

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

RULE 1. Title. - These Rules and Regulations shall be known as the Implementing Rules and Regulations 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" known as the *Food Safety Act of 2013*".

Rule 1.1 *These rules are promulgated to facilitate compliance with the provisions of the Food Safety Act of 2013.*

RULE 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.

RULE 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

RULE 4. Definition of Terms. - All terms in The Food Safety Act 2013, and other terms added in these Rules and Regulations are defined as follows:

(a) "Accreditation" is the third party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment task. It is an endorsement of a conformity assessment body's competence, credibility, independence and integrity in carrying out its conformity assessment activities.

(b) "Act" refers to RA 10611 or the Food Safety Act of 2013.

(c) "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

(d) "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.

(e) "Agriculture or Fishery Establishment" means the fishing vessel, site, buildings and other structure of any unit of a food business, used for production (including operations carried out in the crop industry, animal husbandry, aquaculture, fish capture, chemical and fertilizer industries and veterinary medicine) post harvest 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.

(f) "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.

(g) "Audit" refers to a systematic and functionally independent examination to determine whether activities and related results comply with planned objectives.

(h) "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.

(i) "Batch" or "Lot" means a quantity of any food products produced during a given cycle of manufacture.

(j) "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.

(k) "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.

(m) "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.

(n) "Establishment" means a sole proprietorship, a partnership, a corporation, an institution, an association or an organization engaged in the manufacture, importation, exportation, sale, offer for sale, distribution, donation, transfer, use, testing, promotion, advertising, or sponsorship of food products, including the facilities and installation needed for its activities.

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

(p) "Fees" means either the usual licensing, accreditation and registration charges, or other related regulatory fees such as fees from sale of publications and services (including but not limited to laboratory testing, training, and extension services), assessment fees, fines, penalties, and other fees and charges outside the usual licensing, accreditation and registration fees.

(q) "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.

(r) "Food/Dietary Supplement" means a processed food product intended to supplement the diet that bears or contains one or more of the following dietary ingredients: vitamin, mineral, amino acid, herb, or other dietary substance of botanical, animal, artificial or natural origin to increase the total daily intake in amounts conforming to the latest Philippine recommended energy and nutrient intakes or internationally agreed minimum daily requirements. It is usually in the form of capsules, tablets, liquid, gels, powders or pills and is not represented for use as a conventional food or as the sole item of a meal or diet or a replacement for drugs and medicines.

(s) "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.

(t) "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.

(u) "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.

(v) "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.

(w) "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.

(x) "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.

(y) "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.

(z) "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.

(aa) "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.

(bb) "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.

(cc) *"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.

(dd) "FSCO" means Food Safety Compliance Officer hired by the Food Business Operator.

(ee) *"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.

(ff) *"Good hygienic practices (GHP)"* 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.

(gg) *"Good manufacturing practices (GMP)"* 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.

(hh) *"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.

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

(jj) *"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.

(kk) *"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.

(ll) "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.

(mm) "Laboratory Assessment" is a process undertaken by an accreditation body to determine the competence, capability and conformance of a laboratory, based on particular standard(s) and other normative documents for a defined scope of accreditation.

(nn) "Licensing by 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 food products.

(oo) "Licensing by DA" means the process of approval by the DA of an application to operate an establishment for the production (including operations carried out in the crop industry, animal husbandry, aquaculture, fish capture, chemical and fertilizer industries and veterinary medicine) post harvest treatment, preparation, packaging, transport and/or storage of food in the primary production and post harvest stages of the food supply chain in accordance with the requirements of the Food Safety Act.

(pp) "Manufacturer", means an establishment engaged in any and all operations involved in the production of food products including preparation, processing, compounding, formulating, filling, packaging, repackaging, altering, ornamenting, finishing and labeling with the end in view of its storage, sale or distribution: Provided, that the term shall not apply to the compounding and filling of food products in restaurant or other retail establishments. A trader shall be categorized as a manufacturer.

(qq) *"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).

(rr) "Micro, Small, Medium and Large Enterprise" refers to the size classification of food businesses following the classification used by the Department of Trade and Industry (DTI).

(ss) *"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.

(tt) *"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.

(uu) "National Dairy Authority (NDA)" a Food Safety Regulatory Agency under the Department of Agriculture

(vv) *"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.

(ww) "Other Acts of Misbranding" may also refer to misinformation or misleading information on the label or other information materials authorized by the regulatory agencies. It shall not refer to copyright, trademark, or other intellectual property-like instruments.

(xx) "Pasteurization" is the heating of "raw" milk to 63 ° C (145 ° F) for 30 minutes or 72 ° C (161 o F) for 15 seconds to destroy pathogenic bacteria. The pasteurized milk is rapidly cooled to 3.33 ° C (38 ° F) and stored at 2-4 ° C to achieve a shelf life of 7-10 days. Pasteurization has a negligible effect on the taste and nutritive characteristics of milk. The term "fresh" is applicable to pasteurized milk as consumers assume that fresh milk is pasteurized milk.

(yy) *"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).

(zz) "Points of Entry" means international ports and airports.

(aaa) "Port of Entry" refers to a domestic port open to both foreign and coastwise trade. The term includes principal ports of entry and subports of entry. A "principal port of entry" id the chief port of entry of the collection wherein it is situated and is the permanent station of the Collector of such port. Subports of entry are under the administrative jurisdiction of the Collector of the principal port of entry of the district. Whenever the term "port of entry" is used herein, it shall include "airport of entry".

(bbb) *"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.

(ccc) "Postmarketing surveillance" refers to activities involved in safety and quality monitoring of fresh and processed food products and farm inputs. This shall also include among others adverse events reporting, product safety update reporting, collection and testing of food products in the market.

(ddd) "Precautionary Measures" are protective 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.

(eee) "Prepackaged" means packaged or made up in advance in a container, ready for sale to the consumer, or for catering purposes.

(fff) "Primary processing" refers to the physical alteration of raw agricultural or fishery products with or without the use of mechanical facilities. This term is not covered by the definition of "Processing".

(ggg) *"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.

(hhh) "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.

(iii) *"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.

(jjj) "Processed Food" means the product resulting from the application of physical, chemical or biological processes

which substantially or completely changes the physico-chemical and/or sensory characteristics of the raw material.

(kkk) "Registration by DA" means the process of approval of an application to produce and market food in the primary production and post harvest stages of the food supply chain and farm inputs.

(lll) "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.

(mmm) "Retailer" means any Food Business Operator who sells or offers to sell any fresh or processed food and/or farm inputs directly to the general public.

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

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

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

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

(rrr) "Risk Categorization" refers to the classification of food establishments, 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. Following are the guidelines for categorizing food:

- (1) High-risk foods: foods that may contain pathogenic microorganisms and will support the formation of toxins or the growth of pathogenic microorganisms and foods that may contain harmful chemicals. Raw meat, fish, oysters, poultry and milk are examples of high-risk foods. Other examples include tofu, meat pies and salami. These foods pose a particularly high risk if they are not processed or cooked adequately.*
- (2) Medium-risk foods: foods that may contain pathogenic micro-organisms but will not normally support their growth because of food characteristics; or food that is unlikely to contain pathogenic micro-organisms because of food type or processing, but may support the formation of toxins or the growth of pathogenic micro-organisms. Examples are some fruits and vegetables, juices, canned meats, pasteurized milk, dairy products, ice cream, peanut butter, cooked rice and lasagna and milk-based confectionery.*
- (3) Low-risk foods: foods that are unlikely to contain pathogenic microorganisms and will not normally support their growth because of food characteristics and foods that are unlikely to contain harmful chemicals. Examples are grains and cereals, bread, carbonated beverages, sugar-based confectionery, alcohol and fats and oils.*

(sss) "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.

(ttt) "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.

(uuu) "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.

(vvv) "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 review as a basis for continuing improvement of food safety measures.

(www) "Secondary processing" refers to the further physical transformation of primary processed agricultural or fishery products. This term is not covered by the definition of "Processing".

(xxx) "Sterilization"

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

(zzz) "Trader" means any FBO who buys and sells food in the primary production and post harvest stages of the food supply chain and farm inputs as a regular course of their business.

(aaaa) "Trader" (as registered by the DOH), means any establishment which is a registered owner of a food product and procures the raw materials and packing components, and provides the production monographs, quality control standards and procedures, but subcontracts the manufacture of such product to a licensed manufacturer. In addition, a trader may also engage in the distribution and marketing of its products.

ARTICLE III

BASIC PRINCIPLES OF FOOD SAFETY

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

RULE 5.1 This section describes the factors to be considered when determining whether food is unsafe or injurious to health. It 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 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 Processed and pre-packaged foods shall be presented in accordance with their intended use as provided for in the specific guidelines developed and determined by the DOH.

(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.

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;

(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.

ARTICLE IV

GENERAL PRINCIPLES

RULE 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 *The general principles contained in this Act shall serve as the framework for the development of food safety standards, regulations and measures for meeting the objectives of food law to ensure a high level of food safety and fair practices in the food trade.*

RULE. 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 be used as a process to objectively combine and analyse scientific data on food safety hazards and to arrive at the best options for managing food borne risks.*

Rule 7a.2 *Risk categorization shall guide the DA and the DOH in the conduct of food establishment inspections, evaluation of food products for registration, for trade and/or for implementing any other official control measure. The DA and the DOH shall classify food business operation as high risk, medium risk or low risk.*

(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 among others, 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, how to demonstrate effectiveness, 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 should be discussed between risk assessors and managers early in the process to ensure two-way communication. This strategy should also cover who should present information to the public, and the manner in which it will be done which includes the measures that can be taken by stakeholders to prevent, reduce, or eliminate the risk.

Rule 7d.2 DOH and DA shall inform stakeholders of the nature of food borne risks and the measures that can be taken as soon as possible through the most appropriate means.

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

Rule 7e.1 HACCP-based system shall be encouraged as a major preventive program for controlling hazards in the operations of the food business operators. FBOs implementing HACCP based system in compliance with the requirements of FSRAs may avail of incentives as may be established by the DA and DOH.

Rule 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

Rule 8a.1 Food business operators engaged in processed and pre-packaged foods shall secure market authorization from FDA for their establishment and their products prior to manufacture and market distribution.

Rule 8a.2 Food inspection and monitoring systems shall include assessing the potential for adulteration, misbranding and other forms of fraud.

Rule 8a.3 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 this Act.

Rule 8a.4 The food business operators prior to marketing, advertising, promoting products should be fully compliant with all regulatory requirements relative thereto.

(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 DOH and DA shall strengthen the enforcement of labelling and advertising requirements by intensifying post-marketing surveillance.

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

RULE 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 DOH and DA shall develop, adopt and/or amend 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 OIE and IPPC relevant to food safety may also be considered in developing

food safety 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 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 FDA and the DA 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 shall be implemented through the National Codex Organization (NCO) and its Manual of Operations.

(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.

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

RULE 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

Rule 11a.1 The DOH and DA, whenever they develop a new standard, policy, or guidelines, shall conduct public consultations in order to secure the confidence of consumers, trading partners and the industry.

Rule 11a.2 Following public consultations or at an appropriate time, Food Business Operators may inform DOH and DA 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 DOH and the DA shall enforce the appropriate measures or product recall guidelines and other relevant policies.

RULE 12. *Application to Trade.* - Imported foods, foods produced and processed locally whether distributed for domestic and export markets shall comply with the same safety requirements as follows:

(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 agreement.

(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 Pursuant to Section 12 of the Act, the DOH and the DA shall develop the regulations on cargo/shipment inspections and clearance procedures for imported products prior to assessment of the Bureau of Customs for the appropriate tariffs.

Rule 12b. 2 Importers shall notify the DA and the DOH of incoming food shipments not less than forty eight (48) hours for the DA and not less than ten (10) days for the DOH 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.3 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.4 Arriving shipments may or may not require physical inspection based on its risk categorization as high risk, medium risk and low risk.

Rule 12b.5 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.6 Imported shipments shall meet Philippine regulations and standards and the standards of the country of origin. Where no standards exist in the country of origin, the FSRAs of the country of origin or the importer should be able to demonstrate that the shipment was produced under a food safety regime equivalent to national standards.

Rule 12b.7 Within one hundred eighty (180) days after the approval of this IRR, the DA-DOH, in consultation with the Bureau of Customs shall develop the regulations and define and set the parameters of the inspection and clearance procedures of imported food shipments to be conducted by the DA and the DOH within their respective jurisdiction.

Rule12b.8 The approved regulations shall be subject to periodic review and amendment as necessary.

(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 Pursuant to Section 12 of the Act, the DA and the DOH shall develop and issue within 180 working days after the approval of this IRR and consultation with the Bureau of Customs the regulations on exported foods under their respective jurisdiction.

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

Rule12c.3 The approved regulations shall be subject to periodic review and amendment as necessary.

ARTICLE V

RESPONSIBILITIES ON FOOD SAFETY

RULE 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 Food Business Operators (FBOs) shall be primarily responsible for ensuring safety of their food products and compliance of their production systems to the requirements of food safety law.

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

Rule 13.3 FBOs shall validate the codes prior to adoption as well as monitor its effectiveness during their operations. 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.

Rule 13.4 FBOs in the primary production and post harvest stages, processed and pre-packaged sector of the food supply chain will be encouraged to implement a HACCP-based system or an equivalent food safety control program in their operation.

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

Rule 13.6 FBOs operating within the jurisdiction of the Bureau of Quarantine (BOQ) of the DOH as provided for in Article V, Section 18(c) of the Act shall ensure that their food products comply with GMP/HACCP provisions and that their food handlers and stewards have valid BOQ health certificates.

RULE 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 have a Food Safety Compliance Officer (FSCO) who has passed a training course for FSCO certified by the DA and the DOH.

Rule 14a.2 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.3 Large and Medium scale food businesses engaged in the production of food in the primary and post harvest sector of the food supply chain shall designate a Food Safety Compliance Officer (FSCO) who is a graduate of food-related courses including but not limited to agriculture, animal science, fisheries, veterinary medicine, food technology, chemistry, chemical/industrial/sanitary engineering and related fields. To qualify as FSCO, graduates of related fields must have training and work experience in food safety.

Rule 14a.4 Large and Medium scale food businesses engaged in the manufacture of processed and pre-packaged food shall designate a Food Safety Compliance Officer (FSCO) who is 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. To qualify as FSCO, graduates of allied technical courses must have training and work experience in food safety.

Rule 14a.5 The FSCO shall oversee the implementation and coordinate the food safety programs and activities of the food business consistent with the provisions of this IRR.

Rule 14a.6 The FBO shall ensure that designated FSCO should attend required trainings being conducted by the DA, DOH, DILG, LGU and other recognized training service providers in accordance with Article IX, Section 31 of the Act.

Rule 14a.7 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, and provide assurances that such food is not adulterated, contaminated, misbranded, and misleading. FBOs shall monitor the performance of those controls, and maintain records of monitoring as a matter of routine practice.

Rule 14a.8 FBOs shall take proactive move in monitoring sustained compliance to standards and relevant regulatory policies and be responsible to immediately report to the regulatory agency any food safety issue

which may put the consumer's health in danger.

Rule 14a.9 *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.10 *FBOs producing processed and pre-packaged food shall develop a Food Safety 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. 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 also be acceptable to the DA and/or the DOH and 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.

Rule 14c.1 *FBOs shall allow authorized officers of the FSRAs to enter at an appropriate or reasonable 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 upon shall be undertaken in a timely and effective manner. The actions undertaken shall be subject to verification by the FSRAs.*

(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 consumer of the unsafe or non-compliant food product withdrawn from the market in accordance with their product recall program.*

RULE 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;

Rule 15a.1 *Primary production shall involve activities related to the production of primary produce such as but not limited to the growing of plants and animals for safe food, with the view of placing these foods in the market.*

Rule 15a.2 *Post harvest handling in agriculture or fishery establishments shall refer to treatments applied to foods immediately after harvest and prior to consumption, without causing significant changes in the foods' physical form or chemical composition. These treatments involve primary processing or secondary processing and are essential to making the primary produce marketable and/or to enhancing its marketability:*

- *Slaughtering of animals*
- *Pasteurization, cooling and packaging of milk after collection from the milk producing animal as a batch process*
- *Removal of field heat in fruits*
- *Surface drying such as of onions, beans, legumes and nuts*
- *Drying of grains*
- *Fermentation of beans such as coffee and cacao*
- *Milling of sugarcane in bulk for further processing, paddy and corn*
- *Shelling of corn*

- *Dehulling of paddy to produce brown rice*
- *Sizing, sorting and grading*
- *Washing, peeling and/or pre-cutting*
- *Cutting*
- *Icing*
- *Chilling*
- *Freezing*
- *Salting and pickling of fresh fish*
- *Deboning*
- *Packaging*
- *Fortification of rice*

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

Rule 15b.1 The food safety control activities that are being implemented by DOH FSRAs are the following:

- *Regulation of establishments for processed and prepackaged food including milk, fish, sugar, meat, coconut products and cooking oil*
- *Regulation of processed and prepackaged food products including milk, fish, sugar, meat, coconut products and cooking oil*
- *Testing of processed and prepackaged food for compliance with standards*
- *Development of Philippine National Standards for processed and prepackaged food*
- *Accreditation of private testing laboratories*

Rule 15b.2 The FDA shall strengthen the postmarket surveillance system in monitoring sustained compliance of locally produced and imported processed and prepackaged food in the market.

Rule 15b.3 NEC now known as EB shall do monitoring and epidemiological studies on food borne illnesses.

Rule 15b.4 The BOQ shall take all the necessary measures to ensure sanitation and food safety within their areas of responsibility as per RA 9271 and PD 856. This shall include food service establishments (FSEs) at points of entry (POE - international ports and airports), in-flight catering services, and domestic inter-island vessels.

(c) The LGUs shall be responsible for food safety in food businesses such as, but not limited to, activities in 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 LGU shall take all the necessary measures to ensure sanitation and food safety within their territorial jurisdiction.

Rule 15c.2 The Act shall serve as a framework for the LGUs in formulating and implementing their local ordinances in support of food safety.

Rule 15c.3 To facilitate and promote the implementation of food safety regulation as required by the Act, the DA and DOH shall establish a mechanism for coordinating with the LGUs in enforcing national food safety standards and regulations in the above food businesses within their jurisdiction.

(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;

Rule 15d.1 The DILG shall take all the necessary measures to enjoin the LGUs in effectively implementing food safety and sanitary rules and regulations.

Rule 15d.2 The DILG shall monitor and report to the Food Safety Regulation Coordinating Board the enforcement of food safety regulations by the LGUs.

(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 may deputize the LGUs to enforce national food safety regulations.*

(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 in collaboration with the DILG shall implement capacity building programs for 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 DOH shall develop and conduct training programs for LGU food safety inspectors and other LGU officers.*

(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 15.g.1 *The DA and DOH shall link and coordinate with LGUs to monitor hazards in the food supply chain.*

RULE 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;
- (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 regulatory agencies for the food commodities and agricultural inputs indicated in Section 16 (a) to (i) shall be referred to as the DA Food Safety Regulatory Agencies (DA FSRAs) for purposes of this Act.*

Rule 16.2 *The mandate for food safety of DA FSRA's shall be implemented by the DA Secretary through the following DA officials:*

Rule 16.2.1 *The DA Undersecretary for Policy and Planning who shall oversee the following*

- a)** *Compliance of all food safety standards and regulations of the DA with national interests and international protocols and effective participation of the DA in regional and international activities on food safety.*
- b)** *Provision of food safety standards and of testing, training and research for policy making and for use in regulatory enforcement.*
- c)** *Coordination of food safety regulatory activities within the DA and between the DA and the DOH, for the DA Secretary in the Food Safety Regulation Coordinating Board provided for in ARTICLE VI.*

Rule 16.2.2 *The Executives of DA Agencies in SECTION 16 (a) to (i) who shall be responsible for the*

following:

- a) *Cost-effective development and implementation of appropriate food safety regulations based on and in accordance with the provisions of this Act and its Implementing Rules and Regulations.*
- b) *Risk based inspection of domestic, imported and exported foods.*

Rule 16.3 In accordance with the oversight responsibilities of the Undersecretary for Policy and Planning in Section 17 of this Act, the Agency Heads of DA FSRAs shall clear all regulatory issuances for food safety with the DA Undersecretary for Policy and Planning to provide a system for review in relation to the effects of these issuances on international agreements and fair practices in trade.

Rule 16.4 The DA FSRA's shall develop, modify and implement as necessary a Food Safety Regulatory System based on a risk management plan with a mechanism for monitoring, review and continuous improvement.

Rule 16.5 The current food safety control activities that are being implemented by DA FSRAs are the following:

a. *Bureau of Animal Industry (BAI) - Regulatory Agency for the safe production of animals for food*

- *Investigates, studies and reports the cause of dangerous communicable diseases in livestock and poultry and formulates programs for the prevention, control and eradication of animal diseases*
- *Regulates the preparation, sale, traffic, shipment and importation of viruses, serum, toxins or analogous products used for the treatment of animals*
- *Licenses establishments engaged in the manufacture, trading, distribution and sale and/or promotion of veterinary drugs and products intended for mass medication, vaccines and other biological products labelled for veterinary use, disinfectants and insecticides intended for the environment and for animal equipment and facilities*
- *Registers veterinary drugs and products intended for mass medication and prescribes requirements for their prudent use*
- *Ensures implementation of the Good Animal Husbandry Practices (GAHP) in coordination with the DA Regional Food Offices (RFOs).*
- *Regulates the manufacture, importation, labelling, advertising, distribution and sale of livestock and poultry feeds.*

b. *National Dairy Authority (NDA) - Regulatory Agency for Fresh Milk in the primary production and postharvest handling stage of the food supply chain*

- *Enforcement of GAP and GAHP in local dairy farms*
- *Registration of local dairy farms and chilling centers*
- *Audit of food safety programs and licensing of local fresh milk processors, local dairy farms and chilling centers*
- *Enforcement of Good Production and Hygienic Handling Practices and HACCP for local fresh milk*
- *Operation of testing laboratories for the analysis of local fresh milk and its products*

c. *National Meat Inspection Service (NMIS) - Regulatory agency for the safety of meat and meat products in the primary production and postharvest handling stages of the food supply chain*

- *Enforcement of food safety standards and other measures to ensure pure, wholesome and safe supply of meat and meat products in the domestic market and for export*
- *Evaluation, classification and accreditation of local and foreign meat establishments seeking to export meat and meat products into the country*
- *Inspection and monitoring and accreditation of slaughterhouses and other meat establishments*
- *Inspection and certification of meat and meat products*
- *Registration of meat inspectors and handlers*
- *Implementation of the Meat Inspection Code of the Philippines as amended*

d. *Bureau of Fisheries and Aquatic Resources (BFAR) - Regulatory Agency for the primary production and postharvest handling of fishery and aquatic products in the fresh and postharvest stages of the food supply chain.*

- *Inspection, licensing/registration/approval and monitoring of all fishery establishments importing/exporting fish and fishery/aquatic products to the European Union and other international markets.*
- *Inspection and certification of fish and fishery/aquatic products for compliance with Philippine food safety standards and regulations of products for the European Union and other international markets.*
- *Enforcement of HACCP including prerequisite programs and other risk based control measures for*

fish and fishery/aquatic products to ensure food quality & safety for the European Union and other international markets.

- *Training and certification of food safety officers.*
 - *Ensuring the safety of aquaculture inputs and biological agents used in aquaculture through, but not limited, to the following:*
 - *Registration of veterinary drugs and products, labelled for use in aquaculture and aquatic animals.*
 - *Licensing of establishments manufacturing veterinary drugs and products labelled for use in aquaculture and aquatic animals*
 - *Prescribing and dispensing veterinary drugs used in aquaculture and aquatic animals.*
 - *Implementation of a national residue control program for aquacultured fishery products, and enforcement of regulatory action on findings.*
 - *Monitoring of marine biotoxins in shellfish producing areas, and implementation of risk management options*
 - *Operation of laboratories for the testing needs of the above functions.*
 - *Communication and management of risks and development of interactive exchange among stakeholders*
- e. Bureau of Plant Industry (BPI) – Regulatory Agency for the primary production and postharvest handling of plants for food**
- *Monitoring of pesticide residue, microbiological and chemical contaminants in primary production and post harvest stages in the food supply chain*
 - *Registration, Inspection and Monitoring of farms except those registered by other DA FSRAs.*
 - *Regulation of Genetically Modified Plants for foods in primary production and post harvest stages in the food supply chain*
- f. Fertilizer and Pesticide Authority (FPA) - Regulatory Agency for the safe use of pesticides and agrochemicals during the primary production and postharvest handling of plants and animals used for food**
- *Licensing of persons/corporation/cooperatives or establishments involved in activities related to but not limited to the handling, manufacturing, repacking, reformulating and storing of fertilizers, pesticides and other agrochemicals*
 - *Registration of fertilizers, pesticides and all other agrochemicals including organic agricultural inputs and biotechnology-derived agrochemicals like plant incorporated protectants and approval of product label statements for their safe and effective use*
 - *Accreditation of pesticide handlers but not limited to Certified Pesticide Applicators, Professional Pesticide Advisers (PPA), Accredited Responsible Care Officer (ARCO), Master Instructor-Responsible Care Officer (MI-RCO), Responsible Care Officer (RCO), Accredited Pesticide Dispenser (APD) and Accredited Researchers*
 - *Accreditation of laboratories analyzing fertilizer, pesticides and agrochemical formulations and residues for the Agency*
 - *Monitoring of the safe handling, use and application of fertilizers, pesticides and other agrochemicals used in the country*
 - *Regular updating of FPA regulatory guidelines based on international guidelines to ensure that fertilizers, pesticides and other agrochemicals used in the country are safe to human health and the environment.*
- g. Philippine Coconut Authority (PCA) shall be responsible for coconut products in the primary production and post-harvest stages in the food supply chain**
- *Development of the Integrated Food Safety Program*
 - *Development of Good Agricultural Practices (GAP)*
 - *Providing training on GAP and GHP*
 - *Development and validation of HACCP*
 - *Development and establishment of Philippine National Standards and Codes of Hygienic Practice*
 - *Assist the DOH in monitoring / ensuring Vitamin A fortification of coconut cooking oil and palm oil*
 - *Control and monitoring of aflatoxin levels*
 - *Provide laboratory services for the analysis of chemicals (including aflatoxin and heavy metals), physical and microbiological properties*
 - *Issuance of commodity clearance for export based on results of laboratory analysis .*
 - *Enforcing copra quality improvement as to moisture content*
 - *Monitoring of Polycyclic Aromatic Hydrocarbon (PAH) levels in coconut oil*
- h. Sugar Regulatory Administration (SRA) – Regulatory agency responsible for primary production and**

postharvest stages of sugar in the food chain

- *Provision of extension services to farmers on Good Agricultural Practices for sugarcane*
- *Audit of sugar mills, refineries and muscovado mills including implementation of Good Hygienic Practices*
- *Enforcement of Philippine National Standard for raw and white sugar and muscovado and conduct of compliance checks through laboratory analysis*
- *Development and updating, in coordination with BAFS, the Philippine National Standard for Muscovado and Codes of Practice for the production of sugars and updating methods of analysis of sugar based on International Commission for Uniform Methods of Sugar Analysis (ICUMSA)*
- *Registration of sugar mills and refineries for compliance with the Philippine National Standard for raw and white sugars*
- *Issuance of Sanitary Certificates for sugars*
- *Monitoring of the consumption and traceability of sugars in the supply chain*
- *Analysis of abandoned and auctioned sugar for fitness for human consumption*

i. National Food Authority (NFA)

- *Implementation of the program for pest control in NFA warehouses*
- *Implementation of the Philippine Grains Standardization Program for both government and commercial grains*
- *Implementation of good warehousing policies and practices*
- *Mandatory compliance of private rice mills and warehouses, retailers, wholesalers and haulers with cleaning and sanitation standards prior to issuance of NFA licenses/permits.*
- *Advocacy programs on proper post-harvest practices for paddy rice, rice and corn*

Rule 16.7 *Within one year from the implementation of this IRR, the DA FSRAs shall develop and implement a food safety regulatory program consistent with this Act on the basis of a Risk Management Plan described in ARTICLE IV Section 7. Current activities of the DA FSRAs in Rule 16.6 shall be made a part of the Risk Management Plan of the food safety regulatory programs of DA FSRAs when completed.*

The Bureau of Agriculture and Fisheries Standards (BAFS) 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 16.8 *BAFS shall be the DA agency responsible for developing, adopting, and/or amending food safety standards and codes of practice for the use of DA FSRAs in developing/implementing food safety regulations. BAFS may accommodate requests for food standards from other DA agencies, provided the requirements of DA FSRAs are given priority and the timely development of these standards are met.*

Rule 16.9 *BAFS shall establish the policies and procedures to ensure a transparent, science-based mechanism for the development of standards. These policies and procedures shall be made into a manual of operations which shall include but shall not be limited to the following:*

- *Preparation of the Priority List*
- *Qualification and terms and conditions for the use of Experts in risk assessment and in providing scientific advice to the NCO and the DA.*
- *Functional separation but strong interactive exchange between Risk Assessors and Risk Managers in the risk assessment process for the development of standards.*
- *Sourcing of scientific inputs*
- *Process of validation and approval*
- *Documentation*
- *Dissemination*
- *Others as found necessary and relevant*

Rule 16.10 *BAFS shall organize the DA Risk Assessment Expert Body for the development of food safety standards and the provision of scientific advice to the Undersecretary for Policy and Planning, the Agency Heads of DA FSRAs and the National Codex Organization.*

Rule 16.11 *BAFS shall be responsible to the DA Undersecretary for Policy and Planning for the attainment of targets for food safety standards and for the appropriateness of these standards to the needs of the DA FSRAs and the DA in general.*

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

Rule 16.12 *FDC shall 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, for a fee.*

Rule 16.13 *It shall be the Coordinating Laboratory for the DA Laboratories and in this capacity, shall have the following functions :*

- a) Establish comparative testing between DA laboratories as necessary*
- b) Identify the DA laboratories that will function as the National Reference Laboratory for specific analytes.*
- c) Ensure that DA laboratories use validated laboratory methods and analyse their samples according to ISO/IEC 17025 until accredited to ISO 17025 by the Philippine Accrediting Office.*
- d) Promote close coordination in testing activities between the laboratories*

Rule 16.14 *It shall provide testing services to FBOs for a fee.*

Rule 16.15 *FDC shall carry out the researches needed for establishing science-based policies for food safety at the DA Office of Undersecretary for Policy and Planning. This shall include but shall not be limited to the generation of scientific data for risk assessment, the evaluation of risk management options, the establishment of equivalence in food safety control systems and other research needs.*

Rule 16.16 *FDC shall develop and conduct training programs on food safety and on food safety regulations in accordance with the provisions of Article IX Section 31 of this Act.*

Rule 16.17 *FDC shall prepare its food testing, research and training targets as provided for in this Act within one year from the implementation of this IRR. It shall be responsible to the DA Undersecretary for Policy and Planning for the attainment of targets and the implementation of effective programs for food testing, training and research.*

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 16.18 *Appropriate personnel and funding shall be provided by the DA at the initial stages of the implementation of this Act to start critical functional activities at the Office of Policy and Planning, the DA FSRAs, BAFS and FDC based on the financial and manpower requirements prepared by the above agencies.*

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 16.19 *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 issues in the food supply chain.*

RULE 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

Rule 17.1 *The DA Undersecretary for Policy and Planning shall have oversight functions over the development and proper coordination of the functional activities of the DA and the coordination of these activities with the DOH the DILG, LGUs and the Bureau of Customs (BOC).*

Rule 17.2 *The Undersecretary shall be assisted by a Food Safety Oversight Unit which shall be established and initially funded by the DA.*

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 17.3 *The Undersecretary for Policy and Planning shall supervise the role of BAFS, FDC and the Codex Contact Point as defined in this IRR.*

Rule 17.4 *The DA Undersecretary for Policy and Planning shall oversee DA participation in the National Codex*

Organization in codex meetings and in all international activities on food safety and food safety regulation.

Rule 17.5 The FDC shall be transferred from the NFA to the DA after approval of the NFA Council without diminution of personnel salaries and benefits for the direct supervision by the Undersecretary for Policy and Planning as required.

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 17.6 The initial requirements for funds and manpower to support the oversight functions of the Undersecretary for Policy and Planning shall be provided by the DA.

RULE 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 in coordination with DILG shall develop guidelines for the fast food chain establishments to declare nutrition information on calories and other nutrients/food substances on their regular menu as determined by DOH.

Rule 18a.2 The FDA-CFRR Licensing and Registration Division shall be responsible for evaluating processed and pre-packaged food products and establishments for the purpose of issuance of authorizations and conditions to be observed.

Rule 18a.3 The FDA Center for Food Regulation and Research 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 processed food products and food/dietary supplements.

Rule 18a.4 The CFRR shall issue LTO to all food business establishments within its jurisdiction as a requirement before commencing operations.

Rule 18a.5 The CFRR shall require the registration of all processed and pre-packaged food products before it is sold, offered for sale or distributed for public consumption.

(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 18b.1 In coordination with the FDA Policy and Planning Office, the CFRR shall create a Technical Working Group led by the Product Research and Standards Development Division (PRSD) in the development of food standards.

Rule 18b.2 The CFRR shall take the lead in the development of food and food safety regulations.

(2) Post-market monitoring;

Rule 18b.3 The CFRR shall establish and maintain the post market monitoring system (PMS) of food products, including programs for monitoring, fact-finding activities, and procedures for risk-based inspection.

Rule 18b.4 The FDA Regional Field Offices in accordance with PMS shall institute and strengthen post market monitoring system by inspection, collection and testing of processed and pre-packaged food in the market.

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

Rule 18b.5 The CFRR shall develop protocols and guidelines on HACCP and other risk-based control measures as may be necessary for the effective implementation of RA 10611.

Rule 18b.6 The FDA Regional Field Offices shall ensure the effective enforcement and coordination of HACCP and other risk-based control measures.

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

Rule 18b.7 *The CFRR shall ensure the regular participation of FDA country delegates to strengthen its international commitment.*

Rule 18b.8 *The FDA, in the performance of its function, as Chair of processed food commodities and other committees of Codex, shall follow the NCO Manual of Operations.*

Rule 18b.9 *The CFRR shall strengthen the country's positions through the conduct and use of science-based studies and research taking into consideration all other sources of scientific information.*

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

Rule 18b.10 *The FDA shall develop national food safety emergency response mechanism.*

Rule 18b.11 *The CFRR shall coordinate with the HPCS in the development and implementation of risk communication.*

Rule 18b.12 *The CFRR shall communicate food safety risks as identified by recognized risk assessors.*

Rule 18b.13 *The CFRR shall conduct consultative discussions among stakeholders and maintain local and international linkages on food safety.*

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

Rule 18b.14 *The CFRR Laboratory Support Division shall participate in Proficiency Tests (PT) to evaluate the performance of the method and to enhance the capability of the laboratory as well as the staff.*

Rule 18b.15 *The CFRR Laboratory Support Division shall undertake oversight, and/or audit of all satellite laboratories.*

Rule 18b.16 *The CFRR Laboratory Support Division shall establish analytical data and maintain a database to serve as basis for the preparation of food product standards and recommend standards of identity, safety, purity, and quality.*

Rule 18b.17 *The CFRR Laboratory Support Division shall conduct health technology assessment as necessary and to accredit private food testing laboratories.*

Rule 18b.18 *The CFRR Laboratory Support Division shall conduct tests and validate methods that are not routinely performed in other laboratories for confirmatory and/or investigatory purposes and to resolve disputes in test results, when necessary.*

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

Rule 18b.19 *The CFRR, through its Licensing and Registration Division, shall develop a database of common food safety hazards and food and water-borne diseases in coordination with National Epidemiology Center now named as Epidemiology Bureau.*

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

Rule 18b.20 *The CFRR shall identify priority areas of research and development on food product safety and quality and institute strategies in their implementation.*

Rule 18b.21 *The CFRR, through its PRSDD, shall undertake, when appropriate, oversight/audit of related researches that would ensure the safety and quality of food products.*

Rule 18b.22 *The CFRR shall strengthen its capabilities on product safety and quality standards by fostering collaborative research with partner institutions.*

Rule 18b.23 *The CFRR shall conduct capacity building and improvement in the conduct and management of research and development on product safety and quality standards and in the translation of research results*

into policy and practices.

(9) Certification of food safety inspectors.

Rule 18b.24 FDA shall allocate funds for the certification of food safety inspectors (ISO 17020).

Rule 18b.25 The CFRR shall establish the procedures in training of its inspectors on food safety. Each inspector shall also undergo local or international training on risk management and risk-based inspection.

Rule 18b.26 The CFRR shall develop training manuals in coordination with academe and other government agencies for conducting certified training courses for food safety inspectors.

Rule 18b.27 Certification of food safety inspectors may be given by recognized third party certifying bodies accredited by the Philippine Accreditation Office (PAO).

(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".

RA No. 9271 is the Quarantine Act of 2004 which specifies the following functions of the BOQ:

Rule 18c.1 Adoption of the HACCP system in monitoring the Food Safety program;

Rule 18c.2 Enforcement of GMP-HACCP provisions and guidelines;

Rule 18c.3 Issuance of Health Certificate to stewards and food handlers;

Rule 18c.4 Issuance of Vibrio cholera Clearance Certificate for all outgoing food stuff;

Rule 18c.5 Continuous enhancement of food safety capacity of BOQ and concessionaires in keeping with international standards;

Rule 18c.6 Development of data base system for Food Safety Program;

Rule 18c.7 Periodic monitoring and evaluation of Food Safety program in its area of responsibility;

Rule 18c.8 Strong participation in the Food Safety Regulation Coordinating Board;

Rule 18c.9 Surveillance of human infectious diseases including food and water borne disease outbreaks potentially entering the country;

Rule 18c.10 Institute processes and procedures, including reasonably appropriate risk-based preventive controls that provide the same level of public health protection as those required for both domestic and international suppliers

(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 National Epidemiology Center (NEC), now named as the Epidemiology Bureau (EB) of the Department of Health, through its Public Health Surveillance Division, shall conduct surveillance of human infectious diseases of outbreak potential within the jurisdiction of the Republic of the Philippines through the Regional Epidemic and Surveillance Units (RESUs) of the 17 Regional Health Offices.

Rule 18d.2 The EB shall strengthen and enhance the food and waterborne related diseases surveillance and reporting system (e.g. Philippine Integrated Disease Surveillance and Response - PIDSRS, FHSIS) to include poisonings, outbreaks and epidemics:

Rule 18d.3 Immediately investigate food-borne outbreaks, epidemics, poisonings, illnesses and diseases brought about by biological, chemical, microbiological and radioactive food-borne contaminants;

Rule 18d.4 Provide resources and timely information to local health units as part of the routine surveillance and outbreak investigations;

Rule 18d.5 Improve coordination and data sharing with health partners and the general public including complaints from the general public;

Rule 18d.6 Increase LGU participation in national surveillance networks;

Rule 18d.7 Expand and integrate national surveillance systems;

Rule 18d.8 Enhance laboratory and epidemiological methods for agent identification, outbreak detection and investigation;

Rule 18d.9 Systematic collection and advanced testing of samples from outbreaks of unknown etiology;

Rule 18d.10 Improve the attribution of specific illnesses to specific foods;

Rule 18d.11 The surveillance and outbreak/epidemic investigation of food and waterborne diseases shall follow the PIDS policy guidelines.

Rule 18d.12 Surveillance and outbreak/epidemic investigation reports shall be furnished to the DPCB and HPCS and/or Regional Health Education and Promotion Officer for preparation and implementation of Risk Communication Plan, if warranted;

Rule 18d.13 The EB shall coordinate with the Research Institute for Tropical Medicine, Reference Laboratory for confirmation of samples from human with food and waterborne diseases

Rule 18d.14 The NCDPC, now named as the Disease Prevention and Control Bureau (DPCB), shall conduct a periodic evaluation of food safety related programs to determine the effectiveness in achieving legislated intent, purposes, and objectives in coordination with other DOH offices, Department of Agriculture and other concerned government agencies.

Rule 18d.15 The DPCB shall 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 National Center for Health Promotion (NCHP) renamed under Executive Order 366 as the Health Promotion and Communication Service (HPCS) shall be responsible for advocating food safety awareness, information and education to the public.

Rule 18e.2 HPCS shall:

Rule 18e.2.1 Develop Health Promotion and Communication and/or Risk Communication plan for food safety in collaboration with the Food and Drug Administration, Disease Prevention and Control Bureau, Epidemiological Bureau, Bureau of Quarantine and other concerned government agencies;

Rule 18e.2.2 Develop information, education and communication (IEC) prototype materials for mass production and/or adoption of LGUs and other partners

Rule 18e.2.3 Secure the approval of IEC materials from concerned DOH offices and other government agencies, if necessary

Rule 18e.2.4 Disseminate food safety messages and information through appropriate media and interpersonal channels

Rule 18e.2.5 Mobilize resources to support the implementation of the HPC/Risk Communication Plan

Rule 18e.2.6 Lead the implementation of the HPC Plan in collaboration with the DOH concerned offices, Local Government Units and other partners

Rule 18e.2.7 Determine audience reach and immediate effects of the HPC or Risk Communication Plans

(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 NCDPC now named as Disease Prevention and Control Bureau (DPCB) in coordination with FDA shall:*

Rule 18f.1.1 *Implement the risk management for food safety program. The implementation of hazard analysis and control principles and the observance of sanitation requirements and hygiene rules shall be applied at all levels in compliance to Chapter 3, IRR on Food Establishments of PD 856, Code on Sanitation of the Philippines.*

Rule 18f.1.2 *Review existing guidelines to improve policies pertaining to micronutrient supplementation, food fortification of food products and food labelling.*

Rule 18f.1.3 *Develop standards and plans that takes into account biological, chemical and radiological threat agents*

Rule 18f.1.4 *Integrate its food safety plan which will include hazard analysis, risk-based controls, monitoring and corrective actions to the National Food Safety plan to be headed by CFRR.*

Rule 18f.1.5 *Conduct relevant researches with academic institutions, professional organizations and non-government organizations, as may be necessary on the toxic effect brought about by chemical contamination.*

Rule 18f.1.6. *Enhance the food safety network through the event based surveillance system and strengthen the Inter-Agency Committee on Environmental Health with the DOH as Chair.*

Rule 18f.1.7 *Establish the capacity development programs to upgrade the skills and knowledge of health personnel on food safety including health promotion and communication and risk communication and the BOQ at ports and airports.*

Rule 18f.1.8 *Review and update existing policies and guidelines, regulations related to food safety program*

Rule 18f.1.9 *Develop guidelines on the decontamination and disposal of contaminated, adulterated and sub-standard processed and pre-packaged food products*

Rule 18f.1.10 *Provide technical assistance to NCHP on the development of advocacy materials for dissemination.*

(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.

RULE 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 LGUs shall require the fastfood chain establishments to declare nutrition information on calories and other nutrients/food substances on their regular menu based on standards determined by DOH.*

Rule 19a.2 *The LGUs shall recognize the BOQ areas of responsibility as defined in Article V, Section 18(c) of the*

Act.

(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:

(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 in the following areas :*

- a) Policy and regulatory issues arising from implementation of measures and of official controls.*
- b) Effect of regulations on food import - export activities.*
- c) Exchange of information on standards and regulatory issuances and scientific data on hazards, epidemiological studies, monitoring and surveillance activities and others.*
- d) The management of risk, the control of fraud, and the identification and evaluation of emerging risks*
- e) Evaluation of the impact of testing, training and research programs.*
- f) Others*

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

Rule 20b.1 *The Board shall determine the regulatory agency that shall enforce regulations when enforcement mandates based on ARTICLE V of the ACT, are found to overlap.*

Rule 20b.2 *The Board shall establish the policies and procedures for decision making and its implementation. This shall be carried out as soon as the FSRCB is organized.*

Rule 20b.3 *The FSRA's shall implement their current food safety control activities until overlapping areas in mandates and functional activities are resolved by the Food Safety Regulation Coordinating Board as organized and mandated in ARTICLE VI.*

(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 Board 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 and the DOH 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 Board shall review the effectiveness and appropriateness of coordinated regulatory activities and research and training programs. The Review shall be carried out at the end of each year unless relevant information from monitoring and surveillance activities indicates the need for an earlier review of said*

activities.

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

Rule 20f.1 The Board 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 Board may apply for/accept grants from local and international sources to fund research and training programs and monitoring and surveillance activities.

RULE 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, BLHD, RITM.

Rule 21a.2 The Board may invite representatives from the food industry associations/organizations and/or consumer groups as resource persons as may be deemed necessary.

Rule 21a.3 In the event that the Board requires voting as recourse for decision making, all member departments namely DOH, DA, DILG, DTI, DOST, and Leagues of Barangays, Municipalities, Cities and Provinces shall each be entitled to one vote.

Rule 21a.4 BAFS and FDC

(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;

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

Rule 21b.2 The manual should also include provisions for the following, among others:

Rule 21b.2.1 Consultative Task Force chaired by the Director of CFRR or his/her appointed permanent representative to facilitate broad consultation with industry and trade groups and other concerned stakeholders and advice the Board on pertinent issues on food safety and its regulation in the processed and pre-packaged sector of the food chain;

Rule 21b.2.2 Consultative Task Force chaired by the Director of a DA FSRA or his/her appointed permanent representative to facilitate broad consultation with industry and trade groups and other concerned stakeholders and advice the Board on pertinent issues on food safety and its regulation in the primary production and post harvest sectors of the food chain;

Rule 21b.2.3 Scientific Task Force to assist and advise the Board on matters of scientific nature needed in food control decision making, including scientific questions relating to food safety and hygiene; food standards and code of practice; research; nutritional value and content of food and labelling; risk-based implementation of food inspection services; and monitoring and evaluation including regulatory impact assessment.

(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 through the FDA Director General shall create a Food Safety Division within CFRR which will serve as the Secretariat in addition to its major activities relating to food safety.*

Rule 21c.2 *The DA through the DA Undersecretary for Policy and Planning shall create a functional division from the existing manpower to be part of the secretariat.*

(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.

RULE 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.

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

ARTICLE VII

CRISIS MANAGEMENT

RULE 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 *The Members of the Food Safety Regulation Coordinating Board shall establish a rapid alert system for identifying and subsequently notifying the Board of the existence of a direct or indirect threat to human health from a food. Information from the system should include identification of the product, the nature of the risk and appropriate risk management actions that can be taken.*

RULE 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.

RULE 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

RULE 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 this Act. It shall be a part of the Food Safety Regulatory System of 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 riskbased 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 or equivalent personnel who is a graduate 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 of allied technical courses must have training and work experience in food safety.

Rule 26c.2 Food safety officers or equivalent personnel involved in food inspection shall undergo training and shall be certified every three years by the Philippine Accreditation Office (PAO) or an equivalent organization.

Rule 26c.3 Testing shall be carried out by chemists or microbiologists 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;

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

RULE 26f.1 A manual of procedures for food inspectors shall be developed by DA FSRAs within one year from the approval of the Act and its IRR. Initial funding for the development of this manual of procedures shall be provided by the DA.

RULE 26f.2 Food testing laboratories shall have manuals of Good Laboratory Practice, calibration procedures and a manual of validated testing methods compliant with Codex 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 accepted provided that they are certified or accredited to the appropriate ISO standard by the Philippine Accrediting Office.

Rule 26g.2 The fees for third party service providers of official controls shall be obtained from fees paid by FBOs to FSRA for food inspection, testing and certification activities.

(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 initial funds necessary to develop, establish, and initially implement the manual of procedures for official controls shall be provided by the DA.

RULE 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.

Rule 27c.1 Properly applied, traceability can contribute to protecting the consumer against food borne hazards and deceptive marketing practices. It can also facilitate product recall. FBOs shall be required to establish traceability records which will indicate at the minimum where the food/food ingredient immediately came from and where it will immediately proceed.

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

Rule 27c.2 The FDA and the DA shall assist NEC in establishing mechanism for tracing food-borne disease outbreak from production to consumption.

RULE 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 The FDA-CFRR, through its Licensing and Registration Division, shall mandate, order, review, and implement a Risk Management Plan on any food product within its authority for conformance with the FDA standards.

Rule 28.2 Product certificates or establishment licenses to operate shall be issued when products or establishments have been verified by examination or objective evidence, to meet specified requirements of the food law for the product or the establishment.

RULE 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 as they gain experience in the inspection of various food products, systems and technologies. Training programs shall established competence such as through examinations, certification and others.*

(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 manual and shall undergo periodic review.*

RULE 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 with the local or international standards for good laboratories practices and method validation and seek accreditation to ISO 17025 and specify the period for the achievement of this objective in their work program.*

Rule 30a.2 *Food testing shall be carried out by independent laboratories accredited by the FDA in accordance with FDA existing rules and regulations and other local and international standards applicable to testing laboratories and shall have a valid ISO 17025 certification/accreditation.*

(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;

Rule 30c.1 *The DA and the DOH shall provide technical supervision and monitor the operations of their Satellite Laboratories.*

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

Rule 30d.1 *Laboratory analysts shall be licensed professionals in the required profession for testing.*

Rule 30d.2 *Laboratory analysts shall have continuous competency assessment for method and equipment used in food analysis.*

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

Rule 30e.1 *The DA and the DOH may avail of services of private testing laboratories provided these are accredited to ISO 17025.*

ARTICLE IX

TRAINING AND CONSUMER EDUCATION

RULE 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 The DA and the DOH shall conduct certified training courses.

Rule 31.2 The DA and the DOH may partner with the academe and professional associations in providing food safety trainings.

Rule 31.3 The DA and DOH shall recognize third party institutions to conduct training of food sanitary inspectors.

RULE 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.

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

Rule 33.1 The DA, the DOH, and the LGUs shall provide funds for the initial implementation of the Act.

Rule 33.2 The DA, the DOH and the LGUs shall provide funds for the development and implementation of training and consumer education programs.

ARTICLE X

FOOD-BORNE ILLNESS MONITORING, SURVEILLANCE AND RESEARCH

RULE 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.

Rule 34b.1 The DA and DOH shall link and coordinate in monitoring pesticide residues, food additives, veterinary drug residues in food and chemical, biological, and other contaminants under their jurisdiction.

RULE 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 DOH and the DA 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 DOH and the DA 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

RULE 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

RULE 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.

RULE 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 impossible 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

RULE 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. These implementing rules and regulations may be jointly amended and/or updated from time to time by the Department of Agriculture and the Department of Health.

Rule 39.2 All doubts in the interpretation of these Rules and Regulations 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 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.

RULE 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.

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