

THIRTEENTH CONGRESS OF THE
REPUBLIC OF THE PHILIPPINES
First Regular Session

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SENATE
OFFICE OF THE SECRETARY

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SENATE

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S. No. 593

INTRODUCED BY HON. MANUEL B. VILLAR JR.

EXPLANATORY NOTE

The Constitution, Article 2, Section 15 provides:

The State shall protect and promote the right to health of the people and instill health consciousness among them.

There is a need to establish a national program that will require persons who produce or process food for human consumption to adopt specific measures to prevent or minimize food safety hazards related to their products.

Hence, this bill seeks to protect public health by ensuring that the food industry has effective programs in place to assure the safety of food products consumed in the Philippines.


MANUEL B. VILLAR, JR.

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S. No. 593

INTRODUCED BY HON. MANUEL B. VILLAR JR.

**AN ACT ESTABLISHING A COMPREHENSIVE PROGRAM TO ENSURE THE
SAFETY OF FOOD PRODUCTS INTENDED FOR HUMAN CONSUMPTION**

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

SECTION 1. Short title - This Act shall be known as the "Consumer Food Safety Act of 2004."

SECTION 2. Definitions - In this Act,

(1) CONTAMINANT- The term "contaminant" includes a bacterium, a chemical contaminant, a natural toxin, a virus, a parasite, and a physical hazard, that when found on or in food can cause human illness or injury.

(2) FACILITY- The term "facility" includes any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that handles or processes food.

(3) FOOD SAFETY LAW- The term "food safety law" means this Act and other related laws on food safety.

(4) PROCESS- The term "process" means the commercial harvesting, preparation, manufacture, or transportation of a food product.

(5) SECRETARY- The term "Secretary" means the Secretary of Health.

SECTION 3. ADMINISTRATION OF NATIONAL PROGRAM

(1) NATIONAL PROGRAM- The Secretary shall administer, in accordance with the provisions of this Act, a national program for the purpose of protecting public health by ensuring that the food industry has effective programs in place to assure the safety of food products consumed in the Philippines.

(2) BASIS FOR PROGRAM - The program shall--

(A) Be based on a comprehensive analysis of the hazards associated with different food products and with the processing (including harvesting) and handling of different food products, including the identification and evaluation of

(i) The severity of the potential public health hazards;

(ii) The sources and specific points of potential contamination that may render food products unsafe for human consumption; and

(iii) The potential for persistence, multiplication, or concentration of naturally occurring or added contaminants in foods, including food products; and

(B) Take into consideration the distinctive characteristics of food processing and handling.

(b) PROGRAM ELEMENTS- The program shall provide for-

(b.1) Implementation of a national system for the annual registration of facilities (including facilities of importers) with the Secretary;

(b.2) Development of a program to oversee the implementation of process controls in facilities, including the establishment and enforcement of health-based standards for

(A) Substances that may contaminate food; and

(B) safety and sanitation in the processing and handling of food products;

(b.3) Establishment of inspection and oversight procedures to monitor that facilities are utilizing preventive controls to minimize or eliminate identifiable hazards in food;

(b.4) Implementation of a national system for quarterly inspections of facilities (including facilities of importers), except for facilities that meet the Secretary's standards for exceptional or negligible-risk facilities;

(b.5) Implementation of procedures and requirements to ensure the safety of imported food products;

(b.6) Coordination with other agencies in carrying out inspection, enforcement, and monitoring relating to the safety of food products;

(b.7) Implementation of a national surveillance system to assess the public health hazards associated with the human consumption of food products;

(b.8) Implementation of a sampling program to ensure that industry programs to prevent food contamination are effective and that food products meet the standards established in paragraph (2);

(b.9) Development of public education and advisory programs relating to the safety of food products; and .

(b.10) Implementation of a research program to further the objectives of this Act.

SECTION 4. Registration of processors and importers

(a) REGISTRATION

(1) IN GENERAL- Any facility engaged in processing or handling food products for consumption in the Philippines, including any facility of an importer, shall be registered with the Secretary. To obtain the registration-

(A) For a domestic facility not described in subparagraph (B), the owner, operator, or agent in charge of the facility shall submit an application to the Secretary; and

(B) For a facility of an importer, or for a foreign facility, the importer seeking to import the food product processed or handled in the facility shall submit the application.

(2) APPLICATION

(A) IN GENERAL- The applicant shall submit the application to the Secretary in such manner and containing such information as the Secretary shall prescribe by regulation.

(B) SUBMISSION- The applicant shall submit the application not later than 24 months after-

(i) The date of enactment of this Act; or

(ii) The date the facility first processed or handled food, if later than such date of enactment.

(C) CONTENTS- In the case of an application submitted for a foreign facility, the application shall contain, at a minimum, such information as the Secretary may require demonstrating that the facility, and the foreign nation involved, will permit inspections described in this Act.

(3) PROCEDURE- Upon receipt and review of a completed application described in paragraph (1), the Secretary shall issue to the applicant a certificate of registration unless the Secretary finds that there is good cause for denial of the application. The Secretary shall promptly notify the applicant of the denial, include in the notification a written explanation of the reasons for such denial, and provide an opportunity for a hearing or reapplication upon request.

(b) SUSPENSION OF REGISTRATION

(1) BASIS- The registration of a facility, including the facility of an importer, may be suspended immediately by the Secretary for

(A) Failure to permit access to the facility for inspection under this Act;

(B) Violation of a food safety law, including a regulation issued under a food safety law, concerning the facility, in a case in which the Secretary determines that such suspension is likely to prevent a significant risk of adverse health consequences; or

(C) Conviction of the applicant or registrant in any court of—

(i) Any felony relating to food, whether or not the felony is based upon the acquisition, handling, or distribution of adulterated or misbranded food; or

(ii) More than 1 violation of any law relating to food, whether or not the violation involves any fraud in connection with transactions in food.

(2) IMPACT- No person may introduce a food product, or offer a food product for import into the Philippines, a facility with a suspended registration.

(3) REINSTATEMENT- Any registration suspended under paragraph (1) may be reinstated whenever the Secretary determines that the suspension is no longer necessary.

(c) EXEMPTION AUTHORITY- The Secretary may by regulation exempt classes of facilities from the requirements of subsection (a) if the Secretary determines that the registration of such facilities is not needed for effective enforcement of a food safety law.

SECTION 5. Process controls to reduce the contamination of food Products -

(a) IN GENERAL- The Secretary shall, on the basis of the best available scientific and technological data, prescribe regulations to--

(1) Limit the presence of contaminants and other potentially harmful substances in food products;

(2) Ensure that all facilities registered under this Act implement appropriate process controls to control and reduce the presence and growth of contaminants and other potentially harmful substances in food products;

(3) Ensure that all processed or ready-to-eat food products are processed and handled in a sanitary manner, using reasonably available techniques and technologies to minimize any contaminants or other potentially harmful substances likely to cause food borne illness; and

(4) Ensure that food products intended for final processing outside commercial establishments are labeled with instructions for handling and preparation for consumption that, when adhered to, will destroy any contaminant or other potentially harmful substance likely to cause food borne illness.

(b) REGULATIONS

(1) *IN GENERAL*- In implementing subsection (a), the Secretary shall, not later than 1 year after the date of enactment of this Act, issue regulations that require each facility registered under this Act to adopt process controls adequate to protect public health by controlling and reducing the presence and growth of contaminants and other potentially harmful substances in food products prepared in the facility.

(2) *ELEMENTS*- Such regulations shall

(A) Set standards for sanitation in food products;

(B) Set tolerances for biological, chemical, and physical contaminants in food products, as appropriate;

(C) Require process controls to assure that food products are safe and that relevant regulatory and other safety standards, including the standards and tolerances described in subparagraphs (A) and (B), are met;

(D) Require record keeping to monitor compliance with the process controls;

(E) Require sampling (in accordance with the sampling guidelines described in this Act) to assure that the process controls are effective and that regulatory and other safety standards are being met; and

(F) Provide for agency access to records kept under subparagraph (D) and submission of copies of such records to the Secretary as the Secretary determines to be appropriate.

(c) PROCESS CONTROLS FOR USE OF FOOD INGREDIENTS-The Secretary may require any person, firm, or corporation that has responsibility for or control over food ingredients and that is registered under this Act to adopt process controls, to the extent the Secretary determines that such process controls are needed to assure the protection of public health.

SECTION 6. Tolerances for contaminants in food -

(a) TOLERANCES- In adopting tolerances for facilities registered under this Act, the Secretary shall establish tolerances limiting the quantity, in food products, of contaminants, except those that, when found in food products, may render such products unsafe for human consumption. Such tolerances may include indicators (including indicator organisms) from which the presence of a contaminant in a food product may reasonably be inferred. In developing a tolerance for a contaminant, the Secretary shall take into account the extent to which consumers may be exposed to such contaminant from sources other than food, and the extent to which such contaminant can be avoided or minimized in the commercial processing and handling of such food.

(b) REGULATIONS-

(1) IN GENERAL- The Secretary, after notice and an opportunity for comment, shall promulgate regulations to implement subsection (a) not later than 48 months after the date of enactment of this Act. In promulgating such regulations, the Secretary shall establish tolerances for the contaminants that the Secretary determines have the greatest public health impact, as early as feasible after the date of enactment of this Act.

(2) BASIS- A tolerance established under this section shall be based on--

(A) a scientific analysis of the public health risks attributable to the contaminant for which the tolerance is established; and

(B) analysis of the public health risks attributable to the contaminant for sensitive groups, such as children, elderly individuals, pregnant women, and individuals with compromised immune systems.

(3) REVISIONS- The Secretary shall, in a timely manner, issue revisions to the regulations under paragraph (1) that take into account new information relating to the contaminants involved.

(c) REPORT- The Secretary shall prepare and submit to Congress a report on the progress of the Secretary in establishing tolerances under this section. The report shall include a description of the research that has been conducted with respect to such tolerances and the research, that needs to be conducted before additional tolerances may be established under this section, the health significance of the lack of such additional tolerances, a timetable for the establishment of such tolerances, and the estimated costs, including costs of research, associated with the establishment of such tolerances. The report shall be submitted not later than 18 months after the date of enactment of this Act, and biennially thereafter during the 6-year period that begins on such date of enactment.

SECTION 7. Inspections of processors and importers -

(a) NATURE OF INSPECTIONS

(1) IN GENERAL- The inspection system referred to in this Act shall provide for regular and unannounced inspections of facilities (including facilities of importers) registered under this Act to determine if such facilities are operated in a sanitary manner and if food products processed or handled in the facilities is in violation of a food safety law.

(2) SCHEDULE- The Secretary shall inspect each facility described in paragraph (1) at least quarterly, except that the Secretary shall specify an alternative inspection frequency for a facility

that the Secretary determines to be an exceptional or negligible-risk facility under standards issued under paragraph (3).

(3) STANDARDS- The Secretary shall issue standards for determining whether a facility is an exceptional or negligible-risk facility. In issuing the standards, the Secretary shall classify facilities by considering the hazards associated with the type of product being produced at a facility, the facility's history of compliance and food safety problems, and such other factors as the Secretary may determine to be appropriate.

(4) EXAMINATION OF CLASSIFICATIONS- Each inspection of a facility classified as an exceptional or negligible-risk facility shall include an examination of whether the facility is appropriately classified under the standards issued under paragraph

(b) CONDUCT OF INSPECTIONS-

(1) SCOPE- An inspection under subsection (a) of any domestic or foreign facility (including a facility of an importer) shall extend to all things in the facility (including records required to be maintained under subsection (e), processes, controls, and premises) that bear on whether food products are in compliance with a food safety law. The inspection shall include a review of processing or handling records and sampling of food products. Access to records may include the copying of such records.

(2) AUTHORITIES- In conducting such inspections, officers or employees duly designated by the Secretary, on presenting appropriate credentials to the owner, operator, or agent in charge of a facility, are authorized-

(A) To enter at reasonable times any facility described in subsection (a) in which persons are engaged in the processing or handling of food products (including a facility of an importer), which may include entering any vehicle being used to transport or hold food products for processing or handling;

(B) To inspect in a reasonable manner such facility (which may include inspecting a vehicle described in subparagraph (A)), including all pertinent equipment, finished and unfinished materials, containers, labeling, processes, controls, and premises; and

(C) To collect and retain samples of food products or ingredients or of any other items found during an inspection that may contribute to a finding of whether such food products are in violation of a food safety law.

(3) REPORT- Immediately after completion of the inspection, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report, in writing, setting forth any conditions or practices observed that indicate that either process controls are inadequate to prevent or minimize food safety hazards or that any food product from such facility is in violation of a food safety law.

(c) PRODUCT DETENTION AND CONDEMNATION

(1) IN GENERAL- If, during an inspection conducted under this section of a domestic facility, an officer or employee making the inspection determines that a food product is in violation of a food safety law, such officer or employee may order the food product segregated, impounded, and if objection is not made within 48 hours after the issuance of the impoundment order, condemned. If objection is made within such 48 hours, food products that are in perishable form may be processed to the extent necessary to prevent spoilage, and the Secretary shall expeditiously commence a hearing regarding the determination and any action required for compliance with the food safety laws.

(2) RELEASE- If the Secretary determines that, through relabeling or other action, such food product can be brought into compliance with the food safety laws, the food product may be released following a determination by the Secretary that such re-labeling or other action as specified by the Secretary has been performed.

(3) DESTRUCTION- Any food product condemned under paragraph (1)

(A) In a case in which no objection is made under paragraph (1);

(B) After the hearing and any judicial review; or

(C) After failure of the owner, operator, or agent to perform re-labeling or other action described in paragraph (2); shall be destroyed under supervision of the Secretary.

(d) OFFICIAL MARK- The Secretary shall prescribe by regulation conditions under which any food product shall display an official mark, when needed to facilitate exports, that signifies that the food product has been processed and handled in accordance with standards approved by the Secretary. The Secretary may assess a fee for the use of mark. The Secretary shall deposit all deposit fees received under this subsection in an account, and may use the funds in the account to carry out enforcement activities under the food safety laws, or to carry out this Act.

(e) MAINTENANCE OF RECORDS- The registrant for each facility registered under this Act shall maintain and make available for inspection by the Secretary such records as the Secretary may prescribe. Such records shall be maintained for a reasonable period of time as determined by the Secretary. The records shall include information concerning-

(1)(A) The origin, receipt, delivery, sale, movement, holding, and disposition of food products, or ingredients for food products, processed or handled at the facility;

(B) The identity and amount of ingredients used in the food involved;

(C) The processing or handling of the food;

(D) The results of laboratory, sanitation, or other quality control tests performed on the food or in the facility; and

(E) Consumer complaints concerning the food or the packaging of the food; and

(2) Other matters reasonably related to whether food products processed or handled at the facility may be in violation of a food safety law.

SECTION 8. Imports

(a) **ROLE OF SECRETARY-** Not later than 24 months after the date of enactment of this Act, the Secretary shall establish and administer a comprehensive and efficient system to ensure the safety of food products imported into the Philippines. In administering the system, the Secretary shall routinely inspect facilities registered under this Act in exporting nations and imports at ports of entry into the Philippines, as provided in this Act. The Secretary shall assure that the facilities are operating in compliance with existing food safety laws, through such verification and other activities as the Secretary considers to be necessary.

(b) IMPORT REQUIREMENTS

(1) **SAFETY STANDARDS-** No food product may enter the Philippines, or be withdrawn from a facility for consumption in the Philippines if such food product appears to be in violation of a food safety law.

(2) **TREATMENT-** Upon entry for consumption in the Philippines, food products that are not prohibited from entry or from withdrawal from a facility under paragraph (1) shall be considered to be and treated as domestic food products, except that all labeling of such products shall clearly identify the country of origin to facilitate the identification of products linked to outbreaks of illness.

(c) INSPECTION OF IMPORTS-

(1) **EXAMINATIONS, INSPECTIONS, SAMPLING AND OTHER PROCEDURES-** Food products that are offered for importation, or withdrawn from a facility, for consumption in the Philippines, shall be subject to examinations, inspections, sampling, and such other procedures as the Secretary may determine to be appropriate at the port of entry or at the facility registered under this Act in the exporting nation by officers or employees duly designated by the Secretary. Such procedures shall be conducted with such frequency and in such manner as the Secretary may prescribe by regulation.

(2) RANDOM OR INTENSIFIED PROCEDURES- Food products from a nation that is certified for such food products under subsection (e)(3) shall be subject to random examinations, inspections, sampling, and other procedures under paragraph (1). Food products from a nation that is not certified for such food products under subsection (e)(3) shall be subject to such intensified examinations, inspections, sampling, and other verification procedures, including inspection in the exporting nation, under paragraph (I), as the Secretary determines are necessary to ensure compliance with the food safety laws.

(d) DETENTION OF IMPORTED FOOD PRODUCT- If, during an inspection' or other verification procedure carried out under this section at a port of entry, an officer or employee conducting the procedure determines that a food product is in violation of a food safety law, such officer or employee may order the food product segregated, impounded, and if objection is not made within such 48 hours, condemned. If objection is made, within such 48 hours such food products that are in perishable form may be processed to the extent necessary to prevent spoilage, and the Secretary shall expeditiously commence a hearing regarding the determination and any action required for compliance with the food safety laws. The final condemnation or other disposition of such food product shall be subject to the provisions of this Act.

(e) AGREEMENTS WITH FOREIGN NATIONS

(1) EVALUATION- The Secretary may enter into an agreement described in paragraph (2) with any nation desiring to export food products to the Philippines. Prior to concluding such an agreement, the Secretary shall evaluate the food safety program of the foreign nation to determine if such program provides at least the same level of protection, with respect to food products intended for export to the Philippines, as domestic laws that affect the safety of the food supply. In such evaluation, the Secretary shall consider-

(A) The potential for health, sanitary, environmental, or other conditions within the foreign nation to adversely affect the safety of food products exported from such nation; and

(B) How well the food safety programs of the foreign nation function to minimize any adverse effects on such safety.

(2) REQUIREMENTS- Any agreement under this subsection with a nation desiring to export food products to the Philippines shall

(A) Require that the exporting nation shall--

(i) Establish and maintain a food safety system that is adequate to ensure that the food products intended for export to the Philippines are not in violation of the food safety laws; and

(ii) Promptly notify the Secretary of any violations affecting the safety of food products exported or intended for export to the Philippines;

(B) Provide for such activities (whether in the exporting nation or at the port of entry during importation) by the Secretary, including examinations, inspections, sampling, and other procedures, at such stages in the growth or harvest of food, or in the processing or handling of food products, as the Secretary considers to be appropriate to ensure that the food safety program of the exporting nation continues to provide at least the same level of protection, with respect to food products intended for export to the Philippines, as domestic laws that affect the safety of the food supply and

(C) provide for reciprocity with respect to the treatment of food imports and exports between the Philippines and the exporting nation.

(3) CERTIFICATION- If the Secretary determines that a nation desiring to export food products to the Philippines has a program that provides at least the same level of protection, with respect to food products intended for export to the Philippines, as domestic laws that affect the safety of the food supply, the Secretary shall, upon entry into force of an agreement under paragraph (1), certify the types of food products for which the nation maintains such a program.

(4) REVIEWS OF CERTIFICATIONS-

(A) IN GENERAL- The Secretary shall periodically or for good cause, and not less than once every 3 years, review certifications made under paragraph (3), and shall revoke the certification of, any nation that the Secretary determines is not maintaining a food safety program that provides at least the same level of protection, with respect to food products intended for export to the Philippines, as domestic laws that affect the safety of the food supply.

(B) IMPACT ON AGREEMENTS- The Secretary shall review and modify, as needed, an agreement made under paragraph (1) with any nation whose certification has been revoked under subparagraph (A).

SECTION 9. Separability Clause - If any provision or part hereof, is held invalid or unconstitutional, the remainder of the law or the provision not otherwise affected shall remain valid and subsisting.

SECTION 10. Repealing Clause - Any law, presidential decree or issuance, executive order, letter of instruction, administrative order, rule or regulation contrary to or inconsistent with the provision of this Act is hereby repealed, modified or amended accordingly.

SECTION 11. Effectivity Clause - This Act shall take effect fifteen (15) days after its publication in at least two (2) newspapers of general circulation.

Approved,