



Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City, Metro Manila

Fifteenth Congress
First Regular Session

HOUSE BILL NO. **4417**

Introduced by Hon. Mark Llandro L. Mendoza, Hon. Irvin M. Alcala,
Hon. Danilo E. Suarez, and Hon. Sharon S. Garin

EXPLANATORY NOTE

Food should not cause harm to consumers when it is prepared and eaten in accordance with its intended use. Food-borne illnesses occur, however, because food is exposed to hazards that can cause illness during its production up to its preparation for human consumption.

Food borne-illness is a documented public health problem. According to the World Health Organization food and water-borne diarrheal diseases kill an estimated 2.2 million people yearly in developing countries.

Hazards to the safety of food as well as the measures needed to control these vary with the type of food and the circumstances under which it is made available. Pathogenic microorganisms and viruses grow on foods when hygienic and other conditions are poorly controlled. For example, residues of antibiotics are in fish and meats due to the improper use of these drugs during production. Pesticide residues are in plant foods when pesticides are not applied as prescribed. Fungal toxins proliferate in corn and peanuts when improperly dried. Toxic metals as lead, cadmium and mercury from the environment and other sources find their way to fishes. Harmful chemicals also get into food through inappropriate use of food additives or through intentional adulteration for economic gain. There are also emerging hazards as pathogens that are more virulent or are emerging in new food vehicles. Globalization is partly held responsible for this as it has changed the way food is produced, processed and distributed.

The prevention of food-borne illness is the responsibility of all in the industry who handle food in the food supply chain. Verification of the effectivity of measures taken by the industry to prevent food borne illness is, however, the responsibility of governments as this can only be achieved through regulation.

The rise in incidence of food-borne illness and the growth in knowledge on food safety have made countries vigilant about the way the safety of food is regulated. This resulted to the development of food safety regulations as part of international protocols to which we are signatory. Many countries in the European Union, as well as the United States, have

restructured their regulatory systems in response to these protocols. Others have strengthened their systems as an essential step to gaining access to markets. Upgrading our food safety regulatory system is called for in the light of what is now known regarding food safety as well as the effects of this on our trade in foods and food products.

Building a sound food regulatory system will require the cooperative effort of the three government agencies involved in ensuring safe food. The Department of Agriculture (DA) which is responsible for fresh foods and food commodities, the Department of Health (DOH), for processed and packaged foods and the Department of Interior and Local Governments (DILG), which supervises the regulation of food safety by the Local Government Units (LGU's).

There are several weaknesses in the food safety regulatory system that have to be addressed. Foremost among these is that the laws of regulatory agencies have ill defined mandates and a weak basis for food safety regulation. This has led to overextension and duplication of services as well as gaps in regulation. The exceptions are the enabling laws of the Food and Drug Administration (FDA) of the DOH (in RA 3720 and RA 9711) and of the National Meat Inspection Service (NMIS) of the DA (in RA 9296). The regulation of the FDA however is combined with drugs; while that of the NMIS is mainly on the safety of meat for export and import.

Current primary and secondary legislations create overlapping jurisdictions over specific functions and areas. The mandate of LGU's over food safety as defined in the Local Government Code of 1991 overlaps with the jurisdictions of the DA and the DOH. Similarly overlapping jurisdictions occur between the DA and the DOH for food safety in the Consumer Act (RA 7394). The enabling laws of the Bureau of Fisheries and Aquatic Resources for canned fish and of the NMIS for processed meats overlap with that of the DOH for processed foods.

Currently there is no mechanism for coordination between the agencies that could lead to a smooth resolution of overlapping mandates or to the utilization of each agency's institutional strengths for more effective regulatory programs. Instead complex and multiple legal instruments have been issued by the agencies. While this is not unexpected since the area of food safety regulation is not straightforward and requires the constant application of new measures, a strategy for harmonizing and streamlining the various legal issuances through a basic food safety act appears necessary.

An important component of food safety regulations are food safety standards. There are few mandatory food safety standards in national regulations. The mandate of the Bureau of Agriculture and Fisheries Product Standards (BAFPS) to set standards overlaps with that of other agencies as NMIS (for meat), BFAR (for fish) and the Fertilizer and Pesticide Authority (FPA) for pesticide residues. Considering the situation, a mechanism for developing food safety standards has to be put in place by BAFPS.

The food safety standards developed by the Codex Alimentarius Commission (CAC) are used as basis for the acceptance of food products in trade. A National Codex Organization (NCO) was recently established to strengthen country participation at Codex. The NCO which is a joint body of the Department of Agriculture and the Department of Health should be recognized as part of the food safety regulatory system and ensured support by government.

Conformity with standards is determined through several activities, of which testing is among the most demanding of professional skill due to the increasing complexity of food testing methods and equipment. More professional management to bring this activity to required levels of proficiency is necessary.

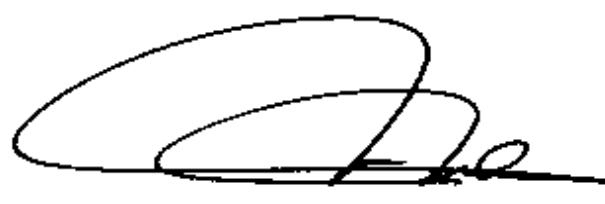
Correcting existing weaknesses in the food safety regulatory system should also involve upgrading manpower skills in the understanding of food safety. A wide gap currently exists between the requirements of regulations and our understanding of these requirements. Properly closing this gap will go a long way towards improving the performance of agencies and facilitating compliance with measures by farmers and fisherfolks and small industries.

Food safety regulations can become barriers to trade due to differences in concepts between countries on what makes food safe. International protocols thus require that regulations be based on science as it provides a basis for demonstrating equivalence in food safety control measures of countries. A strong research and development (R&D) program is necessary to support a science-based regulatory system. Epidemiological studies on food-borne illness and surveillance studies on contaminants in foods have to be carried out. These studies which provide a basis for the identification and assessment of risks also enable agencies to provide the greatest attention to those food safety hazards that pose the greatest risks.

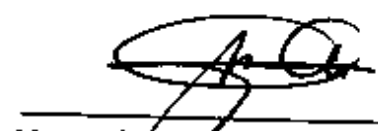
Technologies that will enable the industry especially farmers, fisherfolk and small scale industries to comply with regulations and market their products competitively should also be established through R & D.

The regulatory system needs to be strengthened to be at par with requirements for ensuring food safety. Considering that there are three agencies involved, this can only be achieved if the agencies are well coordinated to work together towards this objective. A single Food Safety Act based on common principles for food safety should provide the needed legal framework for coordination and for streamlining legal issuances for official controls, training and research. Making this feasible should enable the agencies to respond effectively to changes in requirements for food safety brought about by markets, new information and new technologies.



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**Introduced by Hon. Mark Llandro L. Mendoza, Hon. Irvin M. Alcala,
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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

ARTICLE 1
Title, Declaration of Policy and Objectives

SECTION 1. *Short Title.* – This Act shall be known as “*The Food Safety Act of 2011.*”

SECTION 2. *Declaration of Policy.* – It is the policy of the State to develop and maintain a food safety regulatory system that will ensure the highest level of protection of human health in the consumption of food, fair practices in the food trade and market access of local foods and food products.

SECTION 3. *Objectives.* – The objective of this Act is to strengthen the food safety regulatory system in the country by:

- (a) delineating the mandates and responsibilities of government agencies involved;
- (b) providing a mechanism for coordination and accountability in the implementation of regulatory functions;
- (c) establishing policies and programs for addressing food safety hazards, developing appropriate standards and control measures;
- (d) strengthening the scientific basis of the regulatory system, and upgrading the capability of farmers; and
- (e) fisherfolk, industries, consumers and government personnel to play their roles in ensuring food safety.

ARTICLE II

Definition of Terms

SECTION 4. *Definition of Terms.* – With regards to this Act, the following key definitions are given:

- (a) "Contaminants" 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 husbandry, animal husbandry and veterinary medicine) manufacturing, processing, preparation, treatment, packing, packaging, transport or holding of such food as a result of environmental contamination. The item does not include insect fragments, rodent hairs and other extraneous matter.
- (b) "Control Measure" refers to any action and activity that can be used to prevent or eliminate a food safety hazard or to reduce it to an acceptable level.
- (c) "Food" refers to any substance or product whether processed, partially processed or unprocessed reasonably expected to be ingested by humans. "Food" includes drinks, chewing gum and water which is intentionally incorporated into the food during its manufacture, preparation and treatment. "Food" shall not include Feeds, Live animals unless they are prepared for placing in the market for human consumption, Plants prior to their harvesting, Medicinal products, Cosmetics, Tobacco and tobacco products, Narcotics or psychotropic substances
- (d) "Feed" refers to any substance or product including additives, intended to be used for oral feeding to animals.
- (e) "Food Business" refers to any undertaking whether public or private carrying out any of the activities related to or at any of the stages of the food supply chain.
- (f) "Food Business Operator" refers to the person responsible for ensuring that the requirements of food law are met within the food business under his/her control.
- (g) "Food hygiene" (hereinafter called Hygiene) refers to the measures and conditions necessary to control hazards that create food safety risks and to ensure fitness for human consumption of a food of plant or animal origin taking into account its intended use.
- (h) "Food Law" refers to the laws, regulations and administrative provisions governing food in general and food safety in particular. They cover any stage of production, processing and distribution of food and its preparation for human consumption.
- (i) "Food Safety" refers to the assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.
- (j) "Food Safety Regulatory System" refers to the combination of regulations, food safety standards, inspection, testing, data collection and surveillance carried out by each of the three government agencies in the implementation of their responsibilities for the control of food safety risks in the food supply chain.
- (k) "Food Supply Chain" refers to all the stages in the production of food from primary production, postharvest handling, distribution, processing and preparation for human consumption. Primary production includes farming of plants and live animals, aquaculture production of seafoods, and the "catching" of marine fishes at sea. Postharvest handling includes minimal transformation of plant and animal foods after primary production such as removal of field heat for fruits, slaughter of animals, sorting and grading, icing and freezing, and the milling of grain. Distribution includes transport and storage. Processing involves extensive transformation of food as canning, manufacture of

juices, dehydration, and the packaging of products. Preparation is the cooking or other preparations to which food is subject prior to its consumption.

- (l) "Hazard Analyses at Critical Control Points (HACCP)" refers to the scientific and systematic method of ensuring food safety by identifying and assessing potential risks critical to food safety existing at points during a given stage in the food supply chain, such as points in the processing of a food. It also pertains to methods of establishing permanent control methods at such points. These points are known as critical control points. They are points in any of the stages in the food chain (raw materials, location, process, recipe of the food, transportation etc.) which should be controlled to eliminate or reduce risks to an acceptable level.
- (m) "Hazard" refers to a biological, chemical or physical agent in a food with a potential to cause an adverse effect on health.
- (n) "Inspection" refers to the examination of facilities of food business or establishment and their management and production systems. This also deals with: examination of these entities' documents, finished product testing and feeding practices (for animal foods), and of the origin and destination of production inputs and outputs. This is in order to verify compliance with legal requirements in all cases.
- (o) "Micro, small, medium and large scale industries" refers to the classification of industries of the Department of Trade and Industry.
- (p) "National Codex Organization" refers to the organization created by a Joint Department Order, Department of Agriculture Administrative Order No 01 Series of 2008 and Department of Health, Administrative Order No 2008-0030. It establishes the policies and procedures, and defines the objectives to be reached in country participation at the Codex Alimentarius Commission. The latter is an organization under the aegis of the Food and Agriculture Organization and the World Health Organization that develops and adopts science-based food safety standards, codes of practice and other texts, for the protection of consumer health and fair trade.
- (q) "Official Control" refers to all types of control made by the regulatory agency to verify compliance with standards, operating procedures, practices and other requirements.
- (r) "Primary Production" refers to the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter; and the rearing and growing of fish and other seafoods in aquaculture ponds. It also includes fishing, and the hunting and catching of wild products.
- (s) "Processing" refers to any action that substantially alters the initial product including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion and a combination of those processes.
- (t) "Risk" refers to the likelihood of an adverse health effect and the severity of this effect following exposure to a hazard
- (u) "Risk Analysis" refers to the process consisting of three interrelated components: risk assessment, risk management and risk communication.
- (v) "Risk Assessment" refers to the scientific evaluation of known or potential adverse health effects resulting from human exposure to food-borne hazards. The scientific process consists of four phases, namely: hazard identification, hazard characterization, exposure assessment and risk characterization. It includes quantitative risk assessment, which emphasizes reliance on numerical expressions of risk, and also qualitative expressions of risks, as well as an indication of the attendant uncertainties.

- (w) "Risk Management" refers to the process, distinct from risk assessment, consisting of weighing policy alternatives to accept, minimize or reduce assessed risks and if necessary, to select and implement appropriate prevention and control measures. It is carried out in consultation with interested parties, considering the results of risk assessment and other possible factors.
- (x) "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 and risk managers, consumers, food and feed business operators, academia and other stakeholders including explaining the results of risk assessment and risk management decisions and databases.
- (y) "Regulatory Agency" refers to a particular agency in the Department of Health or the Department of Agriculture in the Philippines, responsible for verifying compliance with official measures for the control of food safety risks, and for compliance with the requirements of this Act. It is also any other agency to which specific powers have been assigned or delegated by the regulatory agency to carry out the above tasks.
- (z) "Safe for human consumption" in relation to food, means that the food has been produced by applying all food safety requirements appropriate to its intended use; it meets criteria for product performance and process arrived at from an analysis of risks for specified hazards; it does not contain hazards at levels that are harmful to human health as defined by national regulations or international standards when national standards do not exist.
- (aa) "Traceability" refers to the ability to trace and follow a food, feed, a food producing animal or any substance intended to be or expected to be incorporated into a food or feed through all stages of its production, processing and distribution.

ARTICLE III

Basic Principles of Food Safety

SECTION 5. *Food Safety Requirements.* – To ensure food safety, food should not be placed in the market if it is unsafe. Food safety requirements shall also be guided by the following principles:

- (a) Food shall be deemed unsafe if it is determined to be injurious to health and unfit for human consumption;
- (b) In determining whether food is unsafe, regard shall be given to the following:
 1. The normal conditions of use of the food by the consumer
 2. The normal conditions maintained at each stage of production, processing 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.
 5. To 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 avoiding specific health effects from a particular food or category of foods.
- (c) In determining whether any food is injurious to health, regard shall be given to the following:
 1. probable immediate, short term or long term effects on subsequent generations, of that food on health

2. probable cumulative effects
 3. particular health sensitivities of a specific category of consumers where the food is intended for that category
- (d) In determining whether any food is unfit for human consumption, regard shall be given to determining unacceptability of the food according to its intended use due to contamination by extraneous matter, or through putrefaction, deterioration or decay.
 - (e) 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
 - (f) Food that complies with specific national provisions governing food safety shall be deemed safe in so far as the aspects covered by national law and regulations are concerned.
 - (g) Compliance of a food product with specific provisions applicable to that food shall not prejudice the competent authorities to take appropriate measures to impose restrictions on entry into the market or to require its withdrawal from the market, where there is reason to suspect and the food product shows, food safety related risks.

ARTICLE IV **General Principles**

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

SECTION 7. *Use of Science and Risk analysis.* – The following principles shall serve as basis for the use of science and risk analysis:

- (a) The development of food legislation and standards and the conduct of inspection and other activities shall be based on the analysis of risk, except where this approach is not feasible due to circumstances, or due to the nature of the control measure.
- (b) Risk assessment shall be based on sound scientific evidence and shall be undertaken in an independent, objective and transparent manner. Scientific information as obtained from scientific literature, epidemiological and surveillance studies, other data that supports the risk assessment shall be used.
- (c) Risk management shall take into account the results of risk assessment relevant to local conditions, potential for enforcement, costs of compliance and others as relevant to the situation.
- (d) Risk communication shall be carried out between risk assessors and risk managers in a transparent manner. Food safety risks shall also be communicated to farmers, fisherfolk and food business operators to encourage compliance with the implementation of control measures; and to relevant sectors of society affected by the law or the risks addressed, in order to strengthen confidence in its provisions.
- (e) Food business operators are encouraged to implement a HACCP – based system for food safety assurance in their operations. Training on hazard analysis and the selection and management of critical control points shall be provided to industry and government by accredited HACCP trainers.

SECTION 8. *Protection of Consumer Interests.* – Consumer interest shall be a vital consideration in food safety, thus:

- (a) Food legislation shall aim at the protection of consumer's interests by the prevention of fraudulent practices, and practices which mislead the consumer;
- (b) The labelling, advertising and 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, information which is made available about them through whatever medium, shall not mislead consumers. Where relevant, the presentation of goods shall provide consumers a basis to make informed choices in relation to the food they purchase.

SECTION 9. *Use of International Standards.* – When international standards exist, these shall be taken into consideration for adoption into food law in accordance with the following policies:

- (a) The standards of the Codex Alimentarius Commission shall be adopted into national laws; except when these are in conflict with what is necessary to protect consumers and scientific justification exists for the action taken.
- (b) A body jointly organized by the DA and the DOH shall establish the policies and procedures for country participation in the standards making processes of the Codex Alimentarius Commission and the incorporation of Codex standards into national regulations. The current National Codex Organization with its Terms of Reference and Manual of Operations is herein designated as this body.
- (c) Participation at Codex shall be in accordance with the principles of this Act and shall be financially supported by the government.

SECTION 10. *Precaution.* – In specific circumstances when the available relevant information for use in risk assessment is insufficient to show that a food 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 information for a more objective assessment of risk and after a review of the measure over a reasonable period of time depending on the nature of the risk and the type of scientific information needed to clarify the scientific uncertainty.
- (b) The measure shall be no more restrictive to trade than required and should be proportionate to the level of protection required for consumers.

SECTION 11. *Transparency.* – The implementing agencies shall utilize public consultation and public information dissemination to ensure transparency in the regulation of food.

- (a) Public consultation - 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.
- (b) Public information - In case of suspicion that food may pose a risk to human health, regulatory authorities shall take appropriate steps to inform the general public about the nature of the risk to health, the affected foods, types of food and the necessary measures to prevent, reduce or eliminate the risk

SECTION 12. *Application to Trade.* – The provisions of this Act apply to foods and food products produced, processed, distributed and prepared for the domestic and export

markets. Imported food must also be in compliance with this Act and with international agreements to which the Philippines is party.

ARTICLE V

Responsibilities for Food Safety

SECTION 13. *Principal Responsibility of Food Business Operators.* – Food business operators at all stages of production, processing and distribution shall ensure that food satisfies the requirements of food law relevant to their activities in the food supply chain and shall verify that such requirements are met.

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

- (a) Food business operators shall be knowledgeable of the specific requirements of food law relevant to their activities in the food supply chain and the activities of the government agencies that implement it. They shall adopt and apply and be well informed of codes and principles for good practice. Farmers and fisherfolk and micro and small industries shall be assisted to adopt these in their operations.
- (b) If a food business operator considers or has reason to believe that a food which it produced, processed, distributed or imported is not safe or not in compliance with food safety requirements, it shall immediately initiate procedures to withdraw the food in question from the market and inform the regulatory authority.
- (c) Food business operators shall collaborate with the regulatory authorities on action taken to avoid or reduce risks posed by a food which they supply or have supplied.
- (d) Where the 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 from consumers products already supplied to them when other measures are not sufficient to achieve a high level of health protection.

SECTION 15. *Principal Responsibilities of Government Agencies.* In pursuance of this Act, government agencies shall have the following responsibilities:

- (a) The Department of Agriculture (DA), Department of Health (DOH) shall be responsible for food safety in specified stages of the food supply chain, the DA in the primary production and postharvest stages, the DOH in the processing and packaging stages. The DILG shall supervise the Local Government Units' (LGU) enforcement of food safety and sanitary rules and regulations as well as the latter's inspection and compliance monitoring of business establishments and facilities within its territorial jurisdiction engaged in all stages of the food supply chain. It shall be jointly responsible with LGU's for the safety of food produced, processed and distributed within the municipalities, including restaurants and other food service establishments and street vended foods.
- (b) The DA and the DOH shall be responsible for the establishment of policies and of food safety standards. In carrying out this mandate, they shall coordinate with the DILG, conduct surveillance for biological, chemical and physical contaminants, epidemiological studies on food borne-illness and other research activities. The data from these activities will be used for evaluating the nature

and sources of food safety hazards in the food supply chain and the analysis of risks due to these hazards.

- (c) The DA, DOH and DILG shall verify through their relevant activities and through the coordination of these activities within the FSRCB, that appropriate control measures to conform to standards are enforced and that all laws, standards and regulations are implemented by food business operators, farmers and fisherfolks. For this purpose, the DA and the DOH in compliance with their responsibilities for food safety in the food supply chain shall provide training programs to food control officials of the DILG and LGU's and audit through the DILG, the effectivity of training programs and control measures implemented in the municipalities. A system of official controls and other activities shall be maintained by each agency as appropriate to the circumstances.
- (d) Delegation of responsibilities for the performance of official controls can be carried out. Provisions shall be made on the conditions under which this shall take place.
- (e) The DA and the DOH shall provide technical support to the DILG in the training of manpower, on the enforcement of food safety regulations, testing of product samples and others. They shall ensure through relevant procedures that the DILG participates in national projects and activities on food safety including those of the National Codex Organization

SECTION 16. *Specific Responsibilities of the Department of Agriculture.* – The Department of Agriculture shall have the following responsibilities:

- (a) The DA shall be responsible for the development of standards and the enforcement of standards and food safety regulations at the primary production and postharvest handling stages of the food supply chain and of the foods and food products locally produced or imported in this category. Changes to this provision shall be made through the Food Safety Regulation Coordinating Board (Article VI).
- (b) The primary production activities in the food supply chain as defined in this Act includes among others, the farming of plants and live animals for food (including its milk and eggs), farming of seafoods and the catching of fishes and marine products at sea. The postharvest handling activities includes but is not limited to animal slaughter and its processes, grain milling and its processes, freezing and its processes; and simpler activities as washing, sorting, icing and cutting of fresh plant and animal foods.
- (c) The DA shall ensure through relevant activities and through the coordination of these activities with the DOH and the DILG that the standards and regulations enforced shall include but will not be limited to the following:
 - 1. The health of animals used for food
 - 2. The safety of the water supply in agricultural farms, aquaculture farms and bodies of water where fish and marine products are caught;
 - 3. The safety of feed ingredients and feeds for animals used for food;
 - 4. The safe use of allowed agricultural chemicals and other production inputs;
 - 5. Sanitation in production and postharvest handling facilities such as facilities for dehusking, desheiling, drying of palm fruit, packing houses for fruits and vegetables, animal houses, holding and fattening pens, vapour heat treatment plants for fruits, grains and other food warehouses, ships, fish ports, trading posts, slaughterhouses and similar facilities;
 - 6. Maximum allowed levels of contaminants as residues of pesticides and of veterinary drugs in plant and animal foods, pathogenic microorganisms,

fungus toxins in grains and other foods and other hazards in the production and post harvest handling stages of the food supply chain;

7. Procedures for traceability; and

8. Other components of good agricultural, animal husbandry, aquaculture and manufacturing practices.

Specifically, the DA shall monitor and verify that the relevant requirements of the law are fulfilled by farmers and fisherfolk and food business operators of domestically produced and imported foods in this category.

(d) The DA shall carry out surveillance studies for contaminants in plant and animal foods and in the environment in coordination with other government departments through the FSRCB.

(e) The DA Secretary shall designate the food safety regulatory agencies that will be responsible for food safety regulatory functions at the DA and clearly describe their mandates. The current regulatory agencies of the DA are the following: the Bureau of Animal Industry (BAI, for live animals), the National Meat Inspection Service (NMIS, for the safety of meats), the Bureau of Fisheries and Aquatic Resources (BFAR, for the safety of fisheries and aquaculture products particularly those exported to the EU), the Bureau of Plant Industry (BPI, for plant foods), the Fertilizer and Pesticide Authority (FPA, for pesticides) the Philippine Coconut Authority (PCA, for coconut), the Sugar Regulatory Commission (SRC, for sugar) and the National Food Authority (NFA, for rice and corn).

(f) On an *interim basis*, the Office of the Undersecretary for Policy and Planning, Project Development and R&D shall exercise oversight of the regulatory functions of agencies designated by the Secretary in section 16e to undertake the regulation of food safety. It shall be provided with the needed personnel and funds to carry out this task.

(g) On a permanent basis, the Office of the Undersecretary for Policy and Planning, Project Development and R&D shall exercise supervision over codex activities, the development of food safety standards, the management of food testing laboratories and the implementation of research and training activities in the production and postharvest portions of the food supply chain, as designated in this Act. The Office shall be the Codex Contact Point. It shall be provided with the needed functional divisions, experienced manpower, incremental staffing and funds for the exercise of these permanent functions.

(h) As it has several agencies with food safety regulatory mandates as well as other related regulatory responsibilities (as plant health and animal health), the DA shall create a permanent Undersecretary and Office for Regulations to include Food Safety Regulation. The *interim* functions of the Office of the Undersecretary for Policy and Planning, Project Development and R&D (16f) shall be transferred to this Office as soon as it is created. The new Office shall be strengthened with appropriate functional divisions, incremental personnel and funds to carry out its task.

(i) The Bureau of Agriculture and Fisheries Product Standards (BAFPS) shall establish food safety standards at the primary production and postharvest stages of the food supply chain and the appropriate mechanisms for carrying this out. BAFPS will be under the administrative supervision of the Office of the Undersecretary for Policy and Planning, Project Development and R&D

(j) The Food Development Center shall be transferred from the National Food Authority to the DA as the Food Safety and Quality Development Center (FSQDC) under the Office of the Undersecretary for Policy and Planning, Project Development and R&D. It shall supervise food safety testing laboratories at the

DA and manage the training and research programs of the DA as indicated in Article IX.

(k) The FSQDC shall have the following other functions:

1. Conduct food testing for contaminants (chemical and microbiological) as the official DA laboratory for contaminants testing;
2. Identify, establish and verify food safety control measures as delegated by the DA for which the DA has no agency with a food safety regulatory mandate;
3. Develop and conduct training for DA personnel and the industry on HACCP and other training courses within its area of expertise; and
4. Provide other technical services to the DA and its food safety regulatory agencies in the implementation of their food safety mandates.

(l) The services of FSQDC to the DA and other clients shall be provided on a fee for service basis in accordance with its current policies. The FSQDC shall continue to provide all other technical services it currently provides to the industry to ensure product quality and safety.

(m) The FSQDC shall be allowed to retain the fees collected from the provision of services. This shall constitute a revolving fund that FSCDC can use to defray its operating expenses. This is necessary as delays in the release of budgetary allocations may not make it possible for the Center to provide technical services efficiently and as planned. A revolving fund from retained fees shall be created for this purpose.

(n) The FSQDC shall be strengthened in terms of establishing functional divisions and incremental staffing to implement this mandate including upgrading of equipment and facilities as provided for in DA programs. An initial budget of one hundred fifteen million Philippine Pesos (115,000,000 PHP) shall be appropriated for the initial year of implementation of this Act. Thereafter such amount or as may be necessary for the continuous operation of the FSQDC shall be included in the General Appropriations Act. The assets and facilities of the FSQDC shall be transferred to the DA.

SECTION 17. *Specific Responsibilities of the Department of Health.* – The Department of Health shall have the following responsibilities under this Act:

(a) The DOH shall be responsible for the development of standards and the enforcement of standards and the implementation of food safety regulations at the processing and product packaging stages of the of the food supply chain and of the foods and food products locally produced or imported in this category. Changes to this provision shall be made through the Food Safety Regulation Coordinating Board (Article VI).

(b) The activities in the processing and product packaging stages of the food supply chain as defined in this Act includes among others, the application of pre-processing and processing techniques on plant and animal foods that substantially changes the form and quality of the plant or animal used as raw material. Products in this category are sold in packaged form directly to the consumer, are processed before or after packaging to obtain the quality and stability desired and are labelled to provide appropriate information regarding the product, to the consumer.

(c) It shall ensure through relevant activities and through the coordination of these activities with the DA and DILG through the FSRCB, that standards and regulations in food law at the processing and pre-packaging stages of the food

supply chain, are enforced. This shall include but will not be limited to standards for the following;

1. Good Hygienic and Manufacturing Practices;
 2. Traceability;
 3. Safety of ingredients and packaging materials;
 4. Adequacy of thermal and non-thermal processing procedures;
 5. Safety of functional foods and nutraceuticals;
 6. Safe use of allowed food additives and processing aids;
 7. Absence of unallowed chemicals and biological contaminants;
 8. Maximum levels of unavoidable chemical and biological contaminants;
 9. Proper labelling and use of label claims; and
 10. Others as identified.
- (d) The food safety regulatory agency of the Department of Health is the Food and Drug Administration as defined by RA 3720 and RA 9711. It shall be provided with adequate qualified personnel, functional divisions and funds to implement its responsibilities as indicated in this Act.
- (e) The enforcement of this mandate requires coordination with the DA in the designation of responsibilities at stages in the food supply chain where their mandates overlap as ensuring safety of meat (under the mandate of the DA) for processing into canned meat, or fish for canned fish and others.
- (f) The DOH as the authority on the short and long term effects of food safety hazards on human health shall conduct and document epidemiological studies on food-borne illness for use in risk assessment. It shall establish the food safety risk assessment bodies required for this purpose. It shall be strengthened in terms of establishing functional divisions and incremental staffing and funds to carry out this function.

SECTION 18. *Specific Responsibilities of the Department of Interior Local Government.* –
The following are the responsibilities of the Department of Interior and Local Government:

- (a) The DILG shall be responsible for the enforcement of the Code of Sanitation, the food standards developed by the DA and the DOH and the enforcement of food safety regulations at the municipal level. Changes to this provision shall be made through the Food Safety Regulation Coordinating Board (Article VI).
- (b) It shall ensure through relevant activities and through the coordination of these activities with the DA and the DOH and through the FSRCB, that sanitation standards and relevant food safety standards are enforced in the municipalities particularly in slaughterhouses, public markets and in micro and small food establishments where food is processed, prepared and/or sold. This shall include but will not be limited to the enforcement of the following standards:
1. Sanitation as indicated in the Sanitation Code PD 856 particularly in public markets, slaughterhouses, micro and small food processing establishments and public eating places;
 2. Code for Good Slaughtering Practices;
 3. Code for Proper Food Handling;
 4. Code for Good Hygienic and Manufacturing Practices;
 5. Safe use of food additives, processing aids and sanitation chemicals; and
 6. Proper labelling of pre-packaged foods.
- (c) The DILG shall support the DOH and the DA in the collection and documentation of food-borne illness data, surveillance and research.

- (d) The DILG shall participate in training programs, standards development and other food safety activities taking place at the national level in coordination with the DA and the DOH.

Article VI

Creation of a Food Safety Regulation Coordinating Board (FSRCB)

SECTION 19. Powers and Functions. – A Food Safety Regulation Coordinating Board is hereby created which shall have the following powers and functions:

- (a) Authority to link the mandates, control functions and activities of the DA, the DOH and the DILG in food safety regulation and modify these as needed due to changing requirements of markets, new technologies, new food safety risks and other causes.
- (b) Identify agency/s responsible for enforcement when jurisdiction over specific functions and areas overlap between the DA, DOH and DILG. Ensure effective enforcement where a coordinated approach to food safety regulation is necessary.
- (c) Establish the policies and procedures for coordination of regulatory systems as implemented by the DA the DOH and the DILG.
- (d) Evaluate the effectivity of standards, conformity assessment activities, the performance of food testing laboratories and their accreditation to international standards. Oversee the overall effectiveness of the food safety regulatory system and of the research and training programs.
- (e) Designate which organization will implement food safety regulations in the use of new technologies as biotechnology, nanotechnology, food irradiation and others.
- (f) Coordinate crisis management and planning during food safety incidents and monitor the Rapid Alert System for Foods as provided in Article VI of this Act.

SECTION 20. Organization. - Within 30 days from the effectivity of this Act, the Secretaries of the DA, DOH and the DILG shall organize the FSRCB in accordance with the following rules:

- (a) The FSRCB shall be chaired by the Secretary of the DA and co-chaired by the Secretary of the DOH or their authorized representatives at the Undersecretary level. The members of the FSRCB shall be the Heads of food safety regulatory agencies of the DA, the DOH and a representative of the DILG. A representative each from the DTI and the DOST at the Director level shall also be included.
- (b) Within 12 months from the effectivity of this Act or earlier, the FSRCB shall have completed its Procedural Manual as approved by the Chair and Co-Chair of the FSRCB. The manual shall contain the rules for the conduct of meetings, decision-making, and others. Funds shall be allocated for the expenses of a Working Group created by the FSRCB to prepare this manual.
- (c) The FSRCB shall have an administrative and technical secretariat at the DOH. Both the DOH and the DA shall be strengthened and empowered in terms of funding and establishing functional divisions and incremental staffing to organize the administrative and technical personnel for the operation of the FSRCB.
- (d) Funds shall also be allocated by the agencies to pay for the organization of meetings as well as the expenses for the participation of members of the FSRCB and secretariats as well as invited experts to the meetings.

SECTION 21. *Accountability for Food Safety Regulation.* – The food safety regulatory agencies of the DA, DOH and the DILG, shall be individually responsible for ensuring food safety at the stages of the food supply chain within their specified mandates, functions and responsibilities. They shall also be responsible to ensure the same for mandates, functions and activities that are modified by agreement through the FSRCB. The FSRCB shall be responsible for regulations that are implemented on a coordinated basis between the agencies.

ARTICLE VII

Crisis Management

SECTION 22. *Rapid Alert System.* – A rapid alert system for the notification of a direct or indirect risk to human health due to food should be established by the FSRCB as a network between regulatory agencies and other relevant agencies.

SECTION 23. *Emergency Measures.* – Where it is evident that food originating from within the country or imported from another country is likely to constitute a serious risk to human health, the Government 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 the placing on the market or use of the food in question
2. Laying down special conditions for the food in question
3. Any other appropriate interim measure

(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
3. Any other appropriate interim measures

SECTION 24. *Plan for Crisis Management.* – The regulatory agencies in cooperation with other relevant government agencies shall prepare a general plan for the management of a threat to food safety requiring coordinated action. 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 by provisions in place.

ARTICLE VIII

Implementation of Food Safety Regulations

SECTION 25. *Policies on Official Controls.* - Official controls are established to verify compliance with food law and shall be prepared by each agency. Official controls include routine surveillance checks of food establishments and more intensive checks involving inspections, verifications, audits, sampling and testing of samples. The following shall govern the conduct of official controls:

- (a) Implementing regulations for official controls to be performed by each agency shall also be prepared by each agency in accordance with the principles established in this Act;

- (b) 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 to carry out their duties properly;
- (c) Provisions shall be made for official controls to be delegated to other competent bodies as decided by the regulatory agency and of the conditions under which this shall take place. When official controls are delegated, appropriate coordination and other procedures shall be in place and effectively implemented;
- (d) The frequency of official controls shall be proportionate to the severity and likelihood of occurrence of the food safety risks being controlled;
- (e) The regulatory agency or body performing official controls shall meet operational criteria and procedures established by the agencies to ensure impartiality and effectiveness;
- (f) Official controls shall be carried out on the basis of documented procedures to ensure that these are carried out uniformly and are of a consistently high quality; *and*
- (g) The agencies responsible for the implementation of official controls shall be strengthened and empowered in terms of funding and the establishment of functional divisions and incremental staffing to perform official controls according to the principles indicated in this Act.

SECTION 26. *Traceability.* – Traceability shall be established for certain commodities at relevant stages of production, processing or distribution, when needed to ensure compliance with food safety requirements. The rule on traceability also covers production inputs such as feeds, food additives, ingredients, packaging materials and other substances expected to be incorporated into a food. 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. food-producing animal;
 - 3. production chemicals as pesticides and drugs; and
 - 4. production and processing inputs as feeds, food additives, food ingredients, packaging materials, or any substance expected to be incorporated into a food.
- (b) have in place, systems and procedures which allow this information to be available to the regulatory authorities on demand.
- (c) have in place 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 on demand.

SECTION 27. *Registration of Establishments.* – Any food establishment or foreign food establishment or food business operator engaged in production, postharvest handling, processing, packing, holding or producing food for consumption shall be registered. Special derogations shall be provided due to geographical location and after an assessment of risks, especially for micro, small and medium sized operators.

SECTION 28. *Inspection of Food Business Operators.* - Regular inspection of food business operators shall be performed by the regulatory authorities or the control bodies delegated to conduct the activity. In addition, the following rules shall also be followed in the conduct of inspection:

- (a) Inspection shall take into account mandatory food safety standards the results of HACCP inspections, the implementation of good practices and other requirements of regulations;
- (b) The frequency of inspection 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) Unscheduled inspections shall be carried out as needed; and
- (d) Inspectors shall have defined skills and shall be regularly evaluated by suitable procedures to verify their continuing competence. Training and appropriate procedures should also be in place to ensure that the results of inspection are interpreted in a uniform way.

SECTION 29. *Food Laboratory Testing.* - Food testing shall be carried out by laboratories accredited to international standards. They shall work in accordance with internationally approved procedures or criteria-based performance standards and methods of analysis that have, as far as possible been validated. To be accredited, the laboratories should meet the following requirements:

- (a) The laboratories shall be adequately funded.
- (b) They shall be professionally managed and organized to ensure the absence of a conflict of interest situation in the conduct of testing.
- (c) The laboratories shall be responsible for providing evidence of the credibility of test results from submitted samples.
- (d) The agencies through the FSRCB shall minimize duplication in testing to the extent feasible in order to achieve efficiency in laboratory operations.

ARTICLE IX

Training, Consumer Education and Research

SECTION 30. *Training.* – Farmers and fisherfolks and micro, small and medium scale food business operators as well as government personnel shall be trained on the requirements of food safety regulations and the understanding of these requirements. Industry personnel and farmers and fisherfolks shall be further trained on the codes of good practice relevant to their activities. Government personnel shall be further trained on the scientific basis for the provisions of the law. Other training needs shall be implemented as identified. The following rules shall be followed in the establishment of the training programs

- (a) The training program shall be developed by the FSQDC or other agencies and private organizations accredited to provide the required training;
- (b) A consumer education program shall be developed by the DA, the DOH and the DILG as appropriate to the circumstances; and
- (c) Funds will be provided for the development and implementation of training and consumer education programs.

SECTION 31. *Food-Borne Illness Monitoring, Surveillance and Research.* – The government through the FSRCB and in support of risk analysis, shall implement a program for food borne illness monitoring, surveillance for hazards in the food supply chain and establishment of other data for risk assessment. It shall implement other research activities as technologies for assisting industries to comply with regulations. The Bureau of Agricultural Research of the DA and the Department of Science and Technology in cooperation with the FSRCB shall establish the mechanisms for the conduct of research in these areas.

ARTICLE X
Policy on Fees

SECTION 32. *Policy on Fees.* – Fees may be collected and retained by the agency for the inspection of production and processing facilities and for the laboratory testing of food samples. Fees shall be based on an officially approved procedure for estimating the cost of the activity undertaken. The fees retained shall constitute the Revolving Fund for the agency to augment existing appropriations therefore subject to government accounting and auditing rules and regulations.

ARTICLE XI
Penalties and Sanctions

SECTION 33. *Civil and Criminal Penalties.* – The specific laws of each agency will lay down the rules on measures and penalties applicable to infringements of this Act. Where there are no such specific laws, any person that violates this Act may be assessed a penalty of not more than Php1,000,000 for such act or other measures as mandatory training that will prevent the said violation. The violations and penalties shall be specified by the Secretaries of the DA and the DOH in the Implementing Rules and Regulations (IRR).

ARTICLE XII
Transitory Provisions

SECTION 34. *Implementing Rules and Regulations (IRR).* – The IRR shall be prepared jointly by the DA and the DOH ninety (90) days from the creation of the FSRCB or no more than 120 days after the effectivity of this Act.

ARTICLE XIII
Miscellaneous and Final Provisions

SECTION 35. *Separability Clause.* – If any provision of this Act is declared invalid or unconstitutional the other provisions not affected thereby shall remain in full force and effect.

SECTION 36. *Repealing Clause.* – All laws, presidential decrees, executive orders, rules and regulations inconsistent with the provision of this Act are hereby repealed.

ARTICLE XIV
Effectivity

SECTION 37. *Effectivity.* – This Act shall take effect fifteen days following its publication in at least two (2) newspapers of general circulation or in the Official Gazette, whichever comes first.

Approved,