shall not divide or subdivide rejected lots to suit the owner or consignee.

4. The products cannot be ship back through another port other than from the same used to enter the country without the consent of SESPAS.

5. If the owner or consignee fails to take the actions required for rejected products, SESPAS shall take the actions needed for the

destruction of the product and by legal means that empowers shall require the responsible pay of the cost incurred in this action.

6. Product previously rejected shall not enter again into the country under any circumstances.

TITLE XL
OF THE INFRACTIONS AND SANCTIONS

Article 665 Violations to the precepts of these regulations and other dispositions arising thereof, shall be sanctioned by the Secretary of State of Public Health and Social Assistance (SESPAS) through the Directorate General of Environmental Health, without prejudice to the corresponding to the courts, where constitutive of crime.

Article 666 SESPAS can take the following penalties according to the severity of the fault:

1. Regulatory Action. When detaining a product, rejecting equipment or facilities, stop or slow the process velocity or reject the process of a particular product. A rejected card or retained card may indicate this action.

2. Partial withdrawal of the inspection. When suspending inspection activities, the use of official seals and marks to a particular process in a certain area of the establishment that may be temporary or permanent according to the type of fault that has been committed.

3. Closing of the establishment. When the Inspection Service determines that the establishment shall not be processing because the product is not considered suitable for human consumption, this closure can be temporary or permanent according to the type of fault that has been committed.

Article 667 When the Inspection Service considers applying number 3 from previous article shall notify immediately the Food and Beverage Risk Control Department and obtain authorization to implement this sanction and deliver it in writing to the responsible of the establishment. When the inspector has to apply number 2 from the previous article shall notify and consign in his record book.

Article 668 Considered as minor faults that deserve regulatory action are those that do not interfere with the process or handling of the products inspected and approved for human consumption, such as:

1. Equipment and utensils with some visible cleaning and disinfection deficiencies.

2. Lack of information provided to the Inspection Service.

3. Minor sanitary faults in the establishment.

4. A slight fault in the non-humanitarian treatment of animals for slaughter.

5. Others that by their nature do not threaten the food.

Article 669 Considered as less serious faults are those that deserve the partial withdrawal of the inspection, as in the following cases:

1. The persistence of a minor fault in the following fifteen (15) days of notification.

2. The interference on the work of the Inspection Service by the company or their employees.

3. When a critical point is not under control, or the controls are not adequate.

4. When the raw material source is not known.

5. The loss of efficiency of several equipments that mean direct danger to the food.

6. The establishment is not conducting the sampling for E. coli.

7. The establishment has failed in the results for Salmonella.

8. When the establishment does not send a product that the Inspection Service has marked as condemned to the digester for its destruction.

9. The establishment is not applying or modifying correctly the HACCP and SSOP.

10. Others that by its nature affect directly the product.

Article 670 Considered as serious faults are those where proceeds closure of the establishment or definitive suspension by the Inspection Service when:

1. A minor fault with three consecutive notifications not corrected by the company.

2. Repetition of a fault considered less serious.

3. Fails applying the HACCP system procedures as required by these regulations.

4. Fails applying the SSOP procedures.

5. If the REJECTED or DETAINED card placed by the Inspector Officer in any local, product, equipment, or other device is removed without authorization.

6. The company or its employees that interfere with the Inspection Service and sends to the consumer products out of the patterns demanded or fraudulent.

7. There is presence of pathogenic organisms in the products produced at levels that may affect consumers' health.

8. Serious faults in human treatment produced in the slaughter of animals.

9. Loss of control of the maintenance measures for the environment.

10. Violation of the sanitary norms established, putting economic arguments.

11. There is open interference with the Inspection Service by intimidation, assault, attack or attempted assault or attack on the officials.

12. Meat products that have not been authorized for the human consumption are sold or transported for national consumption or the export.

13. Improperly use or forge a mark, seal, label or letterhead, or any other means used to identify meat products.

14. Other causes take place that by their specific nature seriously affect the quality and food safety.

Article 671 The application of sanctions will be as follows:

1. When the applied sanction is by infraction of minor offense or a regulatory action is applied shall make an oral and written warning.

2. When the applied sanction is by infraction of less serious offense, the Inspection Service will give written evidence on the attempt of suspension of the Inspection to the establishment. In a term no greater to forty-eight (48) hours must notify to the competent authority that the fault has been corrected and the application of a preventive procedure for their non-recurrence. Otherwise, proceed to the temporary suspension of Inspection Services.

3. When the committed faults are serious, it shall be applied the closing of the establishment without notice, until the management signs a commitment of cooperation with SESPAS to comply with the precepts contained in these regulations and that the faults are clearly corrected, until then no work shall be allowed in the establishment or exit of their products.

Article 672 These Regulations modify as necessary any other regulation or provision that is contrary with respect to health inspection of meat and meat products for domestic consumption and for export.