DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

October 22, 1999

Dear Colleague:

I am inviting you to attend one of three public meetings that the Food and Drug Administration (FDA) is holding to address issues related to bioengineered foods. In the 21st century, biotechnology will have a profound effect on the way we live. Modern biotechnology, or bioengineering, refers to the use of recombinant DNA and related techniques to alter the genetic makeup of living organisms. These techniques allow scientists to identify and isolate genes of interest from any organism and to put them into any other organism, as well as to introduce targeted genetic changes in organisms. The practical effect is to create opportunities for developing foods with such characteristics as greater pest and drought resistance, higher yield, improved nutrition, and better taste. FDA's current policy for regulating bioengineered foods was established in 1992, and over the past five years, a number of foods derived from bioengineered plants have been introduced into the U.S. market place. I believe that now is an appropriate time to review FDA's experience with these foods and to hear from consumers on these important issues.

The purpose of the meetings on "Biotechnology in the Year 2000 and Beyond" is to discuss the agency's approach to regulating bioengineered foods, to find out how the public views our approach, and to receive comments about the most appropriate ways to inform the public about bioengineered foods. The meetings will be held on November 18, in Chicago, Illinois, November 30, in Washington, D.C., and December 13, in Oakland, California. Mr. Joseph Levitt, Director, Center for Food Safety and Applied Nutrition, will moderate the meeting in Washington, D.C.; Ms. Sharon Smith Holston, Deputy Commissioner for International and Constituent Relations, will moderate the meeting in Oakland; and I will be the moderator for the Chicago meeting. Representatives from consumer groups, industry, and academia will be invited to make presentations on scientific and safety issues and on public information and labeling.

I encourage you to attend one of these meetings and to share your views with the agency and others interested in this important issue. Your input will assist the agency in evaluating and refining, as necessary, its policies and procedures for regulating bioengineered foods. The enclosed Federal Register notice includes more detailed information including instructions on how to register for the meetings.

Sincerely yours,

Jane E. Henney, M.D.
Commissioner of Food and Drugs

Enclosure

a larger number of submissions under the provisions discussed as follows:

Section 814.102 estimate assumes that 20 sponsors per year will submit a request for HUD designation. It is estimated to require 40 staff hours to complete each HUD designation request.

Section 814.104 estimate assumes that 15 sponsors per year will submit an HDE application after receiving HUD designation. FDA estimates that it will require an average of 320 staff hours to complete each HDE application.

Section 814.110(a) requires that a new indication for use of an HUD approved under this part be submitted as a new HDE application complying with § 814.104. All burden under this section is included under the estimate for § 814.104.

Section 814.106 estimate assumes that 4 times per year FDA will request or the sponsor will submit additional information or resubmit an HDE or HDE supplement for approximately 15 of the submitted HDE applications. FDA estimates that it will require the respondents to take an average of 50 staff hours to complete each amendment or resubmitted application. If FDA refuses to file the HDE application, requests for an informal conference (under § 814.112(b)) will be processed as an HDE amendment. Responses to approvable and not approvable letters (§ 814.116(b), (c), and (d)) will be processed as HDE amendments. A request for an opportunity for an informal hearing, prior to FDA issuing an order withdrawing approval, under § 814.118(d), will be processed as an HDE amendment. Because FDA only tracks amendments, and not the reasons for the amendment, the burden estimates for the sections listed in Tables 1 and 2 of this document are included in the burden estimate for § 814.106.

Section 814.108 estimate assumes that it will receive approximately 12 supplements for the submitted HDE applications. It is estimated that it will take approximately 80 staff hours to complete each supplemental application.

Section 814.116(d)(3) estimate assumes that it will receive approximately one request to withdraw an HDE application per year, based on withdrawals submitted in FY 1997 and FY 1998. FDA estimates it will take no longer than 1 staff hour to complete each written withdrawal notice.

Section 814.124(a) estimate assumes that five physicians will use HUD's in emergency situations before obtaining institute and review board (IRB) approval. FDA estimates that notification under this section will take an average of 1 hour per response.

Section 814.124(b) estimate assumes that one holder of an approved HDE will notify FDA of IRB withdrawal of approval. FDA estimates that it will take an average of 2 staff hours to notify FDA of IRB withdrawal.

Section 814.126(b)(1), following the implementation of the FDA Modernization Act, was amended to incorporate section 520(m)(5) of the act, which provides FDA the authority to require an HDE applicant to demonstrate continued compliance with the HDE requirements, if the agency believes that such a demonstration is necessary to protect the public health or has reason to believe that the criteria for the HDE exemption are no longer met. FDA amended this section to delete the requirement of an annual report and to include instead a periodic reporting requirement that will be established by the approval order for the HDE. This provision permits the agency to obtain sufficient information for it to determine whether there is reason to question the continued exemption of the device from the act's effectiveness requirements.

FDA anticipates that because of this amendment, the 15 HDE holders will remain active and therefore, estimates that 15 periodic reports will be received. FDA also estimates that it will take an average of 120 staff hours to complete a periodic report as a result of this amendment.

II. Explanation of Recordkeeping Burden Estimate

Section 814.126(b)(2) estimate assumes that 15 HDE holders per year will maintain records of certain required information. It is estimated that it will take an average of 2 staff hours to maintain this information.

Dated: October 18, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99-27756 Filed 10-22-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-4282]

Biotechnology in the Year 2000 and Beyond; Public Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing three public meetings on issues within FDA's jurisdiction related to foods (both human and animal) derived from plants developed using bioengineering techniques. The purpose of these public meetings is for the agency to share its current approach and experience over the past 5 years regarding safety evaluation and labeling of food products derived from bioengineered plant varieties, to solicit views on whether FDA's policies or procedures should be modified, and to gather information to be used to assess the most appropriate means of providing information to the public about bioengineered products in the food supply. These meetings will afford consumers, industry, and academia an opportunity to provide focused comment on these issues in a manner that will assist FDA in evaluating and refining its existing policies and procedures.

DATES: The meetings are scheduled as follows:

1. Thursday, November 18, 1999, 9 a.m. to 6 p.m., Chicago, IL.
2. Tuesday, November 30, 1999, 10 a.m. to 7 p.m., Washington, DC.
3. Monday, December 13, 1999, 9 a.m. to 6 p.m., Oakland, CA.

Submit written comments by January 13, 2000.

ADDRESSES: The meetings will be held at the following locations:

1. Chicago—One Prudential Plaza, Plaza Club, 40th floor,130 East Randolph St., Chicago, IL 60601.
2. Washington, DC— Grand Hyatt Washington, 1000 H St. NW., Washington, DC 20001.
3. Oakland—Elihu Harris State Office Building, 1515 Clay St., Oakland, CA 94612.

Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, or via e-mail to www.fda.gov/ohrms/dockets. Comments are to be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

For general information:

Nega Beru, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3090, FAX 202-418-3131, e-mail nberu@bangate.fda.gov.

For information about and registration for the public meeting in Chicago, IL:

Darlene Bailey, Chicago District (HFR-CE 645), Food and Drug Administration, 300 S. Riverside

Plaza, Suite 550–South, Chicago, IL 60606, 312–353–7126, FAX 312–886–3280, e-mail dbailey@ora.fda.gov.

For information about and registration for the public meeting in Washington, DC:

Patricia Alexander, Office of Consumer Affairs (HFE–40), Food and Drug Administration, Rockville, MD 20857, 301–827–5006, FAX 301–827–3052, e-mail palexand@oc.fda.gov.

For information about and registration for the public meeting in Oakland, CA:

Janet McDonald, San Francisco District (HFR–PA100), Food and Drug Administration, 1431 Harbor Bay Pkwy., Alameda, CA 94502–7070, 510–337–6845, FAX 510–337–6708, e-mail jmcdonal@ora.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA published a notice in the **Federal Register** of May 29, 1992 (57 FR 22984), entitled "Statement of Policy: Foods Derived from New Plant Varieties" (the 1992 policy) that clarified the agency's interpretation of the Federal Food, Drug, and Cosmetic Act (the act) with respect to foods derived from new plant varieties, including foods derived from plants developed through recombinant DNA techniques. The 1992 policy was issued in response to inquiries from developers and the public regarding food safety and labeling issues related to foods derived from bioengineered plants. The 1992 policy discussed how such foods would be regulated within the existing legal framework of the act and provided comprehensive guidance to developers for the safety and nutritional assessment of such foods. The agency's guidance, based on the agency's understanding of bioengineering advances in food and agriculture research then current, was intended to assist developers in meeting their legal duty under the act to ensure that relevant scientific, safety, and regulatory issues are resolved prior to commercial distribution of such foods. A basic principle of the 1992 policy is that the critical consideration in evaluating the safety of such foods should be the objective characteristics of the food product or its components rather than the fact that new development methods were used. Consistent with the 1992 policy, FDA believes that it is in the best interests of the public, the regulated industry, and the agency for developers to inform FDA about foods derived from new plant varieties developed through bioengineering prior to commercial distribution. Thus, FDA established procedures through which developers can consult with the agency, and through which these consultations can be brought to closure. FDA prepared guidance on the consultation procedures and made it available on its home page on the World Wide Web (http://www.fda.gov/cfsan under "Biotechnology").

FDA considers a consultation to be completed when all safety and regulatory issues have been resolved. Since 1994, when FDA completed its evaluation of the first food product developed using bioengineering (the Flavr Savr™ tomato), private firms have completed consultations with FDA on food safety, nutritional, and labeling issues for foods derived from over 40 different bioengineered plants.

The 1992 policy also addressed the labeling of foods derived from new plant varieties, including plants developed by genetic engineering. Under this policy and applicable law, FDA requires special labeling if the composition of a food developed through genetic engineering or any other method differs significantly from its conventional counterpart. For example, if a new food contains a protein derived from a food that commonly causes allergic reactions (and the developer cannot demonstrate that the protein is not an allergen), labeling would be necessary to alert sensitive consumers because they would not expect to be allergic to that food. Likewise, a new food that has a decrease in nutrients from the food's traditional counterpart would be required to contain that additional information on its label. In addition, the agency requires that the name of a new food be revised when that food is derived from a bioengineered plant that differs from its traditional counterpart such that the customary common or usual name no longer applies to the new food. FDA is not aware of information that would distinguish genetically engineered foods as a class from foods developed through other methods of plant breeding and, thus, the agency does not require that such foods be specially labeled to disclose the method of development. FDA believes that it would be useful to the public, the regulated industry, and the agency to conduct a series of public meetings to share the agency's current approach and experience over the past 5 years regarding its oversight of food products developed through bioengineering, to solicit views on whether FDA's process should be modified, and to gather information to be used to assess the most appropriate means of providing information to the public about bioengineered products in the food supply.

As part of the meetings, FDA will describe its current approach to regulating foods from bioengineered plants as well as the agency's experience over the past 5 years regarding safety testing and labeling of these products. FDA also intends to invite representatives from consumer groups, industry, and academia to make presentations on scientific and safety issues and to invite representatives of these same groups to make presentations on public information and labeling. Finally, there will be opportunities for oral presentations by preregistered members of the public.

II. Scope of Discussion

The scope of these three public meetings will be limited to the issues discussed in this document. A brief discussion on each of the issues with specific questions on which FDA seeks comment follows.

A. Scientific/Safety Issues

1. Has FDA's consultation process achieved its intended purpose? Based on experience to date, should this regulatory approach "sunset," continue in its current state, be made mandatory, or otherwise be revised?

2. What newly emerging scientific information related to the safety of foods derived from bioengineered plants is there, if any? Are there specific tests which, if conducted on such foods, would provide increased assurance of safety for man or animals consuming these foods?

3. What types of food products derived from bioengineered plants are planned for the future? Will these foods raise food safety issues that would require different approaches to safety testing and agency oversight? If so, what are those approaches?

B. Public Information Issues

1. Should FDA's policy requiring labeling for significant changes, including changes in nutrients or the introduction of allergens, be maintained or modified? Should FDA maintain or revise its policy that the name of the new food be changed when the common or usual name for the traditional counterpart no longer applies? Have these policies regarding the labeling of these foods served the public?

2. Should additional information be made available to the public about foods derived from bioengineered plants? If so, what information? Who should be responsible for communicating such information?

3. How should additional information be made available to the public: e.g., on the Internet, through food information phone lines, on food labels, or by other means?

III. Registration and Requests to Make Oral Presentations

If you would like to attend the meetings, you must register with the appropriate contact person (addresses above) 15 days prior to the meeting you wish to attend by providing your name, title, business affiliation, address, telephone, and fax number. To expedite processing, this registration information also may be faxed to the appropriate contact person (fax number above). If you need special accommodations due to disability, please inform the contact person when you register. If, in addition to attending, you wish to make an oral presentation during the meeting, you must so inform the contact person when you register and submit: (1) A brief written statement of the general nature of the views you wish to present; (2) the names and addresses of all persons who will participate in the presentation; and (3) an indication of the approximate time that you request to make your presentation. Depending upon the number of people who register to make presentations, FDA may have to limit the time allotted for each presentation.

IV. Comments

Interested persons may, on or before January 13, 2000, submit written comments to the Dockets Management Branch (address above). You may also send comments to the Dockets Management Branch via e-mail to www.fda.gov/ohrms/dockets. You should annotate and organize your comments to identify the specific issues to which they refer. You must submit two copies of comments, identified with the docket number found in brackets in the heading of this document, except that you may submit one copy if you are an individual. You may review received comments in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

V. Transcripts

A transcript of each meeting will be made. You may request a copy of any transcript in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. You may also examine the transcripts of the meetings at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday, as well as on the FDA web site, http://www.fda.gov.

Dated: October 18, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99-27694 Filed 10-20-99; 8:49 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Opthalmic Drugs Subcommittee of the Dermatologic and Ophthalmic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Opthalmic Drugs Subcommittee of the Dermatologic and Ophthalmic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 17, 1999, 8:30 a.m. to 5 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact: Tracy Riley or Angie Whitacre, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7001, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12534. Please call the Information Line for up-to-date information on this meeting. Current information may also be accessed on the Internet at FDA's website at www.fda.gov.

Agenda: The subcommittee will discuss new drug application 21-119 Visudyne™ (verteporfin for injection, QLT Therapeutics, Inc.), for treatment of age-related macular degeneration in patients with predominantly classic subfoveal choroidal neovascularization.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 12, 1999. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9:30 a.m. Time allotted for each presentation may be limited. Those desiring to make formal presentations should notify the contact person before November 12, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 14, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99-27757 Filed 10-22-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Gastrointestinal Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Gastrointestinal Drugs Advisory Committee

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on November 16, 1999, 9 a.m. to 5 p.m.

Location: Holiday Inn, The Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Joan C. Standaert, Center for Drug Evaluation and Research (HFD-180), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 419-259-6211, or John M. Treacy (HFD-21), 301-827-7001, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12538. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss new drug application 21-107, Lotronex™ (alosetron HCl), Glaxo-Wellcome Pharmaceuticals, to be indicated for treatment of irritable bowel in female patients with diarrhea predominance.

DRAFT

OMB is reviewing.

Backgrounder

U.S. Department of Agriculture — Department of Health and Human Services

2000 President's Food Safety Initiative

February 22, 1999

For the third consecutive year, the Department of Health and Human Services (HHS) and the Department of Agriculture (USDA) have coordinated a multi-agency effort to protect the health of the American public by improving the safety of the Nation's food supply. Through joint planning, agencies can maximize the use of their resources and achieve the greatest improvements in food safety. This process began with the May 1997 report to the President, entitled, Food Safety from Farm-to-Table: A National Food Safety Initiative. The report recognized foodborne illness as an emerging public health hazard that required aggressive government action, identified critical gaps in the food safety system for controlling or eliminating foodborne pathogens from the food supply, and proposed a strategy for closing those gaps.

1998 and 1999 Activities

The 1998 budget initiative brought much-needed new resources to enhance surveillance of foodborne disease and outbreaks and better coordinate our response to outbreaks, improve inspections and compliance–particularly seafood HACCP inspections, target important new research and risk assessment to critical scientific gaps, and strengthen education and training especially of those who handle food at critical points from the retail setting to the home. The 1999 initiative built on science-based gains made in these areas, and placed increased emphasis on ensuring the safety of domestic and imported fresh produce and imported foods; targeted retail food safety education; transformed traditional meat and poultry inspection systems to science-based HACCP systems; and developed scientific information and tools to control a greater range of food safety hazards.

2000 Budget Request

For 2000, the Administration is proposing an increase of $74.8 million for the President's Food Safety Initiative. Of this amount, $40 million is allocated to HHS and $34.8 million to USDA. The 2000 President's Food Safety Initiative builds on the foundation established in 1998 and 1999. Additional resources will be targeted to: (1) further develop a nationally integrated, seamless, and science-based food safety system, (2) enhance public health surveillance and increase the speed and efficiency of responses to outbreaks of foodborne illness, and (3) place greater emphasis on the control of foodborne hazards in the pre-harvest phase of the farm-to-table continuum. Funding is requested for the following activities:

Enhance Surveillance and Investigation to Improve Outbreak Response (+$16.4 million):

HHS (+$16.4 million): The Food and Drug Administration (FDA), working through the Centers for Disease Control and Prevention (CDC) will expand PulseNet to provide more direct access by more district laboratories, and increase outbreak response and associated traceback activities based on FoodNet data. FDA will begin initial development of electronic communication and data sharing systems for use in Federal-State monitoring and traceback activities. FDA, working with CDC, will also expand and increase the overall capacity of the National Antimicrobial Resistance Monitoring System (NARMS) and the number of States covered to assure a higher probability of detecting emerging resistant pathogens capable of animal to human transmission and to minimize the occurrence of foodborne outbreaks including those from outside of the United States. CDC will identify foodborne hazards and characterize the risk posed by those hazards, increase the speed with which the presence of hazards in foods can be determined and controlled, and improve the accuracy and timeliness of public health data that justify food safety control programs and evaluate their effectiveness. CDC will also work with the States to improve diagnostic capacity for viruses and parasites, and expand the network of States with capacity to interact electronically with CDC to evaluate and improve diagnostic practices.

Strengthen Coordination and Improve Efficiency (+$0.5 million):

USDA (+$0.5 million): The Food Safety and Inspection Service (FSIS) will assign district epidemiologists to work with State Departments of Agriculture and Public Health to better coordinate responses to foodborne disease outbreaks and recalls. Efforts will be directed at increasing the speed and efficiency of responding to outbreaks of foodborne illness and to prevent further outbreaks. Funds will provide the specialized training, supplies, technology, and equipment for district epidemiology officers. This effort will further assist Federal, State, and Local integration in support of a seamless national food safety program.

Expand Inspection and Compliance Efforts with Additional Emphasis on High Risk Foods, Imported Produce, and Enhancing Federal-State Partnerships (+$19.3 million):

HHS (+$16.9 million): FDA will increase inspection coverage and frequency of coverage of domestic firms, with the highest risk firms being inspected once per year beginning in FY 2001. FDA will increase the number of inspections of foreign processors and will conduct evaluations of foreign food productions systems. FDA will continue to provide training to State and local food safety officials and industry in the effective use of preventive control systems, such as hazard analysis and critical control point (HACCP) systems–especially seafood HACCP systems, and to perform inspections of HACCP systems. FDA will provide States resources and "hands-on" training to promote the adoption of the Food Code by retail establishments.

USDA (+$2.4 million): In 2000, all State meat and poultry establishments will be required to have implemented hazard analysis and critical control point (HACCP) systems. By that time, the 26 State meat and poultry inspection programs will be required to amend their regulations to make them equal to Federal regulations. To facilitate this transition, FSIS will conduct the pathogen testing required by the HACCP rule of State inspected meat and poultry products in FSIS laboratories. In addition,

FSIS will conduct comprehensive reviews of State laboratories to validate the ability of these laboratories to meet HACCP testing requirements. Demonstrating compliance with pathogen testing requirements of the HACCP rule will be a major prerequisite for permitting interstate shipment of State inspected product. Assisting States will integrate and unify efforts to create a seamless national inspection program.

Improve Capability to Estimate Risks Associated with Foodborne Hazards (+$7.9 million):

HHS (+$1.5 million): FDA will develop methods for predicting the risk associated with foodborne pathogens and will develop partnerships with government, industry, and academic scientists to conduct studies that demonstrate comparability of disease across species. FDA will continue a program of research in quantitative risk assessment (particularly for microbial hazards) that is targeted to address the limitations in risk assessment methodologies. FDA will continue to build the activities of the interagency Risk Assessment Consortium that provides a forum for coordination of Federal microbial risk assessment research. FDA through the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) will continue development of a risk assessment clearinghouse to better establish government, industry, and academic partnerships.

USDA (+$6.4 million): The Agricultural Research Service (ARS), the Cooperative State Research, Education, and Extension Service (CSREES), the Economic Research Service (ERS), and the National Agricultural Statistics Service (NASS) will extend risk assessment modeling and data collection to include the pre-harvest phase for all foods. Previous risk assessment activities have focused on post-harvest operations. This pre-harvest modeling is necessary to determine the effects of various production practices, processing, and transportation systems on the behavior and subsequent contamination of poultry, beef, and swine as they are presented for slaughter. A Nationwide survey of fruit and vegetable producers and packinghouses will be conducted to establish a baseline of agricultural handling practices related to food safety. Data from the survey would be used to target food safety education materials and to conduct economic analyses concerning food safety related agricultural practices.

Continue to Develop and Disseminate Targeted Food Safety Education Materials (+$2.4 million):

HHS (+$1.5 million): FDA, in cooperation with USDA and other Federal, State, and local agencies, will develop multi-lingual education programs for food service workers and will implement a National education and training program to ensure greater safety in retail food preparation practices, including the use of HACCP principles in retail establishments. Efforts will focus on the development of education materials for educating and training relating to proper storage, handling, and transportation practices identified in the Food Code. In addition, FDA will develop educational messages for using antimicrobial drugs for use in animal foods.

USDA (+$0.9 million): CSREES, will develop educational programs that target high-risk, under-served populations who are at increased risk from developing foodborne illnesses, such as the elderly, children, and immuno-compromised individuals. Food safety education materials will also be provided to very small retailers and distributors to increase their awareness of their food safety

responsibilities as part of a Nationwide education and training program. In additional CSREES will develop and implement training programs for producers, veterinarians, and crop consultants on good manufacturing and agricultural practices that can minimize microbial contamination of their products.

Accelerate Food Safety Research (+$28.2 million):

USDA (+$24.5 million): ARS and CSREES will support research projects that will contribute to the development of effective methods of handling and treating agricultural products to minimize microbiological contamination. Control of animal production practices, including manure management, will prevent possible distribution of pathogens to crops or other animals from surface runoff and irrigation waters. In addition, improved detection methodologies will be developed to enable producers to monitor their production processes for contamination. Research will also be supported to develop the knowledge necessary to prevent the development of antibiotic drug resistance. Research results will be used to develop strategies to prevent both the emergence and the maintenance in food producing animals of pathogenic and non-pathogenic antibiotic resistant bacteria. The Agricultural Marketing Service (AMS) will establish microbiological baselines for pathogens on fruits and vegetables. This information will contribute to the identification of microbiological hazards and the development of intervention strategies to reduce the food safety risks posed by these products.

HHS (+$3.7 million): FDA will expand research on methods development and prevention technologies. FDA will collaborate with other Federal agencies and the private sector at the National Center for Food Safety and Technology (NCFST) and with academia to translate preventive technologies and techniques into appropriate versions for use by small firms and consumers. FDA and USDA will expand mechanisms to transfer technologies to States, small and large firms, foreign governments, consumers, and others. FDA will expand its ongoing research on the development of methods for detecting foodborne pathogens in animal feeds.

PRESIDENT'S FOOD SAFETY INITIATIVE
FY 2000 BUDGET

ACTIVITY	1997	1998	1999	2000 Budget	Proposed Increase
	Dollars in Thousands				
SURVEILLANCE:					
USDA:					
Food Safety and Inspection Service	$1,000	$1,500	$1,500	$1,500	$0
Economic Research Service	32	32	282	285	3
Subtotal, USDA	1,032	1,532	1,782	1,785	3
HHS:					
Food and Drug Administration	737	3,897	3,897	10,297	6,400
Centers for Disease Control and Prevention	4,500	14,500	19,000	29,000	10,000
Subtotal, HHS	5,237	18,397	22,897	39,297	16,400
Subtotal, Surveillance	6,269	19,929	24,679	41,082	16,403
COORDINATION:					
USDA:					
Food Safety and Inspection Service	0	0	0	500	500
HHS:					
Food and Drug Administration	7,173	7,723	7,723	7,723	0
Subtotal, Coordination	7,173	7,723	7,723	8,223	500
INSPECTIONS:					
USDA:					
Food Safety and Inspection Service	0	565	10,113	12,513	2,400
HHS:					
Food and Drug Administration	73,244	81,114	105,614	122,514	16,900
Subtotal, Inspections	73,244	81,679	115,727	135,027	19,300

ACTIVITY (Cont.)	1997	1998	1999	2000 Proposal	Pro Increase
	Dollars in Thousands				
RISK ASSESSMENT:					
USDA:					
Agricultural Research Service	5,461	4,498	4,909	7,309	2,400
Cooperative State Research, Education, and Extension Service	145	150	2,612	3,702	1,090
Food Safety and Inspection Service	0	0	3,260	3,260	0
Economic Research Service	33	33	236	686	450
National Agricultural Statistics Service	0	0	0	2,500	2,500
Office of the Chief Economist	62	60	158	158	0
Subtotal, USDA	5,701	4,741	11,175	17,615	6,440
HHS:					
Food and Drug Administration	2,589	6,539	6,539	8,039	1,500
Subtotal, Risk Assessment	8,290	11,280	17,714	25,654	7,940
EDUCATION:					
USDA:					
Cooperative State Research, Education, and Extension Service	2,365	2,365	7,365	8,287	922
Food Safety and Inspection Service	0	0	3,659	3,659	0
Food And Nutrition Service	0	0	2,000	2,000	0
Office of the Chief Economist	27	38	38	38	0
Economic Research Service	420	420	420	420	0
Subtotal, USDA	2,812	2,823	13,482	14,404	922
HHS:					
Food and Drug Administration	4,800	6,870	6,870	8,370	1,500
Centers for Disease Control and Prevention	0	0	476	476	0
Subtotal, HHS	4,800	6,870	7,346	8,846	1,500
Subtotal, Education	7,612	9,693	20,828	23,250	2,422
RESEARCH:					
USDA:					
Agricultural Research Service	44,186	50,351	64,959	74,279	9,320
Cooperative State Research, Education, and Extension Service	3,724	6,250	14,788	23,799	9,011
Agricultural Marketing Service	0	0	112	6,297	6,185
Subtotal, USDA	47,910	56,601	79,859	104,375	24,516
HHS:					
Food and Drug Administration	20,793	27,193	27,693	31,393	3,700
Subtotal, Research	68,703	83,794	107,552	135,768	28,216
TOTAL, INITIATIVE	171,291	214,098	294,223	369,004	74,781

PRESIDENT'S FOOD SAFETY INITIATIVE
FY 2000 PROPOSAL

TOTAL INITIATIVE	1997	1998	1999	2000 Proposal	Increase Over 1999
	Dollars in Thousands				
USDA:					
Agricultural Research Service	$49,647	$54,849	$69,868	$81,588	$11,720
Cooperative State Research, Education, and Extension Service	6,234	8,765	24,765	35,788	11,023
Agricultural Marketing Service	0	0	112	6,297	6,185
Food Safety and Inspection Service	1,000	2,065	18,532	21,432	2,900
Economic Research Service	485	485	938	1,391	453
Office of the Chief Economist	89	98	196	196	0
National Agricultural Statistics Service	0	0	0	2,500	2,500
Food and Consumer Service	0	0	2,000	2,000	0
Subtotal, USDA	57,455	66,262	116,411	151,192	34,781
HHS:					
Food and Drug Administration	109,336	133,336	158,336	188,336	30,000
Centers for Disease Control and Prevention	4,500	14,500	19,476	29,476	10,000
Subtotal, HHS	113,836	147,836	177,812	217,812	40,000
TOTAL, INITIATIVE	171,291	214,098	294,223	369,004	74,781

Facsimile Cover Sheet

Food Safety Initiative

U.S. Department of Agriculture
Office of Communications
Office of the Director/Press Secretary
Washington, D.C. 20250
Phone: 202.720.4623
Fax: 202.720.5043

Date: 2/22/99

To: TOM F.

Company/Agency:

Phone:

Fax: 456-7431

From: ANDY

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FOR RELEASE UPON DELIVERY
TUESDAY, FEBRUARY 23, 1999

REMARKS BY

DONNA E. SHALALA

U.S. SECRETARY OF HEALTH AND HUMAN SERVICES

NATIONAL FOOD SAFETY CONFERENCE

WASHINGTON, D.C.

*THIS TEXT IS THE BASIS OF SECRETARY SHALALA'S ORAL REMARKS. IT SHOULD BE USED WITH THE UNDERSTANDING THAT SOME MATERIAL MAY BE ADDED OR OMITTED DURING PRESENTATION.

As I think all of you know, I was just up on Capitol Hill testifying on behalf of the President's budget proposal. But what perhaps only some of you know is that included in the President's budget is a $105 million increase in funds for food safety.

So, I hope you'll believe me when I tell you that, while I would have enjoyed spending my morning here with you, I really did have 105 million good reasons to be somewhere else.

I am glad to have the chance to speak with you just for a moment.

This, of course, is the first national conference ever for state secretaries and commissioners of agriculture and health. It's a unique chance to take a close look at the issues and events that have been impacting food safety throughout this country – at both the state and national level.

But what makes this conference so very important isn't just that it provides us a setting to consider where we've been. It also offers us an opportunity to discuss where we need to go.

From this Administration's very first days, President Clinton, Vice President Gore USDA, HHS -- all of us -- have worked hard to ensure that the safety of our nation's food supply receives the attention it deserves.

That vision is what led to the President's Food Safety Initiative and the creation of the President's Food Safety Council. For the first time ever, we have a structure in place to assure that HHS, USDA – and every other government agency involved with food safety – works cooperatively to meet common goals.

As I think Secretary Glickman already mentioned, one example of that new cooperation is that FSIS and FDA staff are now going to be exchanging more information than ever before in the field. What that means is that district offices of each agency will tell their counterparts about recalls, contamination, mislabeling or unhealthy conditions.

Now, we haven't always seen that kind of cooperation in the past, but because of our vision of what food safety ought to be, you're going to see more of it in the future.

And, I can tell you, that same commitment to food safety guides the FDA, the CDC – and my entire Department -- every working day.

For example, at the CDC, we launched PulseNet, a national public health laboratory network that fingerprints bacteria so we can do an even better job detecting foodborne illness. At the same time, we've also expanded FoodNet: our Foodborne Disease and Active Surveillance Network, a system many of you have implemented through sentinel

sites at the state level. We all know that CDC scientists are disease detectives. Well, let me tell you: we plan to be to foodborne disease what the FBI is to organized crime.

In our implementation of HAACP for seafood in 1998, the FDA inspected every domestic seafood processor in this country. A number of you here helped us. And we're going to be back and do it again this year.

Over the last year, the FDA also developed an improved technique that can directly detect and quantify *E. coli* within 30 minutes. It used to take as long as two days!

And today, I'm proud to announce that we made the best even better in our new, 1999 model Food Code.

The model Food Code, which was just published, is now available from the FDA. Soon you'll even be able to download it from a new web site sponsored jointly by HHS, USDA and EPA. The name of our site? It's FoodSafety--dot--gov.

This is the 4th Edition of the model Food Code, and I think it's the best ever. Take a look and you'll see model state legislation for safe food handling. Practical guidelines that can – and should – be adopted and implemented in every government agency responsible for managing food safety risks.

Last June, Secretary Glickman and I wrote every Governor asking them to support adoption of the model Food Code in their state. Some states have already moved ahead and done just that. But we need your support to see to it that the code is also adopted and implemented in those that haven't.

This new model Food Code – together with our other initiatives -- represents something else, too: our commitment to provide public health professionals with the best, science-based measures to reduce risk factors.

And that same commitment is reflected in President's budget.

Instead of wasting precious tax dollars on new bureaucracies, we're carefully investing in scientific research, consumer education and better enforcement. Under the President's new spending plan, funding for the FDA's food safety programs will be increased by $30 million. That means increased domestic inspections of high-risk foods and laboratory analysis. And it's going to allow us to expand coverage of imported food products, too.

With these dollars, we'll be able to expand FDA – and State – outbreak response and traceback activities. We'll be able to educate more consumers. And we'll be able to focus on ways to prevent contamination and develop new methods to detect and identify pathogens. Sure, it costs money, but what's more important is that it saves lives.

That's not all. The President's budget also provides a $10 million increase for the CDC's food safety programs. With those funds the CDC will be able to help more State Health Departments plug into PulseNet. We'll be able to standardize rapid, new testing techniques. And we'll also be able to expand our prevention efforts. I'm talking about the kind of prevention efforts that led to the reduction of dome diseases, such as *group B streptococcal* or GBS.

Between 1993 and 1995 we saw a 40 percent reduction in GBS cases in communities that implemented the CDC's GBS guidelines. That's what a sound, science-based prevention initiative can achieve, and we need to see more of it.

But you and I know it's not just a question of how many dollars are allocated here in Washington: It's also how well we work with you in the states. That's why I was so proud of the role HHS and USDA played last September when local, state and federal officials met in Kansas City.

The topic on everyone's mind then was coordination and how government -- at every level -- could play its part to assure food safety from the farm to the supper table. In many respects, I think it's the same topic that's before us today. It's taking the scientific knowledge we're generating at the federal level and seeing that it's put to work for families all across this country.

When I was Chancellor of the University of Wisconsin we used to call that the Land Grant philosophy. But it was something else, too: common sense. And, I'm convinced that's the only way we can create the seamless, integrated food safety system America needs – and deserves.

Thank you, and have a great conference.

REMARKS OF AGRICULTURE SECRETARY DAN GLICKMAN
NATIONAL FEDERAL-STATE FOOD SAFETY CONFERENCE
WASHINGTON, D.C. - FEBRUARY 23, 1999

INTRODUCTION

Thank you, Cathie [*Woteki*]. It always helps to have somebody who works for you introduce you. I see a lot of familiar faces ... folks I've worked with for some time ... folks I met at the NASDA conference yesterday. These are tough times for agriculture, and we all are working hard to help see farmers and ranchers through to more prosperous days. After many years in this job and as a Congressman representing an agricultural district, I know that food safety is an important part of this picture. Safe food sells. The more we improve the world's safest food supply, the more value we add to U.S. agriculture and the greater the contribution we make to the public health.

I've been in this job almost four years. Before that, I was a Congressman from Kansas, where I lived and breathed wheat and cattle. After 18 years of that, I was prepared for all the questions I get in this job about grain exports and cattle prices. But I was a little surprised that these questions ran second to the ones I field most. No matter where I am, people come up to me and ask: 'How do I cook a hamburger right? When do I know my Thanksgiving turkey is done? How can I be ***sure***?'

I was at a charity dinner a couple years back where Cokie Roberts of ABC News was the emcee. When she introduced me after the meal, she got up and said she watched me eat the ***whole*** time, and everything ***I*** ate, ***she*** ate, because she ***knew*** it would be ***safe***. Now, that's a risky strategy. You could gain a few pounds. But it goes to show that food safety is an issue that hits home with everyone. This issue touches each of us - no matter who we are - in a very direct way.

In doing so, it gives government an opportunity to do what it does best. Many of you took an airplane to be here. Very few people question government's duty to ensure the planes we fly in our safe. No one objects to government's role ensuring that if a bank sinks, our life savings don't go down with the ship. As our country takes steps to protect us from threats of terrorism, I don't know of a single person who would stand up and cry 'pork.' The same is true of the food on our plate. We want our government to protect us in ways that we cannot protect ourselves.

And, when I say 'the government,' by no means do I refer solely to the Department of Agriculture. One thing I've learned from the breadth of questions I field is that people don't ***care*** if it's USDA or FDA; they don't care if it's a ***federal*** meat inspector or a ***state*** public health inspector; they just want ***their*** government to do its job and do it well.

From the Pacific Northwest outbreak that took place right when the President took office to the recent tragic Listeriosis outbreak, this Administration has taken the issue of food safety very personally. We have sought - through greater investments in research, more modern, science-based inspections, state-of-the art DNA fingerprinting and surveillance - to turn the tables on food-borne illness. We are well on our way to achieving that goal -- thanks to our work, to the

strong backing of American families and to a strong, growing partnership with all of you.

Whether visiting Dr. Kobayashi and his team in Washington State who stopped the Pacific Northwest Outbreak or talking to professors at Tennessee State about their food safety research or hearing about the state public health folks who worked around the clock to help us stop the Listeria outbreak, I am regularly reminded that this Administration is hardly alone in its work. Everyone in this room works on food safety every day. So, as I work toward the President's goal of a 'seamless' food safety system, I know that I need you to work with me to cast aside the local/state/federal turf battles that mean ***nothing*** to that parent watching their child eat dinner.

This is the first conference of its kind bringing together the top people at the federal and state level who are responsible for food safety. On the one hand, I am surprised it's taken this long. It seems so obvious. On the other hand, I am proud that this gathering takes place on ***my*** watch. And, I know that I and all of my food safety colleagues at USDA are proud to play host today.

From the money we spend every year, to the seven USDA agencies that are involved with food safety issues, to the wide range of our work -- from research to risk assessment to surveillance to education to inspections -- USDA is ***the*** largest government food safety entity in the world.

But we know that we alone cannot overcome today's significant challenges: new, more virulent pathogens; ***old*** pathogens finding their way onto ***new*** foods; consolidation in agriculture leading to more food being processed in one place and then shipped across the country - making it harder to pull suspect food ***back*** or even to ***identify*** a problem that's so geographically dispersed; people eating more meals away from home; folks eating more ***imported*** foods, particularly produce, and a growing senior population whose immune systems are more vulnerable.

The unfortunate truth is that food can be contaminated at any point from farm to table, and it becomes crystal clear that we need our respective strengths, resources and people power working together to create a ***seal*** of safety for consumers that covers every kind of food.

USDA ACCOMPLISHMENTS

I can't help but cite food safety problems in other parts of the world. Remember last year's bird-flu epidemic in Hong Kong, where they killed all the chickens? Afterwards, consumers in that country cut their poultry purchases in ***half***. In post-mad cow Europe, beef sales plummeted by 40%. We don't see those kinds of extreme market reactions here. And, that tells me that all of us are doing something ***right*** because consumers here - by and large - have ***confidence*** in their food supply, and they have confidence in us, that we are putting their safety first. That's an important statement about our public health commitment - at the state ***and*** federal levels - and, I am utterly convinced, it is a statement that U.S. agriculture can take to the bank.

And, the news is getting better. Last year, HACCP, our revolutionary new, science-based meat and poultry inspection system, debuted in the larger plants. In HACCP's first nine months, we've seen more than a 40% drop in salmonella in ground beef. We now are phasing the system in at

smaller plants. Our focus there is on ensuring compliance – so we maintain one strong standard – while helping companies succeed with their transition. So we are working closely with the plants.

USDA has come a long way since the 1994 reorganization which pulled our food safety duties ***out*** of the marketing arena – where there was at least an ***appearance*** of conflict of interest. Now, we have a separate, ***independent*** food safety agency – run by America's first and only Undersecretary for Food Safety who is at USDA. We've also dramatically expanded our food safety research agenda – going after problem pathogens that affect the entire ***range*** of foods – from meats and poultry to fruits and vegetables. When this Administration came in, you would rarely hear the word public health uttered at USDA. Now, we have an ***Office*** of Public Health and Science, within our food safety mission, which is headed by some of the top food safety and public health experts in the world. These changes make a tremendous difference as we shift to a more science-based approach.

LISTERIA

Our response to the Listeriosis outbreak is just the most recent example of science and greater coordination protecting people and saving lives. This was a terrible tragedy that occurred across ***19*** states. The individual doctors treating the victims had little chance of connecting the dots across such a wide area and recognizing the outbreak. Fortunately, through the Pulsenet system which USDA helped build, these doctors could give samples from their hospital to their state health office and from there, the data enters a nationwide surveillance system which verified the match and alerted us that these illnesses were coming from the same culprit bacteria. Good scientific investigating tracked that bacteria to its source, the company conducted a recall, and we saw a dramatic drop-off in illnesses.

We all want to reach the day when there are ***zero*** illnesses, a day when we achieve our ultimate goal of total prevention, and no family has to go through what the families of these victims have been through. But we are not there yet. We at USDA are working very hard, alongside many of you, to explore what more can be done to combat Listeria. I hope we also heed what the experts are telling us -- that ***without*** the strong coordination among the various public health authorities that we had in recent weeks, and ***without*** this national surveillance network that this President worked so hard to expand, we would likely ***still*** have an outbreak on our hands. We would not have been able to pinpoint its source, and lives would have remained at risk.

USDA/STATE/FEDERAL COOPERATION

Greater coordination is how we achieve a seamless food safety system, and that is the ultimate goal of the President's Council on Food Safety which he created last year. It charges me and Secretary Shalala, and Dr. Neal Lane, the director of the Office of Science and Technology Policy, to develop a unified strategy for achieving food safety at the federal level, and in coordination with the states – covering everything from our respective budgets to research.

One small way we are improving coordination at the federal level is through a new

Memorandum of Understanding that formalizes the working relationship between FDA and USDA inspectors. Sometimes we work in the same plants, inspecting the different products that fall under our purviews. This MOU ensures that our inspectors – if they see a potential problem that does not affect 'their food' -- make sure the right person is informed.

We also have a new coalition that's come together to work on interstate shipment issues. Right now, state-inspected meat is forbidden by law from shipping across state lines. Historically, this has been a thorny issue. Some folks thought it would never work out. Well, I'll have you know that USDA is in the final stages of clearing legislation -- which we hope can be considered during ***this*** Congress – to free up interstate shipments. And, I'll have you know that in this year's budget, we've asked for money to ***help*** state labs upgrade their inspection technology, so as many states as possible are in a position to take advantage of this breakthrough.

Another issue we are working on with all of you is the Food Code that helps ensure that the best science is behind the various state regulations regarding restaurant food safety. I know that Secretary Shalala is going to talk later today about this issue. It's one more way we can give consumers peace of mind, no matter who is responsible for any one aspect of food safety.

Some look at all of this work and see a hodge-podge of food safety efforts. But the fact is we at USDA are in daily collaboration with state, local and federal agencies... We have a Joint Institute for Food Safety Research – which is working between federal agencies, with the land-grant universities and others to develop a coordinated food safety research strategy to ensure that every federal research dollar is put to its best possible use ... We've more than quadrupled our food safety education budget in the past two years ... USDA provides over $40 million to the 26 states who run their own inspection efforts – covering ***half*** of their costs ... We are working on partnerships with state veterinarians to develop and encourage producers to adopt voluntarily on-farm practices that promote food safety ... We helped create FORC-G, a team of federal and state food safety experts who respond to outbreaks – quickly, effectively, and as one team.

So whether it's these issues, or transportation or retail issues, we are working more closely together, and I believe we are starting to see dividends. It's my hope that we can continue down this path -- making the best strategic use of our resources, building on our various strengths and going forward as equal partners. I hope that this conference can serve as an important step in the right direction, strengthening our farm economy and helping us deliver safer food to Americans and people around the world. Thank you.

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FDA Vows Top Priority for Food-Safety Items

By Rochelle Sharpe
Staff Reporter of The Wall Street Journal

WASHINGTON — The Food and Drug Administration said it will give top priority to petitions for new food additives that could improve food safety.

The agency said that it will expedite the review of proposed additives that could cut the risk of food-borne illnesses caused by such toxins as *E. coli, salmonella* and *cyclospora*. Food-borne illnesses cause an estimated 9,000 deaths and 33 million illnesses in the U.S. each year, said Joseph Levitt, director of the FDA's Center for Food Safety and Applied Nutrition.

"We want to provide an incentive to companies that want to develop these kinds of products," Mr. Levitt said. "We'll move them to the head of the [application] line, so no time is wasted."

Currently, the petitions are considered in the order they are submitted, and can take years to be approved.

It took the FDA four years to approve chlorine dioxide for sanitizing peeled or cut produce that would later be frozen, said the National Food Processors Association, the trade group that submitted the food additive petition. The association was surprised by the delay, since the sanitizer already had been approved for cleaning whole fruits, said Timothy Willard, an association spokesman.

Similarly, the FDA took four years to approve the irradiation of beef, even though the agency had already approved irradiation for fruits, vegetables, spices, poultry and pork, Mr. Willard said.

For purposes of food-safety law, irradiation is considered a food additive because it produces changes in food.

Mr. Levitt said his office is reviewing food-additive applications to see if any would qualify for the expedited review. He said he believed that a few companies might qualify, but could not mention any by name.

Of the hundreds of food-additive applications now pending at the FDA, only about a dozen are designed to improve food safety.

Waiting for the FDA to consider an application is only one reason why petitions get delayed. Often, companies spend years providing extra data requested by the FDA. Although the FDA will not change its regular review procedures for these expedited petitions, Mr. Levitt said he believed that companies benefiting from the speedy treatment would submit more complete data in their initial petitions.

"There really is a need for more products," said Mr. Levitt, who views the change as part of the agency's larger push to improve food safety. There's a major research effort under way to develop more effective ways to prevent food-borne illnesses, he said. Earlier this week, the Clinton administration proposed increasing the fiscal 2000 budget for food safety by $105 million, or 12%.

Clinton Pledges New Aid for Hog Farmers

By Bruce Ingersoll
And Jeanne Cummings
Staff Reporters of The Wall Street Journal

WASHINGTON — The Clinton administration promised to seek several new ways to bail out hog farmers from their worst financial crisis in 50 years.

One possibility is for the government to buy hogs now for delivery in the summer. The government also is considering plans to airlift many of the hogs it buys, as well as pork shipments as food assistance, to Central American nations trying to recover from Hurricane Mitch, and to slaughter some hogs for domestic meal programs if such pork would otherwise go to waste.

Hog producers met yesterday with President Clinton and other senior officials and came away somewhat buoyed by the administration's commitment to shore up pork prices and ease a growing cash and credit crunch in North Carolina, the Midwest and other hog-producing areas.

Mr. Clinton reassured the group that he understands the need "to act immediately," said Sen. Kent Conrad (D., N.D.), one of four farm-state senators attending the meeting.

To ease a hog glut, the administration will look into whether the Agriculture Department has the authority to engage in forward contracting, said John Podesta, White House chief of staff. In theory, the government would pay cash-strapped farmers upfront for hogs that wouldn't be delivered for slaughter until summer. By that time, hog prices are projected to return to break-even levels.

Forward contracting would provide hard-pressed producers with a "cash bridge," said Mr. Podesta.

Last month, hog prices collapsed to their lowest levels in 50 years, primarily because the supply of market-ready hogs exceeded the industry's slaughter capacity. In some parts of the Hog Belt, prices dropped below $10 per hundredweight. That means a 250-pound hog that once fetched about $120 brought less than $50.

A few pork packers' willingness last month to set price minimums of $15 to $25 per hundredweight has provided some relief. But University of Missouri economists estimate that U.S. pork producers still lost $2.5 billion in 1998.

The administration already has granted leniency to hog producers that rely on government credit. It also stepped up government purchases of pork for the school-lunch program and overseas food aid, among other things.

Pork and beef producers have long complained about anticompetitive practices in the meat-packing industry, which is dominated by a handful of large companies in the wake of significant consolidation. Yesterday, administration officials said that they would consider a range of options for investigating those complaints, including an inquiry by the Justice Department's antitrust division.

SEC to Fine Firms, Ending Nasdaq Probe

By Michael Schroeder
And Anita Raghavan
Staff Reporters of The Wall Street Journal

The Securities and Exchange Commission plans to impose more than $15 million in fines on about 26 securities firms in a settlement that would wrap up the lone unresolved case in the government's long-running probe into alleged trading abuses in the past on the Nasdaq Stock Market.

The SEC also will file civil charges against as many as 50 individual traders, the most defendants it has named in a single case, according to lawyers familiar with the case. The settlement with the firms, as well as with any individuals who choose to settle, is expected to be announced as early as Monday.

Among the charges: failing to provide the best prices for customer orders; intentionally delaying trade reports; failing to honor quoted prices on the Nasdaq market; and failing to reasonably establish and enforce policies and procedures to supervise Nasdaq traders. Spokesmen at the firms and the SEC declined to comment.

The industrywide deal – in which the firms and the settling individuals wouldn't admit or deny wrongdoing – would conclude a tumultuous chapter in the nearly 30-year history of the Nasdaq Stock Market, which has grown from a small electronic market to rival the New York Stock Exchange in trading volume. The problems surfaced in 1994, when dealers trading on Nasdaq became the target of SEC and Justice Department investigations and civil lawsuits alleging price manipulation that cost investors an estimated several billion dollars.

Under the deal, the firms' broker-dealer units with the most violations would pay more in fines. As many as a half-dozen – including **PaineWebber Group** Inc.; **Warburg Dillon Read**, formerly known as UBS Securities Inc.; and **J.P. Morgan** & Co. – would pay fines of more than $1 million each.

Another half-dozen firms, including Smith Barney Inc., now **Salomon Smith Barney**, are expected to pay between $500,000 and $1 million, people with knowledge of the deal say. Several others, including **Merrill Lynch** & Co., the nation's biggest brokerage firm; Morgan Stanley & Co., which has since merged with Dean Witter, Discover & Co., to form **Morgan Stanley Dean Witter** & Co.; and **Charles Schwab**

Please Turn to Page C13, Column 1

Continued From Page C1

Corp.'s Mayer & Schweitzer Inc. unit, would each pay between $250,000 and $500,000. The brokerage firm, formerly known as Dean Witter Discover, which is now also part of Morgan Stanley Dean Witter, and **Lehman Brothers Holdings** Inc. would each pay fines of less than $250,000.

The settlement would be the last in the five-year probe. A year earlier, 30 Wall Street firms agreed to pony up $910 million to settle class-action litigation on behalf of investors who said they were overcharged in the Nasdaq market. Under a 1996 settlement with the Justice Department, securities firms were required to beef up oversight of their trading desks, but no fines were imposed.

More than two years ago, the SEC reached an agreement with the **National Association of Securities Dealers**, which owns and operates Nasdaq. That accord resulted in a 157-page report that shed light on trading practices in the Nasdaq Stock Market. Nasdaq agreed to pay $100 million to shore up regulation of the market.

Many of the firms facing the heftiest fines routinely taped conversations between their traders that provided the fodder for the SEC's cases. **Goldman, Sachs** & Co., by contrast, didn't broadly tape its traders and isn't being charged, these people say. A Goldman spokesman declined to comment.

The securities firms and the SEC have been negotiating a settlement since this past summer. In anticipation of a deal, many firms had informed managers that some traders, who could be named in civil suits, would be taking a "vacation" near the year's end.

Two issues in particular bogged down negotiations. The firms unsuccessfully fought charging individuals in civil cases, arguing that this would destroy a trader's career. The SEC is seeking to suspend traders from 30 days to more than a year, but is expected to name few, if any, managers in the civil cases.

The firms also balked at the SEC's insistence on an independent consultant to monitor the firms' compliance with trading rules. The firms ultimately agreed to the SEC's selection of its former general counsel, Jim Doty. Firms would submit for his review their plans for preventing future violations, which must ultimately be approved by the SEC.

THE WALL STREET JOURNAL
WEDNESDAY, JANUARY 6, 1999

(1) break down 21/8 FDA/USDA

(2) how many new plants 90's? a.m. (Suspend ~~[illegible]~~ plants)

(3) State inspection of meats ✓

(4) data base sharing – FDA

(5) Food net expand – FDA

(6) Fairness research / what USDA

(7) What's an ~~inspection~~ int'l [illegible] system

21/~~8~~6 (3)

Who to call [illegible]

fuller out

1. Research –
USDA getting

2. FSIS
Plant – tomorrow

3. Interstate shipment

Original justification
~~$~~832
→ half a hour

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(1) Flat budget fuller → – OMB agreed
17,

(2) FDA thinks tonight – USDA – 2 tomorrow – debates

(3) Group

FY 2000 Food Safety Initiative

President Clinton will recommend a $72 million expansion of his National Food Safety Initiative in his fiscal 2000 budget proposal. If enacted, the budget would result in a third year of significant growth in government efforts to prevent potentially deadly foodborne illness through a comprehensive, science-based inspection, surveillance, research and education system. The new funds are to shared by the Department of Agriculture (USDA), which which would receive $32 million, and the Department of Health and Human Services would receive about $40 million for the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC).

Improving Domestic and International Food Safety Inspections

The President proposes to greatly expand inspections of domestic and imported food products. He would ensure that the FDA inspect every high risk food manufacturer under its jurisdiction in the United States at least once each year (FDA is still checking). (Other food manufacturers would be inspected twice as often as they are now. **FDA checking to see if they can still do with $30 million)** Imported food would also be subject to increased scrutiny. FDA would double the number of inspections conducted of foreign food production systems from 100 to 200. The FDA has jurisdiction over all food products except meat, poultry, and egg products, which are under USDA's jurisdiction. For USDA, which conducts daily inspections of meat and poultry products, funds would be provided for continuing phase-in of HACCP, the Agriculture Department's science-based, prevention-oriented meat and poultry inspection system, which has already helped to reduce significantly dangerous pathogens levels. HACCP, currently in effect in the nation's largest plants, will be phased in at smaller plants over the next 13 months.

The President's plan also envisions even greater coordination among federal and state agencies handling food safety issues. For the first time, state and federal inspection results will be shared by electronic connection, reducing overlapping efforts and enhancing the ability of authorities to focus on public health improvements. USDA will strengthen its 26 federal-state partnerships to facilitate the interstate shipment of state-inspected meat and poultry products.

Public Health Research and Surveillance

The funding increase would also enable better surveillance of foodborne illness. CDC would expand its foodborne illness monitoring system, called "FoodNet," and its computerized database to identify unique illness "fingerprints," called "PulseNet." This expanded surveillance network if the heart of our nation's foodborne disease early warning system and was helpful in identifying the recent *Listeria monocytogenes* outbreak.

Finally, USDA and FDA's food safety research efforts would also benefit from the President's budget proposal. Expanded research would focus on:

- creating new detection tests for dangerous contaminants such as Salmonella in eggs, Cyclosopra in fresh produce, and test methods for E. Coli 0157:H7 in foods in which it cannot now be tested,
- helping farmers better control potentially dangerous bacteria and fungi in fruits and vegetables,
- combating antibiotic resistance in food-producing animals,

The President's Joint Institute of Food Safety Research will continue developing a strategic plan for conducting and coordinating all federal food safety research efforts and work closely with the private sector and academia in the process.

The President's proposal builds on a strong record of food safety accomplishments, ensuring that Americans eat the safest possible food. Last year, the President proposed a $101 million increase in food safety funding, more than $80 million of which was ultimately approved by Congress in the final budget. The Administration has put in place improved safety standards for meat, poultry, and seafood product, and has begun the process of developing enhanced standards for fruit and vegetable juices. [Add other accomps.] With these funds the Administration has put in place improved safety standards for meat, poultry, and seafood product, and has begun the process of developing enhanced standards for fruit and vegetable juices. [Add other accomps.]

Insert Budget Table

FDA'S YEAR 2000 FOOD SAFETY GOALS
(If funds are appropriated)

INSPECTIONS

- o Establish a nationally integrated food safety system with Federal, state, and local authorities.
  - 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).
  - 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
- o FDA will have an enhanced international food safety program, which will include evaluations of other countries' food safety systems and provision of technical assistance to foreign countries who import to this country (thereby continuing the shift to ensuring that foods are safely produced before they arrive at our shores).

RESEARCH

- o FDA will be able to ensure the applicability and effectiveness of the new preventive control techniques used to ensure the safety of seafood, juices, eggs, fresh produce and other foods.
- o New detection tests will be developed for such dangerous contaminants as Salmonella in eggs and Cyclosopora in fresh produce, and test methods for E. coli 0157:H7 in foods in which it cannot now be detected.

OUTBREAK RESPONSE

- o With its increased surveillance, CDC expects an increase of 40% of foodborne illness from E. coli 0157:H7 and salmonella, and 10% for all foodborne illness. Funding is needed so that FDA will have the laboratory and staff capability to respond rapidly to those outbreaks when they occur--to track down their source and prevent further danger.
- o CDC's new PulseNet contaminant tracing system will be connected to FDA's laboratories, thus enabling FDA to use this state-of-the-art disease detection system to control foodborne illness at the source.

RETAIL

- CDC estimates that one-third of foodborne illness comes from retail establishments. A majority of states will adopt FDA's model food code that raises the standards for safer handling of food in restaurants, nursing homes, hospitals, and grocery stores. If funding is available, FDA can provide the necessary training and education to state and local inspectors (as well as industry) to implement those new standards.

EDUCATION

- Targeted resources are needed so that the most vulnerable (e.g., elderly, very young, and pregnant women) will be taught how they should and can avoid contaminated food. The result will be that their behavior will begin to change so that the most severe illnesses and deaths can be prevented.

RISK ASSESSMENT

- New information will become available about how much of a contaminant must be in a food to make people sick (such as Listeria) and how certain contaminants (such as Salmonella) can best be controlled.

Food Safety FY2000 Budget Q&As
12/29/98

Q: What are high risk foods?

A: High risk foods are ready-to-eat foods that support bacterial growth such as raw and pre-cooked seafood products. - how many, how often, what %. -

Q: How often does FDA inspect foods currently?

A: Since the early 1980s, the number of food establishment inspections conducted by FDA has declined from over 21,000 to the current level of approximately 5,600 inspections per year. Consequently, FDA now inspects domestic establishments on average about once every seven or eight years, including inspections carried out under contract by the states. With regard to imported food products, the number of entries has increased from 1.1 million per year in FY 1991 to 2.1 million per year in FY 1997. FDA's level of coverage for imported foods has declined from 7.6 percent in 1993 to the current level of 1.6 percent in 1997.

Q: As the result of funding in the President's FY2000 budget, how often will domestic firms be inspected?

A: The President proposes to greatly expand inspections of domestic and imported food products. He would ensure that the FDA inspect every high risk food manufacturer under its jurisdiction in the United States at least once each year. Other food manufacturers would be inspected twice as often as they are now (from once every eight years to once every four years **FDA checking**). The FDA has jurisdiction over all food products except meat, poultry, and egg products, which are under USDA's jurisdiction. For USDA, which conducts daily inspections of meat and poultry products, funds would be provided for continuing phase-in of the Hazard Analysis Critical Control Point (HACCP), the Agriculture Department's science-based, prevention-oriented meat and poultry inspection system, which has already helped to reduce significantly dangerous pathogens levels. HACCP, currently in effect in the nation's largest plants, will be phased in at smaller plants over the next 13 months.

Q: As the result of funding in the President's FY2000 budget, how often will imported food be inspected?

A: Imported food would also be subject to increased scrutiny. FDA would double the number of inspections conducted of foreign food production systems from 100 to 200. USDA would use new funds to increase visits of U.S. inspectors and scientists to foreign

operations to determine the source of problems that may pose a safety hazard in imported produce.

Q: What is the listeria outbreak?

A: Four persons were killed and 40 others became sick by a strain of bacteria called listeria which probably came from tainted meat such as hot dogs and cold cuts. On December 22, Bil Mar Foods, a division of Sara Lee Corporation, announced that it was voluntarily recalling hot dogs and other packaged meats because of possible contamination with *Listeria monocytogenes*. Sara Lee said it is cooperating with investigators from the federal Centers for Disease Control and Prevention and the U.S. Department of Agriculture. About 1,800 cases of food poisoning caused by Listeria are reported annually in the United States. Listeriosis is a serious infection caused by eating food contaminated with a bacteria. Illness is most serious for pregnant women, newborns, and adults with weakened immune systems. Symptoms of listeriosis include fever, muscle aches, and sometimes nausea or diarrhea. In serious cases, the nervous system is involved and symptoms include headache, stiff neck, confusion, loss of balance, or convulsions. To avoid listeriosis illness, cook raw food from animal sources thoroughly; wash raw vegetables thoroughly; avoid unpasteurized milk; and wash hands, knives, and cutting boards after handling uncooked foods.

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release October 2, 1997

PRESIDENT CLINTON ANNOUNCES INITIATIVE TO ENSURE THE SAFETY OF IMPORTED AND DOMESTIC FRUITS AND VEGETABLES
October 2, 1997

Today President Clinton will announce an initiative to upgrade domestic food safety standards and to ensure that fruits and vegetables coming from overseas are as safe as those produced in the United States. The President will ask Congress to enact legislation that will require the Food and Drug Administration (FDA) to halt imports of fruits, vegetables and other food products produced in countries that do not meet U.S. food safety requirements. The President will direct the Department of Health and Human Services (HHS) and the Department of Agriculture (USDA) to work cooperatively with the agricultural community to develop guidance on good agricultural and manufacturing practices for fruits and vegetables.

Enhanced FDA Oversight for Imported Foods. The President will send legislation to Congress that will 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 on par with 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 -- comparable to existing law that requires 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. The President will also commit to providing the necessary funds in his Fiscal Year 1999 budget to enable the FDA to dramatically expand 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 make effective use of its new authority.

Development of Guidance on Good Agricultural and Manufacturing Practices. The President will direct the Secretary of Health and Human Services, in partnership with the Secretary of Agriculture and in cooperation with the agricultural community, to develop guidance on good agricultural and manufacturing practices within one year. This guidance will take into account differences in both crops and regions and will address potential food safety problems throughout the food production and distribution system such as sanitation, worker health, and water quality. The guidance -- the first-ever specific safety standards for fruits and vegetables -- 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, the President will also direct the FDA and USDA to develop coordinated outreach and educational activities.

Improvement of Monitoring and Inspection Activities Abroad. In addition to committing substantial resources to expand the FDA's international food inspection force, the President will direct the Secretaries of Health and Human Services and Agriculture to report within 90 days on how to improve the monitoring of agricultural and manufacturing practices abroad, to assist foreign countries to improve these practices where necessary, and to prevent the importation of unsafe produce. The President will urge consideration of ways to target inspection and testing toward those areas where problems are most likely to occur.

Clinton Administration Accomplishments In Improving Food Safety

The President's announcement builds on a strong record of food safety initiatives, ensuring that Americans eat the safest possible food. The Administration has put into place improved safety standards for meat, poultry and seafood products, and has begun the process of developing enhanced standards for fruit and vegetable juices. The Administration also has expanded research, education and surveillance activities throughout the food safety system.

* October, 1997. President announces new initiative to enhance FDA oversight over imported foods and develop guidance on good agricultural and manufacturing practices for fruits and vegetables.

* May, 1997. Administration announces comprehensive new initiative to improve the safety of nation's food supply -- Food Safety from Farm to Table -- detailing a $43 million food safety program, including measures to improve surveillance, outbreak response, education, and research.

* January, 1997. President announces new Early-Warning System to gather critical scientific data to help stop food borne disease outbreaks quickly and to improve prevention systems further.

* August, 1996. President signs Safe Drinking Water Act of 1996. The law requires drinking water systems to protect against dangerous contaminants like cryptosporidium, and gives people the right to know about contaminants in their tap water.

* August, 1996. President signs Food Quality Protection Act of 1996, which streamlines regulation of pesticides by FDA and EPA and puts important new public-health protections in place, especially for children.

* July, 1996. President Clinton announces new regulations that modernize the nation's meat and poultry inspection system for the first time in 90 years. New standards help prevent E.coli bacteria contamination in meat.

* December, 1995. Administration issues new rules to ensure seafood safety. Utilizes HACCP regulatory programs to require food industries to design and implement preventive measures and increase the industries' responsibility for and control of their safety assurance actions.

* 1994. CDC embarks on strategic program to detect, prevent, and control emerging infectious disease threats, some of which are food borne, making significant progress toward this goal in each successive year.

* 1993. Vice-President's National Performance Review issues report recommending government and industry move toward a system of preventive controls.

whubbard @ bangate.fda.gov
12/29/98 06:08:00 PM

Record Type: Record

To: Thomas L. Freedman

cc:
Subject: ...no subject...

Here are the answers to your questions:

1) The dollar breakdown for the $30M that we would recommend are:

$3M - Antibiotic Resistance (to our vet med center)

$5M - Surveillance (to hook FDA labs to the CDC Pulsenet system and to state labs, and to do additional tracebacks for the source of contamination when disease outbreaks occur)

$17.4M - Inspections

$12.5 - Domestic Inspections (would get high risk inspections done at least once a year, plus the necessary followup when problems are found; would allow HACCP training; $3M of this would go to states)

$5M for imports (increased inspections of imports and for evaluation of other countries' system)

$1M - Education (targetted at high risk populations, such as the elderly, very young, and immune compromised)

$3M - Research ($2M for domestic, $1M for imports; would allow additional test methods development to detect pathogens and to assess preventive control techniques)

$.5M - Risk Assessment (to do additional risk assessments)

Re: the question about state coordination, you could add a phrase that it will mean greater uniformity, consistency, and common standards among the states and with the Federal government in safety standards.

Re: the question about PulseNet, it would enable CDC to expand PulseNet to 30 state health departments with capacity for E.coli and Salmonella identification. [I don't know how many they do now, but I think its' about 10.]

Re: the research question about test methods, an example could be that "when the cyclospora outbreak occurred last year from tained raspberries, scientists had no test to find the contaminant in the berries; this funding will allow such tests to be developed."

With regard to the table: We have some serious concerns with the way the resources are currently shown. Using a base year distorts the comparison of resouces among the agencies because of different definitions in the base. If there was a consistent way of showing base resources, that would be fine. FDA defined activities that fall under the 6 categories identified for FSI (surveillance, etc.). Our base resources show what we did in 1997 (before the "official" FSI). If at all possible, the table should start with 1998 with the first increments for FSI and build from there.

whubbard @ bangate.fda.gov
12/29/98 06:24:00 PM

Record Type: Record

To: Thomas L. Freedman

cc:
Subject: ...no subject...

In response to your question about FDA inspections of foreign food production systems, new funds would allow FDA to send technical experts to other countries to examine the food growing, processing, and transportation systems, to determine if they meet high standards for safe production.

Eric Olsen <Eric.Olsen @ usda.gov>
12/29/98 06:04:00 PM

Record Type: Record

To: Mary L. Smith/OPD/EOP, Thomas L. Freedman/OPD/EOP

cc: Caren.Wilcox @ usda.gov (Receipt Notification Requested) , Cathie.Woteki @ usda.gov (Receipt Notification Requested)

Subject: Food Safety Questions

This is in response to Tom's questions about Interstate shipment, the scope of product that will be covered under HACCP, examples on research, and a detailed description of each agencies activities. I will have to get full info to you in the am, but here goes my informal version.

On Interstate:

Current law prohibits plants that are subject to State inspection from shipping products interstate. Most of these are small plants. Current law also requires that State inspection programs be at least equal to the Federal program.

USDA has conducted an open process over the past couple of years with all stakeholders to address the question of allowing state inspected product to be shipped interstate, including extensive consultation with an advisory committee and several public meetings.

Under the legislative proposal being developed, to be eligible to ship product interstate, States must have successfully implemented HACCP, the Administration's meat and poultry inspection reform. In addition, FSIS will conduct in-depth audits of every state program and the State will need to respond to any recommendations from FSIS for improving their program. Finally, FSIS will conduct the microbiological testing necessary to ensure that State inspected plants are meeting the pathogen reduction performance standard.

Scope of Product that will be covered under HACCP

As I told you, it is better to look at the percentage of product that is covered under HACCP than the percentage of plants. Currently, we cover a fairly large percentage of all meat and poultry products (but I don't recall specifics) but a small percentage of plants. There are something like 2000 plants coming on line in January. I will get you the precise number as well as an estimate of the percentage of product covered in the morning.

Research

You also asked for examples of how we will help farmers control potentially dangerous bacteria and fungi in fruits and vegetables, I need to get back to

you in the morning. The following may be helpful, however. We will determine how bacteria and fungi normally present on plants influence the growth and survivability of human pathogens, including developing data on characteristics of high quality products that resist the growth of pathogens. We will also develop technologies (chemical, physical) and strategies to control the pathogens, including handling procedures, rinses, etc to reduce pathogen populations on produce.

Agency specific breakdown

You asked for a description as to how each USDA agency will utilize its funds under the initiative. I will get a more precise description in the morning.

However, the following may be helpful:

FSIS: enhanced state partnerships, inspection, surveillance, and education
Ag Marketing Service AMS: surveillance/research ---data collection
Cooperative State Research, Education and Extension Service CSREES-- research and education (consumer and producer) (extramural research)
Agricultural Research Service (ARS)--USDA conducted research
National Ag Statistics Service NASS--Surveillance/data collection/survey
Chief Economist OCE-- risk assessment
Economic Research Service--risk assessment

Need more specific breakdown — how much to each of these activities?

FY 2000 Food Safety Initiative

President Clinton will recommend a $72 million expansion of his National Food Safety Initiative in his fiscal 2000 budget proposal. If enacted, the budget would result in a third year of significant growth in government efforts to prevent potentially deadly foodborne illness through a comprehensive, science-based inspection, surveillance, research and education system. The new funds are to shared by the Department of Agriculture (USDA), which which would receive $32 million, and the Department of Health and Human Services would receive about $40 million for the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC).

how broken down? (+ what does each do?)

Improving Domestic and International Food Safety Inspections

The President proposes to greatly expand inspections of domestic and imported food products. He would ensure that the FDA inspect every high risk food manufacturer under its jurisdiction in the United States at least once each year (FDA is still checking). ~~(Other food manufacturers would be inspected twice as often as they are now.~~ **FDA checking to see if they can still do with $30 million)** Imported food would also be subject to increased scrutiny. FDA would double the number of inspections conducted of foreign food production systems from 100 to 200. The FDA has jurisdiction over all food products except meat, poultry, and egg products, which are under USDA's jurisdiction. For USDA, which conducts daily inspections of meat and poultry products, funds would be provided for continuing phase-in of HACCP, the Agriculture Department's science-based, prevention-oriented meat and poultry inspection system, which has already helped to reduce significantly dangerous pathogens levels. HACCP, currently in effect in the nation's largest plants, will be phased in at smaller plants over the next 13 months.

how often now?

how many plants how large? how small? how many of each?

The President's plan also envisions even greater coordination among federal and state agencies handling food safety issues. For the first time, state and federal inspection results will be shared by electronic connection, reducing overlapping efforts and enhancing the ability of authorities to focus on public health improvements. USDA will strengthen its 26 federal-state partnerships to facilitate the interstate shipment of state-inspected meat and poultry products.

Public Health Research and Surveillance

examples — specific (how it works)

The funding increase would also enable better surveillance of foodborne illness. CDC would expand its foodborne illness monitoring system, called "FoodNet," and its computerized database to identify unique illness "fingerprints," called "PulseNet." This expanded surveillance network if the heart of our nation's foodborne disease early warning system and was helpful in identifying the recent *Listeria monocytogenes* outbreak.

Expand how? Anyway, you still say this increased was already expanded.

What is a high-risk plant?
How many are there?
How often do they get inspected now?

What does this mean?
100 → 200 countries?

Finally, USDA and FDA's food safety research efforts would also benefit from the President's budget proposal. Expanded research would focus on:

- creating new detection tests for dangerous contaminants such as Salmonella in eggs, Cyclosopra in fresh produce, and test methods for E. Coli 0157:H7 in foods in which it cannot now be tested,
- helping farmers better control potentially dangerous bacteria and fungi in fruits and vegetables,
- combating antibiotic resistance in food-producing animals,

The President's Joint Institute of Food Safety Research will continue developing a strategic plan for conducting and coordinating all federal food safety research efforts and work closely with the private sector and academia in the process.

The President's proposal builds on a strong record of food safety accomplishments, ensuring that Americans eat the safest possible food. Last year, the President proposed a $101 million increase in food safety funding, more than $80 million of which was ultimately approved by Congress in the final budget. The Administration has put in place improved safety standards for meat, poultry, and seafood product, and has begun the process of developing enhanced standards for fruit and vegetable juices. [Add other accomps.] With these funds the Administration has put in place improved safety standards for meat, poultry, and seafood product, and has begun the process of developing enhanced standards for fruit and vegetable juices. [Add other accomps.]

Insert Budget Table

CSPI Center for Science in the Public Interest

Publisher of *Nutrition Action Healthletter*

Date: 2/12/99

Time: 1040 am

FAX COVER SHEET

TO: Tom Freedman

Company: White House Domestic Policy Council

Fax Number: 456-7431 Phone Number: _____

Total Number of pages INCLUDING this cover sheet: 2

SENDER: Zoe Enga for Caroline Smith DeWaal

SENDER'S Phone Number: x364

SUBJECT: LA Times Editorial "Bad Politics, Bad Meat"

COMMENTS:

Tel: (202) 332-9110
Fax: (202) 265-4954
Suite 300
1875 Connecticut Avenue, N.W.
Michael F. Jacobson, Ph.D.
Executive Director

LOS ANGELES TIMES EDITORIALS

Bad Politics, Bad Meat

In the summer of 1996, the Clinton administration began implementing the nation's first new meat inspection system in 90 years, reassuring Americans preparing for their summer picnics that federal food inspectors would discard their medieval "poke and sniff" inspection methods and adopt modern scientific tests to detect microscopic pathogens.

The new system, however, was only partly phased in, and consumers seem less protected than ever. Last month, the Agriculture Department said it found more meat contaminated with the *E. coli* bacterium in 1998 than it had in the previous four years combined. And last week, the federal Centers for Disease Control reported that hot dogs tainted with a deadly strain of listeria bacteria had killed at least 11 adults, caused five miscarriages and sickened about 73 people in 14 states.

Federal regulators say they are working to determine where the breakdown in food safety lies, but the truth is that they already know plenty about what's wrong and how to make it right.

On Wednesday, federal regulators said they are working to determine where the breakdown in food safety lies, but the truth is that they already know plenty about what's wrong and how to make it right. For years reputable food safety experts for consumer groups have been unsuccessfully petitioning Congress to take these modest steps toward needed reform:

- Require meat processing plants to test for dangerous microbes. While the food inspection system begun three years ago requires slaughterhouses that produce only raw meat to test for *E. coli* bacteria, it does not require meat processing plants to test for any harmful microbes. At a minimum, Agriculture Secretary Dan Glickman should require listeria testing in processed foods because that bacterium breeds well in cold environments like refrigerated supermarket shelves.
- Set federal rules governing how meat processors determine the "sell-by" and "pull-by" dates they stamp on hot dogs, bologna and other packaged foods. Once, luncheon meats would expire several weeks after being packaged; now, preservatives allow "sell-by" dates to stretch up to half a year, even though the government admits it has no research to indicate that preservatives can ward off bacteria like listeria for that long.
- Grant "mandatory notification and recall authority" to the Agriculture Department and the Food and Drug Administration. Currently, meat and poultry manufacturers, restaurants and other food industries are not required to report contamination when they find it, and federal food agencies have no authority to require companies to recall tainted food. No federal agency can conduct responsible oversight this way. Last month, Tom Harkin (D-Iowa) introduced a bill to grant such authority in the Senate, and later this month House Democrats will introduce their own version.
- Consolidate food oversight into a single federal agency. Currently food oversight is scattered over six federal agencies; even the inspectors themselves often don't know who's in charge.

Food safety has become needlessly politicized, with each side submitting reform plans it knows the other will reject: The White House, for instance, proposed funding reform by taking away tobacco subsidies, which enraged Southern Republicans.

The listeria victims illustrate the costs of this cynical game. Washington needs to put politics aside long enough to let science take its rightful role in food oversight.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

FEB 25 1999

Food Safety

Dear Colleague, FDA Foods Community:

This month marks the completion of my first year as Director of FDA's Center for Food Safety and Applied Nutrition (CFSAN). I have very much appreciated the support and feedback I have received from many of you, including your continuing interest in receiving up-to-date information on CFSAN activities. Within that spirit, I am pleased to enclose with this letter a summary of CFSAN accomplishments from February 1, 1998 – February 1, 1999. As you may recall, on September 11, 1998, I distributed a "progress report" highlighting our "recent" program accomplishments. The list enclosed with this letter is an update of that report. This year-end report contains many new items, and those new items are clearly identified by an asterisk. I am very proud of all that we have accomplished.

In particular, I would like to highlight: (1) Implementation of the President's Food Safety Initiative (FSI) as our highest priority (e.g., seafood inspections; Good Agricultural Practices; and labeling for unpasteurized juice); (2) Focus on productivity and output (e.g., food additive petitions; health claims); and (3) Development, with public input, of the Center's 1999 Program Priorities document.

I also want to bring you up-to-date on who will be filling key CFSAN leadership positions. Effective March 1, 1999, Janice Oliver will assume the role of Deputy Center Director, and as such, will have line management responsibility over the major program offices. Assisting Ms. Oliver and I on my senior management team will be: L. Robert Lake, Director of Regulations and Policy; Morris Potter, D.V.M. (formerly of CDC), Director of the Food Safety Initiative; Robert Buchanan, Ph.D. (formerly FSI lead scientist, and prior to that of USDA) as my Senior Science Advisor; and Juanita Wills, Director of Management Systems. I believe the breadth and experience of these five individuals, combined with the talent and expertise of CFSAN's Office Directors, will serve the Center and the pubic very well. I believe that this management team also strengthens the Center's foundation as a science-based regulatory agency.

In closing, I will say that this past year has truly been the most satisfying year of my 20 years at FDA, and I look forward to working with you in the future.

Sincerely,

Joseph A Levitt

Joseph A. Levitt
Director
Center for Food Safety
and Applied Nutrition

Enclosure

Program Accomplishments
February 1, 1998 - February 1, 1999

Program Priorities:

- * *Stakeholder Input:* Held a public meeting to solicit input from stakeholders on establishment of program priorities.

- * *"CFSAN 1999 Program Priorities:"* Established an internal priority-setting process and developed CFSAN's priority workplan for 1999. A copy of the workplan is available on the CFSAN's home page (www.cfsan.fda.gov).

Food Safety:

A. Hazard Analysis and Critical Control Points (HACCP)

- *Guidance on Seafood HACCP:* Publication of the second edition of the "Fish & Fishery Products Hazards and Controls Guide" to assist seafood processors in the development of their HACCP plans.

- * *Seafood HACCP Implementation:* In calendar year 1998, completed goal to inspect virtually all domestic seafood processors (approximately 4000 firms). Issued untitled letters to seafood processors (nearly 70% of those inspected) regarding ways to improve implementation of their HACCP programs.

- * *Florida State Shellfish Program:* In conjunction with the Interstate Shellfish Sanitation Conference, improved compliance with national Shellfish Sanitation Program control measures in selected Florida shellfish processors to ensure that shellfish are processed under sanitary conditions.

- *Juice HACCP:* Publication of a proposed regulation to require processors of packaged fruit and vegetable juices to implement HACCP to prevent contamination of their products.

- * *Scientific Workshops on 5-Log Reduction:* Conducted two scientific workshops for industry representatives on measuring and validating the 5-log reduction in pathogenic microorganisms.

- *HACCP at Retail:* Initiation of a pilot HACCP food safety program in retail settings.

B. Produce Initiative

- *Presidential Report:* In conjunction with USDA, issued a report to the President on implementation of the produce initiative.

- *Meetings on Produce*: Held public meetings to solicit comment on the draft Good Agricultural Practices/Good Manufacturing Practices guidance document.

- * *Guidance*: Publication of the final Good Agricultural Practices/Good Manufacturing Practices guidance document to assist produce growers and packers in minimizing food safety hazards.

- *Sprouts:* Met with industry representatives to discuss ongoing cooperative research on interventions to assure the safety of sprouts.

C. Additional Prevention and Education Efforts

- *Juice Labeling*: Publication of a final regulation requiring a warning on unprocessed, packaged fresh fruit and vegetable juices.

- * *Small Entity Compliance Guide*: Developed a guidance document entitled, "Warning and Notice Statement: Labeling of Juice Products Small Entity Compliance guide," which contained questions and answers on how to comply with the juice labeling regulation.

- * *Citrus Juices*: Publication of a notice in the Federal Register announcing an accelerated plan for citrus juices to assure that industry achieves a 5-log reduction for pathogens in lieu of the labeling requirement.

- *Prevention Measures for Eggs*: In conjunction with USDA, publication of an advanced notice of proposed rulemaking to ensure the safety of shell eggs.

- *Food* Code: Effective interactions with the Conference of Food Protection leading to agreements on revision of the Food Code.

- * *Educational Efforts*: Continued efforts to educate consumers to practice safe food handling via the "Fight BAC" campaign. Development of a public awareness campaign on the risk that unpasteurized or untreated fruit and vegetable juices may present to vulnerable populations.

C. Additional Prevention and Education Efforts - continued

- *Cider:* Conducted workshops in the midwest and northeast apple growing areas on juice safety targeted to small producers.

- * *Food Safety Web Site*: Established a new "gateway" web site (www.FoodSafety.gov), to help the public more readily find government food safety information.

- * *Foodborne Pathogenic Microorganisms and Natural Toxins Handbook ("Bad Bug Book"):* Publication of a revised handbook that provides basic facts regarding foodborne microorganisms and natural toxins. The manual is available on the Center's home page (www.cfsan.fda.gov) as well as on CD-ROM through AOAC International.

D. Outbreak Containment and Response

- *DNA Fingerprinting*: In conjunction with CDC and USDA, establishment of a new computer network and database system to permit DNA fingerprinting of pathogens to be compared nationwide.

- * *Outbreak Response*: Responding to disease outbreaks, in conjunction with FDA's field offices, state and local officials, and other federal agencies, including *Salmonella agona* in toasted oat cereal, *Salmonella seftenberg* in alfalfa sprouts, *Vibrio parahaemolyticus* in oysters, and *E. coli* 0157:H7 in a variety of food products.

- * *Cyclospora in Raspberries*: Conducted three site visits to Guatemala in follow-up to last year's outbreak of *cyclospora* in raspberries, and worked with Guatemalan raspberry producers to develop a Model Plan of Excellence.

- * *Rapid Response Team:* In conjunction with CDC and the Council of State and Territorial Epidemiologists, established a Rapid Assessment Team to provide quick review of epidemiological reports of foodborne illness.

E. Research and Risk Assessment

- *Food Safety Research Plan*: Development of a three-year research plan that outlines the microbiological and microbial risk assessment research that CFSAN will conduct to support the food safety initiative.

E. Research and Risk Assessment - continued

- *Joint Research Plan for Produce*: In collaboration with USDA and other federal agencies, developed a broad research plan to enhance the safety of fresh fruits and vegetables in the U.S.

- *Interagency Consortium*: Development of a Risk Assessment Consortium at the Joint Institute for Food Safety and Applied Nutrition (JIFSAN), a collaborative activity between FDA and the University of Maryland. The consortium, which includes participation from all federal agencies with responsibilities for food safety (i.e., FDA, CDC, USDA, and EPA), will coordinate and guide federal risk assessment research related to food safety.

- *Risk Assessment Clearinghouse*: Through the Risk Assessment Consortium, established a clearinghouse for data, methodology and research advances that are needed for assessment models.

- *JIFSAN:* Conducted scientific meetings on the role of risk assessment in food safety; dose-response modeling for foodborne pathogens; and the risks posed by transmissible spongiform encephalopathies (TSEs).

- *Workshop on Packaging Materials*: Held a workshop at the National Center for Food Safety and Technology (Moffett Center) to discuss cooperative research aimed at establishing the safety of additional packaging materials for use with irradiation.

- * *Presidential Report*: In conjunction with USDA, issued a report to the President on the proposed structure, operating principles, and goals of the Joint Institute for Food Safety Research (JIFSR).

- * *JIFSR:* In conjunction with USDA, convened a public meeting to solicit input on establishment of JIFSR.

- * *Bacteriological Analytical Manual: Publication of a revised manual that reflects the preferred test methods to use in testing food for microbial pathogens.*

E. Research and Risk Assessment - continued

- * *Methods/Technology Development:*

  -- Development of an improved technique that reduces the time it takes to detect and quantify harmful *E. coli* from 24 to 48 hours to within 30 minutes;

  -- development of an intervention technology to inactivate pathogens in certain packaged foods by use of high hyrdostatic pressure;

  -- development of methods that increase the speed and simplicity to detect ochratoxins in grains and emetic toxin produced by *Bacillus cereus;*

  -- development of the first method for detection of Norwalk virus in contaminated shellfish.

NOTE: A more complete compilation of FDA's FY 98 accomplishments under the FSI may be found on our home page (www.cfsan.fda.gov).

Food Additives

- *Artificial Sweeteners*: Approval of Sucralose and Acesulfame-K.
- *Olestra:* Comprehensive postmarket review of Olestra by the Food Advisory Committee.
- * *Antimicrobial Agents*: Approval of two antimicrobial agents: chlorine dioxide in water to wash fruits and vegetables; and acidified solutions of sodium chlorite for use in processing red meat.
- *Irradiation Labeling:* Publication of a final rule on the prominence of labeling for irradiated products.
- * *GRAS Notifications:* Completed review of eight GRAS notifications as part of a pilot program.
- * *Food Quality Protection Act*: In conjunction with EPA, issued a notice clarifying jurisdiction over antimicrobials that are used in food or food-contact articles.

Food Additives - continued

- * *Expedited Review:* Implementation of new procedures to expedite the review of food additives that are intended to decrease the incidence of foodborne illnesses through their antimicrobial actions against human pathogens that may be present in food.

Health Claims/Labeling

- *Health Claims for Psyllium:* Publication of a final rule providing for health claims on the association between soluble fiber from psyllium husk and reduced risk of coronary heart disease.

- *"Healthy" Labeling:* Publication of a final rule allowing use of the term "healthy" on the labels of certain frozen and canned fruits and vegetables and enriched cereal grain products.

- *Guidance on Claims:* Publication of a guidance document for industry on health and nutrient content claims based on an authoritative statement, in accordance with the FDA Modernization Act of 1997.

- * *Guidance on Nutrition Labeling:* Publication of a guidance document for industry, "FDA Nutrition Labeling Manual - A Guide for Developing and Using Data Bases."

- *Denial of Claims:* Publication of interim final rules prohibiting nine health or nutrient content claims that were not appropriately based on an authoritative statement.

- * *Health Claims for Soy:* Publication of a proposed rule providing for health claims on the association between soy protein and reduced risk of coronary heart disease.

Dietary Supplements

- *White House Report:* Published response to recommendations in the White House Report on labeling of dietary supplements.

- *Structure/Function Claims:* Publication of a proposed rule on statements made for dietary supplements concerning the effect of the product on the structure or function of the body.

Dietary Supplements - continued

- *Nutrition Labeling*: Publication of a final rule revising nutrition labeling requirements for dietary supplements that contain liquid extracts.

- * *"Per day" Nutrition Labeling:* Publication of a proposed rule revising the nutrition labeling requirements for dietary supplements to allow companies to list the amount and daily value percent of their products' ingredients on a "per day" basis.

- * *Health Claims:* Publication of a proposed rule on health claims for dietary supplements based on an authoritative statement.

- * *Thirty-Day Notifications:* Reviewed 504 30-day notifications from manufacturers who plan to use a structure/function claim on a particular product; issued 109 letters in response to such notifications. (FY 98 accomplishment)

- * *Seventy-five-Day Notifications:* Reviewed 18 premarket notifications for supplements containing new dietary ingredients. (FY 98 accomplishment)

Cosmetics

- *FDA Linkages:* Establishment of stronger linkages with FDA's Center for Drug Evaluation and Research related to cosmetics in order to make more effective use of limited resources.

- * *Voluntary Registration Program:* Reactivation of the Voluntary Cosmetic Registration Program. (Jan. '99)

- * *Stakeholders Meeting:* Held a public meeting to solicit input on priorities and strategies for the cosmetics program in light of funds provided by Congress for program restoration. (Jan. '99)

International Activities

- *Harmonization*: Continued participation in international activities to ensure that international standards and guidelines are consistent with U.S. requirements.

International - continued

- * *Codex Alimentarius*: Provided the U.S. Delegate or Alternate Delegate to 13 of 16 Codex Committees; participated in the development of 95 Codex food standards; and established the FDA Codex Management Group.

- * *SPS Activities:* Actively participated as part of the U.S. delegations in all meetings of the World Trade Organization (WTO) Sanitary and Phytosanitary (SPS) Committee to assure that the WTO SPS Agreement will be administered and interpreted in a manner that will not undermine FDA statutes or ability to protect U.S. consumers; reviewed all briefs and oral arguments for dispute settlement of three SPS cases.

- * *European Commission, Quadrilateral and Trilateral Meetings:* Participated in a number of bilateral meetings with the European Commission, quadrilateral meetings with counterparts from Australia, Canada, and New Zealand and Trilateral meetings with Canada and Mexico to share information on food safety activities and to harmonize approaches to the regulation of foods and cosmetics.

- * *International Visitors*: Briefed more than 650 international visitors on CFSAN program activities and accomplishments.

Federal-State-Local Integration

- * *Fifty-State Meeting:* Hosted a meeting of federal, state and local food safety officials to initiate development of a plan for a nationally integrated food safety system.

- * *Follow-up Meeting:* As a follow-up to the 50-state meeting, convened a meeting of the six workgroups and the Coordinating Committee to elect chairpersons, identify short-term and long-term goals for each work group, and establish a timeline for completion of work group activities.

- * *Outreach:* Met with consumer groups and industry representatives to solicit input on the development of a plan for a nationally integrated food safety system.

Scientific Publications

- * *Manuscripts and Abstracts:* CFSAN-developed detection methods, research results and guidance were shared with the scientific community through publication of approximately 160 manuscripts and over 100 abstracts.

Additional Outreach

- * *Industry Outreach and Education*: In conjunction with USDA and the Institute of Food Technologists, conducted food law and regulations seminars for industry; educated U.S. food establishments on the labeling of FDA-regulated products; in collaboration with the Mexican government, developed a seminar to assist Mexican food producers in the safe production of exported foods; educated the Japanese food ingredients industry on FSI.

- * *Consumer Inquiries*: Responded to more than 50,000 calls from consumers to CFSAN's toll-free Food Information Line and to more than 6000 electronic mail inquiries on a variety of food-related nutrition, safety, and labeling issues.

Mary - This is what EPA ...

4/26/99

EPA PROPOSAL FOR INTER-AGENCY FOOD SAFETY STRATEGIC PLAN GOALS AND OBJECTIVES

Goal 1: Sound Science

Objectives:

- Develop and improve data, methods, models, and measures to assess health effects, including a better understanding of the factors that affect sensitivity to foodborne ~~illness~~ (e.g., age, health status).
- Develop new and improve existing data, methods, models, and measures to assess exposure, including improved analytical and surveillance methods.
- Develop better, integrated risk assessment methods and conduct risk assessments.
- Develop and improve prevention methods and risk management practices to prevent/control foodborne illness (e.g., IPM, pasteurization, packaging, handling techniques, etc.).
- Better coordinate research on the highest priority food safety issues and efficiently leverage Federal agencies' research resources.

Goal 2: Improve Surveillance, Outbreak Investigation and Response

Objectives:

- Enhance and expand foodborne disease /hazard monitoring and surveillance systems.
- Identify, investigate and track the causes of foodborne infections to determine sources and exposed populations.
- Provide better information to health professionals and physicians about the causes and effects of foodborne illness to more effectively detect and treat these illnesses.
- Improve outbreak coordination and investigation amongst Federal, state, and local agencies for more efficient, effective responses to foodborne contamination and illness.
- Strengthen and expand traceback, intervention and recall capability; improve coordination on tracebacks and recalls.

Goal 3: Insure Protective standards, ~~Regulations~~, Inspection, and Enforcement

Objectives:

- Improve the safety of the nation's food supply to protect public health to the greatest extent possible through priority- and science-based standards, guidance, and other measures (including effective food safety management strategies by processors and providers).
- Develop and implement preventive techniques and controls (e.g., IPM).
- Insure effective and efficient monitoring and inspection of the food supply.
- Protect our food supply in accordance with U.S. statutes ~~without unduly interfering with trade~~ and internationally harmonized science-based standards.
- Insure water will not contaminate food during its production, processing or reconstitution.

Goal 4: Expand Information/Education/Communications for Americans

Objectives:

- Enhance the public's timely accessibility to accurate information that will help them make informed decisions about their food and the risks.
- Provide education and information to eliminate unsafe food handling practices at each point in the food chain (producers, processors, transporters, preparers, retailers, and consumers).
- Improve communication and information to the public so that they are informed about foodborne illness incidences but are not unduly alarmed.

Goal 5: Create a Seamless Food Safety System

Objectives:

- Insure a complete set of Federal statutory authorities for an effective, prevention-based food safety system, including authorities for information collection and dissemination, rulemaking, inspection, ~~and~~ enforcement, and expedited review of food safety technologies.
- Develop and implement a seamless Federal food safety system that supports effective regulation and administration of food safety programs.
- Coordinate and integrate Federal, state and local actions to provide efficient, ~~and~~ effective, and timely protection of the food supply and eliminate gaps.
- Insure sufficient capacity and capability at all levels of government to carry out the monitoring, inspections, outbreak response, trackback, and training necessary for an appropriate level of public protection nationwide.

Draft: 4/28/99

Office of Food Safety
Food Safety and Inspections Service

Goal 1:

Establish a national research and new technology infrastructure to ensure adequate scientific support for food safety risk assessment and risk management from farm-to-table

Goal 2:

Create and utilize a national and international risk assessment capability

Goal 3:

Create a seamless national and international food safety risk management system from farm to table

Goal 4:

Ensure that all people who produce, process, handle, prepare or come in contact with food, including consumers, shall understand, accept and take responsibility for food safety

Goal 5:

Identify and eliminate risk associated with the production of raw agriculture commodities

Goal 6:

Identify and eliminate the risk associated with processing, transporting, storing, retailing and delivering food to consumers

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→ Food Safety

II

106TH CONGRESS
1ST SESSION

S. 823

To establish a program to assure the safety of processed produce intended for human consumption, and for other purposes.

IN THE SENATE OF THE UNITED STATES

APRIL 15, 1999

Mr. HARKIN (for himself and Mr. DURBIN) introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

---

A BILL

To establish a program to assure the safety of processed produce intended for human consumption, and for other purposes.

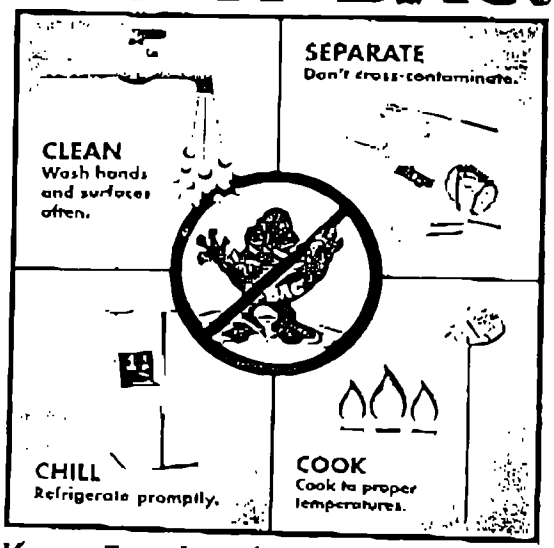
Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Fruit and Vegetable Safety Act".

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

FIGHT BAC!



Keep Food Safe From Bacteria™

Food Safe.

FAX

FOOD AND DRUG ADMINISTRATION
FOOD SAFETY INITIATIVE STAFF
200 C STREET, S.W.
WASHINGTON, D.C. 20204
PHONE: 202-260-8920
FAX: 202-260-9653

Date: 5/4/99 No. of Pages (including cover) 21

To: C Gabriel OSTP Fax No.
T Faerman DPC
M Smith DPC Phone No.
W Taylor OMB D Flower-Lake OMB
From: M Makinowski OMB Phone No. 260-8920
L. Carson Fax No. 202-260-9653

MESSAGE

FSE Strategic Planning Mtg
5/5/99

To: smtp[cgabriel@ostp.eop.gov], smtp[smith_ml@al.eop.gov], smtp[taylor_w@al.eop.gov], smtp[cathie.woteki@usda.gov], smtp[caren.wilcox@usda.gov], smtp[tom.billy@usda.gov], smtp[margaret.glavin@usda.gov], smtp[karen.huleback@usda.gov], smtp[eileen.kennedy@usda.gov], smtp[wayland.susan@epamail.epa.gov], smtp[nelson.judy@epamail.epa.gov]
Cc: Cynthia Hammett@OCD@FDA.CFSAN, Morris Potter@FSI@FDA.CFSAN
From: Lou Carson@FSI@FDA.CFSAN
Certify: N
Subject: FSI Strategic Planning Meeting: 5/5
Date: Tuesday, May 4, 1999 at 6:31:36 pm EDT
Attached: h:\fsisched.doc, a:\revstkhl.doc

The following documents are provided for discussion for the FSI Strategic Planning meeting held on May 5 @ 2PM at USDA Whitten Bldg.

1. Scope of the Council's Comprehensive Strategic Food Safety Plan 12/16/98 by downloading from the internet site:
http://www.foodsafety.gov/~fsg/cscope.html

2. Calendar of Events- attached; filename-fsisched

3. Stakeholders Public Meetings document-attached; filename-revstkhl

Lou Carson

President's Council on Food Safety

U.S. Department of Agriculture | Department of Health and Human Services | Environmental Protection Agency | Department of Commerce

Scope of the Council's Comprehensive Strategic Food Safety Plan

December 16, 1998

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 the caloric labeling of food. 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 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, regulated substances without pre-market approval (e.g., dietary supplements), 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
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, animal manures, 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)

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).

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

<u>All Chemicals:</u>

- 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 effortscould 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.
- Dietary supplements are a complex, difficult issue which would bring in different

constituencies, and thus complicate the strategic planning process.

- 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: Chemical contaminants and regulated/pre-market approved 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 these 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).

Regulated/no pre-market approval substances (e.g., dietary supplements) should be considered "collateral activities" and should not be included within the scope since there is relatively less need for interagency coordination of this work, and inclusion of these substances could increase the complexity of the planning process beyond what is manageable at this time.

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 categorized 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 bysome 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 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):

- Inclusion within the scope would provide attention to the important role of processing water in food safety; if food processing water is not add ressed in the strategic plan, it will not cover all of the important challenges that need to be addressed.

- 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.

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 andprovides 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., sewage 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 (e.g., Food Code) is important, but can be accomplished without these 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 &	EPA FDA	Extramural research, outreach, and education on elimination, mitigation, and detection of hazards.	Research, Regulatory Support, & Education	Pathogens Chemicals	Core

Extension Service					
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	Core
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	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)

		travel.			
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
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.	Regulation, Guidance, Research, & Risk	Pathogens Chemicals Animal wastes	Core (water in food production &

		Provides criteria for ambient water contamination, watershed controls, and other pathogen elimination/protection authorities.	assessment	Other agricultural wastes	processing) Collateral (drinking water/direct consumption, water for recreation)
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; biosolids) 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	

Meeting Schedule

April, 1999

11-12	Canadian Federation of Independent Grocers Honolulu, HI
15-17	International Fresh Cut Produce Association Tampa, FL
24-26	Retail Bakers Association Minneapolis, MN
28-30	North East Food and Drug Officials Association Sturbridge, MA

May, 1999

1-6	National Conference on Interstate Milk Shippers(NCIMS) Atlanta, GA
2-5	Food Marketing Association Chicago, IL
18-21	Central Atlantic States Association and Association of Food and Drug Officials of the Southern States (Joint Annual Conference) Virginia Beach, VA
22-26	National Restaurant Association Chicago, IL
30-6/2	Canadian Council on Grocery Distributors Banff, AB, Canada
30-6/2	American Society for Microbiology Chicago, IL

June, 1999

5-9	Association of Food and Drug Officials (AFDO) (also) Mid Continental Association of Food & Drug Officials San Antonio, TX

11-15	Grocery manufacturers Association White Sulfur Springs, WV
13-15	Northeast Association of State Departments of Agriculture Rehoboth Beach, DE
20-23	Southern Association of State Departments of Agriculture Charleston, WV
23-26	National Association of Attorneys General Nashville, TN

July, 1999

6-9	National Environmental Health Association Nashville, TN
11-13	Western Association of State Departments of Agriculture Jackson Hole, WY
11-14	National Nutritional Foods Association Las Vegas, NV
14-17	National Association of City and County Health Officials Dearborn, MI
16-19	Council of State Governments Sun Valley, ID
17-21	Midwestern Association of State Departments of Agriculture Traverse City, MI
23-25	Produce Marketing Association Monterey, CA
24-27	Institute of Food Technology Chicago, IL
24-28	National Conference of State Legislatures Indianapolis, IN
29-31	National Association of Local Boards of Health Salt Lake City, UT

August, 1999

1-4	International Association of Milk, Food and Environmental Sanitarians Dearborn, MI
7-10	National Governor's Association St. Louis, MO

September, 1999

8	Labor day
11	Rosh Hashanah
11-15	Western Association of Food and Drug Officials Denver, CO
18-21	North Central Association of Food and Drug Officials Indianapolis, IN
20	Yom Kippur
26-28	Food Marketing Institute-Int'l Berlin, Germany
26-28	FMI- Meal Solutions St Louis, MO
26-28	National Association of State Departments of Agriculture St George, UT
28-10/1	Association of State and Territorial Health Officials Savannah, GA
28-10/3	National Fisheries Institute Miami, FL

October, 1999

3-6	American Frozen Food institute Boston, MA

6-8	National Broiler Council Washington, DC
11	Columbus Day
23-26	Produce Marketing Association Atlanta, GA
28-31	American Meat Institute Chicago, IL
31-11/2	Food Distributors International St Louis, MO

November, 1999

2	Election day
2-5	National Fisheries Institute-Annual Convention Nashville, TN
11	Veterans Day
7-11	American Public Health Association-Annual Convention Chicago, IL
25	Thanksgiving

December, 1999

3-7	Council of State Governments Annual Meeting and Leadership Forum, Quebec City, Canada
25	Christmas

January, 2000

1	New Years Day

8-12	National Turkey Federation Orlando, FL
9-12	International Dairy Foods Association Palm Springs, CA
17	Martin Luther King Day
26-29	National Cattleman's Beef Association Phoenix, AZ

February, 2000

12-15	National Conference of Lieutenant Governors-State/Federal Meeting, Washington, DC
18-20	National Meat Association Monterey, CA
26-28	United Fresh Fruit and Vegetable Association Phoenix, AZ
TBA	National Association of State Departments of Agriculture Mid Winter Conference

March, 2000

20-22	American Frozen Foods Association San Francisco, CA

April, 2000

5-12	Conference for Food Protection Milwaukee, WI

STAKEHOLDER PARTICIPATION IN STRATEGIC PLANNING FOR FEDERAL FOOD SAFETY INITIATIVE:

BACKGROUND:

As a critical part of the President's Food Safety Initiative, federal agencies have employed various means to involve stakeholders along the entire farm to table continuum and to seek their input into the management and problem solving process. Stakeholder efforts are an important component for overall success of the Initiative. Nevertheless, finding the appropriate vehicle to successfully address the key issues has been problematic; some of the attempts have offered an open forum in name only rather than full, frank and considered discussion to achieve mutually consistent goals and objectives.

Several key points must be met for successful participation by all:

- Continuous meaningful involvement
- Substantive contribution to developing the issues, implementing program and achieving results
- Constructive, open communication and effort to achieve a common understanding at all levels
- Consensus or shared goals and objectives

OPTIONS:

We recommend that the FSI Strategic Planning Task Force consider a combination of mechanisms to reach constituents and have substantive dialogue. Federal Register Notices will be used to announce each meeting as well as the availability of documents and a dockets number for submission of comments.

1. Summer Public Meeting: One day - Announce and discuss planning strategy document and establish a docket to receive written comments.

2. Describe the strategic planning framework at the FSI website and open an electronic docket to receive comments. Release draft outlines of each section of the plan electronically two weeks before the Fall meeting to allow interested parties time to consider the drafts and alternative proposals.

3. Fall Public Meeting with facilitated breakout sessions: To discuss and improve draft documents outlining the Strategic Plan. Begin the public meeting with a set of formal presentations of each section draft and its rationale. Breakout groups could be divided by goals and objectives of strategic plan (agenda item for May 5 meeting) or by focus areas of the scope document (attached). Each breakout session will be professionally facilitated and 1-2 representatives of each Agency who helped prepare draft outlines will participate in the discussion in each session to stimulate interactive debate to prepare for drafting a document from each session. Each breakout session document will become part of the larger strategic planning document.

4. A number of other means to optimize stakeholder input were discussed and may be useful parts of the overall package of stakeholder activities. Two options are identified below.
    a. Satellite downlink at public meetings (presentation portion only - not breakout sessions).
    b. Discussions tagged to or held as part of scheduled scientific meetings of professional or trade associations. We could attempt to schedule a half-day meeting immediately before or after scheduled meetings, or work with the program committee of the meeting to create a session on the strategic plan within the regularly scheduled meeting. Meetings should be selected from the calendar of events (attached).

Center for Science in the Public Interest

The Center for Science in the Public Interest was founded in 1971 by public-interest scientists who believed that consumers need knowledgeable experts to represent their interests before the government and to balance industry's well-financed lobbying efforts. CSPI's financial support comes from its 200,000 dues-paying members, the sale of educational publications, and foundation grants.

CSPI is a leading advocate of modern national nutrition policies and a contaminant-free food supply. It is also a leading proponent of a progressive, preventive approach to reducing alcohol abuse. CSPI publishes consumer-oriented materials on food and alcohol, including *Nutrition Action Healthletter*, books, posters, and computer software.

Center for Science in the Public Interest
1875 Connecticut Avenue, N.W.
Suite 300
Washington, D.C. 20009-5728

Dear Tam-

I said NICE
things about
your record!

Caroline

see page 6