SUPREME DECREE Nº 007-98-SA

Approved: 24 September 1998

Published: 25 September 1998

HEALTH

Approval of the Regulation on Health Surveillance and Control of Food and Beverages

SUPREME DECREE Nº 007-98-SA

THE PRESIDENT OF THE REPUBLIC:

WHEREAS

The General Health Law No. 26842 lays down the general rules on health surveillance and control of food and beverages for the protection of health;

In order to comply with the provisions under the General Health Law, it is necessary to regulate the conditions, requirements and hygienic-sanitary procedures to which the production, transport, manufacture, storage, fractioning, processing and sale of food and beverages for human consumption must adhere, as well as those relating to health registration, health certification of foodstuffs for export and health surveillance of food and beverages;

It is necessary to adapt, replace, and repeal administrative provisions that are not in line with the General Health Law and related laws, in order to unify and harmonize existing regulations on health surveillance and control of food and beverages;

To ensure the production and supply of safe and wholesome food and beverages for human consumption and to facilitate safe trade, it is necessary to incorporate into health legislation the General Principles of Food Hygiene recommended by the Codex Alimentarius Commission;

In conformity with the provisions of Law No. 26842 and Legislative Decrees No. 560 and 584;

Pursuant to provisions under Article 118, subsection 8), of the Constitution of Peru;

WHEREOF:

Article 1. The regulations on Health Surveillance and Control of Food and Beverages are approved, consisting of nine Titles, nineteen Chapters, one hundred and twenty-five Articles, seventeen Complementary, Transitory, and Final Provisions and twenty-eight Definitions.

Article 2. This Supreme Decree shall be endorsed by the President of the Council of Ministers, the Minister of Economy and Finance, the Minister of Fisheries, the Minister of Agriculture, the Minister of Industry, Tourism, Integration and International Trade Negotiations and the Minister of Health, and shall come into force from the day following its publication.

Issued at the Government House in Lima, on the twenty-fourth day of September in the year nineteen hundred and ninety-eight.

ALBERTO FUJIMORI FUJIMORI

Constitutional President of the Republic

ALBERTO PANDOLFI ARBULU

President of the Council of Ministers

JORGE BACA CAMPODONICO

Minister for Economy and Finance

LUDWIG MEIER CORNEJO

Minister for Fisheries

RODOLFO MUÑANTE SANGUINETI

Minister for Agriculture

GUSTAVO CAILLAUX ZAZZALI

Minister for Industry, Tourism, Integration and
International Trade Negotiations

MARINO COSTA BAUER

Minister for Health

SUPREME DECREE Nº 007-98-SA

REGULATION ON HEALTH SURVEILLANCE AND CONTROL OF FOOD AND BEVERAGES

SUPPLEMENTARY, TRANSITIONAL AND FINAL PROVISIONS

TITLE I

GENERAL INFORMATION

Article 1. Pursuant to the provisions of the General Health Law, No. 26842, and in accordance with the General Principles of Food Hygiene of the Codex Alimentarius, these regulations establish:

a) The general rules of hygiene and the health conditions and requirements for the production, transport, manufacture, storage, preparation and sale of food and beverages for human consumption in order to ensure their safety.

b) The conditions, requirements and procedures for the registration, re-registration, modification, suspension and cancellation of the Health Registration of Food and Beverages.

c) The conditions, requirements and procedures for the health certification of foodstuffs and the authorization of exporting establishments.

d) The rules governing the health surveillance of activities and services linked to the production and mobilization of foodstuffs.

e) Health security measures , violations and applicable penalties.

All natural and legal persons that participate or intervene in any of the processes or operations that involve activities and services related to the production and circulation of food products, are comprised on the scope of these regulations.

Article 2. All food and beverages, or raw materials intended for their preparation, must meet the organoleptic characteristics, chemical composition and microbiological standards set forth in the corresponding health regulation.

TITLE II

HEALTH SURVEILLANCE BODIES

Article 3. Health surveillance of food production of animal and plant origin

The Ministry of Agriculture is responsible for the health surveillance of the breeding of animals for human consumption, animal health for the production of milk, meat and eggs, as well as the sanitary surveillance of the production of vegetables for human consumption.

Article 4. Health surveillance of hydrobiological products

Sanitary surveillance of the capture, extraction or collection, transport, and processing of hydro-biological products as well as the hygienic conditions at landing sites of these products is carried out by the Ministry of Fisheries.

Article 5. Health surveillance of establishments manufacturing, storing and fractioning food and beverages and of passenger food services in means of transport

The health surveillance of industrial establishments manufacturing food and beverages, with the exception of those used in processing hydrobiological products, as well as the sanitary surveillance of establishments for the storage and fractionation of food and beverages and passenger food services in means of transport, are carried out by the Ministry of Health.

The deconcentrated health units nationwide, as appropriate, exercise, by delegation of the Ministry of Health, the surveillance of such establishments and services.

Article 6. Health surveillance of food and drink marketing and processing facilities and food and beverage dispensing.

The sanitary surveillance of food and beverages' transport, and the surveillance of facilities for the marketing, processing and sale of food and beverages, with the exception of establishments involved in the fractioning of food and beverages and passenger food services in means of transport, are municipal functions.

These entities shall be responsible for the sanitary surveillance of the production and street vending of food and beverages, and for assuring compliance with the provisions of Article 15 under these regulations.

Article 7. Monitoring the health quality and safety of industrial food and drink

The Ministry of Health is responsible for monitoring the health and safety of food and beverages subject to health registration.

Article 8. Field surveillance of food and beverage labelling and advertising

Surveillance in the field of food and beverage labelling and advertising is carried out by the National Institute for the Defense of Competition and the Protection of Intellectual Property – INDECOPI

TITLE III

FOOD AND DRINK MANUFACTURING

CHAPTER I

Food of animal origin

Article 9. Care in animal husbandry

The rearing of animals for human consumption must be carried out in compliance with health standards and animal health measures.

Animals that have died due to illness or accident must be disposed of in a sanitary manner. Their sale and consumption is prohibited.

Article 10. Meat production

The sanitary conditions for the production of meat for human consumption are subject to the rules issued by the Ministry of Agriculture after coordination with the Ministry of Health.

For the purposes of these regulations, meat production includes rearing, feeding, transport of live animals, and rendering, storage, transport and marketing of meats and offal.

Article 11. Quality of food for animals intended for consumption

Animals intended for human consumption must be raised in accordance with good poultry and livestock husbandry practices and must not be supplied with feed which may contain:

a) Pathogenic agents of human or animal origin.

b) Veterinary drugs, pesticides, agricultural chemicals or other chemical substances in quantities and during exposure times likely to leave residues in the fresh meat exceeding the maximum limits laid down by the Codex Alimentarius.

Article 12. Veterinary inspection

All meat intended for direct human consumption or for industrial preparations must come from approved slaughterhouses and must have been declared fit for consumption by the responsible veterinary surgeon.

Article 13. Transport of animals

Animals intended for human consumption must be transported in such a way that they are not contaminated or harmed.

For this purpose, the transport of animals must comply with the following requirements:

a) Provide facilities for loading and unloading animals.

b) Animals of different species will be separated during transport to prevent injuries.

c) Transport vehicles must be provided with adequate ventilation.

d) If animals are transported on double deck vehicles, the upper deck floor must be waterproof.

e) Transport vehicles must be kept in a good state of repair and cleanliness and must be washed and disinfected before loading and after unloading of the animals.

The Ministry of Agriculture is charged with issuing the specific provisions on the transport of animals to the slaughterhouse and monitoring compliance.

Article 14.- Slaughterhouses

The construction, opening and operation of a slaughterhouse, the procedure for pre- and post-mortem inspection, as well as confiscation and condemning, are subject to the rules approved by the Ministry of Agriculture.

Article 15. Pig breeding

The feeding of pigs with food scraps from rubbish and hospital contaminated areas is prohibited.

Pigs may be fed with leftover food from feed services, provided that such leftovers are heat treated. This treatment should be maintained for five (5) minutes from the start of ebullition. The breeder must be provided of the necessary equipment for this purpose.

Open field pig breeding is forbidden to prevent their feeding on rubbish and/or fecal matter.

Animals raised in unhealthy conditions will be subject to confiscation and final disposition by the municipal authority.

Article 16. Egg production

Appropriate health measures must be adhered to when producing eggs to prevent the risk of transmitting diseases through this product. To this end, the Ministry of Agriculture, in coordination with the Ministry of Health, will prepare and disseminate Good Poultry Practices documentations.

Article 17. Milk production

Milk production in dairy establishments must be carried out in compliance with the animal health standards laid down by the Ministry of Agriculture.

Article 18. Milk health and safety

Milk's sanitary quality and safety parameters laid down in the health standard for each type of milk product, as issued by the Ministry of Health.

Article 19. Restrictions on the capture, extraction or collection of hydrobiological products.

The capture, extraction or harvesting of hydro-biological products intended for direct human consumption, using fishing tackle with or without vessels, is prohibited in areas receiving wastewater discharges, both domestic and industrial. This ban applies to areas within a radius of two (2) nautical miles from the point of discharge from the collector.

Where hydro-biological products are found to originate from areas affected by such emissions, it is the responsibility of the Ministry of Fisheries to seize and destroy such products. Violators will be sanctioned by the Ministry of Fisheries in accordance with the provisions of the General Fisheries Law and its regulations.

Article 20. Transport of hydro-biological products

The conditions for the transport of hydro-biological products from the capture, extraction or harvesting area shall prevent their exposure to contamination or their degradation. To this end, the vessels must be equipped with equipment and other means necessary for product conservation. At the end of each operation the holds, decks and equipment as well as the containers used on board must be washed and disinfected.

Article 21 Landing places for hydro-biological products

Landing places for hydro-biological products must provide sufficient space for the proper handling of the product and to preserve their sanitary quality and safety. These places must have a sufficient supply of potable water and ice to preserve the product.

Article 22. Handling of hydro-biological products

Hydro-biological products, from their capture, extraction or collection to their sale to the public or delivery to the processing plant, must be handled, conserved and transported at temperatures close to 0°C. For this purpose, ice boxes or isothermal transport vehicles with ice or refrigeration may be used.

When processing plants have direct ship-to-plant unloading systems, products may be deposited in pools equipped with appropriate preservation systems to prevent the product from degradation or alteration.

CHAPTER II

Food of plant origin

Article 23. Vegetable production

The production of plants for human consumption must comply with the Good Agricultural Practices issued by the Ministry of Agriculture.

Article 24. Prohibition of using wastewater for irrigation

The use of wastewater, treated or untreated, for the irrigation of creeping and short-stemmed vegetables for raw consumption as well as creeping fruit plants is prohibited.

Article 25. Fruit and vegetable handling

The transport, storage and marketing of fruit to be eaten in the shell and of vegetables shall be carried out in boxes, baskets, sacks or other appropriate packaging which prevents contact between the fruit and the ground or transport platform.

It is forbidden to cool the vegetables with water from ditches or any other source that does not guarantee water potability.

Municipalities are responsible for monitoring compliance with this provision.

Article 26 Pesticide residues and fungi prevention

In the production and harvesting of plants for human consumption, the necessary measures should be taken to ensure that agricultural pesticide residues in plants do not exceed the maximum limits set by the Codex Alimentarius.

In the harvest and storage of vegetables, especially cereals and seeds, the necessary measures should also be taken to prevent the presence of fungi, particularly those that generate toxins, as well as exposure to other contaminating substances.

Article 27. Forced ripening of fruits

It is forbidden to use ripening accelerating or triggering substances that pose a risk, hazard or harm to the health of the consumer.

CHAPTER III

Other products

Article 28. Salt for human consumption

Salt for human consumption must be free of nitrites and any other toxic or dangerous substances identified in health standards. Salt will contain iodine and fluorine aggregates in the proportion established by the Ministry of Health.

Article 29. Sanitary quality of ice

Ice intended for direct consumption and for the preservation of foodstuffs must be made with drinking water and in establishments which comply with the provisions contained in Title IV under these Regulations.

Such ice must meet the physical, chemical and bacteriological specifications for water for human consumption as set out in the standard issued by the Ministry of Health.

TITLE IV

FOOD AND BEVERAGE MANUFACTURING

CHAPTER I

Physical infrastructure and manufacturing facilities

Article 30. Location of factories

Food and beverage factories should not be less than 150 meters from the location of any establishment or activity which, because of their operations or tasks, fosters the proliferation of insects, gives off dust, fumes, vapors or bad odors, or may contaminate food and beverage products.

Conversely, the same ban as outlined above applies to activities and establishments intended to set up in the proximity of already established food and beverage manufacturing facilities.

Land that has been a landfill, dump, burial ground, marshland or that is exposed to flooding cannot be used to set up food and beverage manufacturing facilities.

Municipalities shall verify compliance with the provisions of this provision when granting the respective municipal permits.

Article 31. Sole purpose premises

Premises used for the manufacture of food and drink shall not be directly connected to dwellings or premises where other types of activities are carried out.

Article 32. Access routes

Access roads and travel areas within the premises must be paved and suitable for the type of traffic for which they are intended.

Article 33. Structure and finishes

The structure and finish of establishments for food and beverage manufacturing should be built with waterproof and rodent resistant materials.

In the manufacturing or production rooms:

a) The joints between the walls and the floor should be grooved to facilitate washing and to avoid the accumulation of foreign matter.

b) Floors will slope towards conveniently arranged gutters or drains to facilitate washing and draining of liquids.

c) The wall surfaces shall be smooth and painted with washable light-colored paint.

d) Ceilings must be designed, constructed and finished so that they are easy to clean, prevent the accumulation of dirt and minimize water condensation and mold.

e) Windows and other openings should be constructed to prevent the accumulation of dirt, should be easy to clean and must be provided with means to prevent the entry of insects or other animals.

The refurbishment of already built premises is subject to this provision.

Article 34. Lighting

Industrial establishments must have adequate natural lighting. Natural lighting can be complemented with artificial lighting where necessary, preventing it from generating shadows, reflections or being blinding.

The intensity, quality and distribution of natural and artificial lighting must be appropriate to the type of work, taking into account the following minimum lighting levels:

a) 540 LUX in areas where a detailed examination of the product is carried out.

b) 220 LUX in production rooms.

c) 110 LUX elsewhere.

Article 35. Ventilation

Factory facilities must be provided with adequate ventilation to prevent excessive heat as well as water vapor condensation and allow for the removal of contaminated air. Air shall not flow from a dirty area to a clean one. Ventilation openings must be provided with air grill vents or other protection of anti-corrosion material, installed in such a way that they can be easily removed for cleaning.

CHAPTER II

Distribution of rooms and location of equipment

Article 36. Distribution of the rooms

Food and beverage manufacturing facilities must be laid out so as to avoid cross-contamination of products due movement of rolling equipment or personnel and the proximity of personal hygiene facilities to the manufacturing rooms.

Article 37. Equipment and utensils

Equipment and utensils used in food handling should be made of

materials that do not produce or emit toxic substances or impregnate food and drink with unpleasant odors or tastes. They will be non-absorbent; rust-proof and capable of withstanding repeated cleaning and disinfection. The surfaces of equipment and utensils must be smooth and free from holes and cracks.

Article 38. Hygienic design of equipment and utensils

Equipment and utensils must be designed to allow easy and thorough cleaning and disinfection. Fixed equipment must be installed so as to allow proper cleaning.

Article 39. Cooling equipment

All refrigerated rooms must be equipped with temperature measurement and recording devices. These devices must be placed in a visible location and kept in good state of repair and working order.

CHAPTER III

Water supply, sewage disposal and solid waste collection

Article 40. Water supply

Only water that complies with the physical-chemical and bacteriological standards for water for human consumption set out in the specifications issued by the Ministry of Health shall be used for food and beverage manufacturing.

Factories shall be supplied with water collected directly from the public grid or from wells, and the systems used for water storage shall be constructed, maintained, and protected so as to avoid water contamination.

Food and beverage factory management must provide systems to ensure a permanent and sufficient supply of water throughout the premises.

Article 41. Reuse of treated industrial wastewater

Food and beverage factories can recover industrial wastewater and reuse it, after treatment, for pre-washing of containers. Exceptionally, subject to prior authorization by the Ministry of Health's General Directorate of Environmental Health, it may be used in the final washing of containers, provided that the treatment system in place assures the resulting water meets the

physical-chemical and bacteriological standards for water for human consumption.

Article 42. Wastewater disposal

Wastewater must be disposed of in conformity with relevant regulations.

Article 43. Collection and disposal of solid waste

Solid waste must be kept in plastic or metal containers properly covered or capped.

Solid waste will be disposed of in conformity with the regulations on urban cleanliness issued by the Ministry of Health.

CHAPTER IV

Operational considerations

Article 44. Process flow

To prevent the risk of cross-contamination of products, the manufacture of food and drink should follow a forward flow in clearly separated stages proceeding from dirty to clean areas. The flow of personnel, equipment, utensils, materials and instruments assigned or corresponding to dirty areas shall not be allowed into clean areas.

Article 45. Cooling chambers

Food and beverage factories producing easily spoiled products must be equipped with cooling chambers.

Article 46. Accessory or complementary installations and equipment

Any food and beverage manufacturing ancillary or complementary facility or equipment which may result in product contamination, must be located in areas away from production areas.

Article 47. Safety and control devices

The equipment used in manufacturing, intended to ensure the sanitary quality of the product, must be equipped with safety, control and recording devices permitting to verify compliance with the procedures of the treatment applied.

Article 48. Care on the production floor

No other products, articles, implements or materials that are foreign or alien to the products made in these rooms may be kept or stored

in the rooms where the product is made.

CHAPTER V

Staff hygiene and sanitation of premises

Article 49. Staff health status

Personnel involved in making food and beverages, or who have access to the manufacturing room, shall not be carriers of, or have symptoms of, infectious disease. The employer will permanently guard against their occurrence.

Article 50. Cleaning and personal appearance of staff

Staff working in food and beverage production rooms must be completely clean. Hands should not have cuts, sores or other skin conditions and nails should be kept clean, trimmed and unpolished. The hair must be completely covered. No rings, bracelets or other decorative objects should be worn when handling food.

Such personnel must wear light-colored work clothes provided by the employer and worn exclusively for their work. Clothing shall consist of a cap, shoes, overalls or jacket and pants and must be in good condition and clean.

When processing and packaging products manually, without further treatment against any possible contamination by handlers, the personnel involved must be provided with masks and gloves. Using gloves does not exempt from washing hands.

Personnel involved in equipment and container washing operations must also be provided with waterproof aprons and boots.

Article 51. Maintenance personnel

The personnel assigned to the cleaning and maintenance of the food and beverage manufacturing areas, even if outsourced, must comply with the personnel cleanliness, dress and appearance provisions set forth in the preceding article. Their clothing shall be of the same type, but in a different color.

Article 52. Food hygiene training

Management of food and drink establishments should make arrangements to ensure that personnel involved product manufacturing shall receive adequate and ongoing training on the hygienic handling of food and beverages, and in personal hygiene.

Article 53. Staff clothing

Food and beverage manufacturing establishments must provide personnel working in manufacturing rooms or their cleaning and maintenance, including outsourced services, with adequate changing rooms and facilities to keep their work and daily clothes separately.

Article 54. Staff restrooms

Food and beverage manufacturing establishments must be provided with restrooms for personnel that are maintained clean and in good state of repair, as per the following list:

a) From 1 to 9 persons: 1 toilet, 2 washbasins, 1 shower, 1 urinal.
b) From 10 to 24 persons: 2 toilets, 4 washbasins, 2 shower, 1 urinal.
c) From 25 to 49 persons: 3 toilets, 5 washbasins, 3 shower, 2 urinals.
d) From 50 to 100 persons: 5 toilets, 10 washbasins, 6 shower, 4 urinals.
e) More than 100 persons: 1 additional toilet for every 30 people.

Toilets, washbasins and urinals must be made of porcelain.

Article 55. Hand washing and disinfection facilities

All personnel in the product manufacturing area shall, while on duty, wash their hands with soap and water, before starting work, immediately after using the toilet and handling dirty or contaminated material, and as often as necessary. Hands should be washed and disinfected immediately after handling any potential disease transmitting material.

Signs will be posted indicating the obligation to wash hands. There must be adequate monitoring to ensure that this requirement is met.

Article 56. Cleaning and disinfection of premises

Immediately after finishing work for the day or as often as appropriate, floors, auxiliary structures and walls of food handling areas shall be thoroughly cleaned.

Precautions shall be taken to prevent food from being contaminated when rooms, equipment and utensils are cleaned or disinfected with water and detergent or with disinfectant.

Disinfectants must be suitable for the purpose intended and any residues must be removed after their use to prevent potential food contamination.

A factory cleaning and disinfection program should be in place and reviewed and checked during inspection.

Cleaning utensils intended for the manufacturing area must be for their exclusive use there. They may not be moved from the dirty to the clean areas.

Article 57. Pest and animal access control

Establishments must be kept free of rodents and insects. To prevent the entry of rodents and insects from the collectors, metal lids shall be placed on the boxes and inspection boxes of the drainage net-works and, in the channels for collecting washing water, metal grids and water traps in their connection with the drainage network.

The application of rodenticides, insecticides and disinfectants shall be carried out as appropriate to avoid contamination of the food

product.

Measures shall be taken to prevent domestic and wild animals from entering the establishment.

CHAPTER VI

Sanitary quality and safety control

Article 58. Sanitary quality and safety control

Every food and beverage factory must carry out health and safety quality control of the products it produces. This control shall be based on the Hazard Analysis and Critical Control Point (HACCP) system, which will be the reference standard for health surveillance.

Article 59. Procedure for the application of the HACCP system

The implementation of the HACCP system in the food and drink industry shall be done according to the following procedure:

a) The manufacturer must prepare the HACCP Plan corresponding to the manufacturing process of the product(s) he produces, adhering for this purpose to the health regulations applicable to the product(s) in question as well as the regulations governing the application of the HACCP system in the manufacture of food and beverages. Once elaborated and validated in the plant by the manufacturer himself, he must apply the Plan to the manufacturing process of his products.

b) The person concerned shall provide the body responsible for the health surveillance of the manufacture of food and drink with a copy of the HACCP plan, for the purposes of official technical validation and periodic inspection.

c) The HACCP plan drawn up by the manufacturer must be subject to on site technical validation by the body responsible for the health surveillance of food and drink manufacturing. The purpose of this validation is to verify the suitability of the HACCP Plan and its effective application in manufacturing.

The corresponding report must include details of any objections resulting from the technical validation carried out and the time

allowed for the manufacturer to rectify them. Once the deadline has expired, the health surveillance authority shall verify on site that the objections have been rectified. If the manufacturer has not rectified these objections, the appropriate health measures will be applied, if necessary.

The manufacturer will bear the cost of the official technical validation of the manufacturing HACCP Plan.

d) The manufacturer must periodically carry out all the verifications needed to assure the manufacturing process HACCP Plan is properly enforced.

Additionally, changes in production operations, product formulation, relevant hazard analysis information, critical control points and any changes in regulated application of the HACCP system will be subject to verification by the manufacturer to ensure the HACCP Plan is appropriate and complies globally with the requirements of the HACCP system or if, on the contrary, it requires modifications and re-evaluation.

Monitoring the HACCP system in factories shall be part of the regular inspections carried out by the body responsible for the health surveillance of food and beverage factories. Health inspections shall include a general assessment of the potential risks associated with the activities or operations of the plant in regards of product safety, and in particular, critical control points.

Article 60. Recording of information

Food and beverage factories are required to draft and file documented all information substantiating the implementation of the HACCP Plan. The control and monitoring procedures for critical points applied and omitted, recording the results obtained, and the corrective measures adopted to regain control of the critical points, must be recorded accurately and efficiently and must be consolidated in a file which shall be available to the competent health surveillance body as required.

Article 61. Manufacturer's responsibility

The manufacturer and the quality control official are jointly responsible for the sanitary quality and safety of the food and beverages that are released for marketing.

CHAPTER VII

Raw materials, food additives and packaging

Article 62. Sanitary quality of raw materials and food additives

Raw materials and additives intended for food and beverage manufacturing must meet the health quality requirements set out in the health standards issued by the Ministry of Health.

Article 63. Allowed additives

The use of food additives other than those permitted by the Codex Alimentarius is prohibited. Flavorings accepted by the Food and Drug Administration of the United States of America (FDA), the European Union and the Flavor and Extractive Manufacturing Association (FEMA) are also permitted.

No unauthorized food additives may be kept on the premises of food and drink factories.

Article 64. Packaging

Packaging for the use of food and beverages and their raw materials shall comply with the provisions of Articles 118 and 119 of these regulations.

Packaging previously used for products other than food and drink for human consumption may not be reused. Returnable food and beverage containers may be reused, provided they can be washed and sterilized to preserve packaging safety standards.

CHAPTER VIII

Sanitary inspection to factories

Article 65. Procedure for health inspection

The sanitary inspection of food and beverage factories and sampling of processed products for analysis will adhere to the inspection guidelines approved by the Ministry of Health or the Ministry of Fisheries, as applicable.

Article 66. Facilities for health inspection

The owner, the manager, or the person responsible for the factory will grant the facilities for inspection and sampling.

Article 67. Powers of the inspector

The inspectors are empowered to carry out the following actions:

a) To evaluate the hygiene and sanitary conditions of food and beverage factories.

b) To sample, where appropriate, products for analysis. The manufacturer must provide the samples, when so required.

c) To demand correcting inadequate manufacturing, storage and dispatch practices.

d) To freeze, seize and confiscate defective, contaminated, altered or adulterated products.

e) Temporarily closing establishments when the health or technical operating conditions pose serious and imminent risk to consumer health.

f) To exclude food handlers from the manufacturing room when their health may contaminate food.

When inspection provides for the application of a safety measure, the inspector shall, under their responsibility, file the corresponding report within twenty-four (24) hours of the inspection to the holder of the competent body so that the latter may ratify, modify or suspend the measure adopted.

For factories processing hydro-biological products, carrying out the actions provided for in paragraph e) of this provision shall be subject to the procedure established in the rules issued by the Ministry of Fisheries.

Article 68. Formulation of the inspection report

Once the inspection has been completed, the inspector shall draw up the corresponding report in triplicate, indicating the place, date and time of the inspection, detail deficiencies and recommendations, and deadlines for their correction. Explanations provided by the owner, manager or official in charge of the establishment will be recorded in the minutes.

The minutes shall be signed by the inspector and the person responsible for the establishment. Should the latter refuse to do so, this shall be recorded in the minutes without affecting the validity of the minutes.

Article 69. Destination of unsuitable products

The final disposal and/or destruction of food or drink unfit for human consumption is subject to the regulation issued by the Ministry of Health.

TITLE V

OF STORAGE AND TRANSPORT OF FOOD AND DRINK

CHAPTER I

Storage

Article 70. Storage of raw materials and finished products

The storage of raw materials and finished products, whether domestic or imported origin, shall be carried out in areas intended exclusively for this purpose. Appropriate areas must be provided to protect their sanitary quality and safety, and to avoid cross-contamination risks. No other material, product or substance that could contaminate the stored product may be kept or stored in such environments.

Raw materials and finished products shall be stored in separate rooms.

The warehouses located outside the factory premises must comply with Articles 30, 31, 32, 33, 34, 35, 39, 42 and 43 of these regulations.

Article 71. Storage of perishable products

Perishable products must be stored in refrigeration or freezing chambers, as appropriate. Storage temperatures and relative humidity inside the chambers must meet applicable health standards.

Other food which may lead to cross-contamination of products must not be stored in the same chilling room unless it is properly packaged, conditioned and sealed.

Article 72. Stowage of non-perishable products

Food and beverages as well as raw materials must be stored on pallets or shelves at least 0.20 meters off the floor and 0.60 meters from the ceiling.

To allow air circulation and better insect and rodent control the clearance between rows of stacks and between them and the wall will be at least 0.50 meters.

Article 73. Stowage of perishable products

Stowage of products in cold chambers must allow cold air to flow and not interfere with the temperature exchange between the air and the product. Products shall be placed on shelves, stacks or racks, at least 0.10 meters off the floor, 0.15 meters from the walls and 0.50 meters from the ceiling.

The size of the stacks must allow adequate product cooling.

When conditioning the shelves or stacks, sufficient corridors or free spaces will be provided to facilitate product inspections.

Article 74. Sanitary inspection of warehouses

Sanitary inspection of warehouses for raw materials and finished goods, whether domestic or imported, shall be carried out in accordance with the provisions under Articles 65 to 69 of these Regulations.

CHAPTER II

Transport

Article 75. Conditions

Food and beverages, as well as the raw materials, ingredients and additives used in their manufacture or processing, must be transported so as to prevent contamination or spoilage.

The transport of foodstuffs, and their raw materials, ingredients and additives, shall be subject to the following:

a) Depending on the type of product and travel time, the vehicles must be conditioned and provided with sufficient means to protect the products from the effects of heat, humidity, dryness, and any other undesirable effects that may be caused by the exposure of the product to the environment.

b) Compartments, receptacles, hoppers, chambers, or containers may not be used for the transport of anything other than food and beverages to prevent the latter's contamination.

c) Foodstuffs, and their manufacturing or processing raw materials, ingredients and additives, must not be transported in the same compartment, receptacle, hopper, chamber or container in which toxins, pesticides, insecticides and any other similar substances have been kept or traveled, and which may contaminate the product.

d) When different types of food, or food together with non-food products, are transported simultaneously in the same bin, hopper, platform or container, the cargo must be conditioned so that

there is effective separation between them, where necessary, to avoid cross-contamination risk.

Article 76. Cleaning and disinfection of vehicles

Any compartment, receptacle, platform, hopper, chamber or container used for the transport of foodstuffs, or their manufacture or processing raw materials, ingredients and additives, must be cleaned and disinfected, and deodorized if necessary, immediately before loading.

Article 77. Loading, stowage and unloading

Loading, stowage and unloading procedures shall prevent cross-contamination of products.

TITLE VI

MARKETING, PROCESSING AND SALE OF FOOD AND BEVERAGES

CHAPTER I

Marketing

Article 78. Marketing facilities

Food and beverage marketing establishments are those premises used for the fractioning and packaging of food and beverages, including supply markets, self-service shops, market fairs, collection and distribution centers, and warehouses.

Article 79. Sanitary requirements of establishments

Establishments engaged in food trade must comply with the following minimum requirements:

a) Be located away from any source of contamination.

b) Kept clean.

c) Be well lit and ventilated.

d) Have a sufficient supply of drinking water and drainage systems.

e) Have ceilings, walls and floors in a good state of hygiene and

repair.

f) To feature personal hygienic facilities.

g) To have an area for the internal disposal of solid waste.

The physical conditions for each type of establishment are subject to the health regulations issued by the Ministry of Health.

Article 80. Food fractioning

The packaging of natural products or the repackaging of industrialized products for retail sale must be carried out in establishments which comply with the provisions set forth in Articles 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 42, 43, 49, 50, 51, 52, 53, 54, 55, 56 and 57 of these regulations.

The packaging of the fractioned products shall comply with the provisions of Articles 118 and 119 under these regulations.

The following minimum information must be indicated on the labels of these packages:

a) Name of product.

b) Name or company name and address of the packer and/or distributor.

When an industrialized product subject to health registration is fractioned, the labelling of the package of the fractioned product shall include, in addition to the information detailed in paragraphs a) and b) above, the information listed in paragraphs b), c), d), e), f), and h) of Article 117 under these regulations.

The health inspection of establishments engaged in the fractioning and packaging of food and beverages shall be performed pursuant to the provisions of Articles 65 to 69 under these regulations.

CHAPTER II

Processing and sale

Article 81. Processing and retail establishments

Food and beverage establishments include restaurants, collective food services, school food services and passenger food services in means of transport.

Article 82. Sanitary requirements of establishments

Establishments engaged in the production and sale of food and beverages must comply with the following minimum requirements:

a) Include an area for the storage of non-perishable products with adequate ventilation and lighting and sufficient capacity for its volume of operations. The products shall be ordered by type and with strict stock rotation. Chemicals shall be stored in a separate area.

b) The kitchen area shall be large enough to prevent meal cross-contamination. The kitchen floor shall be quality, non-absorbent, corrosion-resistant material. It will slope towards drains that allow the evacuation of liquids and shall be fitted with appropriate devices (grilles, siphons) to prevent bad smells and the ingress of rodents and insects.

   The walls' materials shall be smooth, non-absorbent and painted with washable light-colored paint. Roofs shall be designed so as to prevent accumulation of dust or condensation vapors. The joints between the walls and the floor will be half-round.

c) To have enough drinking water to cover the needs of the premises. The internal water distribution grid shall feature the necessary number of connections for room cleaning and washing.

d) To have personal hygienic facilities for the users.

e) To have clothing and sanitary services for the personnel in proportion to the number of workers, pursuant to ratios set forth in Article 54 of these regulations.
   To have deposits for plastic material, provided with bags, for waste collection. There shall be a separate place to put away kitchen waste, which shall be disposed of daily.

f) To have adequate refrigeration facilities, when storing or selling products susceptible to alteration or decay owing to heat.

The specific and operational requirements of these establishments

are set out in the corresponding health standard issued by the Ministry of Health.

Article 83. Preparation and sale of food and drinks on public thoroughfares

Street preparation and vending of food and beverages on public streets shall meet the requirements and conditions laid down in the relevant health regulations.

Municipalities are responsible for the health surveillance of such activities.

CHAPTER III

Food handlers

Article 84. Identification of handlers

Food handlers are persons who come into direct contact with food during their work. A food handler is anyone who:

a) Is involved in the distribution and sale of fresh, unpackaged products.

b) Is involved in any of the stages that comprise food processing and packaging, when these operations are carried out manually without further treatment to remove any possible contamination originating in the food handler.

c) Is involved in the culinary preparation and serving of food for direct consumption.

Article 85. Requirements for handlers

Food handlers, in addition to complying with the requirements of Articles 49, 50, 52, 53 and 55 of these regulations, must receive training in food hygiene based on Good Handling Practices. Such training must be ongoing.

Staff training is the responsibility of the employer. At the employer's option, the training may be provided by the municipalities, private entities or specialized natural persons.

TITLE VII

FOOD AND BEVERAGE EXPORTS

Article 86. Official Export Health Certificate

Only exceptionally and at the exporter's request, the General Directorate of Environmental Health (DIGESA) may issue an Official Health Certificate for the export of food and beverages.

The Certificate shall be issued using formats whose contents shall reflect the type of product and the particular specifications requested by the exporter.

The Official Export Health Certificate does not constitute a pre-shipment document, nor shall it be required by Customs as a condition for product clearance.

Article 87 Shipping lot

The Official Export Health Certificate mentioned in the previous article shall be issued for each dispatch or shipment batch and country of destination.

Each consignment may consist of more than one production batch and be intended for one or more customers in the importing country.

Article 88. Request for certification

To request an Official Export Health Certificate, the interested party must submit to DIGESA, not fewer than three (3) working days prior to the date of shipment, an application including the following information:

a) Name or business name and address of exporter.

b) Product identification:

b.1) Scientific name of animal or plant species.

b.2) Condition and type of treatment.

b.3) Batch code, as applicable.

b.4) Type of packaging

b.5) Number of packing units.

b.6) Net weight.

b.7) Required storage and transport temperature.

c) Origin of product:

c.1) Name and rating number of the factory.

c.2) Extraction or harvesting area, in the case of bivalve mollusks, echinoderms, tunicates and marine gastropods.

d) Destination of product:

d.1) Place of origin or boarding.

d.2) Country, port of arrival and place of destination.

d.3) Mode of transport.

d.4) Name of the recipient, address and place of destination.

e) Languages in which the certificate must be issued.

Article 89. Mandatory documents for the request

Attached to the request, the interested party must submit the following documentation:

a) Report of the hygiene and sanitary evaluation of the product to be shipped regarding storage conditions, packaging and wrapping, issued by an inspection body accredited by INDECOPI.

a) Analysis report issued by a laboratory accredited by INDECOPI, concerning the samples selected and taken from the respective shipment batch by the inspection body referred to in subparagraph of this provision.

b) Voucher of fee payment for certification, pursuant to provisions under the Single Text of Administrative Procedures (TUPA, by its acronym in Spanish) of the Ministry of Health.

Article 90. Inspection, sampling, and analysis procedures

The inspection, sampling and analysis activities referred to in the preceding provision are performed pursuant to the methods, techniques or procedures set forth by the Ministry of Health.

At the request of a party, inspections, sampling, and analyses in addition to those provided for in the rules of the Ministry of Health may be carried out, in which case the interested party must indicate in its request the methods, techniques or procedures to be used.

Article 91. Laboratory and inspection body services

The laboratory and the inspection body accredited by INDECOPI are freely chosen by the interested party, who shall directly contract their services and cover the respective costs.

Article 92. Deadline for the issue of the certificate

Within two (2) working days as from the date of filing the application by the requesting party, DIGESA shall review the file and, if complete, shall issue the corresponding Official Export Health Certificate.

Article 93. Determination of the health suitability of shellfish farming or harvesting areas

The determination of the sanitary suitability of the areas of shellfish farming, extraction or harvesting shall be carried out by DIGESA, following a request by a party, who will submit the corresponding sanitary evaluation report issued by the Ministry of Fisheries.

The Ministry of Fisheries shall verify once a year, or whenever there is reasonable evidence of contamination of the water or its nutrients, whether sanitary standards compatible with the qualification are maintained. The results of such verification must be communicated to DIGESA in good time for the relevant purposes.

The costs of the health assessment and the verification of health fitness referred to in this provision shall be borne by the interested party.

Article 94. Factory sanitary qualification

Only exceptionally and at the request of a party, DIGESA will carry out the health clearance of food and beverage factories.

Article 95. Qualification concept

Qualification is the process to verify the establishment meets all the sanitary requirements and conditions indicated for the manufacture of export products.

Article 96. Request for factory qualification

To obtain the factory sanitary authorization, the interested party must apply to DIGESA and provide the following information:

a) Name or company name of manufacturer.

b) Factory location.

c) Name and brand of the product(s) for which the authorization is requested.

d) Descriptive report of the product's manufacturing process.

e) Factory HACCP Plan for the product(s) to be evaluated.

f) Names and signatures of the applicant and quality control official.

Article 97. Authorization processing and issuing

Within five (5) working days from the date of receipt of the application, DIGESA shall visit the factory to perform the hygiene and sanitary, and operational assessment. The inspection must verify:

a) If the factory meets all the requirements established in Title IV of these regulations and health standards corresponding to the product(s) it manufactures.

Whether the factory is effectively enforcing its HACCP Plan procedures in the manufacturing process for the product(s) for which authorization is requested.

If the factory meets the aforementioned requirements, DIGESA shall provide the corresponding authorization within three (3) working days after the inspection.

Article 98. Inspection of authorized factories

DIGESA shall carry out six-monthly inspections at authorized factories to verify standards compatible with the authorization.

Without prejudice to the application of health measures and penalties, if the factory does not maintain standards compatible with the qualification, the authorization shall be suspended until the factory corrects the observed deficiencies.

Any suspension longer than six (6) months shall result in the cancellation of the qualification.

Article 99. Cost of assessment

The costs demanded of DIGESA by the assessment and inspection of the requesting factories shall be borne by the interested party.

Article 100. Information on areas of extraction or harvesting and farming of qualified shellfish and qualified factories

DIGESA shall provide importing countries that so require an updated list of extraction or harvesting and farming areas for qualified seafood and factories authorized to export, as well as any suspensions and cancellations.

TITLE VIII

HEALTH REGISTRATION OF INDUSTRIAL FOOD AND B EVERAGES

CHAPTER I

Registration

Article 101. Health Registration Authority

The General Directorate of Environmental Health (DIGESA) of the Ministry of Health is the body responsible at the national level for registering, re-registering, modifying, suspending, and cancelling the Health Registry for food and beverages and carrying out health surveillance of the products subject to registration.

Article 102. Mandatory health registration

Only industrialized food and beverages marketed in the country are subject to health registration.

For the purposes of the Health Registry, industrialized food or beverages are those final products intended for human consumption, obtained by physical, chemical or biological transformation of inputs of plant, animal, or mineral origin and containing food additives.

Article 103. Food and beverages that do not require a health registry are:

a) Food and beverages in their natural state, whether or not they are packaged for marketing, such as grains, fruit, vegetables, meat, and eggs, among others.

b) Samples with no commercial value.

c) Products donated by foreign entities for charitable purposes.

Article 104. Powers and obligations derived from the Health Registry

Obtaining the Health Registration of a product authorizes its manufacture or import and marketing by the holder of the registration, under the conditions established in this regulation. The holder of the health registration is responsible for the sanitary quality and safety of the food or beverage it releases for marketing.

The health registration is granted for each product or group of products and manufacturer. A group of products comprises those produced by the same manufacturer, which have the same qualitative composition of basic ingredients that identifies the group and which share the same food additives.

Article 105. Affidavit for health registration

For registration or re-registration in the Health Registry, an affidavit application must be presented signed by the interested party, in which the following information must be included:

a) Name or company name, address and Unified Registration number of the natural or legal person applying for registration.

b) Name and brand of the product or group of products for which the Health Registration is requested.

c) Name or company name, address and country of the manufacturer

d) Results of the physical-chemical and microbiological analysis of the finished product, processed by the factory's quality control laboratory or by an accredited laboratory in Peru.

e) List of ingredients and quantitative composition of the additives, identifying the latter by their generic name and their international numerical reference.

f) Conservation and storage conditions.

g) Data on the packaging used, considering type and material.

h) Shelf life of the product under normal conditions of conservation and storage.

i) Production batch identification system.

j) If it is a food or drink for special diets, its nutritional properties should be stated.

Attached to the application must be the Certificate of Free Marketing and the Certificate of Use if the product is imported, as well as proof of payment for registration.

Article 106. Codification of the Health Registry

The codification of the Health Registry shall be done as follows:

RSA 000N (National Food Health Registry 000) for a national product.

RSA 000E (Foreign Food Health Registration 000) for and imported product.

Article 107. Processing of the request for Health Registration

The application for registration or re-registration of products in the Health Registry will be admitted for processing, provided that the file meets the requirements set forth by the law and these regulations.

Within the period of seven (7) working days referred to in Article 92 of the General Health Law, DIGESA may refuse to issue the document accrediting the registration on the grounds set out in paragraphs a), b), c) and d) of Article 111 under these regulations. If so, the application for registration submitted shall cease to have legal effect. The pronouncement of DIGESA must be recorded in a duly reasoned resolution, which must be notified to the customs agency of Peru for the relevant purposes.

The good's sanitary quality is verified after registration or re-registration in the Health Registry, pursuant to the corresponding regulations.

Article 108. Validity of the Health Registration

The Food and Beverage Sanitary Registration is valid for five (5) years, as from the date of its granting.

It may be renewed upon application for re-registration submitted by the holder of the registration between sixty (60) and seven (7) working days before the expiry date. The registration of the products whose re-registration is not requested before seven (7) days, expires automatically at the expiration of the period for which it was granted. Any application submitted after this period shall be processed as a new Health Registration.

Re-registration in the Health Registry is subject to the same conditions, requirements and deadlines established for registration. The validity of the re-registration shall be counted from the date of expiry of the registration whose renewal is requested.

If there is a stock of the product on the market whose registration has expired without its renewal having been requested, these must be withdrawn from the market by the registration within ninety (90) calendar days, on expiry of which its confiscation shall be ordered and the public shall be informed that the product does not have a Registration.

Article 109. Modifications to the health registration

Any modification or change in the data and conditions under which the health registration was granted to a product or group of products, must be reported in writing to DIGESA, at least seven (7) working days before it is carried out, together with substantiating information.

Article 110. Suspension of health registration

DIGESA may suspend a product's health registration until its holder changes the product's composition and/or packaging, as appropriate, when:

a) The Codex Alimentarius Commission reports an additive or its use concentration levels are harmful to health.

b) The United States Food and Drug Administration (FDA) or other internationally recognized body issues information that determines the packaging material is harmful to health.

Article 111. Cancellation of the health registration

The health registration of a product can be cancelled at any time when:

a) Any adulteration or falsification is detected in the reports, documents or information presented at the time of applying for health registration .

b) Objections are made on the documentation and technical information submitted when applying for health registration, provided that these are not corrected by the concerned party within thirty (30) calendar days, as from DIGESA's notification of such objections.

c) Prohibited food additives are added to the product or are allowed to exceed the maximum limits.

d) Prohibited packaging materials are used.

e) Objections are made on the documentation and technical information filed when applying for health registration, provided that these are not corrected by the concerned party within thirty (30) calendar days, as from DIGESA's notification of such objections.

Article 112. Transfer of health registration

Health registration granted to a product may only be transferred by its holder to a different person, if the latter is duly incorporated in Peru as a manufacturing or importing company.

Article 113. Certificates of Free Trade and Use

DIGESA shall keep an updated list by country of the competent authorities that may the Certificate of Free Trade and the Certificate of Use, and shall make it available to the public on a regular basis.

The Certificate of Free Trade or the Certificate of Use issued by an authority other than the any of those listed above shall be considered valid, provided that it is endorsed by the Peruvian consulate in the foreign country, or an office acting as such, which will accredit the issuer is a competent authority pursuant to the provisions in force in the foreign country. The same provision shall apply if the aforementioned list does not identify the competent authority to issue it.

The Certificate of Use will be considered to have been submitted when:

a) DIGESA has official information indicating that the certificate is not issued in the manufacturing country or in the exporting country.

b) The person requesting health registration of a product certifies the manufacturing or exporting country does not issue such certification, by presenting the necessary documents to that effect.

Article 114. Import of registered food and beverages

A registered food or beverage may be imported and sold by someone who is not the holder of the health registration. To this end, DIGESA shall issue the interested party with a Health Registration Certificate for the imported product.

Anyone who imports and markets a product, covered by an Imported Product Health Registration Certificate, have the same obligations and responsibilities as the holder of the registration, with regard to the health quality and safety of the product. In this case, the name or business name, address and Single Registration of the importer must be printed or labelled on each consumer sales package.

The Health Registration Certificate of the imported product shall be issued within seven (7) working days of the application to DIGESA and shall have the same expiry date as the health registration of the corresponding product.

The interested party must indicate in their application:

a) Purpose of the request.

b) Health registration number of the product being applied for.

c) Name or corporate name, address and Single Registry of the applicant.

It must also be accompanied by proof of payment for certificate fees.

Article 115. Validity of foreign documents

Documents issued abroad must be no older than one (1) year from the date of issue and must be accompanied by their respective Spanish translation.

CHAPTER II

Labelling

Article 116. Labelling

For marketing, all food and beverages must be labelled in accordance with the provisions of this regulation.

Article 117. Contents of labelling

Labelling must comply with the provisions established by the Peruvian Metrological Standard for Labelling of Packaged Products and show at least:

a) Name of product.

b) List ingredients and additives used in preparing the product.

c) Name and address of manufacturer.

d) Name, company name and address of importer, which may appear on an additional label.

e) Sanitary Registration Number.

f) Expiry date, when required by the product in accordance with the Codex Alimentarius or the applicable Peruvian sanitary standard .

g) Batch code or key.

h) Special conservation conditions, if the product so requires.

CHAPTER III

Packaging

Article 118. Packaging conditions

The product's packaging must be made of harmless material, free from substances that can be transferred to the product and affect its safety, and manufactured so as to maintain the health quality and composition of the product throughout its life.

Article 119. Packaging materials

Packaging, which is made of metal, metal alloy or plastic

materials, where applicable, may not:

a) Contain impurities consisting of lead, antimony, zinc, copper, chrome, iron, tin, mercury, cadmium, arsenic or other metals or metalloids that may be considered harmful to health, in quantities or at levels exceeding the maximum permitted limits.

b) Contain residual monomers of styrene, vinyl chloride, acrylonitrile or any other residual monomer or substance which may be considered harmful to health, in quantities exceeding the maximum permitted limits.

The maximum permitted limits mentioned in points a) and b) above are set forth in the corresponding health regulation issued by the Ministry of Health.

This provision also applies, where appropriate, to laminates, varnishes, films, coatings or parts of packaging which come into contact with food and drink.

The use of packaging made from recycled paper, cardboard or second-hand plastic is prohibited.

TITLE IX

SECURITY MEASURES, INFRINGEMENTS AND PENALTIES

Article 120. Security measures

In application of the rules on monitoring the health quality and safety of food and beverages under this regulation, as well as the health rules and other mandatory provisions deriving therefrom, one or more of the following health security measures may be provided for:

a) Confiscation, seizure, transport, recall from the market and destruction of foodstuffs.

b) Temporary suspension of food and drink production and trade

activities.

c) Restriction of the transit of foodstuffs.

d) Temporary or permanent closure of all or part of the company's facilities.

e) Suspension of health registration.

f) Cancellation of health registration.

g) Other provisions laying down special rules on matters covered by Title III under this Regulation.

The Ministry of Agriculture is responsible for restricting the transit of animals, meat, and fresh agricultural products.

The health surveillance bodies shall apply the corresponding health safety measures in strict accordance with the criteria set out in Article 132 of the General Health Law.

Article 121. Infringements of health rules on the manufacture, fractioning, and storage of food and beverages and passenger food services in means of transport

The following are infringements of the health rules on the manufacture, fractioning and storage of food and beverages, and passenger food services in means of transport, as appropriate:

a) Failure to comply with the provisions relating to the location, construction, distribution and fitting out of establishments.

b) Lack of supply of potable water, and of appropriate sewage and solid waste disposal systems.

c) To manufacture products in unsuitable premises that result in deficient operations.

d) Failure to observe the rules of hygiene in the handling of food and beverages, and personnel cleanliness.

e) Failure to comply with the provisions relating to the cleaning up of the premises.

f) Failure to control the sanitary quality and safety of products.

g) Use of raw materials of poor sanitary quality, prohibited food additives or in concentrations above the maximum permitted limits and prohibited packaging material.

h) Impeding inspections.

i) To manufacture, store, fraction or distribute contaminated or adulterated products.

j) Fractioning products in breach of health regulations.

k) To store raw materials and finished products in unhygienic conditions.

l) To store and distribute products whose health registry has expired.

ll) Failure to comply with the provisions on the preparation of food and beverages for consumption by passengers in means of transport.

m) Failure to comply with other mandatory provisions set forth by these regulations and the health rules deriving from them.

Article 122. Infringements to the rules on food and beverages health registration

The following are infringements to the rules on the health registration of food and beverages:

a) To manufacture, store or market products without health registration.

b) To show on the labels of the containers a health registration number that does not correspond to the registered product.

c) To modify or change the data and conditions declared for obtaining the health Registration, without having reported such change in the form and conditions set out in these regulations.

d) Incorporating into the food or drink food additives that are prohibited or exceeding the maximum limits.

e) To use containers made of forbidden materials.

Article 123. Sanctions

Offenders as defined in Articles 121 and 122 of these regulations shall be subject to one or more of the following sanctions:

a) Warning.

b) Fine between an between one half (0.5) and one hundred (100) Tax Units.

c) Temporary closure of establishment.

d) Definitive closure of establishment.

e) Cancellation of health registration.

Sanctions shall be applied in strict accordance with the criteria set out in Article 135 of the General Health Law.

The definitive closure of the establishment entails the cancellation of any health registrations granted.

The scale of fines for each type of infringement is determined by resolution of the Minister of Health. The fine must be paid within a maximum of fifteen (15) working days from the day following notification of the penalty. In the event of non-compliance, the authority that imposed the fine shall order its legal collection pursuant to law.

Article 124. Cancellation of health registration

Without prejudice to the other sanctions which should be applied to the offending establishment, when the competent health surveillance body detects food or beverages containing prohibited or excess food additives, or whose containers are made of prohibited materials, it must notify DIGESA under its responsibility so that it may, if appropriate, cancel the health registration of the objected product(s).

Article 125. Infringements of rules on the production, transport, marketing, processing and sale of food and beverages.

The specific rules on the production, transport, marketing, processing and sale of food and beverages indicate the penalties that may be levied by the relevant supervisory bodies, in accordance with the provisions of this regulation and the health rules laid down therein.

SUPPLEMENTARY, TRANSITIONAL AND FINAL PROVISIONS

First. The Ministry of Health, by means of a ministerial resolution, may commission private entities, after evaluating their technical and administrative capabilities, to inspect the establishments and services it must oversee, and to conduct technical validation activities and periodic monitoring of the application of HACCP plans in food and beverage factories. The decentralized health units nationwide, to which the functions referred to in this provision have been delegated, may entrust the execution of the aforementioned activities to private entities authorized by the Ministry of Health.

Staff of the institutions retained for this purpose may not enforce health security measures or the penalties provided for in this regulation. If an infringement is detected or if the application of a health safety measure is required, the corresponding entity must immediately notify DIGESA or, where appropriate, the deconcentrated health unit competent to adopt the relevant measures.

Second. The Ministry of Health may arrange for audits to be conducted on the procedures followed by the private institutions referred to in the preceding provision, which shall be carried out in accordance with auditing standards issued by the Ministry of Health.

Third. For purposes of enforcing this regulation, account shall be taken of the definitions set out in the Annex "Definitions", which is an integral part of these legal provisions.

Fourth. By resolution of the Minister of Health, within one (1) year as from the effective date of these regulations, the health standards applicable to the manufacture of foodstuffs shall be issued, which shall define at least the following elements:

a) The characteristics of the respective product or group of products, including those of the raw materials used for their manufacture.

b) The conditions to be adhered to in manufacturing, including Good Manufacturing Practices.

c) Permitted food additives and maximum permitted concentrations.

d) Maximum allowed contaminants.

e) Applicable hygiene specifications.

f) Microbiological and physico-chemical criteria of sanitary quality and safety.

g) Sampling procedures.

h) Analytical determinations and applicable analysis methodologies.

i) The requirements to be met by industrial facilities.

Pending the issuance of the relevant standard, the manufacture of food and beverages is governed by the Codex Alimentarius standards applicable to the product(s) being manufactured and, to the extent not provided for therein, by the provisions of the United States Food and Drug Administration (FDA).

Fifth. Within two (2) months as from the coming into force of these regulations, the procedure for the application of the HACCP system in the manufacture of food and beverages shall be approved by a resolution of the Minister of Health.

Sixth. Food and beverage manufacturers have a maximum period of two (2) years, as from the coming into force of the health regulation applicable to the product(s) they manufacture, to prepare the HACCP plan and implement it in the manufacturing process.

They may apply the HACCP system in the manufacturing process of their products, in anticipation of the health standard mentioned in the preceding paragraph, subject to the standard governing the procedure for the application of HACCP in the manufacture of food and beverages and to the relevant Codex Alimentarius standards. In this case, the provisions of Articles 59 and 60 of these Regulations shall apply.

Seventh. The time limit referred to in the first paragraph of the sixth provision of this regulation does not apply to small and micro food businesses. Its incorporation into the HACCP system shall be done progressively, pursuant to special regulations, which will be approved by Supreme Decree endorsed by the Minister of Health and the Minister of Industry, Tourism, Integration and International Trade Negotiations. The provisions of this paragraph shall not exempt them from compliance with other provisions of these regulations applicable to them or from the health control of their activities by the competent surveillance body.

At the request of these companies, the Ministry of Health shall provide them with technical support and training for the preparation of HACCP plans, their technical validation and their enforcement in manufacturing their products, as well as their compliance with the general hygiene standards applicable to them.

For the purposes of this provision, small and micro enterprises are those so defined in Articles 1, 2 and 3 of Legislative Decree No. 705.

Eighth Food and beverage manufacturers, until they incorporate the HACCP system into the manufacture of their products, shall continue to carry out, as part of the process of health and safety quality control of the products they produce, analytical controls of each batch of product manufactured before it is released to markets.

The manufacturer must document the results of the tests referred to in this provision, and these results must be reviewed by the competent health surveillance body during the inspection.

The results of the analysis must include the following information:

a) Name of the factory or accredited laboratory.

b) Report number.

c) Name of product.

d) Code or key.

e) Physico-chemical and microbiological tests carried out and their findings.

f) Date of analysis.

g) Signatures of the head of quality control and the head of the laboratory.

Ninth. By Supreme Decree, the activities and services regulated by these regulations shall be determined and progressively incorporated into the application of the HACCP system, as well as the deadlines and procedures for its enforcement.

Tenth. The Ministry of Health shall publish the list of food additives referred to in Article 63 of these Regulations as well as the corresponding updates.

Eleventh. While there are not enough inspection bodies accredited by INDECOPI to inspect, sample and verify storage, packaging and packing for export conditions, referred to in points a) and b) of Article 89 under these regulations, technical experts technologists accredited by DIGESA may continue to carry out these functions. In this case, the interested party may retain the services of an inspection body accredited by INDECOPI or of any of the technical experts accredited by DIGESA.

A resolution of the Minister of Health may terminate the role of technical experts in the inspection, sampling and verification of storage, packing and packaging for export.

Twelfth. Until the health regulation on packaging materials referred to in Article 119 of these regulations is issued, that which is established by the Food and Drug Administration of the United States of America (FDA) or by another organization of recognized international prestige that is determined by Resolution of the Minister of Health shall apply.

Thirteenth. Within one (1) year from the effective date of these regulations, the following provisions shall be issued by resolution of the Minister of Health:

a) Manual of Procedures for the Issuance of the Official Health Certificate for the Export of Food and Beverages and the Approval of Establishments for Export.

b) Maximum allowed impurities and waste substances in packaging materials.

c) Health standard for the operation of collective and school food services.

d) Health standard for passenger food services in means of transport.

e) Sanitary standard for the operation of warehouses, food and beverage collection and distribution centers.

f) Sanitary standard for the operation of food and beverage fractioning and packaging establishments.

g) Sanitary regulations for the operation of supply markets, self-service stores, market fairs, and warehouses.

h) Health regulations for the operation of restaurants and related services.

i) Health standard for the immobilization, seizure, confiscation and final disposal of food and beverages unfit for human consumption.

Guide to procedures for the inspection and sampling of products in establishments for the manufacture, storage, fractioning and packaging of food and drink and passenger food services in means of transport.

j) Good Food and Beverage Handling Practices.

Fourteenth. Within six (6) months as from the effective date of these regulations, the Ministry of Agriculture shall issue the rules on

Good Agricultural Practices, Good Livestock Practices and Good Poultry Practices. It shall also issue the regulation for the production, transport, processing and marketing of dairy products.

Within the same period, the Ministry of Fisheries shall issue, in coordination with the Ministry of Health, the health rules governing the capture and/or extraction, transport, industrialization and marketing of hydro-biological products, including those from aquaculture activities.

Fifteenth. The National Codex Alimentarius Committee shall be created as an cross-agency coordination body responsible for the periodic review of food health and safety standards, with the aim of proposing their harmonization with applicable international standards.

The National Codex Alimentarius Committee will be made up of a representative of the Ministry of Health, who will chair it, as well as a representative of each of the following bodies: Ministry of Agriculture, Ministry of Fisheries, Ministry of Economy and Finance, Ministry of Industry, Tourism, Integration and International Commercial Negotiations, Ministry of Foreign Affairs, National Institute for the Defense of Competition and Protection of Intellectual Property (INDECOPI, by its acronym in Spanish), and the Export Promotion Commission (PROMPEX, by its acronym in Spanish).

To carry out its functions, the National Codex Alimentarius Committee shall set up technical commissions involving the private sector, the Peruvian university system and renowned professional experts.

Within sixty (60) days as from the effective date of this Supreme Decree, the rules of operation of this committee shall be approved by resolution of the Minister of Health.

Sixteenth. The following provisions are hereby repealed:

a) Supreme Decree dated March 4, 1966, referring to the control of crown cap factories.

b) Ministerial Resolution No. 0179-83-SA/DVM dated 18 August 1983 concerning the list of artificial colorings.

c) Ministerial Resolution No 0262-83-SA/DVM dated 22 November 1983 on the acceptable daily intake of artificial sweeteners used in the manufacture of products for dietary use.

d) Ministerial Resolution No. 0026-84-SA/DVM dated 14 February 1984 approving the health rules governing low erucic acid rapeseed oil intended for human consumption.

e) Ministerial Resolution No. 0034-84-SA/DVM dated 29 February 1984 on the use of titanium dioxide.

f) Vice-Ministerial Resolution No. 0140-86-SA-DVM dated 24 October 1986, concerning health surveillance of roadside restaurants.

g) Supreme Decree No. 026-88-SA of 18 October 1988 on income generated by food protection activities.

h) Vice-Ministerial Resolution No. 0023-89-SA-DVM, dated 2 March 1989, approving the procedural guidelines for the granting of health passes and permits.

i) Directorial Resolution No. 046-89-DITESA/SA, dated 28 March 1989, referring to the collection of revenues as set forth by D.S. No. 026-88-SA.

j) Supreme Decree No. 001-97-SA, dated 14 May 1997, approving the Sanitary Regulation of Food and Beverages for Human Consumption.

k) Ministerial Resolution No. 519-97-SA/DM, dated 13 November 1997, concerning the official health certification of food and beverages for human consumption intended for export.

l) Ministerial Resolution No. 535-97-SA/DM dated 28 November 1997 on the General Principles of Food Hygiene

ll) Other provisions which oppose this regulation.

Once the health rules referred to in subparagraphs c), d), i) of the Thirteenth Provision of these regulations have been issued, the following provisions shall be repealed:

a) Supreme Resolution No. 0019-81-SA/DVM, dated 17 September 1981, approving the rules for the establishment and operation of collective food services.

b) Supreme Decree No. 026-87-SA, dated June 4, 1987, which approves the Regulations for the Hygienic and Sanitary Operation of School Kiosks.

c) Supreme Decree No. 012-77-SA, dated 13 October 1977, approving the Regulations on Water and Food Safety and Waste Treatment in National and International Transport

d) Supreme Decree No. 19-86-SA of 10 July 1986 on procedures for the classification of foodstuffs unfit for human consumption, belonging to food aid programs and agencies.

e) Ministerial Resolution No 0726-92-SA/DM of 30 November 1992 on prepared foodstuffs for passenger consumption.

Seventeenth. This regulation shall come into full force and effect from the day following its publication.

ANNEX

Definitions

1. Inspection report: Document containing the main aspects considered in the inspection and the results of same, including the deficiencies to be corrected within defined deadlines.

2. Food or beverage: Any substance or mixture of substances intended for human consumption, including alcoholic beverages.

3. Food or beverages for special diets: Product specially processed or prepared to meet particular nutritional needs determined by specific physical, physiological or metabolic conditions. Its composition must be substantially different from that of ordinary foods of a similar nature where such foods exist.

4. Food additive: A substance added to food and beverages to improve their organoleptic characteristics and their storage conditions.

5. Good Manufacturing Practices (GMP): A set of good practices, the observance of which will ensure the sanitary quality and safety of food and beverages.

6. Sanitary quality: Set of microbiological, physical, chemical and organoleptic requirements that a food must to be considered safe for human consumption.

7. Certificate of Free Commercialization: Official document issued by a competent authority certifying that the product is sold freely in the manufacturing or exporting country.

8. Codex Alimentarius: Joint FAO/WHO Food Standards Program, consisting of a collection of food standards aimed at protecting consumer health and ensuring fair food trade practices.

9. Condemning: Process for the destruction or de-naturing of products unfit for consumption and available in a sanitary manner.

10. Damage to health: Presentation of signs, symptoms, syndromes or diseases attributable to the consumption of contaminated, altered or adulterated food or beverages.

11. Packaging: Any cover or structure intended to contain one or more units of a packaged product.

12. Container: Any container or wrapping that contains and is in contact with food and beverages for human consumption or its ingredients.

13. Stowage: Convenient arrangement of products in a warehouse, cold room or refrigerator, in the transport vehicle.

14. Food and beverage factory: An establishment where raw materials of vegetable, animal or mineral origin are industrially processed using physical, chemical or biological processes to obtain food or beverages for human consumption, regardless of the volume of production or the technology employed.

15. Safety: Absence of risk to human health.
16. LUX: Lighting unit of measurement.
17. Seafood: Any edible invertebrate animal that has its natural habitat in the water. It includes mollusks, crustaceans, echinoderms and tunicates, among others.
18. Raw material: Any input used in the manufacture of food and beverages, excluding food additives.
19. Mycotoxins: Substances generated by certain strains of fungi, whose ingestion has toxic effects on humans and animals.
20. Country of origin: Country where the product is manufactured.
21. Healthcare quality parameters: Analytical determinations that define the minimum level of sanitary quality of a food or industrialized product.
22. Hazard: A biological, chemical, or physical agent in or on food or beverages that may cause an adverse health effect.
23. HACCP Plan: A document prepared in accordance with HACCP standards to ensure the control of hazards that are important for food safety in the food chain segment under consideration.
24. Final product: Finished product, packaged or unpackaged, ready for consumption.
25. Critical Control Point: Phase, stage, or section at which a control must be applied to prevent, deter, eliminate, or reduce to acceptable levels a food or beverage's safety hazard
26. Labelling: All information relating to the product that is printed or attached to its packaging or accompanies it. Advertising copy is not considered labelling.
27. HACCP system (Hazard Analysis and Critical Control Points system): A system to identify, evaluate and control hazards that are important for food safety. It privileges the control of the process over the analysis of the final product.
28. Health surveillance: A set of observation and assessment activities carried out by the competent authority on the health conditions of the production, transport, manufacture, storage, distribution, processing, and sale of food aimed at protecting health.