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[ REPUBLIC ACT NO. 10611 ]

AN ACT TO STRENGTHEN THE FOOD SAFETY REGULATORY SYSTEM IN THE COUNTRY TO PROTECT CONSUMER HEALTH AND FACILITATE MARKET ACCESS OF LOCAL FOODS AND FOOD PRODUCTS, AND FOR OTHER PURPOSES

*Be it enacted by the Senate and House of Representatives of the Philippines in Congress assembled:*

ARTICLE I

DECLARATION OF POLICY AND OBJECTIVES

SECTION 1. *Short Title.* - This Act shall be known as the "Food Safety Act of 2013".

SEC. 2. *Declaration of Policy.* - Section 15, Article II of the 1987 Philippine Constitution declares that the State shall protect and promote the right to health of the people and

instil health consciousness among them. Furthermore, Section 9, Article XVI provides that the State shall protect consumers from trade malpractices and from substandard or hazardous products. Toward these ends, the State shall maintain a firm to fork food safety regulatory system that ensures a high level of food safety, promotes fair trade and advances the global competitiveness of Philippine foods and food products.

SEC. 3. *Objectives.* – To strengthen the food safety regulatory system in the country, the State shall adopt the following specific objectives:

(a) Protect the public from food-borne and water-borne illnesses and unsanitary, unwholesome, misbranded or adulterated foods;

(b) Enhance industry and consumer confidence in the food regulatory system; and

(c) Achieve economic growth and development by promoting fair trade practices and sound regulatory foundation for domestic and international trade.

Towards the attainment of these objectives, the following measures shall be implemented:

(1) Delineate and link the mandates and responsibilities of the government agencies involved;

(2) Provide a mechanism for coordination and accountability in the implementation of regulatory functions;

(3) Establish policies and programs for addressing food safety hazards and developing appropriate standards and control measures;

(4) Strengthen the scientific basis of the regulatory system; and

(5) Upgrade the capability of farmers, fisherfolk, industries, consumers and government personnel in ensuring food safety.

## ARTICLE II DEFINITION OF TERMS

SEC. 4. *Definition of Terms.* – For purposes of this Act, the following terms shall be defined as follows:

(a) *Advertising* refers to the business of conceptualizing, presenting or making available to the public, through any form of mass media, fact, data or information about the attributes, features, quality or availability of food and its related products for the purpose of promoting its sale or distribution and enhancing economic activity.

(b) *Adulteration* refers to an act which leads to the production of food which:

(1) Bears or contains any poisonous or deleterious substance that may render it injurious to the health of the public;

(2) Bears or contains any added poisonous or deleterious substance in amounts exceeding established maximum limits or standards for good manufacturing practice;

(3) Contains in whole or in part filthy, putrid or decomposed substance that is unfit for human consumption;

(4) Has been prepared, packed or held under unsanitary conditions;

(5) In whole or in part, is the product of a diseased animal or an animal which has died through ways other than slaughter;

(6) Is in a container having in whole or in part any poisonous or deleterious substance;

(7) Has been intentionally subjected to radiation unless the use of radiation is in conformity with an existing regulation or exemption;

(8) Becomes injurious to health because of the omission or abstraction of a valuable constituent; or if any substance has been substituted wholly or in part; or if damaged or made

inferior which has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight or reduce its strength or to make it appear better or greater than it is;

(9) Has not been prepared in accordance with current acceptable manufacturing practice as promulgated by way of regulation; and

(10) Uses expired ingredients.

(c) *Authorization* refers to the permission embodied in a document granted by a regulatory agency to a natural or juridical person who has submitted an application for a food business operation from primary production, post harvest handling, distribution, processing, manufacture, importation, exportation, sale, and offer for sale, distribution, transfer and preparation for human consumption. The authorization can take the form of a permit, license, certificate of registration and certificate of compliance or exemption or any similar document.

(d) *Contaminant* refers to any substance not intentionally added to food which is present in such food as a result of the production (including operations carried out in crop industry, animal husbandry and veterinary medicine) post harvest handling, manufacturing, processing, preparation, treatment, packing, packaging, transport or holding of such food as a result of environmental contamination.

(e) *Control measure* refers to any action and activity that can be used to prevent or eliminate food safety hazard or to reduce it to an acceptable level.

(f) *Crisis management* refers to a proactive approach of addressing a situation, where a risk to consumers, animal or plant health cannot be controlled by normal existing mechanisms, through a plan which can be activated when such emergency arises.

(g) *Food* refers to any substance or product whether processed, partially processed or unprocessed that is intended for human consumption. It includes drinks, chewing gum, water and other substances which are intentionally incorporated into the food during its manufacture, preparation and treatment.

(h) *Feed* refers to any substance or product, including additives, intended to be used for oral feeding to animals.

(i) *Food-borne illnesses* refer to diseases, usually either infectious or toxic in nature, caused by agents that enter the body through the ingestion of food.

(j) *Food business* refers to any undertaking, whether public or private, that carries out any of the activities related to, or any of the stages of the food supply chain.

(k) *Food business operator* refers to a person engaged in the food business including one's agents and is responsible for ensuring that the requirements of this Act are met by the food business under one's control.

(l) *Food hygiene* (hereinafter referred to as hygiene) refers to the measures and conditions necessary to control hazards that could lead to food-borne illnesses and to ensure fitness for human consumption of a food of plant or animal origin taking into account its intended use.

(m) *Food law* refers to the laws, regulations and administrative provisions governing food in general, donated food and food safety at any stage of production, processing, distribution and preparation for human consumption.

(n) *Food safety* refers to the assurance that food will not cause harm to the consumer when it is prepared or eaten according to its intended use.

(o) *Food safety regulatory agencies (FSRAs)* refer to the following national government agencies:

Under the Department of Agriculture (DA) – the Bureau of Animal Industry, the National Meat Inspection Service, the Bureau of Fisheries and Aquatic Resources, the Bureau of Plant Industry, the Fertilizer and Pesticide Authority, the Philippine Coconut Authority, the Sugar Regulatory Administration and the National Food Authority.

Under the Department of Health (DOH) – the Food and Drug Administration, the Center for Food Regulation and Research and the Bureau of Quarantine.

(p) *Food safety officer* refers to a professionally qualified and properly trained officer appointed by a food safety regulatory agency or by local government units (LGUs) in accordance with the appropriate civil service rules and regulations.

(q) *Food safety regulatory system* refers to the combination of regulations, food safety standards, inspection, testing, data collection, monitoring and other activities carried out by food safety regulatory agencies and by the LGUs in the implementation of their responsibilities for the control of food safety risks in the food supply chain.

(r) *Food supply chain* refers to all stages in the production of food from primary production, post harvest handling, distribution, processing and preparation for human consumption. Preparation is the cooking or other treatments to which food is subjected prior to its consumption.

(s) *Good agricultural practices (GAP)* refer to the practices that address environmental, economic and social sustainability for on-farm processes, and which result in safe and quality food and nonfood agricultural products.

(t) *Good manufacturing practices* refer to a quality assurance system aimed at ensuring that products are consistently manufactured, packed, repacked or held to quality standards appropriate for the intended use. It is thus concerned with both manufacturing and quality control procedure.

(u) *Good hygienic practices* refer to all practices regarding the conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain.

(v) *Hazard Analyses at Critical Control Points (HACCP)* refer to a science-based system which identifies, evaluates and controls hazards which are significant for food safety at critical points during a given stage in the food supply chain.

(w) *Hazard* refers to a biological, chemical or physical agent in food with a potential to cause adverse effect on health.

(x) *Inspection* refers to the examination of food, food production facilities or establishments, and the management

and production systems of food businesses, including the examination of documents, finished product testing and registration, and of the origin and destination of production inputs and outputs to verify compliance with legal requirements by an agency mandated to perform food safety regulatory and/or enforcement functions.

(y) *Label* refers to the display of written, printed or graphic matter upon the immediate container, tag, literature or other suitable material affixed thereto for the purpose of giving information as to identify components, ingredients, attributes, directions for use, specifications and such other information as may be required by law or regulations.

(z) *Micro, small and medium enterprise (MSME)* refers to food businesses as defined within the classification of industries by the Department of Trade and Industry (DTI).

(aa) *Misbranding* refers to deliberate labelling or advertising of food that is misleading, where the labelling and/or advertising claims certain food properties that cannot be supported by a reliable source, a certifying body or by scientific evidence.

(bb) *Official control* refers to all types of controls and control activities made by regulatory agencies to verify compliance with standards, operating procedures, practices and other regulatory requirements. It includes routine monitoring of food establishments and more intensive checks involving inspections, verifications, audits, sampling and testing of samples and recall of defective products.

(cc) *Person* refers to any person, natural or juridical including, but not limited to, the following persons: (i) food business operators; and (ii) food safety officers and other regulatory personnel of the DA, the DOH and the Department of the Interior and Local Government (DILG).

(dd) *Post harvest stages* refer to the stages in the food supply chain involving the minimal transformation of plant and animal foods after primary production such as removal of field heat for fruits, slaughter of animals, sorting, grading and cutting of fresh plant and animal foods, icing and freezing, and the milling and storage of grain.

(ee) *Primary production* refers to the production, rearing or growing of primary products including harvesting, milking and farmed animal production up to slaughter; and the rearing and growing of fish and other seafood in aquaculture ponds. It also includes fishing, and the hunting and catching of wild products.

(ff) *Processing* refers to any action that substantially alters the initial raw materials or product or ingredients including, but not limited to, heating, smoking, curing, maturing, drying, marinating, extraction, extrusion and a combination of those processes intended to produce food.

(gg) *Risk* refers to the likelihood of an adverse health effect and the severity of this effect following exposure to a hazard.

(hh) *Risk analysis* refers to a process consisting of three (3) interrelated components: risk assessment, risk management and risk communication.

(ii) *Risk assessment* refers to the scientific evaluation of known or potential adverse health effects resulting from human exposure to biological, chemical and physical hazards.

(jj) *Risk management* refers to the process of weighing policy alternatives to accept, minimize or reduce assessed risks and if necessary, to select and implement appropriate prevention and control measures.

(kk) *Risk communication* refers to the interactive exchange of information and opinions during the course of risk analysis on the hazards and risks among risk assessors, risk managers, consumers, food and feed business operators, academia and other stakeholders.

(ll) *Food safety standards* refer to the formal documents containing the requirements that foods or food processors have to comply with to safeguard human health. They are implemented by authorities and enforced by law; and are usually developed and published under the auspices of a national standards body.

(mm) *Traceability* refers to the ability to follow the movement of a food through specified stages of production, processing and distribution.

(nn) *Monitoring* refers to the systematic gathering of data through the sampling of commodities as well as monitoring of food-borne diseases, collation and interpretation of collected data.

### ARTICLE III

#### BASIC PRINCIPLES OF FOOD SAFETY

SEC. 5. *Food Safety Requirements.* – To ensure food safety, the following general guidelines shall be observed:

(a) In determining whether food is unsafe, the following shall be considered:

(1) The normal conditions of the use of food by the consumer;

(2) The normal conditions maintained at each stage of primary production, processing, handling, storage and distribution;

(3) The health of plants and animals from where the food is derived;

(4) The effect of feeds, crop protection chemicals and other production inputs on otherwise healthy plants and animals; and

(5) The information provided to the consumer. This includes the information provided on the label or any information generally available to the consumer. This should aid consumers in avoiding specific health effects from a particular food or category of foods.

(b) In determining whether food is injurious to health, regard shall be given to the following:

(1) The probable immediate, short-term or long-term effects on subsequent generations of that food on health;

(2) The probable cumulative effects; and

(3) The particular health sensitivities of a specific category of consumers where the food is intended for that category.

(c) In determining whether food is unfit for human consumption, regard shall be given to the unacceptability of the food according to its intended use due to contamination by extraneous matter or through putrefaction, deterioration or decay;

(d) Where unsafe food is part of a batch, lot or consignment of food of the same class or description, it shall be presumed that all food in that batch, lot or consignment is also unsafe;

(e) Food that complies with specific national law or regulations governing food safety shall be deemed safe insofar as the aspects covered by national law and regulations are concerned. However, imported food that is declared unsafe by the competent authority of the exporting country after entry into the country shall be withdrawn from the market and distribution channels; and

(f) Compliance of a food product with specific standards applicable to a specific food shall not prohibit the competent authorities to take appropriate measures or to impose restrictions on entry into the market or to require its withdrawal from the market, where there is reason to suspect that such food product shows food safety related risks.

#### ARTICLE IV

##### GENERAL PRINCIPLES

SEC. 6. *Food Law Objectives.* – Food law shall aim for a high level of food safety, protection of human life and health in the production and consumption of food. It shall also aim for the protection of consumer interests through fair practices in the food trade.

SEC. 7. *Use of Science-based Risk Analysis.* – The following shall guide the use of science and risk analysis in food safety regulation:

(a) The development of food safety legislation and standards and the conduct of inspection and other official control activities shall be based on the analysis of risk, except where this approach is not feasible due to circumstances, or due to the nature of the control measure;

(b) Risk assessment shall be based on sound scientific evidence and shall be undertaken in an independent, objective and transparent manner. Scientific information as obtained from scientific literature, epidemiological and monitoring studies and other data that supports the risk assessment shall be used;

(c) Risk management shall take into account the results of risk assessment relevant to local conditions, potential for enforcement, cost of compliance and others as may be relevant to the situation;

(d) Risk communication shall be carried out between risk assessors and risk managers in a transparent manner. Food safety risks shall also be communicated to farmers, fisherfolk and food business operators to encourage compliance with the implementation of control measures and to relevant sectors of society affected by the law or the risks addressed in order to strengthen confidence in its provisions; and

(e) Food business operators shall be encouraged to implement a HACCP-based system for food safety assurance in their operations.

SEC. 8. *Protection of Consumer Interests.* – The protection of consumer interest shall be geared towards the following:

(a) Prevention of adulteration, misbranding, fraudulent practices and other practices which mislead the consumer; and

(b) Prevention of misrepresentation in the labelling and false advertising in the presentation of food, including their shape, appearance or packaging, the packaging materials used, the manner in which they are arranged, the setting in which they are displayed, and the product description including the information which is made available about them through whatever medium. Where relevant, the presentation of goods shall provide consumers a basis to make informed choices in relation to the food they purchase.

SEC. 9. *Setting of Food Safety Standards.* – The DA and the DOH shall set the mandatory food safety standards. The following shall guide the setting of standards:

(a) Standards shall be established on the basis of science, risk analysis, scientific advice from expert body/bodies, standards of other countries, existing Philippine National Standards (PNS) and the standards of the Codex Alimentarius Commission (Codex), where these exist and are applicable;

(b) Codex standards shall be adopted except when these are in conflict with what is necessary to protect consumers and scientific justification exists for the action taken;

(c) The DA and the DOH shall establish the policies and procedures for country participation at Codex and the incorporation of Codex standards into national regulations. The current National Codex Organization (NCO) is herein designated as the Body to serve this purpose. The DA and the DOH shall designate a third level officer as coordinator for Codex activities for their respective departments; and

(d) Participation at Codex shall be in accordance with the principles of this Act and shall be financially supported by the government.

SEC. 10. *Precaution.* – In specific circumstances when the available relevant information for use in risk assessment is insufficient to show that a certain type of food or food product does not pose a risk to consumer health, precautionary measures shall be adopted. When such precautionary measures are issued, the following rules shall govern:

(a) The adopted measure shall remain enforced pending the submission of additional scientific information based on the nature of the risk and type of information needed to clarify the scientific uncertainty; and

(b) The measure shall be no more restrictive to trade than required and should be proportionate to the level of protection required for consumers.

SEC. 11. *Transparency.* – The implementing agencies shall conduct public consultation and disseminate relevant information to ensure the following:

(a) Public consultation during the preparation, evaluation and revision of food legislation shall be open, transparent and direct or through representative bodies unless the urgency of the problem does not allow it; and

(b) In cases where it is suspected that food may pose a risk to human health, regulatory authorities shall take appropriate steps to inform the general public about the nature of the risk to health, the affected foods, types of food and the necessary measures to prevent, reduce or eliminate the risk.

SEC. 12. *Application to Trade.* – Foods imported, produced, processed and distributed for domestic and export markets shall comply with the following requirements:

(a) Food to be imported into the country must come from countries with an equivalent food safety regulatory system and shall comply with international agreements to which the Philippines is a party;

(b) Imported foods shall undergo cargo inspection and clearance procedures by the DA and the DOH at the first port of entry to determine compliance with national regulations. This inspection by the DA and the DOH shall always take place prior to assessment for tariff and other charges by the Bureau of Customs (BOC). The BOC and the Association of International Shipping Lines (AISL) shall provide the DA and the DOH documents such as the Inward Foreign Manifest of Arriving Vessels to enable the DA and the DOH to identify shipments requiring food safety inspection. Shipments not complying with national regulations shall be disposed according to policies established by the DA and the DOH; and

(c) Exported foods shall at all times comply with national regulations and regulations of the importing country. Returned shipments shall undergo border inspection clearance as provided in Section 12(b) hereof.

## ARTICLE V

### RESPONSIBILITIES ON FOOD SAFETY

SEC. 13. *Principal Responsibility of Food Business Operators.* – Food business operators shall ensure that food satisfies the requirements of food law relevant to their activities in the food supply chain and that control systems are in place to prevent, eliminate or reduce risks to consumers.

supermarkets, school canteens, restaurants, catering establishments and water refilling stations. The LGU shall also be responsible for street food sale, including ambulant vending;

(d) The DILG, in collaboration with the DA, the DOH and other government agencies shall supervise the enforcement of food safety and sanitary rules and regulations as well as the inspection and compliance of business establishments and facilities within its territorial jurisdiction;

(e) The LGUs may be called upon by the DOH and the DA to assist in the implementation of food laws, other relevant regulations and those that will hereafter be issued;

(f) The DA and the DOH shall capacitate the LGUs and provide necessary technical assistance in the implementation of their food safety functions under their jurisdiction. In compliance with this responsibility, they shall provide training to the DILG and the LGUs and shall periodically assess the effectiveness of these training programs in coordination with the DILG; and

(g) The DA and the DOH, in cooperation with the LGUs, shall monitor the presence of biological, chemical and physical contaminants in food to determine the nature and sources of food safety hazards in the food supply chain.

SEC. 16. *Specific Responsibilities of the Department of Agriculture.* – The DA shall be responsible for the development and enforcement of food safety standards and regulations for foods in the primary production and post harvest stages of the food supply chain. It shall monitor and ensure that the relevant requirements of the law are complied with by farmers, fisherfolk and food business operators. Pursuant thereto, the DA Secretary shall ensure that the food safety regulatory mandates and functions for fresh plant, animal, fisheries and aquaculture foods of the DA agencies are clearly defined. The agencies under the DA with food safety regulatory functions are the following:

(a) The Bureau of Animal Industry (BAI), for food derived from animals including eggs and honey production;

(b) The National Dairy Authority (NDA), for milk production and post harvest handling;

SEC. 14. *Specific Responsibilities of Food Business Operators.* – Food business operators shall have the following responsibilities under this Act:

(a) Food business operators shall be knowledgeable of the specific requirements of food law relevant to their activities in the food supply chain and the procedures adopted by relevant government agencies that implement the law. They shall adopt, apply and be well informed of codes and principles for good practices. Micro and small industries shall be assisted to facilitate their adoption of such practices;

(b) If a food business operator considers or has reason to believe that a food which it produced, processed, distributed or imported is not safe or not in compliance with food safety requirements, it shall immediately initiate procedures to withdraw the food in question from the market and inform the regulatory authority;

(c) Food business operators shall allow inspection of their businesses and collaborate with the regulatory authorities on action taken to avoid risks posed by the food product/s which they have supplied; and

(d) Where the unsafe or noncompliant food product may have reached the consumer, the operator shall effectively and accurately inform the consumers of the reason for the withdrawal, and if necessary, recall the same from the market.

SEC. 15. *Principal Responsibilities of Government Agencies.* – The DA, the DOH, the DILG and the LGUs shall have the following responsibilities:

(a) The DA shall be responsible for food safety in the primary production and post harvest stages of food supply chain and foods locally produced or imported in this category;

(b) The DOH shall be responsible for the safety of processed and prepackaged foods, foods locally produced or imported under this category and the conduct of monitoring and epidemiological studies on food-borne illnesses;

(c) The LGUs shall be responsible for food safety in food businesses such as, but not limited to, activities in slaughterhouses, dressing plants, fish ports, wet markets,



(c) The National Meat Inspection Service (NMIS), for meats;

(d) The Bureau of Fisheries and Aquatic Resources (BFAR), for fresh fish and other seafoods including those grown by aquaculture;

(e) The Bureau of Plant Industry (BPI), for plant foods;

(f) The Fertilizer and Pesticide Authority (FPA), for pesticides and fertilizers used in the production of plant and animal food;

(g) The Philippine Coconut Authority (PCA), for fresh coconut;

(h) The Sugar Regulatory Administration (SRA), for sugar cane production and marketing; and

(i) The National Food Authority (NFA), for rice, corn and other grains.

The Bureau of Agriculture and Fisheries Product Standards (BAFPS) shall develop food safety standards including those for organic agriculture. The BAFPS shall establish the mechanism for the development of science-based food safety standards for fresh plant, animal, fisheries and aquaculture foods and shall use the services of experts from the FSRA, other government agencies, academe and private sector.

The Food Development Center (FDC) of the NFA shall provide scientific support in testing, research and training.

When necessary and when funds allow, the appropriate food safety units shall be created within the above-stated agencies. To strengthen these organizations, they shall be provided with the necessary personnel out of the existing manpower of the DA.

Finally, the DA shall, in coordination with other government agencies, monitor the presence of contaminants in foods of plant, animal and fishery origin and shall formulate and implement measures to address incidents of food contamination.

SEC. 17. *The Undersecretary for Policy and Planning, Research and Development (R&D) and Regulations.* – Oversight functions for the Food Safety Act shall be assigned to the Undersecretary for Policy and Planning, R&D and Regulations.

The Undersecretary for Policy and Planning, R&D and Regulations shall directly supervise the Food Development Center and the BAFPS and shall be the coordinator for Codex activities at the DA and the Codex Contact Point.

The Undersecretary for Policy and Planning, R&D and Regulations shall be provided with the necessary manpower and funds from existing resources to ensure the smooth and efficient discharge of its functions.

SEC. 18. *Specific Responsibilities of the DOH.* – The DOH shall bear the following specific responsibilities:

(a) The DOH shall ensure the safety of all food processing and product packaging activities.

(b) The FDA Center for Food Regulation and Research shall be responsible for implementing a performance-based food safety control management system which shall include, but not limited to, the following:

(1) Development of food standards and regulations;

(2) Post-market monitoring;

(3) Enforcement of HACCP and other risk-based control measures;

(4) Strong participation in Codex and other international standard setting bodies;

(5) Communication of risks and development of interactive exchange among stakeholders;

(6) Establishment of laboratories for food safety and strengthening the capabilities of existing laboratories;

(7) Development of a database of food safety hazards and food-borne illness from epidemiological data;

(8) Strengthening R&D capabilities on product safety and quality standards; and

(9) Certification of food safety inspectors.

(c) The Bureau of Quarantine (BOQ) shall provide sanitation and ensure food safety in its area of responsibility in both domestic and international ports and airports of entry, including in-flight catering, food service establishments, sea vessels and aircraft as provided for in the implementing rules and regulations (IRR) of Republic Act No. 9271 and Presidential Decree No. 856, otherwise known as the "Code on Sanitation of the Philippines".

(d) The National Epidemiology Center (NEC), the Research Institute of Tropical Medicine (RITM) and the National Center for Disease Prevention and Control (NCDPC) shall conduct and document epidemiological monitoring studies on food-borne illnesses for use in risk-based policy formulation. Food safety risk assessment bodies shall be established for this purpose.

(e) The National Center for Health Promotion (NCHP) shall be responsible for advocating food safety awareness, information and education to the public.

(f) The NCDPC shall strategize actions to help ensure the safety of food, reduce the risk of food contamination and food-borne diseases, address the double burden of micronutrient deficiencies and noncommunicable diseases and to regularly evaluate the progress made.

(g) The DOH and the FDA Center for Food Regulation and Research shall be strengthened in terms of establishing food safety functional divisions and incremental staffing of food safety officers and experts and be provided with funds including the fees collected from services.

SEC. 19. *Specific Responsibilities of the DILG and the LGUs.* – The DILG and the LGUs shall bear the following responsibilities:

(a) The LGUs shall be responsible for the enforcement of the "Code on Sanitation of the Philippines" (Presidential Decree No. 856, December 23, 1975), food safety standards and food

safety regulations where food is produced, processed, prepared and/or sold in their territorial jurisdiction. This shall include, but shall not be limited to, the following:

(1) Sanitation particularly in public markets, slaughterhouses, micro and small food processing establishments and public eating places;

(2) Codes of Practice for production, post harvest handling, processing and hygiene;

(3) Safe use of food additives, processing aids and sanitation chemicals; and

(4) Proper labelling of prepackaged foods.

(b) The DILG shall support the DOH and the DA in the collection and documentation of food-borne illness data, monitoring and research.

(c) The DILG and the LGUs shall participate in training programs, standards development and other food safety activities to be undertaken by the DA, the DOH and other concerned national agencies.

## ARTICLE VI

### FOOD SAFETY REGULATION COORDINATING BOARD (FSRCB)

SEC. 20. *Powers and Functions.* – There is hereby created a Food Safety Regulation Coordinating Board, hereinafter referred to as the Board, with the following powers and functions:

(a) Monitor and coordinate the performance and implementation of the mandates of the DA, the DOH, the DILG and the LGUs in food safety regulation;

(b) Identify the agency responsible for enforcement based on their legal mandates when jurisdiction over specific areas overlap;

(c) Coordinate crisis management and planning during food safety emergencies;

(d) Establish the policies and procedures for coordination among agencies involved in food safety;

(e) Continuously evaluate the effectiveness of enforcement of food safety regulations and research and training programs;

(f) Regularly submit reports to the Congressional Committees on Health, Agriculture and Food, and Trade and Industry; and

(g) Accept grants and donations from local and international sources.

SEC. 21. *Organization.* – Within thirty (30) days from the effectivity of this Act, the Secretaries of the DA, the DOH and the DILG shall organize the Board in accordance with the following rules:

(a) The Board shall be chaired by the DOH Secretary and co-chaired by the DA Secretary. The alternate chair for the DOH shall be the FDA Director General and the alternate co-chair for the DA Secretary shall be the Undersecretary for Policy and Planning, R&D and Regulations. The members of the Board shall be the heads of the food safety regulatory agencies of the DA, the Director of the FDA Center for Food Regulation and Research, a representative field operator of the DILG with the rank of a Director, the heads of Leagues of Barangays, Municipalities, Cities and Provinces and a representative each from the DTI and the DOST with the rank of a Director. Directors of other DOH agencies with food safety concerns shall join the meeting as it may be deemed necessary by the DOH;

(b) Within twelve (12) months from the effectivity of this Act, the Board shall submit a manual of procedures containing the rules for the conduct of meetings and decision-making, among others;

(c) The Board shall be assisted by administrative and technical secretariat at the DOH. Both the DOH and the DA shall establish functional divisions and shall organize the administrative and technical personnel for the operation of the Board. The personnel needed under this section shall be taken from the existing manpower of each department; and

(d) Funds shall be allocated by the respective agencies concerned with food safety to pay for the organization of meetings, participation of Board members, secretariat, experts and the expenses of a working group to be created by the Board to prepare its manual of procedures.

SEC. 22. *Accountability for Food Safety Regulation.* – The FSRAs of the DA and the DOH, in coordination with the LGUs, shall be responsible in ensuring food safety at various stages of the food supply chain within their specified mandates.

## ARTICLE VII

### CRISIS MANAGEMENT

SEC. 23. *Rapid Alert System.* – A rapid alert system for the notification of a direct or indirect risk to human health due to food shall be established by the FSRCB.

SEC. 24. *Emergency Measures.* – Where it is evident that food originating from within the country or imported from another country is likely to constitute serious risk to human health, the Board, in coordination with the FSRAs of the DOH and the DA, shall immediately adopt one or more of the following measures, depending on the gravity of the situation:

(a) In the case of food of national origin:

(1) Suspension of its distribution in the market or the use of the food in question;

(2) Laying down special conditions for the food in question; and

(3) Any other appropriate interim measures.

(b) In the case of food from another country:

(1) Suspension of imports of the food from all or parts of the third country concerned and, where applicable, from the third country of transit;

(2) Laying down special conditions for the food in question from all or part of the third country concerned; and

(3) Any other appropriate interim measures.

SEC. 25. *Plan for Crisis Management.* – The Board, in coordination with the FSRAs and other relevant government agencies, shall prepare a general plan for the management of a threat to food safety such as radiation contamination of food, food shortage requiring coordinated action and other crisis situations which may compromise food safety. This plan shall specify the situations representing a direct or indirect risk to human health deriving from food which are not likely to be prevented, eliminated or reduced to an acceptable level.

## ARTICLE VIII

### IMPLEMENTATION OF FOOD SAFETY REGULATIONS

SEC. 26. *Policies on Official Controls.* – Official controls are established to verify compliance with food laws and regulations and shall be prepared by each agency. The following shall govern the exercise of official controls:

(a) Official controls shall be implemented by way of regulations prepared by the FSRAs in accordance with the principles established in this Act;

(b) The frequency of official controls shall be proportionate to the severity and likelihood of occurrence of the food safety risks being controlled;

(c) Official controls shall be based on appropriate techniques, implemented by an adequate number of suitably qualified and experienced personnel and with adequate funds, facilities and equipment;

(d) The regulatory agency or body performing official controls shall meet operational criteria and procedures established by the agencies to ensure impartiality and effectiveness;

(e) Any personnel of FSRAs such as, but not limited to, food inspectors shall perform official controls at the highest level of competence and integrity, ever mindful of conflict of interest situations;

(f) Policies and procedures for official controls shall be documented in a manual of operations to ensure consistency, high quality, uniformity, predictability and transparency;

(g) Provisions shall be made for official controls to be delegated to other competent bodies as determined by the regulatory agency and of the conditions under which this shall take place. When official controls are delegated, appropriate coordination and other procedures including oversight shall be in place and effectively implemented. The accountability over the delegated function shall remain with the regulatory agency; and

(h) The agencies responsible for the implementation of official controls shall be provided with the necessary funding and technical support out of their existing budget to perform official controls according to the principles indicated in this Act.

SEC. 27. *Traceability.* – Traceability shall be established for foods at relevant stages of production, post harvest handling, processing or distribution, when needed to ensure compliance with food safety requirements. The rule on traceability shall also cover production inputs such as feeds, food additives, ingredients, packaging materials and other substances expected to be incorporated into a food or food product. To ensure traceability, food business operators are required to:

(a) Be able to identify any person or company from whom they have been supplied with:

(1) Food;

(2) A food-producing animal;

(3) Production chemicals as pesticides and drugs; and

(4) Production, post harvest handling and processing inputs such as feeds, food additives, food ingredients, packaging materials, or any substance expected to be incorporated into food or food product.

(b) Establish and implement systems and procedures which allow the above information to be available to the regulatory authorities on demand; and

(c) Establish systems and procedures to identify the other businesses to which their products have been supplied. This information shall be made available to the regulatory authorities upon demand.

Traceability in case of food-borne disease outbreak shall be established by the National Epidemiology Center (NEC) of the DOH.

SEC. 28. *Licensing, Registration of Establishments.* – Appropriate authorizations shall be developed and issued in the form of a permit, license and certificate of registration or compliance that would cover establishments, facilities engaged in production, post harvest handling, processing, packing, holding or producing food for consumption in accordance with the mandated issuances of regulatory agencies issuing such authorizations. Special derogations shall be provided due to geographical location and after an assessment of risks, especially for micro, small and medium-sized food business operators and health products.

SEC. 29. *Inspection of Food Business Operators.* – Regular inspection of food business operators shall be performed by the FSRAs or the control bodies delegated to conduct the activity. In addition, the following rules shall be followed in the conduct of inspections:

(a) Inspection shall take into account compliance with mandatory food safety standards, the implementation of HACCP, good manufacturing practices and other requirements of regulations;

(b) The frequency of inspections shall be based on the assessment of risks. Establishments producing high risk foods or carrying out high risk activities shall be inspected more frequently;

(c) Inspectors shall have defined skills on risk-based inspection and shall be regularly evaluated based on suitable procedures to verify their continuing competence; and

(d) Appropriate procedures shall be in place to ensure that the results of inspection are interpreted in a uniform manner.

SEC. 30. *Food Testing Laboratories.* – The following shall guide the management and operation of food testing laboratories:

(a) Food testing shall be carried out by laboratories accredited in accordance with international standards. Those that are not currently accredited shall apply for accreditation within a specified period of time;

(b) Testing shall be carried out using the internationally approved procedures or methods of analysis that have been validated;

(c) Laboratories shall be organized and managed to prevent conflict of interest in the conduct of testing;

(d) Laboratories shall be staffed with analysts with the required expertise and professional competence; and

(e) FSRAs may recognize private testing laboratories accredited by the Philippine Accreditation Office (PAO) of the DTI to support their testing needs.

## ARTICLE IX

### TRAINING AND CONSUMER EDUCATION

SEC. 31. *Training.* – Skills training and other instructional/educational activities shall be regularly provided to food business operators, food handlers and to government personnel as follows:

(a) Food business operators particularly micro, small and medium scale enterprises shall be trained on the requirements of food safety regulations and the understanding of these requirements. Personnel shall be trained on HACCP, on the codes of good practice and on technologies that will enable them to comply with regulations;

(b) Mandatory training on safe food handling and similar courses shall be implemented for food handlers of food businesses; and

(c) Government personnel shall be trained on the scientific basis for the provisions of the law and on the conduct of official controls.

The different PSRAs shall identify training needs and the appropriate training programs. Mandatory training programs shall be developed and implemented by accredited training providers.

SEC. 32. *Consumer Education.* – A consumer education program shall be developed by the DA, the DOH and the LGUs in partnership with the Department of Education, the implementation of which shall be carried out by the latter.

SEC. 33. *Funding.* – Funds shall be provided for the development and implementation of training and consumer education programs.

## ARTICLE X

### FOOD-BORNE ILLNESS MONITORING, SURVEILLANCE AND RESEARCH

SEC. 34. *Food-borne Illness Monitoring and Surveillance.* – The government, in support of risk analysis, shall implement the following programs:

(a) An integrated food-borne disease monitoring system that links to the sources of food contamination in collaboration with the DOH-NEC and the NCDPC; and

(b) Identification of hazards in the food supply chain and assessment of levels of exposure to the hazards.

SEC. 35. *Research.* – The government and academe shall develop and implement a program of research on cost effective technologies and codes of practice for assisting farmers, fisherfolk, micro, small and medium scale enterprises and other stakeholders to enable them to comply with food safety regulations.

## ARTICLE XI

### POLICY ON FEES

SEC. 36. *Collection of Fees.* – The DA, the DOH and the LGUs, where applicable, shall be allowed to collect fees for the inspection of food products, production and processing facilities, issuance of import or export certificates, laboratory testing of food samples and other fees as may be deemed necessary.

Fees shall be based on an officially-approved procedure for estimating the cost of the activity undertaken and shall be subject to government accounting and auditing rules and regulations.

## ARTICLE XII

### PROHIBITIONS, PENALTIES AND SANCTIONS

SEC. 37. *Prohibited Acts.* – It shall be unlawful for any person to:

(a) Produce, handle or manufacture for sale, offer for sale, distribute in commerce, or import into the Philippines any food or food product which is not in conformity with an applicable food quality or safety standard promulgated in accordance with this Act;

(b) Produce, handle or manufacture for sale, offer for sale, distribute in commerce, or import into the Philippines any food or food product which has been declared as banned food product by a rule promulgated in accordance with this Act;

(c) Refuse access to pertinent records or entry of inspection officers of the FSRA;

(d) Fail to comply with an order relating to notifications to recall unsafe products;

(e) Adulterate, misbrand, mislabel, falsely advertise any food product which misleads the consumers and carry out any other acts contrary to good manufacturing practices;

(f) Operate a food business without the appropriate authorization;

(g) Connive with food business operators or food inspectors, which will result in food safety risks to the consumers; and

(h) Violate the implementing rules and regulations of this Act.

SEC. 38. *Penalty.* – Any person who shall violate any provision of this Act shall suffer the penalties provided hereunder:

(a) For the first conviction, a fine of not less than Fifty thousand pesos (P50,000.00) but not more than One hundred thousand pesos (P100,000.00) and suspension of appropriate authorization for one (1) month shall be imposed;

(b) For the second conviction, a fine of not less than One hundred thousand pesos (P100,000.00) but not more than Two hundred thousand pesos (P200,000.00) and suspension of appropriate authorization for three (3) months shall be imposed;

(c) For the third conviction, a fine of not less than Two hundred thousand pesos (P200,000.00) but not more than Three hundred thousand pesos (P300,000.00) and suspension of appropriate authorization for six (6) months shall be imposed;

(d) For violation resulting in slight physical injury of a person, upon conviction, a fine of not less than Two hundred thousand pesos (P200,000.00) but not more than Three hundred thousand pesos (P300,000.00) and suspension of appropriate authorization for six (6) months shall be imposed. The offender shall also pay the hospitalization and rehabilitation cost of a person;

(e) For violation resulting in less serious or serious physical injury of a person, upon conviction, a fine of not less than Two hundred thousand pesos (P200,000.00) but not more than Three hundred thousand pesos (P300,000.00) and suspension of appropriate authorization for one (1) year shall be imposed. The offender shall also pay the hospitalization and rehabilitation cost of a person;

(f) For violation resulting in death of a person, upon conviction, the penalty of imprisonment of not less than six (6) months and one (1) day but not more than six (6) years and one (1) day and a fine of not less than Three hundred thousand pesos (P300,000.00) but not more than Five hundred thousand pesos (P500,000.00) and permanent revocation of appropriate authorization to operate a food business shall be imposed.

If the offender does not have the appropriate authorization, the imposable fines shall be doubled.

If the offender is a government personnel, in addition to the penalty prescribed herein, said personnel shall be subjected to the appropriate civil service laws.

If the offender is a naturalized citizen, in addition to the penalty prescribed herein, the naturalization certificate and the registration in the civil registry of said citizen shall be cancelled. Immediate deportation after payment of fine and service of sentence shall also be imposed.

If the offender is an alien, said alien shall be summarily deported after payment of fine and service of sentence and perpetually barred from entering the country.

Any director, officer or agent of a corporation who shall authorize, order or perform any of the acts or practices constituting in whole or in part a violation of Section 37 hereof, and who has knowledge or notice of noncompliance received by the corporation from the concerned department, shall be subjected to the penalties under this section.

In case the violation is committed by, or in the interest of a foreign juridical person duly licensed to engage in business in the Philippines, such license to engage in business in the Philippines shall immediately be revoked.

## ARTICLE XIII

### FINAL PROVISIONS

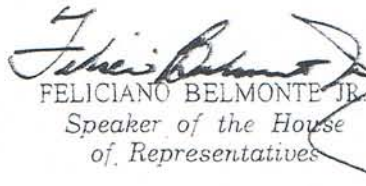
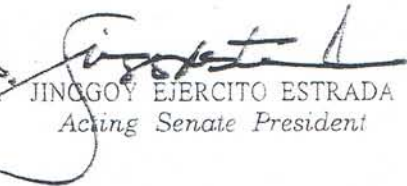
SEC. 39. *Implementing Rules and Regulations.* – The DA and the DOH shall jointly issue the implementing rules and regulations within ninety (90) days after the effectivity of this Act.

SEC. 40. *Separability Clause.* – If any provision of this Act is declared invalid or unconstitutional, the other provisions not affected thereby shall remain in full force and effect.


SEC. 41. *Repealing Clause.* – All laws, presidential decrees, executive orders, rules and regulations inconsistent with the provisions of this Act are hereby repealed, amended or modified accordingly.


SEC. 42. *Effectivity.* - This Act shall take effect fifteen (15) days after its publication in two (2) newspapers of general circulation.

Approved.


  
 FELICIANO BELMONTE JR. JINGGOY EJERCITO ESTRADA  
*Speaker of the House of Representatives* *Acting Senate President*

This Act which is a consolidation of Senate Bill No. 3311 and House Bill No. 6474 was finally passed by the Senate and the House of Representatives on June 5, 2013.

  
 MARILYN B. BARUA-YAP  
*Secretary General*  
*House of Representatives*

  
 EMMA LIRIO-REYES  
*Secretary of the Senate*

Approved: AUG 23 2013


  
 BENIGNO S. AQUINO III  
*President of the Philippines*



CERTIFIED COPY:  
  
 MARIANITU M. DIMAANDAL  
 DIRECTOR IV  
 MALACANANG RECORDS OFFICE  
 AUG 22 2013





Republic of the Philippines  
**DEPARTMENT OF AGRICULTURE**  
**DEPARTMENT OF HEALTH**

**JOINT DA-DOH ADMINISTRATIVE ORDER**  
**NO. 2015-0007**  
**20 February 2015**

**THE IMPLEMENTING RULES AND REGULATIONS  
OF REPUBLIC ACT NO. 10611, "AN ACT TO STRENGTHEN THE  
FOOD SAFETY REGULATORY SYSTEM IN THE COUNTRY TO  
PROTECT CONSUMER HEALTH AND FACILITATE MARKET  
ACCESS OF LOCAL FOODS AND FOOD PRODUCTS, AND FOR  
OTHER PURPOSES" OTHERWISE KNOWN AS THE "*FOOD  
SAFETY ACT OF 2013.*"**

Pursuant to the provisions of Section 39, Republic Act 10611, otherwise known as the "Food Safety Act of 2013", the Department of Agriculture (DA) and the Department of Health (DOH) hereby jointly adopt and promulgate the following Rules and Regulations:

## ARTICLE I

### DECLARATION OF POLICY AND OBJECTIVES

SECTION 1. *Short Title.* - This Act shall be known as the "Food Safety Act of 2013".

Rule 1.1 These Rules and Regulations shall be known as the Implementing Rules and Regulations (IRR) of Republic Act 10611, "An Act To Strengthen The Food Safety Regulatory System In The Country To Protect Consumer Health And Facilitate Market Access Of Local Foods And Food Products, And For Other Purposes" otherwise known as the "Food Safety Act of 2013".

Rule 1.2 These rules are promulgated to facilitate compliance with the provisions of the Food Safety Act of 2013.

Rule 1.3 The Food Safety Act of 2013 shall be the framework for implementing the farm to fork Food Safety Regulatory System.

SECTION 2. *Declaration of Policy.* - Section 15, Article II of the 1987 Philippine Constitution declares that the State shall protect and promote the right to health of the people and instil health consciousness among them. Furthermore, Section 9, Article XVI provides that the State shall protect consumers from trade malpractices and from substandard or hazardous products. Toward these ends, the State shall maintain a farm to fork food safety regulatory system that ensures a high level of food safety, promotes fair trade and advances the global competitiveness of Philippine foods and food products.

SECTION 3. *Objectives.* - To strengthen the food safety regulatory system in the country, the State shall adopt the following specific objectives:

- (a) Protect the public from food-borne and water-borne illnesses and unsanitary, unwholesome, misbranded or adulterated foods;
- (b) Enhance industry and consumer confidence in the food regulatory system; and
- (c) Achieve economic growth and development by promoting fair trade practices and sound regulatory foundation for domestic and international trade.

Towards the attainment of these objectives, the following measures shall be implemented:

- (1) Delineate and link the mandates and responsibilities of the government agencies involved;

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Department of Health

- (2) Provide a mechanism for coordination and accountability in the implementation of regulatory functions;
- (3) Establish policies and programs for addressing food safety hazards and developing appropriate standards and control measures;
- (4) Strengthen the scientific basis of the regulatory system; and
- (5) Upgrade the capability of farmers, fisherfolk, industries, consumers and government personnel in ensuring food safety.

## ARTICLE II

### DEFINITION OF TERMS

SECTION 4. *Definition of Terms.* - For the purposes of this Act, the following terms shall be defined as follows:

(a) *Advertising* refers to the business of conceptualizing, presenting or making available to the public, through any form of mass media, fact, data or information about the attributes, features, quality or availability of food and its related products for the purpose of promoting its sale or distribution and enhancing economic activity.

(b) *Adulteration* refers to an act which leads to the production of food which:

- (1) Bears or contains any poisonous or deleterious substance that may render it injurious to the health of the public;
- (2) Bears or contains any added poisonous or deleterious substance in amounts exceeding established maximum limits or standards for good manufacturing practice;
- (3) Contains in whole or in part filthy, putrid or decomposed substance that is unfit for human consumption;
- (4) Has been prepared, packed or held under unsanitary conditions;
- (5) In whole or in part, is the product of a diseased animal or an animal which has died through ways other than slaughter;
- (6) Is in a container having in whole or in part any poisonous or deleterious substance;
- (7) Has been intentionally subjected to radiation unless the use of radiation is in conformity with an existing regulation or exemption;



- (8) Becomes injurious to health because of the omission or abstraction of a valuable constituent; or if any substance has been substituted wholly or in part; or if damaged or made inferior which has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its strength or to make it appear better or greater than it is;
- (9) Has not been prepared in accordance with current acceptable manufacturing practice as promulgated by way of regulation; and
- (10) Uses expired ingredients.

(c) *Authorization* refers to the permission embodied in a document granted by a regulatory agency to a natural or juridical person who has submitted an application for a food business operation from primary production, post harvest handling, distribution, processing, manufacture, importation, exportation, sale, and offer for sale, distribution, transfer and preparation for human consumption. The authorization can take the form of a permit, license, certificate of registration and certificate of compliance or exemption or any similar document.

(d) *Contaminant* refers to any substance not intentionally added to food which is present in such food as a result of the production (including operations carried out in crop industry, animal husbandry and veterinary medicine) post harvest handling, manufacturing, processing, preparation, treatment, packing, packaging, transport or holding of such food as a result of environmental contamination.

(e) *Control measure* refers to any action and activity that can be used to prevent or eliminate food safety hazard or to reduce it to an acceptable level.

(f) *Crisis management* refers to a proactive approach of addressing a situation, where a risk to consumers, animal or plant health cannot be controlled by normal existing mechanisms, through a plan which can be activated when such emergency arises.

(g) *Food* refers to any substance or product whether processed, partially processed or unprocessed that is intended for human consumption. It includes drinks, chewing gum, water and other substances which are intentionally incorporated into the food during its manufacture, preparation and treatment.

(h) *Feed* refers to any substance or product, including additives, intended to be used for oral feeding to animals.

(i) *Food-borne illnesses* refer to diseases, usually either infectious or toxic in nature, caused by agents that enter the body through the ingestion of food.

(j) *Food business* refers to any undertaking, whether public or private, that carries out any of the activities related to, or any of the stages of the food supply chain.



(k) *Food business operator* refers to a person engaged in the food business including one's agents and is responsible for ensuring that the requirements of this Act are met by the food business under one's control.

(l) *Food hygiene* (hereinafter referred to as hygiene) refers to the measures and conditions necessary to control hazards that could lead to food-borne illnesses and to ensure fitness for human consumption of a food of plant or animal origin taking into account its intended use.

(m) *Food law* refers to the laws, regulations and administrative provisions governing food in general, donated food and food safety at any stage of production, processing, distribution and preparation for human consumption.

(n) *Food safety* refers to the assurance that food will not cause harm to the consumer when it is prepared or eaten according to its intended use.

(o) *Food safety regulatory agencies (FSRAs)* refer to the following national government agencies:

Under the Department of Agriculture (DA) – the Bureau of Animal Industry, the National Meat Inspection Service, the Bureau of Fisheries and Aquatic Resources, the Bureau of Plant Industry, the Fertilizer and Pesticide Authority, the Philippine Coconut Authority, the Sugar Regulatory Administration and the National Food Authority.

Under the Department of Health (DOH) – the Food and Drug Administration, the Center for Food Regulation and Research and the Bureau of Quarantine.

(p) *Food safety officer* refers to a professionally qualified and properly trained officer appointed by a food safety regulatory agency or by local government units (LGUs) in accordance with the appropriate civil service rules and regulations.

(q) *Food safety regulatory system* refers to the combination of regulations, food safety standards, inspection, testing, data collection, monitoring and other activities carried out by food safety regulatory agencies and by the LGUs in the implementation of their responsibilities for the control of food safety risks in the food supply chain.

(r) *Food supply chain* refers to all stages in the production of food from primary production, post harvest handling, distribution, processing and preparation for human consumption. Preparation is the cooking or other treatments to which food is subjected prior to its consumption.

(s) *Good agricultural practices (GAP)* refer to the practices that address environmental, economic and social sustainability for on-farm processes, and which result in safe and quality food and nonfood agricultural products.

(t) *Good manufacturing practices* refer to a quality assurance system aimed at ensuring that products are consistently manufactured, packed, repacked or held to quality

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standards appropriate for the intended use. It is thus concerned with both manufacturing and quality control procedure.

(u) *Good hygienic practices* refer to all practices regarding the conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain.

(v) *Hazard Analyses and Critical Control Points (HACCP)* refer to a science-based system which identifies, evaluates and controls hazards which are significant for food safety at critical points during a given stage in the food supply chain.

(w) *Hazard* refers to a biological, chemical or physical agent in food with a potential to cause adverse effect on health.

(x) *Inspection* refers to the examination of food, food production facilities or establishments, and the management and production systems of food businesses, including the examination of documents, finished product testing and registration, and of the origin and destination of production inputs and outputs to verify compliance with legal requirements by an agency mandated to perform food safety regulatory and/or enforcement functions.

(y) *Label* refers to the display of written, printed or graphic matter upon the immediate container, tag, literature or other suitable material affixed thereto for the purpose of giving information as to identify components, ingredients, attributes, directions for use, specifications and such other information as may be required by law or regulations.

(z) *Micro, small and medium enterprise (MSME)* refers to food businesses as defined within the classification of industries by the Department of Trade and Industry (DTI).

(aa) *Misbranding* refers to deliberate labelling or advertising of food that is misleading, where the labelling and/or advertising claims certain food properties that cannot be supported by a reliable source, a certifying body or by scientific evidence.

(bb) *Official control* refers to all types of controls and control activities made by regulatory agencies to verify compliance with standards, operating procedures, practices and other regulatory requirements. It includes routine monitoring of food establishments and more intensive checks involving inspections, verifications, audits, sampling and testing of samples and recall of defective products.

(cc) *Person* refers to any person, natural or juridical including, but not limited to, the following persons: (i) food business operators; and (ii) food safety officers and other regulatory personnel of the DA, the DOH and the Department of the Interior and Local Government (DILG).

(dd) *Post harvest stages* refer to the stages in the food supply chain involving the minimal transformation of plant and animal foods after primary production such as removal of field heat for fruits, slaughter of animals, sorting, grading and cutting of fresh plant and animal foods, icing and freezing, and the milling and storage of grain.



(ee) *Primary production* refers to the production, rearing or growing of primary products including harvesting, milking and farmed animal production up to slaughter; and the rearing and growing of fish and other seafood in aquaculture ponds. It also includes fishing, and the hunting and catching of wild products.

(ff) *Processing* refers to any action that substantially alters the initial raw materials or product or ingredients including, but not limited to, heating, smoking, curing, maturing, drying, marinating, extraction, extrusion and a combination of those processes intended to produce food.

(gg) *Risk* refers to the likelihood of an adverse health effect and the severity of this effect following exposure to a hazard.

(hh) *Risk analysis* refers to a process consisting of three (3) interrelated components: risk assessment, risk management and risk communication.

(ii) *Risk assessment* refers to the scientific evaluation of known or potential adverse health effects resulting from human exposure to biological, chemical and physical hazards.

(jj) *Risk management* refers to the process of weighing policy alternatives to accept, minimize or reduce assessed risks and if necessary, to select and implement appropriate prevention and control measures.

(kk) *Risk communication* refers to the interactive exchange of information and opinions during the course of risk analysis on the hazards and risks among risk assessors, risk managers, consumers, food and feed business operators, academia and other stakeholders.

(ll) *Food safety standards* refer to the formal documents containing the requirements that foods or food processors have to comply with to safeguard human health. They are implemented by authorities and enforced by law; and are usually developed and published under the auspices of a national standards body.

(mm) *Traceability* refers to the ability to follow the movement of a food through specified stages of production, processing and distribution.

(nn) *Monitoring* refers to the systematic gathering of data through the sampling of commodities as well as monitoring of food-borne diseases, collation and interpretation of collected data.

Rule 4.1 Other terms used in these Rules and Regulations are defined as follows:

Rule 4.1a *Accreditation* is the formal recognition by an independent body, generally known as an accreditation body that a certification body is capable of carrying out certification. Accreditation is not obligatory but it adds another level of confidence, as 'accredited' means the certification body has been independently checked to make sure it operates according to international standards. In the Philippines, the official accreditation body is the Philippine

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Accreditation Bureau (PAB). Food Safety Regulatory Agencies can provide *Official Accreditation* which is the procedure by which a government agency having jurisdiction formally recognizes the competence of an inspection and/or certification body to provide inspection and certification services.

Rule 4.1b *Act* refers to Republic Act 10611 or the Food Safety Act of 2013.

Rule 4.1c *Agriculture or Fishery Establishment* means the farm, fishing vessel, buildings, and other facilities of a food business used for production of primary and postharvest foods (including operations carried out in the crop industry, animal husbandry, aquaculture, and fish capture), postharvest handling, preparation, treatment, packaging, transport and/or storage, but excluding those sites, buildings and structures, such as laboratories, administrative offices and other areas where food is not handled and where people handling food do not enter. Agriculture or Fishery Establishment shall also include facilities involved in activities related to agrochemicals and other inputs in the primary and postharvest stages of production.

Rule 4.1d *Aquaculture* refers to fishery operations involving all forms of breeding, raising and farming of fish and other fishery species in fresh, brackish and marine water areas.

Rule 4.1e *Audit* refers to a systematic and functionally independent examination to determine whether activities and related results comply with planned objectives.

Rule 4.1f *Batch* means a set of units of a product that is uniform in character and quality obtained from a given process under practically identical circumstances and produced in a given place within one defined production period. The food business operator must define the batch.

Rule 4.1g *Certification* means the procedure by which official certification bodies or officially recognized certification bodies provide written or equivalent assurance that foods or food control systems conform to food safety requirements. Certification of food may be, as appropriate, based on a range of inspection activities which may include continuous on-line inspection, auditing of quality assurance systems, and examination of finished products. *Official Inspection and Certification Systems* are administered by FSRAs or government agencies having jurisdiction.

Rule 4.1h *Code of Good Agricultural Practices (GAP) for Food Safety* means practices used to prevent or reduce the risk of hazards occurring during production, harvesting, and postharvest handling of produce.

Rule 4.1i *Code of Good Animal Husbandry Practices (GAHP) for Food Safety* means practices used to prevent or reduce the risk of hazards related to food safety occurring during production, harvesting, postharvest handling of poultry, livestock and their products as sources of human food as well as ensuring animal health and welfare.

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Rule 4.1r *Fraud or Fraudulent Practice* refers to any act or omission, including a misrepresentation, that knowingly or recklessly misleads, or attempts to mislead, a party to obtain a financial or other benefits or to avoid an obligation or for other reasons.

Rule 4.1s *FSCO* means Food Safety Compliance Officer designated by the Food Business Operator.

Rule 4.1t *High risk activities* means activities commonly applied in any part of the food supply chain that may cause food-borne diseases to consumers if left uncontrolled.

Rule 4.1u *Labelling* includes any written, printed or graphic matter that is present on the label, accompanies the food, or is displayed near the food, including that for the purpose of promoting its sale or disposal.

Rule 4.1v *Laboratory Accreditation* means an attestation conveying formal demonstration of a laboratory's competence and capability to carry out specific scientific and technical tests or analytical service with respect to food products.

Rule 4.1w *Licensing by the DA* means the process by which DA FSRAs approve an application, of a person, corporation, cooperative, agriculture or fishery establishment, or other juridical persons, for authority to operate an establishment or to engage in any activity in the primary production and postharvest stages of the food supply chain to produce safe primary and postharvest animal and plant food and inputs. It includes facilities involved in activities related to agrochemicals and other inputs in the primary and postharvest stages of production. The approval will require proving capability to operate a facility or establishment or to engage in activities in the primary production and postharvest stages of the food supply chain and covered by the license.

Rule 4.1x *Licensing by the DOH* means the process of approval by the DOH of an application to operate or establish an establishment prior to engaging in the manufacture, importation, exportation, sale, offer for sale, distribution, transfer, and where applicable the use, testing, promotion, advertisement, and for sponsorship of processed and prepackaged food products.

Rule 4.1y *Lot* refers to a set of units of a product which has been produced and/or manufactured and/or packaged under similar conditions. A lot can consist of several batches.

Rule 4.1z *National Dairy Authority (NDA)* is a Food Safety Regulatory Agency under the Department of Agriculture

Rule 4.1aa *Packaged* is primary or postharvest food made up in advance in a container with or without the label, for further processing, for catering purposes, or for sale to institutional buyers and/or consumers.

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Rule 4.1bb *Point of Entry* means a passage for international entry or exit of travelers, baggage, cargo, containers, conveyances, goods and postal parcels as well as agencies and areas providing services to them on entry or exit.

Rule 4.1cc *Post-market surveillance* refers to activities involved in safety and quality monitoring of primary and postharvest food, production inputs, processed and prepackaged food after market authorization has been issued. This shall also include among others adverse events reporting, product safety update reporting, collection and testing of food products in the market.

Rule 4.1dd *Precautionary Measures* are protective interim measures used where there is uncertainty as to the existence or extent of risks to human health without having to wait until the reality and seriousness of those risks become fully apparent through the establishment of sufficient scientific data.

Rule 4.1ee *Prepackaged* is processed food made up in advance in a container, labeled and ready for sale to the consumer, or for catering purposes.

Rule 4.1ff *Private Testing Laboratory* means a legal entity, other than a government testing laboratory, that engages in the business of conducting tests, calibration, assay, examination measurements, or analytical services with respect to fresh and processed food products and farm inputs.

Rule 4.1gg *Recalls* mean actions taken to remove a product from the market.

Rule 4.1hh *Registration by DA* means the process by which DA FSRAs enter information about agriculture and fishery establishments engaged in the primary production and postharvest stages of the food supply chain including facilities involved in activities related to agrochemicals and other inputs in the primary and postharvest stages of production, in an official list or official system for entering names and information of the DA FSRAs.

Rule 4.1ii *Registration by DOH* means the process of approval of an application to register processed and pre-packaged food products prior to engaging in the manufacture, importation, exportation, sale, offer for sale, distribution, transfer, and where applicable, the use, testing, promotion advertisement, and for sponsorship of food products.

Rule 4.1jj *Risk-Based Inspection* refers to inspection focused on risk factors (i.e. those that may cause food-borne disease in consumers if left uncontrolled) to determine the adequacy of a food business operator's quality and safety management.

Rule 4.1kk *Risk Categorization* refers to the classification of food businesses, food operations and/or food products as high risk, medium risk or low risk based on inherent and potential food safety risks in the production/processing system and/or on the possibility of the presence of microbiological and chemical hazards in the food produced; and history of compliance by the establishment with its quality and safety management systems and pertinent regulations.



Rule 4.1ll *Risk Management Plan* as required by the FDA, means a set of food product vigilance activities and interventions designed to identify, characterize, prevent or minimize risks relating to food products, and the assessment of effectiveness of those interventions. The risk management plan is a requirement for the issuance of the appropriate authorization.

Rule 4.1mm *Risk Management Plan of the DA-FSRA* refers to a framework for prioritizing food-borne risks and for optimizing risk management options and control measures. It provides for monitoring and reviews as a basis for continuing improvement of food safety measures.

Rule 4.1nn *Street-vended foods or Street Foods* means ready-to-eat foods prepared and/or sold by vendors in the streets and other public places.

### ARTICLE III

#### BASIC PRINCIPLES OF FOOD SAFETY

SECTION 5. *Food Safety Requirements.* – To ensure food safety, the following general guidelines shall be observed:

Rule 5.1 Food safety requirements shall guide decision-making on potential adverse health effects that may occur from the consumption of the food and the need to identify risk management options.

Rule 5.2 The food business operator (FBO) and the regulatory agency shall take the necessary steps to be knowledgeable of the conditions under which food could become unsafe or injurious to health.

(a) In determining whether food is unsafe, the following shall be considered:

(1) The normal conditions of the use of food by the consumer;

Rule 5a.1. Food shall be presented in accordance with their intended use as provided for in the specific guidelines developed and determined by the FSRA.

(2) The normal conditions maintained at each stage of primary production, processing, handling, storage and distribution;

(3) The health of plants and animals from where the food is derived;

(4) The effect of feeds, crop protection chemicals and other production inputs on otherwise healthy plants and animals; and

(5) The information provided to the consumer. This includes the information provided on the label or any information generally available to the consumer. This should aid consumers in avoiding specific health effects from a particular food or category of foods.

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Rule 5a.2 All information provided to consumers on food and its preparation, such as during cooking demonstrations, cooking shows, fresh and processed food product launching and other similar activities, shall observe the requirements for hygienic food handling and other practices for safe food preparation.

(b) In determining whether food is injurious to health, regard shall be given to the following:

(1) The probable immediate, short-term or long-term effects on subsequent generations of that food on health;

Rule 5b.1. The DOH shall monitor the effects of food on the health of individuals and on subsequent generations (e.g. non-communicable diseases, micronutrient deficiencies).

(2) The probable cumulative effects; and

(3) The particular health sensitivities of a specific category of consumers where the food is intended for that category.

(c) In determining whether food is unfit for human consumption, regard shall be given to the unacceptability of the food according to its intended use due to contamination by extraneous matter or through putrefaction, deterioration or decay;

Rule 5c.1 In declaring a food unfit for human consumption, the condition of the food shall be evaluated through physical, chemical, microbiological, microscopic and other tests, whenever necessary.

(d) Where unsafe food, is part of a batch, lot or consignment of food of the same class or description, it shall be presumed that all food in that batch, lot or consignment is also unsafe;

(e) Food that complies with specific national law or regulations governing food safety shall be deemed safe insofar as the aspects covered by national law and regulations are concerned. However, imported food that is declared unsafe, by the competent authority of the exporting country after entry into the country shall be withdrawn from the market and distribution channels; and

(f) Compliance of a food product with specific standards applicable to a specific food shall not prohibit the competent authorities to take appropriate measures or to impose restrictions on entry into the market or to require its withdrawal from the market, where there is reason to suspect that such food product shows food safety related risks.

Rule 5f.1 FSRAs shall restrict entry into the market or apply other measures to protect consumer health when food meeting specific standards is subsequently found to be a potential source of food safety related risks. The measures shall be enforced until new scientific data are obtained and/or after appropriate testing and inspection are carried out to confirm safety of the food.



## ARTICLE IV

### GENERAL PRINCIPLES

**SECTION 6. Food Law Objectives.** - Food law shall aim for a high level of food safety, protection of human life and health in the production and consumption of food. It shall also aim for the protection of consumer interests through fair practices in the food trade.

Rule 6.1 These general principles shall serve as the framework for the development of food safety standards, regulations and measures for meeting the objectives of the Act to ensure a high level of food safety and fair practices in the food trade.

**SECTION 7. Use of Science-based Risk Analysis.** - The following shall guide the use of science and risk analysis in food safety regulation:

- (a) The development of food safety legislation and standards and the conduct of inspection and other official control activities shall be based on the analysis of risk, except where this approach is not feasible due to circumstances, or due to the nature of the control measure;

Rule 7a.1 Risk analysis shall be the basis for the development of food safety standards and regulations. It shall objectively combine and analyze scientific data on food safety hazards in order to arrive at the best options for managing food-borne risks.

Rule 7a.2 The risk analysis shall cover all hazards directly or indirectly, intentionally or unintentionally introduced into the food. This shall include hazards coming from packaging materials, cleaning agents, and other sources.

Rule 7a.3 Risk categorization shall guide the DA and the DOH in the conduct of food establishment inspections, testing and evaluation of food products, and/or for implementing any other official control measures. The DA and the DOH shall classify food businesses and their operations as high risk, medium risk, or low risk.

Rule 7a.4 The FSRA shall implement measures, even in the absence of risk analysis, under the following circumstances:

- In cases of emergency situations declared by national and/or international authorities, unforeseen events, or other situations posing an imminent danger to public health due to food-borne hazards;
- Food safety hazard has not been identified but relevant scientific information suggests a link between consumption of a food and the appearance of serious health effects; and
- Other similar circumstances.

- (b) Risk assessment shall be based on sound scientific evidence and shall be undertaken in an independent, objective and transparent manner. Scientific



information as obtained from scientific literature, epidemiological and monitoring studies and other data that supports the risk assessment shall be used;

Rule 7b.1 DOH and the DA shall cooperate in establishing an effective system for developing and sharing scientific data from local epidemiological, monitoring and surveillance studies for use in the assessment of risk.

(c) Risk management shall take into account the results of risk assessment relevant to local conditions, potential for enforcement, cost of compliance and others as may be relevant to the situation;

Rule 7c.1 DA and DOH shall use a Risk Management Plan based on the principles of risk analysis to develop and implement a Food Safety Regulatory System with a mechanism for monitoring, review and continuous improvement.

Rule 7c.2 The choice of risk management options shall consider the cost of compliance, impact on the ability of the industry to innovate and to be competitive, the feasibility of implementation, potential for verification and enforcement, consistency with existing domestic and international food standards and with the country's international obligations, and others.

(d) Risk communication shall be carried out between risk assessors and risk managers in a transparent manner. Food safety risks shall also be communicated to farmers, fisherfolk and food business operators to encourage compliance with the implementation of control measures and to relevant sectors of society affected by the law or the risks addressed in order to strengthen confidence in its provisions; and

Rule 7d.1 The risk communication strategy shall be discussed between risk assessors and managers early in the process to ensure two-way communication.

Rule 7d.2 The strategy should designate the person who will present information to the public and the manner through which it shall be done. The information shall be conveyed in the most appropriate means and shall include the nature of food-borne risks and the measures that can be taken by stakeholders to prevent, reduce, or eliminate the risk.

(e) Food business operators shall be encouraged to implement a HACCP-based system for food safety assurance in their operations.

SECTION 8. *Protection of Consumer Interests.* - The protection of consumer interest shall be geared towards the following:

(a) Prevention of adulteration, misbranding, fraudulent practices and other practices which mislead the consumer, and

Rule 8a.1 Any of the acts indicated in the definition for adulteration shall constitute adulteration.



Rule 8a.2 Any misinformation or misleading information on the label or other information materials shall also constitute misbranding.

Rule 8a.3 FBOs engaged in processed and prepackaged foods shall secure market authorization from the Food and Drug Administration (FDA) for their establishment and their products prior to manufacture and market distribution as per existing regulations.

Rule 8a.4 Food inspection and monitoring systems shall include assessing the potential for adulteration, misbranding, and other forms of fraud.

Rule 8a.5 Penalties shall be imposed against incidents of adulteration, misbranding and other forms of fraud in accordance with Article XII Section 37(e) Section 38 of the Act.

Rule 8a.6 The FBOs shall be fully compliant with all regulatory requirements prior to marketing, advertising, or promoting products.

(b) Prevention of misrepresentation in the labelling and false advertising in the presentation of food, including their shape, appearance or packaging, the packaging materials used, the manner in which they are arranged, the setting in which they are displayed, and the product description including the information which is made available about them through whatever medium. Where relevant, the presentation of goods shall provide consumers a basis to make informed choices in relation to the food they purchase.

Rule 8b.1 The DA and the DOH shall strengthen the enforcement of labelling and advertising requirements by intensifying post-market surveillance.

Rule 8b.2 The DA and the DOH shall develop and set the standards on labelling and advertising.

SECTION 9. *Setting of Food Safety Standards.* - The DA and the DOH shall set the mandatory food safety standards. The following shall guide the setting of standards:

(a) Standards shall be established on the basis of science, risk analysis, scientific advice from expert body/bodies, standards of other countries, existing Philippine National Standards (PNS) and the standards of the Codex Alimentarius Commission (Codex), where these exist and are applicable;

Rule 9a.1 The DA and the DOH shall develop, adopt, amend and/or revise food safety standards according to the principles and procedures in the Act. The DA shall establish standards and codes of practice for fresh foods or foods from the primary production and postharvest sectors of the food supply chain and the DOH-FDA, for processed and prepackaged foods.

Rule 9a.2 Recommendations of the Office International des Epizooties (OIE), International Plant Protection Convention (IPPC), and other international bodies relevant to food safety may also be considered in developing food safety standards.

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Rule 9a.3 To the extent feasible, the DA and DOH shall endeavour to harmonize national standards with international and regional standards.

(b) Codex standards shall be adopted except when these are in conflict with what is necessary to protect consumers and scientific justification exists for the action taken;

Rule 9b.1 Policies and procedures for the adoption of Codex standards or other appropriate standards into national standards and regulations shall be established by the DA and the DOH.

Rule 9b.2 Adoption of standards other than Codex shall be based on risk assessment.

(c) The DA and the DOH shall establish the policies and procedures for country participation at Codex and the incorporation of Codex standards into national regulations. The current National Codex Organization (NCO) is herein designated as the Body to serve this purpose. The DA and the DOH shall designate a third level officer as coordinator for Codex activities for their respective departments; and

Rule 9c.1 The DA and the DOH shall ensure that the country contributes effectively to the development of international standards at Codex as these underpin food safety regulations, promote harmonization and contribute to the development of national standards.

Rule 9c.2 Country participation in the work of the Codex Alimentarius Commission (CAC) shall be implemented through the NCO and its Manual of Operations. The consultative process being implemented by the NCO involving public and private stakeholders shall be strengthened.

(d) Participation at Codex shall be in accordance with the principles of RA 10611 and shall be financially supported by the government

Rule 9d.1 The DA and the DOH shall fund, as specified in the NCO Manual of Operations, the attendance to Codex meetings and of activities related to ensuring effective participation of the country in the work involved in the development of Codex standards. The NCO shall prepare a program of activities and budget for funding by the DA and DOH.

SECTION 10. *Precaution.* - In specific circumstances when the available relevant information for use in risk assessment is insufficient to show that a certain type of food or food product does not pose a risk to consumer health, precautionary measures shall be adopted. When such precautionary measures are issued, the following rules shall govern:

(a) The adopted measure shall remain enforced pending the submission of additional scientific information based on the nature of the risk and type of information needed to clarify the scientific uncertainty; and

(b) The measure shall be no more restrictive to trade than required and should be proportionate to the level of protection required for consumers.





Rule 10b.1 The FSRAs shall implement precautionary measures to protect the health of its consumers whenever a food safety risk exists but scientific data are inadequate. The needed scientific data shall be established within a reasonable period of time as determined by the DA or the DOH.

SECTION 11. *Transparency.* - The implementing agencies shall conduct public consultation and disseminate relevant information to ensure the following:

Rule 11.1 Food safety measures shall be notified to the World Trade Organization (WTO) in accordance with international obligations.

(a) Public consultation during the preparation, evaluation and revision of food legislation shall be open, transparent and direct or through representative bodies unless the urgency of the problem does not allow it; and

Rule 11a.1 The DA and the DOH, whenever they develop food safety regulation, shall consult relevant stakeholders including consumer groups and the industry through public consultations.

Rule 11a.2 Following public consultations or at an appropriate time, FBOs may inform the DA and the DOH in writing of the impact of the regulation on business.

(b) In cases where it is suspected that food may pose a risk to human health, regulatory authorities shall take appropriate steps to inform the general public about the nature of the risk to health, the affected foods, types of food and the necessary measures to prevent, reduce or eliminate the risk.

Rule 11b.1 The DA and the DOH shall develop a Risk Communication Plan to fully and effectively inform the general public about food safety risks.

SECTION 12. *Application to Trade.* - Foods imported, produced, processed and distributed for domestic and export markets shall comply with the following requirements:

(a) Food to be imported into the country must come from countries with an equivalent food safety regulatory system and shall comply with international agreements to which the Philippines is a party.

Rule 12a.1 The DA and the DOH shall determine whether the country of origin has an equivalent food safety regulatory system which is compliant with international agreements.

Rule 12a.2 The FSRAs shall develop protocols and procedures to evaluate a foreign country's food safety regulatory system and determine its equivalence with that of the national system.

Rule 12a.3 List of countries determined by the FSRAs to have equivalent food safety regulatory system shall be made available and used in determining eligibility to export into the Philippines.

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(b) Imported foods shall undergo cargo inspection and clearance procedures by the DA and the DOH at the first port of entry to determine compliance with national regulations. This inspection by the DA and the DOH shall always take place prior to assessment for tariff and other charges by the Bureau of Customs (BOC). The BOC and the Association of International Shipping Lines (AISL) shall provide the DA and the DOH documents such as the Inward Foreign Manifest of Arriving Vessels to enable the DA and the DOH to identify shipments requiring food safety inspection. Shipments not complying with national regulations shall be disposed according to policies established by the DA and the DOH; and

Rule 12b.1 The DA and the DOH shall develop the regulations on cargo/shipment inspections and clearance procedures for imported products prior to assessment of the BOC for the appropriate tariffs.

Rule 12b.2 Inspections and clearance procedures shall be consistent with Article IV of the Act, the Sanitary and Phytosanitary Measures (SPS) Agreement and Codex.

Rule 12b.3 Importers shall notify the DA and the DOH of incoming food shipments within a period prescribed by the FSRA before these arrive at port of entry. The notification shall be called the Import Notification Document (IND) and shall contain among others, the information needed by the DA or the DOH to determine whether or not the food will require physical inspection on arrival.

Rule 12b.4 The BOC shall provide the DA and the DOH with the Inward Foreign Manifest of arriving vessels of AISL and non-AISL members and break bulk organizations as the vessels arrive.

Rule 12b.5 Arriving shipments may or may not require physical inspection based on its risk categorization as high risk, medium risk and low risk.

Rule 12b.6 Arriving shipments may or may not require laboratory testing. If a shipment requires testing, it may be held at the port or transferred to another location. The physical transfer of the shipment while awaiting laboratory testing is not an indication that the shipment has been cleared for entry.

Rule 12b.7 Imported shipments shall meet Philippine standards and regulations and those of the country of origin. Where no standards exist in the country of origin, the FSRA of the country of origin or the importer shall demonstrate that the shipment was produced under a food safety regime equivalent to national standards.

Rule 12b.8 Within one hundred eighty (180) days after the approval of this IRR, the DA and the DOH, in consultation with the BOC, shall develop the regulations and set the parameters of the inspection and clearance procedures of imported food shipments. The inspection and clearance procedures shall be conducted by the DA and the DOH within their respective jurisdiction.

Rule 12b.9 The approved regulations shall be subject to periodic review and amendment as necessary.

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(c) Exported foods shall at all times comply with national regulations and regulations of the importing country. Returned shipments shall undergo border inspection clearance as provided in Section 12(b) hereof.

Rule 12c.1 The DA and the DOH, in consultation with the BOC, shall develop and issue the regulations on exported foods under their respective jurisdiction within 180 working days after the approval of this IRR.

Rule 12c.2 Similarly, the DA and the DOH, in consultation with the BOC, shall develop and issue regulations on returned shipments of foods under their respective jurisdiction within 180 working days after the approval of this IRR.

Rule 12c.3 The approved regulations shall be subject to periodic review and amendment as necessary.

## ARTICLE V

### RESPONSIBILITIES ON FOOD SAFETY

SECTION 13. *Principal Responsibility of Food Business Operators.* - Food business operators shall ensure that food satisfies the requirements of food law and that control systems are in place to prevent, eliminate or reduce risks to consumers.

Rule 13.1 FBOs shall be primarily responsible for ensuring safety of their food products and compliance of their production and distribution/trading systems to the requirements of the Act.

Rule 13.2 FBOs shall ensure that foods they produce are prepared according to standards, codes of practice and other control measures as prescribed by the FSRAs that prevent or minimize food safety hazards or reduce the hazards to acceptable levels.

Rule 13.3 Farmers and fisherfolks as well as FBOs in small and micro industries shall be assisted by the DA and DOH in coordination with the local government units (LGUs) to implement the standards and codes of practice.

Rule 13.4 FBOs in the primary production and postharvest stages, processed and prepackaged sector of the food supply chain shall be encouraged to implement a HACCP-based approach or an equivalent food safety control program in their operations.

Rule 13.5 When required by markets, FBOs shall implement a HACCP-based system or an equivalent food safety control program in their operations.

Rule 13.6 FBOs operating within the jurisdiction of the BOQ of the DOH shall ensure that their food products comply with Good Manufacturing Practices (GMP)/HACCP provisions and that their food handlers and stewards have valid BOQ health certificates.

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**SECTION 14. *Specific Responsibilities of Food Business Operators.*** - Food business operators shall have the following responsibilities under the Act:

(a) Food business operators shall be knowledgeable of the specific requirements of food law relevant to their activities in the food supply chain and the procedures adopted by relevant government agencies that implement the law. They shall adopt, apply and be well informed of codes and principles for good practices. Micro and small industries shall be assisted to facilitate their adoption of such practices;

Rule 14a.1 All food businesses shall designate a Food Safety Compliance Officer (FSCO) who has passed a prescribed training course for FSCO recognized by the DA and/or the DOH.

Rule 14a.1.1 For micro and small enterprises, the owner may serve as the FSCO or a consultant FSCO may be employed part time or full time basis.

Rule 14a.1.2 Large and medium scale food businesses engaged in the production of food in the primary and postharvest sector of the food supply chain shall designate a FSCO who is preferably a graduate of food-related courses including but not limited to agriculture, animal science, fisheries, veterinary medicine, food technology, chemistry, chemical/industrial/sanitary engineering. Graduates of other courses must have work experience on food safety.

Rule 14a.1.3 Large and medium scale food businesses engaged in the manufacture of processed and prepackaged food shall designate a FSCO who is preferably a graduate of food-related courses including but not limited to food technology, food and nutrition, chemistry, microbiology, chemical/sanitary engineering, veterinary medicine, fisheries, agriculture. Graduates of other courses must have work experience on food safety.

Rule 14a.2 The FSCO shall oversee the implementation of the food safety programs and activities of the food business consistent with the provisions of this IRR.

Rule 14a.3 The FBO shall ensure that the designated FSCO attends the required trainings conducted by DA, DOH, LGU or other recognized training service providers.

Rule 14a.4 FBOs shall, in accordance with the general principles of food safety, identify and evaluate the hazards that could affect food, identify and implement preventive controls to significantly minimize or prevent the occurrence of such hazards. The FBOs shall ensure that such food is not adulterated, contaminated, misbranded, and misleading. FBOs shall monitor the performance of control measures and maintain monitoring records as a matter of routine practice.

Rule 14a.5 FBOs shall be proactive in monitoring sustained compliance to standards and relevant regulatory policies. FBOs shall immediately report to the



concerned FSRA any food safety issue which may put the consumer's health in danger.

Rule 14a.6 FBOs shall develop their respective product recall program, in accordance with the requirement of the concerned FSRA, to handle the products that are not safe or not in compliance with food safety requirements.

Rule 14a.7 FBOs producing processed and prepackaged food shall develop a Risk Management Plan as basis for the issuance of appropriate authorizations by the DOH.

(b) If a food business operator considers or has reason to believe that a food which it produced, processed, distributed or imported is not safe or not in compliance with food safety requirements, it shall immediately initiate procedures to withdraw the food in question from the market and inform the regulatory authority;

Rule 14b.1 FBOs shall immediately report to the FSRA products that are not safe or not in compliance with food safety requirements. They shall also report any incident that indicated that the said product has caused or contributed to the death, serious illness or serious injury to a consumer or any person. The same shall be withdrawn from the market, in accordance with their respective product recall program, and disposed according to the procedures prescribed by the DA and/or the DOH.

Rule 14b.2 Food not fully or adequately in compliance with food safety regulations but which can be brought into compliance through simple methods such as re-labelling, re-packaging, sorting and/or cooking, may be recommended to be brought into compliance by the FBO if the method of treatment proposed is acceptable to the DA and/or the DOH. The resulting product shall be compliant with all regulatory requirements upon determination of the DA and/or the DOH.

(c) Food business operators shall allow inspection of their businesses and collaborate with the regulatory authorities on action taken to avoid risks posed by the food product/s which they have supplied; and

Rule 14c.1 FBOs shall allow authorized officers of the FSRAs to enter at an appropriate time any establishment including agriculture or fishery establishment in which food is produced, processed and/or stored or to enter any vehicle used to transport food to inspect for compliance with food safety regulations.

Rule 14c.2 In case of non-compliance with food safety regulations, FBOs shall ensure that adequate and appropriate corrective and preventive actions agreed between the FBO and the FSRA shall be undertaken in a timely and effective manner. The actions undertaken shall be subject to verification by the FSRA.

(d) Where the unsafe or noncompliant food product may have reached the consumer, the operator shall effectively and accurately inform the consumers of the reason for the withdrawal, and if necessary, recall the same from the market.



Rule 14d.1 The FBO shall inform the concerned FSRA and the consumer of the unsafe or non-compliant food product to be withdrawn from the market in accordance with the approved product recall program.

SECTION 15. *Principal Responsibilities of Government Agencies.* - The DA, the DOH, the DILG and the LGUs shall have the following responsibilities:

(a) The DA shall be responsible for food safety in the primary production and post-harvest stages of food supply chain and foods locally produced or imported in this category;

Rule 15a.1 In performing this responsibility, the DA shall ensure that all laws, standards, policies, and programs assuring the safety of primary and postharvest food, foods locally produced or imported under this category are implemented.

Rule 15.a.2 Primary food is food obtained from the primary production stage of the food supply chain. Primary production refers to the production, rearing or growing of primary products including harvesting, milking and farmed animal production up to slaughter, and the rearing and growing of fish and other seafood in aquaculture ponds. It also includes fishing, and the hunting and catching of wild products.

Rule 15a.3 Postharvest food is food obtained from postharvest stages of the food supply chain. Postharvest stages involve minimal transformation of plant and animal foods after primary production such as removal of field heat for fruits, slaughter of animals, sorting, grading and cutting of fresh plant and animal foods, icing and freezing, and the milling and storage of grain.

Rule 15a.4 Postharvest handling activities are essential to food safety and trade as these activities control hazards and enhance the marketability of primary and postharvest foods.

Rule 15a.5 Primary production and postharvest handling activities include transport and dry and/or cold storage of primary and postharvest foods are subject to the requirements of the Act.

Rule 15a.6 The DA shall prescribe the control measures, standards, Codes of GAP/GAHP/GAqP for Food Safety, other codes of practice, and other requirements for the safety of primary and postharvest foods, both locally produced and imported under this category, and shall verify that these requirements are met.

Rule 15a.7 To ensure food safety during primary production, the health of plants and animals from where the food is derived, the effects of feeds, crop and aquaculture protection chemicals, veterinary drugs, biological products, and other production inputs shall be considered and made part of food safety regulations.

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Rule 15a.8 The DA shall assist the LGUs in establishing a mechanism for the issuance and enforcement of ordinances and regulations for food safety based on national standards within their territorial jurisdiction.

Rule 15a.9 The DA shall strengthen the monitoring and surveillance system for hazards in the primary production and postharvest stages of the food supply chain.

(b) The DOH shall be responsible for the safety of processed and prepackaged foods, foods locally produced or imported under this category and the conduct of monitoring and epidemiological studies on food-borne illnesses;

Rule 15b.1 In performing this responsibility, the DOH shall ensure that all health laws, standards, policies, and programs assuring the safety of processed and prepackaged foods, processed foods but not prepackaged, foods locally produced or imported under this category and the conduct of monitoring and epidemiological studies on food-borne illnesses shall be strictly implemented.

Rule 15b.2 Processed food is the product obtained from the processing stage of the food supply chain. The processing stage of the food supply chain is that stage that substantially alters the initial raw materials or product or ingredients including, but not limited to, heating, smoking, curing, maturing, drying, marinating, extraction, extrusion and a combination of those processes intended to produce food.

Rule 15b.3 Transport and storage of processed and prepackaged foods shall be subject to the requirements of the Act.

Rule 15b.4 The DOH through the FDA shall prescribe the control measures, standards, regulations and requirements for the safety of processed and prepackaged foods, and shall verify that these and all requirements of food law related to activities and products, including locally produced and imported processed food products under this category, are met.

Rule 15b.5 The DOH through the FDA shall ensure compliance with the food and nutrition labelling requirements for processed and prepackaged food.

Rule 15b.6 The DOH shall prescribe the requirements for nutrition labelling of processed and prepackaged food to meet objectives for the control of chronic diseases. It shall provide guidance to LGUs in the nutrition labelling of food served in a FSE.

Rule 15b.7 The DOH shall strengthen the post-market surveillance system for monitoring sustained compliance with product standards and regulations including measures to control misbranding, adulteration, and other forms of fraud in locally produced and imported processed and prepackaged food in the market.

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Rule 15b.8 The DOH, through the National Epidemiology Center (NEC) now known as the Epidemiology Bureau (EB), shall conduct the monitoring and epidemiological studies on food-borne illness.

Rule 15b.9 The DOH through the BOQ shall ensure sanitation and food safety measures in FSEs at points of entry, in-flight catering services and domestic and international shipping vessels.

Rule 15b.10 The DOH shall assist the LGUs in establishing a mechanism for the issuance and enforcement of ordinances and regulations for food safety based on national standards within their territorial jurisdiction.

(c) The LGUs shall be responsible for food safety in food businesses such as, but not limited to, activities in slaughterhouses, dressing plants, fish ports, wet markets, supermarkets, school canteens, restaurants, catering establishments and water refilling stations. The LGU shall also be responsible for street food sale, including ambulant vending;

Rule 15c.1 The LGUs shall be responsible for the implementation of the food safety requirements of foods produced within their areas of jurisdiction. They shall be guided by national regulations. This shall include primary, postharvest, processed and prepackaged foods marketed in traditional markets as well as restaurants and school canteens, catered foods, street vended, and/or ambulant-vended foods and the requirements for activities and facilities for the production, handling, processing, preparation, transport and storage of these foods.

Rule 15c.2 The DA and the DOH shall establish a mechanism to assist the concerned LGUs in ensuring that foods produced outside but marketed within their area of jurisdiction meet DA and DOH food safety requirements.

Rule 15c.3 The DA and the DOH shall coordinate and provide technical assistance to LGUs in the enactment of ordinances and regulations pertaining to their jurisdiction in the Act.

(d) The DILG, in collaboration with the DA, the DOH and other government agencies shall supervise the enforcement of food safety and sanitary rules and regulations as well as the inspection and compliance of business establishments and facilities within its territorial jurisdiction;

(e) The LGUs may be called upon by the DOH and the DA to assist in the implementation of food laws, other relevant regulations and those that will hereafter be issued;

Rule 15e.1 The DA and the DOH shall establish mechanisms for coordinating with the LGUs in enforcing national food safety standards and regulations in food businesses within their areas of jurisdiction.

Rule 15e.2 The DA and the DOH may delegate official controls to the LGUs and specify the conditions under which this shall take place.

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(f) The DA and the DOH shall capacitate the LGUs and provide necessary technical assistance in the implementation of their food safety functions under their jurisdiction. In compliance with this responsibility, they shall provide training to the DILG and the LGUs and shall periodically assess the effectiveness of these training programs in coordination with the DILG; and

Rule 15f.1 The DA and the DOH shall develop and implement capacity building programs for the LGUs such as but not limited to training courses, advocacy, information dissemination and including participation in national, regional, and international activities on food safety.

Rule 15f.2 The DA and the DOH shall conduct training programs for LGU food safety inspectors and other LGU personnel.

Rule 15f.3 The DA and the DOH shall regularly evaluate the effectiveness of training programs and develop assessment criteria for this purpose.

(g) The DA and the DOH, in cooperation with the LGUs, shall monitor the presence of biological, chemical, and physical contaminants in food to determine the nature and sources of food safety hazards in the food supply chain.

Rule 15g.1 The DA and the DOH shall link and coordinate with LGUs to monitor hazards in the food supply chain. Monitoring shall be used among others, to determine the effectiveness of the food safety regulatory system.

SECTION 16. *Specific Responsibilities of the Department of Agriculture.* – The DA shall be responsible for the development and enforcement of food safety standards and regulations for foods in the primary production and postharvest stages of the food supply chain. It shall monitor and ensure that the relevant requirements of the law are complied with by farmers, fisher folks and food business operators. Pursuant thereto, the DA Secretary shall ensure that the food safety regulatory mandates and functions for fresh plant, animal, fisheries and aquaculture foods of the DA agencies are clearly defined. The agencies under the DA with food safety regulatory functions are the following:

(a) The Bureau of Animal Industry (BAI), for food derived from animals including eggs and honey production;

(b) The National Dairy Authority (NDA), for milk production and post harvest handling;

(c) The National Meat Inspection Service (NMIS), for meats;

(d) The Bureau of Fisheries and Aquatic Resources (BFAR), for fresh fish and other seafoods including those grown by aquaculture;

(e) The Bureau of Plant Industry (BPI), for plant foods;

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(f) The Fertilizer and Pesticide Authority (FPA), for pesticides and fertilizers used in the production of plant and animal food;

(g) The Philippine Coconut Authority (PCA), for fresh coconut;

(h) The Sugar Regulatory Administration (SRA), for sugar cane production and marketing; and

(i) The National Food Authority (NFA), for rice, corn and other grains.

Rule 16.1 The DA FSRAs for primary and postharvest foods and agriculture and aquaculture inputs for primary production indicated in Section 16 (a) to (i) shall be referred to as the DA FSRAs. They shall strengthen their food safety regulatory systems based on a risk management plan with provisions for review and monitoring for continuous improvement.

Rule 16.2 The mandate for food safety in the DA shall be the responsibility of the DA Secretary, assisted by the Heads of the DA FSRAs, Bureau of Agriculture and Fisheries Standards (BAFS) and the Food Development Center (FDC), and the concerned Undersecretary supervising them. The Undersecretary for Policy and Planning, Research and Development (R&D) and Regulations shall provide oversight.

Rule 16.3 The DA Undersecretary for Policy and Planning, R&D and Regulation shall ensure that all regulatory issuances are compliant with national policies and international commitments, oversee technical support to DA FSRAs provided by BAFS and FDC and DA participation in all national and international activities on food safety.

Rule 16.4 The DA FSRAs shall implement the official controls for verifying that primary and postharvest foods meet regulatory requirements for consumer health, consumer protection, and trade. They shall be responsible for the registration of food businesses, licensing of agriculture and fishery establishments, official certification of products and services, official accreditation of inspection and certifying bodies, and other official controls prescribed by the regulatory system and in compliance with the international commitments.

Rule 16.5 The DA Secretary may put into place arrangements among the DA FSRAs when necessary to improve efficiency and cost-effectiveness of services.

The Bureau of Agriculture and Fisheries Product Standards (BAFPS) shall develop food safety standards including those for organic agriculture. The BAFPS shall establish the mechanism for the development of science-based food safety standards for fresh plant, animal, fisheries and aquaculture foods and shall use the services of experts from the FSRA, other government agencies, academe and private sector.

Rule 16.6 BAFPS now known as the Bureau of Agriculture and Fisheries Standards (BAFS) shall be the DA agency responsible for developing, adopting, and/or amending/revising food safety standards and codes of practice for



primary and postharvest foods for the use of DA FSRAs in developing/implementing food safety regulations.

Rule 16.7 BAFS shall establish the policies and procedures for a transparent, science-based mechanism for the development of standards, which shall include but shall not be limited to the following activities:

- Preparation of the Priority List for standards development
- Qualification and terms and conditions for members of the DA pool of scientific experts
- Promoting functional separation but effective interaction between the DA pool of scientific experts and the DA FSRAs
- Ensuring effective sourcing of scientific data including the design of technical projects for data generation
- Validation and impact evaluation of standards and codes of practice

Rule 16.8 The BAFS shall organize the DA pool of scientific experts for the development of food safety standards and the provision of scientific advice to the Secretary, the Undersecretary for Policy and Planning, R&D and Regulations, the DA FSRAs and the NCO. The members of the DA pool of scientific experts shall come from academe, research institutions, and other relevant organizations.

Rule 16.9 BAFS shall organize Technical Working Groups (TWGs) to develop food safety standards based on the scientific advice of the DA pool of scientific experts.

Rule 16.10 The members of the DA pool of scientific experts and the TWGs shall be entitled to honoraria and other allowable emoluments for every meeting attended in relation to their functions, subject to existing laws, rules and regulations.

The Food Development Center (FDC) of the NFA shall provide scientific support in testing, research and training.

Rule 16.11 FDC shall be the Coordinating Laboratory for DA Laboratories and in this capacity shall;

- Coordinate testing activities and conduct comparative testing as necessary
- Promote the implementation of Good Laboratory Practice (GLP)
- Provide testing services to DA FSRAs for the analysis of chemical, biological and physical contaminants in food, particularly those requiring analysis at very low levels using specialized equipment

Rule 16.12 FDC shall implement research projects to support science-based food safety policies, standards and regulations and coordinate these projects with the Bureau of Agricultural Research (BAR) and the academe.

Rule 16.13 FDC shall develop and conduct relevant training programs on food safety for DA FSRAs and FBOs in coordination with the Agricultural Training Institute (ATI).



Rule 16.14 FDC shall collect fees for testing, training and research services it provides to DA FSRAs, FBOs and other interested parties.

Rule 16.15 FDC shall prepare the guidelines for the provision of testing, training and research services to the DA within one year from the implementation of this IRR.

When necessary and when funds allow, the appropriate food safety units shall be created within the above-stated agencies. To strengthen these organizations, they shall be provided with the necessary personnel out of the existing manpower of the DA.

Rule 16.16 The DA FSRAs, BAFS, FDC and the Office of the Undersecretary for Policy and Planning, R&D and Regulations shall create functional food safety units, whenever necessary, to implement their food safety functions. In doing so, the DA may utilize or restructure existing units. Funds shall be provided by the DA and its agencies concerned with the implementation of the Act. Additional requirements shall be subject to the usual government processes, rules and regulations.

Finally, the DA shall, in coordination with other government agencies, monitor the presence of contaminants in foods of plant, animal and fishery origin and shall formulate and implement measures to address incidents of food contamination.

Rule 16.17 The DA shall coordinate with the DOH in establishing an effective system between them and with other government agencies for the collection and analysis of data on food safety hazards in the food supply chain.

SECTION 17. *The Undersecretary for Policy and Planning, Research and Development (R&D) and Regulations.* - Oversight functions for the Food Safety Act shall be assigned to the Undersecretary for Policy and Planning, R&D and Regulations.

The Undersecretary for Policy and Planning, R&D and Regulations shall directly supervise the Food Development Center and the BAFS and shall be the coordinator for Codex activities at the DA and the Codex Contact Point.

Rule 17.1 The FDC of NFA shall be under the direct supervision of the Undersecretary for Policy and Planning, R&D and Regulations after undergoing legal processes to make the direct supervision possible.

Rule 17.2 The Office of the Undersecretary for Policy and Planning, R&D and Regulations shall be the Codex Contact Point (CCP) and shall oversee the DA participation in the work of the CAC and the NCO.

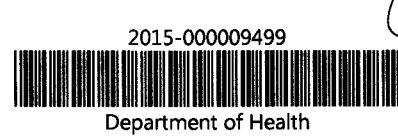
The Undersecretary for Policy and Planning, R&D and Regulations shall be provided with the necessary manpower and funds from existing resources to ensure the smooth and efficient discharge of its functions.

Rule 17.3 The requirements for funds and manpower to support the oversight functions of the Undersecretary for Policy and Planning, R&D and Regulations shall initially be provided by the DA.

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SECTION 18. *Specific Responsibilities of the DOH.* - The DOH shall bear the following specific responsibilities:

(a) The DOH shall ensure the safety of all food processing and product packaging activities.

Rule 18a.1 The DOH through FDA shall be responsible for the overall regulation of all activities pertaining to processed food (prepackaged or not prepackaged) including, but not limited to, inspection, licensing, registration, post-market monitoring, and laboratory analysis. It shall regulate the manufacture, importation, exportation, distribution, sale, offer for sale, transfer, promotion, advertisement, sponsorship of, and/or, where appropriate, the use and testing of all processed and prepackaged food products and food supplements/dietary supplements.

Rule 18a.2 The FDA Center for Food Regulation and Research (CFRR) shall implement the official controls for verifying that processed and prepackaged foods meet regulatory requirements for consumer health, consumer protection, and trade.

Rule 18a.3 The FDA through the Regional Field Offices (RFOs), in performing their primary function of inspecting establishments and monitoring their compliance, shall strengthen the effective enforcement of GMP, HACCP, and other risk-based control measures.

(b) The FDA Center for Food Regulation and Research shall be responsible for implementing a performance-based food safety control management system which shall include, but not limited to, the following:

(1) Development of food standards and regulations;

Rule 18b1.1 The FDA CFRR Product Research and Standards Development Division shall be responsible for developing, adopting, and/or amending/revising food safety standards and codes of practice for processed and prepackaged foods. It shall strengthen and ensure sustained development of science-based policies and continued updating of quality work procedures. The policies and procedures shall be incorporated in the FDA systems including but not limited to:

- a. Food standards and regulations to be researched, developed, amended/revised, or updated
- b. Development of protocol, procedures and qualifications for the identification, recognition or organization of a pool of multi-disciplinary food experts from relevant regulatory, health, academe, research institutions, professional organizations to be known as DOH Joint Scientific Expert Group (JSEG) which shall provide scientific advice to the DOH and its joint undertaking with other agencies including the NCO



- c. The JSEG shall be entitled to allowable honoraria and other emoluments for every meeting attended in relation to their functions subject to accounting and auditing rules and regulations and availability of funds

(2) Post-market monitoring;

Rule 18b2.1 The FDA CFRR shall establish and maintain the post-market monitoring system (PMS), including programs for monitoring, fact-finding activities, procedures for risk-based inspection, and collection for testing of locally produced and imported processed and prepackaged food in the market.

(3) Enforcement of HACCP and other risk-based control measures;

(4) Strong participation in Codex and other international standard setting bodies,

Rule 18b4.1 The FDA CFRR shall ensure the regular participation of country delegates to activities of Codex and other international standard setting bodies. It shall strengthen the country's positions through the conduct and use of science-based studies and research taking into consideration all sources of scientific information.

(5) Communication of risks and development of interactive exchange among stakeholders;

Rule 18b5.1 The FDA CFRR shall collaborate with the Health Promotion and Communication Service (HPCS) in the development and implementation of a risk communication system on food safety as identified by recognized risk assessors. The system shall include consultative discussions among stakeholders to maintain local and international linkages on food safety.

(6) Establishment of laboratories for food safety and strengthening the capabilities of existing laboratories;

Rule 18b6.1 The FDA CFRR Laboratory shall strengthen the conduct of quality monitoring activities through laboratory testing/analysis of processed and prepackaged food, regular participation in Proficiency Testing (PT), continuous performance of method development, validation or verification, upgrading its equipment, oversight the FDA satellite laboratories and laboratory accreditation of food testing laboratories.

(7) Development of a database of food safety hazards and food-borne illness from epidemiological data;

Rule 18b7.1 The FDA CFRR shall develop a database of common food safety hazards and food and water-borne diseases in coordination with the EB and the DA.



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(8) Strengthening R&D capabilities on product safety and quality standards; and

Rule 18b8.1 The FDA CFRR shall identify national areas of research and development on food product safety and quality and institute strategies in their implementation, foster collaboration with partner institutions, conduct capacity building and improvement activities for effective translation of research results into policy and practices, and undertake, when appropriate, oversight/audit of related researches that would ensure the safety and quality of food products.

(9) Certification of food safety inspectors.

Rule 18b9.1 The FDA CFRR shall allocate funds for the certification of food safety inspectors (International Organization for Standardization (ISO) 17020). Certification of food safety inspectors may be given by recognized third party certifying bodies accredited by the PAB.

(c) The Bureau of Quarantine (BOQ) shall provide sanitation and ensure food safety in its area of responsibility in both domestic and international ports and airports of entry, including in-flight catering, food service establishments, sea vessels and aircraft, as provided for in the implementing rules and regulations (IRR) of Republic Act No. 9271 and Presidential Decree No. 856, otherwise known as the "Code on Sanitation of the Philippines".

Rule 18c.1 The BOQ shall adopt HACCP system; enforce GMP-HACCP provisions and guidelines; conduct surveillance of human infectious diseases including food and water-borne disease outbreaks potentially entering the country; develop data base system and conduct periodic monitoring and evaluation of Food Safety program in its area of responsibility; institute processes and procedures, including reasonably appropriate risk-based preventive controls that provide the same level of public health protection including issuance of Health Certificate to stewards and food handlers and *Vibrio cholera* Clearance Certificate for all outgoing foodstuff as required for both domestic and international suppliers; provide relevant safety regulation inputs to the FSRCB.

Rule 18c.2 The BOQ shall coordinate with the LGUs in recognizing the areas of responsibility as defined in Article V, Section 18(c) of the Act.

(d) The National Epidemiology Center (NEC), the Research Institute of Tropical Medicine (RITM) and the National Center for Disease Prevention and Control (NCDPC) shall conduct and document epidemiological monitoring studies on food-borne illnesses for use in risk-based policy formulation. Food safety risk assessment bodies shall be established for this purpose.

Rule 18d.1 The NEC, now named as the EB of the DOH, through its Public Health Surveillance Division, shall be responsible for the overall planning, management, direction, evaluation, and impact assessment for the prevention and control of food- and water-borne illness programs.

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Rule 18d.2 The RITM, Reference Laboratory in coordination with EB shall conduct confirmation of samples from human with food and water-borne diseases.

Rule 18d.3 The NCDPC, now named as the Disease Prevention and Control Bureau (DPCB), shall conduct a periodic evaluation of DOH food safety related programs to determine its effectiveness in achieving legislated intent, purposes, and objectives in coordination with other DOH offices. It shall also provide technical assistance and logistics in the conduct of surveillance of outbreak or epidemic investigations.

(e) The National Center for Health Promotion (NCHP) shall be responsible for advocating food safety awareness, information and education to the public.

Rule 18e.1 The NCHP now named as the HPCS shall be responsible for advocating food safety awareness, information and education to the public.

Rule 18e.2 HPCS shall develop Health Promotion and Communication (HPC) and/or risk communication plan for food safety in collaboration with the FDA, DPCB, EB, BOQ, and other concerned government agencies; and lead the implementation of the HPC Plan in collaboration with the DOH concerned offices, LGUs and other partners.

(f) The NCDPC shall strategize actions to help ensure the safety of food, reduce the risk of food contamination and food-borne diseases, address the double burden of micronutrient deficiencies and non-communicable diseases and to regularly evaluate the progress made.

Rule 18f.1 The DPCB, in collaboration with FDA and other offices within the DOH, shall develop strategic actions on risk management activities or programs relating to food safety that affects health; review existing guidelines to improve policies pertaining to micronutrient supplementation, food fortification of food products and food labelling; develop guidelines on the decontamination and disposal of contaminated, adulterated and sub-standard processed and prepackaged food products; and provide guidance for LGUs in issuing ordinances to control excessive consumption of food substance leading to the development of non-communicable diseases such as, but not limited to, diabetes, hypertension, cardiovascular diseases, obesity and others.

Rule 18f.2 The DOH through DPCB, in coordination with DILG, shall assist in the development of food safety guidelines for the FSEs relating to the prevention of non-communicable diseases.

(g) The DOH and the FDA Center for Food Regulation and Research shall be strengthened in terms of establishing food safety functional divisions and incremental staffing of food safety officers and experts and be provided with funds including the fees collected from services.

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Rule 18g.1 The FDA CFRR shall be in charge of the food safety regulatory program of the FDA-DOH. It shall create a Food Safety and Quality Division within CFRR for this purpose. The Division shall provide technical assistance to the DOH Secretariat of the FSRCB.

**SECTION 19. *Specific Responsibilities of the DILG and the LGUs.*** - The DILG and the LGUs shall bear the following responsibilities:

(a) The LGUs shall be responsible for the enforcement of the "Code on Sanitation of the Philippines" (Presidential Decree No. 856, December 23, 1975), food safety standards and food safety regulations where food is produced, processed, prepared and/or sold in their territorial jurisdiction. This shall include, but shall not be limited to, the following:

- (1) Sanitation particularly in public markets, slaughterhouses, micro and small food processing establishments and public eating places;
- (2) Codes of Practice for production, post harvest handling, processing and hygiene;
- (3) Safe use of food additives, processing aids and sanitation chemicals; and
- (4) Proper labelling of pre-packaged foods.

Rule 19a.1 The FSRAs shall coordinate with and assist the DILG and LGU in implementing and enforcing its food safety function and encourage them to use the food safety regulations and standards including food additives, food/nutrition labelling and other relevant food safety policies as references.

(b) The DILG shall support the DOH and the DA in the collection and documentation of food-borne illness data, monitoring and research.

(c) The DILG and the LGUs shall participate in training programs, standards development and other food safety activities to be undertaken by the DA, the DOH and other concerned national agencies.

## ARTICLE VI

### FOOD SAFETY REGULATION COORDINATING BOARD (FSRCB)

**SECTION 20. *Powers and Functions.*** - There is hereby created a Food Safety Regulation Coordinating Board, hereinafter referred to as the Board, with the following powers and functions:

Rule 20.1 The FSRCB shall establish the policies and procedures for decision making and its implementation. This shall be carried out as soon as the FSRCB is organized.

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Rule 20.2 The FSRCB, when necessary, may seek the assistance and advice of technical persons and other agencies on matters needed in food safety decision making.

(a) Monitor and coordinate the performance and implementation of the mandates of the DA, the DOH, the DILG and the LGUs in food safety regulation;

RULE 20a.1 The FSRCB shall monitor and evaluate DA-DOH coordination including but not limited to the following areas:

- Policy and regulatory issues that arise from the implementation of measures and official controls;
- Effect of regulations on food import and export trade activities;
- Exchange of information on standards and regulatory issuances and scientific data on hazards, epidemiological studies, monitoring and surveillance activities and others;
- The management of risk, the control of fraud, and the identification and evaluation of emerging risks; and
- Evaluation of the impact of testing, training and research programs.

(b) Identify the agency responsible for enforcement based on their legal mandates when jurisdiction over specific areas overlap;

(c) Coordinate crisis management and planning during food safety emergencies;

Rule 20c.1 The FSRCB shall be responsible for preparing a crisis management plan and the Chair and Co-Chair shall lead food control activities during an actual crisis. The Co-chair of the FSRCB shall be specifically responsible for crises originating from and/or affecting primary production and the postharvest handling portion of the food supply chain.

Rule 20c.2 All members of the FSRCB shall contribute information that will strengthen decision-making during the crisis.

(d) Establish the policies and procedures for coordination among agencies involved in food safety;

Rule 20d.1 The FSRCB shall develop a system for the timely exchange of information between the DA, the DOH, the DILG, and the LGUs on matters related to food safety.

(e) Continuously evaluate the effectiveness of enforcement of food safety regulations and research and training programs;

Rule 20e.1 The FSRCB shall review the effectiveness and appropriateness of enforcement of food safety regulations, coordinated regulatory activities, research, and training programs. The review shall be carried out at the end of each year unless relevant information from monitoring and surveillance activities indicate the need for an earlier review of said activities.

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(f) Regularly submit reports to the Congressional Committees on Health, Agriculture and Food, and Trade and Industry; and

Rule 20f.1 The FSRCB shall submit an annual report to the Congressional Committees on Health, Agriculture, Food, and Trade and Industry as required by the Act.

(g) Accept grants and donations from local and international sources.

Rule 20g.1 The FSRCB may apply for/accept grants from local and international sources to fund research, training programs, and monitoring and surveillance activities on food safety except from entities regulated by FSRAs.

**SECTION 21. Organization.** - Within thirty (30) days from the effectivity of this IRR, the Secretaries of the DA, the DOH and the DILG shall organize the Board in accordance with the following rules:

(a) The Board shall be chaired by the DOH Secretary and co-chaired by the DA Secretary. The alternate chair for the DOH shall be the FDA Director General and the alternate co-chair for the DA Secretary shall be the Undersecretary for Policy and Planning, R&D and Regulations. The members of the Board shall be the heads of the food safety regulatory agencies of the DA, the Director of the FDA Center for Food Regulation and Research, a representative field operator of the DILG with the rank of a Director, the heads of Leagues of Barangays, Municipalities, Cities and Provinces and a representative each from the DTI and the DOST with the rank of a Director. Directors of other DOH agencies with food safety concerns shall join the meeting as it may be deemed necessary by the DOH;

Rule 21a.1 The heads of DOH agencies with food safety concerns that shall join the meeting as determined by the DOH including but not limited to BOQ, EB, DPCB, HPCS, Bureau of Local Health Development (BLHD), and RITM.

Rule 21a.2 The heads of FDC and BAFS shall be represented at the FSRCB as determined by the FSRCB.

Rule 21a.3 The FSRCB may invite representatives from the academe, food industry associations/organizations and/or consumer groups as resource persons as may be deemed necessary.

Rule 21a.4 In the event that the FSRCB requires voting as recourse for decision making, all member departments namely DOH, DA, DILG, Department of Trade and Industry (DTI), Department of Science and Technology (DOST), and Leagues of Barangays, Municipalities, Cities and Provinces shall each be entitled to one vote.

(b) Within twelve (12) months from the effectivity of this Act, the Board shall submit a manual of procedures containing the rules for the conduct of meetings and decision-making, among others;

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Rule 21b.1 The FSRCB shall create a TWG to prepare a manual of procedures within twelve (12) months from the approval of this IRR. The manual of procedures shall contain the rules and procedures for the conduct of the FSRCB's activities, meetings, and decision-making.

(c) The Board shall be assisted by administrative and technical secretariat at the DOH. Both the DOH and the DA shall establish functional divisions and shall organize the administrative and technical personnel for the operation of the Board. The personnel needed under this section shall be taken from the existing manpower of each department; and

Rule 21c.1 The DOH shall establish the administrative Secretariat to the FSRCB. The Food Safety and Quality Division created within the FDA CFRR shall provide technical assistance to the FSRCB Secretariat in addition to its major activities relating to food safety.

Rule 21c.2 The DA through the DA Undersecretary for Policy and Planning, R&D and Regulations shall create a functional division from where the administrative and technical support to the DA participation to the FSRCB shall be designated.

(d) Funds shall be allocated by the respective agencies concerned with food safety to pay for the organization of meetings, participation of Board members, secretariat, experts and the expenses of a working group to be created by the Board to prepare its manual of procedures.

**SECTION 22. *Accountability for Food Safety Regulation.*** - The FSRA's of the DA and the DOH, in coordination with the LGUs, shall be responsible in ensuring food safety at various stages of the food supply chain within their specified mandates.

Rule 22.1 Responsibility and oversight functions for the implementation of coordinated activities shall reside in the Chair and Co-Chair of the FSRCB.

## ARTICLE VII

### CRISIS MANAGEMENT

**SECTION 23. *Rapid Alert System.*** - A rapid alert system for the notification of a direct or indirect risk to human health due to food shall be established by the FSRCB.

Rule 23.1 A national rapid alert system for food and feed shall be established to identify and subsequently notify of the existence of a direct or indirect risk to human health from food.

Rule 23.2 The protocols and procedures for the national rapid alert system for food and feed shall consider existing international systems.

Rule 23.3 The FSRCB shall designate a national contact point for the national rapid alert system for food and feed.

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SECTION 24. *Emergency Measures.* - Where it is evident that food originating from within the country or imported from another country is likely to constitute serious risk to human health, the Board, in coordination with the FSRAs of the DOH and the DA, shall immediately adopt one or more of the following measures, depending on the gravity of the situation:

(a) In the case of food of national origin:

- (1) Suspension of its distribution in the market or the use of the food in question;
- (2) Laying down special conditions for the food in question; and
- (3) Any other appropriate interim measures.

(b) In the case of food from another country:

- (1) Suspension of imports of the food from all or parts of the third country concerned and, where applicable, from the third country of transit;
- (2) Laying down special conditions for the food in question from all or part of the third country concerned; and
- (3) Any other appropriate interim measures.

SECTION 25. *Plan for Crisis Management.* - The Board, in coordination with the FSRAs and other relevant government agencies, shall prepare a general plan for the management of a threat to food safety such as radiation contamination of food, food shortage requiring coordinated action and other crisis situations which may compromise food safety. This plan shall specify the situations representing a direct or indirect risk to human health deriving from food which are not likely to be prevented, eliminated or reduced to an acceptable level.

Rule 25.1 In the event of food shortage or other emergency situations, the equivalency requirements for food safety regulatory system in Section 12 of the Act may be reconsidered upon evaluation of the FSRAs and approval of the FSRCB.

## ARTICLE VIII

### IMPLEMENTATION OF FOOD SAFETY REGULATIONS

SECTION 26. *Policies on Official Controls.* - Official controls are established to verify compliance with food laws and regulations and shall be prepared by each agency. The following shall govern the exercise of official controls:



(a) Official controls shall be implemented by way of regulations prepared by the FSRAs in accordance with the principles established in this Act;

Rule 26a.1 Official controls shall be based on Section 26 (a) to (h) of the Act. It shall be a part of the Food Safety Regulatory System of the DA and the DOH.

(b) The frequency of official controls shall be proportionate to the severity and likelihood of occurrence of the food safety risks being controlled;

Rule 26b.1 Official control procedures shall be risk-based and shall include risk-based inspection, testing, certification and audits.

(c) Official controls shall be based on appropriate techniques, implemented by an adequate number of suitably qualified and experienced personnel and with adequate funds, facilities and equipment

Rule 26c.1 Food inspection shall be carried out by inspectors under the supervision of food safety officers (FSO) or equivalent personnel who are graduates of food-related courses including but not limited to chemistry, food and nutrition, food technology, microbiology, chemical/sanitary engineering, veterinary medicine, fisheries, agriculture. To qualify as FSO, graduates must have training and/or work experience in food safety.

Rule 26c.2 FSO or equivalent personnel involved in food inspection shall pass a certified training course on food inspection every three years.

Rule 26c.3 The FSRAs shall ensure that adequate funds, facilities, and equipment for the implementation of official controls are provided.

Rule 26c.4 Testing for official controls shall be carried out by professionally licensed personnel depending on the test methods being implemented.

(d) The regulatory agency or body performing official controls shall meet operational criteria and procedures established by the agencies to ensure impartiality and effectiveness;

(e) Any personnel of FSRAs such as, but not limited to, food inspectors shall perform official controls at the highest level of competence and integrity, ever mindful of conflict of interest situations;

Rule 26e.1 Any personnel of the FSRAs, who in the performance of their official function obtain proprietary information, shall observe strict confidentiality in the handling and use of said information.

(f) Policies and procedures for official controls shall be documented in a manual of operations to ensure consistency, high quality, uniformity, predictability and transparency;

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Rule 26f.1 A manual of procedures for food inspectors shall be developed by FSRAs within a reasonable period of time after the approval of this IRR. Initial funding for the development of this manual of procedures shall be provided by the DA and the DOH.

Rule 26f.2 Food testing laboratories shall have manuals on GLP, calibration procedures, and a manual of validated testing methods compliant with Codex/ISO requirements. Steps shall be taken to accredit food testing laboratories to ISO 17025.

(g) Provisions shall be made for official controls to be delegated to other competent bodies as determined by the regulatory agency and of the conditions under which this shall take place. When official controls are delegated, appropriate coordination and other procedures including oversight shall be in place and effectively implemented. The accountability over the delegated function shall remain with the regulatory agency; and

Rule 26g.1 Third party service providers of inspection, testing and certification activities can be officially accredited by the FSRAs or accredited to the appropriate ISO standard by the PAB.

(h) The agencies responsible for the implementation of official controls shall be provided with the necessary funding and technical support out of their existing budget to perform official controls according to the principles indicated in this Act.

Rule 26h.1 The funds necessary to implement the manual of procedures for official controls shall be provided by the DA and the DOH.

SECTION 27. *Traceability.* - Traceability shall be established for foods at relevant stages of production, post harvest handling, processing or distribution, when needed to ensure compliance with food safety requirements. The rule on traceability shall also cover production inputs such as feeds, food additives, ingredients, packaging materials and other substances expected to be incorporated into a food or food product. To ensure traceability, food business operators are required to:

(a) Be able to identify any person or company, from whom they have been supplied with:

- (1) Food;
- (2) A food-producing animal;
- (3) Production chemicals as pesticides and drugs; and
- (4) Production, post-harvest handling and processing inputs such as feeds, food additives, food ingredients, packaging materials, or any substance expected to be incorporated into food or food product.

(b) Establish and implement systems and procedures which allow the above information to be available to the regulatory authorities on demand; and



(c) Establish systems and procedures to identify the other businesses, to which their products have been supplied. This information shall be made available to the regulatory authorities upon demand.

Traceability in case of food-borne disease outbreak shall be established by the National Epidemiology Center (NEC) of the DOH.

Rule 27.1 FBOs shall be required to establish a traceability system which will indicate at the minimum where the food/food ingredient immediately came from and where it will immediately proceed. The systems implemented by FBOs shall be based on principles and standards of Codex and other international standard bodies.

Rule 27.2 The traceability system established by the FBOs shall be verified by the concerned FSRAs.

Rule 27.3 The DA and other concerned agencies of the DOH shall assist the EB in tracing food-borne disease outbreak from production to consumption.

**SECTION 28. *Licensing, Registration of Establishments.*** - Appropriate authorizations shall be developed and issued in the form of a permit, license and certificate of registration or compliance that would cover establishments, facilities engaged in production, post-harvest handling, processing, packing, holding or producing food for consumption in accordance with the mandated issuances of regulatory agencies issuing such authorizations. Special derogations shall be provided due to geographical location and after an assessment of risks, especially for micro, small and medium-sized food business operators and health products.

Rule 28.1 Authorizations shall be issued when products or establishments have been verified by examination or objective evidence, to meet specified requirements of the Act for the product or the establishment. In issuing appropriate authorizations, the FSRAs may consider modifying or updating existing authorization or establish new ones as necessary.

Rule 28.2 As part of their regular mandates, the LGUs shall issue business permits to FBOs indicating compliance with the sanitation code and such other food safety requirements that may be prescribed. Such permit authorizes FBOs to market their products within their territorial jurisdiction.

Rule 28.3 The DA and DOH shall issue appropriate authorizations to FBOs in accordance with mandated issuances of FSRAs authorizing FBOs to market their products for national and/or international markets.

**SECTION 29. *Inspection of Food Business Operators.*** - Regular inspection of food business operators shall be performed by the FSRAs or the control bodies delegated to conduct the activity. In addition, the following rules shall be followed in the conduct of inspections:





(a) Inspection shall take into account compliance with mandatory food safety standards, the implementation of HACCP, good manufacturing practices and other requirements of regulations;

(b) The frequency of inspections shall be based on the assessment of risks. Establishments producing high risk foods or carrying out high risk activities shall be inspected more frequently;

(c) Inspectors shall have defined skills on risk-based inspection and shall be regularly evaluated based on suitable procedures to verify their continuing competence

Rule 29c.1 Inspectors shall attend training programs designed to strengthen their capabilities in the inspection of food, systems and technologies. Training programs shall establish competence through but not limited to examinations and certifications.

(d) Appropriate procedures shall be in place to ensure that the results of inspection are interpreted in a uniform manner.

Rule 29d.1 Methodologies for inspection shall be incorporated in the manual and shall undergo periodic review.

SECTION 30. *Food Testing Laboratories.* - The following shall guide the management and operation of food testing laboratories:

(a) Food testing shall be carried out by laboratories accredited in accordance with international standards. Those that are not currently accredited shall apply for accreditation within a specified period of time;

Rule 30a.1 DA and DOH laboratories shall conform to the national and/or international standards for GLP and method validation. They shall seek and maintain accreditation to ISO 17025.

Rule 30a.2 Food testing can be carried out by third party laboratories officially accredited by the FSRAs. The criteria for the official accreditation of third party laboratories shall be established by the FSRAs.

(b) Testing shall be carried out using the internationally approved procedures or methods of analysis that have been validated;

Rule 30b.1 Food testing laboratories shall conduct verification of the validated test methods or procedures.

(c) Laboratories shall be organized and managed to prevent conflict of interest in the conduct of testing;

(d) Laboratories shall be staffed with analysts with the required expertise and professional competence, and

Rule 30d.1 The competence of the laboratory analysts shall be regularly assessed.

(e) FSRAs may recognize private testing laboratories accredited by the Philippine Accreditation Office (PAO) of the DTI to support their testing needs.

## ARTICLE IX

### TRAINING AND CONSUMER EDUCATION

SECTION 31. *Training.* - Skills training and other instructional/educational activities shall be regularly provided to food business operators, food handlers and to government personnel as follows:

(a) Food business operators particularly micro, small and medium scale enterprises shall be trained on the requirements of food safety regulations and the understanding of these requirements. Personnel shall be trained on HACCP, on the codes of good practice and on technologies that will enable them to comply with regulations;

(b) Mandatory training on safe food handling and similar courses shall be implemented for food handlers of food businesses; and

(c) Government personnel shall be trained on the scientific basis for the provisions of the law and on the conduct of official controls.

The different FSRAs shall identify training needs and the appropriate training programs. Mandatory training programs shall be developed and implemented by accredited training providers.

Rule 31.1 All training programs on food safety shall include the requirements of the Act.

Rule 31.2 The DA and the DOH shall develop and conduct food safety trainings designed specifically for FSCOs, the FBOs, and the FSRAs. Other government institutions, the academe, professional associations and third party service providers may also conduct food safety trainings provided that these are recognized by the FSRAs.

Rule 31.3 The DA and the DOH may partner with other government institutions, the academe, professional associations and third party service providers in providing these food safety trainings.

SECTION 32. *Consumer Education.* - A consumer education program shall be developed by the DA, the DOH and the LGUs in partnership with the Department of Education, the implementation of which shall be carried out by the latter.

SECTION 33. *Funding.* - Funds shall be provided for the development and implementation of training and consumer education programs.



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Rule 33.1 The DA and the DOH shall provide funds for the development and initial implementation of training and consumer education programs through the regular appropriations of FSRAs and other relevant agencies.

## ARTICLE X

### FOOD-BORNE ILLNESS MONITORING, SURVEILLANCE AND RESEARCH

SECTION 34. *Food-borne Illness Monitoring and Surveillance.* - The government, in support of risk analysis, shall implement the following programs:

(a) An integrated food-borne disease monitoring system that links to the sources of food contamination in collaboration with the DOH-NEC and the NCDPC; and

Rule 34a.1 The DOH-NEC and the NCDPC shall collaborate with the FSRAs in strengthening the sharing of information on food-borne diseases for the development of appropriate risk management measures.

(b) Identification of hazards in the food supply chain and assessment, of levels of exposure to the hazards.

Rule 34b.1 The DA and DOH shall link and coordinate their activities in identifying and monitoring hazards in the food supply chain such as pesticide residues, food additives, veterinary drug residues in food and chemical, biological, and other contaminants under their jurisdiction. The results shall be used to create a database on the national food safety situation.

SECTION 35. *Research.* - The government and academe shall develop and implement a program of research on cost effective technologies and codes of practice for assisting farmers, fisherfolk, micro, small and medium scale enterprises and other stakeholders to enable them to comply with food safety regulations.

Rule 35.1 The DA and the DOH shall include cost-effective technologies and codes of practice relative to food safety regulations in their respective research agenda or research priorities.

Rule 35.2 The DA and the DOH shall engage the academe and other relevant institutions in the conduct of research.

Rule 35.3 Results of such research shall be used in the development of policies and improvement of food safety regulations.



## ARTICLE XI

### POLICY ON FEES

SECTION 36. *Collection of Fees.* - The DA, the DOH and the LGUs, where applicable, shall be allowed to collect fees for the inspection of food products, production and processing facilities, issuance of import or export certificates, laboratory testing of food samples and other fees as may be deemed necessary.

Fees shall be based on an officially-approved procedure for estimating the cost of the activity undertaken and shall be subject to government accounting and auditing rules and regulations.

Rule 36.1 FSRAs shall issue a schedule of fees for services provided.

## ARTICLE XII

### PROHIBITIONS, PENALTIES AND SANCTIONS

SECTION 37. *Prohibited Acts.* - It shall be unlawful for any person to:

- (a) Produce, handle or manufacture for sale, offer for sale, distribute in commerce, or import into the Philippines any food or food product which is not in conformity with an applicable food quality or safety standard promulgated in accordance with this Act.
- (b) Produce, handle or manufacture for sale, offer for sale, distribute in commerce, or import into the Philippines any food or food product which has been declared as banned food product;
- (c) Refuse access to pertinent records or entry of inspection officers of the FSRA;
- (d) Fail to comply with an order relating to notifications to recall unsafe products;
- (e) Adulterate, misbrand, mislabel, falsely advertise any food product which misleads the consumers and carry out any other acts contrary to good manufacturing practices;
- (f) Operate a food business without the appropriate authorization;
- (g) Connive with food business operators or food inspectors, which will result in food safety risks to the consumers; and
- (h) Violate the implementing rules and regulations of this Act.

SECTION 38. *Penalty.* - Any person who shall violate any provision of this Act shall suffer the penalties provided hereunder:



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Rule 38.1 The existing rules of procedures in administrative proceedings in each FSRA shall be applied in the handling of cases and violations committed under the Act and its IRR. The Executive Order No. 292 or the Administrative Code and the Rules of Court shall be applicable in suppletory manner.

Rule 38.2 Prior to, or pending administrative proceedings, any temporary preventive measures being exercised by each FSRA shall apply.

(a) For the first conviction, a fine of not less than Fifty thousand pesos (P50,000.00) but not more than One hundred thousand pesos (P100,000.00) and suspension of appropriate authorization for one (1) month shall be imposed;

(b) For the second conviction, a fine of not less than One hundred thousand pesos (P100,000.00) but not more than Two hundred thousand pesos (P200,000.00) and suspension of appropriate authorization for three (3) months shall be imposed;

(c) For the third conviction, a fine of not less than Two hundred thousand pesos (P200,000.00) but not more than Three hundred thousand pesos (P300,000.00) and suspension of appropriate authorization for six (6) months shall be imposed;

(d) For violation resulting in slight physical injury of a person, upon conviction, a fine of not less than Two hundred thousand pesos (P200,000.00) but not more than Three hundred thousand pesos (P300,000.00) and suspension of appropriate authorization for six (6) months shall be imposed. The offender shall also pay the hospitalization and rehabilitation cost of a person;

(e) For violation resulting in less serious or serious physical injury of a person, upon conviction, a fine of not less than Two hundred thousand pesos (P200,000.00) but not more than Three hundred thousand pesos (P300,000.00) and suspension of appropriate authorization for one (1) year shall be imposed. The offender shall also pay the hospitalization and rehabilitation cost of a person;

(f) For violation resulting in death of a person, upon conviction, the penalty of imprisonment of not less than six (6) months and one (1) day but not more than six (6) years and one (1) day and a fine of not less than Three hundred thousand pesos (P300,000.00) but not more than Five hundred thousand pesos (P500,000.00) and permanent revocation of appropriate authorization to operate a food business shall be imposed.

If the offender does not have the appropriate authorization, the imposable fines shall be doubled.

If the offender is a government personnel, in addition to the penalty prescribed herein, said personnel shall be subjected to the appropriate civil service laws.

If the offender is a naturalized citizen, in addition to the penalty prescribed herein, the naturalization certificate and the registration in the civil registry of said citizen shall be cancelled. Immediate deportation after payment of fine and service of sentence shall also be imposed.

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If the offender is an alien, said alien shall be summarily deported after payment of fine and service of sentence and perpetually barred from entering the country.

Any director, officer or agent of a corporation who shall authorize, order or perform any of the acts or practices constituting in whole or in part a violation of Section 37 hereof, and who has knowledge or notice of noncompliance received by the corporation from the concerned department, shall be subjected to the penalties under this section.

In case the violation is committed by, or in the interest of a foreign juridical person duly licensed to engage in business in the Philippines, such license to engage in business in the Philippines shall immediately be revoked.

Rule 38.3 The administrative penalties provided under the Act shall be in addition to whatever penalties provided under other relevant laws which may penalize the same acts.

Rule 38.4 For violation of prohibited acts of the Act and its IRR, both criminal action in court and the administrative action may be instituted separately and independent of one another. The filing of the administrative complaint and the imposition of administrative penalties shall be lodged with the concerned FSRA.

Rule 38.5 The filing of action for violation of prohibited acts resulting in death of a person and the imposition of the corresponding penalty of imprisonment shall be lodged with the appropriate courts.

### ARTICLE XIII

#### FINAL PROVISIONS

SECTION 39. *Implementing Rules and Regulations.* - These implementing rules and regulations are jointly issued by DA and the DOH as mandated by Section 39 of the Food Safety Act 2013.

Rule 39.1 The IRR of the Act may be jointly amended and/or updated, if the need arises, by the DA and the DOH.

Rule 39.2 All doubts in the interpretation of the IRR shall be resolved in favour of the protection of the health of consumers and in a manner consistent with the declared policies and objectives of RA 10611.

Rule 39.3 Transitory Provisions:

Rule 39.3a Within thirty (30) days from the effectivity of this IRR, the Secretaries of the DA, the DOH, and the DILG shall organize the FSRCB.

Rule 39.3b An ad hoc secretariat is hereby created to assist and support the Secretaries of the DA, the DOH, and the DILG in identifying the members of the FSRCB and prepare the agenda for the first Board meeting. It shall be composed of at least 2 representatives from each Department. The ad hoc secretariat shall automatically cease to function



immediately upon the organization of an administrative and technical secretariat pursuant to Article VI, Section 21 (c) of the Act. The funding and personnel requirements for the ad hoc secretariat shall be provided by the DA, DOH and DILG from their existing funds and manpower complements.

Rule 39.3c The functions, duties and responsibilities pertaining to one FSRA but is presently being performed by another FSRA pursuant to previous formal agreements or issuances shall be continuously performed by the latter until the same are transferred to the concerned FSRA.

Rule 39.3d The transfer and absorption of the functions, duties and responsibilities belonging to the former shall be in accordance with the transition plan to be finalized and approved during the first Board meeting and implemented within 24 months from the effectivity of this IRR. Notwithstanding, the transfer and absorption of the functions, duties and responsibilities shall take effect immediately after 24 months from the effectivity of this IRR.

Rule 39.3e The transition plan shall include, among others:

- i. The efficient transfer of all processed and pre-packaged food applications (product registration and license of establishments) and consumer complaints with the Consumer Arbitration Officer of the Department of Agriculture on processed and pre-packaged food, together with all the required documents, records and relevant information to the DOH-FDA;
- ii. The DOH-FDA, with the assistance of DA-BFAR, shall pursue in securing EU certification to processed fish products exported to EU; and
- iii. The DA and DOH shall jointly undertake an information dissemination to notify relevant stakeholders of the transfer of regulatory activities based on their mandates and endeavour to continuously coordinate and cooperate for the effective implementation of the Food Safety Act.

SECTION 40. *Separability Clause.* - If any provision of these implementing rules and regulations is declared invalid or unconstitutional, the other provisions not affected thereby shall remain in full force and effect.

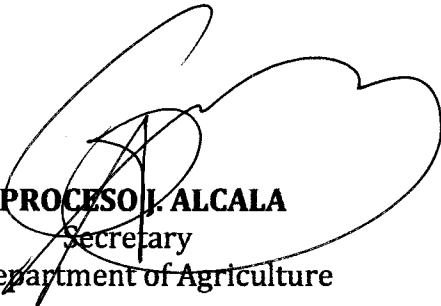
SECTION 41. *Repealing Clause.* - All laws, presidential decrees, executive orders, rules and regulations inconsistent with the provisions of the Food Safety Act 2013 and these




implementing rules and regulations are hereby repealed, amended or modified accordingly.

SECTION 42. *Effectivity.* - These implementing rules and regulations shall take effect fifteen (15) days after its publication in two (2) newspapers of general circulation.

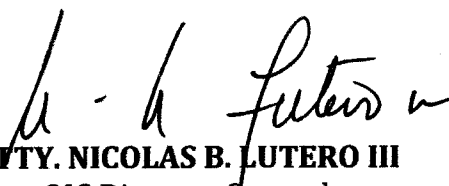
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