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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 inCongress assembled:

## ARTICLE I DECLARATION OF POLICY AND OBJECTIVES

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

**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;

(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 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 he 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.

(I) *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 safely 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 identities, 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.

(II) 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

**Section 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 he presumed that all food in that hatch, 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

**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.

**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;

(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 he 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.

**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

(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.

**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;

(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.

**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.

**Section 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.

**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;

(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

**Section 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.

**Section 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.

**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;

(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, 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 tins 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.

**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 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;

(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.

**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 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.

**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.

(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.

**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 prepackaged foods.

(b) The DILG shall support the DOH and the DA in the collection and documentation of foodborne 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:

(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.

**Section 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.

**Section 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

**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.

**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.

# 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;

(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.

**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.

**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.

**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; and

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

**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;

(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

**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.

**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.

#### 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

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

**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.

# 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.

## 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 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.

**Section 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;

(e) For the third conviction, a line 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 line 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) Fur violation resulting in less serious or serious physical injury of a person, upon conviction, a line 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 line 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 line 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

**Section 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.

**Section 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.

**Section 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.

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

Approved,

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

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.

(Sgd.) EMMA LIRIO-REYES Secretary of the Senate (Sgd.) MARILYN B. BARUA-YAP Secretary General House of Representatives

Approved: AUG 23 2013

(Sgd.) BENIGNO S. AQUINO III President of the Philippines