

THE WHITE HOUSE
WASHINGTON

March 3, 1998

FOOD SAFETY EVENT

DATE: March 4, 1998
LOCATION: Roosevelt Room
BRIEFING TIME: 1:30 pm - 1:20 pm
EVENT TIME: 1:45 pm - 2:45 pm
FROM: Bruce Reed

I. PURPOSE

To highlight the introduction of legislation in the Senate that you proposed to ensure the safety of imported fruits and vegetables, and to receive a progress report from USDA and HHS on the development of guidance on good agricultural and manufacturing practices.

II. BACKGROUND

You will be speaking to an audience of approximately 40 consumer advocates, food industry representatives, families, and Members of Congress.

You will be making the following announcements:

Challenge to Congress to Enhance FDA Oversight for Imported Foods. You will challenge Congress to pass the food safety legislation to be introduced by Senators Mikulski and Kennedy to require the FDA to halt imports of fruits, vegetables, and other food products from any foreign country with food safety systems and standards that are not equivalent to those of the United States. The legislation also will require the FDA to halt imports from countries or facilities that do not allow FDA inspections to occur. This legislation, which you proposed last fall, was previously introduced in the U.S. House of Representatives by Reps. Eshoo and Pallone. You have committed to providing approximately \$27 million in your Fiscal Year 1999 budget to enable the FDA to dramatically expand its international food inspection force.

① halt
equivalent
criteria
② ~~certification~~
factor
FDA
work

Agency Report on Guidance on Good Agricultural and Manufacturing Practices.

You will announce that you have received a report from Secretaries Shalala and Glickman on the progress they have made in providing guidance on good agricultural and manufacturing practices to domestic and international growers, harvesters, handlers, and transporters of fresh fruits and vegetables as requested in a Presidential Directive on October 2, 1997. This report outlines the progress made -- and the steps still to be taken -- to develop the voluntary guidance by October 1998. The guidance -- the first-ever specific safety standards for fruits and vegetables -- will address potential food safety

problems throughout the production and distribution system and help ensure the sanitation and safety practices of all those seeking to sell produce in the U.S. market. The report also provides both short- and long-term plans for technical assistance, education, and outreach activities to support the implementation of the guidance.

III. PARTICIPANTS

Briefing Participants:

The Vice President
Secretary Shalala
Secretary Glickman
Bruce Reed or Elena Kagan

Event Participants:

The Vice President
Senator Barbara Mikulski
Gloria Doyle, Chevy Chase, MD, who became ill after eating imported raspberries.

Standing on stage, but not speaking:

Secretary Shalala
Secretary Glickman
Lead Deputy FDA Commissioner Michael Friedman
Congresswoman Eshoo and other Members of Congress

IV. PRESS PLAN

Open Press.

V. SEQUENCE OF EVENTS

- The Vice President will make welcoming remarks and introduce Senator Mikulski.
- Senator Mikulski will make remarks and introduce Gloria Doyle.
- Gloria Doyle will make remarks and introduce **YOU**.
- **YOU** will make remarks and then depart.

VI. REMARKS

Remarks Provided by Speechwriting.



United States Department of Agriculture
Food Safety and Inspection Service

FAX

To:

Tom Freedman

Fax #:

456-37431

Subject:

Date:

Pages:

including this cover sheet.

COMMENTS:

*Food Safety
recalls*

From the desk of

Thomas J. Billy
Administrator

331-E Jamie L. Whitten Building
Washington, DC 20250

202-720-7025
or 720-8217
Fax 205-0158

*Tom
Mark*

Rehigh.tab

RECALL AUTHORITY

National Highway Traffic Safety Administration

Official	Statute	Action
Secretary of Transportation	49 USC § 30101	The Secretary of Transportation has the authority to determine that a motor vehicle contains a defect related to motor vehicle safety or does not comply with an applicable motor vehicle safety standard . The manufacturer of the defective or noncomplying motor vehicle must remedy the defect or noncompliance by one of the following methods: 1. By repaking the vehicle. 2. By replacng the vehicle with an identical or reasonable equivalent vehicle. 3. By refunding the purchase price, less a reasonable allowance for depreciation.

RECALL AUTHORITY**Food and Drug Administration**

Official	Statute	Action
Secretary of Health and Human Services	The Food Drug and Cosmetic Act	The Secretary shall by regulation prescribe the scope and extent of recalls of infant formula necessary and appropriate for the degree of risks to human health presented by the formula subject to recall. If the manufacturer of an infant formula has knowledge which reasonably supports the conclusion that an infant formula which has been processed by the manufacturer and which has left an establishment subject to the control of the manufacturer: — may not provide the nutrients required — may be otherwise adulterated or misbranded The manufacturer shall promptly notify the Secretary of such knowledge. If the Secretary determines that the infant formula presents a risk to human health, the manufacturer shall immediately take all actions necessary to recall shipments of such infant formula from all wholesale and retail establishments, consistent with recall regulations and guidelines issued by the Secretary.

RECALL AUTHORITY

Environmental Protection Agency

Official	Statute	Action
EPA Administrator	Clean Air Act - Mobile Sources - 42 USC §§ 203 and 211 The Federal Insecticide Fungicide and Rodenticide Act - 7 USC § 136-q(b)	EPA has authority to recall vehicles that do not meet emissions requirements. EPA has the authority to recall fuel and fuel additives that are not in accordance with EPA regulatory requirements. The Administrator can order a recall if the product is suspended or canceled under Section 6 and if necessary to protect health or the environment. Section 6 addresses administrative review and suspension requirements.

03-05-98:06:19PM:USDA

RECALL AUTHORITY**Consumer Product Safety Commission**

Official	Statute	Action
United States Consumer Product Safety Commission	15 USC § 2064	Authorizes the United States Consumer Product Safety Commission to order the manufacturer or any distributor or retailer of a product that presents a substantial product hazard to take the following actions: 1. To bring such product into conformity with the requirements of the applicable consumer product safety rule or to repair the defect in such product. 2. To replace such product with a like or equivalent product which complies with the applicable consumer product safety rule or which does not contain the defect. 3. To refund the purchase price of such product (subject to provisions for a reasonable allowance).

FDA. Tab

Food and Drug Administration

Official	Statute	Area of Concern	Triggering Activity	Remedies
Secretary Of Health and Human Services	Food, Drug and Cosmetic Act (21 USC § 333)	Medical Devices and Pesticide Residues	Can assess civil penalties against any person that introduces into interstate commerce or delivers for introduction into interstate commerce an article of food that is adulterated by an unapproved pesticide within the meaning of section 402a. Can assess civil penalties against any manufacturer or distributor who violates a prohibition against the selling, purchasing or trading of drug samples, or who fails to report a conviction of one of its representatives of this prohibition.	◆ Civil penalties from \$50,000 in the case of an individual not to exceed \$500,000 for all such violations. ◆ Civil penalties from \$50,000 for each violation not to exceed \$1,000,000 for all such violations.

Epa. tab

Environmental Protection Agency

Official	Statute	Area of Concern	Triggering Activity	Remedies
EPA Administrator	Resource Conservation and Recovery Act (42 USC § 6928)	Hazardous waste.	Violation of the Act.	◆ Authority to assess penalties in administrative penalty order, not to exceed \$25,000 per day of non-compliance for each violation.
	Clean Air Act (42 USC § 7413)	Air Quality	Has violated any requirement or prohibition of an applicable implementation plan. Has violated any requirement or prohibition of the Act.	◆ Violations of section 203: - may subject the violator to a civil penalty of up to \$25,000 per violation not to exceed \$200,000.
	Clean Water Act (33 USC § 1319)	Water Quality	Violation of the Act or permit condition.	◆ The Administrator can deem penalties of up to \$25,000 a day.

Occupational Safety and Health Administration

Official	Statute	Area of Concern	Triggering Activity	Remedies
Secretary of Labor	Section 17, Occupational Safety and Health Act of 1970 (29 USC § 666)	Safe and healthful working conditions for working men and women.	Includes, but is not limited to: * willful violation of any standards established for the safety of the workplace. * failure to correct a violation of any standard, rule or order pursuant to this act. * giving of advance notice of an inspection without authority from the Secretary. * knowingly making a false statement, representation, or certification in any application, record, report, plan, or other document filed.	♦ Civil penalties from \$7,000 to \$70,000 for each violation.

Federal Reserve Board

Official	Statute	Area of Concern	Triggering Activity	Remedies
Secretary of Treasury	Federal Reserve Act (12 USC § 504)	Any member bank which, and any institution-affiliated party with respect to such member bank, that recklessly engages in an unsafe or unsound practice in conducting the affairs of such member banks or breaches any fiduciary duty which is part of a pattern of misconduct or causes more than a minimal loss to such member bank is subject to a civil penalty.	Federal Reserve Act authorizes the Board to: Section 29 Impose civil penalties on banks and affiliates for unsafe or unsound violations. Section 8 Impose civil penalties on any company or individual who violates the BHC Act. The Bank Secrecy Act Establishes civil money penalties for violation such as: - failure to file required currency transaction reports.	Section 29 ◆ Penalties up to \$5,000 for minimal violations and \$25,000 for unsafe and unsound violations. Section 8 ◆ Penalties of not more than \$25,000 for each day a violation occurs.

Consumer Product Safety Commission

Official	Statute	Area of Concern	Triggering Activity	Remedies
Commissioner, Consumer Product Safety Commission	Consumer Product Safety Act (15 USC § 2069)	The passage in 1972 of the Consumer Product Safety Act, and the creation of the United States Consumer Product Safety Commission, acknowledged the need for a national response to the thousands of reported injuries and deaths each year in accidents associated with consumer products. The U.S. Consumer Product Safety Commission administers the Consumer Product Safety Act (15 USC 2051, regulating risks of injury associated with consumer products); the Federal Hazardous Substance Act (15 USC 1261, applicable to certain hazardous household substances); the Poison Prevention Packaging Act of 1970 (15 USC 1471, requiring food, drugs, cosmetics, and hazardous household substances to be packaged in child resistant packaging); the Flammable Fabrics Act (15 USC 1191, dealing with the unreasonable risks of occurrence of fire leading to death or personal injury, or significant property damage, associated with fabrics and related materials, interior furnishings, and wearing apparel); and the Refrigerator Safety Act (15 USC 1211, enacted to prevent the entrapment of children in abandoned refrigerators). In addition to civil penalties, the Commission can order and set standards necessary to eliminate or reduce the risk of injury associated with a consumer product; order manufacturers, distributors, and retailers to inform consumers and to give public notice of a substantial product hazard; or ban products which present an unreasonable risk of injury for which no feasible consumer product safety standard would adequately protect the public.	Can assess civil penalties against any person who: * attempts to sell or distribute any consumer product which has been declared a banned, hazardous product by the CPSC. * manufactures for sale, offers for sale, distributes in commerce, or imports into the U.S. any consumer product which doesn't meet the CPSC's standards. * alters or destroys any part of a label on a hazardous substance while in interstate commerce. * who fails or refuses to permit access to or copying of records, or fails or refuses to establish or maintain records.	◆ Maximum penalty per violation - \$5000 ◆ Maximum for series of violations - 1.25 million

Agr. Tab

U.S. Department of Agriculture

Official	Statute	Area of Concern	Triggering Activity	Remedies
Secretary of Agriculture	Animal Welfare Act (7 USC § 2149)	Ensuring the humane care and treatment of animals used in research, exhibition, or as pets.	Any violation of the Act or regulations.	◆ \$2,500 civil penalty for each violation of the Act, ◆ \$1,500 civil penalty for failure to obey a cease and desist order issued by the Secretary under the Act.
Secretary of Agriculture	Pecan Promotion and Research Act of 1990 (7 USC § 6009)	Commodity research, promotion and consumer information program.	Violation of the Act, including failure to pay fees or assessments.	◆ Civil penalties from \$1,000 to \$10,000 per violation.
Secretary of Agriculture	Lime Promotion, Research, and Consumer Information Act of 1990 (7 USC § 6207)	Commodity research, promotion and consumer information program.	Violation of the Act, including failure to pay fees or assessments.	◆ Civil penalties from \$500 to \$5,000 per violation.
Secretary of Agriculture	Soybean Promotion, Research, and Consumer Information Act (7 USC § 6307)	Commodity research, promotion and consumer information program.	Violation of the Act, including failure to pay fees or assessments.	◆ \$1,000 civil penalties for each violation.
Secretary of Agriculture	Honey Research, Promotion, and Consumer Information Act (7 USC § 4610)	Commodity research, promotion and consumer information program.	Violation of the Act, including failure to pay fees or assessments.	◆ Civil penalties from \$500 to \$5,000 per violation.

Official	Statute	Area of Concern	Triggering Activity	Remedies
Secretary of Agriculture	Agricultural Marketing Agreement Act of 1937 (7 USC § 608c(14)(B))	Agricultural commodities and products.	Violation of an order issued by the Secretary regulating the handling of specific agricultural commodities and products.	◆ \$1,000 civil penalties for each violation of an order.
Secretary of Agriculture	Act of February 2, 1903 (21 USC § 122)	Prevention of the introduction and dissemination of animal disease.	Any violation of the Act or regulations.	◆ \$1,000 civil penalty for each violation of the Act.
Secretary of Agriculture	Plant Quarantine Act (7 USC § 163)	Prevention of the introduction and dissemination of plant pests and disease.	Any violation of the Act or regulations.	◆ \$1,000 civil penalty for each violation of the Act.
Secretary of Agriculture	Federal Plant Pest Act (7 USC § 150gg)	Prevention of the introduction and dissemination of plant pests.	Any violation of the Act or regulations.	◆ \$1,000 civil penalty for each violation of the Act.
Secretary of Agriculture	Horse Protection Act (15 USC § 1825)	Soring of horses.	Detection of soring of a horse through inspections of horse shows and exhibitions.	◆ \$2,000 civil penalty for each violation of the Act.

Official	Statute	Area of Concern	Triggering Activity	Remedies
Secretary of Agriculture	Packers and Stockyard Act (7 USC § 193)	Prevention of unfair, discriminatory, or deceptive practices by meat packers, stockyards, and poultry dealers.	Unfair, discriminatory or deceptive practices by meat packers, stockyards, and poultry dealers as identified by the Act.	♦ \$10,000 for each violation of the Act.

USDA CAN USE FINES TO STOP WHICH OF THE FOLLOWING OFFENSES?

Circuses mistreating elephants	YES
Dealers buying or selling dogs and cats without a license	YES
Incorrect weighing and accounting for livestock by packers	YES
A dealer selling undersized potatoes	YES
A zoo's improper treatment of its animals	YES
Failing to file reports with the onion committee	YES
Exchanging food stamps for cash	YES
A handler's failure to keep appropriate records on watermelons	YES
Interstate movement of certain livestock without a health certificate	YES
Violating food safety laws and regulations	NO

Mar. 6, 1998 11:40AM

No. 5040 P. 3/3
From: USDA

**TO PROTECT CONSUMERS, THE GOVERNMENT CAN
ORDER THE RECALL OF—**

Baby swings	YES
Infant formula	YES
Seat belts	YES
Coffee makers	YES
Juice extractors	YES
Cribs	YES
Toys	YES
Automobiles	YES
Gasoline	YES
Insecticides	YES
Meat	NO
Poultry	NO

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Incorrect weighing and accounting for livestock by packers

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A zoo's improper treatment of its animals

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Failing to file reports with the union committee

YES

Exchanging food stamps for cash

YES

A handler's failure to keep appropriate records on watermelons

YES

Interstate movement of certain livestock without a health certificate

YES

Violating food safety laws and regulations

NO

Rahim,
Here is the food
Safety chart I
promised yesterday
on fines & recalls.
You were interested
in attaching to
Reg. Reform.

Toma

**TO PROTECT CONSUMERS, THE GOVERNMENT CAN
ORDER THE RECALL OF—**

Baby swings	YES
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Seat belts	YES
Coffee makers	YES
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Rahn -

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Here is the

Incorrect weighing and accounting for livestock by packers

YES

food safety fines

A dealer selling undersized potatoes

YES

& recalls cost.

A zoo's improper treatment of its animals

YES

Great issue. You were

Failing to file reports with the onion committee

YES

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Exchanging food stamps for cash

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to Reg. Reform.

A handler's failure to keep appropriate records on watermelons

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Tou

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Poultry	NO

*Food
Safety Fruits/Veggies*

**INITIATIVE TO ENSURE THE SAFETY
OF IMPORTED AND DOMESTIC
FRESH FRUITS AND VEGETABLES**

STATUS REPORT





DEPARTMENT OF HEALTH AND HUMAN SERVICES
and
U.S. DEPARTMENT OF AGRICULTURE
Washington, D.C.



FEB 24 1998

The Honorable William Jefferson Clinton
The White House
Washington, DC 20500

Dear Mr. President:

Attached is our report, as requested in your October 2, 1997 Directive, on progress made on the Initiative to Ensure the Safety of Imported and Domestic Fruits and Vegetables. The report is a synopsis of the progress we have made in providing Good Agricultural Practices and Good Manufacturing Practices guidance to domestic and international growers, harvesters, handlers, and transporters of fresh fruits and vegetables.

The report also discusses our plans for extending existing programs in order to improve the monitoring of agricultural and manufacturing practices domestically and abroad, to assist domestic and foreign producers to improve those practices, where necessary, to prevent the distribution and importation of unsafe produce, and to accelerate research to support these activities.

Sincerely,

Donna E. Shalala
Secretary of Health and Human Services

Dan Glickman
Secretary of Agriculture

Enclosure

Initiative to Ensure the Safety of Imported and Domestic Fresh Fruits and Vegetables: Status Report

Background

American consumers enjoy one of the safest food supplies in the world. However, over the last several years there has been an increase in reported outbreaks of foodborne illness associated with both domestic and imported fresh fruits and vegetables. In May 1997, as part of the President's Food Safety Initiative, the Department of Health and Human Services (DHHS), the Department of Agriculture (USDA), and the Environmental Protection Agency (EPA) sent to the President a report that identified produce as an area of concern. On October 2, 1997, President Clinton announced a new initiative to ensure that our fruits and vegetables, including those imported from other countries, meet the highest health and safety standards.

The President called on Congress to give the Food and Drug Administration (FDA) the authority to better assure that food imports meet existing United States food safety laws and regulations. Legislation has been introduced in the House of Representatives that would enhance FDA's ability to ensure the safety of all foods imported into the U.S. The legislation would enhance FDA's ability to protect U.S. consumers while being consistent with U.S. trade rights and obligations.

In addition, the President directed the Secretary of Health and Human Services and the Secretary of Agriculture to work together in close cooperation with the agricultural community to develop the first-ever safety guidance for the growing, processing, shipping, and selling of fruits and vegetables. This voluntary guidance will address potential food safety problems throughout the production and distribution system and help ensure the sanitation and safety practices of all those seeking to sell produce in the U.S. market. This second component of the President's Directive — voluntary guidance — is an important outreach and education effort, reflecting the Administration's commitment to direct resources toward improving food safety and the availability of food safety technologies.

The President's FY 1999 budget includes funds necessary to expand FDA's international capabilities; full implementation in FY 1999 will be contingent on receiving adequate appropriations.

This Report

The President asked the two Secretaries to report back to him with a plan and schedule for developing this guidance. This report presents the progress made to develop voluntary guidance for the growing, processing, shipping, and selling of fruits and vegetables and the schedule and plans to accomplish these and the other elements of the President's produce initiative. To meet the President's goal that our produce meet the highest health and safety standards, the Departments will develop voluntary Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs) guidance for produce (henceforth referred to as guidance). GAPs cover production practices including growing, harvesting, handling, and transportation. GMPs primarily address harvesting and transportation, but also include aspects of manufacturing such as processing and packaging. GAPs and GMPs by necessity, overlap and are interrelated.

This report also describes interdependent activities that will help industry successfully apply the voluntary guidance. For example, the domestic and foreign industry may require technical assistance from U.S. agencies to effectively apply the voluntary guidance. Education and outreach efforts will be provided to the domestic and foreign industry and these activities will be based on a strong underlying, accelerated research program. In the long-term, research and risk assessment on fresh produce will be incorporated in the multi-year Food Safety Initiative research planning process. Development of this interagency research planning process is being facilitated by the White House Office of Science and Technology Policy.

The U.S. produce industry, states, and many countries exporting fresh fruits and vegetables to the U.S. have already taken significant steps to develop and implement improved agricultural practices and guidelines. Activities in this initiative, particularly in developing the voluntary GAP/GMP guidance, recognize this effort and build on it.

I. Good Agricultural Practices/Good Manufacturing Practices Guidance

Status: FDA, working with the USDA, is preparing a general GAP/GMP guidance document. FDA plans to publish the document as proposed voluntary guidance with opportunity for public comments. This guidance, titled "Guide to Minimizing Microbial Food Safety Hazards for Fresh Fruits and Vegetables", describes science-based good agricultural practices that farmers and producers may use for water quality, manure management, sanitation (both field and facility sanitation, as well as worker hygiene), and handling and transportation. The guidance also describes use of producer identification and information on the flow of the product through distribution channels. This information can facilitate source identification, should a commodity be associated with a foodborne illness outbreak. This guidance can be used by both domestic and foreign fresh fruit and vegetable producers to help ensure the safety of their produce. The guidance, which is a science-based evaluation of risks, will be consistent with World Trade Organization obligations and will not impose unnecessary or unequal restrictions or barriers on either domestic or foreign producers. The agencies recognize that appropriate use of pesticides and related antimicrobial agents play an important role in controlling microbial contamination, but caution that excessive or inappropriate use of these substances does not take the place of GAPs/GMPs.

FDA and USDA sponsored, with states, a series of public meetings from mid-November to mid-December, 1997, in which the agricultural community, the international trade community, consumers, and the scientific community participated. The purpose of these meetings was to give participants the opportunity to offer their perspective on the working draft guidance and provide comments, technical information, and suggested modifications to the draft guidance. The National Advisory Committee on Microbiological Criteria for Foods' Fresh Produce Subcommittee (a USDA/FDA advisory committee) was present at the first public meeting. Based on information exchanged at that first public meeting and Subcommittee members' expertise, the Subcommittee provided recommendations that were incorporated into the working draft guidance document. This revised working draft document was subsequently used as the basis of discussion at a series of meetings for the agricultural community. These "grassroots" meetings were held at six regional locations around the country during December. The agencies also presented the draft guidance to representatives of embassies and individuals associated with importing produce into the U.S. at an international meeting in December. Feedback from the agricultural community through the "grassroots" meetings and other fora is essential to be sure that the guidance being developed is practical and applicable. Development of the final guidance will draw on scientific data and

other information that describes the fresh fruit and vegetable industry domestically and in countries exporting products to the U.S.

FDA, with USDA, will oversee a task force (with representation from other federal agencies and states) to assist in developing additional guidance if sound science, risk, or experience with general guidance indicate a need. The additional guidance may be tailored to reduce the potential for microbial contamination with specific pathogens (e.g., *E. coli* O157:H7, *Cyclospora*) and to reduce contamination associated with particular hazards (e.g., microbially-derived toxins) and commodities. This type of guidance can also be designed to minimize microbial contamination through particular pathways, such as control of water quality, worker sanitation and health, field and facility sanitation, and transportation and handling of produce. Options are being explored to determine the most efficient ways to provide industry with effective guidance that yields the most benefit for the resources expended. Any additional guidance will be developed through an open process involving industry, consumers, academia, states, and public health professionals, including the FDA public review and comment process.

The general guidance may be augmented as information about scientific advances and risks associated with fresh produce received from a variety of sources, (e.g., foodborne illness outbreaks and research) indicates the need for targeted guidance or refinement of the general guidance.

Timeline:

Short-term — October - December 1997

- a. FDA drafted proposed voluntary GAP/GMP guidance
- b. FDA and USDA held a public meeting and a meeting of the National Advisory Committee on Microbiological Criteria for Foods to solicit comments and recommendations on the guidance
- c. FDA and USDA conducted grassroots and international meetings to receive comments and information from the public

Mid-term — January - May 1998

- a. FDA, working with representatives from USDA, EPA, Occupational Safety and Health Administration (OSHA), and the State Departments of Agriculture and of Health from California, Florida, and Michigan, will analyze comments and information from the public, grassroots, and international meetings and revise guidance incorporating that information
- b. Publish revised guidance as a proposal in the Federal Register
- c. Comment period of 75 days for public to submit comments and information pertaining to the guidance

Long-term — June 1998 and beyond

- a. Evaluate comments and revise guidance into final guidance
- b. Publish final guidance in the Federal Register by October 2, 1998
- c. Create an interagency committee to evaluate the need for additional guidance and, if additional guidance is needed, oversee and direct the development of that guidance
- d. Develop a strategy to refine existing guidance, incorporating advances in science and knowledge about produce safety and information about new risks
- e. Develop risk assessment techniques to use in evaluating the effectiveness of and refining (based on that evaluation) implemented food safety control strategies

Supporting Information: To complement data and information being developed domestically, comparable data and country information, such as epidemiologic data on human health and food safety legislation and regulations affecting production, handling, and storage of produce for selected countries that export produce to the U.S. will be compiled by mid-July, 1998.

Timeline:

Short-term — November 1997 - June, 1998

- a. Identify and compile current data concerning primary sources of fresh fruits and vegetables
- b. Identify and compile available data about domestic agricultural practices and foreign food safety legislation and regulation for selected countries that export produce to the U.S. This information will support the scientific (including evaluation of risks) approach.
- c. Identify gaps in current data

Mid-term — June - August 1998

Federal and state government agencies will develop a proposal to fill data gaps in consultation with industry

Long-term — September 1998 and beyond

Using available funding, implement a plan to fill gaps.

II. Technical Assistance and Education and Outreach

Technical Assistance:

Technical expertise and resources must complement the voluntary guidance to achieve improvement in the safety of fresh fruits and vegetables. The guidance will be most effective when safety is bolstered at every step in the process, from in-field operations through distribution to the consumer. U.S. government agencies, FDA and USDA in particular, will work with appropriate U.S. and foreign government public health and agricultural agencies, as well as with industry groups, to provide technical assistance needed to support appropriate application of the guidance by the produce industry. If a foreign government is interested in learning more about the U.S. guidelines and systems for assuring the safety of domestically produced and imported fresh fruits and vegetables, overseas personnel from USDA and State Department will collaborate as necessary to facilitate these visits. Likewise, in order to provide technical assistance or followup to foodborne illness outbreaks, these overseas personnel will facilitate visits of FDA and/or Centers for Disease Control and Prevention (CDC) investigators or scientists to foreign operations to ascertain the source of problems that may pose a safety hazard in produce exported to the U.S.

USDA and FDA plan to work with a broad spectrum of representatives from the public and private sector in foreign countries and in the U.S. to promote appropriate application of the guidance and improve production and processing practices. These include officials from the health and agriculture agencies in foreign countries, the Food and Agriculture Organization, the World Health Organization, and subsidiary organizations (e.g., Pan American Health Organization), as well as exporter associations and multinational banks. In the U.S., the agencies will work with appropriate land grant colleges and universities, state agencies, and industry associations. In working with domestic and foreign groups, it is critical that in addition to technical assistance, we provide clear guidance on the legal requirements for offering fresh food for sale in the U.S. With this understanding, the foreign and domestic government, industry, and academic groups can

guide producers' decisions about what, if any, modifications of current practices are appropriate for industry to satisfy U.S. legal requirements for foods. As part of this effort, USDA and FDA will share new technologies as they are developed to enhance the safety of fresh fruits and vegetables, such as improved manure treatment methods, more sensitive analytical methods, and post-harvest treatments to reduce levels of or eliminate pathogens on produce.

Timeline:

Short-term — November 1997 - September 1998

- a. Form an interagency cadre to establish procedures to develop technical assistance and education outreach programs, to identify gaps in data to understand agricultural practices, and to assess effectiveness of the programs
- b. Identify ongoing programs providing technical assistance to domestic producers and selected foreign countries that export to the U.S. related to produce safety
- c. Integrate the goals of the President's Directive into ongoing programs where appropriate
- d. Identify gaps where technical assistance may not be available

Long-term — September 1998 and beyond

- a. Develop and implement a strategy to provide technical assistance necessary to achieve the goals of the President's Directive
- b. Evaluate effectiveness of GAP/GMP guidance and update the guidance accordingly

Education and Outreach: Education and outreach programs are essential to foster appropriate application of the guidance by the domestic and international fresh fruit and vegetable industry. These programs are pivotal to industry's understanding of the essential principles of the guidance, as well as the scientific and practical reasons for application of the guidance as everyday production and processing practice. Others in the distribution chain from the fruit and vegetable producers to the final user—the consumer—must be reached by these programs in order to assure that the care taken to prevent microbial contamination in growing, harvesting, processing, and transporting is not thwarted by later mishandling.

USDA, through its partnership with State Cooperative Extension Services in the United States, will provide leadership for the Directive's producer outreach and educational strategy. USDA, FDA and CDC will plan a national food safety scientific and education conference in 1998 to share current scientific and educational information on food safety risks that can further enhance the microbiological safety of fresh fruits and vegetables, to apprise scientific experts and extension professionals of the voluntary general guidance document, and to discuss methods for promoting appropriate application of the guidance. The guidance will be incorporated into extension programs focused on the best management practices in fruit and vegetable production. It will also serve as a basis for directing program resources to help assure appropriate application of production practices which minimize contamination of fruits and vegetables. State and local extension agents can play a vital role in the successful application of the guidance, since they are knowledgeable about on-farm production practices and can provide expert advice on how producers can incorporate interventions recommended in the guidance to reduce the risk of microbial contamination at the farm level.

To reach the domestic produce industry workforce, the guidance and associated educational materials must be available in native languages and must use terms understood by this diverse community. Multi-lingual materials are also needed for use in foreign countries. To meet these needs, FDA and USDA will work with industry and foreign governments to provide translations of the guidance documents, as well as associated training and information materials, as the documents are finalized.

We anticipate that education and outreach activities will reach beyond the immediate needs of the growers, harvesters, processors, and distributors of fresh produce to the wholesale and retail segments of the industry and to the consumer. Expanded education efforts will be directed to increasing awareness of how to enhance the safety of fresh fruits and vegetables, as well as about use of safe practices for handling and storing fresh produce.

The information provided at the grassroots and international meetings will help the agencies prioritize outreach activities and preparation of materials. FDA and USDA anticipate drawing on the resources and expertise of other agencies and industry groups to provide outreach and education, particularly targeted to specific regional needs in the U.S. The agencies have met with representatives of state agriculture departments and the industry to begin discussions of how best to make available needed training and information. We anticipate that industry itself will be a primary vehicle for outreach and education activities.

In the international arena, USDA will be instrumental in facilitating the development of education and training programs. The USDA's International Cooperation and Development staff can facilitate development of cooperative training programs on the guidance, in collaboration with other agencies capable of providing funding for these activities. The State Department will facilitate FDA and USDA contacts with foreign governments and industry groups to inform them of the guidance and provide technical assistance. USDA will also explore mechanisms to obtain the resources and expertise from other international organizations, such as the Food and Agriculture Organization and the Inter-American Institute for Cooperation on Agriculture, in order to facilitate discussions on produce safety issues. FDA and USDA will evaluate the scope of GAP/GMP education programs and materials needed to educate foreign governments and organizations, factoring in information provided at the international meeting.

Timeline:

Short-term — March - May 1998

- a. Working with industry, develop a program to provide growers, harvesters, distributors, and other aspects of the industry with background and information about the hazards, particularly microbial, associated with fresh produce
- b. FDA and USDA will convene a National food safety and education conference on fruits and vegetables to discuss the draft guidance
- c. Pending finalization of the guidance, take preliminary steps to determine mechanisms for providing information and assistance to the domestic industry in applying guidance. Likewise, preliminary steps will be taken to develop a program targeted to foreign producers.

Mid-term — July - September 1998

- a. FDA and USDA will develop a strategy to educate producers and promote the appropriate application of the final voluntary general guidance which involves federal agencies, states, and the industry.

- b. Work with other groups (foreign governments, foreign industry groups) to develop a strategy for promoting the appropriate application of voluntary guidance

Long-term — October 1998 and beyond

- a. Develop a strategy for refining outreach efforts to meet needs identified by specific producer and industry sectors.

III. Focused Inspections and Verifying Application of Guidance

Inspection and Testing: Inspections of fresh fruit and vegetable operations in combination with sampling and testing provides FDA and USDA with scientific information about the microbial quality of both domestic and imported products. Identification of microbiological problems allows implementation of prevention or intervention measures before illness occurs. It also aids in targeting educational outreach and technical assistance.

FDA will expand its fresh fruit and vegetable inspection and testing program for domestic and imported produce. Additional resources will be focused particularly on sampling products from areas, in the U.S. and abroad, where there is evidence that a potential hazard exists and preventive measures are lacking.

Verification: Verifying the application of the guidance, particularly in segments of the industry where microbial foodborne illnesses have occurred, is integral to determining its effectiveness in reducing the risk associated with fresh fruits and vegetables. The USDA and FDA will use evaluation of risks and survey techniques, such as USDA's Fruit Survey and Vegetable Survey and FDA field surveys of processors, to determine the extent of application of the guidance by both the domestic and foreign industry and the effectiveness of the GAP/GMP program in reducing the occurrence of pathogenic microorganisms and the incidence of produce-associated illnesses. The first survey will be conducted to determine current practices, specifically those practices that have the most impact on public health and those that are covered in the general guidance. This baseline information will be augmented with information from other sources, such as foreign governments and state agencies, on current practices. A second, more extensive, survey on practices will be conducted at a later date. This information — from the surveys and other sources — will be used to evaluate application of the guidance and to make necessary adjustments in the GAP/GMP program, including refinements of the guidance.

Timeline: FDA's inspection and sample collection and analysis activities will be expanded. Increased inspection and testing efforts are budget dependent and would be desirable to help evaluate the effectiveness of the general and additional guidance. The verifying activity will begin in FY 1999.

IV. Accelerated Food Safety Research

Successful implementation of this initiative relies on scientific research and characterization of the risks to public health posed by microbial contamination. The overall research goal identified in this initiative is development of cost-effective intervention and prevention strategies to reduce the incidence of foodborne illness. Research will also support development of improved detection methods useful in a variety of environments and targeted to sources of contamination. These methods will be used to support long-term surveillance and monitoring of both domestic and

imported produce at the point of production and harvest (e.g., methods for detection of *Cyclospora* and Hepatitis A on produce) and to support development of control and prevention strategies that augment use of general and additional GAP/GMP guidance.

FDA and USDA both have vigorous research programs in areas related to development of pathogen detection and quantification methodology, as well as development of control and prevention interventions. EPA and USDA research would be conducted to assess the significance of pathogen concentrations in natural (free-flowing) and agricultural water supplies and potential subsequent contamination of fruits and vegetables through irrigation practices.

FDA and USDA are individually and collectively reviewing their respective FY 1998 research projects related to fresh fruits and vegetables to identify specific research that can be accelerated. USDA and FDA have held research planning meetings with other agencies conducting food safety related research, including the CDC, EPA, Department of Defense, Department of Energy, National Science Foundation, and National Institutes of Health (NIH). In addition, the agencies have met with industry and consumer representatives to determine what food safety research is currently ongoing or in the developmental stages outside the government and to identify research needs from this outside perspective.

The agencies are developing a coordinated research plan for reducing microbial risk in produce. The research plan is scheduled to be available in early 1998. Four specific areas for research focus have been identified as: improved detection methods, resistance to traditional preservation techniques, antibiotic resistance, and development of intervention strategies. Research is currently underway in all these areas. Among the areas to be further investigated are: packaging, storage, and preservation technologies; production practices; and use of post-harvest treatments to reduce levels of unavoidable microbial contamination. NIH research on pathogenicity and clinical human disease will support both development of detection methods and the risk assessments necessary to evaluate control strategies for the target pathogens.

Research and characterization of risks is a high priority. Research on preventive technologies and intervention strategies to reduce or eliminate microbial contamination is a specific priority. Work will be conducted on manure treatment or composting techniques to assure that the manure is acceptable for application to a specific commodity. Post-harvest chemical (such as use of antimicrobial agents in wash water) and physical treatments will be investigated for fruits and vegetables, as will methods of preventing the persistence and growth of pathogens on both whole and minimally processed produce during storage and transportation. Another area of research that will be accelerated is methods development, specifically methods to detect *Cyclospora* and Hepatitis A on produce. Studies of chemical pattern recognition (trace-element fingerprints) to identify where specific foods were grown or processed will also aid in tracebacks to determine both the source of foods and the pathogens implicated in foodborne illness outbreaks.

Timeline:

Short-term — September 1997 - March 1998

- a. Initiated interagency review of research related to safety of fresh fruits and vegetables
- b. Research plan will be available in early 1998 that will identify fresh fruit and vegetable-related research

Long-term — April 1998 and beyond

- a. Develop an ongoing process for interagency review of research progress and identification of new research needed
- b. Develop schedule for making the updated research plan available periodically

V. Participants in this Initiative

The following agencies are contributing to this initiative: the Food and Drug Administration, the National Institutes of Health, and the Centers for Disease Control and Prevention in the Department of Health and Human Services; the Agricultural Marketing Service, the Agricultural Research Service, the Animal and Plant Health Inspection Service, the Cooperative State Research, Education, and Extension Service, the Economic Research Service, the Foreign Agricultural Service, the Food Safety and Inspection Service, the National Agricultural Statistics Service, the Natural Resources Conservation Service, and the Office of Risk Assessment and Cost Benefit Analysis in the U.S. Department of Agriculture; the Environmental Protection Agency; the Department of Labor's Occupational Safety and Health Administration; and the Department of Defense's U.S. Army-Natick Research Development and Engineering Center are also working on segments of the initiative.

USDA CAN USE FINES TO STOP WHICH OF THE FOLLOWING OFFENSES?

Circuses mistreating elephants	YES
Dealers buying or selling dogs and cats without a license	YES
Incorrect weighing and accounting for livestock by packers	YES
A dealer selling undersized potatoes	YES
A zoo's improper treatment of its animals	YES
Failing to file reports with the onion committee	YES
Exchanging food stamps for cash	YES
A handler's failure to keep appropriate records on watermelons	YES
Interstate movement of certain livestock without a health certificate	YES
Violating food safety laws and regulations	NO

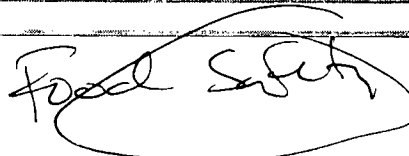
*Food
Safety*

**TO PROTECT CONSUMERS, THE GOVERNMENT CAN
ORDER THE RECALL OF—**

Baby swings	YES
Infant formula	YES
Seat belts	YES
Coffee makers	YES
Juice extractors	YES
Cribs	YES
Toys	YES
Automobiles	YES
Gasoline	YES
Insecticides	YES
Meat	NO
Poultry	NO

MAR. 6. 1998 11:40AM

NO. 5040 P. 2/3
From: USDA



Q&A for Presidential Initiative to Improve the Safety of Imported Fruits and Vegetables
October 10, 1997

Q: What did the Administration propose with regard to food safety?

A: I proposed legislative and executive actions that will further improve the safety of fresh fruits and vegetables, especially those imported into the U.S. The legislation will require the FDA to halt imports of fruits, vegetables, or other food from any foreign country whose food safety systems and standards are not on par with those of the U.S. I will back up this legislation by providing the necessary funds in my FY99 budget to enable FDA to expand dramatically its international food inspection force so that it can make good use of this new authority.

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report
In addition, I directed the Secretaries of Health and Human Services and Agriculture to take additional steps to improve the safety of both imported and domestic fruits and vegetables. Specifically, I asked the Secretaries to issue within one year guidance on good agricultural practices and good manufacturing practices for fruits and vegetables. By providing the first-ever specific safety standards for fruits and vegetables, the guidance will improve the agricultural and manufacturing practices of all those, foreign and domestic, seeking to sell produce in the U.S. market.

Q: Why is your Administration proposing these actions?

A: There have been dramatic changes in the produce department of the grocery store. Thirty years ago, most produce sections only had around a dozen items year round, increasing to as many as 50 in the summer. Today, the chances are that there are 400 or more items in the produce section and they are there all year round. Last year, 38 percent of the fruit and 12 percent of the vegetables Americans ate were imported.

We have changed as well. Americans are eating more fresh fruits and vegetables than ever before, and our nation's health experts tell us we will live longer, better quality lives as a result. Our environment is also changing. We are finding "new" exotic bugs such as cyclospora and *E. coli* O157:H7 on our food that once were not there.

We must ensure that these changes do not increase the risk to American consumers of foodborne illnesses. Although raw produce -- including that imported from foreign countries -- is now safe, experts have suggested ways to make further improvements, and my actions accord with their recommendations.

Q: Are you saying that imported produce is unsafe?

A: There is no data indicating that imported fruits and vegetables are more unsafe than domestic products. But some recent outbreaks of foodborne illness have been traced back

to imports and it is important that foreign fruits and vegetables be held to the same safety standards as American products. The steps we are taking today are adding additional layers of protection. I am making sure that there are no gaps in our food safety system -- that high safety standards apply to imported as well as domestic food, and to fruits and vegetables as well as to meat, poultry, and seafood.

Q: Will foreign countries have to comply with Good Agricultural and Manufacturing Practices if they want to export fruits and vegetables to the U.S.?

A: We expect that exporting countries will develop similar practices that address potential food safety problems in their countries for one simple reason: they want to be able to sell food in our market, and they want that food to be safe.

We do not know whether a country that does not comply with the new guidance will be able to import fruits and vegetables into the United States. The answer to this question depends on the exact content of the guidance, as well as on intricate legal determinations regarding equivalency between different countries' food safety systems. What is clear is that the FDA will have to cut off imports from countries that do not comply with existing legal standards applicable to domestic produce.

Q: Doesn't this legislation impose trade barriers to food imports at a time when you are saying you want to lower them? Is this legislation consistent with free trade?

A: This legislation is consistent with free trade and all our treaty obligations. We have no obligation to open our borders to imports that pose a greater risk than domestic products to American consumers. As long as we are not imposing any greater requirements on foreign countries -- as long as we are only holding them to our standards -- we are acting consistently with our trade policy.

Q: Are these actions meant to provide political cover with respect to the food safety issue because it has become a part of the Fast Track trade debate?

A: No. This is a part of my broad food safety agenda -- my longstanding commitment to ensuring that Americans' food supply is the safest in the world. It does not relate to Fast Track.

Q: What makes you think this new legislation can be effective? Do you seriously think you are going to be able to put FDA inspectors in every country abroad?

A: My proposed legislation would give the FDA the same kind of responsibility that the USDA already has for meat and poultry. The USDA system has worked well to ensure that countries with inferior safety standards can't import their meat and poultry. The

FDA should be able to run a similarly effective system that inspects food safety systems and standards abroad and prevents imports from countries that do not provide the protections that the U.S. does.

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

October 2, 1997

REMARKS BY THE PRESIDENT
ON FOOD SAFETY REGULATIONS

The Rose Garden

10:59 A.M. EDT

THE PRESIDENT: Thank you, Mr. Vice President, Secretary Shalala, Deputy Secretary Rominger, Cathie Woteki, Dr. Friedman, all the representatives of the groups that have helped us come to this day.

Our government made a fundamental promise to the American people of a bountiful and safe food supply way back at the beginning of this century. It is a promise that we have had to renew our commitment to periodically over the years, and a promise that needed a lot of work when I became President. From the day I took office, I worked very hard to honor that commitment, to make our food supply -- the world's safest -- even safer.

In 1993, the Vice President's national performance review recommended an overhaul of our food safety procedures so that we could use the best scientific technology available in inspection methods, to make sure that we had put in the best preventive controls to keep our food supply the world's safest.

Since then, we have taken major steps. We first put in place rigorous new safety standards for seafood, meat and poultry products, throwing out archaic and ineffective methods of inspection that had not been updated for nearly a century. We've required slaughterhouses to test for deadly E. Coli and salmonella bacteria. We've begun developing new safety standards for fruit and vegetable juices. We've strengthened our system of guaranteeing that our drinking water will remain safe, and improved public health protections for pesticide uses on food. And we brought a host of federal agencies together to boost food safety research, education and surveillance efforts around our nation. In so doing, we're using the world's best science to help prevent food contamination tragedies before they happen, to make sure our supply of food is as safe as it can be.

Today, our food supply remains the world's safest, but we can't rest on those accomplishments. We have to do more. At the time when Americans are eating more and more food from around the globe, we must spare no effort to ensure the safety of our food supply from whatever source.

Today, I want to tell you the new steps we're taking to ensure that our fruits and vegetables, including those imported from other countries, meet the highest health and safety standards. First, I'm asking Congress to give the Food and Drug Administration the power and the obligation to ban the importation of fruits, vegetables and other foods from countries whose safety precautions do not meet American standards. This new law would be similar to a law that already requires the United States Department of Agriculture to keep meat and poultry from countries with inferior food safety systems out of our stores.

In my next budget, I will provide enough funds to ensure that the FDA can fully implement this new legislation by dramatically expanding its international food inspection force. With these

MORE

efforts, we can make sure that no fruits and vegetables cross our borders, enter our ports, or reach our dinner tables without meeting the same strict standards as those grown here in America. Our food safety system is the strongest in the world, and that's how it's going to stay.

I'm also directing the Secretary of Health and Human Services and the Secretary of Agriculture to work together in close cooperation with the agricultural community to develop the first-ever specific safety standards for the growing, processing, shipping and selling of fruits and vegetables. These standards will address potential food safety problems throughout the production and distribution system, and they'll improve the sanitation and safety practices of all those seeking to sell produce in the United States market.

I'm asking Secretary Shalala and Glickman to report back to me within 90 days with a complete schedule for developing these standards within a year. I'll also ask them to submit a comprehensive plan to improve the monitoring of food safety programs abroad, to help foreign countries upgrade their safety precautions and toughen food inspections at the border.

Being a parent is perhaps the toughest job in the world. Our parents deserve the peace of mind that comes from knowing the food they set before their children is safe. With today's new actions, we can help make their jobs much easier.

And, again, let me thank all of those who were involved in this effort as I sign this order. Thank you very much.

(The order is signed.)

THE PRESIDENT: Thanks. (Applause.)

Q Mr. President, will you be using the line item veto

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THE PRESIDENT: Excuse me?

Q Will you be using the line item veto on any of the appropriations bills that you've just passed -- that you've just signed?

THE PRESIDENT: Well, let me say, I have received only -- I've received one memorandum for my staff on one bill. And that came in late last night, so I haven't read it. But I will consider it -- as the bills come in, I will ask for a review of the potential uses by specific bill and make judgments as we go along. I have nothing to report at this time, because I have received only one memorandum and I haven't read it.

Q What about the census, sir? Do you have any concerns concerning the Commerce bill and the particular ways that the money will be used for the census?

THE PRESIDENT: Well, my feeling is that we ought to do the census as well as we can. I don't think this is a complicated issue. The National Science Foundation has recommended this statistical sampling method. The man who did President Bush's census says that it's the only way to get the most accurate count. I just want to do whatever the Census Bureau believes, the full-time professionals, believe is the most accurate thing to do.

I think that's a heavy constitutional responsibility we have, to conduct a census that is as accurate as possible based on what the professionals say. This ought to be a professional, not a political judgment. And that's the position I will take throughout.

MORE

Q Mr. President, did the Democratic Party send money to the states because of federal election law restrictions?

Q Mr. President, there are fresh fruit and vegetables producers that are saying --

THE PRESIDENT: Well, wait a minute. I'll take both of them. Go ahead first.

Q There are fresh fruit and vegetable producers that are saying that you're acting with this action as the world food police and that your actions here today are unwarranted and that's going to complicate the trade environment.

THE PRESIDENT: Well, I hope it doesn't complicate the trade environment. But, you know, it seems to me that we have no higher responsibility than to protect the health and safety of our citizens, and everyone who has been following all of your reporting over the last four or five years knows that we have had continuing challenges in food safety. We have millions of people who get sick every year. And we're not trying to unfairly target foreign producers of food into our market; we don't ask them to meet any standards we don't meet. And indeed, if you look at the actions of this administration over the last four years, when we started, I think you can make a compelling case that we started working on things that were problems coming out of the American market first. So I just don't think that's right.

I don't want it to complicate the trade environment, but I'm not interested in trade in things that will make the American people sick.

Q Mr. President, did the Democratic National Committee send money to the states in order to get around the federal spending limits that went along with accepting federal money for the national campaign, sir?

THE PRESIDENT: It's my understanding that everything the Democratic National Committee did had the prior approval of the lawyers. If they cleared it all in advance, then it was perfectly legal. And when this issue was raised about a year ago, the exact issue, I believe that that was clarified at that time. I'm sure that they had legal advice that they followed, and I believe the Republicans said that they did some of the same things and also had prior legal clearance.

Q Mr. Clinton, do you that Mrs. Reno -- she's been advised to go forward with the 90-day investigation into the fundraising calls of the Vice President -- and perhaps Mr. Gore would like to comment, too --

THE PRESIDENT: I think that --

Q -- do you feel that the 90-day investigation would be helpful?

THE PRESIDENT: Well, if you read the statute, she can consider certain things in the 90-day period that are not permitted in the 30-day period. But I think this is a legal question and it should be done based on an independent legal review with no pressure from the outside, from me or from anyone else. And that's the way I intend to keep it, at least on my part.

Thank you.

END

11:09 A.M. EDT

THE WHITE HOUSE
Office of the Press Secretary

Food Safety

For Immediate Release

October 2, 1997

October 2, 1997

MEMORANDUM FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES
THE SECRETARY OF AGRICULTURE

SUBJECT: Initiative to Ensure the Safety of Imported
and Domestic Fruits and Vegetables

American consumers today enjoy the safest food supply in the world, and I am proud of my Administration's record in this area. We have taken significant steps to ensure that we maintain the safest food possible. We have put in place improved safety standards for meat, poultry, and seafood products, and we have begun the process of developing enhanced safety standards for fruit and vegetable juices. We have also expanded research, education, and surveillance activities through coordinated efforts of all agencies involved in food safety issues. Together, these measures will greatly improve the safety of the Nation's food supply.

We need to build on these efforts, and today I ask you to do so by focusing on the safety of fruits and vegetables. Although the produce Americans eat is very safe, we can and must do even better, especially at a time when Americans are eating more fruits and vegetables from all over the world. Last year, 38 percent of the fruit and 12 percent of the vegetables consumed by Americans came from overseas. We must ensure that fruits and vegetables coming from abroad are as safe as those produced in the United States, especially as we upgrade our own domestic standards.

To help accomplish this task, I plan to send to the Congress proposed legislation that will require the Food and Drug Administration (FDA) to halt imports of fruits, vegetables, or other food from any foreign country whose food safety systems and standards are not on par with those of the United States. This legislation, which will be similar to existing law requiring the USDA to halt the importation of meat and poultry from such countries, will enable the FDA to prevent the importation of potentially unsafe foreign produce. My Fiscal Year 1999 budget will provide the necessary funds to enable the FDA to expand dramatically its international food inspection force. With this greatly increased ability to inspect food safety conditions abroad and at points of entry, the FDA will be able to determine when to halt the importation of fruits and vegetables from foreign countries.

Today, I hereby direct two administrative actions that will better ensure the safety of fruits and vegetables coming from abroad, while continuing to improve the safety of domestic produce.

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(OVER)

First, I direct the Secretary of Health and Human Services, in partnership with the Secretary of Agriculture and in close cooperation with the agricultural community, to issue within 1 year from the date of this memorandum, guidance on good agricultural practices and good manufacturing practices for fruits and vegetables. This guidance should address ways to prevent potential sources of contamination, should take into account differences in both crops and regions, and should address food safety issues throughout the food production and distribution system. By providing the first-ever specific safety standards for fruits and vegetables, the guidance will improve the agricultural and manufacturing practices of all those seeking to sell produce in the U.S. market. To ensure that this guidance has the widest possible effect, I also direct the development of coordinated outreach and educational activities.

Second, I direct the Secretary of Health and Human Services and the Secretary of Agriculture, to report back to me within 90 days from the date of this memorandum with a status report and complete schedule for the good agricultural and manufacturing practices, and a plan on how to improve the monitoring of agricultural and manufacturing practices abroad, to assist foreign countries to improve those practices where necessary, and to prevent the importation of unsafe produce, including by detecting unsafe food at the dock or border. I especially urge you to consider the best ways to target inspection and testing toward those areas where problems are most likely to occur.

In addition to taking these actions, you should accelerate whatever food safety research is necessary to support them. You should also call upon the Environmental Protection Agency, the Department of Labor, and other agencies as necessary to provide you with assistance in achieving this goal. These steps, taken together and in coordination with the proposed legislation I will send to the Congress, will improve the safety of fruits and vegetables for all Americans.

WILLIAM J. CLINTON

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THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

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THE PRESIDENT: I think that --

Q -- do you feel that the 90-day investigation would be helpful?

THE PRESIDENT: Well, if you read the statute, she can consider certain things in the 90-day period that are not permitted in the 30-day period. But I think this is a legal question and it should be done based on an independent legal review with no pressure from the outside, from me or from anyone else. And that's the way I intend to keep it, at least on my part.

Thank you.

END

11:09 A.M. EDT

THE WHITE HOUSE
Office of the Press Secretary

Food Safety

For Immediate Release

October 2, 1997

October 2, 1997

MEMORANDUM FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES
THE SECRETARY OF AGRICULTURE

SUBJECT: Initiative to Ensure the Safety of Imported
and Domestic Fruits and Vegetables

American consumers today enjoy the safest food supply in the world, and I am proud of my Administration's record in this area. We have taken significant steps to ensure that we maintain the safest food possible. We have put in place improved safety standards for meat, poultry, and seafood products, and we have begun the process of developing enhanced safety standards for fruit and vegetable juices. We have also expanded research, education, and surveillance activities through coordinated efforts of all agencies involved in food safety issues. Together, these measures will greatly improve the safety of the Nation's food supply.

We need to build on these efforts, and today I ask you to do so by focusing on the safety of fruits and vegetables. Although the produce Americans eat is very safe, we can and must do even better, especially at a time when Americans are eating more fruits and vegetables from all over the world. Last year, 38 percent of the fruit and 12 percent of the vegetables consumed by Americans came from overseas. We must ensure that fruits and vegetables coming from abroad are as safe as those produced in the United States, especially as we upgrade our own domestic standards.

To help accomplish this task, I plan to send to the Congress proposed legislation that will require the Food and Drug Administration (FDA) to halt imports of fruits, vegetables, or other food from any foreign country whose food safety systems and standards are not on par with those of the United States. This legislation, which will be similar to existing law requiring the USDA to halt the importation of meat and poultry from such countries, will enable the FDA to prevent the importation of potentially unsafe foreign produce. My Fiscal Year 1999 budget will provide the necessary funds to enable the FDA to expand dramatically its international food inspection force. With this greatly increased ability to inspect food safety conditions abroad and at points of entry, the FDA will be able to determine when to halt the importation of fruits and vegetables from foreign countries.

Today, I hereby direct two administrative actions that will better ensure the safety of fruits and vegetables coming from abroad, while continuing to improve the safety of domestic produce.

more

(OVER)

First, I direct the Secretary of Health and Human Services, in partnership with the Secretary of Agriculture and in close cooperation with the agricultural community, to issue within 1 year from the date of this memorandum, guidance on good agricultural practices and good manufacturing practices for fruits and vegetables. This guidance should address ways to prevent potential sources of contamination, should take into account differences in both crops and regions, and should address food safety issues throughout the food production and distribution system. By providing the first-ever specific safety standards for fruits and vegetables, the guidance will improve the agricultural and manufacturing practices of all those seeking to sell produce in the U.S. market. To ensure that this guidance has the widest possible effect, I also direct the development of coordinated outreach and educational activities.

Second, I direct the Secretary of Health and Human Services and the Secretary of Agriculture, to report back to me within 90 days from the date of this memorandum with a status report and complete schedule for the good agricultural and manufacturing practices, and a plan on how to improve the monitoring of agricultural and manufacturing practices abroad, to assist foreign countries to improve those practices where necessary, and to prevent the importation of unsafe produce, including by detecting unsafe food at the dock or border. I especially urge you to consider the best ways to target inspection and testing toward those areas where problems are most likely to occur.

In addition to taking these actions, you should accelerate whatever food safety research is necessary to support them. You should also call upon the Environmental Protection Agency, the Department of Labor, and other agencies as necessary to provide you with assistance in achieving this goal. These steps, taken together and in coordination with the proposed legislation I will send to the Congress, will improve the safety of fruits and vegetables for all Americans.

WILLIAM J. CLINTON

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5542

President's Council on Food Safety

Old Executive Office Building, Room 324
December 16, 1998
10:00 a.m. — 11:00 a.m.

- 10:00** **Introductions and Opening Remarks**
 Dan Glickman
 Secretary, United States Department of Agriculture
- Donna Shalala**
 Secretary, United States Department of Health and Human Services
- Neal Lane**
 Assistant to the President for Science and Technology and
 Director of the Office of Science and Technology Policy
- 10:05** **Elements of the Executive Order**
 Bruce Reed, Assistant to the President for Domestic Policy
- 10:10** **Discussion and Approval of Charter**
 Catherine E. Woteki, Under Secretary for Food Safety, USDA
- 10:15** **Discussion and Approval of Council's Scope**
 Lynn R. Goldman, Assistant Administrator for Prevention, Pesticides and Toxic Substances, EPA
- 10:30** **FY2000 Budget and Future Crosscut**
 Jacob Lew, Director of the Office of Management and Budget
- 10:40** **Comprehensive Plan**
 James A. O'Hara, Deputy Assistant Secretary for Health, HHS
- 10:45** **NAS Report Assessment**
 Cliff Gabriel, Office of Science and Technology Policy
- 10:50** **Joint Institute for Food Safety Research**
 Eileen Kennedy, Deputy Under Secretary for Research, Education and Economics, USDA
 William Raub, Deputy Assistant Secretary for Science Policy, HHS
- 10:55** **Closing Remarks**
 Dan Glickman
 Secretary, United States Department of Agriculture
- Donna Shalala**
 Secretary, Health and Human Services
- Neal Lane**
 Assistant to the President for Science and Technology and
 Director of the Office of Science and Technology Policy

16y 20:00
2/21/99

BACKGROUND

On January 25, 1997, the President announced his food safety initiative. He directed the Secretaries of Agriculture and Health and Human Services and the Administrator of the Environmental Protection Agency to identify ways to further improve the safety of the food supply. Those agencies held public meetings with consumers, producers, industry, states, universities, and the public, and reported back to the President. The Report, issued in May 1997, was entitled *Food Safety from Farm to Table, A National Food-Safety Initiative*. To implement the report, USDA and HHS submitted joint budget requests for pathogen research, surveillance, risk assessment, inspection, and education for FY98, FY99 and FY 2000.

The report made a commitment to prepare a comprehensive 5-year strategic plan, with the participation of all concerned parties. The President's Council on Food Safety was established in August 1998 under E.O. 13100 to: 1) develop a comprehensive strategic Federal food safety plan; 2) advise agencies of priority areas for investment in food safety and ensure that Federal agencies annually develop coordinated food safety budgets for submission to the Office of Management and Budget (OMB); and 3) ensure that the Joint Institute for Food Safety Research (JIFSR) establishes mechanisms to guide Federal research efforts toward the highest priority food safety needs.

A coordinated food safety strategic planning effort is needed to build on common ground and to tackle some of the difficult public health, resource, and management questions facing Federal food safety agencies. The strategic plan will focus on not just microbial contamination but the full range of issues that are discussed in the scope of the food safety decision paper. It will also identify actions necessary to ensure the safety of the food Americans consume. The charge is to develop a comprehensive strategic long-range plan that addresses the steps necessary to achieve a seamless food safety system including key public health, resource, and management issues regarding food safety. The plan will be used to set priorities, improve coordination and efficiency, identify gaps in the current system and mechanisms to fill those gaps, continue to enhance and strengthen prevention and intervention strategies, and develop performance measures to show progress. Each agency will incorporate the relevant parts of the strategic plan into its Government Performance and Results Act (GPRA) strategic plan, commensurate with its budget.

In developing the strategic plan, the Council will consult with all interested parties and will consider both short-term and long-term issues including new and emerging threats, and the special needs of vulnerable populations such as children and the elderly.

Additionally, at the request of Congress, the National Academy of Sciences (NAS) conducted a study of the current food safety system to: 1) determine the scientific basis of an effective food safety system; 2) assess the effectiveness of the current system; 3) identify scientific and organizational needs and gaps; and 4) provide recommendations on scientific and organizational changes needed to ensure an effective food safety system. The NAS released its findings, conclusions, and recommendations in an August 20, 1998 report, *Ensuring Safe Food from Production to Consumption*.

The following papers address the Charter of the President's Council on Food Safety and the process for preparing an assessment of the NAS report, for developing a Food Safety Strategic Plan for all Federal food safety agencies, and for coordinated food safety Federal budgets.

(Final 12/11)

PRESIDENT'S COUNCIL ON FOOD SAFETY

CHARTER

Article I: Purpose.

On August 25, 1998, the President, by Executive Order 13100, established the President's Council on Food Safety ("Council") to improve the safety of the food supply through science-based regulation and well-coordinated inspection, enforcement, research, and education programs. The purpose of the Council is to protect the health of the American people by preventing foodborne illness through improving the safety of the food supply by means of science-based regulation and well-coordinated surveillance and investigation, inspection, enforcement, research, and educational programs. The Council is to: develop and update periodically a comprehensive strategic plan for Federal food safety activities; make recommendations to the President on how to implement the comprehensive strategy and enhance coordination among Federal agencies, State, local and tribal governments, and the private sector; advise Federal agencies in setting priority areas for investment in food safety and developing a coordinated food safety budget for the Administration; and to oversee research efforts of the Joint Institute for Food Safety Research. The President also directed the Council to evaluate and report back to him on the proposals contained in the National Academy of Sciences (NAS) report on food safety.

This Charter provides the basis for collaboration among the members of the Council in carrying out its responsibilities as set forth in the Executive Order.

Article II: Membership

The following individuals shall be members of the Council:

1. Secretary of Agriculture,
2. Secretary of Commerce,
3. Secretary of Health and Human Services,
4. Administrator of the Environmental Protection Agency,
5. Director of the Office of Management and Budget,
6. Assistant to the President for Science and Technology/Director of the Office of Science and Technology Policy,
7. Assistant to the President for Domestic Policy, and
8. Director of the National Partnership for Reinventing Government.

Each member may designate a senior Federal employee to serve as an alternate representative to perform the duties of the Council member.

Article III: Co-Chairs

The Secretaries of Agriculture and of Health and Human Services and the Assistant to the President for Science and Technology/Director of the Office of Science and Technology Policy, or their designated alternates, shall serve as co-chairs of the Council.

The co-chairs shall provide leadership and direction to the Council, and coordinate the formation and schedule of standing committees. Each meeting will be led by one co-chair, and this responsibility shall rotate quarterly among the co-chairs.

Article IV: Staff Support Services

Staff support services for the activities of the Council will be provided by the Co-Chairs through a Secretariat, which will consist of a senior Federal employee from the Department of Agriculture and one from the Department of Health and Human Services. Other members may provide additional staff support services, as necessary. The Secretariat will facilitate planning, coordination, and communication among Council members.

Article V: Meetings

The Council shall meet on a quarterly basis at a time and location chosen by the co-chairs. Additional meetings may be held at the call of the co-chairs or at the request of a majority of the members.

A majority of the Council membership shall constitute a quorum for the transaction of business. All decisions made by the Council at the meetings shall be by consensus defined as substantial agreement as determined by the chair.

The Secretariat will prepare updates of the Council's activities and make the information available for public inspection and copying and on the Council Internet web site.

The Council will prepare a report for submission to the President on October 1 of each year. The report will contain, at a minimum, a description of the Council's activities and accomplishments during the preceding fiscal year, a description of the planned activities for the coming year, a review of strategic planning objectives, and progress made toward accomplishing those objectives.

Article VI: Duties and Responsibilities

The specific responsibilities of the Council are to:

1. Develop and update periodically a comprehensive strategic Federal food safety plan ("plan") to reduce the incidence of foodborne illness and its chronic sequelae by further

enhancing the safety of the nation's food supply and monitoring the impact of these enhancements. The plan will address public health, resource, and management questions facing Federal food safety agencies and will focus on the full range of food safety issues, including the needs of regulatory agencies and the actions necessary to ensure the safety of the food Americans consume. The planning process will consider both short-term and long-term issues including new and emerging threats to the nation's food supply and the special needs of vulnerable populations such as children and the elderly. In developing this plan, the Council will take into consideration the findings and recommendations of the NAS report "Ensuring Safe Food from Production to Consumption" and the review of Federal food safety research by the interagency working group under the auspices of the National Science and Technology Council.

The strategic plan will help set priorities, improve coordination and efficiency, identify gaps in the current system and ways to fill those gaps, enhance and strengthen prevention and intervention strategies, and identify reliable measures to indicate progress.

The Council will conduct public meetings to engage consumers, producers, industry, food service providers, retailers, health professionals, State and local governments, Tribes, academia, and the public in the strategic planning process.

2. Consistent with the strategic plan, advise Federal agencies of priority areas for investment in food safety and work with member agencies in developing annual food safety budgets for submission to the Office of Management and Budget (OMB) to sustain and strengthen priority activities on food safety, eliminate duplication, and ensure the most effective use of resources for achieving the goals of the plan.

3. Oversee the Joint Institute for Food Safety Research (JIFSR). The Council will evaluate the reports from JIFSR on food safety research activities and give direction to JIFSR on research needed to establish the most effective possible food safety system.

4. Evaluate and report to the President on the NAS report, "Ensuring Safe Food from Production to Consumption". After providing opportunity for public comment, including public meetings, the Council will, by February 21, 1999, report to the President on the Council's response to and recommendations concerning the NAS report and appropriate additional actions to improve food safety.

Article VII: Committees

The co-chairs, after consultation with Council members, shall establish committees of Council members, their alternates, or other Federal employees, as they deem necessary, to facilitate and carry out effectively the responsibilities of the Council. Such committees shall report to the Council.

The following committee shall be established by the co-chairs:

JIFSR Executive Research Committee

This committee will evaluate the reports from the JIFSR on its efforts to coordinate food safety research and make recommendations to the Council regarding research needed to establish the most effective possible food safety system.

Article VIII: Web Site

The Council shall establish an Internet web site. The Department of Agriculture shall be the system owner of the web site and shall be responsible for maintaining it. The Council website will provide links to websites of all federal agencies having food safety responsibilities.

Article IX: Effective Date

This Charter shall become effective on the latest date affixed below and may be modified with supplemental agreements signed by all the members of the Council.

Secretary of Agriculture

Secretary of Commerce

Secretary of Health
and Human Services

Administrator of Environmental
Protection Agency

Director of Office
of Management and Budget

Assistant to the President for Science
and Technology/Director of the
Office of Science and Technology
Policy

Assistant to the President
for Domestic Policy

Director of the National Partnership
for Reinventing Government

Discussion Paper: Assessment of NAS Report "Ensuring Safe Food from Production to Consumption"

Action Required: Approval of plan to provide the President with an assessment of the NAS Report "Ensuring Safe Food from Production to Consumption."

BACKGROUND: In response to the Congressionally mandated Food Safety study, the National Academy of Sciences (NAS) established a study committee and obtained input from Federal agencies and other stakeholders of the Federal food safety system. The NAS issued its report on August 20, 1998. Congress viewed this study as part one of a possible two-part process. Had the NAS recommended that a single Federal food safety agency be required to achieve adequate performance and levels of public health protection, Congress planned to appropriate additional funds to support a second NAS study, which would focus on how such an agency should function. The NAS Committee did not explicitly recommend the establishment of a single Federal food safety agency, and funds for part two were not appropriated for fiscal year 1999. On August 25, 1998, the President issued a directive tasking the Council on Food Safety to provide him with an assessment of the NAS report in 180 days (by February 21, 1999). Specifically, the President directed:

"...the Council to review and respond to this report as one of its first orders of business. After providing opportunity for public comment, including public meetings, the Council shall report back to me within 180 days with its views on the NAS's recommendations. In developing its report, the council should take into account the comprehensive strategic Federal food safety plan that it will be developing."

Four public meetings have been held to solicit stakeholder input on the NAS report (October 2, in Arlington, VA; October 20, in Sacramento, CA; November 10, in Chicago, IL; and December 8 in Dallas, TX).

RECOMMENDATION: The Interagency Food Safety Working Group recommends that the Council establish a task force consisting of one representative from each of the following agencies: OSTP, HHS, USDA, EPA, OMB, and DOC. This 6 person task force will systematically assess the NAS report by providing a) agency/department specific analysis of the strengths and weaknesses of the report's findings and recommendations, including whether the agency/department agrees or disagrees and why; b) an assessment of the cross-agency/department issues identified by the report; and c) recommendations on whether to incorporate particular elements of the NAS report into the Council's comprehensive strategic plan. If appropriate, the task force should identify barriers to implementation. Each task force representative will be responsible for coordinating input from within his or her own agency. The task force will be chaired by OSTP and will provide a draft report to the Council by February 5, 1999. Once the report is submitted to the President by February 21, 1999, the Council may seek additional public input on its assessment of the NAS report's recommendations.

DISCUSSION PAPER: Process for developing a Food Safety Strategic Plan for all Federal food safety agencies

ACTION REQUIRED: Approval of a process for preparing a food safety strategic plan

The President's Council on Food Safety will be responsible for development of a 5-year Federal food safety strategic plan. The charge is to develop a comprehensive strategic long-range plan that addresses the steps necessary to achieve a seamless food safety system including key public health, resource, and management issues regarding food safety and to ensure the safety of food. The plan will be used to set priorities, improve coordination and efficiency, identify gaps in the current system and mechanisms to fill those gaps, continue to enhance and strengthen prevention and intervention strategies, and develop performance measures to show progress. Each agency will incorporate the relevant parts of the strategic plan into its Government Performance and Results Act (GPRA) strategic plan, commensurate with its budget. The scope of the strategic plan (e.g., microbial vs. chemical contamination) is to be determined by the Council.

The food safety agencies have already taken the first steps to develop the food safety strategic plan, by participating in interagency strategic planning sessions and developing a draft vision statement for the U.S. food safety system and the roles of all those involved in food safety.

In addition, during 1997 and 1998, the federal food safety agencies engaged a wide range of stakeholders in discussions about food safety issues through a series of public meetings and through written comments to public dockets.

RECOMMENDATION: Convene a committee to develop a comprehensive food safety strategic plan based on the recommendations received from the various constituencies. The committee will consist of representatives from each of the following agencies: HHS, USDA, EPA, CDC, and NPR.

The committee will follow the following process:

- First conduct a content analysis of the transcripts and dockets of the 1998 meetings and public comments to determine the major themes, issues, and subject areas that emerged during the public outreach phase.
- Consider the conclusions and recommendations of the National Academy of Sciences' report on *Ensuring Safe Food from Production to Consumption*, the review of Federal food safety research and the research plan currently being developed by an interagency working group under the auspices of the National Science and Technology Council, input from the 50-State meeting on state/local issues and recommendations, and input from the agencies involved.
- Develop a proposed set of strategic goals and objectives and present a draft strategic plan to the President's Council.



To: President's Council on Food Safety
Fax #: (See DISTRIBUTION LIST)
Re: Materials for December 16, 1998 Council Meeting
Date: December 11, 1998
Pages: 14, including this cover sheet.

FACSIMILE

Enclosed are: an Agenda for the December 16, 1998, meeting; a background paper; and papers that address the Charter of the President's Council on Food Safety, an assessment of the NAS report, the process for developing a Food Safety Strategic Plan for all Federal food safety agencies, and the process for coordinated Federal food safety budgets.

DISTRIBUTION LIST:

Eric Olsen, USDA-OSEC	720-2166
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Mark Weatherly, OMB	395-4941
Dana Flower Lake, OMB	395-4941
Jean Logan, NPR	632-0390
Steve Dewhurst, USDA-OBPA	720-6067
Tom Billy, USDA-FSIS	690-4437

From the desk of...

A. Charles Danner
 USDA-FSIS
 Office of Management
 Room 347-E, Whitten Building
 14th & Independence Ave., SW
 Washington, DC 20250

202-720-4425
 Fax: 202-690-1742

To: President's Council on Food Safety

Fax # (See Distribution List)

Re: Materials for December 16, 1998 Council Meeting

Date: December 14, 1998

Pages: 15, including this cover sheet.

Enclosed is the Discussion Paper on the "Scope of the Council's Comprehensive Strategic Food Safety Plan". This should be added to the material received Friday for the meeting this coming Wednesday. Please call Judy Nelson at 202-260-4177 if there are problems with this fax.

DISTRIBUTION LIST:

Eric Olson, USDA-OSEC	720-2166
Cathie Woteki, USDA-OFS	690-0820
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Dana Flower Lake, OMB	395-4941
Jean Logan, NPR	632-0390
Steve Dewhurst, USDA-OBPA	720-6067
Tom Billy, USDA-FSIS	690-4437
Keith Pitts, USDA-OSEC	720-2166

DISCUSSION PAPER: Scope of the Council's Comprehensive Strategic Food Safety Plan

ACTION REQUIRED: Decision on the scope--what's in and what's out--of the Council's initial actions and comprehensive strategic Federal food safety plan.

INTRODUCTION: The Food Safety Initiative (FSI) initially focused on the goal of reducing the number of illnesses caused by microbial contamination of food and water. This past summer when the food safety agencies developed the draft vision statement, it was assumed that the scope of the strategic plan would be broadened beyond the FSI to include chemical hazards in the food supply. The National Academy of Sciences (NAS) report broadly defined food safety as "not only the avoidance of foodborne pathogens, chemical toxicants, and physical hazards, but also issues such as nutrition, food quality, labeling, and education". While the scope of the NAS study included all these components, the report focused primarily on microbial, chemical and physical hazards from "substances that can cause adverse consequences" in domestically-produced and imported foods, including additives, pesticides and animal drug residues.

"Food safety", as used in this paper, includes public health concerns arising in both traditional and novel (e.g., genetic modification) methods of food production, processing, and preparation and covers domestic as well as imported foods. For the Council's purposes in determining the scope of the strategic plan, this paper identifies two categories of activities: "core food safety activities" and "collateral" or related activities. "Core food safety activities" include programs or activities whose mission or purpose is to enhance the safety of the nation's food supply and protect public health by reducing the annual incidence of acute and chronic foodborne illness. Other key considerations in defining "core" activities include: relative public health risks, need for interagency coordination, and public perception.

"Collateral activities" are related to and have implications for food safety but are undertaken to serve another primary purpose or mission, such as insuring fishable and swimmable waters. Specific "core" research or regulatory actions may need to be coordinated with these collateral activities, and vice versa, but "collateral activities" will not be included in the strategic plan. Collateral activities will be identified for coordination or integration as the need arises, and, in the future, could be brought within the scope of the strategic plan and the Council's work.

This framework is designed to allow the Council to focus on "core" activities that have a direct impact on food safety. Once developed, the strategic plan should assist the agencies to address the important food safety challenges by identifying priorities and making the best use of limited resources. This paper does not, therefore, determine priorities within the scope for Federal attention and resources, but rather leaves those decisions to the strategic planning process. Further, activities within the scope may not all be addressed in the same depth or at the same time in the plan depending on the assessment of the public health risks and potential benefits of action. The scope of the coordinated annual budgets may be the same or a subset of the strategic plan (or might even include a collateral activity if it was deemed appropriate). The strategic plan will inform the budget deliberations, but it may not be necessary or feasible to develop joint budgets in the first few years that are as broad as the plan.

RECOMMENDATION: It is recommended that the Council and the strategic plan focus on "core food safety activities" defined as microbial hazards, chemicals (chemical contaminants and

regulated substances with and without pre-market approval), physical hazards, and hazards from water used in food processing and from water and manures used in production on the farm. Other “collateral activities” that are less directly related to the safety of the food supply will be considered for collaborative efforts or enhanced coordination on a specific, targeted basis as needed. Included in this second category are: the nutrition programs and certain other waterborne hazards (e.g., drinking water/direct consumption, water for recreation).

Table 1: Food Safety Activities & Recommended Categorization for Scope Purposes

	Core	Collateral
Microbial Hazards	X	
Chemical Contaminants	X	
Regulated/Pre-Market Approved Substances	X	
Regulated/No Pre-Market Approval Substances	X ¹	
Physical Hazards	X	
Water Used in Food Production & Processing	X	
Drinking Water/Direct Consumption & Water For Recreation		X
Nutrition Programs		X

Microbial hazards in food and water, as defined in the FSI, will be addressed by the Council and in the strategic plan. Microbial hazards include not only known and emerging problems due to human pathogens in imported and domestic food (from farm to table) and antibiotic resistance in pathogens, but also some naturally-occurring toxicants (e.g., mycotoxins). The strategic plan will include Federal programs for research, monitoring, surveillance, regulation and prevention (including biosolids, irradiation of food, etc.), voluntary and mandatory certification and inspection, and enforcement as well as labeling and education (e.g., “Fight BAC!™”) that alert consumers to potential hazards (e.g., untreated juice) or encourage use of safe food practices to avoid microbial contamination.

OPTIONS: The remainder of this paper defines and examines options which, separately or in combination, would expand the scope beyond pathogens and make the strategic plan more comprehensive along the lines suggested by NAS. Table 2 (attached) provides information on food safety activities at each agency. The options include:

Option 1: Chemical Substances, including:

- a.) Chemical Contaminants
- b.) Regulated/Pre-Market Approved Substances
- c.) Regulated/No Pre-Market Approval Substances (e.g., Dietary Supplements)

¹ There is not unanimous agreement on this recommendation.

- Option 2: Physical Hazards
- Option 3: Water, including:
 - a.) Drinking Water/Direct Consumption
 - b.) Water Used in Food Processing
 - c.) Water Used in Food Production (on the farm)
- Option 4: Nutrition Programs

Option 1: Chemical Substances: Chemicals can get into the food supply in a number of ways as described below. Under this option, FDA, USDA, EPA and CDC chemical-related food safety responsibilities would be considered in the strategic plan. The plan would address chemical/pesticide research (including research on preventive controls and intervention strategies), monitoring/surveillance (food and human diseases), regulation and related voluntary programs, inspection, enforcement, education and outreach.

a. Chemical Contaminants: Chemical contaminants may be either intrinsic (e.g., naturally occurring toxic constituents) or added to food (e.g., synthetic chemicals and metals), including approved substances used at unauthorized levels. This category includes environmental contaminants (e.g., methyl mercury in fish, lead in baby food), industrial contamination (e.g., dioxin in chicken feed, polybrominated biphenyls in animal feed), byproducts of manufacturing and process-induced components of foods (e.g., nitrosamines and pyrolysis products), and unauthorized levels of pesticides, food additives, and animal drug residues.

b. Regulated/Pre-market Approved Substances: This category includes substances that receive pre-market approval for specific uses in/on food and are either intentionally added (e.g., food additives) or may be present in food at or below legal and "safe" levels (e.g., pesticides). It includes food and feed additives (e.g., coloring agents, preservatives, food packaging waxes), flavors, enzymes, artificial sweeteners, pesticides (both residues in/on food and antimicrobials used to control pathogens), sanitizers, components of packaging materials (e.g., plasticizers, fungicide treated fruit and vegetable wraps), and animal drugs (including residues in meat and/or milk). Because of broad public concern about the risks posed by chemicals in food, they have historically been the subject of Federal attention and regulation.

c. Regulated/No Pre-Market Approval Substances: Another type of regulated product, dietary supplements, poses potential health risks. This class of food and ingredients does not undergo pre-market approval to evaluate safety before the products are marketed. Among the substances of concern are naturally-occurring and added substances in dietary supplements (particularly herbals and botanicals, such as ephedrine alkaloids in ma huang and *Digitalis lanata* in a plantain-containing supplement). Similarly, nutrients present in either low or high levels may pose health risks to vulnerable populations in products specifically designed to meet their needs (e.g., infant formula, medical foods, and foods for special dietary purposes). Also included in this category are certain other food ingredients (e.g., self-determination of GRAS, prior sanctioned additives) and the use of biosolids (i.e., sludge) in food production.

There are several reasons to include chemicals as “core activities” in the strategic plan.

All Chemicals:

- Food safety involves protecting consumers from a wide range of potential hazards including the risks posed by chemicals in the food supply.
- Chemicals are an integral part of food safety, and should be included if we are to create a seamless system.
- The NAS report specifically cited the need to include chemical hazards in any discussion of food safety and called for development of a comprehensive strategic plan for food safety; there would be a significant gap if chemicals were not addressed in the plan.
- The plan will be perceived by the public as deficient if chemicals are left out.
- Including chemicals broadens the Federal programs included in the plan and the stakeholders, and should bring additional opportunities for coordination or integration within the food safety system.

Chemical Contaminants:

- Some resource efficiencies in surveillance and enforcement efforts could likely be achieved by integrating work on microbial and chemical contamination.
- Chemical contaminants of foods have been shown to trigger chronic illnesses, such as cancer, and cause other adverse health effects (e.g., mutagenesis, impaired childhood development).

Regulated/Pre-Market Approved Substances:

- Significant Federal programs/resources at HHS, EPA and USDA are devoted to ensuring public health by regulating chemicals in food; since the mission of these programs includes food safety, they should be part of the food safety strategic plan.
- There is public concern about the safety of pesticide residues, food additives, and other chemicals added to food (including the presence of allergens where not expected).
- There is a direct link between certain regulated chemicals and our ability to control microbial contamination. For example, antimicrobials, pesticides and certain food additives play a role in controlling microbial contamination of food. These areas could benefit from coordination.
- Some of these regulated substances present new and important challenges for the food safety system (e.g., endocrine disruption, effects on vulnerable populations) that should be considered in the strategic plan.
- With respect to pesticides:
 - EPA regulates pesticide residues in/on food under the Federal, Food Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA); EPA’s GPRA goal for the pesticides program is “Safe Food”.
 - There is a need for improved coordination on pesticides since EPA establishes pesticides residue levels, USDA and FDA monitor for such levels in food, and FDA enforces the standards.
 - The Food Quality Protection Act has focused substantial EPA resources on reassessing pesticide residue levels in/on food to account for cumulative and aggregate exposure from all uses of pesticides as well as drinking water; changes

- will be needed throughout the Federal system as it is implemented.
- The NAS report on *Pesticides in the Diets of Infants and Children* raised food safety concerns about pesticides, especially for a vulnerable subpopulation.

Regulated/No Pre-Market Approval Substances:

- There is growing interest in dietary supplements and dietary ingredients; some supplements, including herbal products, may pose a risk of adverse health effects because they contain a toxic constituent. The Dietary Supplement Health and Education Act exempted dietary supplements from Federal pre-market approval of their safety, so effective post-market approaches are needed.
- Some dietary supplements present new challenges for the food safety system (e.g., impacts on vulnerable populations) that should be considered in the strategic plan.
- Little is known about the risks of some dietary supplements; FDA could benefit from improved coordination and prioritization of research on components of dietary supplements, such as botanicals and trace minerals, that is being done at USDA and NIH.
- The President's Dietary Supplements Commission called for additional research and monitoring; this need is not currently being met, but might be with increased attention by other agencies or through the strategic planning process.
- Dietary supplements have received insufficient Federal attention and has the potential for being a food safety problem in the future.
- The public perception that dietary supplements are not foods and that dietary supplement safety has been reviewed by FDA before marketing needs to be changed; inclusion in the FSI would help to change that public perception.
- Addition of dietary ingredients, such as the botanical St. John's Wort, to conventional foods (e.g., soup) is a growing trend in the food industry that is not anticipated to wane.
- More attention is needed to the potential problems of some food additives, especially those that were grandfathered in under the statute.

There are, however, some reasons to exclude chemicals from the "core".

All Chemicals:

- The urgency of the problem with pathogens warrants a focus on microbial contamination alone.
- There are legal, scientific, regulatory and organizational distinctions that make chemical issues different from microbes; it may be an awkward blend and create challenges in terms of balancing competing priorities.

Chemical Contaminants:

(No specific cons)

Regulated/Pre-Market Approved Substances:

- The potential risks associated with this diverse group of substances varies widely in scope and severity; some believe that including them may broaden the scope beyond what is manageable.
- Some of these substances may not be priorities, and thus may not need to be included

initially. For example, there are classes of pesticides (e.g., plant growth regulators with no toxic mode of action) that are addressed differently from those with a toxic mode of action. Similarly, risks posed by regulated food/feed additives are generally well characterized and addressed in terms of science and regulation.

- Pesticide residues are being extensively addressed due to the recent legislation; USDA and EPA are coordinating in various fora, including the Tolerance Reassessment Advisory Committee.

Regulated/No Pre-Market Approval Substances:

- Dietary supplements are mainly an HHS issue; there is less need for coordination in this area than with microbes and the other chemical categories.
- There are too many Federal activities included in the plan; some believe that expanding it to include dietary supplements would broaden the scope beyond what is manageable.

Recommendation: All chemical categories (i.e., chemical contaminants, regulated/pre-market approved substances, and regulated/no pre-market approval substances) should be included within the scope of the Council's efforts and its strategic plan since the mission of these programs is to ensure safe food. Because chemicals are in the strategic plan does not mean that they all pose public health risks of the same type or magnitude, or that they will all be a priority in the plan or for budget initiatives; however, their inclusion will provide opportunities for better coordination, integration, and resource efficiencies. Further, continued progress on goals and objectives for microbial hazards can be ensured by adding chemical activities slowly on a priority basis to the budget, so that they can be absorbed into the overall FSI work in an orderly fashion (exact timing for budget inclusion to be determined by the Budget Task Force).

Dietary supplements should be included within the scope since low or toxic levels of nutrients or other constituents in foods that are specially designed for vulnerable populations (e.g., infant formulas, medical foods, other foods for special dietary purposes), and foods containing components/supplements that may cause adverse health effects can pose public health risks. [Note: There is not unanimous agreement on inclusion of dietary supplements.]

Option 2: Physical Hazards This includes a diverse set of "foreign" physical hazards in food that can cause serious harm if consumed, including stones, bones, metal chips or parts, and glass. Included also in this category are insect and rodent infestations (e.g., insects in flour, rat droppings). For purposes of this paper, tampering is included here although it is recognized that tampering may include the addition of biological and microbiological agents, as well as chemical or other agents, to foods to intentionally harm the consumer. This category was included in NAS' definition of food safety concerns, but received little attention in the report.

Reasons for inclusion of physical hazards in the "core activities" include the following.

- Some physical hazards can result in significant harm to individuals.
- USDA experiences numerous incidents of metals and other fragments from machinery and other sources in meat which are a risk for the public.
- The public perceives contamination with physical hazards as part of the food safety issue.
- USDA and FDA statutes cover control and prevention of physical hazards, and USDA

- has resources devoted to inspecting for physical hazards.
- These hazards are relatively easy to detect and may be easy to mitigate with only a little increased Federal attention and without additional resources.

Reasons to not include physical hazards in the “core activities” are as follows.

- The urgency of the problem with pathogens and chemicals warrants a focus on them.
- Food processors and handlers have numerous safeguards in place to protect against physical hazards and tampering in order to avoid liability and other costs as well as the harmful publicity associated with incidents of easily-detected foreign materials in food.
- Partly for the reason cited above and because these hazards generally do not pose as significant a threat to public health as microbes and chemicals, some food safety agencies have paid less attention to physical hazards. Expanding the scope to include them seems unnecessary and would divert Federal resources from more significant public health risks.
- The food safety system for controlling these hazards is perceived by some to not be broken, with the exception of dealing with tampering and bioterrorism, and thus does not warrant increased attention at this time.

Recommendation: Physical hazards should be included in the “core food safety activities”, and addressed in the strategic plan. Preventing these hazards is part of the mission of some food safety agencies and is a problem, especially for meat.

Option 3: Waterborne Hazards Water is an essential component of food production, processing and preparation; food production and processing are also a significant source of contamination to the nation’s waters. Public water suppliers provide a majority of the drinking water used for washing and final preparation of food, including use in reconstituted food products available in restaurants and the home. Waterborne hazards include: pathogens in irrigation and other waters used on farms and ranches that can contaminate food -- sometimes as a result of poor farming practices, in particular mismanagement in the application of sludge biosolids and animal wastes; pathogens and chemicals in surface or groundwater from point and non-point sources that can contaminate food; microbes and chemicals in public and private water supplies used for food processing and preparation; and chemicals and especially pathogens in public drinking water (*Cryptosporidium* in Milwaukee; *E coli* in Alpine, Wyoming).

There are several reasons to include waterborne hazards as “core activities” in the strategic plan.

All Water Uses:

- The food safety strategic plan may be perceived by the public as deficient if waterborne hazards are not addressed.
- Water, whether for consumption by humans or animals, is considered “food” under FFDCA, and the biomedical community considers water to be a food.
- Some programs to reduce pathogen contamination of water are already included in the FSI, and EPA’s research on pathogens to support its drinking water program is in the OSTP research Inventory -- i.e., microbial contamination of water is already in the FSI.
- Several common waterborne pathogens can be transmitted by the foodborne route.
- There is a need to coordinate government research on pathogens to ensure efficiency and

non-duplication of Federal research (e.g., the agencies share mutual objectives in the areas of risk assessment, health effects, dose response, and analytical methods for pathogens whether in food or water).

- States will view the strategic plan as deficient if water is not dealt with at least from the standpoint of foodborne illness; the ongoing effort with state and local governments to develop a plan for integration of Federal, state and local food safety activities (which will feed into the strategic plan) is considering water.

Drinking Water/Direct Consumption:

- Drinking water is used in home and restaurant food preparation, and is added to food during manufacturing or packaging (e.g. canning.).
- Bottled water, which is regulated by FDA, is considered a food.

Water Used in Food Processing (washing, icing, preparation):

- Water is used in most food processing; use of potable water is a fundamental requirement of all regulations and guidance (GMPs, GAP/GMP guidance for produce, HACCP regulations, and recommended codes -- e.g., Pasteurized Grade A milk code).
- Overlaps and gaps exist in the authority of federal agencies (USDA, FDA, and EPA) to assure the safety of water used in food processing.
- Inclusion within the scope would provide attention to the important role of processing water in food safety; if food processing water is not addressed in the strategic plan, it will not cover all of the important challenges that need to be addressed.

Water Used in Food Production (on the farm; irrigation, washing food, application of manures):

- Inclusion within the scope would provide attention to the important role of irrigation water in food safety; the plan needs to address the role of water in food production for it to have credibility.
- Irrigation water and animal manures can be a pathway for contamination of food by pathogens; several acute disease outbreaks have occurred from this route (e.g., *Cryptosporidium* in apple juice), and thus there is a need for coordination of surveillance and inspections.
- Water is used in some food production, and use of potable water is a requirement of FDA guidance (e.g., GAP/GMP guidance for produce).
- EPA is responsible for the quality of shellfish growing waters and provides guidance, while FDA is responsible for the safety of shellfish meats grown in these waters; these programs could benefit from coordination.
- EPA develops fish advisories for locally-caught fish, while FDA develops action levels for commercial seafood; inconsistencies in the action levels/fish advisories might be addressed through these joint efforts.
- The President's Clean Water Action Plan has brought the impact of non-point sources of pollution on the nation's surface water into sharp focus for EPA, USDA, and the Department of Interior (DOI). However, the impact on the nation's food supply of irrigation and manure application was not fully addressed.
- There are gaps in Federal authority to ensure the safety of water used in food production.

However, there are also reasons why waterborne hazards should not be included in the “core” activities.

All Water Uses:

- The main purposes of EPA's water programs are to insure fishable and swimmable surface waters and safe tap water for drinking.
- Inclusion of all water programs in the food safety initiative could divert EPA resources from its primary responsibilities under the Safe Drinking Water Act (SDWA) and the Clean Water Act (CWA), including meeting statutory and judicial deadlines, and may expand the scope beyond what is manageable.
- It will be extremely difficult, if not impossible, to separate EPA's regulation/enforcement water program budget for food safety from the budget for the entire water program.

Drinking Water/Direct Consumption:

- Tap water that is safe for drinking is also safe for food production, processing and consumption. The SDWA regulates all water suppliers who service more than 25 people or have more than 15 connections. The States fill in the gap for systems that service less than 25 people/15 connections.
- There are synergies between the drinking water program and the clean water program that would make it difficult to separate them from each other, and unproductive to include them in the FSI. These synergies include source water protection and clean water activities, and EPA's two revolving loan funds that pay for infrastructure upgrades and sewer systems.
- The distribution system for drinking water is different than for food products, so the kind of response to microbial contamination is different. We know where the drinking water is coming from because of the fixed pipe system. As a result, while drinking water can pose microbial contamination threats, there is little to be gained by integration with food safety risks.
- FDA's bottled water program and the Food Code for retail establishments relies on SDWA standards.

Water Used in Food Processing (washing, icing, preparation):

- EPA does not regulate water in food production, processing, preparation and consumption any differently than it does drinking water; consumer safety from food processing uses of water has not been a primary concern for EPA.

Water Used in Food Production (on the farm: irrigation, washing food, application of manures):

- USDA, DOI, and EPA already coordinate on regulatory issues through the President's Clean Water Action Plan and through the Animal Feeding Operation Strategy.

Recommendation: Waterborne hazards should be considered "core" for those specific activities related to on the farm food production and to food processing. This would include coordination on research and development and on other activities related to:

- Production: Irrigation and other on the farm practices involving water application to crops and application of manures or biosolids (i.e., sludge) to crops; and

- Processing: Water used in food preparation, shipping, and on-site handling, especially with respect to small drinking water systems and unregulated water suppliers.

Assuring the safety of water used for drinking or other direct consumption, and of surface water used for recreation or ecological protection, should be considered a “collateral activity” which is related to food safety but the primary mission of which is not to reduce foodborne illnesses. Collaboration to avoid duplication of research efforts and ensure adequate EPA input into development of FDA and USDA guidelines for areas not included in the “core” (e.g., Food Code) is important, but can be accomplished without the other areas of the water category being a part of the strategic plan.

Option 4: Nutrition Programs There are several HHS and USDA programs as well as public-private partnerships designed to define and educate the American people on the benefits of a healthy, nutritious diet. USDA and FDA have developed the food pyramid, which recommends daily consumption of quantities of fruits, vegetables, meat and grains. Both agencies also have labeling programs designed to inform the public on the caloric and nutritional content of food. These programs are important in encouraging the consumption of a healthy, nutritious diet which can help to reduce the incidence of both acute and chronic disease.

Some believe that these nutrition programs are aligned with food safety and should be part of the “core activities” for the following reasons.

- The Federal government cannot ensure a healthy and affordable food supply, as outlined in the draft vision, without consideration of the nutrition programs.
- This would provide an opportunity to develop public health messages about both the nutritional benefits and the infectious/toxicologic hazards associated with various foods.
- Nutrition information could send a positive, constructive message to the American people, making food safety about more than just food contamination and foodborne illness. Food safety could also be about eating a wholesome, balanced diet to reduce the risk of disease, particularly chronic diseases (e.g., some cancers), developmental effects, and malnutrition.

On the other hand, the nutrition programs might not be considered “core activities” for several reasons.

- Inclusion of the nutrition programs could dilute FSI efforts on infectious and toxicologic hazards to the point of ineffectiveness, and the nutrition programs do not need attention or funding.
- The intent of the nutrition programs is to promote healthy eating habits by the American people and reduce the incidence of chronic disease; their primary purpose is not to enhance the safety of the food supply.

Recommendation: Federal programs to define and promote a healthy diet should be considered “collateral activities”. They can support and help to implement the vision of a safe, healthy and affordable food supply, but are not designed to ensure food safety. It is recognized that some labeling has specific food safety goals (e.g., warning labels on untreated, raw juices and allergen warnings) and this labeling is included in the “core” activities.

TABLE 2
FEDERAL ACTIVITIES RELATING TO FOOD SAFETY

Responsible Federal Agency	Other Agencies Involved	Activity	Type of Activity	Issues Addressed	Core or Collateral Activity
U.S. Department of Agriculture					
Food Safety & Inspection Service	FDA EPA CDC	Sets standards for meat, poultry and egg products shipped interstate; inspects domestic and imported meat and poultry and enforces standards; recalls adulterated products.	Regulation, Inspection, Enforcement, & Education	Pathogens Chemical residues Physical hazards Food quality	Core
Agricultural Marketing Service	EPA	Pesticide data program to monitor and collect pesticide residue information for EPA risk assessment; microbial data program surveillance and monitoring; voluntary quality certification program.	Regulatory Support, Monitoring, & Risk Assessment	Pesticides Pathogens Food quality	Core
Agricultural Research Service	EPA FDA	Intramural research on elimination, mitigation and detection of hazards	Research, Regulatory Support, & Education	Pathogens Chemicals	Core
Cooperative State Research, Education & Extension Service	EPA FDA	Extramural research, outreach, and education on elimination, mitigation, and detection of hazards.	Research, Regulatory Support, & Education	Pathogens Chemicals	Core
Animal & Plant Health Inspection Service	EPA FDA	Animal and plant health, regulation of biotechnology and irradiation	Regulation, Inspection, & Enforcement	Biotechnology Irradiation	Core
Economic Research Service	EPA FDA	Data collection, interpretation and cost-benefit analyses of foodborne illnesses.	Regulatory Support, Guidance, & Risk Assessment	Pesticide uses Chemicals Pathogens	Core
National Agricultural Statistical Service	EPA FDA	Data collection and monitoring	Regulatory Support, & Risk Assessment	Pesticides	Core
Grain Inspection, Packers & Stockyards Administration	FDA	Monitors the accuracy of aflatoxin testing services.	Monitoring	Mycotoxins	

Responsible Federal Agency	Other Agencies Involved	Activity	Type of Activity	Issues Addressed	Core or Collateral Activity
Office of Risk Assessment & Cost Benefit Analysis	EPA FDA	Data interpretation, guidance, technical assistance and risk assessment	Regulatory Support, Guidance, & Education	Pathogens Pesticides Chemical hazards	Core
Office of Pest Management Policy	EPA FDA	Data collection, interpretation, guidance, and risk assessment	Regulatory Support, & Guidance	Pesticides	Core
Food & Drug Administration					
Center for Food Safety & Applied Nutrition	USDA EPA CDC DOC HCFA States	Set standards, policy & guidance to ensure minimal levels of microbial & chemical contaminants & physical hazards; monitor foods for those hazards. Evaluate safety & approve use of food ingredients, antimicrobials and certain processing techniques (e.g., irradiation). Enforce tolerances for pesticides in foods (including meat & poultry). Inspect food establishments and imported foods. Conduct risk assessments & risk prioritization. Investigate major foodborne outbreaks, except meat & poultry. Monitor safety of special nutritionals (e.g., dietary supplements). Administer cooperative federal/state programs in milk, shellfish, food service and interstate travel.	Regulation, Research, Risk assessment, Monitoring Inspection, Enforcement, Guidance, & Education	Pathogens Chemicals hazards Chemical contaminants Pesticide residues Mycotoxins Physical hazards Labeling Nutrition	Core (all programs, except some labeling) Collateral (some labeling)
Center for Veterinary Drugs	USDA CDC	Evaluate safety & approve use of animal drugs & ingredients in animal feeds. Set standards, policy & guidance to ensure minimal levels of microbial & chemical contaminants in animal feeds and minimal occurrence of antibiotic resistant pathogens in food animals and feeds. Conduct risk assessments & risk prioritizations. Conduct research on antimicrobial resistance & methods for analysis for pathogens & contaminants. Monitor occurrence of antibiotic resistance in pathogens in food animals and animal feeds.	Regulation, Research, Risk assessment, Monitoring, Enforcement, & Education	Veterinary drugs Chemical contaminants Regulated substances Pathogens	Core

Responsible Federal Agency	Other Agencies Involved	Activity	Type of Activity	Issues Addressed	Core or Collateral Activity
Centers for Disease Control & Prevention					
Centers for Disease Control & Prevention	USDA FDA EPA	Investigates outbreaks of foodborne illness; monitors and collects information on food- and waterborne illnesses; conducts nationwide surveillance for food- and waterborne diseases; designs and implements surveillance systems; does reference identification; performs research on diagnostic and subtyping methods; assesses prevention efficacy; assists state and local health agencies; and training and education.	Surveillance, Monitoring, Outbreak investigation, Research, Technical Assistance, Training, & Education	Food- and waterborne pathogens FoodNet & PulseNet Infectious disease outbreaks Chemical hazards	Core
U.S. Environmental Protection Agency					
Office of Prevention, Pesticides & Toxic Substances	USDA FDA CDC	Regulation of pesticide uses, residues in/on food and antimicrobials for control of pathogens. Supports investigations of certain chemical contamination incidents and regulates chemicals and metals not covered by FIFRA, FQPA & FFDCA.	Regulation, Guidance, & Risk Assessment	Pesticides Chemical contaminants	Core
Office of Water	USDA CDC FDA DOI	Regulates drinking water quality and biosolids; establishes water discharge standards for facilities. Provides criteria for ambient water contamination, watershed controls, and other pathogen elimination/protection authorities.	Regulation, Guidance, Research, & Risk Assessment	Pathogens Chemicals Animal wastes Other agricultural wastes	Core (water in food production & processing) Collateral (drinking water/direct consumption, water for recreation)

Responsible Federal Agency	Other Agencies Involved	Activity	Type of Activity	Issues Addressed	Core or Collateral Activity
Office of Research & Development	OSTP USDA FDA	Responsible for research on pathogens in water, pesticide testing methods, chemical monitoring methods development, and risk assessment issues; provides technical and scientific advice on risk assessment, and testing and monitoring methods.	Research, Guidance, & Risk Assessment	Chemicals Pesticides Pathogens	Core (pesticides; pathogens) Collateral (pathogens)
Office of Enforcement & Compliance Assurance	FDA USDA	Ensures that pesticides used on crops/food are registered, are not adulterated, and are used correctly. Ensures that data used to support pesticides registration is not fraudulent. Referrals for possible illegal residues. Collects pesticide production information. Inspects & enforces or oversees State inspection & enforcement of CWA & SDWA requirements.	Inspections, Enforcement, Referrals, Regulation, Risk Assessment support, Water discharge standards, & Tap water standards.	Product inspections Use inspections Lab Inspections Pesticide misuse Recalls	Core (pesticides; sludge) Collateral (drinking water/direct consumption & water for recreation)
Department of Commerce					
National Marine Fisheries Service	FDA	Voluntary inspection program for seafood quality.	Inspection	Food quality Toxins Pathogens?	

TALKING POINTS FOR FOOD SAFETY COUNCIL MEETING

- THIS FIRST EVER MEETING OF THE PRESIDENT'S COUNCIL ON FOOD SAFETY IS AN IMPORTANT STEP.
- WE HAVE MADE PROGRESS. THIS YEAR WE'VE:
 - REGULATED JUICES;
 - CREATED A JOINT INSTITUTE ON RESEARCH
 - PROPOSED LEGISLATION TO GIVE FDA AUTHORITY TO HALT IMPORTS OF FRUITS AND VEGETABLES THAT DON'T MEET OUR STANDARDS.
- NOW WE ARE HERE BECAUSE WE RECOGNIZE THE NEED FOR A COORDINATED APPROACH.
- TODAY FDA AND USDA ARE SIGNING A MEMORANDUM OF UNDERSTANDING TO BEGIN THE PROCESS OF BETTER COORDINATING INSPECTION OF PLANTS BETWEEN THE AGENCIES.
- THE PRESIDENT'S COUNCIL ON FOOD SAFETY IS THE NEXT LOGICAL STEP IN THE PRESIDENT'S VISION OF TAKING FOOD SAFETY INTO THE TWENTY-FIRST CENTURY.
- THE EXECUTIVE ORDER REQUIRED THREE ACTIVITIES OF THE COUNCIL:
 - (1) A COMPREHENSIVE STRATEGIC PLAN;
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OPTION

- YOU COULD MAKE A SPECIFIC REQUEST FOR THE FOOD INITIATIVE.
 - IT BUILDS ON WHAT WE HAVE DONE;
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STRENGTHENING OUR WORK WITH STATES AND LOCALITIES; AND
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Food Safety Initiative

Policy Rationale and Cost: Advancing food safety is one of the Administration's signature issues and this year's initiative would maintain our leadership in the area by working to establish a nationally integrated food safety system with Federal, state, and local authorities. The initiative includes measures by FDA, USDA and CDC.

FDA: The majority of FDA's request (\$25.6 million) would go toward expansion of their inspection and compliance capability. As part of its efforts to integrate efforts with non-federal agencies, FDA will enter into contracts and partnerships so that states will follow FDA guidelines and procedures. Among the tangible goals FDA states they could accomplish if the initiative were funded: for the first time in decades, FDA will ensure that every high risk food manufacturer in the United States is inspected at least once a year; for other food firms, inspections will be twice as often as today (from once every 8 years to once every 4 years) and for the first time ever, state and Federal inspection results will be shared, via an electronic connection, that will reduce overlapping efforts and greatly enhance the ability of those authorities to improve public health. The measure also boosts our international capability so that FDA will increase the number of international inspections from 100 to 250 and will conduct evaluations of foreign food production systems. In addition, FDA seeks \$9.0 million improving its traceback capabilities; \$6.9 million for new research programs and \$2.7 for risk assessment; and \$4.7 million in new education funding. (**Cost:** \$48.9 million over the FY99 request.)

CDC: The goal is to create a national system that provides comprehensive data on the occurrence of food-borne illness that can be used by agencies at every level to combat food-borne illness. The majority of the investment is targeted toward surveillance activities, specifically expanding the scope of FoodNet and the capacity of PulseNet to better capture pathogen DNA fingerprints of both *E. coli* O157:H7 and *Salmonella enteritidis* and include more state health departments in the network. This expanded surveillance network is the heart of our nation's food-borne disease early warning system. The current surveillance system does not provide adequate coverage of the US population. (**Cost:** \$18 million over the FY99 request.)

USDA: USDA complains that while OMB more than fully funded their initiative, they imposed \$473 million in user fees on FSIS and failed to provide a needed \$30.6 million for obligated salary increases and redeployment of inspectors. This is on top of a flat budget when the agency is trying to implement extensive new HACCP reforms. FSIS has very little discretionary money, since most is tied up in inspector salaries and other fixed costs. USDA has stated that OMB's failure to include the \$30.6 million will force them to shut down the inspection program during the last 9 days of the year or furlough over 300 employees. The Secretary has sent a letter complaining that the lack of salary funds effectively downsizes his inspection force and undercuts the commitment the President made to improve food safety and effectively regulate meat and poultry. (**Cost:** The salary increases and inspector redeployment cost \$30.6 million).

Uncertainties:

USDA. The USDA/OMB dispute on user fees is an old one, and USDA acknowledges they will probably lose again. USDA may suggest a compromise they think OMB might agree to: include the full funding request for FSIS in the budget (\$652 million) but elsewhere in the budget acknowledge that the Administration expects user fees to cover \$473 million of the cost. The argument being that currently Congress is not technically being requested to provide the actual amount the Administration and most observers think it really needs.

Vetting.

These proposals have been developed by the USDA, FDA, and CDC and explained to OMB. OSTP has also been involved in their development.

We have not consulted with consumer groups, but it seems likely they would strongly support the initiative. The groups have called us to support the idea that there be some new initiative, and to complain in general about user fees. It seems likely we will get significant flack for the user fees from Congress and consumer groups, especially if we have no new initiative.

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USDA: USDA complains that while OMB more than fully funded their initiative, they imposed \$473 million in user fees on FSIS and failed to provide a needed \$30.6 million for obligated salary increases and redeployment of inspectors. This is on top of a flat budget when the agency is trying to implement extensive new HACCP reforms. FSIS has very little discretionary money, since most is tied up in inspector salaries and other fixed costs. USDA has stated that OMB's failure to include the \$30.6 million will force them to shut down the inspection program during the last 9 days of the year or furlough over 300 employees. The Secretary has sent a letter complaining that the lack of salary funds effectively downsizes his inspection force and undercuts the commitment the President made to improve food safety and effectively regulate meat and poultry. (**Cost:** The salary increases and inspector redeployment cost \$30.6 million).

Uncertainties:

USDA. The USDA/OMB dispute on user fees is an old one, and USDA acknowledges they will probably lose again. USDA may suggest a compromise they think OMB might agree to: include the full funding request for FSIS in the budget (\$652 million) but elsewhere in the budget acknowledge that the Administration expects user fees to cover \$473 million of the cost. The argument being that currently Congress is not technically being requested to provide the actual amount the Administration and most observers think it really needs.

Vetting.

These proposals have been developed by the USDA, FDA, and CDC and explained to OMB. OSTP has also been involved in their development.

We have not consulted with consumer groups, but it seems likely they would strongly support the initiative. The groups have called us to support the idea that there be some new initiative, and to complain in general about user fees. It seems likely we will get significant flack for the user fees from Congress and consumer groups, especially if we have no new initiative.

FIGHTING HOMELESSNESS

This is a proposed initiative that we received from the VA to address more fully the needs of homeless veterans. According to the Federal Plan to Break the Cycle of Homelessness, there are as many as 600,000 homeless persons on any given night. The National Coalition of Homeless Veterans estimates that there are 275,000 homeless veterans on any given night. They estimate that there would be double that number over the course of a year. This initiative would reach 50,000 additional veterans per year (150,000 over 3 years) for a total of approximately \$60 million per year.

I. FEDERAL PROGRAMS TO ADDRESS HOMELESSNESS

The McKinney Act, which was enacted in 1987, is the major federal legislation addressing homelessness. McKinney funding for targeted homeless assistance has increased dramatically. The McKinney Act grant assistance programs fund activities that provide homeless men, women, and children, with emergency food and shelter, surplus goods and property, transitional housing, some supportive housing, primary health-care services, mental health care, alcohol and drug abuse treatment, education, and job training. HUD currently administers nearly 70 percent **check** of the McKinney Act funds, or spends approximately \$1 billion on homelessness per year (OMB).

There are three major VA programs that work with the homeless:

1. Homeless Grant and Per Diem. This program awards grants to community-based organizations to acquire transitional housing with services. In FY 94 through FY 97, 101 grants were awarded to 84 non-profit or state or local government agencies in 36 states. There is approximately \$5 million per year for new grants. Pays up to \$16/day for ongoing operational costs.
2. Homeless Chronically Mentally Ill Veterans Program. The HCMI program places homeless veterans needing more intensive treatment into one of its roughly 200 contracted community-based facilities. The program serves over 20,000 homeless veterans per year, with over 3,000 receiving residential treatment. The average cost per day is \$38.
3. Domiciliary Care for Homeless Veterans. Treatment takes place in approximately 1500 dedicated beds at VA medical center domiciliaries.

SPECIFIC PROPOSAL FROM VETERANS AFFAIRS

A. Increase Funding for VA's Homeless Grant and Per Diem Program

Background

This program allows for the provision of grants and per diem payments to assist public and non-profit organizations establish and operate new supportive housing and service centers for homeless veterans. Since the first round of funding in 1994, the VA has awarded 101 grants to 84 community agencies in 36 states and the District of Columbia. Total VA funding for these projects was over \$21 million, or approximately \$5 million annually. When these projects are completed, approximately 1,700 new community-based beds will be available for homeless veterans. With the current round of funding that number is expected to grow to 2,200 beds in the future.

1. **Increase funding for new grants by \$7 million.** This additional \$7 million, added to the \$5 million already funded by the VA for a total of \$12 million, would create approximately 1000-5000 new beds annually with services for homeless veterans. At least 75% of the beds would be for eligible veterans.
2. **Increase per diem funding by \$7 million.** This funding is for ongoing operations, and it subsidizes providers, paying no more than one-half of their operating costs. Currently, approximately 3,200 veterans receive services from existing programs. Seven million would pay for approximately 5,000 different veterans receiving care paid for by VA. Within 2 years, more 10,000 homeless veterans annually could be completing treatment in VA quality-approved community setting operated by nonprofit entities, Native American tribes, or state and local governments.
3. **Provide \$5 million in new per diem funding.** P.L. 102-590 that created the Homeless Grant and Per Diem Program did not require an entity to receive a grant in order to be eligible for per diem; however, VA, by regulation and in an attempt to protect its grant investment, has limited per diem to programs that receive a grant. This would help to pay for care of approximately 2000 veterans in non-grantee, yet VA-approved, community-based programs.

Part A summary: \$24 million in funding (\$19 million if existing \$5 million not counted) for treatment and services for more than 5,000 veterans annually with service provided in community-based settings.

B. Increase Funding for Dedicated Staff and Contract Care Dollars at Each VA Medical Center.

Background

There are approximately 150 VA Medical Centers across the country. At 64 of these centers, there are dedicated staff with contract dollars to buy services from community service providers for homeless veterans. At those sites approximately 65 veterans are serviced at each site for an

approximate total of 4,000 veterans. At 10 additional medical centers there are dedicated staff without contract care money.

1. **Increase funding by \$27 million so that each of the approximately 150 VA Medical Centers in the country will have dedicated staff and contract dollars to address the needs of homeless veterans.** If this proposal is initiated with an average of 1.5 FTE per site for a cost of \$100,000 annually and contract care dollars for residential contract care and transportation for a cost of \$150,000 per site annually, there would be, for the first time, a comprehensive nationwide system to address the needs of homeless veterans by having dedicated staff at each VA Medical Center. Costs are approximately \$250,000 annually per site. This would allow as many as 4,000 new veterans to be treated in community residential settings. A total of up to 8,000 homeless veterans could be treated annually under this program by expanding the existing program. **New:** Dedicated staff at all VA Medical Centers would mean that more than 100,000 veterans could be seen and interviewed by VA clinicians in outreach activities over a three-year period. The additional staff (150 FTE) would, on average spend half their time on outreach activities thereby seeing an additional 10,200 veterans each year or more than 30,000 veterans over a three-year period.
2. **Provide \$2 million in new funding for Homeless Women Veterans Programs.** These funds would be used to develop up to 20 new programs for outreach, case management, and to provide residential care for homeless women veterans. Less than 3 percent of veterans treated under current programs are women. Special programs are needed because current offerings are male dominated making many women veterans uncomfortable, particularly considering a high rate of sexual trauma among women veterans. These programs would be largely contracted community care. The Department of Veterans Affairs estimates that up to 500 women veterans could be served annually under this initiative.
3. **Provide \$2 million in new funding for Compensated Work Therapy.** VA's medical care program offers Compensated Work Therapy (CWT) to help homeless veterans become gainfully employed. This program offers many veterans with significant barriers to employment, particularly homelessness, with job readiness experiences. At present, this program helps approximately 3,500 veterans annually to be able to move directly into competitive work in the community, and helps another 10,000 who need additional skills development and training. This program ties very closely with a number of programs at the Department of Labor to help veterans gain employment. The VA estimates that an additional \$2 million could help more than 2,000 veterans by creating new programs at ten sites and increasing program augmentations at 10 additional CWT sites.

Part B summary: \$31 million in funding to provide a VA continuum of care for veterans, including some hard-to-reach rural and women veterans with an estimated 13,200 veterans being assisted annually.

C. Collaboration to Provide Care and Services Needed by Homeless Veterans.

- 1. Increase funding by \$10 million for the Homeless Veterans Reintegration Program (HVRP).** The Department of Labor's Homeless Veterans Reintegration Program (HVRP) provides grants to community-based, nonprofit organizations that work directly with homeless veterans. Currently, this program receives \$2.5 million and has 23 operating sites. The VA estimates that an increase of funding of \$10 million for a total of \$12.5 million would permit grants to be awarded to one or more projects in approximately 37 states. The VA estimates that with an additional \$10 million would allow up to 100 grantees to be funded and that more than 10,000 veterans could be served annually with up to 7,000 placed back on the employment rolls.
- 2. Provide an additional \$2.5 million for Stand Downs.** At almost 100 sites across the country each year, community-sponsored events called "Stand Downs" bring homeless veterans together with community-based service providers; state and local government service providers; VA health care and benefits staff; and many others prepared to assist homeless veterans and their families with housing, health care, employment, legal matters, education, transportation, and other barriers preventing them from reintegrating into the social mainstream. The VA estimates that, with an additional \$2.5 million, more than 100 sites would be able to conduct these one-stop service delivery programs for homeless veterans. A three-year study of 227 events showed that more than 80,000 veterans and their family members were assisted by these events. The VA proposes that these additional funds could be used to help between 25,000 and 50,000 veterans attend "Millennium Stand Downs," which is a White House project (involving Dena Wood and John Hanson) with a goal of ensuring that all veterans will have safe lodging and will be able to secure treatment at the Millennium. The VA estimates that 35,000 veterans a year and over 100,000 over a three-year period could be engaged in first-step recovery activities.
- 3. Fund an additional \$0.5 million to provide excess property to homeless veterans.** The VA, along with the General Services Administration and the Department of Defense, provide excess property each year to homeless veterans. Primarily, this program provides clothing such as boots, hats, coats, pants, shirts, and other excess military personal clothing items. However, sleeping bags, blankets and other items are sometimes available as well. A current inventory lists over 220 items with a total value of more than \$11 million. This Hammer Award-winning program has distributed more than \$35 million of property to homeless veterans during the last four years. The VA proposes a new initiative to add donated civilian clothing, furniture, and equipment to assist thousands of homeless veterans and community-based homeless veterans service providers. The VA estimates that an additional \$0.5 million could secure additional warehouse space and pay for shipping costs associated with this initiative and could help approximately 25,000 to 50,000 veterans. The VA estimates that approximately 40,000 per year and 125,000 veterans over a three-year period would be assisted by this initiative.

4. **Fund an additional \$0.5 million for the North East Program and Evaluation Center.** The North East Program and Evaluation Center (NEPEC) reviews, monitors, and evaluates VA's homeless programs. With all the additional programs and sites suggested under this initiative, additional funding would be needed to ensure a quality review with reliable information. According to the VA, NEPEC's high-quality standards of review are unmatched under any existing homeless program in the country and is the best protection in order to ensure that the highest quality evaluation is conducted.

Part C summary: \$3.5 million in funding for VA and \$10 million for the Department of Labor for job training and services for more than 115,000 homeless veterans annually. While some of these veterans may be duplicated, it would certainly represent the largest commitment ever made to improve the lives of homeless veterans.

D. Improvement of HUD's McKinney Act Funding Sources for Veterans.

Background:

Veteran-specific HUD McKinney Act funded projects are disproportionately under funded, and many projects claiming to be veterans' projects are not really targeted to veterans. After HUD's last round of funding, the VA contacted each of the projects listed by HUD as veteran-targeted or veteran-specific and found that many were not targeted or designed to serve veterans. According to information supplied by HUD, more than \$21 million was earmarked for "veteran" projects; however, VA discovered that more than \$9.5 million was not available for veterans. In its assessment, the VA excluded projects where less than one-third of their clients would be veterans. In fact, the VA found that many of the projects stated that no veterans or less than ten percent of the population to be served were expected to be veterans.

1. **Veteran representation on HUD's local planning boards.** Veterans Service Organizations believe that there is a strong need to have veterans' advocates at the local level because there is no existing mechanism to assist veterans at the national level to ensure that the needs of homeless veterans are addressed.
2. **Require HUD to use the "CHALENG for Veterans" Report.** For more than four years, VA has conducted meetings with strong participation from the veterans community in order to examine the services available locally for homeless veterans, identify the unmet needs of homeless veterans, and develop local action plans to address those unmet needs. This meeting and report called "CHALENG for Veterans" occurs at each VA medical center across the country and contains local resource information and a "veterans community view" of the unmet needs of veterans in the area. The overall information is folded into a national report. The VA proposes to require HUD and its local planning

process to use the “CHALENG for Veterans” report to ensure that the needs of homeless veterans will be met under HUD’s local continuum of care plans. As with any reporting system, the weight each community would give to this information would vary; however, the VA believes that it is imperative that this information be available.

3. **Provide an additional \$4 million to HUD-VASH.** In this joint Supported Housing program with the Department of Housing and Urban Development, VA staff at 35 VA Medical Centers provide ongoing case management and other needed assistance to homeless veterans in permanent housing supported by nearly 2,000 specially-designed HUD rental assistance vouchers. Long-term housing has been identified as one of the top unmet needs of veterans for several years in the CHALENG report. Each VA employee, usually a social worker, manages approximately 30 voucher recipients. The VA estimates that up to 500 HUD Section 8 vouchers are expected to expire in the near future. The VA proposes that all current vouchers for veterans should be held and that more vouchers should be offered for seriously mentally and physically ill homeless veterans. The VA recommends that thirty additional sites be added and that 1,800 vouchers be added. The VA estimates that an additional \$4 million will permit approximately 1,800 veterans to gain long-term housing which will reduce their dependence on the VA health care system. [HUD costs associated with this proposal have not be estimated.]
4. **Americorps.** Military service and civilian volunteer service are highly compatible under the Corporation for National Service’s “Collaboration for Homeless Veterans.” LA VETS is a National Direct grantee from the Corporation and operates a highly effective program with approximately 90 full-time members. Approximately 40 percent of those members are veterans and many of those veterans have been homeless. The VA estimates that a near tripling of full-time members to 250 nationwide would mean operating programs in at least 20 states and providing outreach and coordinating community resources with VA health care for at least 50,000 homeless veterans. VA estimates the cost to the Corporation for National Service to be \$2 to \$3 million per year.

Part D summary: \$4 million in funding to provide long-term housing for approximately 1,800 veterans.

FINAL COSTS/SUMMARY

This proposal would constitute the single largest investment into breaking the cycle of homelessness among veterans. This proposal seeks to increase residential alternatives, community-based contracted care, job preparation activities, stand down activities, the distribution of clothing, and long-term housing. This proposal is estimated to positively impact 100,000 to 150,000 veterans annually. Additional funding for the VA would be \$60.5 million and additional funding for the Department of Labor’s Homeless Veterans Reintegration Program

(HVRP) would be \$10 million. HUD's Section 8 costs are not contained in this estimate. [There appears to be a significant effort to increase section 8 long-term housing alternatives and this would simply urge a portion of those new voucher to be dedicated under this effort. Additional resources in the amount of \$5 million per year for the next two years would be needed. After three years, the increased funding could be reduced to the present level if projections of services are achieved.]

The VA estimates that if 40,000 veterans are returned to work by the third year of this initiative and that each veteran earns \$1,000 per month, the economy will be enriched with \$480 million in paid wages and, that assuming an overall tax rate of 15 percent, there will be \$72 million in additional tax revenues.

**Estimate of Veterans Impacted by Program Area
Over a Three-Year Period**

	Existing (Over 3 Years)	New (Over 3 Yrs)
Outreach	60,000	40,000
Stand Downs	60,000	37,000
Clothing Distribution		
Contract Care	9,000	12,000
Per Diem	10,000	21,000
CWT	40,000	6,000
HVRP	5,000	25,000
Americorps	10,000	15,000
TOTAL	154,000	156,000

	Year 1	Year 2	Year 3
Outreach and Community Contract Clinical Care	27	27	27
New Grants	12	12	12
Per Diem for Grantees	7	7	7

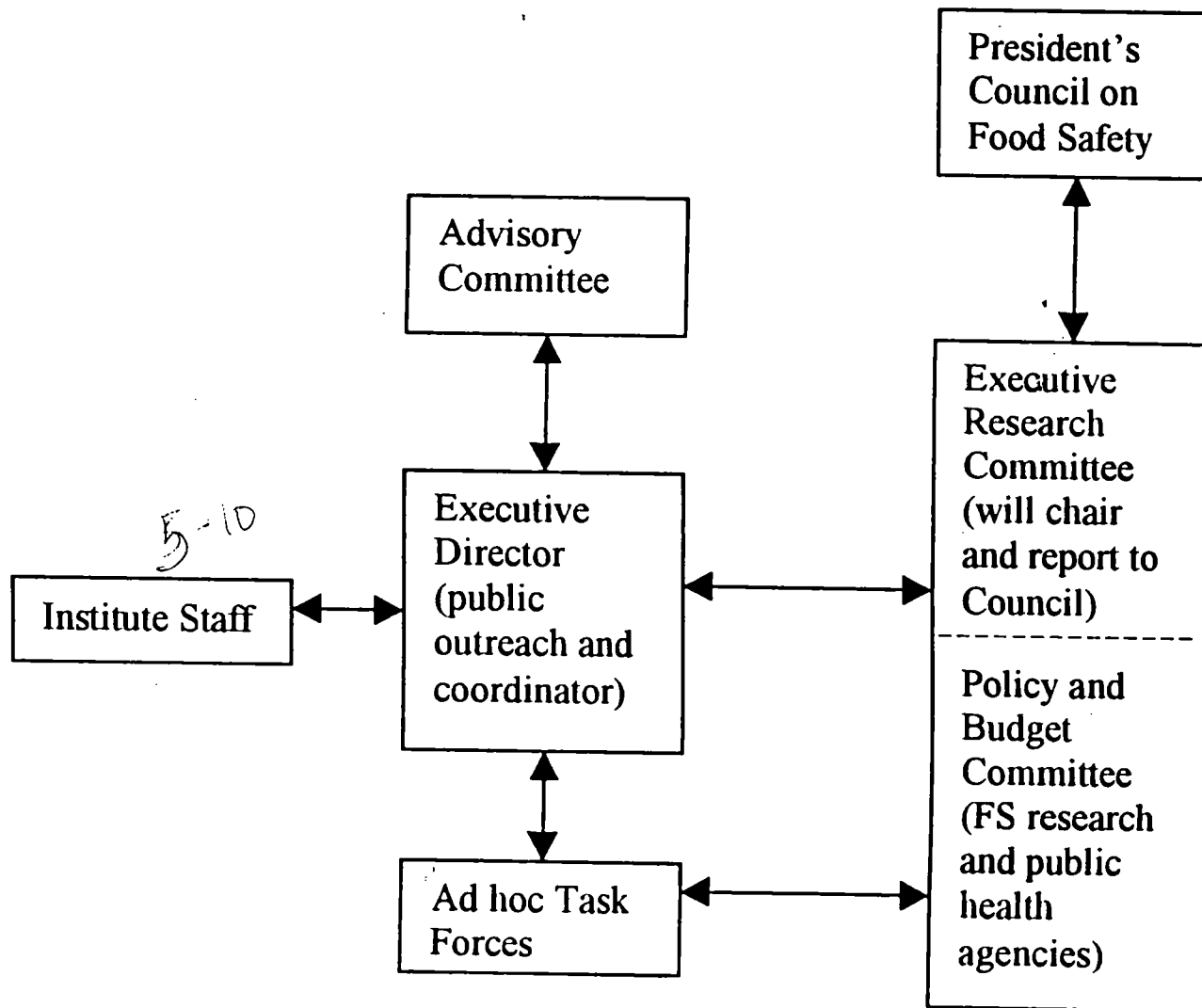
Per Diem for Non-Grantees	5	5	5
Compensated Work Therapy	2	2	2
Stand Downs	2.5	2.5	2.5
Excess Property Distribution	0.5	0.5	0.5
Program Monitoring	0.5	0.5	0.5
<i>Ongoing Efforts</i>		5	10
TOTAL Per Year	56.5	61.5	66.5
Additional Funding - Other Agency Collaborations			
HUD-VASH	1	2	3
Corporation for National Service	3	3	3
HVRP	10	10	10
TOTAL Per Year	14	15	16

Joint Institute for Food Safety Research

- Presidential Directive on July 3, 1998 to Secretaries Glickman and Shalala
- Develop a strategic plan for conducting food safety research activities
- efficiently coordinate all Federal food safety research, including research conducted with the private sector and academia
- Plan to the President in 90 days

Structure of the Institute

- Virtual; no bricks and mortar
- Structure designed to foster coordination and planning
- Core policy and budget committee with flexible task force structure
- Staff



↓ SC
↓ EAC - (chair)
↓ EAC D.C.
↓ EAC staff

5-10

CSPR/HHS/L SDR

Organizing Principles

- Optimize current investment and infrastructure
- Provide centralized communication with stakeholders
- Use current intramural and extramural research programs in innovative ways

Organizing Principles (cont.)

- Mobilize resources to minimize the impact of current and emerging food safety problems
- Increase accountability for federal research priorities and implementation of strategies to the public

Goals and Outcomes

- Coordination in research planning, budget development, and prioritization
- Scientific support of food safety regulation
- Communication/links with other food safety agencies
- Communication/links with industry and academic partners

Implementation Schedule

- December 1998, host public meeting
- March 1999, submit proposal to NSTC
- April 1999, finalize and publish in FR
- May 1999, recruit executive director and appoint advisory committee