FOIA Number: 2008-1524-F

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Food Safety Initiative: Single Agency

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LEVEL 1 - 3 OF 6 STORIES

The Associated Press

November 19, 1997, Wednesday, PM cycle

SECTION: Business News

LENGTH: 170 words

HEADLINE: **Clinton** signs bill modernizing food inspections

DATELINE: WASHINGTON

BODY:

President **Clinton** has signed legislation to pay for modernizing meat and poultry inspections.

The fiscal 1998 appropriations bill provides $ 13.6 billion for the **Agriculture** Department and the Food and Drug Administration, and $ 35.3 billion for food stamps, the child nutrition program, the Commodity Credit Corporation and other programs.

Clinton said Tuesday he was disappointed the legislation did not provide enough money to expand the federal nutrition program for women, infants and children, or WIC.

Clinton had requested $ 4.1 billion to serve 7.5 million people in fiscal 1998. Congress provided $ 3.9 billion to serve 7.4 million people.

"Full participation in WIC is one of my highest priorities, and the funding level that this act provides does not assure that we can achieve this goal," he said.

But **Clinton** said he was pleased that Congress appropriated money to modernize meat and poultry inspections and to study consolidating food safety functions now scattered throughout the government.

LANGUAGE: ENGLISH

LOAD-DATE: November 19, 1997

White House Press Release

STATEMENT BY THE PRESIDENT

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release November 18, 1997

STATEMENT BY THE PRESIDENT

I am pleased to have signed into law today H.R. 2160, the "**Agriculture**, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 1998."

The Act provides $13.6 billion in discretionary budget authority for programs of the Department of **Agriculture** and the Food and Drug Administration. These programs include the Special Supplemental Feeding Program for Women, Infants, and Children (WIC); food safety programs; efforts to reduce children's access to tobacco products; and various programs to protect and support rural communities.

The Act provides a total of $35.3 billion for the Food Stamp program, the Child Nutrition program, the Commodity Credit Corporation, and other mandatory programs.

I am disappointed that the Congress failed to provide the full amount of my requested increase for the WIC program in order to reach a full participation level of 7.5 million women, infants, and children. Full participation in WIC is one of my highest priorities, and the funding level that this Act provides does not assure that we can achieve this goal in FY 1998.

I am concerned about the provision of this bill that alters the administration and funding for research on nutrition programs serving the poor and disadvantaged. The research needs of these important programs should continue to be addressed in the context of the programs' administration. I am asking the Secretary of **Agriculture** to look into this matter and to work with the Director of the Office of Management and Budget on the most effective approach to address my concerns.

I am pleased, however, that the Act includes nearly all of my request for the Food Safety and Inspection Service. The funding provided for meat and poultry inspection will ensure adequate inspection coverage and allow the agency to further implement the modernization of the inspection system that I announced on July 6, 1996. I am also pleased that the Act provides almost all of the requested level for my Administration's food safety initiative and the requested level for our efforts to reduce children's access to tobacco products.

In addition, the Act provides significant increases in rural development programs to improve the quality of life in rural America and help diversify the rural economy. The Act also includes a portion of my proposal to create a Rural Development Performance Partnership, which will provide greater flexibility to tailor Federal assistance to local needs, reflecting my Administration's belief that there is no "one-size-fits-all" solution to the economic challenges facing rural areas. I will continue to seek authority to utilize the full flexibility that was authorized for these programs in the 1996 Farm Bill.

WILLIAM J. CLINTON

THE WHITE HOUSE,
November 18, 1997.

# # #

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FAX TRANSMITTAL SHEET

December 22, 1997

TO: **Jerry Mande**

FAX: **202/456-6027**

TELEPHONE: **202/456-6018**

FROM: **Michael R. Taylor**

NUMBER OF PAGES (including transmittal sheet): **1**

INTERNAL ID: **0571/99998.098200**

Notes/Comments:

Jerry - I faxed the attached to Ron Klain today with a request that he deliver it to the Vice President.

December 22, 1997

MEMORANDUM FOR THE VICE PRESIDENT

I take the liberty of adding a few thoughts to our conversation Saturday night about the single food agency issue.

1. I agree that organizational change of that magnitude will be politically difficult, but the issue is gaining credibility. The consumer organizations are for it; the press attention has been favorable, and the food industry seems more open on the issue now than when you raised it in 1993. At least some in industry see the current arrangements imposing costs and inefficiencies on them, undermining consumer confidence in food safety, and jeopardizing the United States' ability to lead on international harmonization.

2. Rep. Fazio has introduced legislation to create a single food agency and has instigated a National Academy of Sciences study on the issue, which is due to be completed by August 1998. This study should document what's wrong with the current system and put the issue more squarely on the public's radar screen.

3. There is an opportunity now for administration leadership, without committing prematurely to what would still likely be a tough and time-consuming effort. This could be accomplished by: (1) endorsing the NAS study effort and elevating the expectation that its analysis and recommendations will be important, and (2) announcing a parallel effort, run from the White House, to comprehensively review not only organizational issues but also the fragmented and inconsistent statutory framework for the federal food safety program. This would help fulfill the strategic planning commitment already made by HHS, USDA, and EPA in their report to the President last spring and would build on the administration's strong record of modernizing the food safety program and preparing it for success in the global food economy.

4. As a budget issue, organizational and statutory modernization should be understood as an effort to have the best possible system within the constraints of a budget that is unlikely to grow significantly. If reform is presented as an effort to save money, it will lose public support and quickly backfire politically. I personally believe that, with the right organizational and statutory reform, we can do much better on food safety without spending more money.

I stay in close touch with Jerry Mande. Please let Jerry or me know if I can do anything to help on this issue.

Mike Taylor
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The agreement provides $420,000 for a study by the National Academy of Sciences on the scientific and organizational needs for an effective food safety system, including functions overseen by the Food Safety and Inspection Service, the Food and Drug Administration, and other Federal, state and local agencies with responsibilities for food safety. The study will be conducted in two phases. The first phase will examine the current mechanisms in place for assuring a safe food supply and the extent to which they are effective in addressing food safety issues from the farm to the table. It will also analyze the extent to which current functions (i.e., inspection, surveillance, monitoring, research, risk assessment, and education) should be assigned or reassigned to existing or independent food safety agency and identify whether any functions would be

compromised by such an action. If an independent food safety agency is recommended, the second phase will develop further guidance to ensure that the food safety system protects the public's health and is cost-effective. A report on the first phase should be transmitted to the appropriate Committee of Congress no later than August 15, 1998.

105TH CONGRESS
1ST SESSION

S. 1465

IN THE SENATE OF THE UNITED STATES

Mr. DURBIN introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To consolidate in a single independent agency in the executive branch the responsibilities regarding food safety, labeling, and inspection currently divided among several Federal agencies.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Safe Food Act of 1997".

SEC. 2. PURPOSES.

It is the purpose of this Act—

(1) to establish a single agency, the Food Safety Administration, to regulate food safety and label-

ing and to conduct food safety inspections to ensure, with reasonable certainty, that no harm will result from the consumption of food by preventing food-borne illnesses due to microbial, natural, or chemical hazards in food; and

(2) to transfer to the Food Safety Administration the food safety, labeling, and inspection functions currently performed by other Federal agencies.

SEC. 3. DEFINITIONS.

For purposes of this Act:

(1) ADMINISTRATION.—The term "Administration" means the Food Safety Administration established under section 4.

(2) FOOD SAFETY LAWS.—The term "food safety laws" means—

(A) the Federal Meat Inspection Act (21 U.S.C. 601 et seq.);

(B) the Poultry Products Inspection Act (21 U.S.C. 451 et seq.);

(C) the Egg Products Inspection Act (21 U.S.C. 1031 et seq.);

(D) the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), with regard to food safety, labeling, and inspection under that Act;

(E) the food safety responsibilities under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.); and

(F) such other laws and portions of laws regarding food safety, labeling, and inspection that the President considers appropriate to consolidate under the administration of the Administration.

SEC. 4. ESTABLISHMENT OF INDEPENDENT FOOD SAFETY ADMINISTRATION.

(a) ESTABLISHMENT OF ADMINISTRATION.—There is established in the executive branch an agency to be known as the "Food Safety Administration". The Administration shall be an independent establishment, as defined in section 104 of title 5, United States Code.

(b) RESPONSIBILITIES OF ADMINISTRATION.—The Administration shall be responsible for the administration and enforcement of the food safety laws.

SEC. 5. CONSOLIDATION OF SEPARATE FOOD SAFETY AND INSPECTION SERVICES AND AGENCIES.

(a) TERMINATION.—As soon as possible after the effective date of this Act, the President shall terminate the Federal agencies specified in subsection (b) to the extent that the activities of such agencies relate to the administration or enforcement of the food safety laws.

(b) COVERED AGENCIES.—The Federal agencies referred to in subsection (a) are the following:

(1) The Food Safety and Inspection Service of the Department of Agriculture.

(2) The Center for Food Safety and Applied Nutrition of the Food and Drug Administration.

(3) The Center for Veterinary Medicine of the Food and Drug Administration.

(4) The National Marine Fisheries Service of the National Oceanic and Atmospheric Administration of the Department of Commerce.

(5) The Office of Pesticide Programs under the Assistant Administrator of the Environmental Protection Agency for Prevention, Pesticides, and Toxic Substances.

(6) Such other offices, services, or agencies as the President may designate to further the purposes of this Act.

(c) TRANSFER OF ASSETS AND FUNDS.—Consistent with section 1531 of title 31, United States Code, the personnel, assets, liabilities, contracts, property, records, and unexpended balances of appropriations, authorizations, allocations, and other funds of a Federal agency terminated in whole or in part under subsection (a) that are used in connection with the administration or enforcement of the

food safety laws shall be transferred to the Administration upon the termination of the Federal agency. Unexpended funds transferred pursuant to this subsection shall be used by the Administration only for the purposes for which the funds were originally authorized and appropriated.

(d) REFERENCES.—After the termination of a Federal agency under subsection (a), any reference in any other Federal law, Executive order, rule, regulation, document, or other material to that Federal agency or the head of that agency in connection with the administration or enforcement of the food safety laws shall be deemed to be a reference to the Administration.

(e) SAVINGS PROVISIONS.—The termination of a Federal agency under subsection (a) shall not affect—

(1) an order, determination, rule, regulation, permit, agreement, grant, contract, certificate, license, registration, privilege, or other administrative action issued, made, granted, or otherwise in effect with respect to that agency before the termination date regarding functions transferred to the Administration under this Act; and

(2) any suit commenced before the termination of that agency, any other proceeding (including a notice of proposed rulemaking), or any application for any license, permit, certificate, or financial as-

sistance pending before that agency with respect to functions transferred to the Administration under this Act.

SEC. 6. LIMITATION ON AUTHORIZATION OF APPROPRIATIONS.

For the first fiscal year beginning after the date of enactment of this Act, the amount authorized to be appropriated to carry out this Act shall not exceed the amount appropriated for fiscal year 1998 for the Federal agencies to be terminated under section 5(a) to administer the food safety laws.

SEC. 7. EFFECTIVE DATE.

This Act shall take effect on the earlier of—

(1) the date that is 180 days after the date of enactment of this Act; and

(2) such date during that 180-day period as the President may direct in an Executive order.

(DRAFT:January 20)

A BILL

To establish a comprehensive program to ensure the safety of food products intended for human consumption which are regulated by the Food and Drug Administration and sold in interstate commerce.

SECTION 1. SHORT TITLE

(a) SHORT TITLE.-- This Act may be cited as the "Consumer Food Safety Act of 1998."

(b) TABLE OF CONTENTS.-- To be added.

SEC. 2. DEFINITIONS.

(To be added, but will include:

Contaminants include but are not limited to bacteria, chemical contaminants, natural toxins, viruses and parasites that when found on or in food can cause human illness.

Facility includes any factory, warehouse, establishment or importer that handles or processes food.

Processing means the commercial harvesting, preparation, manufacture, or transportation of food products.

Secretary means the Secretary of Health and Human Services.)

TITLE I -- NATIONAL FOOD SAFETY PROGRAM

SEC. 101. ADMINISTRATION OF NATIONAL PROGRAM

(a) IN GENERAL. - (1) Persons who produce or process food for human consumption have the responsibility to prevent or minimize food safety hazards related to their products. The Secretary shall administer a national program for the purpose of protecting human health by ensuring that the food industry has effective programs in place to assure the safety of food products consumed in the United States.

(2) The program shall -

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

(i) the severity of the potential health risks;

(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 and food products.

(B) take into consideration the distinctive characteristics of food production and processing.

(C) establish inspection and oversight procedures to monitor that facilities are utilizing preventive controls to minimize or eliminate identifiable hazards.

(D) require each food processing facility to annually register with the Secretary.

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

(1) implementation of a national system for the registration and quarterly inspection of facilities and importers. Quarterly inspections can be waived by plants that meet the Secretary's standards for exceptional or negligible-risk facilities or importers;

(2) development of a program to oversee the implementation of process controls in food processing facilities;

(3) the establishment and enforcement of health-based standards for (A) substances which may contaminate food and (B) safety and sanitation in the processing and handling of food products;

(4) 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 (1);

(5) implementation of procedures and requirements to ensure the safety of imported food products;

(6) coordination with other federal agencies or State governments in carrying out inspection, enforcement, and monitoring;

(7) implementation of a national surveillance system to assess the health risks associated with the human consumption of food products, in cooperation with the Secretary of Agriculture and the Centers for Disease Control and Prevention.

(8) development of public education and advisory programs; and

(9) implementation of a research program in furtherance of the purposes of this Act.

SEC. 102. REGISTRATION OF PROCESSORS AND IMPORTERS.

(a) IN GENERAL.-- Any facility engaged in processing of food products and any person who imports food products shall register with the Secretary. Application for registration shall be made to the Secretary using such forms and containing such information as the Secretary shall prescribe by regulation within 24 months after the date of enactment of this Act. Upon receipt and review of a completed application, the Secretary shall issue to the applicant a certificate of registration unless good cause is shown why such application should be denied. The Secretary shall promptly notify any applicant of such denial, include 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) The registration may be suspended immediately by the Secretary for --

(A) failure to permit access for inspection under this Act; or

(B) violation of this Act or regulation issued under this Act, where the Secretary determines that such suspension is likely to prevent a significant risk of adverse health consequences.

(2) Any registration suspended under paragraph (1) may be reinstated whenever the Secretary determines that 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 or persons is not needed for effective enforcement of this Act.

SEC. 103. PROCESS CONTROLS TO REDUCE THE ADULTERATION OF FOOD PRODUCTS

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

(1) limit the presence of human pathogens and other potentially harmful substances in food products;

(2) ensure that all registered facilities implement appropriate measures to control and reduce the presence and growth of human pathogens and other potentially harmful substances on food products;

(3) ensure that all fully processed or ready-to-eat food products are processed in a sanitary manner, using reasonably available techniques and technologies to eliminate any human pathogens or other potentially harmful substances likely to cause foodborne illness; and

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

(b) REGULATIONS-- The Secretary shall, within one year of the enactment of this Act, issue regulations that require all registered facilities to adopt processing controls adequate to protect public health and to limit the presence and growth of human pathogens and other potentially harmful substances in food products prepared in any registered facility. Such regulations shall

(1) set standards for sanitation;

(2) set tolerances for biological, chemical and physical hazards as appropriate;

(3) require process controls to assure relevant regulatory and safety standards are met;

(4) require recordkeeping to monitor compliance;

(5) require sampling to assure that processing controls are effective and that regulatory standards are being met; and

(6) provide for agency access to records kept by official establishments and submission of copies of such records to the Secretary as the Secretary deems appropriate.

Public access to records that relate to the adequacy of measures taken by official establishments to protect the public health and to limit the presence and growth of human pathogens and other potentially harmful substances shall be governed by 5 U.S.C. sec. 552 et sec. The Secretary may, as the Secretary deems necessary, require any person, firm, or corporation with responsibility for or control over food ingredients ~~or food products intended for human consumption~~ to adopt processing controls, where such processing controls are needed to assure the protection of public health.

SEC. 104. INSPECTIONS OF PROCESSORS AND IMPORTERS

(a) NATURE OF INSPECTIONS.- (1) The inspection system shall provide for frequent unannounced inspections of food processing and importing facilities to determine if such facilities are operated in a sanitary manner and if food products are unsafe for human consumption, or adulterated or misbranded under the Federal Food, Drug, and Cosmetic Act (21

U.S.C. 301 et seq). Inspections shall include review of processing records and sampling of food products.

(2) Inspections shall be conducted at least quarterly, unless the Secretary determines that the facility is an exceptional or negligible-risk facility, under standards established by the Secretary.

(3) Standards for exceptional or negligible-risk facility shall consider the hazards associated with the type of product being produced; and the facility's history of compliance, food safety problems and such other factors as the Secretary may deem appropriate. The Secretary shall specify an alternative inspection frequency for each facility which is deemed exceptional or negligible-risk. Each inspection shall include an examination of whether the facility continues to meet the standards for exceptional or negligible-risk facilities.

(b) CONDUCT OF INSPECTIONS.-(l) An inspection under subsection (a) of any domestic, foreign or importing facility shall extend to all things therein (including records required to be maintained under subsection (e), processes, controls, and premises) that bear on whether food products are in compliance with this Act or the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.). Access to records may include the copying of such records.

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

(A) to enter at reasonable times any facility in which persons are engaged in the food processing or importing of food products, or to enter any vehicle being used to transport or hold such food products;

(B) to inspect in a reasonable manner such facility or vehicle and 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 unsafe for human consumption or adulterated or misbranded under the Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.)

(3) Within a reasonable time after completion of 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 which indicate that either processing controls are inadequate to prevent or minimize food safety hazards or that any food from such facility is unsafe for human consumption, or adulterated or misbranded under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(c) PRODUCT DETENTION AND CONDEMNATION. - (1) If, during an inspection conducted under this section, an officer or employee making the inspection has reason to believe that a food product is unsafe for human consumption, or adulterated or misbranded under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.), such officer or employee may order the food product segregated, impounded, and if objection is not made within 48 hours, condemned. If objection is made, such food products that are in perishable form may be processed to the extent necessary to prevent spoilage, and a hearing shall be commenced expeditiously.

(2) If the Secretary determines that, through relabeling or other action, such food products can be brought into compliance with this Act and the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the food may be released following a determination by the Secretary that such relabeling or other action as specified by the Secretary has been performed.

(3) Any food product condemned without objection, or after hearing and judicial review, shall be destroyed.

(d) OFFICIAL MARK.-- The Secretary shall prescribe by regulation the conditions under which any food product shall display an official mark that signifies that the food product has been processed in accordance with standards approved by the Secretary.

(e) MAINTENANCE OF RECORDS. -- Each facility or person registered under this section 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, but are not limited to, information concerning --

(1) the origin, receipt, delivery, sale, movement, holding and disposition of food products or ingredients; the identity and amount of ingredients used in the food; the processing of the food; the results of laboratory, sanitation or other quality control tests performed on the food or in the facility; consumer complaints concerning the food or its packaging; and

(2) other matters reasonably related to whether food products may be unsafe for human consumption, or adulterated or misbranded under the Federal Food Drug and Cosmetic Act (21 U.S.C. 301 et seq.).

(f) OTHER INSPECTION RIGHTS AND DUTIES.-- Section 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374) is amended by adding at the end the following new subsection:

"(f) The rights and duties under this section of duly designated officers and employees and of other persons shall apply to enforcement of the Consumer Food Safety Act of 1998 to the same extent and in the same manner as they apply to enforcement of this Act."

SEC. 105. TOLERANCES FOR CONTAMINANTS IN FOOD

(a) TOLERANCES. -- The Secretary shall establish tolerances limiting the quantity of contaminants, except for pesticide residues regulated under section 408 or food additives regulated under section 409 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.), that, when found in food products, may render such products unsafe for human consumption. Contaminants include but are not limited to bacteria, chemical contaminants, natural toxins, viruses and parasites that when found on or in food can cause human illness. Such tolerances may include indicators (including indicator organisms) from which it may reasonably be inferred that a contaminant is present in a food product. In developing a tolerance, 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 handling and processing of such food.

(b)(1) REGULATIONS. -- The Secretary, after notice and an opportunity for comment, shall promulgate regulations to implement section (a) within 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 are having the greatest public health impact as early as feasible after implementation of this act.

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

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

(B) analysis of the risks for sensitive groups, such as children, elderly, pregnant women and the immune compromised.

(3) The Secretary shall, in a timely manner, issue revisions to the regulations under paragraph (1) which take into account new information. The Secretary may contract with the National Academy of Sciences to provide such data or assistance as the Secretary deems necessary.

(c) REPORT. -- The Secretary shall report to the Congress 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 must be conducted before additional tolerances may be established, the health significance of the lack of such additional tolerances, a time table 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 transmitted on or about the end of the 18th month after the date of enactment of this Act, and biennially thereafter during the 6 year period that begins on such date of enactment.

SEC. 106. STATE AND FEDERAL COOPERATION.

(a) IN GENERAL.-- The Secretary shall work with the States in undertaking activities and programs that contribute to the national food safety program so that State and Federal programs function in a coordinated and cost effective manner. With the assistance provided in subsection (b), the Secretary shall encourage States to-

(1) continue, strengthen, or establish State food safety programs, especially with respect to the regulation of retail commercial food establishments, transportation, harvesting, and fresh markets;

(2) establish procedures and requirements for ensuring that food products under the jurisdiction of the State are not unsafe for human consumption;

(b) ASSISTANCE.--(I) The Secretary may provide to a State, for planning, developing, and implementing a food safety program-

(A) advisory assistance;

(B) technical and laboratory assistance and training (including necessary materials and equipment); and

(C) financial and other aid.

(c) SERVICE AGREEMENTS.--The Secretary may, under agreements entered into with Federal, State, or local agencies, use on a reimbursable basis or otherwise the personnel, services, and facilities of such agencies in carrying out their responsibilities under this Act. Such an agreement shall provide that any compliance records, notices, or reports issued in connection with activities under the agreement and in the possession of the agency or government which entered into

the agreement shall be made available in accordance with section 552 of title 5, United States Code. Agreements with a State under this subsection may provide for training of State employees.

SEC. 107. IMPORTS.

(a) ROLE OF SECRETARY.-Within 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 imported into the United States. The Secretary shall routinely inspect processing facilities in exporting nations and imports at ports of entry into the United States. The Secretary shall assure the effective operation through verification and other activities as the Secretary considers necessary.

(b) IMPORT REQUIREMENTS.-(l) No food product may enter the United States, or be withdrawn from a warehouse, for consumption in the United States if such food product-

(A) appears unsafe for human consumption, or adulterated or misbranded under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.);

(B) is not marked or labeled as required by regulations for domestic or imported articles; or

(C) does not comply with the requirements of this section.

(2) Upon entry for consumption in the United States, food products that are not prohibited from entry or from withdrawal from a warehouse under paragraph (1) shall be deemed 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.-(l) Food products that are offered for importation, or withdrawn from a warehouse, for consumption in the United States, shall be subject to examinations, inspections, sampling, and such other procedures at the port of entry or 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) 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. 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 country of origin, as the Secretary determines are necessary to ensure compliance with this Act.

(d) DETENTION OF IMPORTED FOOD PRODUCT.-If during an inspection or other verification procedure carried out under this section, an officer or employee conducting the procedure has reason to believe that a food product is unsafe for human consumption, or adulterated or misbranded under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), such officer or employee may order the food product segregated, impounded, and if objection is not made within 48 hours, condemned. If objection is made, such food products that are in perishable form may be processed to the extent necessary to prevent spoilage, and a hearing shall be commenced expeditiously. The final condemnation or other disposition of such food product shall be subject to the provisions of section 104(c).

(e) AGREEMENTS WITH FOREIGN NATIONS.-(1) The Secretary may enter into an agreement with any nation desiring to export food products to the United States. 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 United States, 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 functions to minimize any adverse effects on such safety.

(2) Any agreement under this subsection with a nation desiring to export food products to the United States 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 United States are safe for human consumption, and not adulterated or misbranded under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); and (ii) promptly notify the Secretary of any violations affecting the safety of food products exported or intended for export to the United States; and

(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 testing, at such stages in the growth or harvest of food, or in the processing or handling of food products, as the Secretary considers 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 United States, as domestic laws that affect the safety of the food supply;

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

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

(4)(A) 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 United States, as domestic laws that affect the safety of the food supply.

(B) 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) of this paragraph.

SEC. II. AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL-There are authorized to be appropriated, to carry out this Act, not to exceed $XXX,000,000 for the fiscal year 199X and $XXX,000,000 for fiscal year 199X.

(b) ASSISTANCE TO STATES.-Of the funds authorized to be appropriated under subsection (a), there are authorized to be appropriated not to exceed $XX,000,000 for fiscal year

199X and $XX,000,000 for fiscal year 199X, for carrying out State program assistance activities under section 106.

(c) RESEARCH PROGRAM AUTHORIZATION.-Of the funds authorized to be appropriated under subsection (a), there are authorized to be appropriated not to exceed $XX,000,000 for each of fiscal years 199X and 199X, for carrying out the research program authorized by section 203.

TITLE II-RESEARCH AND EDUCATION

SEC. 201. PUBLIC HEALTH ASSESSMENT SYSTEM.

(a) COOPERATION WITH THE CENTERS FOR DISEASE CONTROL AND PREVENTION.-The Secretary shall work, through the Centers for Disease Control and Prevention, to include food in an active surveillance system, based on a representative proportion of the population of the United States, and to assess more accurately the frequency and sources of human illness in the United States associated with the consumption of food.

(b) PUBLIC HEALTH SAMPLING.-(l) Within 12 months after the date of enactment of this Act, the Secretary in cooperation with the Secretary of Agriculture shall establish guidelines for a sampling system under which the Secretary and the Secretary of Agriculture shall take and analyze samples of food products to assist the Secretary in carrying out this Act and the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), and to more accurately assess the nature, frequency of occurrence, and amounts of contaminants in food products.

(2) Such sampling system shall provide-

(A) statistically valid monitoring, including market-basket studies, on the nature, frequency of occurrence, and amounts of contaminants in food products available to consumers; and

(B) at the request of the Secretary, such other information, including analysis of monitoring and verification samples, as the Secretary determines may be useful in assessing the occurrence of contaminants in food products.

(c) ASSESSMENT OF HEALTH HAZARDS.- Through the surveillance system referred to in subsection (a) and the sampling system described in subsection (b), the Secretary shall rank food categories based on their hazard to human health and identify appropriate industry and regulatory approaches to minimize hazards in the food supply. Such analysis could include the following:

(1) the safety of commercial harvesting and processing, as compared with the health hazards associated with food products that are harvested for recreational or subsistence purposes and prepared noncommercially;

(2) the safety of food products that are domestically harvested and processed, as compared with the health hazards associated with food products that are harvested or processed outside the United States; and

(3) contamination originating from handling practices that occur prior to or after sale of food products to consumers.

SEC. 202. PUBLIC EDUCATION AND ADVISORY SYSTEM.

(a) PUBLIC EDUCATION.-The Secretary, in cooperation with private and public organizations, including the cooperative extension services and appropriate State entities, shall

design and implement a national public education program on food safety. The program shall provide

(1) information to the public regarding Federal standards and good practice requirements and promotion or public awareness, understanding, and acceptance of such standards and requirements;

(2) information to health professionals so that they may improve diagnosis and treatment of food-related illness and advise individuals whose health conditions place them in particular risk; and

(3) such other information or advice to consumers and other persons as the Secretary determine will promote the purposes of this Act.

(b) HEALTH ADVISORIES. The Secretary, in consultation with the Secretary of Agriculture and the Administrator of the Environmental Protection Agency, shall work with the States and other appropriate entities to

(1) develop and distribute regional and national advisories concerning food safety;

(2) develop standardized formats for written and broadcast advisories; and

(3) incorporate State and local advisories into the national public education program required under subsection (a).

SEC. 203. RESEARCH.

(a) IN GENERAL.-The Secretary shall conduct research to assist in the implementation of this Act, including studies to-

(1) improve sanitation and food safety practices in the processing of food products;

(2) develop improved techniques for the monitoring of food and inspection of food products;

(3) develop efficient, rapid, and sensitive methods for determining and detecting the presence of contaminants in food products;

(4) determine the sources of contamination of food and food products with contaminants; and

(5) develop consumption data with respect to food products.

(b) CONTRACT AUTHORITY.-The Secretary is authorized to enter into contracts and agreements with any State, university, other government agencies or other persons to carry out the activities under this section.

TITLE 11 -- ENFORCEMENT

(PROVISIONS FROM THE PALLONE BILL, HR 3070)

SEC. 301. AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

(a) IN GENERAL- The Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended by adding after section 413 the following new sections:

SEC. 414. NOTIFICATION AND RECALL.

(a) NOTICE TO SECRETARY OF ADULTERATION OR MISBRANDING- Any person (other than a household consumer or other individual who is the intended consumer of an article of food) that has a reasonable basis for believing that any article of food introduced into or in interstate commerce, or held for sale (whether or not the first sale) after shipment in interstate commerce, may be adulterated or misbranded shall immediately notify the Secretary, in such manner and by such means as the Secretary may by regulation prescribe, of the identity and location of such article.

(b) RECALL AND CONSUMER NOTIFICATION-

(1) VOLUNTARY PROCEDURES- If the Secretary finds, upon notification under subsection (a) or otherwise, that any article of food is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce and there is a reasonable probability that such article, if consumed, would present a threat to public health, as determined by the Secretary, the Secretary shall provide the appropriate persons (including the manufacturers, importers, distributors, or retailers) with an opportunity to--

(A) cease distribution of such article,

(B) notify all persons--

(I) producing, manufacturing, packing, processing, preparing, treating, packaging, distributing, or holding such article, or

(ii) to which such article has been distributed, transported, or sold,

to immediately cease distribution of such article,

(C) recall such article,

(D) provide, in consultation with the Secretary, notice to consumers to whom such article was, or may have been, distributed, or

(E) take any combination of the above measures, as appropriate in the circumstances.

(2) PRE-HEARING ORDER TO CEASE DISTRIBUTION AND GIVE NOTICE- If such person refuses to or does not voluntarily cease distribution, make notification, recall such article, or provide notice to consumers, as applicable, within the time and in the manner prescribed by the Secretary, the Secretary shall, by order, require, as the Secretary deems necessary, such person to--

(A) immediately cease distribution of such article,

(B) immediately notify all persons--

(I) producing, manufacturing, packing, processing, preparing, treating, packaging, distributing, or holding such article, or

(ii) to which such article has been distributed, transported, or sold, to immediately cease distribution of such article, or

(C) immediately take the actions specified in both subparagraphs (A) and (B).

(3) NOTIFICATION OF CONSUMERS BY SECRETARY- The Secretary shall, as the Secretary deems necessary, provide notice to consumers to whom such article was, or may have been, distributed.

(c) HEARING ON ORDER- The Secretary shall provide any person subject to an order under subsection (b) with an opportunity for a hearing, to be held as soon as possible but not later than 2 days after the issuance of the order, on the actions required by the order and on why the article that is the subject of the order should not be recalled.

(d) POST-HEARING RECALL ORDER-

(1) AMENDMENT OF ORDER- If, after providing opportunity for a hearing under subsection (c), the Secretary determines that there is a reasonable probability that the article that is the subject of an order under subsection (b), if consumed, presents a threat to public health, the Secretary, as the Secretary deems necessary, may--

(A) amend the order to require recall of such article or other appropriate action,

(B) specify a timetable in which the recall shall occur,

(C) require periodic reports to the Secretary describing the progress of the recall, and

(D) provide notice to consumers to whom such article was, or may have been, distributed.

(2) VACATION OF ORDER- If, after such a hearing, the Secretary determines that adequate grounds do not exist to continue the actions required by the order, the Secretary shall vacate the order.

(e) REMEDIES NOT EXCLUSIVE- The remedies provided in this section shall be in addition to and not exclusive of other remedies that may be available.

SEC. 415. CIVIL PENALTIES.

(a) IN GENERAL-

(1) ACTS SUBJECT TO PENALTY; PENALTY AMOUNT- Any person that commits an act prohibited by section 301 with respect to food may be assessed a civil penalty by the Secretary of not more than $100,000 for each such act. Each such act and each day during which such act continues shall be a separate offense.

(2) NOTICE AND HEARING- No penalty shall be assessed by the Secretary under this section unless such person is given notice and opportunity for a hearing on the record before the Secretary in accordance with sections 554 and 556 of title 5, United States Code.

(3) OTHER REQUIREMENTS- The amount of such civil penalty shall be assessed by the Secretary by written order, taking into account the gravity of the violation, degree of culpability, size and type of business, and any history of prior offenses; and may be reviewed only as provided in subsection (b).

(b) JUDICIAL REVIEW- An order assessing a civil penalty under subsection (a) shall be final and conclusive unless the person files, within 30 days from the effective date of the order, an application for judicial review in the Court of Appeals of the United States for the circuit in which such person resides or has its principal place of business or in the United States Court of Appeals for the District of Columbia Circuit by filing a notice of appeal in such court and by simultaneously sending a copy of such notice by certified mail to the Secretary. The Secretary shall promptly file in such court a certified copy of the record upon which such penalty was assessed. The findings of the Secretary shall be set aside only if found to be unsupported by substantial evidence on the record as a whole.

(c) COLLECTION ACTIONS- If any person fails to pay an assessment of a civil penalty after it has become a final and unappealable order, or after the appropriate court of appeals has entered final judgment in favor of the Secretary, the Secretary shall refer the matter to the Attorney General, who shall institute a civil action to recover the amount assessed in an appropriate district court of the United States. In such collection action, the validity and appropriateness of the Secretary's order imposing the civil penalty shall not be subject to review.

(d) PENALTIES PAID INTO TREASURY- All penalties collected under authority of this section shall be paid into the Treasury of the United States.

(e) SECRETARY'S DISCRETION TO PROSECUTE- Nothing in this Act shall be construed as requiring the Secretary to report for prosecution, or for the institution of libel or injunction proceedings, violations of this Act whenever the Secretary believes that the public interest will be adequately served by assessment of civil penalties.

(f) REMEDIES NOT EXCLUSIVE- The remedies provided in this section shall be in addition to and not exclusive of other remedies that may be available.

SEC. 416. WHISTLEBLOWER PROTECTION.

(a) IN GENERAL- No employee or other person may be harassed, prosecuted, held liable, or discriminated against in any way because that person--

(1) has commenced, caused to be commenced, or is about to commence a proceeding, testified or is about to testify at a proceeding, or assisted or participated or is about to assist or participate in any manner in such a proceeding or in any other action to carry out the purposes, functions, or responsibilities of [the Consumer Food Safety Act of 1998, the Federal Food, Drug, and Cosmetic Act, the Meat Inspection Act or the Poultry Products Inspection Act] (changed from original Pallone bill]; or

(2) is refusing to violate or assist in violation of law, rule, or regulation.

(b) PROCEDURES AND PENALTIES- The process and procedures with respect to prohibited discrimination under subsection (a) shall be governed by the applicable provisions of section 31105 of title 49, United States Code, unless the party bringing an action under this subsection chooses alternative dispute resolution procedures such as mediation or arbitration.

(c) BURDENS OF PROOF- The legal burdens of proof with respect to prohibited discrimination under subsection (a) shall be governed by the applicable provisions of sections 1214 and 1221 of title 5, United States Code.

[END HR 3070, BEGIN ADDITIONAL ENFORCEMENT SECTIONS]

SEC. 417. ADMINISTRATION AND ENFORCEMENT; APPLICABILITY OF PENALTY PROVISIONS; CONDUCT OF INQUIRIES; POWER AND JURISDICTION OF COURTS.

For the efficient administration and enforcement of this chapter, the provision (including penalties) of section 46, 48, 49, and 50 of Title 15 (except paragraphs (c) through (h) of section 46 and the last paragraph of section 49 of Title 15), are made applicable to the jurisdiction, powers, and duties of the Secretary in administrating and enforcing the provisions of this chapter and to any person with respect to whom such authority is exercised. The Secretary, in person or by such agents as he may designate, may prosecute any inquiry necessary to his duties under this chapter in any part of the United States, and the powers conferred by said sections 49 and 50 of Title 15 on the district courts of the United States may be exercised for the purposes of this chapter by any appropriate court.

[SUBPOENA AUTHORITY AND OTHER AUTHORITIES TAKEN FROM MEAT INSPECTION ACT]

SEC. 418. TRACEBACK

The Secretary may impose on a food product requirements for the traceability of such type or class of food product whenever such requirements are necessary to assure the protection of the public health. Traceability requirements shall be established in accordance with regulations and guidelines issued by the Secretary.

[TRACEBACK PROVISION BASED ON THE MEDICAL DEVICE STATUTE]

SEC. 419. CITIZEN'S CIVIL ACTIONS

Any person may commence a civil action against (1) any person who violated any rule, tolerance, order or other action of the Secretary to ensure the safety of food products; or (2) against the Secretary where there is alleged a failure of the Secretary to perform any act or duty to ensure

the safety of food products, which is not discretionary. The district courts shall have jurisdiction, without regard for the amount in controversy, or the citizenship of the parties, to enforce such rule, tolerance, order or other action of the Secretary, or to order the Secretary to perform such act or duty. The suit shall be commenced in the district in which the defendant resides or is found or has an agent. The court may award damages sustained and may, if the court determines it to be in the interest of justice, award the costs of suit, including reasonable attorney's fees and reasonable expert witnesses fees. The remedies provided for in this section shall be in addition to and not in lieu of any other remedies provided by common law or under Federal or state law.

[CIVIL ACTION LANGUAGE BASED ON PROVISIONS OF THE CONSUMER PRODUCT SAFETY ACT, THE CLEAN AIR ACT, AND OTHER ENVIRONMENTAL STATUTES]

[FINAL PROVISION WITH MODIFICATION IS IN THE ORIGINAL HR 3070]

(b) CONFORMING AMENDMENT; PROHIBITED ACT- Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following new subsection:

(x) The failure or refusal to comply with an order issued under section 414(b)(2) or 414(d).

(y) The failure to comply with the Consumer Food Safety Act of 1998.

(DRAFT:January 16)

A BILL

To establish a comprehensive program to ensure the safety of food products intended for human consumption and sold in interstate commerce.

SECTION 1. SHORT TITLE

(a) SHORT TITLE.-- This Act may be cited as the "Consumer Food Safety Act of 1998."

(b) TABLE OF CONTENTS.-- To be added.

SEC. 2. DEFINITIONS.

(To be added, but will include:

Contaminants include but are not limited to bacteria, chemical contaminants, natural toxins, viruses and parasites that when found on or in food can cause human illness.

Facility includes any factory, warehouse, establishment or importer that handles and processes food.

Processing means the commercial harvesting, preparation, manufacture, or transportation of food products.)

TITLE I -- NATIONAL FOOD SAFETY PROGRAM

SEC. 101. ADMINISTRATION OF NATIONAL PROGRAM

(a) IN GENERAL. - (1) Persons who produce, process and sell food for human consumption have the responsibility to prevent or minimize food safety hazards related to their products. The

Secretary shall administer a national program for the purpose of protecting human health by ensuring that the food industry has effective programs in place to assure the safety of food products consumed in the United States regulated under this Act.

(2) The program shall -

(A) be based on a comprehensive analysis of the hazards associated with different food products regulated under this Act and with the harvesting, processing and handling of different food products, including the identification and evaluation of -

(i) the severity of the potential health risks;

(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 and food products.

(B) take into consideration the distinctive characteristics of food production and processing.

(C) establish inspection and oversight procedures to monitor that facilities are utilizing preventive controls to minimize or eliminate identifiable hazards.

(D) require each food processing facility to annually register with the Secretary.

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

(1) implementation of a national system for the registration and quarterly inspection of facilities and importers. Quarterly inspections can be waived by plants that meet the Secretary's standards for exceptional or negligible-risk facilities or importers;

(2) development of a program to oversee the implementation of process controls in food processing facilities;

(3) the establishment and enforcement of health-based standards for (A) substances which may contaminate food and (B) safety and sanitation in the processing and handling of food products;

(4) 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 (1);

(5) implementation of procedures and requirements to ensure the safety of imported food products;

(6) coordination with other federal agencies or State governments in carrying out inspection, enforcement, and monitoring;

(7) implementation of a national surveillance system to assess the health risks associated with the human consumption of food products, in cooperation with the Secretary of Agriculture and the Centers for Disease Control and Prevention.

(8) development of public education and advisory programs; and

(9) implementation of a research program in furtherance of the purposes of this Act.

SEC. 102. REGISTRATION OF PROCESSORS AND IMPORTERS.

(a) IN GENERAL.-- Any facility engaged in processing of food products and any person who imports food products shall register with the Secretary. Application for registration shall be made to the Secretary using such forms and containing such information as the Secretary shall prescribe by regulation within 24 months after the date of enactment of this Act. Upon receipt

and review of a completed application, the Secretary shall issue to the applicant a certificate of registration unless good cause is shown why such application should be denied. The Secretary shall promptly notify any applicant of such denial, include 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) The registration may be suspended immediately by the Secretary for --

(A) failure to permit access for inspection under this Act; or

(B) violation of this Act or regulation issued under this Act, where the Secretary determines that such suspension is likely to prevent a significant risk of adverse health consequences.

(2) Any registration suspended under paragraph (1) may be reinstated whenever the Secretary determines that 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 or persons is not needed for effective enforcement of this Act.

SEC. 103. PROCESS CONTROLS TO REDUCE THE ADULTERATION OF FOOD PRODUCTS

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

(1) limit the presence of human pathogens and other potentially harmful substances in food products;

(2) ensure that all registered facilities implement appropriate measures to control and reduce the presence and growth of human pathogens and other potentially harmful substances on food products;

(3) ensure that all fully processed or ready-to-eat food products are processed in a sanitary manner, using reasonably available techniques and technologies to eliminate any human pathogens or other potentially harmful substances likely to cause foodborne illness; and

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

(b) REGULATIONS-- The Secretary shall, within one year of the enactment of this Act, issue regulations that require all registered facilities to adopt processing controls adequate to protect public health and to limit the presence and growth of human pathogens and other potentially harmful substances in food products prepared in any registered facility. Such regulations shall

(1) set standards for sanitation;

(2) set tolerances for biological, chemical and physical hazards as appropriate;

(3) require process controls to assure relevant regulatory and safety standards are met;

(4) require recordkeeping to monitor compliance;

(5) require sampling to assure that processing controls are effective and that regulatory standards are being met; and

(6) provide for agency access to records kept by official establishments and submission of copies of such records to the Secretary as the Secretary deems appropriate.

Public access to records that relate to the adequacy of measures taken by official establishments to protect the public health and to limit the presence and growth of human pathogens and other potentially harmful substances shall be governed by 5 U.S.C. sec. 552 et sec. The Secretary may, as the Secretary deems necessary, require any person, firm, or corporation with responsibility for or control over food ingredients or food products intended for human consumption to adopt processing controls, where such processing controls are needed to assure the protection of public health.

SEC. 104. INSPECTIONS OF PROCESSORS AND IMPORTERS

(a) NATURE OF INSPECTIONS.- (1) The inspection system shall provide for frequent unannounced inspections of food processing and importing facilities to determine if such facilities are operated in a sanitary manner and if food products are unsafe for human consumption, or adulterated or misbranded under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq). Inspections shall include review of processing records and sampling of food products.

(2) Inspections shall be conducted at least quarterly, unless the Secretary determines that the facility is an exceptional or negligible-risk facility, under standards established by the Secretary.

(3) Standards for exceptional or negligible-risk facility shall consider the hazards associated with the type of product being produced; and the facility's history of compliance, food

safety problems and such other factors as the Secretary may deem appropriate. The Secretary shall specify an alternative inspection frequency for each facility which is deemed exceptional or negligible-risk. Each inspection shall include an examination of whether the facility continues to meet the standards for exceptional or negligible-risk facilities.

(b) CONDUCT OF INSPECTIONS.-(1) An inspection under subsection (a) of any domestic, foreign or importing facility shall extend to all things therein (including records required to be maintained under subsection (e), processes, controls, and premises) that bear on whether food products are in compliance with this Act or the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.). Access to records may include the copying of such records.

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

(A) to enter at reasonable times any facility in which persons are engaged in the food processing or importing of food products, or to enter any vehicle being used to transport or hold such food products;

(B) to inspect in a reasonable manner such facility or vehicle and 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 unsafe for human consumption or adulterated or misbranded under the Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.)

(3) Within a reasonable time after completion of 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 which indicate that either processing controls are inadequate to prevent or minimize food safety hazards or that any food from such facility is unsafe for human consumption, or adulterated or misbranded under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(c) PRODUCT DETENTION AND CONDEMNATION. - (1) If, during an inspection conducted under this section, an officer or employee making the inspection has reason to believe that a food product is unsafe for human consumption, or adulterated or misbranded under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.), such officer or employee may order the food product segregated, impounded, and if objection is not made within 48 hours, condemned. If objection is made, such food products that are in perishable form may be processed to the extent necessary to prevent spoilage, and a hearing shall be commenced expeditiously.

(2) If the Secretary determines that, through relabeling or other action, such food products can be brought into compliance with this Act and the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the food may be released following a determination by the Secretary that such relabeling or other action as specified by the Secretary has been performed.

(3) Any food product condemned without objection, or after hearing and judicial review, shall be destroyed.

(d) OFFICIAL MARK.-- The Secretary shall prescribe by regulation the conditions under which any food product shall display an official mark that signifies that the food product has been processed in accordance with standards approved by the Secretary.

(c) MAINTENANCE OF RECORDS. -- Each person registered under this section 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, but are not limited to, information concerning --

(1) the origin, receipt, delivery, sale, movement, holding and disposition of food products or ingredients; the identity and amount of ingredients used in the food; the processing of the food; the results of laboratory or other quality control tests performed on the food; consumer complaints concerning the food or its packaging; and

(2) other matters reasonably related to whether food products may be unsafe for human consumption, or adulterated or misbranded under the Federal Food Drug and Cosmetic Act (21 U.S.C. 301 et seq.).

(f) OTHER INSPECTION RIGHTS AND DUTIES.-- Section 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374) is amended by adding at the end the following new subsection:

"(f) The rights and duties under this section of duly designated officers and employees and of other persons shall apply to enforcement of the Consumer Food Safety Act of 1998 to the same extent and in the same manner as they apply to enforcement of this Act."

SEC. 105. TOLERANCES FOR CONTAMINANTS IN FOOD

(a) TOLERANCES. -- The Secretary shall establish tolerances limiting the quantity of contaminants, except for pesticide residues regulated under section 408 or food additives regulated under section 409 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.), that, when found in food products, may render such products unsafe for human consumption. Contaminants include but are not limited to bacteria, chemical contaminants, natural toxins, viruses and parasites that when found on or in food can cause human illness. Such tolerances may include indicators (including indicater organisms) from which it may reasonably be inferred that a contaminant is present in a food product. In developing a tolerance, 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 handling and processing of such food.

(b)(1) REGULATIONS. -- The Secretary, after notice and an opportunity for comment, shall promulgate regulations to implement section (a) within 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 are having the greatest public health impact as early as feasible after implementation of this act.

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

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

(B) analysis of the risks for sensitive groups, such as children, elderly, pregnant women and the immune compromised.

(3) The Secretary shall, in a timely manner, issue revisions to the regulations under paragraph (1) which take into account new information. The Secretary may contract with the National Academy of Sciences to provide such data or assistance as the Secretary deems necessary.

(c) REPORT. -- The Secretary shall report to the Congress 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 must be conducted before additional tolerances may be established, the health significance of the lack of such additional tolerances, a time table 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 transmitted on or about the end of the 18th month after the date of enactment of this Act, and biennially thereafter during the 6 year period that begins on such date of enactment.

SEC. 106. STATE AND FEDERAL COOPERATION.

(a) IN GENERAL.-- The Secretary shall work with the States in undertaking activities and programs that contribute to the national food safety program so that State and Federal programs function in a coordinated and cost effective manner. With the assistance provided in subsection (b), the Secretary shall encourage States to-

(1) continue, strengthen, or establish State food safety programs, especially with respect to the regulation of retail commercial food establishments, transportation, harvesting, and fresh markets;

(2) establish procedures and requirements for ensuring that food products are not unsafe for human consumption;

(b) ASSISTANCE.--(1) The Secretary may provide to a State, for planning, developing, and implementing a food safety program-

(A) advisory assistance;

(B) technical and laboratory assistance and training (including necessary materials and equipment); and

(C) financial and other aid.

(c) SERVICE AGREEMENTS.--The Secretary may, under agreements entered into with Federal, State, or local agencies, use on a reimbursable basis or otherwise the personnel, services, and facilities of such agencies in carrying out their responsibilities under this Act. Such an agreement shall provide that any compliance records, notices, or reports issued in connection with activities under the agreement and in the possession of the agency or government which entered into the agreement shall be made available in accordance with section 552 of title 5, United States Code. Agreements with a State under this subsection may provide for training of State employees.

SEC. 107. IMPORTS.

(a) ROLE OF SECRETARY.-Within 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 imported into the United States. The Secretary shall routinely inspect processing facilities in exporting nations and imports at ports of entry into the United States. The Secretary shall assure the effective operation through verification and other activities as the Secretary considers necessary.

(b) IMPORT REQUIREMENTS.-(1) No food product may enter the United States, or be withdrawn from a warehouse, for consumption in the United States if such food product-

(A) appears unsafe for human consumption, or adulterated or misbranded under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.);

(B) is not marked or labeled as required by regulations for domestic or imported articles; or

(C) does not comply with the requirements of this section.

(2) Upon entry for consumption in the United States, food products that are not prohibited from entry or from withdrawal from a warehouse under paragraph (1) shall be deemed 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) Food products that are offered for importation, or withdrawn from a warehouse, for consumption in the United States, shall be subject to examinations, inspections, sampling, and such other procedures at the port of entry or 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) 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. 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 country of origin, as the Secretary determines are necessary to ensure compliance with this Act.

(d) DETENTION OF IMPORTED FOOD PRODUCT.-If during an inspection or other verification procedure carried out under this section, an officer or employee conducting the procedure has reason to believe that a food product is unsafe for human consumption, or adulterated

or misbranded under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), such officer or employee may order the food product segregated, impounded, and if objection is not made within 48 hours, condemned. If objection is made, such food products that are in perishable form may be processed to the extent necessary to prevent spoilage, and a hearing shall be commenced expeditiously. The final condemnation or other disposition of such food product shall be subject to the provisions of section 104(c).

(c) AGREEMENTS WITH FOREIGN NATIONS.-(1) The Secretary may enter into an agreement with any nation desiring to export food products to the United States. 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 United States, 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 and 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 functions to minimize any adverse effects on such safety.

(2) Any agreement under this subsection with a nation desiring to export food products to the United States 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 United States are safe for human consumption, and not adulterated or misbranded under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); and (ii) promptly notify the Secretary of

any violations affecting the safety of food products exported or intended for export to the United States; and

(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 testing, at such stages in the growth or harvest of food, or in the processing or handling of food products, as the Secretary considers 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 United States, as domestic laws that affect the safety of the food supply;

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

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

(4)(A) 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 United States, as domestic laws that affect the safety of the food supply.

(B) 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) of this paragraph.

SEC. 11. AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL.-There are authorized to be appropriated, to carry out this Act, not to exceed $XXX,000,000 for the fiscal year 199X and $XXX,000,000 for fiscal year 199X.

(b) ASSISTANCE TO STATES.-Of the funds authorized to be appropriated under subsection (a), there are authorized to be appropriated not to exceed $XX,000,000 for fiscal year 199X and $XX,000,000 for fiscal year 199X, for carrying out State program assistance activities under section 106.

(c) RESEARCH PROGRAM AUTHORIZATION.-Of the funds authorized to be appropriated under subsection (a), there are authorized to be appropriated not to exceed $XX,000,000 for each of fiscal years 199X and 199X, for carrying out the research program authorized by section 203.

TITLE II-RESEARCH AND EDUCATION

SEC. 201. PUBLIC HEALTH ASSESSMENT SYSTEM.

(a) COOPERATION WITH THE CENTERS FOR DISEASE CONTROL AND PREVENTION.-The Secretary shall work, through the Centers for Disease Control and Prevention, to include food in an active surveillance system, based on a representative proportion

of the population of the United States, and to assess more accurately the frequency and sources of human illness in the United States associated with the consumption of food.

(b) PUBLIC HEALTH SAMPLING.-(1) Within 12 months after the date of enactment of this Act, the Secretary in cooperation with the Secretary of Agriculture shall establish guidelines for a sampling system under which the Secretary and the Secretary of Agriculture shall take and analyze samples of food products to assist the Secretary in carrying out this Act and the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), and to more accurately assess the nature, frequency of occurrence, and amounts of contaminants in food products.

(2) Such sampling system shall provide-

(A) statistically valid monitoring, including market-basket studies, on the nature, frequency of occurrence, and amounts of contaminants in food products available to consumers; and

(B) at the request of the Secretary, such other information, including analysis of monitoring and verification samples, as the Secretary determines may be useful in assessing the occurrence of contaminants in food products.

(c) ASSESSMENT OF HEALTH HAZARDS.- Through the surveillance system referred to in subsection (a) and the sampling system described in subsection (b), the Secretary shall rank food categories based on their hazard to human health and identify appropriate industry and regulatory approaches to minimize hazards in the food supply. Such analysis could include the following:

(1) the safety of commercial harvesting and processing, as compared with the health hazards associated with food products that are harvested for recreational or subsistence purposes and prepared noncommercially;

(2) the safety of food products that are domestically harvested and processed, as compared with the health hazards associated with food products that are harvested or processed outside the United States; and

(3) contamination originating from handling practices that occur prior to or after sale of food products to consumers.

SEC. 202. PUBLIC EDUCATION AND ADVISORY SYSTEM.

(a) PUBLIC EDUCATION.-The Secretary, in cooperation with private and public organizations, including the cooperative extension services and appropriate State entities, shall design and implement a national public education program on food safety. The program shall provide

(1) information to the public regarding Federal standards and good practice requirements and promotion or public awareness, understanding, and acceptance of such standards and requirements;

(2) information to health professionals so that they may improve diagnosis and treatment of food-related illness and advise individuals whose health conditions place them in particular risk; and

(3) such other information or advice to consumers and other persons as the Secretary determine will promote the purposes of this Act.

(b) HEALTH ADVISORIES. The Secretary, in consultation with the Secretary of Agriculture and the Administrator of the Environmental Protection Agency, shall work with the States and other appropriate entities to

(1) develop and distribute regional and national advisories concerning food safety;

(2) develop standardized formats for written and broadcast advisories; and

(3) incorporate State and local advisories into the national public education program required under subsection (a).

SEC. 203. RESEARCH.

(a) IN GENERAL.-The Secretary shall conduct research to assist in the implementation of this Act, including studies to-

(1) improve sanitation and food safety practices in the processing of food products;

(2) develop improved techniques for the monitoring of food and inspection of food products;

(3) develop efficient, rapid, and sensitive methods for determining and detecting the presence of contaminants in food products;

(4) determine the sources of contamination of food and food products with contaminants; and

(5) develop consumption data with respect to food products.

(b) CONTRACT AUTHORITY.-The Secretary is authorized to enter into contracts and agreements with any State, university, other government agencies or other persons to carry out the activities under this section.

TITLE II -- ENFORCEMENT

(PROVISIONS FROM THE PALLONE BILL, HR 3070)

SEC. 301. AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

(a) IN GENERAL- The Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended by adding after section 413 the following new sections:

SEC. 414. NOTIFICATION AND RECALL.

(a) NOTICE TO SECRETARY OF ADULTERATION OR MISBRANDING- Any person (other than a household consumer or other individual who is the intended consumer of an article of food) that has a reasonable basis for believing that any article of food introduced into or in interstate commerce, or held for sale (whether or not the first sale) after shipment in interstate commerce, may be adulterated or misbranded shall immediately notify the Secretary, in such manner and by such means as the Secretary may by regulation prescribe, of the identity and location of such article.

(b) RECALL AND CONSUMER NOTIFICATION-

(1) VOLUNTARY PROCEDURES- If the Secretary finds, upon notification under subsection (a) or otherwise, that any article of food is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce and there is a reasonable probability that such article, if consumed, would present a threat to public health, as determined by the Secretary, the Secretary shall provide the appropriate persons (including the manufacturers, importers, distributors, or retailers) with an opportunity to--

(A) cease distribution of such article,

(B) notify all persons--

(I) producing, manufacturing, packing, processing, preparing, treating, packaging, distributing, or holding such article, or

(ii) to which such article has been distributed, transported, or sold,

to immediately cease distribution of such article,

(C) recall such article,

(D) provide, in consultation with the Secretary, notice to consumers to whom such article was, or may have been, distributed, or

(E) take any combination of the above measures, as appropriate in the circumstances.

(2) PRE-HEARING ORDER TO CEASE DISTRIBUTION AND GIVE NOTICE- If such person refuses to or does not voluntarily cease distribution, make notification, recall such article, or provide notice to consumers, as applicable, within the time and in the manner prescribed by the Secretary, the Secretary shall, by order, require, as the Secretary deems necessary, such person to--

(A) immediately cease distribution of such article,

(B) immediately notify all persons--

(I) producing, manufacturing, packing, processing, preparing, treating, packaging, distributing, or holding such article, or

(ii) to which such article has been distributed, transported, or sold, to immediately cease distribution of such article, or

(C) immediately take the actions specified in both subparagraphs (A) and (B).

(3) NOTIFICATION OF CONSUMERS BY SECRETARY- The Secretary shall, as the Secretary deems necessary, provide notice to consumers to whom such article was, or may have been, distributed.

(c) HEARING ON ORDER- The Secretary shall provide any person subject to an order under subsection (b) with an opportunity for a hearing, to be held as soon as possible but not later than 2 days after the issuance of the order, on the actions required by the order and on why the article that is the subject of the order should not be recalled.

(d) POST-HEARING RECALL ORDER-

(1) AMENDMENT OF ORDER- If, after providing opportunity for a hearing under subsection (c), the Secretary determines that there is a reasonable probability that the article that is the subject of an order under subsection (b), if consumed, presents a threat to public health, the Secretary, as the Secretary deems necessary, may--

(A) amend the order to require recall of such article or other appropriate action,

(B) specify a timetable in which the recall shall occur,

(C) require periodic reports to the Secretary describing the progress of the recall, and

(D) provide notice to consumers to whom such article was, or may have been, distributed.

(2) VACATION OF ORDER- If, after such a hearing, the Secretary determines that adequate grounds do not exist to continue the actions required by the order, the Secretary shall vacate the order.

(e) REMEDIES NOT EXCLUSIVE- The remedies provided in this section shall be in addition to and not exclusive of other remedies that may be available.

SEC. 415. CIVIL PENALTIES.

(a) IN GENERAL-

(1) ACTS SUBJECT TO PENALTY; PENALTY AMOUNT- Any person that commits an act prohibited by section 301 with respect to food may be assessed a civil penalty by the Secretary of not more than $100,000 for each such act. Each such act and each day during which such act continues shall be a separate offense.

(2) NOTICE AND HEARING- No penalty shall be assessed by the Secretary under this section unless such person is given notice and opportunity for a hearing on the record before the Secretary in accordance with sections 554 and 556 of title 5, United States Code.

(3) OTHER REQUIREMENTS- The amount of such civil penalty shall be assessed by the Secretary by written order, taking into account the gravity of the violation, degree of culpability, size and type of business, and any history of prior offenses; and may be reviewed only as provided in subsection (b).

(b) JUDICIAL REVIEW- An order assessing a civil penalty under subsection (a) shall be final and conclusive unless the person files, within 30 days from the effective date of the order, an application for judicial review in the Court of Appeals of the United States for the circuit in which such person resides or has its principal place of business or in the United States Court of Appeals for the District of Columbia Circuit by filing a notice of appeal in such court and by simultaneously sending a copy of such notice by certified mail to the Secretary. The Secretary shall promptly file in such court a certified copy of the record upon which such penalty was assessed. The findings of the Secretary shall be set aside only if found to be unsupported by substantial evidence on the record as a whole.

(c) COLLECTION ACTIONS- If any person fails to pay an assessment of a civil penalty after it has become a final and unappealable order, or after the appropriate court of appeals has entered final judgment in favor of the Secretary, the Secretary shall refer the matter to the Attorney General, who shall institute a civil action to recover the amount assessed in an appropriate district court of the United States. In such collection action, the validity and appropriateness of the Secretary's order imposing the civil penalty shall not be subject to review.

(d) PENALTIES PAID INTO TREASURY- All penalties collected under authority of this section shall be paid into the Treasury of the United States.

(e) SECRETARY'S DISCRETION TO PROSECUTE- Nothing in this Act shall be construed as requiring the Secretary to report for prosecution, or for the institution of libel or injunction proceedings, violations of this Act whenever the Secretary believes that the public interest will be adequately served by assessment of civil penalties.

(f) REMEDIES NOT EXCLUSIVE- The remedies provided in this section shall be in addition to and not exclusive of other remedies that may be available.

SEC. 416. WHISTLEBLOWER PROTECTION.

(a) IN GENERAL- No employee or other person may be harassed, prosecuted, held liable, or discriminated against in any way because that person--

(1) has commenced, caused to be commenced, or is about to commence a proceeding, testified or is about to testify at a proceeding, or assisted or participated or is about to assist or participate in any manner in such a proceeding or in any other action to carry out the purposes, functions, or responsibilities of [the Consumer Food Safety Act of 1998, the Federal Food, Drug,

and Cosmetic Act, the Meat Inspection Act or the Poultry Products Inspection Act] (changed from original Pallone bill]; or

(2) is refusing to violate or assist in violation of law, rule, or regulation.

(b) PROCEDURES AND PENALTIES- The process and procedures with respect to prohibited discrimination under subsection (a) shall be governed by the applicable provisions of section 31105 of title 49, United States Code, unless the party bringing an action under this subsection chooses alternative dispute resolution procedures such as mediation or arbitration.

(c) BURDENS OF PROOF- The legal burdens of proof with respect to prohibited discrimination under subsection (a) shall be governed by the applicable provisions of sections 1214 and 1221 of title 5, United States Code.

[END HR 3070. BEGIN ADDITIONAL ENFORCEMENT SECTIONS]

SEC. 417. ADMINISTRATION AND ENFORCEMENT; APPLICABILITY OF PENALTY PROVISIONS; CONDUCT OF INQUIRIES; POWER AND JURISDICTION OF COURTS.

For the efficient administration and enforcement of this chapter, the provision (including penalties) of section 46, 48, 49, and 50 of Title 15 (except paragraphs (c) through (h) of section 46 and the last paragraph of section 49 of Title 15), are made applicable to the jurisdiction, powers, and duties of the Secretary in administrating and enforcing the provisions of this chapter and to any person with respect to whom such authority is exercised. The Secretary, in person or by such agents as he may designate, may prosecute any inquiry necessary to his duties under this chapter in any part of the United States, and the powers conferred by said sections 49 and 50 of Title 15 on the district

courts of the United States may be exercised for the purposes of this chapter by any appropriate court.

[SUBPOENA AUTHORITY AND OTHER AUTHORITIES TAKEN FROM MEAT INSPECTION ACT]

SEC. 418. TRACEBACK

The Secretary may impose on a food product requirements for the traceability of such type or class of food product whenever such requirements are necessary to assure the protection of the public health. Traceability requirements shall be established in accordance with regulations and guidelines issued by the Secretary.

[TRACEBACK PROVISION BASED ON THE MEDICAL DEVICE STATUTE]

SEC. 419. CITIZEN'S CIVIL ACTIONS

Any person may commence a civil action against (1) any person who violated any rule, tolerance, order or other action of the Secretary to ensure the safety of food products; or (2) against the Secretary where there is alleged a failure of the Secretary to perform any act or duty to ensure the safety of food products, which is not discretionary. The district courts shall have jurisdiction, without regard for the amount in controversy, or the citizenship of the parties, to enforce such rule, tolerance, order or other action of the Secretary, or to order the Secretary to perform such act or duty. The suit shall be commenced in the district in which the defendant resides or is found or has an agent. The court may award damages sustained and may, if the court determines it to be in the interest of justice, award the costs of suit, including reasonable attorney's fees and reasonable expert witnesses fees. The remedies provided for in this section shall be in addition to and not in lieu of any other remedies provided by common law or under Federal or state law.

[CIVIL ACTION LANGUAGE BASED ON PROVISIONS OF THE CONSUMER PRODUCT SAFETY ACT, THE CLEAN AIR ACT, AND OTHER ENVIRONMENTAL STATUTES]

[FINAL PROVISION WITH MODIFICATION IS IN THE ORIGINAL HR 3070]

(b) CONFORMING AMENDMENT; PROHIBITED ACT- Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following new subsection:

(x) The failure or refusal to comply with an order issued under section 414(b)(2) or 414(d).

(y) The failure to comply with the Consumer Food Safety Act of 1998.

CSPI Center for Science in the Public Interest
Publisher of *Nutrition Action Healthletter*

Date: Jan 16

Time: 5:15

FAX COVER SHEET

TO: Jerry Mand

COMPANY: Office of Domestic Policy

FAX NUMBER: 456-6027

PHONE NUMBER:

TOTAL NUMBER OF PAGES *INCLUDING* THIS COVER SHEET: 28

SENDER: Caroline Smith DeWaal

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The New York Times
Op-Ed

August 25, 1997

One Agency for Food Safety

By CAROLINE SMITH DEWAAL

WASHINGTON -- It seems that almost monthly, there is news of yet another outbreak of food poisoning. Last week, Hudson Foods recalled 25 million pounds of potentially contaminated ground beef after 17 people in Colorado contracted poisoning from E. coli O157:H7, a particularly dangerous strain of bacteria.

In March, strawberries contaminated by Hepatitis A were served in public school lunches, causing hundreds of illnesses. In May and June, imported raspberries containing the cyclospora parasite caused more than a thousand people to get sick.

While the Clinton Administration has been tough in addressing these individual emergencies, there is a fundamental flaw in its approach. It has dealt with each crisis as it has come up instead of creating a single process to prevent and deal with all future outbreaks. Now that food is increasingly mass produced and shipped all over the world, this piecemeal approach to addressing safety problems is a hazard to the public health.

Food poisoning is responsible for millions of illnesses and as many as 9,000 deaths every year in the United States. The economic cost of contaminated food is high -- it may be as much as $22 billion per year. This estimate fails to take into account the pain and suffering experienced not only by the victims, but also by their families and extended communities.

And these costs will only increase. According to the Department of Health and Human Services, the incidence of food-borne illnesses and deaths is likely to grow 10 percent to 15 percent over the next decade, as new, more dangerous contaminants are spreading. Also, familiar bacteria like E. coli are appearing in unexpected foods. For example, last year there were several E. coli outbreaks from contaminated lettuce and unpasteurized juice. Moreover, while imported foods have increased by nearly 50 percent since 1992, Government inspection of imports has declined.

That's why President Clinton's food safety initiative, which was recently passed in the balanced budged legislation, isn't comprehensive enough. The initiative proposes tinkering with the current system by establishing new systems of industry-designed hazard controls for processing plants.

But multiple agencies will still share responsibility for inspecting food. The Department of Agriculture oversees meat, poultry and egg products; the Food and Drug Administration inspects and oversees the safety of all other products, and the Environmental Protection Agency sets limits for certain chemicals in food.

The jurisdictions for these agencies sometimes overlap, so there is little accountability, and the agencies also have other duties, like promoting American agricultural products or approving drugs, that interfere with their safety responsibilities. Moreover, the current system is inefficient and focuses too much on recalling food after it has already been contaminated rather than on keeping food from becoming contaminated to begin with.

We need a new approach that combines all the Federal Government's food-related functions into a single agency. There are many benefits to consolidating these duties. For example, safety inspections could be done on a frequent and consistent basis. Currently, food plants regulated by the Department of Agriculture receive daily visits from Government inspectors, while those regulated by the F.D.A., including some that deal with high-risk products like seafood and eggs, are inspected an average of once every 10 years.

A single food safety agency would also have the power and the flexibility to enforce food-safety regulations from farm to table. That would increase the chance that contamination would be caught at an earlier stage, before dozens of people became sick. In addition, the agency would be most effective if it had tough enforcement tools like the authority to recall tainted food and to enforce penalties on companies that don't meet standards.

At a time of Government downsizing and reorganization, we cannot afford to continue to have multiple systems. The only way to achieve a successful system of safety regulation is to create a single agency with uniform standards.

Caroline Smith DeWaal is the director of food safety at the Center for Science in the Public Interest.

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CRS Report for Congress

Food Safety: Recommendations for Changes in the Organization of Federal Food Safety Responsibilities, 1949-1997

April 21, 1998

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Congressional Research Service • The Library of Congress

ABSTRACT

This report describes recommendations to change the structure of federal food safety responsibilities and gives the reader background information on the debate over the last five decades over which structure would best improve the system for ensuring "safe" food for U.S. consumers. The report lists all the major efforts that were made from 1949 through 1997 by groups inside and outside the federal government. The sets of recommendations are placed chronologically under one of four categories, depending on which organizational structure the group thought would improve food safety. The categories of organization are as follows: an independent single food safety agency, the U.S. Department of Agriculture, or the Food and Drug Administration, or with the Consumer Product Safety Commission. This product will be updated periodically. See also CRS Issue Brief 98009, Food Safety Issues in the 105th Congress.

Food Safety: Recommendations for Changes in the Organization of Federal Food Safety Responsibilities, 1949-1997

Summary

This report summarizes twenty-one sets of recommendations, made in the last five decades, for changing the organization of federal food safety responsibilities. Since 1906, food safety responsibilities and inspections have been split by product under different laws. Congress passed the Pure Food Act and the Meat Inspection Act on June 30, 1906. Both Acts placed the responsibility for food safety in the U.S. Department of Agriculture (USDA), Division of Chemistry (later Bureau). That Bureau later became the Food and Drug Administration. Over time, USDA kept responsibility for meat safety, while most other foods came to be regulated by the Food and Drug Administration (FDA) of the Public Health Service in the Department of Health and Human Services (DHHS).

Recommendations for changing the federal food safety system can be fit into one of four categories. The recommendations proposed that 1) a single, independent institution be given responsibility for all food safety; 2) responsibility for all food products should be returned to USDA; 3) responsibility for all food products should be given to FDA; or 4) responsibility for all food products should be given to the Consumer Product Safety Commission (CPSC).

Most of the recommendations had both supporters and critics. Supporters of the first recommendation claim that the agency could promulgate consistent risk-based regulations and inspections for all types of foods, whether meats or canned foods, and increase the confidence of consumers in the U.S. food supply. Critics claim that a single, independent food safety agency would have large start-up costs in an era of tight budgets and would not be able to take advantage of the long-term experience and regulatory organization developed for different foods by USDA and FDA.

Supporters of the second recommendation claim that USDA could utilize its nationwide network for new research and enforcement. Critics claim that USDA has little institutional culture to support legal regulatory work. They are also concerned that USDA's mission of supporting and promoting agriculture would interfere with its ability to take regulatory action when needed.

Supporters of the third recommendation feel that FDA could use its long-term expertise in combining law and science to regulate consumer products. Critics argue that FDA is not organized to regulate all foods, would have to completely change its orientation, and could be overwhelmed by the process.

Supporters of the fourth recommendation claim that under the CPSC, the fragmented federal authority for food safety could be modernized and focused on protecting U.S. consumers by strengthening the links to federal and state public health departments. Critics are concerned that food is unlike other products that the CPSC has regulated and may not receive the attention it deserves.

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Food Safety: Recommendations for Changes in the Organization of Federal Food Safety Responsibilities, 1949-1997[1]

Introduction

At times, consumers have questioned whether the organization of federal food safety efforts works well enough or whether a different system may better serve consumer needs. Questions often revolve around which standards are used when judging whether food is considered safe, and how the federal government should be organized to respond appropriately to food safety concerns. During the past five decades, those concerns have led the executive branch and Congress to consider recommendations for changes in the organization of federal food safety efforts.

This report summarizes twenty-one sets of recommendations, presented to the President or to Congress between 1949 and 1997 to change the structure of food safety responsibilities. These recommendations were developed by entities inside and outside the federal government. They have included Presidential and other official commissions, Members and committees of Congress, the U.S. General Accounting Office (GAO), and prominent food policy representatives. All recommendations have influenced the debate on restructuring the federal organization of food safety.

Background[2]

The federal government's role in food safety began when safety questions about food were referred to the Division (later Bureau) of Chemistry within a newly created Department of Agriculture (USDA) in the latter half of the nineteenth century. USDA's role began to increase when, at the turn of the century, developments in transportation systems increasingly brought processed food into growing cities. The residents of those cities lost the ability that villagers had possessed of being first-hand judges of the food they ate. U.S. consumers began questioning the safety of what they were buying in stores and expressed concern about the safety of chemical preservatives being used by commercial food processors to extend the life of meats, dairy products, and vegetables, and sometimes to mask their decomposition.

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[1] CRS Report 93-955, which this report supersedes, was coauthored by Karen L. Alderson, Library Services Division, Congressional Research Service.

[2] Most of the historical material used to prepare this section was provided by Suzanne White Junod, Ph.D. History Office, Food and Drug Administration.

The conditions of some foods led the Bureau of Chemistry to conduct studies of the extent to which adulterated foods had begun to permeate the nation's food supply. While the chief chemist of USDA at that time, Dr. Harvey W. Wiley, estimated that less than 5% of the nation's food was adulterated, he surmised that the overuse of chemical preservatives such as borax, formaldehyde, benzoate of soda, salicylic acid, and copper salts, commonly used as additives in food, could be harmful to health. Those studies convinced Congress to appropriate funds for Dr. Wiley's famous "poison squad." The squad consisted of a group of young men who were given increasing doses of the chemicals to discover their effects on the human metabolism. Many of the young men became ill when they consumed foods containing preservatives in amounts commonly used at that time. The scientific value of the studies remained questionable, but the effect on the public was dramatic when the results were reported. The "poison squad" stories provoked interest in food safety throughout the country. The time was ripe for federal action.

Under pressure from consumer groups and from President Theodore Roosevelt, Congress passed the 1906 Food and Drugs Act on June 30, 1906.[3] That Act set up the regulatory role of the federal government for foods other than meat and poultry by prohibiting from interstate commerce the sale of food and drugs that were adulterated and/or misbranded. Adulteration in the act was defined as

> ...the intermixture or substitution of substances reducing quality, the abstraction of valuable constituents, the concealment of damage or inferiority, the addition of deleterious ingredients, and the use of spoiled animal or vegetable products.[4]

Misbranding meant placing false or misleading statements on the label. Yet, food safety involved more than adulteration and misbranding. The 1906 Food and Drugs Act also had a provision for enforcement. It required that adulterated foods not only be seized but also destroyed.

In 1905, Upton Sinclair published *The Jungle*, a book about the way meat was mishandled in Chicago's slaughterhouses. It had a major impact on consumers with meat sales falling around the country by nearly a third almost overnight. Congress appointed a commission to examine the charges made in the book. The commission found that while some of the allegations might have been slightly exaggerated, other evidence showed situations actually worse than portrayed by Sinclair. That evidence was used to convince lawmakers to pass the Meat Inspection Act of 1906[5], which set sanitary standards for slaughter of animals and for meat sold in interstate commerce.[6]

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[3]P.L. 59-384, 34 Stat. 768 (1906).

[4]Lauffer Hayes and Frank Ruff, "The Administration of the Federal Food and Drugs Act," in *Food and Drug Law: Cases and Materials*, ed. Peter Barton Hutt and Richard A. Merrill. 2nd ed. (Westbury, New York: The Foundation Press, Inc., 1991), 9.

[5] P.L. 59-242, 21 U.S.C. §601 et seq.

[6]Meat had been separated from other food for special legislative treatment in 1890 and 1891. Federal inspection began as a means of reassuring European nations that U.S. meats were safe. Europe had banned imports of U.S. pork on the charge that it had caused

(continued...)

With the passage of the 1906 Act, USDA began a system of continuous daily inspection in slaughterhouses using organoleptic (sight, smell, touch) means to detect problems. If problems were found, inspectors could instantly condemn carcasses.

With the signing of the 1906 Food and Drugs Act, USDA officials in the Bureau of Chemistry emphasized the development of detection methods to find chemical problems in foods. During the 1920's, conflicts sometimes occurred within the department between officials who were charged with promoting the use of chemicals to produce food and regulators who were concerned about food being adulterated by those chemicals. For example, California apple growers at the time used large quantities of arsenic on apples to fight pests. USDA chemists had set a limit for the maximum amount of arsenic residue that could be left on the fruit. Some of the apples had residues that exceeded that limit. The regulators wanted to declare the apples adulterated; other officials did not.

The conflict in mission began early in the century. The following statement characterizes it:

> The Bureau of Chemistry had originated as a research bureau and law enforcement was a superimposed responsibility. The task of undertaking research designated to improve the methods of utilizing agricultural products was frequently in striking conflict with enforcement of the Pure Food and Drugs law. These conflicts arose, first, because there was a constant tendency to stop a research project so as to permit the scientist to assist in acquiring evidence immediately needed in a lawsuit and second, because the objectives of law enforcement frequently did not coincide with increasing the utilization of a particular agricultural product, but instead might retard its utilization.[7]

In 1927, Dr. Walter Campbell of the Bureau of Chemistry recommended that the Secretary of Agriculture separate the functions of agricultural research and enforcement. At the time, USDA was enforcing several other laws.[8] Campbell suggested that the Secretary of Agriculture create a Food, Drug, and Insecticide Administration (FDIA) within the Department. Congress supported this suggestion and the 1927 appropriations bill created the FDIA and gave it the responsibility to

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[6](...continued)
epidemics of trichinosis. A newspaper scare arose during the Spanish-American War when U.S. packers were blamed for shipping "embalmed beef" that sickened the troops. Investigation attributed some of the trouble to the rapid growth of bacteria in meat exposed to the hot Cuban sun. James Harvey Young, "The Long Struggle for the 1906 Law," *FDA Consumer*, v. 15, no. 5, June 1981, 16.

[7]Michael Brannon,"Organizing and Reorganizing FDA," in *Seventy-Fifth Anniversary Commemorative Volume of Food and Drug Law*. Food and Drug Law Institute Series, (Washington, D.C., Food Drug Law Institute, 1984), 142.

[8]Laws included the Food and Drugs Act (34 Stat. 768 (1906)), the Insecticide Act (7 U.S.C. §121-134), the Caustic Poison Act (15 U.S.C. §410-411), Naval Stores Act (7 U.S.C. §91 et seq.), Federal Import Milk Act (21 U.S.C. §141 et seq.), Filled Milk Act(21 U.S.C. §61 et seq.), and Tea Importation Act(21 U.S.C. §41 et seq.).

enforce the 1906 Pure Foods Act.[9] Simultaneously, the Secretary created a soil and chemistry bureau to handle research functions. In 1930, USDA dropped "insecticide" from the agency's title, and its name became the Food and Drug Administration (FDA).

FDA's new enforcement responsibilities continued to grow as did the agency's commitment to consumer protection. In 1930, Congress passed an act setting standards for canned foods, but excluding canned meat and milk products from those standards. As the New Deal began in 1933, pressures mounted to pass a new law that would fill the gaps in the 1906 Pure Food and Drugs Act. A tragedy occurred in 1937 that resulted in strengthening the federal role of premarket review of drugs. At least 73, and perhaps over 90, persons died as a result of taking "Elixir Sulfanilamide." Franklin Roosevelt's son had recovered from a near fatal infection using sulfanilamide, a European wonder drug. Problems developed when the producer began using diethylene glycol as a solvent for sulfanilamide without first determining that the solvent was safe. The disaster prompted passage of the 1938 amendments to the law, requiring manufacturers to prove a drug's safety to FDA before marketing the drug. Consumers began to support the idea that there should be federal premarket approval for both drugs and substances added to foods.

On June 25, 1938, President Roosevelt signed into law the Federal Food, Drug, and Cosmetic Act of 1938[10] (FFDCA) that today remains the basic authorizing legislation for food safety. Even though USDA had primary responsibility for food safety for almost 80 years, the new law defined more clearly USDA's authority to regulate livestock and poultry feeds and drugs used in animal disease control. After the 1938 law was passed, President Roosevelt said,

> "The work of the Food and Drug Administration is unrelated to the basic function of the Department of Agriculture," and he expressed his belief that "the opportunity for the Food and Drug Administration to develop along increasingly constructive lines" lay in the Federal Security Administration.[11]

In 1940, the President moved FDA out of USDA and into the Federal Security Agency (FSA), a separate part of the executive branch. FSA was a new agency; it had been in existence for only one year. At the time, the FSA mission was to protect the public health, and it had under its jurisdiction the Public Health Service, the Office of Education, the Civilian Conservation Corps, and the Social Security Administration, among other agencies. FDA's responsibilities within the FSA included regulating food quality, sanitation, and consumer protection. Under the new FFDCA, FDA was also given the authority to test the safety of new products and was given research responsibilities. The agency focused on whether a given substance in foods was "poisonous or deleterious" within the meaning of section 406 of the statute. As an operational rule, FDA sought to ban in the diet any substance that proved toxic to laboratory animals at 1% of their diet.

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[9]Donald R. Whitnah, ed., *Government Agencies*, (Westport, CT: Greenwood Press, 1983), 251.

[10]21 U.S.C. §301-392

[11]Brannon, *Organizing and Reorganizing FDA*, 158.

Not everyone agreed with the President's decision about reorganizing FDA. Secretary of Agriculture Henry A. Wallace argued that the meat inspection work of USDA's Bureau of Animal Industry also should be transferred. He claimed,

> This activity might be associated with other health or public welfare work. Meat inspection is of course a technical job and it seems logical to have the technical inspectors attached to the bureau most competent in this field.[12]

However, President Roosevelt was not persuaded; meat and poultry inspection remained within USDA. The USDA meat inspection system had developed on a parallel track within USDA's Bureau of Chemistry for over 50 years. Veterinarians within the Bureau trained inspectors to spot animal diseases. Those inspectors performed continuous inspections of animals before slaughter and examined every carcass for disease and contamination after slaughter. The system positioned the United States to supply meat to the world during World War II.

The war effort was not confined to USDA. Even after FDA was transferred out of USDA, FDA was charged with ensuring the enrichment of breads in 1942 for the soldiers serving in World War II. Several years later (1953), the FSA became the Department of Health, Education, and Welfare (HEW). In 1968, FDA became part of the Public Health Service (PHS) where it added a focus on health and nutrition to its food safety responsibilities.

Since the start of federal regulation, food safety has been the primary responsibility of either of two different cabinet agencies, USDA and Department of Health and Human Services (DHHS). **Table 1** shows which statute and consequently which organization and department has been responsible for carrying out the statutes' mandates for food safety since the federal government became involved.

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[12]Memo to President Franklin D. Roosevelt from Henry Wallace, 20 April 1939. Found in Senate Committee on Governmental Affairs, "Food Regulation: A Case Study of USDA and FDA," Chapter 4, *Study on Federal Regulation*, 95th Cong., 2nd sess., December 1977, S. Rept. 95-91,140.

Table 1. Institutional Chronology of Food Safety Responsibilities, 1862-1998

Years	Statute/plan	Name of Organization	Department
1890-1901	Act of March 3, 1891 and Act of March 2, 1895 on exported meats	Division of Chemistry	USDA
1901-1927	1906 Pure Food Act 1906 Appropriations Act	Bureau of Chemistry and Bureau of Animal Industry	USDA
1927-1930	1906 Pure Food Act 1906 Appropriations Act	Food, Drug, and Insecticide Administration	USDA
1930-1940[13]	1938 Federal Food, Drug, and Cosmetic Act (FFDCA)	Food and Drug Administration	USDA
1940-1953	Reorganization Plan No. 4, effective June 3, 1940.	Food and Drug Administration	Federal Security Agency
1953-1970	1954 Miller Pesticide Act and 1958 Food Additives Amendment (Delaney Clause) 1960 Color Additives Amendment (Delaney Clause)	Food and Drug Administration	Department of Health, Education, and Welfare
(1958-1968)	1958 Humane Slaughter Act; 1967 Wholesome Meat Act; 1968 Poultry Products Act	Meat Inspection Branch of Agricultural Research Service	USDA
1970-1979	Reorganization Plan No. 3 of 1970; sect. 346, 346a, 348, and 408 of FFDCA and 135-135k of FIFRA	All pesticide regulation responsibilities were transferred to EPA as were all functions of Environmental Quality Branch, Plant Protection Division of Agricultural Research Service	Environ-mental Protection Agency (EPA)
(1972)	1972 Meat and Poultry Inspection	Food Safety and Inspection Service	USDA
(1968-1979)	Reorganization Plan of March 1968. Public Health Service Act	Food and Drug Administration Public Health Service	Department of Health, Education, and Welfare
1980-		Food and Drug Administration Public Health Service	Department of Health and Human Services

Source: Peter Barton Hutt and Richard A. Merrill, eds. *Food and Drug Law: Cases and Materials*, 2nd ed., (Westbury, New York: The Foundation Press, Inc., 1991), 4-5.

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[13]The name "Food and Drug Administration" was first used in the Agriculture Appropriation Act of 1931 (46 Stat. 32).

Current Federal Food Safety Responsibilities

Historically, Congress passed laws in reaction to immediate food safety problems. Those laws assigned food safety responsibilities to several executive departments. Today, the primary federal agencies responsible for regulating the safety of the U.S. food supply are the Food and Drug Administration (FDA) under the Public Health Service of the Department of Health and Human Services (DHHS), and the Food Safety and Inspection Service (FSIS) under the U.S. Department of Agriculture (USDA). FDA and USDA together try to ensure that food products, as sold in the United States, will not adversely affect human health.

FDA is charged with ensuring that foods (except meat, poultry, and certain egg products) are safe, nutritious, sanitary, wholesome, and honestly labeled. The primary statute governing FDA's food safety activities is the Federal Food, Drug, and Cosmetic Act (FFDCA).[14] FDA monitors whether food manufacturers are adhering to their legal responsibility of ensuring that foods are not defective, unsafe, filthy, or produced under unsanitary conditions. USDA is responsible for monitoring meat, poultry, and commercially processed egg products under the Federal Meat Inspection Act, as amended, the Poultry Products Inspection Act, as amended, and the Egg Products Inspection Act, as amended. FSIS is directly responsible for the daily inspection of all meat and poultry entering U.S. commerce. FSIS also shares responsibility with FDA on combination products such as stews and pizzas. For example, FSIS regulates all products that contain 2% or more of poultry and poultry products and 3% or more of red meat or red meat products. FDA regulates all other foods.

In total, thirteen agencies in the federal government have food safety responsibilities.[15] FDA has three centers conducting and supporting food safety activities: Center for Food Safety and Applied Nutrition (CFSAN), Center for Veterinary Medicine (CVM), and the National Center for Toxicological Research (NCTR). Besides FSIS, the USDA agencies with food safety responsibilities are the Animal and Plant Health Inspection Service (APHIS),which has regulatory programs to protect animals and plants from pests and disease; the Agricultural Research Service (ARS), which conducts a wide range of food safety related research; the Cooperative State Research, Education, and Extension Service (CSREES), which carries out a program of fundamental and applied research in several areas, including

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[14]Other relevant statutes are the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (P.L. 104-61,Stat.163-172,1947, 7 U.S.C. §136 et seq.); the Public Health Service Act (Chapter 288, 37 Stat. 309 (1912), 7 U.S.C. §201 et seq.); the Fair Packaging and Labeling Act, as amended (P.L. 89-755, 15 U.S.C. §1451 et seq.); the Federal Meat Inspection Act, as amended (P.L. 90-201, 21 U.S.C. §601 et seq.); the Poultry Products Inspection Act (P.L.85-172, 21 U.S.C. §451 et seq.); Federal Import Milk Act (P.L. 69-625, 21 U.S.C. §141 et seq.); Plant Quarantine Act , as amended (P.L 85-36, 7 U.S.C. §150 et seq.) and the Pesticide Monitoring Improvements Act (P.L.100-418, 21 U.S.C. §1401, et seq.).

[15]Detailed information on those responsibilities can be found in Congressional Research Service, *Food Safety Agencies and Authorities: A Primer*, by Jean Rawson and Donna U. Vogt, Report No. 98-91 ENR, 5 February 1998, 6.

food safety and health; and the Economic Research Service (ERS), which provides cost and benefit information on food-borne illnesses. The National Center for Infectious Diseases of the Centers for Disease Control and Prevention (CDC), under DHHS, monitors and investigates food-borne illnesses and diseases and shares that information with the other agencies.

The Environmental Protection Agency (EPA) regulates pesticides and is charged with setting pesticide-residue tolerances for each pesticide-food combination. The Bureau of Alcohol, Tobacco, and Firearms (BATF), of the U.S. Treasury Department, regulates production, distribution, and labeling of alcoholic beverages.[16] The National Marine Fisheries Service (NMFS) of the U.S. Department of Commerce conducts a voluntary fee-for-service seafood inspection program. The Federal Trade Commission (FTC) regulates advertising of food products. The U.S. Customs Service of the Department of the Treasury assists FDA by notifying FDA of incoming shipments of products under FDA jurisdiction. FDA officials examine all paperwork and electronic submissions related to these imports and at times collect samples.

In addition, federal agencies work in close collaboration with state officials. Often, federal agencies such as FDA will train and contract with state enforcement officials to conduct food plant inspections. FDA also developed a model ordinance for milk sanitation and a "Food Code" for retail food store and restaurant sanitation to be adopted by state legislatures. FDA also works with groups such as the Association of Food and Drug Officials of the United States and the Association of Official Analytical Chemists.[17] FDA, in conjunction with the states, regulates animal feed ingredients and feeds as part of the American Association of Feed Control Officials.[18]

Overlapping Responsibilities

Critics charge that part of the "food safety problem" is that U.S. food safety laws and regulations are fragmentary and inconsistent and are not comprehensive. Critics also claim that too many agencies are responsible for food safety activities. Foods posing similar health risks may be inspected by different agencies at different frequencies. The roles that these agencies play depend for the most part on their statutory authority and their resources. One former official who served in both USDA and FDA said that the fragmentation and diversity of the agencies' authority undercuts the government's accountability for food safety, and he added:

> FDA has jurisdiction over plants producing cheese pizza, but rarely inspects such plants. USDA has jurisdiction over plants producing pepperoni pizza, and inspects such plants on a daily basis, after having already inspected both the

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[16]FDA is responsible for all nonalcoholic beverages, and wine beverages (i.e. fermented fruit juices) containing less than 7% alcohol.

[17]James T. O'Reilly, *Food and Drug Administration* (Colorado Springs, Colorado: Shepard's/McGraw-Hill, Inc., Oct. 1993).

[18]Edward L. Korwek, *1997 United States Biotechnology Regulations Handbook*, vol. 1, (Washington, D.C.:Food and Drug Law Institute, 1997), 112.

> animal from which the pepperoni was made and the processing of the meat into pepperoni.[19]

Other examples abound. USDA daily inspects meat and poultry for contamination of various pathogens, including *Listeria monocytogenes* and *E. coli* O157:H7. At the same time, FDA may inspect once every ten years soft cheeses or apple juice in which those same pathogens have been found. Some believe that it is inappropriate for separate agencies using different risk and inspection criteria to regulate the nation's food supply. These critics also think that the same or similar risk criteria should be used by all federal agencies to prevent microbial contamination on all foods.[20]

Others charge that safety cannot be properly regulated when food safety responsibility is placed in the hands of the same agency in charge also of promoting regulated products. Many think that an organization that promotes and subsidizes production agriculture and other consumer products should be separate from one that watches over food safety.

The meaning of "food safety" responsibilities continues to expand. Food safety functions of federal agencies have come to signify certain responsibilities regarding foods. The responsibilities were aptly defined in an FDA report to Congress:

> Under the foods program, FDA sets food standards; evaluates food additives and packaging for potential health hazards; conducts research to reduce food-borne disease to determine specific health impacts of hazardous substances in food and to develop methods for detecting them in foods; and maintains surveillance over foods through plant inspections, laboratory analyses, and legal action where necessary.[21]

USDA carries out similar functions for meats, poultry, and certain egg products.

Whether all food should be regulated by the same or different agencies is currently under debate. Some argue that a clearer direction to food safety policy could emerge if a single, independent agency were charged with administering all food safety programs. Others oppose forming a single agency, asserting that the various agencies with differing expertise strike a balance among divergent interests.

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[19]Michael R. Taylor, "Preparing America's Food Safety System for the Twenty-First Century — Who is Responsible for What When it Comes to Meeting the Food Safety Challenges of the Consumer-Driven Global Economy?" in *Food and Drug Law Journal*, vol. 52, n.1, (Washington, D.C.:Food and Drug Law Institute, 1997) 13.

[20]Dr. Sanford Miller, Professor and Dean, Graduate School of Biomedical Sciences, The University of Texas Health Science Center at San Antonio, telephone conversation with the author, 17 September 1993, (210) 567-3709.

[21]Senate Committee on Agriculture, Rural Development, and Related Agencies, *Appropriation Bill, 1990*, 101st Cong., 2nd sess., 1989, S.Rept. 101-84, as found in Peter Barton Hutt and Richard A. Merrill, *Food and Drug Law: Cases and Materials*, 2nd ed. (Westbury, New York: The Foundation Press, Inc., 1991) 21.

Recommendations for Changes in the Federal Organization of Food Safety Responsibilities

This report contains 21 separate sets of recommendations that have had a significant impact on the debate over whether the federal organization that ensures safe food needs to be changed. This debate has recurred over 48 years with long periods when little interest was expressed in changing the organization for federal food safety. The debate has been carried on by a range of different entities from major government bodies such as presidential commissions, agency commissions, congressional Members, the General Accounting Office (GAO), to interested parties or influential food policy experts.

The recommendations are grouped chronologically into four categories:

- a separate, independent food safety agency or some modification of that idea;
- all food safety functions given to USDA;
- all food safety functions given to FDA;
- all food safety functions be given to the Consumer Product Safety Commission.

The recommendations described in this report were selected because each expresses a position on how the federal organization of food safety could be improved or changed. Each recommendation was acknowledged as contributing to the debate in later documents discussing changes in the organization for federal food safety. The gaps in the chronology represent the fluctuating nature of the debate. The recommendations listed also represent all the major official bodies that debated this issue in the last five decades.

No President or Congress has adopted these recommendations. However, the reports and publicity surrounding each set has added to the debate and helped define current food safety responsibilities. Eight sets of the recommendations would have created some type of independent federal entity for the regulation of food safety, with responsibility for all foods. Two would have given all responsibility to USDA, and 10 would have FDA reorganize and regulate the safety of all foods including meat and poultry. One would have the Consumer Product Safety Commission carry out all food safety functions. The most recent proposals appear to be evenly divided between giving food safety responsibility to a single, independent agency or to a reorganized FDA that links food safety explicitly to public health. Table 2, at the end of the report, summarizes in chronological order the selected sets of recommendations presented to Presidents and Congresses from 1949 to 1997 period.

Most of the reports or recommendations examine what are perceived to be five separate issues in food safety:

- Should food safety be considered to be a public health responsibility only or should it also be linked with research and development of new standards that not only protect consumers but also lead to the development and marketing of new products?

- Will the cost to the federal government increase or decrease if all activities related to regulating food are combined into a single food safety agency?

- By competing among each other for food safety resources, have agencies become more or less efficient in carrying out their food safety functions?

- If Congress and the Administration chose to create an independent food safety agency, should such an agency be independent of or located within the Public Health Service?

- Would U.S. consumers be better protected by having a uniform set of regulations and laws that covered all foods and were enforced by a single agency?

Some believe that one food safety agency could apply consistent and strong food standards that would assist in building public confidence in the federal system of food safety. Others argue that, although some consumers are very vocal in their distress with the current regulatory framework, it does provide some of the safest, most abundant, and least expensive food in the world.

Most believe that pressures for change will continue focusing mainly on streamlining policies for food, nutrition, and veterinary drug activities. There have always been threads that link the different food safety programs with those of production agriculture and nutrition research.

Food Safety Under a Single, Independent Agency

Popular Name and Date

White House Conference on Food, 1969.[22]

Description and Mission of Group Making Recommendations

President Nixon asked a large group of experts to meet and make recommendations on revising the federal regulatory policy for food and on certain aspects of food, nutrition, and health policy. He requested recommendations regarding administration and operations, community affairs, information, and education. The Conference was chaired by Dr. Jean Mayer, and the deputy chairman was James D. Grant.

Summary of Recommendations

The Conference recommended that there should be one federal regulatory policy with respect to safety, sanitation, identity, and labeling of foods. The Conference also recommended that the Secretary of Health, Education, and Welfare (HEW) issue an order establishing a separate interdepartmental coordinating committee on federal food regulatory policy with the aim of implementing national nutritional and health goals. The committee would be comprised of representatives of all federal departments and agencies having jurisdiction over safety, sanitation, identity, and labeling of any food. Within certain schedules, the committee should issue reports on the progress of reconciling all pertinent federal food policies and practices. The committee should initially consider the question of whether a single federal regulatory agency for foods should be established, and particularly whether the jurisdiction of USDA over food products derived from or utilizing inspected meat and poultry should be transferred to HEW.

Dissenting views

Not Available

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[22] *White House Conference on Food, Nutrition, and Health, Final Report*, (Washington, D.C.: White House, 1969), 118-119.

Popular Name and Date

GAO Food Inspection Report, 1970.[23]

Description and Mission of Group Making Recommendations

In a letter to the President of the Senate and the Speaker of the House of Representatives, the Comptroller General of the United States presented the results of a review of the roles of federal organizations involved in inspecting food. GAO's authority to conduct the review was contained in the Budget and Accounting Act of 1921 (31 U.S.C. 53); the Accounting and Auditing Act of 1950 (31 U.S.C. 67); and the authority of the Comptroller General to examine contractor's records as set forth in 10 U.S.C. 231(b).

Summary of Recommendations

Federal food inspection evolved from piecemeal legislation and regulations, designed to solve specific problems when they arose. The report claimed that current practice at the time did not clearly express an overall federal policy on food inspection. Many federal, state, and local organizations performed different parts of the food inspection process. Such a process led to some overlap in responsibility and caused dissatisfaction among members of the food industry. Some of the dissatisfaction related to inspections being made for different purposes and with varying intensity. The GAO recommended that the different agencies arrange agreements among themselves to use the skills and experience of each to establish clearer lines of responsibility, and to reduce overlap. The report did concede that those agreements would be time-consuming to arrange and difficult to administer.

Although the report did not specifically recommend consolidation, it criticized the overlapping inspection activities of USDA, FDA, and other federal agencies and the lack of consistency in their requirements, procedures, and concepts. GAO recommended that the Director, Bureau of the Budget, make a detailed evaluation of the federal food inspection system to see how to improve its administration and determine if it was feasible to consolidate some of the inspection efforts.

Dissenting views

Most of the federal agencies responsible for food inspections agreed to evaluate their separate functions. However, USDA's comments indicated that agency officials believed that GAO had not properly characterized certain USDA inspection functions. In its response letter, as published in the GAO report, it stated,

> Meat inspection, for example, is looked upon primarily as a program for consumer protection or benefit. This it is, but we believe it also facilitates interstate commerce in meats and enhances the market for farm animals sold for meat.

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[23]General Accounting Office, *Need to Reassess Food Inspection Roles of Federal Organizations. Department of Agriculture, Department of Defense, Department of Health Education, and Welfare, Department of the Interior*, Rept. No. B-168966, 30 June 1970.

Similarly meat grading, while it may be primarily looked upon as a program for facilitating marketing or dealing in meat, is recognized by consumers as a purchasing tool and, we believe as well, benefits the farmer by giving him added assurance of a return related to the quality of the animals sold. On the other hand, the consumer benefits from grading of grain are quite indirect. Performance standards are designed to be uniform whether the service is mandatory or voluntary. Thus procedures and regulations are geared to the particular need. The consumer's interests are expected to be recognized and protected in each case. It is the needs, and not whether the primary beneficiary is the producer, consumer, or industry that determines requirements and methods.

Popular Name and Date

Hearings on S. 3419, Consumer Safety Act of 1972.[24]

Description and Mission of Group Making Recommendations

Three committees of the Senate held hearings to discuss S. 3419, the Consumer Safety Act of 1972 and its proposal to restructure food safety responsibilities in the federal government. The Commerce Committee held a hearing on April 13, 1972. The Committee on Government Operations, Subcommittee on Executive Reorganization and Government Research held hearings on April 20, 21, May 2, 3, 1972. The Senate Labor and Public Welfare Committee, Subcommittee of Health held hearings on May 2, 3, 1972.

Summary of Recommendations

The report of the Senate Committee on Labor and Public Welfare stated that the purpose of S. 3419, the Consumer Safety Act of 1972, was to establish an independent agency to regulate foods, drugs, and consumer products. The bill would have combined several different responsibilities under a single agency. For example, all FDA's authority to regulate foods and drugs would be transferred, as would the authority, at that time, of the Center for Disease Control over the licensing of certain clinical laboratories. The Department of Commerce and the Federal Trade Commission authority over flammable fabrics and refrigerator doors would be transferred as would USDA's authority over meat and poultry inspection and animal biological drugs. The purpose of this independent Consumer Safety Agency was to have been to protect consumers against unreasonable risk of injury from hazardous products. The independent agency would have had responsibility to set product safety standards for all consumer products representing unreasonable risk of injury or death.

S. 3419 became the Food, Drug, and Consumer Product Safety Act of 1972.[25] It passed the Senate on June 21. 1972. However, the House did not agree with the transfer of functions administered by FDA. In conference, legislators exempted all food, drugs, devices, and cosmetics as defined in the FFDCA from the jurisdiction of the new Consumer Product Safety Commission.

Dissenting Views

The Nixon Administration thought that the establishment of an independent consumer safety agency would prove to be regressive rather than progressive and

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[24]Senate Committee on Commerce, *Consumer Safety Act of 1972*, 92nd Cong., 2nd sess., 1972, S.Rept. 92-749. Senate Committee on Government Operations, Subcommittee on Executive Reorganization and Government Research, *S.3419, The Consumer Safety Act of 1972*, 92nd Cong., 2nd sess., S.Rept. 92-2. Senate Committee on Labor and Public Welfare, *Food, Drug, and Consumer Product Safety Act of 1972*, 92nd Cong., 2nd sess., S.Rept. 92-835.

[25]P.L. 92-573.

opposed establishment of an independent "Consumer Safety Agency." On March 16, 1972, in a press release on S. 3419, Secretary of Health, Education, and Welfare Richardson stated,

> I think...that if the Food and Drug Administration is going to have any problems of digestion of new responsibilities, the problems would be multiplied several fold by the effort to create a new agency duplicating administrative authorities and having to seek scientific capabilities and resources that are already within the Food and Drug Administration. ... It is ... much greater if we build upon the experience and capabilities of the Food and Drug Administration, than if we start all over again through the creation of comparatively small, isolated outside body. [26]

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[26]Senate Committee on Commerce, *Consumer Safety Act of 1972*, 92nd Cong., 2nd sess., 1972, S.Rept. 92-749; Senate Committee on Government Operations, Subcommittee on Executive Reorganization and Government Research, *S.3419, The Consumer Safety Act of 1972*, 92nd Cong., 2nd sess., S.Rept. 92-2; Senate Committee on Labor and Public Welfare, *Food, Drug, and Consumer Product Safety Act of 1972*, 92nd Cong., 2nd sess., S.Rept. 92-835.

Popular Name and Year of Document

Ralph Nader Report, Sowing the Wind, 1972.[27]

Description and Mission of Group Making Recommendations

This report, sponsored by the Center for Study of Responsive Law, was conducted by an interdisciplinary task force of young professionals trained in law and science. Its members conducted research on a wide range of issues, from the fat and chemical content of hot dogs to the potential birth-defect hazards of pesticides. Ralph Nader wrote the introduction to the report. It had some influence on consumer opinion about certain food hazards.

Summary of Recommendations

The report found that food inspection "remains embarrassed by departmental conflicts of interest and overlapping jurisdictions in USDA and FDA." In its conclusions, the report recommended that meat inspection and chemical monitoring by USDA and FDA should be transferred to a new food safety agency where the goal of protecting public health would be consolidated. It also suggested that food inspection be included in the responsibilities of the independent "consumer safety agency" under consideration at the time in Congress.

Dissenting Views

Not Available

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[27]Harrison Wellford, *Sowing the Wind: A Report from Ralph Nader's Center for Study of Responsive Law on Food Safety and the Chemical Harvest*, (New York: Grossman Publishers, 1972) 354.

Popular Name and Date

GAO's Risk-Based Inspection Report, 1992.[28]

Description and Mission of Group Making Recommendations

GAO published this report in response to a request from the Honorable John D. Dingell, Chairman Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce. GAO's mandate was to examine the consistency, efficiency, and effectiveness of the federal food safety inspection system.

Summary of Recommendations

GAO found that 12 agencies that were involved in food safety inspect similar foods posing similar risks at inconsistent frequencies and under different enforcement authorities. It also found long-standing problems whereby those agencies use their inspection resources inefficiently and do not effectively coordinate with each other. GAO recommended that "Congress hold oversight hearings to evaluate options for revamping the federal food safety and quality system, including creating a single food safety agency responsible for administering a uniform set of food safety laws."

On October 8, 1997, a GAO division director advocated before the Senate Agriculture Committee that all federal food safety functions be assigned to a new agency. He stated that GAO "believes the existing federal food safety structure needs to be replaced with a uniform, risk-based inspection system under a single food safety agency. While some administrative actions can be taken to improve the system, the fundamental changes that are needed will require legislative action."[29]

Dissenting Views

DHHS officials responded to this GAO report by stating that there was no reason to believe that creating a new single agency would improve basic food safety. FDA, through DHHS, suggested that it could, without new legislation, formally establish regulations that could address the nature and extent of problems encountered by the food production industry; the food industry could be held accountable for self-regulation to an even greater degree; and a policy that compares risks could be established through regulation. The response implied that an independent agency was unnecessary. In addition, FDA claimed that the GAO report failed to analyze some major issues for the food industry such as whether the food industry needs uniformity in regulations by states and international harmonization of standards among countries; whether market promotion activities should be commingled with safety regulation; and whether the potential impact of new food technologies, both in producing and

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[28]General Accounting Office, *Food Safety and Quality: Uniform, Risk-based Inspection System Needed to Ensure Safe Food Supply*, GAO/RCED-92-152, June 1992.

[29]Robert A. Robinson, Director, Food and Agriculture Issues, RCED/GAO, "Food Safety: Fundamental Changes Needed to Improve the Nation's Food Safety System," statement for the record before the Senate Committee on Agriculture, Nutrition, and Forestry, 8 October 1997.

developing new and novel foods, would affect how regulations could ensure food safety.

Popular Name and Date

The Durenberger Food Safety Bill, 1993.[30]

Description and Mission of Group Making Recommendations

On August 3, 1993, Senator Durenberger introduced S. 1349, the Food Safety and Inspection Agency Act of 1993. It was referred to the Senate Committee on Governmental Affairs. There were no hearings on this bill.

Summary of Recommendations

The act, if passed, would have placed all food safety and inspection activities in a single, independent agency that, with the guidance of a 15-person expert commission, would have set uniform risk-based inspection standards by which food safety could be ensured. It also would have established a state-federal communications network to educate consumers on potential microbial diseases.

Dissenting Views

Some critics claimed that the proposed bill did not clearly define what a uniform risk-based safety system was or how the existing two separate field-inspection systems would be organized. Also, critics claimed that this bill would have cost the federal government more to create a new agency than to transfer responsibility to an existing agency.

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[30]S. 1349 was introduced by Senator Durenberger on 3 August 1993.

Popular Name and Date

The Torricelli/Bradley Food Safety Bill, 1994.[31]

Description and Mission of the Group Making Recommendations

The Katie O'Connell Safe Food Act (H.R. 3751) was introduced on January 26, 1994, by Representative Robert G. Torricelli. It was referred to the House Committees on Energy and Commerce and Agriculture. On February 1, 1994, it was referred to the Agriculture Subcommittees on Livestock, and Departmental Operations and Nutrition; and on February 24, 1994, it was referred to the Commerce Subcommittee on Health and the Environment. On August 2, 1994, Senator Bradley introduced the Katie O'Connell Safe Food Act (S. 2350); it was referred to the Senate Committee on Agriculture, Nutrition, and Forestry. No hearings were held on either bill. The bills received only a few cosponsors: three for H.R. 3751 and one for S. 2350.

Summary of Recommendations

The act, if it had passed, would have transferred responsibility for enforcing meat, poultry, and egg inspections from FSIS of USDA to an independent federal health agency called the Meat, Poultry and Eggs Inspection Agency. It would have created a position of director of meat, poultry, and eggs inspection and authorized 8 assistant directors. It also would have established an advisory commission made up of representatives from federal and state governments, industry, and the scientific community. This advisory commission would have recommended how the agency could improve inspection by using more technologically advanced techniques in meat, poultry, and egg product inspections.

Dissenting Views

No dissenting views available, but the bill had few cosponsors.

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[31]H.R. 3751 was introduced 26 January 1994; S.2350 was introduced 2 August 1994.

Popular Name and Date

The Fazio-Durbin Food Safety Administration Bill, 1997.[32]

Description and Mission of Group Making Recommendations

In November 1997, Representative Vic Fazio and Senator Richard Durbin introduced identical bills, the Safe Food Act of 1997. On November 4, 1997, H.R. 2801 was referred to the Committees on Agriculture and Commerce and, on November 14, 1997, to the Subcommittee on Health and the Environment. S. 1465 was introduced on November 9, 1997, and referred to the Committee on Government Affairs. So far, there have been no hearings.

Summary of Recommendations

This act, if passed, would consolidate all federal food safety, labeling, and inspection programs into a new independent agency known as the Food Safety Administration (FSA). The new agency would be funded by transferring appropriated funds that are currently designated for food safety functions of four agencies (FDA, USDA, EPA, and National Marine Fisheries Service). According to supporters, the purpose of the new agency would be to replace an outdated, fragmented, and overlapping food safety system. Supporters also say that a single food safety agency could identify the most serious public health risks from specific food-borne pathogens. In addition, resources could be used to develop better testing methods, conduct risk assessments, and identify the most cost-effective interventions without regard to the type of food or bureaucratic "turf."

Dissenting Views

Critics believe that the time is not right for major reform of the current food safety system. Some resist the formation of a new agency because of fear that a whole new FSA would cause dislocation and upheaval. It could also mean that the current parent agencies would have to relinquish their budget authority and control over functions related to food safety. Most opponents to an independent agency advocate allowing the Clinton Administration's 1997 food safety initiatives to take effect. They await the Administration's reports to Congress as to whether these new policies reduce incidences of food-borne illnesses. Other critics claim that the proposed legislation does not define a new food safety mandate to be carried out, but only reorganizes food safety functions by moving the current functions to the new FSA. They argue that a new FSA could be hindered in setting priorities for food safety activities because the bills would not amend or change the basic food safety statutes that establish the policies on which the current food safety system is based. For example, the meat and poultry statutes require that a government inspector be in continuous attendance and the food and drug statute grants FDA the authority to act only when adulterated and/or misbranded foods are found in interstate commerce.

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[32]H.R. 2801 was introduced 4 November 1997; S.1465 was introduced 9 November 1997.

Food Safety Under the U.S. Department of Agriculture

Popular Name and Date

The Hoover Commission Report, May 20, 1949.[33]

Description and Mission of the Group Making Recommendations

Headed by Herbert Hoover, former President of the United States, the Commission on Organization of the Executive Branch of the Government was established in accordance with P. L.80-162, approved July 7, 1947. It was created by unanimous vote of Congress in July 1947, and submitted a series of reports to Congress. The Lodge-Brown Act, which brought the commission into being, conceived of its mission as being bipartisan. Therefore it had six members from each party. Four Commissioners each were chosen by the President of the Senate, the Speaker of the House of Representatives, and President Truman. The Commission members consisted of Herbert Hoover, Chairman; Dean Acheson, Vice Chair; Arthur S. Flemming; James Forrestal; George H. Mead; George D. Aikin; Joseph P. Kennedy; John L. McClellan; James K. Pollock; Clarence J. Brown; Carter Manasco; and James H. Rowe, Jr.

Summary of Recommendations

The commission recommended that all regulatory functions relating to food products be transferred to the Department of Agriculture and that those relating to other products be placed under a reorganized Drug Bureau administered by a public health agency. At the time, four agencies (Federal Security Agency, Federal Trade Commission, the Bureau of Internal Revenue in the Treasury Department, and USDA) exercised food regulatory functions, and some manufacturers had to comply with the regulations of more than one federal agency. The commission noted that many regulations related to food were once the responsibility of the Department of Agriculture. The commission found that, "their separation from other departmental activities [meaning USDA's activities]...creates great overlap and also confuses the public." With food inspections scattered among four government agencies, the commission argued that too many agencies had jurisdiction over food and drug products.

Dissenting views

Two of the commissioners, James K. Pollock, and James H. Rowe, Jr., disagreed with the recommendation to transfer the food regulatory activities of the FDA to USDA. They claimed that the purpose of the food provisions of the FFDCA was to protect the consumer. They advocated that a unified program under the FDA part of the Federal Security Agency should be kept together. They also stated that one food safety system under the FDA, that "safeguarded" consumers from a series of common problems, would accomplish that purpose. The common problems were characterized

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[33] *The Hoover Commission report on organization of the Executive Branch of the Government (1947-1949)*, Westport, CT: Greenwood Press, 1970).

as "economic cheating (misleading and deceptive labels, substitution of cheaper ingredients, short weight); filth and other extraneous or obnoxious materials; harmful products or products containing harmful ingredients." The dissenting Commissioners also believed that splitting the regulatory functions of foods and drugs between two separate agencies would require two sets of laboratories and staffs working independently of each other and would limit the flexibility and economy of work assignments. These commissioners, the Committee on Medical Services, and the Brookings Institution recommended that the [food safety] function be continued as part of a reorganized public health service within the Federal Security Agency or its successor.

Popular Name and Date

Acts Restructuring Meat and Poultry Products Inspection: Wholesome Meat Act of 1967 and the Poultry Products Act of 1968.[34]

Description and Mission of Group Making Recommendations

The Wholesome Meat Act of 1967[35] substantially revised the 1906 Meat Act. Soon afterwards, the Wholesome Poultry Act[36], signed on August 18, 1968, extended to poultry inspection many aspects of the meat inspection act approved in 1967. These acts were the result of a long debate over the differences in federal, state, and local meat inspections. The federal system continued to be responsible for meats moving in interstate commerce and international trade, whereas state and local authorities oversaw meats consumed in their own jurisdictions. Thus, the control over all meat products was mixed; some areas had rigid standards, and others had lax standards. From this background came a call for legislation setting common standards from various interested groups.

The Talmadge-Aiken Act of 1962 had provided for cooperation among federal and state agencies in regulating the marketing of agricultural products. However, few states took advantage of the authority to enter into broad cooperative agreements for meat inspection with USDA. Under the Talmadge-Aiken Act, the states were to establish "equal to" meat inspection systems. In 1967, President Johnson urged that the law be amended to provide greater protection to consumers and federal assistance to states in developing state inspection programs.

Summary of Recommendations

Both Acts required states to have meat and poultry inspection programs "at least equal in rigor to" federally-run programs (under APHIS), even though the state-inspected plants could still market their products only within the state. Under deadlines of December 1969 (meat) and August 1970 (poultry), states could receive federal matching funds to bring their programs up to federal safety and purity standards. One-year extensions could be granted under certain conditions. The Acts encouraged uniformity in the inspection systems and closed loopholes in various phases of the inspection program. Annual reports to Congress on operations and effectiveness of the inspection system were required.

Interest in restructuring the meat and poultry inspection systems had grown as certain Members of Congress became aware that some food additives were becoming a safety problem. Members received letters from constituents concerned about the

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[34]Vivian Wiser, "Part V: Meat and Poultry Inspection in the United States Department of Agriculture," in, *100 Years of Animal Health. 1884-1984*, eds. Vivian Wiser, Larry Mark, and H. Graham Purchase (Beltsville, MD: The Associates of the National Agricultural Library, 1986).

[35]P.L. 90-201.

[36]P.L. 90-492.

presence of nitrosamine, a carcinogen, in bacon. Food processors added nitrite as a curing agent to pork, and that addition caused the formation of nitrosamine when the naturally occurring amine and nitrite combined. Consumers were also alarmed about meat safety when Canada prohibited meats from DES-treated animals (DES — Diethylstilbestrol — is a synthetic estrogenic drug) to be sold in its market. At the time, FDA considered banning its use altogether.

Dissenting views

There were charges that APHIS wanted the complete federalization of meat inspection. A number of representatives of the packing and processing industries joined others from some state agriculture departments opposing the new federal inspection programs. However, over time, the states dropped out of the meat inspection business because of its high cost. By 1976, APHIS inspectors monitored meat and poultry processing in 60% of the nation's plants.

Food Safety Under the Food and Drug Administration

Popular Name and Date

HEW Reorganization Directive of March 1968.[37]

Description and Mission of Group Making Recommendations

President Lyndon Johnson sent a message to Congress on March 4, 1968, with "Health Recommendations." Among the many proposals and recommendations was a directive to the Secretary of Health, Education, and Welfare to submit a "modern plan of organization to achieve the most efficient and economical operation of the health programs of the Federal Government." On March 13, 1968, the Secretary of Health, Education, and Welfare (HEW), Wilbur J. Cohen, announced his first step in carrying out the President's directive. He placed the FDA and the Public Health Service under the direction of Dr. Phillip R. Lee, the Assistant Secretary for Health and Scientific Affairs. The Commissioner of Food and Drugs would report directly to Dr. Lee, rather than to the Secretary. On June 14, 1968, Secretary Cohen's report to the President was made public and recommended the creation of a new Consumer Protection and Environmental Health Service (CPEHS) which would include FDA along with other agencies.

Summary of Recommendations

The rationale for making FDA a part of the newly created CPEHS was stated in the message from the Secretary to the President:

> The fact that similar or interacting contaminants manifest themselves in more than one type of environmental exposure argues strongly for focusing in a single agency the responsibility for identifying the hazards to health, developing and promulgating criteria and standards, and mounting programs that will promote compliance therewith. ... Retention of a separate FDA relates to its history as a regulatory agency with an operational pattern historically different from that of the Public Health Service (PHS). The historic role of the FDA has been primarily one of policing industry to assure compliance with provisions of the FFDCA. ... In the last two years, the FDA has markedly modified its policeman posture [with the food industry.]

The Secretary said that, with this new attitude and with states taking over most of the routine surveillance of industry practices, the justification of keeping FDA and PHS as separate agencies had disappeared.

Dissenting views

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[37]Wallace Janssen, "FDA Since 1962," in unpublished papers, *History of the Department of Health, Education and Welfare During the Presidency of Lyndon Baines Johnson, November 1963 - January 1969*, kept in the FDA History Office by John Swan.

In the 1968 reorganization Directive of the President, CPEHS was formed to deal with environmental problems, but it never received congressional authorization or appropriations. Other federal programs, funded at the time, contributed funding and positions. Dr. Winton Rankin, Deputy Commissioner of FDA reportedly commented: "We gave him [C.C. Johnson, Director of CPEHS] whatever bit of lip service we had to but didn't offer much cooperation. He finally went under." Dr. Rankin also said that he thought that if CPEHS succeeded, FDA would cease to exist.[38]

[38]Brannon, *Organizing and Reorganizing FDA*, 135-174.

Popular Name and Date

The Malek Report, December 10, 1969.[39]

Description and Mission of Group Making Recommendations

On December 10, 1969, Frederick V. Malek, Deputy Undersecretary, Department of Health, Education, and Welfare became chairman of a Special Task Force on the Reorganization of the Consumer Protection Programs. The task force's report to Dr. Charles C. Edwards, FDA Commissioner, was called *Analysis and Recommendations: The Food and Drug Administration Organizational Review*. It contained an organizational and management study of the FDA. The report was delivered August 25, 1970.

Summary of Recommendations

The task force's report proposed a reorganization of FDA because of a growing concern over FDA's ability to carry out its consumer protection responsibilities. The report recommended that FDA become a separate health agency reporting to the Assistant Secretary for Health and Scientific Affairs, and a new Consumer Protection and Environmental Health Service be created separate from FDA. Within FDA, a new bureau for foods, pesticides, and product safety should be created along with a new drug bureau. Each should have full responsibility and authority from initial research to final regulatory action. The rationale was that the new Food Bureau could concentrate on its major product areas without jeopardizing other product areas and would create clearer lines of authority for FDA's compliance activities.

Dissenting Views

Not Available

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[39]House Committee on Interstate and Foreign Commerce, Subcommittee on Commerce and Finance, *Hearings on the Consumer Product Safety Act*, 92nd Cong., 1st and 2nd sess., part 3, Nov. 1, 1971-Feb. 3, 1972, H.Rept. 92-61.

Popular Name and Date

Senate Governmental Affairs Report on Federal Regulation, 1977.[40]

Description and Mission of Group Making Recommendations

The Chairman of the Senate Committee on Governmental Affairs, Abraham Ribicoff, submitted *Study on Federal Regulation* to Walter F. Mondale, President of the Senate on December 21, 1977. The report was prepared under the authority of Senate Resolution 71, which authorized the Governmental Affairs Committee to conduct a study on various aspects of the federal regulatory process.

Summary of Recommendations

Senator Ribicoff hoped that the report would provide a basis for congressional action. The report recommended a transfer of USDA food regulatory functions to FDA. The report stated, "Divided responsibility for regulating food production has resulted in a regulatory program which is often duplicative, sometimes contradictory, undeniably costly, and unduly complex." The report asserted an urgent need to combine and rationalize the dual food regulation system that had existed over 70 years. "We believe the bifurcated food regulatory system should be unified in a single agency."

Dissenting Views

The proposal would have split employees located throughout the country (known as the field force) between the two administrations. USDA officials claimed that USDA's greatest strength was its network of field offices in operation throughout the country, as well as the experience and skills of its field staff. USDA officials were concerned that the transfer of USDA employees to another agency would weaken the network system.

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[40]Senate Committee on Governmental Affairs, "V. Regulatory Organization" in *Study on Federal Regulation*, 95th Cong., 2d sess., December 1977, S.Rept. 95-91, 140.

Popular Name and Date

President Carter's 1978 Government Reorganization Project or White House Study (never released).[41]

Description and Mission of Group Making Recommendations

In February 1978, during testimony before the Appropriations Subcommittee on Agriculture, Rural Development and Related Agencies, chaired by Representative Whitten, spokespersons for the Carter Administration referred to the President's White House Study for Reorganization. Two of the most prominent officials were the Secretary of Agriculture, R. Bergland, and D. Angelotti, Administrator of the Food Safety and Quality Service (FSQS) (a precursor of FSIS).

Summary of Recommendations

The project recommended consolidation of all federal food regulatory functions. The final report did not resolve where the new organization would be located, although the HEW Secretary Joseph Califano suggested that FDA take over USDA's meat and poultry inspection and labeling duties. In 1977, USDA had formed the FSQS. Its mission was to enhance coordination among food inspection activities as well as food grading, certification and purchasing. USDA made clear that it had reorganized itself along functional lines, and, therefore, it did not believe consolidation of its food safety functions with FDA functions would be beneficial.

Dissenting Views

USDA Secretary Bergland countered Secretary Califano's suggestion with the idea that FDA food inspection authority be transferred to the new FSQS. Secretary Bergland stated, "The President's Reorganization Task Force is reviewing the desirability of combining FDA food activities, and USDA food safety and quality activities operations." In November 1977, HEW proposed that USDA's meat and poultry inspection activities and the women-infants-children program be consolidated within HEW. In February 1978, USDA proposed an alternative arrangement of functions. No final reorganization was initiated.

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[41]House Committee on Appropriations, Subcommittee on Agriculture, Rural Development, and Related Agencies, *Hearings on Agriculture, Rural Development and Related Agencies Appropriations for 1979*, 95th Cong., 2nd sess., February 1978, 75 and 367-371.

Popular Name and Date

Lester Crawford, 1980.[42]

Description and Mission of Group Making Recommendations

In 1980, Dr. Lester Crawford became the Administrator of USDA's Food Safety and Inspection Service. In a speech at the 1980 U.S. Animal Health Association annual meeting, he recommended that one agency would do a better job in formulating food regulatory policies.

Summary of Recommendations

Dr. Crawford stated, "Managerially unsound and duplicative systems of regulation will cause us all to still be spinning on our collective wheels decades from now." He suggested a number of alternatives: 1) consolidation of all food safety functions within DHHS; 2) transfer of FDA's Center of Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine (CVM) to USDA; or 3) at least merge CFSAN with CVM.

Dissenting Views

Several food safety activists objected to moving all food safety responsibility to USDA, because USDA is not linked to the Public Health Service as is FDA. They argued that communication could be improved on food safety standards if all food safety agencies were affiliated with public health agencies such as the Centers for Disease Control and the National Institutes of Health.

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[42]Lester Crawford, "Critique of Animal Health Regulation," in *Proceedings of the 84th Annual Meeting*, (Washington, D.C., U.S. Animal Health Association, 1980.)

Popular Name and Date

Dr. Sanford Miller, 1989.[43]

Description and Mission of Group Making Recommendations

Dr. Sanford Miller was the director of the Center for Food Safety and Applied Nutrition at FDA from 1978 to 1987. He is a national voice on public policy relating to nutrition and food sciences.

Summary of Recommendations

In discussing the underlying philosophical dynamic for the leading food safety agencies, which he believed has led to unnecessary controversies, Dr. Miller recommended that it was time to review the structure of food regulation in the United States. He suggested that it would be reasonable for the President and Congress to appoint a very senior level commission to review the requirements for an optimal food regulatory process and make recommendations. Dr. Miller stated, "The commission might very well conclude that the current setup is the best that we can devise, or it may propose a single agency, perhaps at the level of EPA."

Dissenting views

Not Available

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[43]Sanford Miller, "Quest for Safe Food: Knowledge and Wisdom," 1989 S. B. Hendricks Memorial Lecture of the USDA, ARS presented before the American Chemical Society, Miami Beach, Florida, 11 September 1989, (Washington:GPO, 1990), 11.

Popular Name and Date

The Edwards FDA Advisory Committee, May 1991.[44]

Description and Mission of Group Making Recommendations

The committee was chaired by Dr. Charles C. Edwards, the former FDA Commissioner (1969-1973), and former Assistant Secretary for Health (1973-75). One of its members, Dr. David A. Kessler, later became the FDA Commissioner. The purpose of the committee was to examine FDA's mission, responsibility, and structure according to its legislative mandate, and to recommend how FDA could be strengthened to fulfill its mission. The committee was to provide advice accordingly to the Secretary of DHHS and to the Assistant Secretary for Health and did so in the *Final Report of the Advisory Committee on the Food and Drug Administration.*

Summary of Recommendations

The Committee recommended that FDA be removed from the Public Health Service (PHS) and that the FDA Commissioner report directly to the Secretary of Health and Human Services. It also recommended that the Secretary of DHHS directly delegate to the Commissioner the authority to issue regulations implementing all the laws that FDA administers and to manage the daily operations of the Agency.

The Food Policy Subcommittee of the Advisory Committee recommended that FDA move immediately to improve the Center for Food Safety and Applied Nutrition (CFSAN) management system, increase its resources, upgrade the development of its program planning, and delegate additional authority to the CFSAN director. It also recommended that the Commissioner establish one task force to ensure that FDA meet its nutrition labeling obligations and another to assist CFSAN in resolving scientific and technical issues. It also said that it found no evidence to show that FDA's performance would improve if its human food responsibilities were combined with those of USDA. It recommended the establishment of a consistent approach to risk assessment among regulatory agencies responsible for food safety (FDA, EPA, and USDA), including for food derived from animals.

Dissenting Views

The Secretary of DHHS responded that the location in Public Health Service (PHS) was not the source of FDA problems. The Secretary contended that FDA gained from the close scientific interaction with other PHS agencies on issues such as AIDS epidemiology and research, pertussis vaccine, outbreaks of *Salmonella* Enteritidis, dental amalgam problems, and food safety issues.

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[44]Department of Health and Human Services, *Advisory Committee on the Food and Drug Administration, Final Report,* May 1991, Charles C. Edwards, Chairman,, (Washington, 1991) iii-iv, 19-24.

Popular Name and Date

National Performance Review, September 1993.[45]

Description and Mission of Group Making Recommendations

Vice President Al Gore published his report of the National Performance Review (NPR) on September 7, 1993. He had been asked by President Clinton to undertake a 6-month study of the federal bureaucracy and make recommendations on how to create a government that works better and costs less.

Summary of Recommendations

The Review recommended that all federal food safety responsibilities be placed under the FDA.

Dissenting Views

A working group of government food safety officials advising the Vice-President's staff in preparing the NPR had recommended that an independent agency be created that would administer a science-based food safety system that would apply the same standards to all foods, thereby representing a more effective method of preventing food-borne illnesses. The working group also suggested that four policy initiatives were needed in conjunction with creating the new agency. The group suggested locating the new agency within the executive branch so that the congressional committees who would be responsible for oversight and the appropriation of its funds would be those "whose principal concerns are the health and economic welfare of this countries' citizens, and not those whose principal interests are in the economic welfare of the producers of food or the inspected food industries." The group also suggested that Congress should amend existing food safety laws to provide uniform regulatory authority that would be adequate to monitor and control food-borne health hazards at any point in the country's food production system. The group suggested that all food safety research functions be assigned to the single food safety agency. Finally, the group wanted the agency to fill each decision-making position with people who had appropriate scientific backgrounds.

None of those recommendations were in the final National Performance Review report. Some in Congress would have preferred that FSIS absorb all food and seafood inspection responsibilities. For example, House Speaker Thomas S. Foley said that, if USDA regulated all foods, the FDA would be free to concentrate on the safety of drugs.[46]

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[45]Al Gore, "From Red Tape to Results: Creating a Government That Works Better and Costs Less," in *Report of the National Performance Review,* (Washington, D.C., 7 September 1993), 101.

[46]Kenneth J. Cooper, "Hill Turf Fights May 'Reinvent' Gore Proposals," *Washington Post*, 13 September 1993, A19; Also see Rodney E. Leonard, "A Single Food Safety Agency," *Nutrition Week,* v. 23, September 1993, 2.

Popular Name and Date

Carol Tucker Foreman, Safe Food Coalition, October 6, 1993.[47]

Description and Mission of Group Making Recommendations

These recommendations, in the form of a press release issued by the Safe Food Coalition, reflect support for reorganizing food safety functions from the American Public Health Association, Center for Science in the Public Interest; Consumer Federation of America; Consumers Union; Food and Allied Service Trades AFL-CIO; Government Accountability Project; National Consumers League; Public Citizen; Public Voice for Food and Health Policy; United Food and Commodity Workers International Union. Ms. Foreman is a former Assistant Secretary of Agriculture.

Summary of Recommendations

The press release states that the Safe Food Coalition strongly endorses Vice President Gore's National Performance Review recommendation that would transfer USDA's meat and poultry inspection functions to FDA. The Coalition believes that the inspection of meat and poultry should be a public health program and should be within the responsibility of a public health agency. In supporting the consolidation of food safety functions within the FDA, the Coalition cited two concerns that they believed prevented USDA from effectively administering an adequate food safety inspection program. First, they believe that USDA knows more about animal health than human health, and second, that USDA cares more about promoting sales of agricultural products than it does about protecting consumers.

Dissenting Views

Giving the task of regulating meat and poultry to FDA would be similar to "the gnat swallowing the elephant," says a New York Times reporter, Marian Burros, in a newspaper article at the time.[48] FDA currently has about 1,042 full time equivalent (FTE) positions to do all types of inspection and to analysis food samples and other products, whereas FSIS of USDA has about 7,500 FTEs to inspect meat and poultry.

The types of inspections are somewhat different from one agency to the other. FDA staff pointed out that most FDA inspectors have extensive scientific training. FDA inspectors also make periodic inspections of food plants where they can take samples for laboratory analysis, check temperatures in canning processes, check machinery, and collect information in their evaluations to be able to support any regulatory action that may lead to a legal proceeding. FSIS staff explained that FSIS meat and poultry inspectors rely on constant and daily organoleptic inspection (based on sight, touch, or smell) of products as they flow by on the assembly line. FSIS

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[47]Safe Food Coalition, "Safe Food Coalition Endorses Gore Proposal to Consolidate Food Safety Functions," Press Release and Letter to Members of the House, 6 October 1993, Ms. Joy Stevens, FDA/OLA, conversation with author, 2 September 1993.

[48]Marian Burros, "Clinton Plan Would Move Meat and Poultry Inspections to FDA" *New York Times*, 13 September 1993, A18.

inspectors can immediately condemn carcasses that do not pass standards. They also can take samples and send them for laboratory analysis, and inspect both the product and the paperwork connected with exports and imports.[49] In addition to the organoleptic approach, FSIS inspectors check each meat or poultry plant's Hazard Analysis and Critical Control Point (HACCP) plan and records. Every meat and poultry plant must implement, by the year 2000, a HACCP plan that identifies where hazards occur and what steps are needed to control those hazards.[50]

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[49]Mrs. Joy Stevens, FDA/OLA, telephone conversation with author, 23 September 1993. Will Kerr, USDA/FSIS/BFPB, telephone conversation with author 24 September 1993.

[50]Congressional Research Service, *Food Safety Issues in the 105th Congress*,by Donna U. Vogt, IB98009, March 30, 1998; and *Meat and Poultry Inspection Issues*, by Jean Rawson, IB 95062, March 1998.

Popular Name and Date

Hearings in Support of the Vice President's National Performance Review Recommendations for Reinventing the Food Safety System, 1993-1994.[51]

Description and Mission of Group Making Recommendations

A series of five hearings of two subcommittees of the House Committee on Government Operations took place during both sessions of the 103rd Congress. The Subcommittee on Human Resources and Intergovernmental Relations held hearings on Nov. 4 and 19, 1993 (both were on USDA's progress in reforming meat and poultry inspection); May 25, 1994 (review of FDA's food safety programs); Sept 28, 1994 (chemical residues and contaminants in food); and a joint hearing with the Subcommittee on Information, Justice, Transportation, and Agriculture on June 16, 1994 (fresh versus frozen chickens and other issues involving USDA's regulation of poultry products).

Summary of Recommendations

The hearing records contain thousands of pages of testimony and submitted documents from hundreds of experts considering whether the current federal food safety system is adequately protecting U.S. consumers; whether the existing system has a comprehensive federal food safety mission and objective that protects the public's health; and whether Vice President Gore's National Performance Review recommendation to consolidate all federal food safety programs within FDA is warranted. Principally, most of the recommendations discussed the need to revise the food safety system to monitor for microbiological pathogens in the food supply and to prevent food-borne illnesses. Representative Edolphus Towns stated in his opening remarks, "The current federal food safety system is not just fragmented; it is broken. The system is not designed to prevent food-borne disease...There is no question about it. USDA has known for over 20 years that its inspection system cannot detect harmful microbes in meat and poultry, but did absolutely nothing about it." Several witnesses also testified on the need to transfer meat and poultry inspection functions to a "public health" agency because of the perceived conflict in USDA's dual mission, agriculture production and consumer protection.

Dissenting Views

USDA officials testified that they were implementing a "two track" approach for reforming the meat and poultry safety system: first, to maximize the performance of the current inspection system; and second, to design, test, and implement a regulatory program for the future. A key component of this approach was the Pathogen Reduction Program/Hazard Analysis and Critical Control Point system aimed at reducing the likelihood of harmful microorganisms that could enter the food system anywhere in the production, distribution, and consumption chain. USDA officials

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[51]House Committee on Government Operations, *Hearings on Reinventing the Federal Food Safety System*, 103rd Cong., 1st and 2nd sess, v. 1 and 2, 1995, Joint Committee Print.

and representatives from state agriculture and health departments testified that there was no need to reorganize food safety activities because, in carrying out food safety inspections and other activities, they were ensuring already that the foods under their jurisdictions were safe.

Food Safety Under the Consumer Product Safety Commission

Popular Name

The Metzenbaum Bill, 1993.[52]

Description and Mission of Group Making Recommendations

The Food Safety Reform Act of 1993 (S. 1750) was introduced on November 20, 1993, by Senator Metzenbaum and was referred to the Senate Committee on Governmental Affairs. S. 1750 had no cosponsors.

Summary of Recommendations

The act would have transferred to the Consumer Product Safety Commission (CPSC) all food safety and inspection functions of the USDA and the Departments of the Interior and Commerce, FDA, and EPA. It would have established the position of "Executive Director of Food Safety" in the CPSC, which would be charged with preparing and submitting to the appropriate congressional committees a plan for a nationwide food safety database and the implementation of food inspection techniques. The plan would include hazard analysis of critical control points, rapid pathogen detection, trace-back technology, food irradiation, and other necessary techniques. The purpose of this bill would have been to centralize responsibility for the management of all federal food safety activities into one existing agency to lessen the cost on the federal budget.

Dissenting Views

Not Available

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[52]S. 1750 was introduced 20 November 1993.

Table 2. Recommendations for Changes in the Federal Organization of Food Safety Responsibilities, 1949-1997
(In chronological order)

Name and Source	Proposed Changes in Organization
1949 The Hoover Commission Report. U.S. Commission on Organization of the Executive Branch of the Government (1947-1949). May 20, 1949. Westport, CT:Greenwood Press, 1970.	Recommended that all regulatory functions relating to food products to protect the consumer be transferred to USDA and that those relating to other products be placed under a reorganized Drug Bureau administered by the public health agency.
1968 Department of Health, Education, and Welfare Reorganization Directive of March. Found in: Janssen, Wallace. FDA Since 1962. Vol. 1. Unpublished papers entitled History of the Department of Health, Education and Welfare During the Presidency of Lyndon Baines Johnson. November 1963 - January 1969.	Placed FDA under the Public Health Service and in July 1968 made FDA a part of the newly created Consumer Protection and Environmental Health Service (CPEHS). FDA received resources devoted to pesticides, shellfish, product safety, and poison control from other Public Health agencies. FDA then began to operate under the Public Health Service Act.
1967-68 Acts Restructuring of Meat and Poultry Inspection: Wholesome Meat Act of 1967, and the Poultry Products Act of 1968. U.S. Department of Agriculture. Economic Research Service. National Economy and History Branch. Agriculture and Rural History Branch. Unpublished chapters from forthcoming history of the Food Safety and Inspection Service.	Both required states to have meat and poultry inspections programs "at least equal in rigor to" federally run programs (under APHIS), even though the state-inspected plants could still only market their products within the state. Under deadlines of December 1969 (meat) and August 1970 (poultry), states could receive federal matching funds to bring their programs up to federal safety and purity standards. One-year extensions were to be granted under certain conditions.
1969 White House Conference on Food, Nutrition, and Health. Final Report. Washington, D.C. 1969.	Recommended that there should be one federal regulatory policy with respect to safety, sanitation, identity, and labeling of foods.

Name and Source	Proposed Changes in Organization
1969 Malek Report. House Committee on Interstate and Foreign Commerce. Subcommittee on Commerce and Finance. Consumer Product Safety Act. Hearings, 92nd Congress, 2nd sess. Part 3, Nov. 1, 1971-Feb. 3, 1972. Serial No. 92-61. Washington, U.S. Govt. Print. Off., 1972.	Recommended that a new Consumer Protection and Environmental Health Service be created, separate from FDA, with FDA becoming a major health agency reporting to the Assistance Sec. for Health and Scientific Affairs. Within FDA, a new Bureau of Foods, Pesticides, and Product Safety and a Bureau of Drugs would be created, each with full responsibility and authority for all activities from initial research to final regulatory action.
1970 General Accounting Office, Need to Reassess Food Inspection Roles of Federal Organizations. Department of Agriculture, Department of Defense, Department of Health Education, and Welfare, Department of the Interior. Report to the Congress by the Comptroller General of the United States. Rept. No. B-168966. June 30, 1970.	Did not specifically recommend consolidation, but criticized the overlapping inspection activities among USDA, FDA, and other federal agencies. Instead, it recommended that the Director, Bureau of the Budget, make a detailed evaluation of the federal food inspection system to see how to improve its administration and determine if it was feasible to consolidate some of the inspections.
1972 Ralph Nader Report. Wellford, Harrison. Sowing the Wind: A Report from Ralph Nader's Center for Study of Responsive Law on Food Safety and the Chemical Harvest. (New York: Grossman Publishers, 1972), 354.	Found that food inspection "remains embarrassed by departmental conflicts of interest and overlapping jurisdictions in USDA and FDA." In its conclusions, the report recommended that meat inspection and chemical monitoring by USDA and the food inspection functions of FDA be transferred to a new food safety agency to improve the likelihood of protecting the public health.

Name and Source	Proposed Changes in Organization
1972 Hearings before the U.S. Senate on S. 3419. Senate Committee on Commerce, Consumer Safety Act of 1972, 92nd Cong., 2nd sess., 1972, S.Rept. 92-749. Senate Committee on Government Operations, Subcommittee on Executive Reorganization and Government Research, S.3419, The Consumer Safety Act of 1972, 92nd Cong., 2nd sess., S.Rept. 92-2. Senate Committee on Labor and Public Welfare, Food, Drug, and Consumer Product Safety Act of 1972, 92nd Cong., 2nd sess., S.Rept. 92-835.	The purpose of S. 3419, Consumer Safety Act of 1972, was to establish an independent agency to regulate foods, drugs, and consumer products. The bill would have combined under a single agency, a number of different responsibilities. The purpose of this independent Consumer Safety Agency was to have been to protect consumers against unreasonable risk of injury from hazardous products. The independent agency would have had responsibility to set product safety standards for all consumer products representing unreasonable risk of injury or death. S. 3419 became the umbrella legislation and was called the Food, Drug, and Consumer Product Safety Act of 1972. It passed the Senate on June 21. 1972.
1977, Senate Committee on Governmental Affairs Report. U.S. Congress. Senate. Committee on Governmental Affairs. Study on Federal Regulation. Senate Document No. 95-91, 95th Cong., 2d sess. vol. V. Regulatory Organization. December 1977. p. 140.	Recommended a transfer of USDA food regulatory functions to FDA.
1978 President Carter's Government Reorganization Project or White House Study (never released). U.S. Congress. House Committee on Appropriations, Subcommittee on Agriculture, Rural Development, and Related Agencies. Agriculture, Rural Development and Related Agencies Appropriations for 1979. Hearings, Parts 1 and 4, Feb., 1978. Washington, D.C., U.S. Govt. Print. Off., 1978. p. 75 (pt.1), p. 367-371 (pt. 4).	Recommended consolidation of all food regulatory functions of FDA.
1980 Lester Crawford Speech. Crawford, Dr. Lester. Critique of Animal Health Regulation. Proceedings of the 84th Annual Meeting. Washington, D.C., U.S. Animal Health Association, 1980.	Suggested consolidation of all food safety functions within DHHS, transfer of FDA's divisions of Center of Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine (CVM) to USDA, or at least merge CFSAN with CVM.

Name and Source	Proposed Changes in Organization
1989 Dr. Sanford Miller. Quest for Safe Food: Knowledge and Wisdom. 1989 S. B. Hendricks Memorial Lecture presented by Dr. Sanford A. Miller by USDA, ARS before the American Chemical Society, Miami Beach, Florida. September 11, 1989. U.S. Department of Agriculture. Agricultural Research Service. Washington, D.C., U.S. Govt. Print. Off., 1990. p. 11.	Recommended that a special commission be set up to make recommendations on the optimal food safety regulatory process which may be a single agency.
1991 The Edwards Committee Report. U.S. Dept. of Health and Human Services. Advisory Committee on the Food and Drug Administration. Final Report. Charles C. Edwards, Chairman. May 1991. Washington, D.C., 1991. p. iii-iv, 19-24.	Recommended that FDA be removed from the Public Health Service (PHS) and the FDA Commissioner report directly to the Secretary of Health and Human Services
1992 Risk-Based Food Safety Inspection. U.S. General Accounting Office. Food Safety and Quality: Uniform, Risk-based Inspection system Needed to Ensure Safe Food Supply. GAO/RCED-92-152, June 1992.	Recommended that Congress hold oversight hearings to evaluate options for revamping the federal food safety and quality system, including creating a single food safety agency responsible for administering a uniform set of food safety laws.
1993 S. 1349, Food Safety and Inspection Agency Act was introduced by Senator Durenberger and referred to the Senate Committee on Governmental Affairs, August 3, 1993.	Would have placed all food safety and inspection activities in a single, independent agency which would, with the guidance of a 15-person expert commission, set uniform risk-based inspection standards by which food safety would be ensured. In addition, it would have established a state-federal communications network to educate consumers on potential microbial diseases.
1993. National Performance Review. Gore, Al. From Red Tape to Results: Creating a Government that Works Better and Costs Less. Report of the National Performance Review. Washington, D.C. September 7, 1993,101.	Recommended consolidating all federal food safety responsibilities under the FDA.

Name and Source	Proposed Changes in Organization
1993. Carol Tucker Foreman and the Safe Food Coalition, "Safe Food Coalition Endorses Gore Proposal to Consolidate Food Safety Functions," Press Release and Letter to Members of the House, 6 October 1993 in which they strongly supported the National Performance Review recommendation to move the food safety function of inspection of meat and poultry to the FDA. The Coalition is composed of members of the from the American Public Health Association; Center for Science in the Public Interest; Consumer Federation of America; Consumers Union; Food and Allied Service Trades, AFL-CIO; Government Accountability Project; National Consumers League; Public Citizen; Public Voice for Food and Health Policy; United Food and Commercial Workers International Union.	States that the Safe Food Coalition strongly endorses Vice President Gore's National Performance Review recommendation that would transfer USDA's meat and poultry inspection functions to FDA. The Coalition believes that the inspection of meat and poultry should be a public health program and should be within the responsibility of a public health agency. In supporting the consolidation of food safety functions within the FDA, the Coalition cited two concerns that they believed prevented USDA from effectively administering an adequate food safety inspection program. First, they believe that USDA knows more about animal health than human health, and second, that USDA cares more about promoting sales of agricultural products than it does about protecting consumers.
1993 and 1994 Hearings in Support of the Vice President's National Performance Review Recommendations for Reinventing the Food Safety System. House Committee on Government Operations, Hearings, *Reinventing the Federal Food Safety System*, 103rd Cong., 1st and 2nd Sess., Volume 1 and 2. Washington, D.C.:GPO, 1995.	Hearing experts discussed whether the current federal food safety system was adequately protecting U.S. consumers, whether the existing system has a comprehensive federal food safety mission and objective that can protect the public health, and whether Vice President Gore's National Performance Review recommendation to consolidate all federal food safety programs within FDA is warranted.
1993 The Food Safety Reform Act (S. 1750) was introduced on November 20, 1993 by Senator Metzenbaum and referred to the Senate Committee on Governmental Affairs.	Would have transferred to the Consumer Product Safety Commission (CPSC) all food safety and inspection functions of the USDA, and the Departments of the Interior and Commerce, FDA, and EPA.

Name and Source	Proposed Changes in Organization
1994 The Katie O'Connell Safe Food Act (H.R. 3751) was introduced on January 26, 1994 by Representative Robert G. Torricelli; it was referred to the House Committees on Energy and Commerce and Agriculture. On February 24, 1994, it was referred to the Commerce Subcommittee on Health and the Environment; and on Feb. 1, 1994 it was referred to the Agriculture Subcommittees on Livestock, and Departmental Operations and Nutrition. On August 2, 1994, Senator Bradley introduced the Katie O'Connell Safe Food Act (S. 2350); it was referred to the Senate Committee on Agriculture, Nutrition, and Forestry.	Would have transferred responsibility for enforcing meat, poultry, and egg inspections from FSIS of USDA to an independent federal health agency entitled the Meat, Poultry and Eggs Inspection Agency.
1997 The Safe Food Act of 1997 (H.R. 2801/S. 1465). Rep. Vic Fazio and Sen. Richard Durbin introduced identical bills. On Nov. 4, 1997, H.R. 2801 was referred to the Committees on Agriculture and Commerce and on Nov. 14, 1997, H.R. 2801 was referred to the Subcommittee on Health and the Environment. S. 1465 was introduced on Nov. 9, 1997, and referred to the Committee on Government Affairs.	Would consolidate all federal food safety, labeling, and inspection programs into a new single, independent agency known as the Food Safety Administration (FSA). The purpose of the agency would be to identify the most serious public health risks from specific food borne pathogens and use resources to develop improved testing methods, conduct risk assessments, and identify the most cost-effective interventions without regard to the type of food or bureaucratic "turf."