

Withdrawal/Redaction Sheet

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001a. list	re: SSNs and DOBs [partial] (2 pages)	04/07/1997	b(6)
001b. note	re; SSN and DOB [partial] (1 page)	04/07/1997	b(6)
002. list	re: National Food Safety Initiative [partial] (1 page)	03/03	b(6)
003. list	re; National Food Safety Initiative [partial] (1 page)	02/28	b(6)
004. list	re: SSNs and DOBs [partial] (2 pages)	02/26	b(6)
005. list	re; Food Safety meeting [partial] (1 page)	02/28	b(6)
006. list	re: Food Safety Meeting [partial] (2 pages)	02/25	b(6)
007. list	re: Food Safety Meetings [partial] (2 pages)	02/25/13	b(6)
008. list	re: Food Safety Meetings [partial] (1 page)	02/24	b(6)
009. list	re: Food Safety Meetings [partial] (1 page)	02/24	b(6)

COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Elizabeth Drye
OA/Box Number: 10451

FOLDER TITLE:

Food Safety Outreach Meetings

2014-0046-S

rc1398

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

- b(1) National security classified information [(b)(1) of the FOIA]
- b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
- b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
- b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
- b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

Nancy Granise 637-5697 w/GMA

HTTP://WWW.USDA.GOV/
FSIS

HTTP://VM.CFSAN.FDA.GOV/LIST.HTML

FR -

Joan Monteleone (FSIS) 205-5140
720-4150 -

- Walked to HHS EPA Exec Sec. offices -

- HHS John

Tom Billey - 720-7025
Billey

- 1st floor 1st floor
REF. 1st floor

Janice Oliver 205-41307 205-5025

Fred Shank - 705-41850

Lynne Finnerty 720-7100 Exec Sec USDA

Phyllis Kaiser 5-3047 (far)
Duke 54852 (phone)

Leg Affairs - Chuck Kieffer -

Adam Dick Jackson CDC
Cinda Rosen -

Steve Schaub 260-7591

Alan Rubin 260-7589

Barbara McDonald -

PHOTOCOPY
PRESERVATION

**facsimile**
TRANSMITTAL

to: Elizabeth Dye
fax #:
re:
date:
pages: , including this cover sheet.

Draft Notice on 2nd Meeting
of the President's Food Safety Initiative -

Joan Mondshein From the desk of...

Thomas J. Billy
Administrator
Food Safety and Inspection Service
1400 Jefferson Drive, SW
Washington, DC 20250-3700

202-720-7025
Fax: 202-205-0158

Billing Code 3410 - DM - P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. 97-003N]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0074]

President's National Food Safety Initiative

**AGENCY: Food Safety and Inspection Service, USDA
Food and Drug Administration, HHS**

ACTION: Notice.

SUMMARY: The United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) and Research, Education, and Economics; The Department of Health and Human Services' Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC); and the Environmental Protection Agency (EPA) will convene a meeting on March 31 to April 2, 1997, to discuss and develop for the President a comprehensive plan to reduce the annual incidence of foodborne illness by enhancing the safety of the nation's food supply.

DATES: The meetings will be held from 8:00 a.m. to 5:30 p.m. and 7:00 p.m. to 9:00 p.m. on March 31; 8:30 a.m. to 5:00 p.m. on April 1; and from 8:30 a.m. to 1:30 p.m. on April 2, 1997.

ADDRESSES: The meeting will be held at the Hyatt Regency Washington on Capital Hill, 400 New Jersey Avenue, NW, Washington, DC 20001.

FOR FURTHER INFORMATION CONTACT: To register for the meeting, contact Ms. Traci

Phebus at (202) 501-7138, FAX (202) 501-7642, E-mail HACCP.Confer@USDA.GOV, or (800) 485-4429. Participants may reserve a 5-minute public comment period when they register. Space will be allocated on a first come, first served basis. For questions about the meeting or to obtain copies of the draft report *Food Safety From Farm to Table: A New Strategy for the 21st Century, Discussion Draft and Current Thinking, A National Food Safety Initiative* contact Mr. Charles Danner, FSIS, at (202) 502-7138 or Ms. Karen Carson, FDA, at (202) 205-5140. Copies of the draft report also are available from the following: FSIS at <http://www.usda.gov/fsis> or FDA at <http://vm.cfsan.fda.gov/list.html>. Participants who require a sign language interpreter or other special accommodations should contact Ms. Sheila Johnson at (202) 501-7138 by March 24.

SUPPLEMENTARY INFORMATION:

On January 25, 1997, the President directed the Secretaries of USDA and HHS and the Administrator of EPA to work with consumers, producers, industry, States, universities, and the public to identify ways to further improve the safety of our food supply. The President requested that the plan focus on "...further improvement of surveillance, inspection, research, risk assessment, education, and coordination among local, State, and Federal health authorities."

On March 5, 1997, the first public meeting was held to discuss the initiative and the issues identified by food safety experts in the draft report. All attendees received a copy of the draft report and were encouraged to review the document and develop recommendations related to the six topic areas; surveillance, risk assessment, research, inspection, education, and coordination and strategic planning to be presented at the March 31 meeting.

The March 31 session will feature a general session with time allotted for public comment followed by concurrent breakout sessions: New Early Warning System for Foodborne

Illness and Maximizing Inspection to Support HACCP; and in the evening: Strategic Planning.

April 1 will consist of concurrent breakout sessions in the morning: Bioscience Research and Coordination and Partnerships; and in the afternoon: Improving Risk Assessment Tools and Improving Food Safety Education. April 2 will include reports from each of the six breakout sessions and public comment.

The agencies are encouraging individuals to comment on the topics discussed at the March 5, 1997, meeting as well as those listed in this notice under Supplementary Information. Submit written comments as follows: USDA/FSIS Hearing Clerk, Room 3806 South Building, Washington, DC 20250-3700 or Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Drive, Room 1-23, Rockville, MD 20857. Comments are to be identified with the docket number. For those comments directed to USDA use Docket No. 97-003N; for comments directed to FDA, use Docket No. 97N-0074.

Transcripts of the public meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, Room 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. The transcript of the public meeting and all submitted comments will be available for public examination at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Done at Washington, DC, on:

Thomas J. Billy
Administrator
Food Safety and Inspection Service

Fred R. Shank
Director
Center for Food Safety and Applied Nutrition



facsimile
TRANSMITTAL

to: Elizabeth Drye
fax #: 456-5581
re: Food Safety Initiative
date: 3/3
pages: 1, including this cover sheet.

This afternoon @ 3:00 There will
be a final preparation meeting
before the public meeting on Wednesday -
If you would like to conference in,
please give me a call on
720-7025 - The meeting will be at
FDA's C St. bldg, but I'd be happy
to make arrangements.

Sally Funderburg

From the desk of...

Thomas J. Billy
Administrator
Food Safety and Inspection Service
1400 Jefferson Drive, SW
Washington, DC 20250-3700

202-720-7025
Fax: 202-205-0158

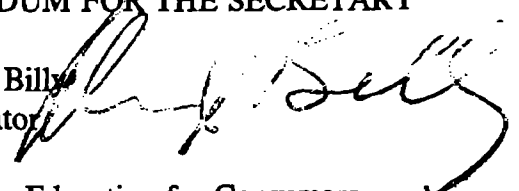
OPTIONAL FORM 99 (7-90)

FAX TRANSMITTAL

of pages ► 2

To <i>Elizabeth Dwyer</i>	From <i>Sally Fernandez</i>
Dept./Agency	Phone # <i>720-7025</i>
Fax #	Fax #
NSN 7540-01-317-7368	5099-101
GENERAL SERVICES ADMINISTRATION	

DECISION MEMORANDUM FOR THE SECRETARY

FROM: Thomas J. Billy
Administrator 

SUBJECT: Food Safety Education for Consumers

FEB 19 1997

ISSUE:

Within USDA, FSIS and CSREES conduct extensive food safety education programs. Many projects are also conducted jointly with FDA and often involve partnerships with industry and trade associations. Recently, several industry groups have expressed interest in forming a private-public partnership to conduct educational campaigns and programs. At this time, USDA and FDA are exploring the possibilities of forming such a cooperative food safety education initiative.

DISCUSSION:

Several industry groups requested a meeting with the Secretary to discuss safe food handling education for consumers. A meeting was held on January 15, 1997 with FSIS Administrator Tom Billy, Eric Olson and several FSIS staff members. The groups are proposing to sponsor a private-public partnership to conduct an educational food safety campaign and requested USDA endorsement and funding or "in kind" participation. The meeting was attended by Sara Lilygren for J. Patrick Boyle, President and C.E.O. of the American Meat Institute (AMI), Tim Hammonds, President, and Dagmar Farr, Vice President for Consumer Affairs, Food Marketing Institute (FMI), Carolyn Ardron, Industry Council on Food Safety, National Restaurant Association (NRA), Kathy Means, Produce Marketing Association, and Lou Raffel, American Egg Board. The industry group subsequently met with the Secretary of Health and Human Services.

This group action stems from a white paper issued by AMI in September calling for more food safety education. The paper was endorsed by FMI. One recommendation contained in the white paper is the establishment of a private-public partnership for food safety education.

FSIS applauded the groups for taking positive steps toward consumer food safety education and expressed the view that we certainly believe a combined effort would have the greatest potential for a truly effective educational program. Tom Billy gave the group a charge to more thoroughly consider boundaries and parameters for such a partnership. It was decided that a small working group of government and industry representatives would be formed to develop a partnership or alliance agreement that all can embrace.

DECISION MEMORANDUM FOR THE SECRETARY

USDA, FDA and CDC are sponsoring a Food Safety Education Conference scheduled for this June. This conference will bring together food safety educators from the fields of academe, public health, industry consumer relations as well as from consumer groups and state and federal government agencies. Highlights of the conference will include recent research findings on consumers' food safety knowledge, attitudes and behaviors and models and methods of food safety educational programs that can change consumers' unsafe food handling behaviors. We are working toward the goal of announcing a public-private partnership at this conference.

Finally, all of this ties into the President's Food Safety Initiative. These activities will be combined with additional efforts to develop the strategies and programs to strengthen food safety education under that initiative.

OPTIONS:

1. Encourage the formation of a partnership and provide USDA funds to that partnership.
2. Encourage the formation of a partnership and provide "in-kind" and staff support, but not provide USDA funds.

RECOMMENDATION:

We recommend option 2. USDA should encourage the formation of a partnership to conduct food safety education. FSIS is currently researching various aspects of a such a partnership. It is further recommended, that the government effort be through "in-kind" projects and staff support, rather than a direct contribution of funds. It may be desirable that government agencies serve in a liaison role to a private partnership. FSIS has concerns that providing federal funding to an industry sponsored campaign could potentially undermine the food safety message. Leaving the expenditure of government funds in the control of the government would ensure that the food safety education messages will be science-based, that the programs undertaken will have the most influence on public health, and will not be compromised by marketing interests.

DECISION BY THE SECRETARY

Approve	_____
Disapprove	_____
Discuss with me	_____
Date	_____
Reviewed by	_____

National Food Safety Initiative Meeting
Monday, March 3, 1997

Attending:

Miscellaneous Groups:

National Turkey Federation, Stuart Proctor

National Broiler Council, Steve Pretanik

USA Poultry and Egg Association, Don Dalton

United Egg Producers, Christine Nelson

American Meat Institute, Sara Lilygren

Excel Corporation, Del Allen

Cargill, Mike Mullins

IBP, Inc., Jim Lochner

ConAgra, Paul Korody

Farmland Foods, Scott Shearer

National Fisheries Institute, Roy Martin

Industry:

National-American Wholesale Grocers' Association, John Block

International Food Information Council, Robert Earl

International Food Additive Council, Rick Cristol

National Council of Chain Restaurants, Chet England

Dorothy K. Craft

02/25/97 12:06:56 PM

Record Type: Non-Record

To: See the distribution list at the bottom of this message
cc: See the distribution list at the bottom of this message
Subject: Food Safety Meetings

MEMORANDUM TO DISTRIBUTION LIST

FROM: Elizabeth Drye, ext. 65573

SUBJECT: Food Safety Meetings

As you know, the President has challenged government, industry, consumers, and producers to work together and identify steps to improve Food Safety.

We are holding White House meetings with these groups this week. If you have not already, please contact Dorothy Craft (email or call ext. 65571) to RSVP who from your office will be attending these meetings. Please note that some of the below meetings have changed since the original email. Thank you.

All Food Safety Meetings

(* indicates that the meeting has changed from the original time/place)

Small Plants Groups:	Monday, February 24, 3:00pm, OEOB 211	✓
Producer Groups:	Tuesday, February 25, 10:00am, OEOB 211	✓
Consumer Groups:	Tuesday, February 25, 4:30pm, OEOB 476	✓
Industry Group I:	Wednesday, February 26, 3:00pm, OEOB 211	✓
Industry Group II:	Thursday, February 27, 4:30pm, OEOB 211	Carrie calls Weds pm
Health/Science/Tech. Group I:	Friday, February 28, 1:00pm, OEOB 211	Carrie -
Health/Science/Tech. Group II:	* Friday, February 28, 2:30pm, OEOB 211	Jennifer
Miscellaneous Groups:	* Monday, March 3, 11:00am, OEOB 211	Carrie -
	(Misc. group includes: Ntl Turkey Fed.; Excel Corp.; Farmland Foods; Ntl Broiler Council, among others.)	

Message Sent To:

Add - Snack Food Assn? For Nancy Gramer.

Sally Katzen/OMB/EOP
Nancy A. Min/OMB/EOP
T J. Glauthier/OMB/EOP
Richard J. Turman/OMB/EOP
Clifford J. Gabriel/OSTP/EOP
jean.logan @ npr.gsa.gov @ inet
K. Lisa Grove/OMB/EOP
K. Lisa Grove/OMB/EOP

Message Copied To:

Phyllis Kaiser-Dark/OMB/EOP
Barbara D. Woolley/WHO/EOP
Alecia Ward/OMB/EOP
Sarah A. Bianchi/OMB/EOP
Donna I. Coleman/OSTP/EOP
Lisa M. Duffey/OSTP/EOP
K. Lisa Grove/OMB/EOP
Elizabeth Drye/OPD/EOP



laurie @ beyondmarketing.com

04/08/97 01:10:00 AM

Record Type: Record

To: Elizabeth Drye

cc:

Subject: Early Warning System Comments

To: Elizabeth Drye, White House

From: Laurie Girand

cc: Caroline Smith-Dewaal, CSPI
Elaine Dodge, STOP
Congressman Tom Campbell
Senator Barbara Boxer
Senator Dianne Feinstein
Jerry Mande, FDA
FDA Dockets

RE: Mandatory Reporting and Microbial Radar

Elizabeth--

It was good to meet you at the meetings this last week. As I mentioned, I wanted to follow up on our conversation with some specifics about the plans for an Early Warning System. As way of background, I should let you know that when I'm not attending meetings on President's Initiatives, I help to define high technology products and market them as a strategic consultant in Silicon Valley. For the last two years, all of my clients have been Worldwide Web or Internet-related.

The present Early Warning System, as defined by the Discussion Draft, is inadequately specified to actually serve as a warning system. At present, the Discussion Draft describes increasing the number of sentinel sites and then tying them together with a network so that they can share genetic fingerprinting information. As you are probably aware, genetic fingerprinting is an advanced test performed to tie multiple cases to an already suspected outbreak. While genetic fingerprinting can be done in 24 hours, it can also take as long as a month. Because most states do not report a suspected outbreak to the CDC for genetic fingerprinting for some period of time, a better term for such a system might be a "Late Warning System."

While I believe such a system might be of research value, it provides little direct benefits to U.S. citizens and would be spotty at best in attempting to cover the increasingly widespread outbreaks that are emerging. The planned sentinel sites would be acting merely as spotlights,

randomly roaming the food safety grounds while a major breakin is occurring. I might add that prior to the State of Washington's detection of the Odwalla outbreak, the sentinel site in California had not identified the emerging epidemic.

I believe ANY Early Warning System should focus on putting in place the basic infrastructure of disease reporting in order to

- * quickly identify emerging epidemics,
- * help send epidemiologists/sentinel sites to investigate such epidemics,
- * and halt emerging epidemics quickly.

Unlike the current description of the Early Warning System, a system that truly addressed these three areas across multiple states could reliably be known as a "National Microbial Defense Radar." Present computer technology is capable of addressing these challenges and more, including exchanging fingerprinting information, at a very low cost to taxpayers with a very high payoff. Such a Microbial Defense Radar could be put in place before the President's second term is complete. It could even possibly be funded through outside sources.

To build such a system, the government would need to support a handful of Internet servers. These servers would run industry standard databases atop industry-standard hardware such as Intel. The databases would need to be customized to deal specifically with gathering reporting information from doctors, clinics and laboratories around the country. To the data gatherer, the database would appear as two forms--first, a basic report form covering patient information and the diagnosis and second, a nationally standardized epidemiological research form. Laboratories and doctors from around the country would have password protected access to enter information on a case by case basis. Confidentiality would be maintained as only the doctor would know the actual patient's name; all information would be entered with a case number.

To enter information about an individual illness, all that a doctor or lab would need to have would be a browser, an Internet-capable, Internet-connected computer and an appropriate password or license number--i.e. no special software or hardware would be needed. At the server back end, the database could be programmed to statistically analyze ongoing reported diagnoses across multiple counties and multiple states so that an epidemic such as Odwalla's would be picked up quickly even if there were only one report in one county, two in another, one here, three there. While government officials and epidemiologists would still need to review the information, it is quite possible that such a system would automatically alert officials and pick up multi-county or multi-state trends days and weeks before a pattern was detected by human beings. The information could be made available to the CDC, State and County Health Departments simultaneously so to ensure the quickest response.

If industry were to produce such a system, the cost of the server hardware and software would run between \$100,000 and \$500,000. The labor costs would run between \$500,000 and \$2.5 million. And, depending on the scope of the project, development of the system could take as little as 6 months

238 Massachusetts Ave. NE, Suite 400
Washington, D.C. 20002
(202) 675-4511
Fax: (202) 675-4512

AESOP Enterprises, Ltd.

Fax

To: Barbara Wooley

From: Stephanie W. Smith

Fax: 456-8882

Pages: 2

Phone:

Date: 05/28/97

Re: 5/29 meeting

CC:

☐ Urgent ☐ For Review ☐ Please Comment ☐ Please Reply ☐ Please Recycle

• **Comments:**

Barbara—per your request attached is some information on AESOP Enterprises, Ltd. and a list of items we would like to cover at tomorrow's meeting:

- 1) Discuss Administration's short and long-term visions for the Food Safety Initiative
- 2) Identify ways in which the land-grant community can assist the Administration and representative agencies.
- 3) Identify key leaders to work with to get the Initiative moving.

Hope this helps. If there is anything else you need, please call.

✓ Terry Nip
✓ Mary Maddaf

AESOP Enterprises, Ltd.

AESOP Enterprises, Ltd. is a consulting firm that specializes in integrating science and policy. The Staff at AESOP have advanced degrees in science and practical experience in policy development. The staff have worked for Congress, as policy specialists for past Secretaries of Agriculture, or for the National Research Council of the National Academy of Science (NAS). They specialize in the following areas:

- ☐ agriculture production;
- ☐ environment and natural resource management;
- ☐ food safety and nutrition;
- ☐ rural and community development; and
- ☐ human resource development

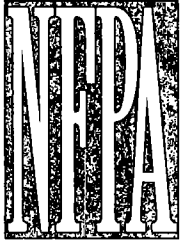
AESOP serves as a liaison for the academic and university community to Congress and the Administration. They provide an electronic newsletter to Deans and Directors of LandGrant Universities, as well as to leaders of agricultural, scientific and professional societies. Their daily task is to see that policy makers have science-based information in a form that they can use at the time that they need it. They brief Congressional Staff and Members, they arrange for expert witnesses during Congressional Hearings and they provide technical expertise to Congressional offices and the Administration.

AESOP works primarily with the national Association of State Universities and Land-Grant Colleges (NASULGC). With NASULGC, AESOP works with the Experiment Station and Extension Committees on Organization and Policy (ESCOP and ECOP). These committees represent the State Agricultural experiment Stations and the State Extension System. On behalf of ESCOP and ECOP, AESOP has played a lead role in addressing science and education issues considered in the current Farm Bill. AESOP has also worked closely with the universities and the Congress in developing new research and education programs to protect water quality from agricultural production practices. AESOP assisted in the development of new programs to promote sustainable agricultural practices. They have also been assigned to monitor food safety issues and assist in developing new initiatives to promote integrated pest management. During the recent reorganization of the U.S. Department of Agriculture, AESOP represented the universities to the Congress during the mediation of controversial elements of the legislation.

AESOP also works for NASULGC's Board on Human Sciences (BOHS). The focus of their activities is on human nutrition, children and youth development, and rural development. AESOP recently assisted the Board in the development of a workshop on Food Systems for Consumer Health. They are also assisting the Board as it explores the development of a Human Sciences Institute.

In addition, AESOP serves as a "Washington Liaison" or office for a number of scientific and professional societies. AESOP represents the Council for Agricultural Science and Technology (CAST); recently assisted the Council in the development of a national workshop on sustainable agriculture. Their staff helps evaluate and review CAST publications for Congress. AESOP also represented the American Society of Agronomy (ASA) the Soil Science Society of America (SSSA) and the Crop Science Society of America (CSSA). They have represented these societies in the Plant and Soil Science Forum, and association that has developed briefing papers for the U.S. Department of Agriculture (USDA).

AESOP also takes on Special projects for federal and Congressional agencies. They assisted in the development of a series of project funded by USDA, the Environmental Protection Agency (EPA) and the U.S. Agency for International Development (USAID). These projects addressed the interactions of agricultural and environmental policy in Central and Eastern Europe, particularly in the areas of water quality, soil erosion and integrated pest management. AESOP has summarized Extension and Soil Conservation Service studies for USDA. They have also served as consultants for the Congressional Office of Technology Assessment (OTA), and the General Accounting Office (GAO).



NATIONAL
FOOD
PROCESSORS
ASSOCIATION

John R. Cady
President and
Chief Executive Officer

1401 New York Ave., NW
1st Floor
Washington, DC 20005

202 639-5917

FAX
202 637-8464

March 4, 1997

Elizabeth Drye
Chief of Staff
Domestic Policy Council
The White House
1600 Pennsylvania Avenue, N.W.,
Washington, DC 20500

Dear Elizabeth:

Thank you for last week's meeting on the Food Safety Initiative. I felt it was productive and, hopefully, will set the stage for a cooperative effort to enhance food safety. The concept behind the Initiative, in general, is supported by almost everyone to whom I have spoken. One can hardly argue against the need for better risk assessment, increased consumer education, and uniformity at all regulatory levels. Soon, however, the details must be addressed, and the funding aspect could be a mortal blow to what could be a significant step forward to make our already excellent food safety system even better.

The National Food Processors Association (NFPA) is the principal science and technical trade association for the food industry. Our three laboratory centers, our scientists and professional staff represent food industry interests on governmental and regulatory affairs and provide research, technical services, education, communication, and crisis management support to industry members. We are leaders in food safety issues and have been instrumental in developing HACCP and teaching HACCP throughout the world. We are not product-specific in our focus and, therefore, we address food science issues related to all products regardless of how they are processed or packaged. I tell you this not as a commercial, but to ensure that the food safety initiative process will make the best use of our knowledge, experience and expertise. We are the food safety experts for the food industry.

I hope you obtained the information and input you needed from the meetings, and I am sure you will have much to include in your report to the President after the March and April public sessions. NFPA's initial disagreements with a few of the proposed activities contained in the Initiative should be viewed as an opportunity for policy and best practices debate and discussion. I hope the Administration will be broad in its thinking, not let the Initiative fail due to initial philosophical differences on funding, science policy, or food processing techniques.

WASHINGTON, DC

DUBLIN, CA

SEATTLE, WA

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Ray A. Myers, President/CEO
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William W. Sprague III, President/CEO
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C. Craig Sullivan, Chairman/CEO
The Clorox Company

Paul S. Walsh, CEO
The Pillsbury Company

Carl S. Watts, President/CEO
Taste Baking Company

Joe M. Weller, Chairman/CEO
Nestle USA, Inc.

Kenneth L. White, Chairman/CEO
Hershey Foods Corporation

William Wrigley, President/CEO
Wm. Wrigley Jr. Company

February 21, 1997

Ms. Elizabeth Drye
White House Domestic Policy Council
The White House
1600 Pennsylvania Avenue, NW
Washington, DC 20500

Dear Elizabeth:

I appreciated the opportunity to talk with you regarding the food safety initiative. We want to offer GMA's resources to assist the Administration in any appropriate way as we attempt to build a consensus around the most effective policy and process to reach an agreement.

I have enclosed a copy of the statement we released yesterday in response to press inquiries about the initiative. You will note that we encourage a food industry/government "partnership" to enhance the nation's food safety system.

I have also enclosed a bio on Dr. Steve Ziller, GMA Vice President, Scientific and Regulatory Affairs. Steve spent over 20 years handling scientific and technical issues for Procter & Gamble.

Please don't hesitate to call us whenever we can be of assistance.

Sincerely,



C. Manly Molpus



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WASHINGTON, DC 20007

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● **Paul J. Weinstein Jr.**

05/08/97 10:05:42 AM

Record Type: Record

To: See the distribution list at the bottom of this message

cc:

Subject: NPR's "31 Agency Initiative"

Please let me know today which of these meetings you want to attend. Bruce would like for DPC staff to participate.

----- Forwarded by Paul J. Weinstein Jr./OPD/EOP on 05/08/97 10:08 AM



Bruce N. Reed

05/06/97 06:55:00 PM

Record Type: Record

To: Paul J. Weinstein Jr.

cc:

Subject: NPR's "31 Agency Initiative"

Message Creation Date was at 6-MAY-1997 23:55:00

Let everybody know about this. Thanks.

----- Forwarded by Bruce N. Reed/OPD/EOP on 05/06/97 07:01 PM

John.Kamensky @ npr.gsa.gov

05/06/97 01:40:00 PM

Record Type: Record

To: Elena Kagan, Bruce N. Reed, Kathleen M. Wallman

cc:

Subject: NPR's "31 Agency Initiative"

This is a "heads up" about a series of meetings starting next week that you or your staff may find of interest.

NPR is undertaking a different approach to its work over the next few years by redirecting its energies toward a handful of about 31 bureau-level agencies that have a big impact on the public, business, or other government agencies.

Elaine Kamarck has been meeting with each of the agency heads from these "reinvention impact centers." The goal is to have them commit to a set of goals that have high customer/citizen impact by 2000. OMB is helping through the GPRA process and their spring management review. We've grouped the 31 into 6 "customer clusters" to allow the agencies to learn from each other and possibly work together on some initiatives. We've asked each of the 31 to prepare a draft 1-page set of goals to share with other members of their clusters. The refined versions will be shared with Gore as he meets with the agencies heads each of the 6 clusters next month.

The first of the staff-level cluster meetings to review the 1-pagers before we send them to Gore is next week.

We've got OMB, Departmental, agency, and designated NPR staff attending, so the meetings will be tight. If there are any meetings your staff would be dying to attend, please let Helene Carlson know (632-0150 or email at: helene.carlson@npr.gsa.gov). She can also answer any questions. The schedule is:

BUSINESS – Cluster #1

Commerce, Health and Human Services, Small Business Administration, Health Care Financing Administration, Patent and Trademark Office, U.S. Foreign and Commercial Service

Wednesday, May 14 at 2:00 at the National Performance Review
750 17th Street, N.W. Suite 200

INTERNAL GOVERNMENT – Cluster #2

Treasury, General Services Administration, Office of Personnel Management, Department of Defense Acquisition and Financial Management Service

Thursday, May 15 at 2:00 at the National Performance Review

TRAVELERS AND OUTDOORS ENTHUSIASTS – Cluster #3

Agriculture, Interior, Justice, State, Treasury, Animal and Plant Health Inspection Service, Bureau of Consular Affairs, Bureau of Land Management, Customs Service, Forest Service, Immigration and Naturalization Service, Park Service.

Friday, May 16 at 2:00 at the National Performance Review

GENERAL PUBLIC – Cluster #4

Commerce, Education, Treasury, FEMA, NASA, Census Bureau, National Weather Service, Student Loans, IRS

Monday, May 19 at 2:00 at the National Performance Review

BENEFICIARIES – Cluster #5

Health and Human Services, Agriculture, Veterans Affairs, Social

Security Administration, Veterans Benefits Administration, Veterans Health Administration, Administration for Children and Families, Food and Consumer Service.

Tuesday, May 20 at 2:00 at the National Performance Review

REGULATORS – Cluster #6

Agriculture, Health and Human Services, Labor, Transportation, Environmental Protection Agency, Federal Aviation Administration, Animal and Plant Health Inspection Service, Food and Drug Administration, Occupational Safety and Health Administration, Food Safety and Inspection Service

Wednesday, May 21 at 2:00 at the National Performance Review

AGENDA
FOOD SAFETY ANNOUNCEMENT MEETING
THURSDAY, MAY 8, 1997

10:35 -

I. LOGISTICS

A. PHOTO-OP

1. LIST OF ATTENDEES FOR VETTING PURPOSES

B. EVENT

- Shalala
- Glickman
- Laurie
- UP.

II. INVITED GUESTS AND MEMBERS OF CONGRESS

-- BARBARA WOOLLEY AND DAVID THOMAS

- Agency attendees. -

- Cabinet

- Moll

- Families

- Everybody Else

III. MESSAGE

A. SECRETARY SHALALA

B. SECRETARY GLICKMAN

C. VICE PRESIDENT GORE

John Cady NFPA

Carol Tudor Foran -

Betsy Woodward AFOP -

La's Director
Spoke of
Hondel.

IV. PRESS STRATEGY

A. PRESS RELEASE -- HEIDI KUKIS

B. REPORT RELEASE

C. VALIDATORS -- INDUSTRY GROUPS, MEMBERS OF CONGRESS AND FAMILY MEMBERS

Heidi regional press
Stakeholder -

V. FACT SHEET AND Q&As

-- ELIZABETH DRYE - done
- q's and A's

VI. OTHER ISSUES

- Fred Hansen. -

Dooley

MOV - Version will sign. - Original

- Barbara will bring. -

To resolve

* Families on stage. -

- Remarks -

- Holding room outside F

TO DO -

* get list to Heidi, -

* Call Manley Moirous. -

* FDA help w/ Laurie Grand's daughter

* HTTP://VM.
CFSA.N.FDA.
GOV/LIST.

WWW.FDA.GOV

↳

TO DO

- Cody [unclear] [unclear]
[unclear] [unclear]
[unclear] [unclear]

Call - responsibilities

Paper

- MOU - Paper for signing; pens; guests
Copies to Barbara

Fact Sheet - back - to Barbara

- comments from OM
- comments from Bruce

Report Provide prevent measures

3:30 - call Kathy

* - Linda - Fred Hansen (260-4711) -
Hilwig -

for generic *E. coli* to verify that their process control systems are working as intended to prevent fecal contamination, the primary avenue of contamination for harmful bacteria.

Mandatory implementation of FDA's seafood HACCP regulation by all processors and importers of seafood will take effect on December 18, 1997. Fishing vessels, common carriers, and retail establishments are exempt from this regulation.

Q. How will this initiative address the problem of *Vibrio vulnificus*?

A. Several elements of the initiative apply to the problem of *Vibrio vulnificus*. Research will be conducted to develop more sensitive analytical methods and also technologies to prevent foodborne illness caused by this pathogen. Education efforts, particularly directed to high risk individuals, will be designed to alert them to the risk and how to avoid it. Under this initiative, surveillance for *Vibrio* will be strengthened by CDC and FDA working with states with the goal of detecting the pathogen early so preventive measures can be implemented. Implementation of seafood HACCP and inspections to verify control measures are working effectively will also have an effect in reducing the incidence of illness attributed to this pathogen.

Q. How will this initiative assure that foodborne outbreaks such as the recent *E. coli* O157:H7 outbreak from apple juice and the hepatitis A outbreak associated with frozen strawberries won't happen again?

A. No one can assure that foodborne illness outbreaks such as these won't occur again. However, this initiative makes great strides in that direction by improving surveillance for the occurrence of foodborne illnesses and their source. Improved coordination between federal, state, and local agencies and rapid exchange of information and data will facilitate rapid implementation of control measures to control any outbreak. Increased research will result in more rapid, accurate, and sensitive methods of detecting and identifying contaminants and tracing them to the source. Improved risk assessment techniques will enable regulatory agencies to target efforts to where the greatest risk to public health lies and expanded education programs will raise public awareness and use of safe food handling practices, thus reducing the likelihood of the home or a retail food establishment being the source of foodborne illness. In combination, the result of all of these elements of the food safety initiative will be a reduced incidence of foodborne illness.

IV. SURVEILLANCE QUESTIONS

Q. What is the current method and level of surveillance for foodborne disease in the United States?

- A. The Centers for Disease Control and Prevention (CDC) work with state health and agriculture officials to track cases and outbreaks through what is currently a passive reporting system that doesn't produce the data we really need to effectively target the highest risk areas. State and local officials are usually the first on the scene in any foodborne outbreak. An important activity included in the initiative is improvement of communication systems to facilitate rapid exchange of information and data associated with the occurrence of foodborne illnesses and outbreaks. Ready access to this information will greatly aid states and localities that carry out the initial investigation into foodborne illness outbreaks.

(ADDITIONAL INFORMATION)

CDC is responsible for surveillance for foodborne disease in the United States. Cases of foodborne illness are reported by the States to CDC using a passive reporting system. CDC epidemiologists work with State epidemiologists and State Departments of Health and Agriculture to track and investigate cases and outbreaks. Reports are usually made of "reportable" diseases or of very severe, unusual, or widespread cases. Ease of reporting has improved with the availability of the Public Health Laboratory Information System (PHLIS).

The data obtained through the passive surveillance system are underestimates of the actual number of foodborne illness. Starting in 1996 (piloted in 1995), in an effort to improve these estimates and determine trends, CDC, with funding from FDA and USDA, began working in 5 sites with State agencies to find cases of foodborne illness by actively searching for cases and isolates through laboratory, hospital and state/local agency records.

Q. Why should we invest additional dollars into "high tech methods"?

- A. The more rapid and accurate the method, the more quickly the problem can be identified. "High tech" methods are more rapid, sensitive, and accurate, allowing scientists to quickly identify a foodborne illness outbreak and its source and initiate preventive measures to limit the spread of the outbreak. Hours and days mean fewer illnesses and deaths and decreased costs associated with health care and lost productivity.

Q. How will enhanced surveillance improve food safety?

- A. CDC, with funding from FDA and USDA, will begin intensively and actively looking for foodborne disease cases and outbreaks in 8 sites around the country, greatly increasing the chances that outbreaks can be detected and stopped before they spread.

The proposed enhancements to the surveillance system will improve food safety in several

ways:

- The enhancements will allow us to detect foodborne illness outbreaks and determine their sources at an earlier time during an outbreak. This will allow actions to be taken (remove product, warn consumers) that will protect more people from disease, save lives, and reduce associated costs (medical, etc.) of the outbreak.
- The enhancements will give us a better understanding of the amount of foodborne illness there is, and alert us to emerging pathogens or changes in patterns, geographic or seasonal, of illness. Knowledge of emerging pathogens in general and in particular foods will allow better prevention processes or methods to be developed and implemented (such as new hazards to be included in a hazard analysis or better controls to be used in a HACCP (Hazard Analysis Critical Control Point) system by a food processor..

Q. How will surveillance for animal drug therapies make our food safer?

- A. Surveillance of food animal populations for human pathogens will help identify the emergence of drug resistant human pathogens which we can not treat effectively. Surveillance for animal drug therapies along with surveillance for antimicrobial resistant organisms will give us information on the need for changes in commonly used antimicrobial treatments and/or need for a longer time interval between drug therapy and slaughter (for clearance of drug residues).

V. RESEARCH

Q. What are the most critical needs in food safety research?

- A. The most critical need in food safety research is for new, improved tools, screening methods and analytical methods to more rapidly and accurately identify and characterize hazards, to evaluate the effectiveness of surveillance initiatives, control and prevention strategies, to conduct risk assessments, and to verify the effectiveness of preventive techniques such as HACCP.

Q. Why do we need to expand food safety research programs?

- A. The wide diversity of broad surveillance and specific monitoring programs associated with tracking and preventing foodborne illness, are dependent on the availability of rapid, reliable and practical state-of-the-art methodology.

The past decade has seen the emergence of several new pathogens, as well as the facility of some previously innocuous microorganisms to evolve into pathogens. Foodborne pathogens are developing new characteristics that overcome our efforts to control them. The preventive mechanisms we relied on in the past to protect food from microbial contamination and to eliminate pathogens from foods may not be sufficient to control the pathogens encountered today. The ability of microorganisms to resist antimicrobial agents, acid, cold and heat, and other stresses, coupled with their proficiency to evolve new virulence factors and novel ways to evade our immune system responses, underscore the seriousness of this public health issue.

Q. Why are improved analytical methods essential to accomplishing the goals of this initiative?

- A. Advanced technologies that permit development of methods that are rapid, sensitive and quantitative are essential for the detection and identification of pathogenic microorganisms and chemical contaminants in a wide variety of situations. Successful implementation of these methods can provide the data to define effective intervention measures to reduce contamination before foods become available to consumers (e.g., on animals and produce on the farm, in animal feed, at processing plants, in product transportation and storage) and to monitor the success of those measures. These tools are essential for verification of HACCP critical control points and the development of surveillance and monitoring systems for foodborne hazards.

Q. How will advancements in risk assessment contribute to food safety? Examples?

- A. A risk assessment is used to characterize the health hazard associated with exposure to contaminants that may cause foodborne illness, such as bacteria, parasites, and naturally occurring toxins. The assessment can then be used to determine the most effective preventive measure to avert the hazard and where in the process it should be applied.

(ADDITIONAL MATERIAL)

For example, there is a risk of illness from the consumption of egg products and there are many points along the route from farm to fork that can increase or decrease that risk. For pasteurized liquid whole eggs, newly developed models suggest that the most important factor may be the pasteurization temperature. A small one degree decrease in pasteurization temperature provides a ten thousand-fold increase in the mean probability of the product causing illness. This information, developed by risk assessors, will be used by risk manager to focus prevention resources on assuring that processors implement precise pasteurization temperature controls for liquid whole egg products.

Q. Given the significant number of food safety issues that need to be addressed, why spend money on risk assessment?

A. Investment in risk assessment will lead to better priority setting and coordination between food safety agencies. Better risk assessment will ultimately lead to more efficient and effective regulations, which will prevent overburdening industry while protecting the public health.

(ADDITIONAL MATERIAL)

Two reports have been released in the last year that address the necessity of improving risk assessment. These are: The National Academy of Sciences' publication *Understanding Risk: Informing Decisions in a Democratic Society* and a report from the Presidential/Congressional Commission on Risk Assessment and Risk Management. Both reports speak to the importance of better risk assessment for public health government agencies.

Lastly, in a global economy the ability to conduct credible risk assessments is essential to addressing issues arising from international trade and trade barriers. To both withstand challenges and to assess the equivalency of differing systems, any standard developed must result from the best application of science through risk assessment procedures.

VI. EDUCATION QUESTIONS

Q. Why are the consumer's and food handler's roles such critical links in the safety of the food supply?

A. Although the American food system is justifiably admired around the globe for its ability to provide consumers with an abundant supply of convenient, economical, high-quality and safe food products, preventable cases of foodborne illness still occur in the United States. Many cases of foodborne disease are caused by home-prepared and retail-prepared food, ostensibly from a lack of knowledge by consumers of the risks involved at all stages of food preparation. Educating consumers and food handlers about the steps they must take to prevent and control foodborne illness is a vital link in the food preparation chain.

Q. What is the long-term goal of the food safety initiative with regard to education?

A. We are focusing on the goal of changing consumers' and retail food workers' food handling behaviors as a priority. The decision to move beyond merely providing information to changing behavior, as well, is based on the success of other health

education efforts, such as cancer and AIDS prevention. We believe that these new strategies and initiatives will lay the groundwork for future education efforts as part of an ongoing process for reducing foodborne illness.

Q. Food safety is an issue that affects everyone. How do you anticipate having such a broad educational reach while still being effective?

A. The only way to have a significant impact with such a broad reach is by allying with many groups -- state and local governments, industry and trade groups, consumers and academia -- so that we speak with one voice. By forming such a network, our messages will be more consistent, more powerful and more widely heard.

A significant step in that direction is the recently formed food safety education partnership involving FDA, USDA, CDC, Department of Education, industry, state representatives, and consumer groups in a nationwide food safety awareness and education campaign directed to the general public. The campaign will be launched nationwide in the next several months. Specifics about the campaign will be discussed at the food safety education conference "*Changing Strategies: Changing Behaviors*" sponsored by FDA, USDA, and CDC June 12-13 in Washington, DC.

Q. What is this public-private partnership on food safety education?

A. Representatives of the food industry, government agencies, and consumer groups have joined together to form a coalition with the primary goal of changing consumer unsafe food handling behavior through a new, widely-promoted public awareness and education campaign. The partnership will develop one overarching theme or slogan and key educational messages to form the foundation of the education campaign. The theme and messages will be channeled through outlets such as the media; local, state, and federal government agencies; public health officials; consumer-based organizations, and the private sector. Specifics about the campaign will be announced at the June 12-13 conference on consumer education "*Changing Strategies; Changing Behavior*".

Participants in the partnership include FDA, CDC, USDA, the Department of Education, AFDO, the American Meat Institute, the Food Marketing Institute, the Produce Marketing Assn., the Industry Council on Food Safety/National Restaurant Assn., the American Egg Board, the Grocery Manufacturers of America, the Coalition for Safe Food, the Consumer Federation of America, and Public Voice for Food and Health Policy.

Q. Who will comprise the National Food Safety Education Council and what will its function be?

- A. As we envision the National Food Safety Education Council, this group will have two primary functions. First, it will be responsible for conducting a review of food safety education messages to assure that they are science-based. Second, the Council will identify emerging food safety risks that require the development of public education messages and materials. Under the auspices of the Council national safe food handling guidelines like the Dietary Guidelines will be developed and periodically reviewed. Risk assessment will be used to identify at-risk audiences for targeted food safety education programs. The composition of the Council will be determined through an open public process, but we anticipate that the membership will include food scientists and educators.

- 30 -J

Elizabeth Drye

March 4, 1997

Page two

The food industry spends billions of dollars ensuring the safety of our products because we care about our customers, the food they eat, and market acceptance of our branded and generic private label foods. We, in the industry, desire strong regulatory agencies and the best food safety system we can obtain. We also believe in doing our part for food safety, and the industry has done an outstanding job in providing the safest processed food there is to the world's consumers.

I hope NFPA can continue to work with you and the agencies on the Initiative, and that all stakeholders will come together and help develop the enhanced food safety system the President has set in motion. Please call if we can be of help. Thanks for including us.

Regards,

A handwritten signature in cursive script, appearing to read "John Cady". The signature is written in black ink and is positioned below the word "Regards,".



FOR IMMEDIATE RELEASE

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WHITE HOUSE FOOD SAFETY INITIATIVE OFFERS PARTNERSHIP POTENTIAL

WASHINGTON, DC ... February 20, 1997 ... Dr. Stephen A. Ziller, Vice President, Scientific and Regulatory Affairs for the Grocery Manufacturers of America (GMA) issued the following statement in reaction to the release of the *Discussion Draft and Current Thinking* on the Clinton Administration's National Food Safety Initiative:

"As makers of America's best known brands of food products, GMA member companies know the importance of food safety for consumers. Our members' names are on every product they sell, and they strive to protect their products' and brands' reputations. Clearly, there is an important role for government in the food safety process, and GMA welcomes the new governmental efforts to help educate consumers and food handlers about proper hygiene and food safety. We see a strong potential for education and partnership drawing upon GMA's experience and technical expertise and government's ongoing oversight responsibility.

"GMA endorses the concept of focusing remedial efforts on the hazards that represent the greatest risks, including the pathogens highlighted in today's discussion paper. We support enhancement of an early warning system to detect and eliminate these pathogens and endorse science-based efforts to improve realistic risk assessment, including the development of better data and modeling techniques and bioscience research. We also support greater coordination of efforts between state and federal government and the private sector.

"GMA and our member companies recognize food safety is everyone's business, and we take our role very seriously. But as in most governmental programs, 'the devil is in the details.' Therefore, we look forward to seeing the details and working with government and others to create a more effective food safety system especially regarding education, research and inspection."

GMA is the organization representing companies that make and market the world's best-known brands of food and consumer packaged goods. GMA is the industry voice on public policy and industry productivity issues, through strategic issues management involving government relations, communications, legal, regulatory, scientific and education advocacy. GMA member companies have sales of 400 billion dollars, representing the largest volume (90%) of all food and consumer packaged goods sold in the U.S.

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Stephen A. Ziller, Ph. D. is Vice President, Scientific and Regulatory Affairs for the Grocery Manufacturers of America, Inc. (GMA). He directs GMA's science and regulatory efforts in more than 10 councils, committees and working groups which develop and support regulatory, legislative, and policy initiatives related to the activities of FDA, USDA, EPA, and other government agencies. Some of the key current priorities being worked in his department include: Hazard Analysis Critical Control Point (HACCP), biotechnology, food allergy, microbiological safety, nutrition and health, pesticides, food labeling, Codex Alimentarius, international regulatory harmonization, and specific food ingredient safety issues. Prior to joining GMA in January of 1994, Dr. Ziller was Associate Director, Professional & Regulatory Services in Procter & Gamble's Food and Beverage Sector. He worked for 26 years developing products and providing analytical, nutrition, toxicology, regulatory, microbiological, and other support for new and existing food, beverage, and food service products. Dr. Ziller received his B.A. in Chemistry from Rockhurst College in Kansas City and his Ph. D. in Biochemistry from the Edward A. Doisy Department of Biochemistry at St. Louis University. He has held many leadership positions in trade and scientific associations such as the Institute of Food Technologists, U.S. Food Industry Codex Coalition, International Council of Grocery Manufacturers Associations, International Food Biotechnology Council, Institute of Shortening and Edible Oils, American Peanut Product Manufacturers, Inc., National Center for Food Safety and Technology, and the Food Research Institute. His professional and scientific memberships include the Institute of Food Technologists, Society of Sigma Xi, American Chemical Society, New York Academy of Sciences, Association of Food and Drug Officials, and the American Association for the Advancement of Science. He served on the Food and Drug Administration's Food Advisory Committee from 1994-1996.

KEY CONSTITUTENT GROUP CONTACTS~~DAF-5~~**CONSUMER ORGANIZATIONS****Safe Food Coalition**

Carol Tucker Foreman, Coordinator; Heather Klinkhamer
(202) 822-8060

Center for Science in the Public Interest

Caroline Smith DeWaal
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Lori Girand (408) 867-9300 or (408) 867-1221 (H)
Vicki Peal (954) 564-0065

Safe Tables Our Priority (STOP)

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National Consumers League

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Public Citizen

Susanna Goodman
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Public Voice for Food and Health Policy

Bob Hahn
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Government Accountability Project

Tom Devine or Felicia Nestor
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Consumers Union

Mark Silbergeld
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Community Nutrition Institute

Rod Leonard, Exec. Director
(202) 776-0599

**President Clinton Announces New Measures to
Reduce Foodborne Illness**
January 25, 1997

Announcement

- . **President Clinton announced a new Early Warning System to help catch and respond to outbreaks of foodborne illness earlier, and to give us the data we need to prevent future outbreaks. The Administration will:**
 - . increase the number of active food safety surveillance sites across the country from 5 to 8 (the current sites are in Northern California, Oregon, Minnesota, Georgia, and Connecticut);
 - . equip these "sentinel" sites and other state health departments with state-of-the-art technology, including DNA "fingerprinting" to identify infectious agents and additional expert disease detectives to trace outbreaks to their source;
 - . link the sites, other state health departments, and Federal public health agencies electronically to allow rapid sharing of lab data -- including digitized fingerprinting data -- nationwide; and
 - . at the sentinel sites, investigate foodborne illnesses in depth to strengthen the scientific basis for our hazard prevention programs.
- . **President Clinton announced he will request an increase of \$43 million in his 1998 budget for food safety to fund the Early Warning System (\$11.5 million), increase seafood safety inspections, and expand food safety research, training and education.**
- . **The President asked for further recommendations.** He directed the Secretaries of Health and Human Services and Agriculture, and the Administrator of the Environmental Protection Agency -- working with consumers, producers, industry, states, universities, and the public -- to identify new ways to advance food safety through government and private sector actions, including public-private partnerships. The President asked for recommendations in 90 days.

Background

- . Although America's food supply is unmatched in quality and quantity, we can do more to eliminate disease caused by foodborne microorganisms. It is estimated that thousands of deaths and millions of illnesses each year are food related, imposing substantial health care costs.
- . We face new challenges involving food safety as we enter the 21st Century. Novel pathogens are emerging. Familiar ones are growing resistant to treatment. Americans eat in restaurants more. And we eat more imported foods, some of which comes from across the globe overnight. These changes require strengthened systems of coordination, surveillance, prevention, inspections, research, risk assessment and education.

Building on Our Accomplishments

- . President Clinton took a number of steps in his first four years to modernize food safety programs and prevent foodborne illnesses.
- . **Building on the recommendations of the Vice President's National Performance Review, the President put in place new science-based, hazard prevention systems for seafood, meat, and poultry.** In late 1995 the Administration issued new rules to ensure seafood safety. In July, 1996 President Clinton announced new regulations -- that begin to take effect next week -- to modernize the nation's meat and poultry inspection system for the first time in 90 years. The Early Warning System announced today will gather critical scientific data to further improve these prevention systems.
- . **In August, 1996 President Clinton signed the Food Quality Protection Act -- a comprehensive overhaul of our laws that regulate pesticides in food.** The new law establishes a single, strong health-based standard, creates special safeguards for children, protects public health and safety by using the best science available, and, for the first time, provides Americans with the "right-to-know" about health risks from pesticides.
- . **Last August, President Clinton also signed a new safe drinking water law that** strengthens protections to ensure that American families have clean, safe tap water to drink.

A NEW "EARLY WARNING SYSTEM" FOR FOODBORNE DISEASE SURVEILLANCE

PROBLEM

Purpose



- NO EARLY WARNING SYSTEM EXISTS THAT CAN CATCH OUTBREAKS EARLY TO PREVENT ILLNESS AND DEATH

RECOMMENDATIONS

- EXPAND AND ENHANCE THE FOODBORNE DISEASE ACTIVE SURVEILLANCE NETWORK (FOODNET) (STRENGTHEN EXISTING SITES, EXPAND #)
- IMPROVE EARLY DETECTION OF FOODBORNE DISEASE NATIONWIDE
 - FUNDS TO STATES TO GATHER EPIDEMIOLOGIC DATA
 - DEVELOP ELECTRONIC CAPABILITY TO COLLECT AND SHARE DATA ON OUTBREAKS
 - BEGIN EPIDEMIOLOGIC STUDY OF HEPATITIS A TO DETERMINE HOW MANY CASES ARE FOODBORNE
- CREATE NATIONAL ELECTRONIC NETWORK FOR BACTERIAL "FINGERPRINT" COMPARISON
- INCREASE SURVEILLANCE FOR ANTIMICROBIAL RESISTANCE OF FOODBORNE PATHOGENS

now

COORDINATION

PROBLEM

- FEDERAL/STATE AGENCIES NOT WELL COORDINATED FOR RESPONSE TO OUTBREAKS
- LACK OF COMMUNICATION, POOR DATA SHARING, MISUNDERSTANDING OF AGENCIES' ROLES

RECOMMENDATIONS

- ENHANCE INFRASTRUCTURE FOR SURVEILLANCE AT STATE HEALTH DEPARTMENTS
- ESTABLISH INTERGOVERNMENTAL GROUP TO COORDINATE INVESTIGATION/RESPONSE
 - ENSURE OUTBREAK CAUSES ARE ESTABLISHED QUICKLY AND ACCURATELY
 - COORDINATE DECISIONS ABOUT GOVERNMENT RESPONSE TO OUTBREAK AND ABOUT FOLLOWUP TO PREVENT RECURRENCE
 - DETERMINE SPOKESPERSON FOR EACH PHASE OF OUTBREAK

INSPECTIONS

PROBLEM

- FDA'S INSPECTION CAPACITY, COVERAGE SEVERELY ERODED (21,000 INSPECTIONS CONDUCTED IN 1981 DOWN TO 5,000 THIS YEAR)
- # OF IMPORTS DOUBLED IN 5 YEARS, NO NEW INSPECTORS; ONLY 2% OF IMPORTS SAMPLED

RECOMMENDATIONS

- IMPLEMENT HACCP FOR SEAFOOD AND EXPAND TO OTHER FOODS--BEGIN WITH 80 NEW SEAFOOD INSPECTORS
- TRANSFER COMMERCE SEAFOOD INSPECTORS TO AN FDA "PERFORMANCE-BASED ORGANIZATION"
- NEW PARTNERSHIPS WITH STATES TO LEVERAGE RESOURCES AND ELIMINATE DUPLICATION
- BETTER COVER IMPORTED FOODS
- AGREEMENTS WITH OTHER COUNTRIES
- CERTIFICATION BY IMPORTERS OF SAFETY

w/ retail
and
industry
better
training

- Seafood / meat poultry HACCP top
- retail

- 20% imports inspected
- importer certification of fruits and vegetables.

RESEARCH

PROBLEM

- NEW FOODBORNE PATHOGENS HAVE EMERGED, LONG-KNOWN ONES HAVE DEVELOPED RESISTANCE TO HEAT & REFRIGERATION, ONCE-INNOCUOUS ONES HAVE BECOME VIRULENT
- AGENCIES CANNOT EVEN DETECT SOME PATHOGENS

RECOMMENDATIONS

- DEVELOP RAPID, COST-EFFECTIVE TESTS FOR PRESENCE OF PATHOGENS
 - CAMPYLOBACTER
 - SALMONELLA
 - CRYPTOSPORIDIUM
 - TOXOPLASMA
 - E. COLI O157:H7
 - HEPATITIS A
- UNDERSTAND HOW PATHOGENS BECOME RESISTANT TO FOOD PRESERVATION AND ANTIBIOTICS
- DEVELOP TECHNOLOGY FOR PREVENTION AND CONTROL

RISK ASSESSMENT

PROBLEM

- RISK ASSESSMENTS NOT WELL DEVELOPED FOR APPLICATION TO FOOD PATHOGENS
- CAN'T MAKE GOOD DECISIONS ABOUT HOW TO PREVENT CONTAMINATION OR HOW TO TARGET PROBLEMS

RECOMMENDATIONS

*Revised proposal —
data we need
on the farm —*

- ESTABLISH RISK ASSESSMENT CONSORTIUM TO SET PRIORITIES AND GUIDE FEDERAL RISK RESEARCH
 - CONSORTIUM TO BE ESTABLISHED AT U. of Md.
- COLLECT DATA TO ASSESS PEOPLE'S EXPOSURE TO MICROBES IN FOOD
- DEVELOP MODELS THAT ENABLE EXTRAPOLATIONS FROM EXPERIMENTAL DATA TO EXPOSURES THAT PEOPLE ARE LIKELY TO GET
- DEVELOP "ECOLOGY" STUDIES FOR MICROBES IN FOOD (RATES OF GROWTH UNDER SPECIFIC CONDITIONS IN FOOD, ETC.)

EDUCATION

PROBLEM

- FOOD PROCESSORS, HANDLERS, AND CONSUMERS LACK KNOWLEDGE OF SAFE FOOD HANDLING PRACTICES
- HEALTH PROFESSIONALS LACK KNOWLEDGE OF DETECTION AND TREATMENT

RECOMMENDATIONS

- DESIGN FOOD HANDLING GUIDELINES (LIKE DIETARY GUIDELINES)
- DEVELOP INFORMATION SYSTEMS (E.G., NATIONAL CLEARINGHOUSE)
- USE TECHNOLOGY (E.G., CONSOLIDATE GOVT. INTERNET SITES, DEVELOP ELECTRONIC CURRICULA)
- DEVELOP EASY-TO-USE VISUALS (LIKE FOOD PYRAMID)
- TRAIN HEALTH PROFESSIONALS

= consider labeling options

- health professionals
- target ~~research~~ ~~institutions~~



OFFICE OF THE COMMISSIONER
OFFICE OF POLICY
5600 FISHERS LANE Rm. 14-81
ROCKVILLE, MD 20857
PHONE - (301)827-3370
FAX - (301)443-5930

Date: 4/7/97

To: Elizabeth Dye

From: Mary Rael

FAX #: 456-7028 5581

Of Pages Not Including Cover: 2

Comments:

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001a. list	re: SSNs and DOBs [partial] (2 pages)	04/07/1997	b(6)
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COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Elizabeth Drye
OA/Box Number: 10451

FOLDER TITLE:

Food Safety Outreach Meetings

2014-0046-S

rc1398

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
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b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

0.00 am April 8, 1997

Room 211

all U.S. citizens

Contact Elizabeth Dye
6-5573

April 7, 1997

Note To: Elizabeth Dye

Below is the list of attendees for the White House Meeting for April 8th at 10am to 11am being held in rm. 211 of the OEOB to discuss the Food Safety Report.

William K. Hubbard
Associate Commissioner for Policy Coordination, FDA

(b)(6) [001a]

Karen L. Hulebak
Senior Policy Analyst, FDA

(b)(6)

Jerold R. Mande
Senior Advisor to the Commissioner, FDA

(b)(6)

William B. Schultz
Deputy Commissioner for Policy, FDA

(b)(6)

Fred R. Shank
Director, CFSAN, FDA

(b)(6)

Janice F. Oliver
Deputy Director, CFSAN, FDA

(b)(6)

Mary M. Agocs
CDC

(b)(6)

Thomas Billy
Administrator, FSIS, USDA

(b)(6)

Catherine Woteki
Acting Undersecretary for Research Education and Economics, USDA

(b)(6)

Joan Mondschein
Confidential Assistant, USDA

(b)(6)

Eric Olsen
Special Assistant to the Secretary, USDA

(b)(6)

Stephen A. Schaub
Senior Microbiologist, EPA

(b)(6)

Dennis R. Lang
Enteric Diseases Program Officer, NIAID/NIH

Donald E. Schriber
Associate Director, CDC

(b)(6)

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001b. note	re; SSN and DOB [partial] (1 page)	04/07/1997	b(6)
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COLLECTION:

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Domestic Policy Council
Elizabeth Drye
OA/Box Number: 10451

FOLDER TITLE:

Food Safety Outreach Meetings

2014-0046-S

rc1398

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RR. Document will be reviewed upon request.

April 7, 1997

Note To: Elizabeth Drye

Below is an addition name to clear for the White House Meeting for April 8th at 10am to 11am being held in rm. 211 of the OEOB to discuss the Food Safety Report.

John Gallivan
Policy Coordinator, HHS

(b)(6)

[0016]

THE WHITE HOUSE

Office of the Press Secretary

Embargoed For Release
Until 10:06 A.M. EST
Saturday, January 25, 1997

RADIO ADDRESS OF THE PRESIDENT
TO THE NATION

The Roosevelt Room

THE PRESIDENT: Good morning. Today, I'm pleased to announce a major new step toward protecting the health and safety of all Americans, especially our children.

Almost a week ago, in my inaugural address, I told the American people that we must lead our country into the 21st century with the American Dream alive for all our children; with the American promise of a more perfect union a reality for all our people; with the light of our freedom illuminating all the world.

I believe we will make this vision real by doing what we've always done in moments of great change -- holding fast to our enduring values. Central among these is the belief that we work tirelessly to make our families stronger and our children safer. Nothing is more important to meeting this goal than seeing to it that Americans live in a world with clean air, safe food, pure water. Hard-working American parents deserve the peace of mind that comes from knowing that the meal they set before their children is safe.

That's why I was so concerned by what happened in Washington State and in two other Western states this fall. Apple juice contaminated with a deadly strain of E Coli bacteria reached supermarket shelves. More than a dozen children, some as young as two, were hospitalized, and one child died.

I'm sure just about every parent in America remembers what E Coli can do. Four years ago this month, tragedy struck hundreds of families in the Western United States when they took their children to fast-food restaurants that served them hamburgers tainted by the E Coli bacteria. Five hundred people became ill, some of them severely, and four children lost their lives.

Our administration has made it a top priority to protect the health and safety of all Americans. I signed into law legislation to keep harmful pesticides off our fruits and vegetables and legislation that keeps our drinking water safe and pure. We put in place strong new protections to ensure that seafood is safe. And last summer we announced steps to modernize our meat and poultry food and safety system for the first time in 90 years. These new safety rules will begin to take effect next week. From now on, all meat and poultry plants will be required to test for E Coli.

We have built a solid foundation for the health of America's families. But clearly we must do more. No parent should have to think twice about the juice that they pour their children at breakfast, or a hamburger ordered during dinner out. That's why, today, I'm announcing new steps to use cutting-edge technology to keep our food safe and to protect our children from deadly bacteria.

MORE

We must continue to modernize the food safety system put in place at the dawn of the 20th century so that it can meet the demands of the 21st century.

First, we will put in place a nationwide early warning system for food-borne illness. Right now the Centers for Disease Control, the Food and Drug Administration and the Agriculture Department sponsor five centers across the country whose mission is to post a lookout for food-borne diseases like E Coli bacteria and Salmonella. Working with state and local governments, these sentinel sites in California, Oregon, Minnesota, Georgia and Connecticut, actively track outbreaks of illnesses caused by contaminated food. Today I'm announcing we'll increase the number of these sites from five to eight, and link them to other state health agencies.

This expanded early warning system will enable us to catch outbreaks sooner and give us the data we need to help us prevent outbreaks from happening in the first place.

Second, we will see to it that the early warning system uses state-of-the-art technology to keep our food safe. We'll increase the number of expert disease detectives to investigate and control food-borne disease outbreaks. We will give these experts the technology to use sophisticated new DNA finger-printing methods to trace dangerous bacteria to their source. We will create a permanent DNA fingerprint library so we can immediately recognize an illness if it reappears. And we will use advance communication networks to speed outbreak information to hospitals and public health agencies all around America.

Third, I'm directing Secretary of Agriculture Dan Glickman, Secretary of Health and Human Service Donna Shalala and the Administrator of the Environmental Protection Agency Carol Browner to work with communities, farmers, businesses, consumer protection groups and all levels of government to come up with additional measures to improve food safety. I want them to pay special attention to research and public education efforts. I want them to focus on what sort of partnerships the government can form with the private sector to meet our goals. And I want them to report back to me with their findings within 90 days.

Finally, let me add that these new public health investments are paid for, line by line, dime by dime, in the balanced budget I will officially send to Congress next month. With this new early warning system to track food-borne illness, we are saying loud and clear that we will use the world's best science to make the world's most bountiful food supply safer than ever before, for our families and for our children. Together we will see to it that our people and our nation are prepared for the 21st century.

Thanks for listening.

END

MAR-28-1997 17:20 FROM FSIS-PEPS-00

TO

97209600 P.01

C O V E R

FAX

The Planning Office

S H E E T

Food Safety and Inspection Service

456-5581

To:

Joan Mondschlein

Fax #:

220-9600

Subject:

Remarks

Date:

Pages:

(including cover sheet)

From:

Elizabeth Dye

COMMENTS:

Redraft # 3

See if this meets Elizabeth
Dye's needs.Linda Russell
501-7138

Fax

Food Safety & Inspection Service
Planning OfficeUSDA/FSIS/PEPS/PL
1099 14th Street NW
Washington, D.C. 20250-3700

Phone: (202) 501-7138

Fax: (202) 501-7642

MAR-25-1997 15:38 FROM F51S-PEPS-00 302 382 0468 TO 93015946777 P.02

March 31, 1997

8:30 Welcome and Opening Remarks

William Schultz
Deputy Commissioner for Policy
Food and Drug Administration
Health and Human Services

Catherine Woteki
Acting Under Secretary
Research, Education and Economics
United States Department of Agriculture

Thomas J. Billy
Administrator
Food Safety and Inspection Service
United States Department of Agriculture

Don Shriber
Associate Director, Washington
Center for Disease Control and Prevention

Tudor Davies
Director, Office of Science and Technology
Office of Water
Environmental Protection Agency

9:00 Overriding Themes, Goals, Purpose and Desired Outcomes

Elizabeth Drye
Associate Director, Domestic Policy Council

Convene panel: Jerold Mande; Moderator, Thomas Billy, Michael Blackwell, Susan Conley, Jaleh Daie, Janice Oliver, Morris Potter, Stephen Schaub, Fred Shank

9:15 Public Comment

10:30 BREAK

11:00 Public Comment

11:40 Structure of Breakout Sessions
Thomas J. Billy
AI Officer

12:00 LUNCH

1:30 - 5:00 Two Concurrent Breakout Sessions

Bioscience Research
Outbreak Coordination

7:00 - 9:00
Evening Session — Plan for Action

April 1, 1997

8:30 Two Concurrent Breakout Sessions

Improving Risk Assessment
Improving Food Safety Education

12:00 LUNCH

1:30 Two Concurrent Breakout Sessions

NewEarly Warning System for Foodborne Illness
Maximizing Inspection to Support HACCP

April 2, 1997

8:30 Welcome
Jerold Mande

Breakout Session Reports

8:45 Bioscience Research
Jane Robens

9:10 Outbreak Coordination
Jerold Mande

9:35 Improving Risk Assessment
Wesley Long

10:00 BREAK

10:15 Improving Food Safety Education
Susan Conley

10:40 A New Early Warning System for Foodborne Illness
Robert Tauxe

11:05 Maximizing Inspection to Support HACCP
Janice Oliver

11:30 Plan for Action
Thomas Billy

11:50 Public Comment

1:15 Closing Remarks
Elizabeth Drye

FOOD SAFETY INITIATIVE

Q. Why is this initiative needed?

A. Foodborne disease is a major public health issue; outbreaks are increasing in seriousness and new disease-causing organisms are appearing in foods not previously associated with "food poisoning" (such as the contaminated raspberries of last summer). It is estimated that thousands of deaths and millions of illnesses a year are food related (according to a 1994 report entitled *Foodborne Pathogens: Risks and Consequences*, published by the Council for Agricultural Science and Technology, a private non-profit organization).

Q: How much will this initiative cost?

A. This initiative would provide an additional \$43 million for food safety to the FY '98 budget. Of that, \$11.5 million is for the new Early Warning System: \$10 million for the CDC; \$1 million for the FDA, and \$500,000 for USDA.

Q: What about the other \$31.5 million?

A: FDA will get \$23 million for seafood safety inspections, research, risk assessment and education; USDA will get \$8.5 million for training, research and education.

Q. What are the major sources of foodborne contamination?

A. Disease-causing organisms can contaminate food at many points. Examples are accidental contact of cow manure on fallen apples, contamination of meat with disease-causing organisms during and after slaughter, or seafood contaminated with naturally occurring microorganisms and toxins.

Q. Are foodborne disease outbreaks increasing?

A. It is hard to get really good estimates of this trend, but there is evidence that cases and outbreaks are increasing in frequency, and it is certainly clear that they are starting to involve increasingly dangerous bacteria, such as the E. coli strain that has caused serious illness and death in recent years.

Q. What foodborne hazards are targeted by this initiative?

A. We will focus on bacteria, parasites, and viruses that can cause serious diarrhea disease, not just the relatively short term, unpleasant intestinal distress usually thought of as "food poisoning." We are also targeting organisms that can cause death, spontaneous abortion, birth defects, and long-lasting illness such as reactive arthritis, and life-threatening paralysis.

- 2 -

Q. What are the benefits of this initiative?

A. We can't make precise estimates, but we believe that this initiative will result in significant reductions in food-related deaths, disease, and health-care costs over the next several years.

Q. How will the food industry and consumer groups be involved in the initiative?

A. President Clinton charged Secretaries Shalala and Clickman and Administrator Browner with recommending further food safety improvements in consultation with all sectors of the food industry, with State and local governments, and with producer and consumer groups.

Q. Will this initiative result in new legislation or new regulations?

A. We don't know yet, perhaps neither. But if new legislation is needed, we will work with the Congress to draft the appropriate bill; and we'll consider the need for new regulations as the agencies make their recommendations over the next 90 days.

Q. Is the Administration planning regulatory action to address the recent incident with apple juice that was contaminated by E coli?

A. FDA recently held a public meeting to seek advice on options for regulatory action to ensure the safety of fruit juices. Obviously, requiring preventive controls for that industry was an approach discussed. A decision should be announced soon.

Q: Where are the current active foodborne disease surveillance sites and what was their role in the Odwalla outbreak?

A: The five foodborne disease active surveillance sites that are currently in operation are the Atlanta, GA metropolitan area, selected counties in Connecticut selected counties in northern California, and the states of Oregon and Minnesota. The first cases in the Odwalla outbreak of apple juice-associated E. coli O157 infections were identified in Washington state. While Washington is not currently an active surveillance site, the health department there uses cutting edge technology and works with CDC's expanding network of collaborating public health laboratories. (In October, the Connecticut site did detect an outbreak of E. Coli caused by apple cider produced in that state.)

- 3 -

Q. Why is DNA "fingerprinting" of bacteria so important?

A: Disease-causing organisms can differ in subtle ways. Fingerprinting allows scientists to identify, match and track microbes, and more quickly link illnesses to specific food products. Digitizing the fingerprints and transmitting them over the Early Warning System's new communications network will allow scientists to work with one another from remote locations, eliminating the need to ship specimens.

Q. What can consumers do now to protect themselves from foodborne illness?

A. There are a number of things that consumers can do, and the initiative will include an educational campaign to inform consumers about these health-protective actions, including such things as cleaning utensils and food-preparation surfaces

Q. Will this new initiative include action against "Mad Cow Disease" that has so frightened Europe?

A. BSE, or "Mad Cow Disease," has not been detected in U.S. cattle. Earlier this month FDA proposed new regulations to help ensure it does not occur here. Those new rules should be finalized later this year.

Q: What does the new food-safety system the President spoke about for meat, poultry and fish entail?

A: The Administration has put in place a regulatory system of preventive controls. This new approach identifies hazards that can threaten food during handling or production and sets up procedures to ensure that those hazards don't occur or are within acceptable limits. These procedures might be as simple as cooking food to a high enough temperature, or ensuring a clean manufacturing line. This approach was first developed for the space program in the 1960s to ensure that safety was built into the product rather than learn of a failure after an astronaut got sick in the space capsule.

Q. The Vice President addressed food safety in his National Performance Review of 1993. He recommended merging USDA's meat inspection program with the FDA's food safety program. Do you intend to implement that recommendation?

A. The Vice President's report made a number of recommendations aimed at improving the efficiency of the nation's food safety programs. Some, such as moving toward a system of preventive controls, have already been achieved. We are also doing everything we can to improve coordination and cooperation among agencies involved in food safety, but we do not intend to make major structural changes as part of this initiative.

- Q. Will the E Coli testing requirements for meat and poultry that take effect next week catch all dangerous E Coli?**
- A. Next week meat and poultry slaughter plants must start testing for generic E Coli. Although generic E Coli is not by itself dangerous, it is an indicator of contamination, and testing for generic E Coli will help us reduce contamination that carries dangerous E Coli bacteria.**

**President Clinton Announces New Measures to
Reduce Foodborne Illness
January 25, 1997**

Announcement

- . **President Clinton announced a new Early Warning System to help catch and respond to outbreaks of foodborne illness earlier, and to give us the data we need to prevent future outbreaks. The Administration will:**
 - . increase the number of active food safety surveillance sites across the country from 5 to 8 (the current sites are in Northern California, Oregon, Minnesota, Georgia, and Connecticut);
 - . equip these "sentinel" sites and other state health departments with state-of-the-art technology, including DNA "fingerprinting" to identify infectious agents and additional expert disease detectives to trace outbreaks to their source;
 - . link the sites, other state health departments, and Federal public health agencies electronically to allow rapid sharing of lab data -- including digitized fingerprinting data -- nationwide; and
 - . at the sentinel sites, investigate foodborne illnesses in depth to strengthen the scientific basis for our hazard prevention programs.
- . **President Clinton announced he will request an increase of \$43 million in his 1998 budget for food safety to fund the Early Warning System (\$11.5 million), increase seafood safety inspections, and expand food safety research, training and education.**
- . **The President asked for further recommendations.** He directed the Secretaries of Health and Human Services and Agriculture, and the Administrator of the Environmental Protection Agency -- working with consumers, producers, industry, states, universities, and the public -- to identify new ways to advance food safety through government and private sector actions, including public-private partnerships. The President asked for recommendations in 90 days.

Background

- . Although America's food supply is unmatched in quality and quantity, we can do more to eliminate disease caused by foodborne microorganisms. It is estimated that thousands of deaths and millions of illnesses each year are food related, imposing substantial health care costs.
- . We face new challenges involving food safety as we enter the 21st Century. Novel pathogens are emerging. Familiar ones are growing resistant to treatment. Americans eat in restaurants more. And we eat more imported foods, some of which comes from across the globe overnight. These changes require strengthened systems of coordination, surveillance, prevention, inspections, research, risk assessment and education.

Building on Our Accomplishments

- . President Clinton took a number of steps in his first four years to modernize food safety programs and prevent foodborne illnesses.
- . **Building on the recommendations of the Vice President's National Performance Review, the President put in place new science-based, hazard prevention systems for seafood, meat, and poultry.** In late 1995 the Administration issued new rules to ensure seafood safety. In July, 1996 President Clinton announced new regulations -- that begin to take effect next week -- to modernize the nation's meat and poultry inspection system for the first time in 90 years. The Early Warning System announced today will gather critical scientific data to further improve these prevention systems.
- . **In August, 1996 President Clinton signed the Food Quality Protection Act -- a comprehensive overhaul of our laws that regulate pesticides in food.** The new law establishes a single, strong health-based standard, creates special safeguards for children, protects public health and safety by using the best science available, and, for the first time, provides Americans with the "right-to-know" about health risks from pesticides.
- . **Last August, President Clinton also signed a new safe drinking water law that** strengthens protections to ensure that American families have clean, safe tap water to drink.



NEWS RELEASE

U.S. FOOD SAFETY SYSTEM NEEDS GREATER GOVERNMENT-INDUSTRY COLLABORATION TO MEET CHALLENGES IN THE 21ST CENTURY

WASHINGTON, DC (March 21, 1997) – The federal government has made substantial progress recently to improve America's food safety system by adopting a new regulatory framework that focuses on prevention and clearly defines the roles industry and government must play. But reform of the system must go further and assign responsibilities more clearly, make better use of scarce resources, and prepare for future challenges, including those posed by persistent foodborne illnesses and the globalization of the food economy, according to an article published in the new *Food and Drug Law Journal*.

The article, titled "*Preparing America's Food Safety System for the 21st Century: Who is Responsible for What When it Comes to Meeting the Food Safety Challenges of the Consumer-Driven Global Economy?*" appears in the Journal's current issue (Volume 52, Issue 1). It is authored by Michael R. Taylor, who served from 1994-96 as both the Acting Under Secretary for Food Safety at the United States Department of Agriculture (USDA), and administrator for its Food Safety and Inspection Service (FSIS). He is now a visiting scholar in the Center for Risk Management at Resources for the Future (RFF).

"There really are two food safety systems in the U.S.," says Taylor. "One for meat and poultry, administered by USDA, and one for seafood and all other components of the food supply, administered primarily by the Food and Drug Administration (FDA). Certainly, the current system is not the one anyone would design if starting with a clean state."

In his article, Taylor argues that the organizational and statutory fragmentation of the current system for food safety – which includes twelve Federal agencies working under thirty-five statutes – hinders the best use of resources; complicates adoption of consistent, risk-based food safety strategies; and is at odds with the clear assignment of responsibility and accountability for food safety. Further, food safety research is conducted by 21 Federal agencies. Although more than \$200 million is spent annually on research activities, Taylor notes that there is no formal coordinating mechanism and government-wide food safety research strategy.

- over -

Contact: MICHAEL TEBO, RFF Public Affairs

Phone (202) 328-5019 | Fax (202) 939-3460 | tebo@rff.org | <http://www.rff.org>
1616 P Street NW, Washington, DC 20036

However, the regulatory changes recently adopted by FDA and USDA are cause for optimism, says Taylor, because they establish a sound conceptual framework for the future. Called the Hazard Analysis and Critical Control Points (HACCP) system, this new approach targets significant risks, minimizes costly command-and-control regulation in favor of performance-based standards, and focuses the food industry and government on what each does best. It aims to systematically prevent food safety problems by clearly defining the food's industry's responsibility -- and respecting its capacity -- to produce safe food, and gives government agencies the modern, scientific tools they need to verify the success of the industry's efforts.

Taylor outlines successes and progress made in food safety in recent years through industry and government collaboration; describes the traditional (and often overlapping) roles and responsibilities for food safety at FDA and USDA; and highlights the differences in day-to-day responsibilities and implementation as well as the strengths and weaknesses of each.

Taylor concludes by identifying some of the key issues that still need to be resolved to meet the food safety-related challenges of the next century. These challenges include: further reducing the risk of foodborne illnesses; successfully managing the introduction of new food technologies; overseeing and facilitating international trade; and maintaining public confidence in the food supply. To meet these challenges, Taylor urges expanded collaboration between industry and government, better coordination within government, and improvement in such areas as epidemiological surveillance of foodborne illness, food safety research, technology development, and food safety education for consumers and commercial food handlers.

Taylor notes that the food safety initiative announced by President Clinton in January 1997 as part of his budget proposal for the next fiscal year is intended to address many of these needs. The initiative, says Taylor, provides a golden opportunity for a national discussion by the food industry, the consumer community and the government about the future of the nation's food safety system.

"The adoption of HACCP is an important step forward in food safety," says Taylor. "But it is only a first step. To satisfy the public's food safety expectations and realize the food industry's full potential in the global food economy, we must work to resolve what we want our food safety system to do for us in the next century, who will be responsible for what, and how we are going to pay for it."

###

In addition to his appointment at RFF, Michael Taylor is a partner at the law firm of King & Spalding. Under Taylor's leadership at USDA, the agency adopted the HACCP system for meat and poultry inspection; established the first performance standards for reducing harmful bacteria in raw meat and poultry; began the elimination of outdated, command-and-control regulation; and realigned and streamlined FSIS management structures to carry out the new food safety system. Before joining USDA, Taylor served for three years as deputy commissioner for policy at FDA where he oversaw the agency's policy development activities and the processing of all regulations.

MEMORANDUM
OF CALL

Previous editions usable

TO:

Elena Kagan

☒

YOU WERE CALLED BY-

☐

YOU WERE VISITED BY-

Elien Vargas

OF (Organization)

EEOC

☐

PLEASE PHONE ▶

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FTS

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AUTOVON

663-4637

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RETURNED YOUR CALL

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MESSAGE

follow-up on
workfare issues

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STANDARD FORM 63 (Rev. 8-81)

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FPMR (41 CFR) 101-11.6

0956
- 9552

Food Safety

(1) Process

(2) Mtg

(3) Report —

- EPA — Alan Rubin
- CDC — Mary Agosh, Mary Potter
- FDA — Bill, Bill, Karen, Jen
- USDA — Jodi

- 98 budget clarity (consensus)
- priority areas
- concrete steps.

NIH — Dennis Lang —
enteric-diseases —

OSTP —

Seafood

inspectors

② Concurrent Sessions
a.m. R.A.
Education

① Meeting —
- Intro
- public comment

p.m. Early Warning System
Mar. Inspection to
Support HACCP

- Concurrent Sessions

bioscience research
coordination and sponsorship

③ Receive Reports from
each session.

public comments

p.m. for strategic planning.
Billie Shank — Facilitator

Ann Elliot - Uranium subjects ~~28~~ Mary Jane Connel. -

- If it's next week - New again message -

↳

- Closeout is running next week. -

Food Safety

- Recommendations
98 budget
specific
Priority Areas
- Add shape -

3 Secretaries

90 Days

Res Surveillance, Coordination, Research, Risk Assessment,
Inspection, Education

FY98 Budget - Consensus

Surveillance; inspection for seafood, research

Immediate
Action
Items

No-Cost Items

Coordination

Partnership - Education Campaign
Commerce Inspectors?

Longer Term (Investments / Investments)

- Transportation Regulation
- dual use of inspectors.

Priority
Items for
longer

Dollar Commitments

New Content - New education commitment

Event?

Process?

- Reorient base
- add'l money in FY98
- Use of add'l areas - Priorities
- As a result of discussions -
w/outside - look at in context
of future (balanced) budget.

NADA, - PNA, Commerce, HHS

- transfer of activities/resources -

Louisa Koch / Michael Deick

- Commerce ~~in~~ the room - Jack
| listening - give Commerce 2 weeks to
see what they think -

Radiation

Sunway - experiment going on now?

22

President's National Food Safety Initiative**DRAFT 2/18/97****President's National Food Safety Initiative
March 31 - April 2, 1997****AGENDA**

Purpose: To discuss and develop for the President a comprehensive plan for reducing, to the greatest extent possible, the annual incidence of foodborne illness by enhancing the safety of the Nation's food supply.

DAY 1

8:00 - 8:30 Registration

8:30 - 8:45 Welcome - Secretary Glickman

8:45 - 10:00 Opening Remarks

(Should include outcomes plus format for the 3 days)

CSREES - Catherine Woteki FDA - Fred Shank

CDC - Morris Potter

FSIS - Tom Billy, *Catherine Woteki*

EPA - Al Rubin

Dr. Tudor Davies, Director Office Science and Technology

10:00 - 10:15

BREAK

10:15 - 12:00

Public Comment

Consists of 5 minute segments where stakeholders may present additional issues or comments for the public record. Space and times will be allocated on a first come first serve basis. Call Lisa Parks 202-501-7138)

12:00 - 1:30

LUNCH

1:30 - 5:00

Two Concurrent Breakout Sessions

**New Early Warning System for Public Health
Improving Risk Assessment Tools**

DAY 2

8:30 - 12:00 Two Concurrent Breakout Sessions

**Developing A Public Health Research Agenda
Improving Food Safety Education**

12:00 - 1:00

LUNCH

1:00 - 5:00

Two Concurrent Breakout Sessions

**Maximizing Inspection to Support HACCP
Expanding Private and Public Sector Partnerships**

President's National Food Safety Initiative

DRAFT 2/18/97

**President's National Food Safety Initiative
March 5, 1997 Meeting**

Purpose: To brief stakeholders about the purpose of the President's initiative and about the agenda for the April conference.

AGENDA

- 8:30 - 9:00 Registration
- 9:00 - 9:45 Welcome
- 9:45 - 11:00 Purpose of the President's Initiative
30 minute presentation
45 minute discussion
- 11:00 - 11:15 BREAK
- 11:15 - 12:30 Agenda for April Conference
30 minute presentation
45 minute discussion
- 12:30 - 1:00 Closing Remarks

*For: Attendees to the Food Safety Initiative
Meeting on Feb. 20. @ 4:45*

*Attached agenda to be discussed @
meeting -*

OPTIONAL FORM 99 (7-90)

FAX TRANSMITTAL

of pages ►

To	From
Dept./Agency	Phone #
Fax #	Fax #

NSN 7540-01-317-7368 5099-101 GENERAL SERVICES ADMINISTRATION

For Thursday's meeting

FEB-18-1997 14:01 FROM FSIS-PEPS-00

TO

7209600

P.04

President's National Food Safety Initiative**DRAFT 2/18/97****DAY 3**

Each segment of Day 3 will consist of reporting out the recommendations of the Day 2 breakout session (20 min.) followed by general discussion (25 min).

8:00 - 8:15	Welcome
8:15 - 9:00	A New Early Warning System for Public Health
9:00 - 9:45	Maximizing Inspection to Support HACCP
9:45 - 10:30	Developing A Public Health Research Agenda
10:30 - 10:45	BREAK
10:45 - 11:00	Improving Risk Assessment Tools
11:00 - 11:45	Improving Food Safety Education
11:45 - 12:30	Expanding Private and Public Sector Partnerships
12:30 - 1:00	Closing Remarks

~~DATE~~ - AFTERNOON**American Society for Microbiology**

Stanley Falkow, Ph.D., President

Michael Goldberg, Ph.D., Executive Director 202-942-9265

Interstate Shellfish Sanitation Conference

Ken Moore 803-788-7559

Infectious Diseases Society of America

P. Frederick Sparling, M.D.

Melissa Sordyl, MBA, Executive Director 703-299-0200

Native American Water Association

Tim Crawford 702-782-6636

P.O. Box 511

Minden, NV 89432

American Public Health Association

Eric Juzenas

(202) 789-5600

Coalition of Hispanic Health & Human Services Organizations

Jane Delgado, Pres/CEO

(202) 387-5000

Assn. Of State and Territorial Public Health Laboratory Directors

Berton w. Wilcke, Ph.D., President

Carl H. Blank, Dr. P.H., Acting Executive Director 202-822-5227

Association of Food and Drug Officials

Betsy Woodward

(904) 488-0670

National Association of State Departments of Agriculture

Rich Kirchoff, Executive Vice President; Mark Nestlen

(202) 296-9680

Conference for Food Protection

Tom Leitzke, Chair

(608) 224-4711

National Environmental Health Association

Peter Thornton, President

(904) 822-6247

State Ag Depts - Rich Kordoff. →
- hardware regulated food items (mustard)
moving in interstate commerce
- Food Reg and Nutrition Comm. - chaired
by Fred - Dir of Ag in Ohio. -

Large event - post surveillance
- Comparison of areas that are geographically
similar
- build from

ASTH PHO Carl Blank. -

New Agency Exec Director. (former CDC)

Putting together microbiology course
/ top initiative will bring together
intrastate (Ag, FDA / Public Health) and
interstate. -

Well done document.

Seafood toxins → add

Environmental and public health v. difference

Comparison of food laboratories - EPA has
Example - (John's notes)

CDC Public Health in

Infection Disease Society of American. —

CDC has cooperative agreement

IHSA and ~~unifarm~~ — universities
include

APHA

Improved Coordination

what?

gaps
in infrastructure

— one big concern is diminishing public health
budgets. FDA also woefully underfunded.
restaurant

public health risk assessment. —

— more relative risk assessment

— where does a pub health agency focus its
efforts.

eg. FSIS research on eggs.

microbial resistance. — big area

Seafood HACCP/TOXINS. — priority is concern.

— Assn of Food and Drug Officials — Bets, Woodard

— disparate need for resources —

— Cyclospora - wake up call — need for
better coordination — lines of

AFDO goal — uniformity in codes; encourage
states to adopt model codes; leaders in Seafood
HACCP implementation (training)

^{R.A. Johnson}
Need for control measures are apt.
Input part needs to be built up

— other countries don't have
the same standard.

— Rpt doesn't adequately acknowledge state inspection role
— E. coli H:0157:H7 particular concern.

APDO board met last night — endorse
the initiative. — Have a lot of inspectors —
need to bring.

^{Santorum}
ISSC — Shellfish Interstate Conference. —

Some pieces that are needed don't
aren't ready — bewitching block

— agree not a adequate alt'n. to states
in Rpt.

— No common process to examine
common goals for states and Feds

involve state elected officials.

& in FIEs at Federal level —

planning / admin / policy dev't.

milk / shellfish / interstate
shippers

States to step in interstate commerce
are required
Conference of Food Protectors. to adopt guidelines.

Need more ^{disease detectives} ~~inspectors~~ in the ~~field~~
milk shippers - I

Outbreak response coordination group -
great potential -

- Help us to understand coordination much
better

Risk Assessment pathogens - critical
F

States have authority to clamp state
waters.

Education - without a doubt -

Food handlers
consumers

are the most imp.

Development of methods for evaluation -

Beats

Small businesses - only $\frac{1}{3}$ of apple cider people
wash their apples.
How to reach them.

- Incidence of microbial in foods -

Industry sits on a lot of data (Eaton)

Kag (USDA) because of microbial testing
requirements in HACCP - national
accreditation program for labs.

Kirchhoff
Also

NSSP - FDA audits. -

Educate

National Conference of State Legislatures

The whole reg effort is not well documented -
who is doing what. -

Extension service - do outreach for food safety. -
figure out role / get them on the job?

NSSP - high risk groups. -
- need it

Mike Osterholm

- 2/3 of states — inadequate surveillance —
\$ to CDC is important — inventory of
current resources — compare to what
we need (needs assessment).
- Coordination — can do a lot now administratively
— ~~not~~ don't wait
- bioscience research
 - left off "new agents."
 - enhance basic research settings for
analyzing new agents.
- A lot of chronic diarrhea — characterize as
chronic disease or irritable bowel
system — Better diagnosis of food
outbreaks. —

Arce [Institute of Food Technologies]

Integration of food and water (food industry
is one of the largest users of H₂O in this country)

— Importation —

Assn of Professionals in Infection Controls.

- members are health-care based.

Janet Shamahor-Bausli Am Society of Microbiology
Int'l

Cent on public health, biomedical research.

- Role of NHT not very prominent —

- bioscience not mentioned

- National Institute of Allergy and Infectious diseases — v. small #

of grants to food borne illness.

- elicitor of advice

- want to work with us in public education campaign

- what do we intend w/ water safety.

~~— 1~~

- Animal Science Robert Nettleton.

- 1/2 in industry

- need understanding of e. coli in the farm — need better data — but don't know much about what happens at the farm.

- what happens ^{processes} ~~are~~ ~~harvest~~ — even starts w/ harvesting — need a focus on irradiation.

- include discussion of innovation.
Real solution.

Losser Crawford - 51 University w/ vet programs.

\$12 Billion in NIH $\rightarrow$ % is lowest in all countries.

Education - beginning there are terrific -
HACCP - inculcate principles -
elegant

Strategic Plan - Compact w/ different
organizations.

- address jurisdictional problem
in longer strategic process
- involve medical community
in education.



Nat'l

Advisory Committees

- FDA
- Meat
-

Berradette Danham — Am Vet Medical Assn.
Canoral Database

NJH, — get involved, —

FDA's Animal Medi

FARD Food
Avoidance
Residue
Database

Racharm

Educarm —

Proharvest issue — how do you deal with findings —

Networks

— Electronic media —
— educarm —

Mike Overholts — moment where people
need to come together

— still need to coordinate w/in
Federal Gov't

— USDA — groups — head to head

CDC - bacterial, viral, parasitic -
Can't get one response

Learn from other countries?

- England has named a chief
food safety officer. -

- Germany has named a chief
food safety officer

- Canada has merged into one agency -

Research training - Is it adequate?
basic training - can't get
top notch microbiologists -

irradiation / terminal pasteurization

- innovative ways - high pulse lights?

OPTIONAL FORM 99 (7-90)

FAX TRANSMITTAL

of pages 3

To	Elizabeth Dyce	From	[Signature]
Dept/Agency	Dyce	Phone	[Signature]
Fax	456-5581	Fax #	
NSN 7540-01-317-7388		5099-101 GENERAL SERVICES ADMINISTRATION	

67

Billing Code 3410-DM-P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. 97-003N]

President's National Food Safety Initiative

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice.

SUMMARY: The United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) and Research, Education, and Economics; The Department of Health and Human Services' Food and Drug Administration (FDA) and Centers for Disease Control; and the Environmental Protection Agency (EPA) will convene a public meeting to discuss the "President's National Food Safety Initiative." At this meeting, participants will be briefed on the purpose of the President's initiative and on the agenda for a second public meeting to be held in April. The goal of the April meeting will be to discuss and develop, for the President, comprehensive recommendations for reducing, to the greatest extent possible, the annual incidence of foodborne illness by enhancing the safety of the Nation's food supply.

DATES: The meeting will be held from 9:00 p.m. until 1:00 p.m. on March 5, 1997.

ADDRESSES: The meeting will be held at the Jefferson Auditorium, 1400 Independence Ave, SW, Washington, DC 20250.

FOR FURTHER INFORMATION CONTACT: To register for the meeting, contact Lisa Parks at (202) 501-7138, FAX (202) 501-7642, or E-mail usdafsis/s=confer@mhs.attmail.com. For questions about the meeting or to obtain copies of a draft report, contact Mr. Charles Danner, FSIS at (202) 501-7138 or Ms. Caren Carson, FDA at (202) 205-5140. Copies of the draft report also are available from the following: FSIS at <http://www.usda.gov/fsis> or FDA at <http://vm.cfsan.fda.gov/list.html>.

SUPPLEMENTARY INFORMATION:

On January 25, 1997, the President directed the Secretaries of USDA and HHS and the Administrator of the EPA to work with consumers, producers, industry, States, universities, and the public to identify ways to further improve the safety of our food supply through government and private sector action, including public private partnerships, and make recommendations to the President. The President requested that the recommendations identify steps to further improve surveillance, inspection, research, risk assessment, education, and coordination among local, State, and Federal health authorities.

To carry out the President's initiative, two public meetings will be held. At the first meeting, government officials will discuss the current thinking on the President's six areas of concern. They also will discuss the agenda and goal of the meeting to be held in April.

At the April meeting, participants will be asked to identify problems and provide recommendations related to the President's six areas of concern. A second Federal Register notice will be published that provides additional information about the time, location, and focus of the April meeting.

Done at Washington, DC, on: FEB 13 1997



Thomas J. Billy
Administrator

National Food Safety Initiative Meeting
Monday, March 3, 1997

Attending:

Miscellaneous Groups:

National Turkey Federation, Stuart Proctor 4

National Broiler Council, Steve Pretanik 5

USA Poultry and Egg Association, Don Dalton

United Egg Producers, Christine Nelson

American Meat Institute, Sara Lilygren End

Excel Corporation, Del Allen 3

Cargill, Mike Mullins 2

IBP, Inc., Jim Lochner 8 — processor of meat products

ConAgra, Paul Korody —

Farmland Foods, Scott Shearer 7

National Fisheries Institute, Roy Martin back (1)

APHA, Mohammed Akhter — inspectors at local level

Industry:

National-American Wholesale Grocers' Association, John Block

International Food Information Council, Robert Earl 6

International Food Additive Council, Rick Cristol

National Council of Chain Restaurants, Chet England (1) Co

Call EPA

Paul Council of Chain Restaurants - Chef England
w/ Burger King

- advocates for customers
- excellent staff. —
- educational concept in public schools. —

- emphasize education —

- ~~eat~~ diagnostics

- doctors, inconsistent reporting mechanisms

- seasonal sites shortcuts. —

Mike Mullus / Carzill - Meat

- good experience — meetings that Tom took
on HACCP implementation.

- agree from the get go is about science and risk.

- accountability. —

Del Allen - Excell Corporation. —

heavily regulated — not anti that?

- simple

- performance based — realistic —
meaningful.

- Distribution. —

Steve Prastnik — National Broker Council

Budget —

Education —

Organization

Consumer education conf.

- technical

Scientific research — once you've made the
determination, how do you control

AMI - public private partnership -
- use the same delivery mechanisms
on

public education - project #1 -

- work in and measure over time
- want to see changes in behavior
not just education

public funding - user fees - gov't should pay
- 1/2 interested in price tags on
all of this

- put illness you find in context
- when you do surveillance - tell
public what that means.

Broiler Council
Farmland Facts - good start. (surveillance inst.)
education critical

Intl Food Ctr to Council

- work in partnership w/ FDA/USDA on public
education council.
- develop food safety msg -

Farmland Industries - farm to table -
Canada to Mexico / N to S

Pic Cristol — 20 canaries in foods —
— state/local officials & educators.

— media — need to educate them.

IBP — #1 in beef/pork production 26 plants
in 12 states.

— all comes to research and education
following outbreak at Jack-in-Box —
michigan had research unit which
could reimburse — to match
Fed dollars.

— education is the key —
— reevaluate regulations

— Mohammed APITA — have to do
the assessment to know where the gaps are —
Gaps b/w Fed agencies. States don't have tools.
Targeted monitoring — of elderly and children.

— Coordination

— on going advisory group —

— Importance of consumer education —

— had successful ad campaign — with coordinated
for nutrition

— have work links in

Seafood Industry

- ✓ Take advantage
- Expanded Sentinal sites - get better #'s from CDC
- back to basics. —
- Use the office of Surgeon General. —
- Give HACCP ~~more~~ to grow and make adjustments. —
- ~~the~~ aquaculture policy. —
Need policy and R&D for it. —
- better support &

Withdrawal/Redaction Marker

Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
002. list	re: National Food Safety Initiative [partial] (1 page)	03/03	b(6)

COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Elizabeth Drye
OA/Box Number: 10451

FOLDER TITLE:

Food Safety Outreach Meetings

2014-0046-S

rc1398

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
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C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

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- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

EVENT: National Food Safety Initiative

DATE: Monday, March 3

TIME: 11:00-12:00

ROOM: 211 OEOB

SPONSORING OFFICE: DPC

LAST NAME	FIRST NAME	DOB	SSN	U.S CITIZEN
-----------	------------	-----	-----	-------------

PRETANIK	STEVE			Y
NELSON	CHRISTINE			Y [002]
LILYGREN	SARA			Y
LOCHNER	JAMES			Y
KORODY	PAUL			Y
SHEARER	SCOTT			Y
MARTIN	ROY			Y
AKHTER	MOHAMMED			Y
PROCTOR	STUART			Y
EARL	ROBERT			Y
DALTON	DON			Y
ENGLAND	CHET			Y
MULLINS	MIKE			Y
ALLEN	DEL			Y
EARL	ROBERT			Y
WATTS	GEORGE			Y
WACHSMUTH	INA KAY			Y
BILLY	TOM			Y
WOTEKI	CATHERINE			Y
SHRIBER	DONALD			Y
DAIE	JALEH			Y
MANDE	JERRY			Y
SHANK	FRED			Y
SUNDLOG	STEPHEN			Y
HORN	FLOYD			Y
POTTER	MORRIS			Y
OLIVER	JANICE FARRELL			Y

(b)(6)

*final status

Meeting: Food Safety
Date: Friday, Feb. 28
Time: 2:30 PM
Location: OEOb Rm 211

NON-AGENCY ATTENDEES:

Dr Michael Osterholm
Council of State and Territorial Epidemiologists
(612) 623-5414
contact: Willis Forrester
ph (770) 458-3811
fx (770) 458-8516

3 Jennifer Thomas
Assoc. of Professionals
in Infection Control
→

Dr. Lester Crawford
Association of American Veterinary Medical Colleges
contact: Lisa Greenhoe
ph(202) 371-9195

Robert Zimbelmen,
Executive Vice President
American Society of Animal Science
(301) 571-1875

2 Joyce Nettleton
Institute of Food Technologies
ph (312) 782-8424
fx (312) 782-8348
born in Kitchener, Ontario

3 Janet Shoemaker-Bausili
American Society of Microbiology
(202) 942-9294

Dr. Bernadette Dunham
Assist. Director for Governmental Relations
American Veterinary Medical Association
789-0007 ext. 1611

INVITED BUT DECLINED:

Federation of American Societies for Experimental Biology
Dr. David Schnakenberg
(301) 530-7110
(he will be out of town that day and no other person in that organization is (as he put it) a "professional", please call for next meeting)

American Institute of Biological Sciences

Roger DeSelvestro

(202) 628-1500 ext. 245

(he said it is not an issue that they deal with and they prefer to stay "in their own range")

National Association of State Universities &

Land Grant Colleges Board on Human Sciences

Karen Craig

(402) 472-2913

(will not be sending any representatives)

Dorothy K. Craft

02/21/97 03:08:10 PM

Record Type: Record

To: See the distribution list at the bottom of this message

cc: Phyllis Kaiser-Dark/OMB/EOP, Sarah A. Bianchi/OMB/EOP, Elizabeth Drye/OPD/EOP

Subject: Food Safety Meetings

MEMORANDUM TO DISTRIBUTION LIST

FROM: Elizabeth Drye, ext. 65573

SUBJECT: Series of Food Safety Meetings

As you may know, the President has challenged government, industry, consumers, and producers to work together and identify steps to improve Food Safety. Next week, we will hold meetings with these groups to which you all are invited. Please call if you have questions.

Food Safety Meetings -- Confirmed

Small Plants Groups: Monday, February 24, 3:00pm, OEOB 211 ✓

Producer Groups: Tuesday, February 25, 10:00am, OEOB 211 ✓ 11545

Consumer Groups: Tuesday, February 25, 4:30pm, OEOB 476 ✓

→ Industry Groups: Wednesday, February 26, 3:00pm, OEOB 211 ✓
(group one) *Sally OMB*

Food Safety Meetings -- Scheduling in Progress -- * Subject to Change *

Miscellaneous Groups: Thursday, February 27, 3:00pm, OEOB 476
(Misc. group includes: Ntl Turkey Fed.; Excel Corp.; *Mon*
Farmland Foods; Ntl Broiler Council, among others.) *Carrie*

Industry Groups: Thursday, February 27, 4:30pm, OEOB 211 ✓ *Jennifer*
(group two)

Health/Science/Tech. Groups: Friday, February 28, ~~10:00am~~ ^{2:30pm}, OEOB 211 ✓ *Jennifer*
(group one)

Health/Science/Tech. Groups: Friday, February 28, 1:00pm, OEOB 211 *Carrie*
(group two) *D. K. Craft*

Friday 1p, 2/1

DAY 6 - AFTERNOON

✓ Interstate Shellfish Sanitation Conference

Ken Moore 803-788-7559

end Infectious Diseases Society of America

✓ ~~P. Frederick Sparling, M.D.~~

Melissa Sordyl, MBA, Executive Director 703-299-0200

Native American Water Association

Tim Crawford 702-782-6636

P.O. Box 511

Minden, NV 89432

6 ✓ American Public Health Association

Eric Juzenas

(202) 789-5600

Coalition of Hispanic Health & Human Services Organizations

Jane Delgado, Pres/CEO

(202) 387-5000

ALDO FALCON

4 ✓ Assn. of State and Territorial Public Health Laboratory Directors

~~Berton W. Wilcke, Ph.D., President~~

Carl H. Blank, Dr. P.H., Acting Executive Director 202-822-5227

✓ Association of Food and Drug Officials

Betsy Woodward

(904) 488-0670

1 ✓ National Association of State Departments of Agriculture

Rich Kirchoff, Executive Vice President; Mark Nestlen

(202) 296-9680

Conference for Food Protection

Tom Leitzke, Chair

(608) 224-4711

✓ 2 National Environmental Health Association

~~Peter Thornton, President~~

(904) 822-6247

Ellen Schor

Also consults

key > USDA
Jahli
Fred

Steve Olsen

Withdrawal/Redaction Marker

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
003. list	re; National Food Safety Initiative [partial] (1 page)	02/28	b(6)

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Elizabeth Drye
OA/Box Number: 10451

FOLDER TITLE:

Food Safety Outreach Meetings

2014-0046-S

rc1398

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- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

EVENT: National Food Safety Initiative

DATE: Friday, February 28

TIME: 1:00-2:00

ROOM: 211 OEOB

SPONSORING OFFICE: DPC

402160 (confirmation #)

LAST NAME	FIRST NAME	DOB	SSN	U.S CITIZEN
-----------	------------	-----	-----	-------------

JUZENAS

ERIC

BLANK

CARL

WOODWARD

BETSY

KIRCHHOFF

RICHARD

SCHROTH

ELLEN

MOORE

KEN

FALCON

ALDOF

SORDYL

MELISSA

WACHSMUTH

INA KAY

BILLY

TOM

WOTEKI

CATHERINE

SHRIBER

DONALD

DAIE

JALEH

MANDE

JERRY

SHANK

FRED

SUNDLOG

STEPHEN

HORN

FLOYD

POTTER

MORRIS

Y

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[003]

(b)(6)

Withdrawal/Redaction Marker

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
004. list	re: SSNs and DOBs [partial] (2 pages)	02/26	b(6)

COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Elizabeth Drye
OA/Box Number: 10451

FOLDER TITLE:

Food Safety Outreach Meetings

2014-0046-S
rc1398

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

- b(1) National security classified information [(b)(1) of the FOIA]
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1100806

Food Safety Meetings / Clear for Elizabeth Drye, X65573 / Contact: Dorothy Craft, X65571
Wednesday, Feb. 26, 3pm, OEOB 211

Tom Billy

(b)(6)

[004]

Catherine Woteki

(b)(6)

Donald Shriber

(b)(6)

Jaleh Daie

(b)(6)

Jerry Mande

(b)(6)

Fred R. Shank, FDA

(b)(6)

Stephen Sundlog

(b)(6)

Dr. Floyd Horn, USDA

(b)(6)

Robert Byrne, Intl Dairy

(b)(6)

(#janet hawil 737-4332)

Steve Anderson, Amer. Frozen Food Inst.

pg 2, 2/26, 3pm

John Cady, Natl Food Processors Assoc.

(b)(6)

(RT) - Science Technical
Reg Legislative

Dagmar Farr, Food Marketing Instit.

(b)(6)

FME - Grocers
Wholesalers

Chester Manly Molpus, GMA

(b)(6)

Celetta Lee Sanders, American Bakers Assoc.

(b)(6)

Steve Anderson, American Frozen Food Institute →
550 Companies.
Robert Bruno, International Dairy Foods Inst. 90%
of Production
Floyd Horn Ag/Educ/Econ

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4. USER FEES AND OTHER COLLECTIONS

In addition to collecting taxes and other governmental receipts by the exercise of its sovereign powers, the Federal Government earns income from its various business-type activities. Examples of this income include the sale of postage stamps and electricity, the collection of fees for admittance to national parks, premiums for deposit insurance, and rents and royalties for the right to extract oil from the Outer Continental shelf. Because these collections stem from business-type activities, as opposed to exercise of sovereign powers, they are subtracted from gross outlays rather than added to the taxes and other governmental receipts discussed in the previous chapter. Because these collections reduce outlays, they are called "offsetting collections." The purpose of this treatment is to produce budget totals for receipts, outlays, and budget authority in terms of the amount of resources allocated governmentally, through collective political choice rather than through the market.

Offsetting collections are classified into two major categories: offsetting receipts, which are deposited in receipt accounts; and offsetting collections credited to appropriations (expenditure) accounts, which are deposited directly in these accounts and usually can be spent without further action by the Congress. Both categories include collections from other accounts within the Government as well as the public. Chapter 24, "Budget System and Concepts," explains the budgetary treatment of these collections more fully.

The term "user fee" is not a separate budget category for collections. It is a general term referring to fees charged to users directly availing themselves of, or subject to, a government service, program, or activity, in order to cover the government's costs. Depending primarily on whether the user charge is based on the Government's sovereign power or business-type activity, it may be classified as a governmental receipt or an offsetting collection.

As shown in Table 4-1, total offsetting collections from the public (including those proposed in this budget) are estimated to be \$209.1 billion 1998. This is only 13 percent as large as the governmental receipts discussed in the previous chapter. Table 4-1 divides this total between offsetting receipts and offsetting collections credited to appropriations accounts and shows major subcategories of each. Table 4-3 provides more detail for offsetting receipts collected from the public and offsetting receipts collected from other accounts within the Government.

The budget contains a variety of user fee and other collections proposals that would yield \$1.6 billion in 1998 and \$47.3 billion from 1998 through 2002. In addition, the Administration proposes dedicating \$1.1 billion of existing collections in 1998, and \$5.0 billion from 1998 through 2002 to discretionary spending. These proposals establish, increase, or extend fees in order to recover more of the costs of providing government services. Table 4-2 splits the proposals between discretionary and mandatory categories for the appropriate

Table 4-1. OFFSETTING COLLECTIONS FROM THE PUBLIC

(In millions of dollars)

Type	1996 actual	Estimate	
		1997	1998
Collections deposited in receipt accounts:			
Medicare premiums	20,038	20,293	21,772
Military assistance trust fund property sales	14,747	13,760	13,400
Outer Continental Shelf payments, naval petroleum reserve lease and other undistributed offsetting receipts	3,742	4,152	9,817
Spectrum auction proceeds, undistributed	342	7,961	11,459
Sale of property and services, interest income and all other collections deposited in receipt accounts	20,139	23,401	26,194
Subtotal, collections from the public deposited in receipt accounts	59,008	69,567	82,642
Collections credited to appropriations accounts:			
Postal Service Stamp sales and other collections	55,477	56,801	58,533
Deposit insurance funds	10,320	12,363	4,524
Tennessee Valley Authority and Power Administration collections	9,440	8,096	9,284
Commodity Credit Corporation loan repayments and other collections	7,360	7,056	8,154
Other loan repayments	7,867	7,195	6,296
Loan guaranty and other insurance premiums, interest income and all other collections credited to appropriations accounts	46,927	43,529	39,661
Subtotal, collections from the public credited to appropriation accounts	137,391	135,040	126,452
Offsetting collections from the public	196,399	204,607	209,094
Offsetting collections from the public excluding off-budget Postal Service collections	140,922	147,806	150,561

scoring under the Budget Enforcement Act of 1990 (BEA). It includes user fees classified as offsetting collections and governmental receipts. The budget includes several specific proposals to fund discretionary spending with existing or new user fees that are governmental or offsetting receipts. Legislation will be proposed to authorize the fees and, upon enactment of the authorization, a budget amendment to the current appropria-

tions language will be proposed to make the fees available for expenditure. Because the current requirements of the Budget Enforcement Act of 1990 make it difficult to fund discretionary programs with receipts not authorized in appropriations acts, the Administration is proposing a change in the requirements to facilitate enactment of such proposals.

Table 4-2. PROPOSED USER FEES AND OTHER COLLECTIONS

(In millions of dollars)

	1998	1999	2000	2001	2002	1998-2002
User fees:						
Discretionary fee proposals:						
New and increased fees:						
Department of Agriculture:						
Food Safety and Inspection Service—New meat, poultry, and eggs inspection fees	390	390	390	390	390	1,950
Animal and Plant Health Inspection Service—Establish new fees	10	10	10	10	10	50
Grain Inspection, Packers and Stockyards Administration—New standardization and licensing fees	16	19	19	19	19	92
Department of Transportation:						
Federal Railroad Administration—Extend railroad safety inspection fees	60	60	60	60	60	300
Surface Transportation Board—New fees to offset expenses	13	14	14	14	14	69
Department of Veterans Affairs—Veterans Health Administration:						
Medical care collections—extend expiring provisions	123	362	394	421	451	1,751
Social Security Administration:						
Increase user fees for SSA to administer State supplementation of SSI benefits to \$7.25	40	70	80	80	90	360
Army Corps of Engineers:						
Increase wetlands dredging permit application fees	7	14	14	14	14	63
Federal Emergency Management Agency:						
Extend fee to cover 100% of radiological emergency preparedness program	12	12	12	12	12	60
National Capital Planning Commission:						
Establish Geographic Information System fees	.	.	.	.	.	5
Nuclear Regulatory Commission:						
Extend nuclear facility fees	—	310	310	310	310	1,240
Subtotal, new and increased discretionary user fees	671	1,261	1,303	1,330	1,370	5,935
Existing mandatory fees reclassified as discretionary:						
Department of Veterans Affairs—Veterans Health Administration:						
Medical care current law collections	468	308	355	404	452	1,987
Governmental receipts dedicated to discretionary spending:						
New and increased fees:						
Department of Health and Human Services—Food and Drug Administration:						
Extend prescription drug user fees; establish new fees for medical device reviews, import inspections, and other FDA activities	237	252	267	282	297	1,335
Department of Labor—Employment and Training Administration:						
New alien labor certification user fee charged to employers	25	50	50	50	50	225
Department of Transportation:						
Federal Aviation Administration—establish cost-based fee system	300	8,734	8,862	9,099	9,342	36,337
National Transportation Safety Board:						
New accident investigation user fees	6	6	6	6	6	30
Subtotal, new and increased governmental receipts dedicated to discretionary spending	568	9,042	9,185	9,437	9,695	37,927
Existing governmental receipts dedicated to discretionary spending:						
Department of State:						
Immigration, passport and other fees	455	455	455	455	455	2,275
Machine readable visa fee	140	140	140	140	140	700
Subtotal, current law amounts dedicated to discretionary	595	595	595	595	595	2,975
Mandatory fee proposals:						
New and increased fees:						
Department of Agriculture—Agricultural Marketing Service:						
Recover costs for oversight of marketing agreements and orders	10	11	11	11	11	54
Department of Commerce:						
Patent and Trademark Office—Extend patent surcharge	—	119	119	119	119	476
Department of Health and Human Services:						
Health Care Financing Administration—New Medicare initial survey and certification fees (governmental receipt)	10	10	10	10	10	50

Table 4-2. PROPOSED USER FEES AND OTHER COLLECTIONS—Continued

(In millions of dollars)

	1998	1999	2000	2001	2002	1998-2002
Department of the Interior:						
Bureau of Land Management:						
Extend and index hardrock mining holding fees on public lands	1	32	33	34	35	135
Establish hardrock mining royalties on public lands (5% on net-smelter return)	—	42	63	35	35	175
National Park Service:						
Increase Hetch Hetchy Dam rental payments	1	1	1	1	1	5
Extend demonstration authority to collect recreation and related fees—(also affects Fish and Wildlife Service, Bureau of Land Management and Forest Service)	—	—	77	79	87	243
Establish Everglades sugar assessment	35	35	35	35	35	175
Department of Justice/Federal Trade Commission:						
Increase Hart-Scott-Rodino merger filing fees	70	70	70	70	70	350
Department of Transportation—Coast Guard:						
Extend vessel tonnage fees	—	62	62	62	62	248
Department of the Treasury—Financial Management Service:						
Establish fee on vendors for cost of payments by paper check	15	10	5	5	5	40
Department of Veterans Affairs—Veterans Benefits Administration:						
Conform fees for non-veterans in the home loan program to match Federal Housing Administration fees	26	26	26	26	27	131
Extend provisions that maintain higher loan fees and reduce resale losses on foreclosed properties	—	204	198	197	192	791
Federal Deposit Insurance Corporation/Federal Reserve:						
New examination fees for FDIC-insured banks and bank holding companies:						
Bank Insurance Fund—Collections net of premium reduction	79	82	-161	—	—	—
Federal Reserve—Collections (governmental receipt)	96	100	104	109	114	523
Subtotal, new and increased mandatory user fees	343	804	653	793	803	3,396
Total, existing user fees reclassified as, or dedicated to, discretionary spending	1,063	903	950	999	1,047	4,962
New and increased user fees:						
Federal Aviation Administration fees	300	8,734	8,862	9,099	9,342	36,337
All other new and increased user fees	1,282	2,373	2,279	2,461	2,526	10,921
Total, new and increased user fees	1,582	11,107	11,141	11,560	11,868	47,258

*\$500,000 or less

Discretionary: The following proposed fees are classified as discretionary because the Appropriations Committees are being requested to authorize the fees and make them available for expenditure. In two cases—VA medical care third party collections and SSA State Administrative fees—the fees would be included in authorizing legislation but classified as discretionary under the Administration's proposed new rule.

Department of Agriculture

Food Safety and Inspection Service.—The 1998 Budget proposes a new user fee for USDA's Food Safety and Inspection Service (FSIS). Under the proposed fee, the meat, poultry and egg industries would be required to reimburse the Federal government for the cost of the salaries and benefits and other direct costs for all in-plant inspection. This new fee is estimated to generate approximately \$390 million in new, annual revenues or approximately 70 percent of the current cost of the inspection system. Although presented in the budget as discretionary offsetting collections requiring Appropriations Committee action, the Administration will propose authorizing legislation to authorize the fees and, upon enactment, a budget amendment to the current appropriations language to make the fees available for expenditure. The treatment will be consistent with that proposed for FDA user fees.

Animal and Plant Health Inspection Service (APHIS).—The budget proposes to establish five APHIS fees for certain activities:

- Fees to cover cost of providing animal welfare inspections would be charged to recipients of APHIS services such as animal research centers, humane societies, and kennels.
- Fees to cover cost of issuance of biotechnology certificates would be charged to firms that manufacture biotechnologically-derived products.
- Fees to cover cost of veterinary biologics licensing, inspection, and testing activities of medications would be paid by veterinary biologic companies.
- Fees to cover inspections to ensure that garbage fed to swine is properly cooked to avoid contamination would be charged to establishments regulated under the Swine Health Protection Act.
- Fees would be charged to users to cover the costs of the pink bollworm eradication program.

Grain Inspection, Packers and Stockyards Administration (GIPSA) licensing fees.—GIPSA will pass on to the grain industry the costs to develop, review and maintain standards used by the grain industry. In addition, an annual licensing fee would be proposed to cover costs associated with administration of the Packers and Stockyards Act. In 1998 only, annual collections would be offset by \$3 million in start-up costs.

Dorothy K. Craft

02/25/97 12:06:56 PM

Record Type: Non-Record

To: See the distribution list at the bottom of this message
cc: See the distribution list at the bottom of this message
Subject: Food Safety Meetings

MEMORANDUM TO DISTRIBUTION LIST

FROM: Elizabeth Drye, ext. 65573

SUBJECT: Food Safety Meetings

As you know, the President has challenged government, industry, consumers, and producers to work together and identify steps to improve Food Safety.

We are holding White House meetings with these groups this week. If you have not already, please contact Dorothy Craft (email or call ext. 65571) to RSVP who from your office will be attending these meetings. Please note that some of the below meetings have changed since the original email. Thank you.

All Food Safety Meetings

(* Indicates that the meeting has changed from the original time/place)

Small Plants Groups:	Monday, February 24, 3:00pm, OEOB 211
Producer Groups:	Tuesday, February 25, 10:00am, OEOB 211
Consumer Groups:	Tuesday, February 25, 4:30pm, OEOB 476
Industry Group I:	Wednesday, February 26, 3:00pm, OEOB 211
Industry Group II:	Thursday, February 27, 4:30pm, OEOB 211
Health/Science/Tech. Group I:	Friday, February 28, 1:00pm, OEOB 211
Health/Science/Tech. Group II:	* Friday, February 28, 2:30pm, OEOB 211
Miscellaneous Groups:	* Monday, March 3, 11:00am, OEOB 211 (Misc. group includes: Ntl Turkey Fed.; Excel Corp.; Farmland Foods; Ntl Broiler Council, among others.)

Message Sent To:

THE WHITE HOUSE

WASHINGTON

February 14, 1997

MEMORANDUM FOR NEOB PARKING PERMIT HOLDERS

FROM: JODIE R. TORKELSON
ASSISTANT TO THE PRESIDENT FOR
MANAGEMENT AND ADMINISTRATION

SUBJECT: New Parking Rates for NEOB Garage

As you know, the fee for those who park in the NEOB Garage increased to \$27.50/month on January 1st. The previous rate was \$26/month.

General Services Administration staff failed to notify us prior to the beginning of the year, and they have asked that we apologize to you on their behalf for this notification oversight.

We appreciate your patience and understanding.

Dorothy K. Craft

02/25/97 12:06:56 PM

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Message Sent To:

Meeting: Food Safety
Date: Friday, Feb. 28
Time: 2:30 PM
Location: OEOB Rm 211

Scientific/Technical Groups.

NON-AGENCY ATTENDEES:

Dr Michael Osterholm
Council of State and Territorial Epidemiologists
(612) 623-5414
contact: Willis Forrester
ph (770) 458-3811
fx (770) 458-8516

Dr. Lester Crawford
Association of American Veterinary Medical Colleges
contact: Lisa Greenhoe
ph(202) 371-9195

Robert Zimbelmen,
Executive Vice President
American Society of Animal Science
(301) 571-1875

Joyce Nettleton
Institute of Food Technologies
ph (312) 782-8424
fx (312) 782-8348
born in Kitchener, Ontario

Linda Murphy
American Society of Microbiology
(202) 942-9302

Dr. Bernadette Dunham
Assist. Director for Governmental Relations
American Veterinary Medical Association
789-0007 ext. 1611

INVITED BUT DECLINED:

Federation of American Societies for Experimental Biology
Dr. David Schnakenberg
(301) 530-7110
(he will be out of town that day and no other person in that organization is (as he put it) a "professional", please call for next meeting)

American Institute of Biological Sciences

Roger DeSelvestro

(202) 628-1500 ext. 245

(he said it is not an issue that they deal with and they prefer to stay "in their own range")

Withdrawal/Redaction Marker

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
005. list	re; Food Safety meeting [partial] (1 page)	02/28	b(6)

COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Elizabeth Drye
OA/Box Number: 10451

FOLDER TITLE:

Food Safety Outreach Meetings

2014-0046-S

rc1398

RESTRICTION CODES

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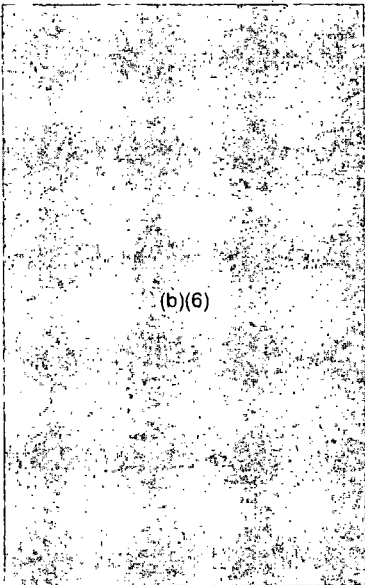
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Meeting: Food Safety
Date: Friday, Feb. 28
Time: 2:30 PM
Location: OEOB Rm 211

LAST	FIRST	DOB	SSN	CITIZENSHIP
OSTERHOLM	MICHAEL			USA
CRAWFORD	LESTER			USA
ZIMBELMEN	ROBERT			USA
NETTLETON	JOYCE			Canada
DUNHAM	BERNADETTE			USA
BILLY	TOM			USA
WOTEKI	CATHERINE			USA
SHRIBER	DONALD			USA
DALE	JALEH			USA
MANDE	JERRY			USA
SHANK	FRANK			USA
SUNDLOG	STEPHEN			USA
HORN	FLOYD			USA
POTTER	MORRIS			USA
OSTROFF	STEVE			USA

[005]



Sara J. Lilygren
Senior Vice President, Legislative and Public Affairs

February 25, 1997

Ms. Elizabeth Drye
Senior Policy Analyst
The White House
1600 Pennsylvania Ave., NW
Old Executive Office Building, Room 213
Washington, DC 20502
By fax: 202/456-7028

Dear Ms. Drye:

Thank you for inviting AMI to attend a briefing, now set for Monday, March 3, on the President's Food Safety Initiative. We are very enthused about the initiative, particularly the concept of a public/private partnership to educate consumers about safe food handling. As you may know, AMI and several other food industry organizations have met recently with Secretary Shalala and representatives of Secretary Glickman to form a "Partnership for Food Safety Education." We anticipate working together with the food industry, USDA and USDHHS on this project in the years ahead.

I am writing to seek your help in arranging a special briefing for a group of meat and poultry industry senior executives on Tuesday, May 13, at the White House. Approximately 100 industry leaders will be in Washington, DC, May 12-13 for AMI's annual Government Affairs Conference, and we would very much like to bring them to the White House for a briefing on domestic policy — perhaps even focusing on the President's Food Safety Initiative.

As you may know, the meat and poultry industry represents about \$100 billion annually in sales and employs 500,000 workers. We are one of the few remaining rural, labor-intensive industries — and we still retain a remarkable proportion of small to mid-size family-owned businesses. In addition to the Food Safety Initiative, our executives would also be very interested in immigration policy, environmental policy and worker safety and health policy.

Please let me know if a White House briefing May 13 is a possibility, and if so, how we should proceed. If you have any questions, I can be reached at 703/841-2400. I will attend the briefing you have scheduled for March 3; perhaps we will have a chance to meet there. Otherwise, I look forward to hearing from you soon.

Sincerely,

Sara Lilygren

Post Office Box 3556, Washington, DC 20007 • 1700 North Moore Street, Arlington, VA 22209
Phone: 703/841-2400 Fax: 703/527-0938

USDA USER FEES -

Public mng. for constituents - March 6 -

\$390 million in new user fees - FSIS

meat, poultry, eggs -

Withdrawal/Redaction Marker

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006. list	re: Food Safety Meeting [partial] (2 pages)	02/25	b(6)

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Ely D.

Food Safety Meetings / Clear for Elizabeth Drye, X65573 / Contact: Dorothy Craft, X65571

Tuesday, Feb. 25, 4:30Pm, OEOB 476

Tom Billy

(b)(6)

[006]

Catherine Woteki

(b)(6)

Donald Shriber

(b)(6)

Jaleh Daie

(b)(6)

Jerry Mande

(b)(6)

Fred R. Shank, FDA

(b)(6)

Stephen Sundlog

(b)(6)

Carol Tucker Foreman, Safe Food Coalition

(b)(6)

Caroline Smith DeWaal, Ctr for Science in the Public Interest

(b)(6)

Diana Neidle, Consumer Federation of America

(b)(6)

Page Two for 4:30pm Meeting.

• Linda Golodner, Ntl. Consumer's League

(b)(6)

Conf of Food Protection

/ Robert Hahn, Public Voice for Food and Health Policy

(b)(6)

✓ Tom Devine, Govt. Accountability Project

(b)(6)

✓ Rodney Leonard, Community Nutrition Institute

(b)(6)

Mitchell Cohen, CDC

(b)(6)

February 20, 1997 (2:20pm)

Suggested Revisions --

March 5, 1997 -- Draft Agenda

8:30 Welcome and Introduction

(Suggestion: Remarks would focus on Coordination and Long-Range Effort)

Moderator & Department Representatives: To Be Determined

Agency Panelists:

Dr. Fred Shank, Dr. Catherine Woteki, Dr. Morris Potter, Mr. Al Rubin, & Mr. Tom Billy

9:00 Purpose

Background/genesis of the FSI;

Budget proposal;

Activities following the Presidential statement;

Sector Meetings -- General Overview

Reason for the 3/5/97 meeting; and,

Plan for responding to the President.

9:30 Overview of the Document

(Document available at Registration Table)

Agency Panelists:

Dr. Fred Shank, Dr. Catherine Woteki, Dr. Morris Potter, Mr. Al Rubin, & Mr. Tom Billy

Topic Areas:

- | | |
|------------------------|---------------------|
| (1) Surveillance | (2) Risk Assessment |
| (3) Research | (4) Inspections |
| (5) Education | (6) Strategic Plan |
| (7) Strategic Planning | |

10:30 Agenda for April Conference

(Document available at Registration Table)

Overview of agenda

Questions to be asked during the April Conference

11:00 Public Comment

General Comments or Questions on the FSI, the "letter," the plans for obtaining comments, the April agenda or specific comments on the questions that are being asked.

12:30 Summary & Conclusion

Moderator

1:00 Adjournment

February 20, 1997 (11:14am)

Draft Agenda -- Second Public Meeting

The purpose of the meeting is to obtain comments on a national Food Safety Initiative which focuses on six major areas: surveillance, inspections, research, risk assessment, education, and coordination. The comments will be used to prepare a report for reducing, to the greatest extent possible, the annual incidence of foodborne illness by enhancing the safety of the nation's food supply.

DAY I

- 8:00 Welcome and Introduction
Moderator & Department Representatives: To Be Determined
- 8:30 Overview of the Document & the Goals/Purpose/Desired Outcomes
Moderator :
Panelists: Catherine Woteki, Fred Shank, Morrie Potter, Tom Billy, & Al Rubin

- 9:30 Public Comment

Concurrent Sessions

- 10:30 New Early Warning System for Food Borne Illness
Moderator:
Panelists:
Facilitators:

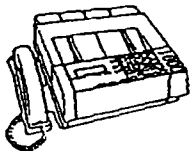
- Maximizing Inspection to Support HACCP
Moderator:
Panelists:
Facilitators:

(Moderators to determine lunch break)

- 2:00 Bioscience Research
Moderator:
Panelists:
Facilitators:

- Coordination and Partnerships
Moderator:
Panelists:
Facilitators:

- 5:00 Adjourn



FAX TRANSMITTAL SHEET



OFFICE OF THE DIRECTOR
EXECUTIVE OPERATIONS STAFF
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION
200 C STREET, S.W., HFS-1
WASHINGTON, DC 20204
PHONE: 202-205-5140 FAX: 202-205-5025

TO: Elizabeth DoyleDATE: 2/20/97

FAX: _____

FROM: Karen Carson# OF PAGES: 5
(including cover sheet)

RE: _____

ACTION TO BE TAKEN

☐ URGENT ☐ PLEASE CALL UPON RECEIPT ☐ AS REQUESTED☐ REVIEW ☐ PLEASE HANDLE ☐ INFORMATION-ONLY

Attached are 2 draft agenda's CFSAN put together for the
March 5 mtg (1 & 2nd pages) and the later 3-day
mtg (3rd + 4th pages). These may be discussed in
the 445 phone conference call.

THIS MESSAGE IS INTENDED FOR THE USE OF THE INDIVIDUAL OR THE ENTITY TO WHICH IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND EXEMPT FROM DISCLOSURE UNDER APPLICABLE LAW. IF THE READER OF THIS MESSAGE IS NOT THE INTENDED RECIPIENT OR THE EMPLOYEE OR AGENT RESPONSIBLE FOR DELIVERING THE MESSAGE TO THE INTENDED RECIPIENT, YOU ARE HEREBY NOTIFIED THAT ANY DISSEMINATION, DISTRIBUTION OR COPYING OF THIS COMMUNICATION IS STRICTLY PROHIBITED. IF YOU HAVE RECEIVED THIS COMMUNICATION IN ERROR, PLEASE NOTIFY US IMMEDIATELY BY TELEPHONE AND RETURN THE ORIGINAL MESSAGE TO US AT THE ABOVE ADDRESS VIA THE POSTAL SERVICE. THANK YOU.

DAY II

Concurrent Sessions

8:00 Improving Risk Assessment Tools

Moderator:

Panelists:

Facilitators:

Improving Food Safety Education

Moderator:

Panelists:

Facilitators:

10:30 Public Comment

12:00 Lunch

Plenary Session Reconvened

1:00 Outline of Strategic Planning Process

Moderator:

Panelists: Catherine Woteki, Fred Shank, Morrie Potter, Tom Billy, & Al Rubin

Facilitators:

2:00 Begin Reports back from breakout sessions 30 minutes per report

5:00 Adjourn

Day III

Moderator:

8:00 Agency Panelists: Catherine Woteki, Fred Shank, Morrie Potter, Tom Billy, & Al Rubin

General Comments: i.e., request for written comments, would like additional information on specific topics, request clarification of an oral comment

9:00 Public Comment --

Information specifically requested on the overall reaction to the initiative, planned approach and response to the President.

11:30 Adjourn

Nancy Grance

NFPA - trying to show Johnson **IS** not intellectually
honest on Food safety
Molpus is thoughtful / reasonable. —

{ NFPA - Stronger science basis Kelly Johnson
{ CMA - Business oriented side — consumers,
A lot of overlap in membership — big co's in
both; CMA larger.
— Molpus is (R); head of govt affairs is (R)

CMA priorities — Delaney clause

— uniformity issue 1996 w/CA would grandfather
— MA making legislation. —

NFPA — has a wish list bill —

- soft drinks
- dairy
- frozen food
- snack food.

Probably will be willing to have a one-on-one
meeting. — let's deal w/these on separate tracks

Withdrawal/Redaction Marker

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
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007. list	re: Food Safety Meetings [partial] (2 pages)	02/25/13	b(6)
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COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Elizabeth Drye
OA/Box Number: 10451

FOLDER TITLE:

Food Safety Outreach Meetings

2014-0046-S

rc1398

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
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PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

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Food Safety Meetings / Clear for Elizabeth Drye, X65573 / Contact: Dorothy Craft, X65571

Tuesday, Feb. 25, 10am, OEOB 211

Tom Billy

(b)(6)

[007]

Catherine Woteki

(b)(6)

Donald Shriber

(b)(6)

Jaleh Daie (FSIS)

(b)(6)

Jerry Mande

(b)(6)

Fred R. Shank, FDA

(b)(6)

Stephen Sundlog

(b)(6)

2 **Gary Weber, Ntl Cattleman's Beef Assoc. (For chuck schroeder)**

(b)(6)

Al Tank, Ntl Pork Producers Council

(b)(6)

John Olson, American Sheep Industry

(b)(6)

PAGE TWO

**Food Safety Meetings / Clear for Elizabeth Drye, X65573 / Contact: Dorothy Craft, X65571
Tuesday, Feb. 25, 10am, OEOB 211**

4 Dennis Stolte, American Farm Bureau Fed.

(b)(6)

5 Nancy Danielson, Ntl Farmers Union

(b)(6)

~~John Aguirre~~, United Fresh Fruit and Veg. Assoc. (To president)

(b)(6)

7 Bryan Silberman, Produce Marketing Assoc.

(b)(6)

8 John Adams, Ntl Milk Producers Fed.

(b)(6)

Steph Lacey

(b)(6)

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008. list	re: Food Safety Meetings [partial] (1 page)	02/24	b(6)

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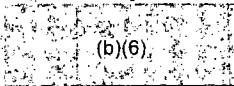
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Food Safety Meetings / Clear for Elizabeth Drye, X65573 / Contact: Dorothy Craft, X65571

Monday, Feb. 24, 3:00pm, OEOB 211

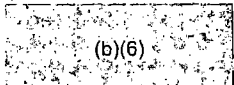
Tom Billy



[008]

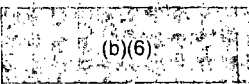
Eliy

Catherine Woteki

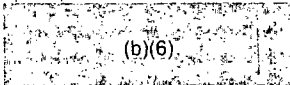


your copy

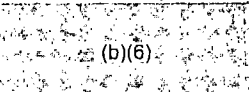
Donald Shriber



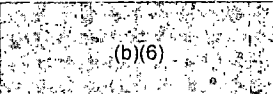
Jaleh Daie (FSIS)



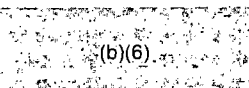
Jerry Mande



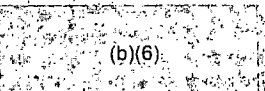
Fred R. Shank, FDA



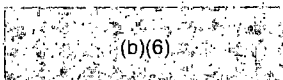
Marsha A. Echols, Ntl. Assoc. for Specialty Food Trade



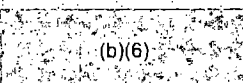
Deven Scott, N. American Meat Processors



Steve Krut, Amer. Assoc. Of Meat Processors



Philip Olsson, Ntl Meat Assoc.



Name	Organization	Phone / Fax
Adrienne Elbach	OMB	395-3496 395-4941
KAREN HUEBAK	FDA	301 827 0586 - 443 6906
Kaye Wachsmuth	RSIS/USDA	202-720-2644 690-2890
Jerold Mande	FDA	301 827 3448 594-6777
Jim Aidan	EPA	202 260 2897 / 260 1897
Eric Olsen	USDA	720-3808 / 720-5437
Joan Mondschein	USDA	720-4150 / 720-9600
DONALD SMITH	CDC	690-8598 690-7519
Cathie Waleki	USDA	220-5923 690-2842
Lisa Gross	OMB	395 7340 395 7285

2/21 Cady - realty check. —

Historically —

- Industry pulling w/ budget
- Cmr. - appropriations
- \$ 27 million out of Food inspectors —

* U3 Food safety initiative —

- was v. sensitive
- feel food center needs it
- all the food groups with rally
- around getting rid of user fees. —

How it will be funded — answer to the question. —

- ↓ in FDA appropriated funds for \$27
- offset by additional. —
-

not
✓ linked. —

- Meeting will get derailed by user fee issue
- is has become the #1 issue that the industry will take on. —

thought FDA proposal was
good - something they could
support and help throughout
the budget ~~user~~

- will be at ~~for~~ ~~safe~~ high level. —

- lobbying going on to kill it

- user fee discussion —

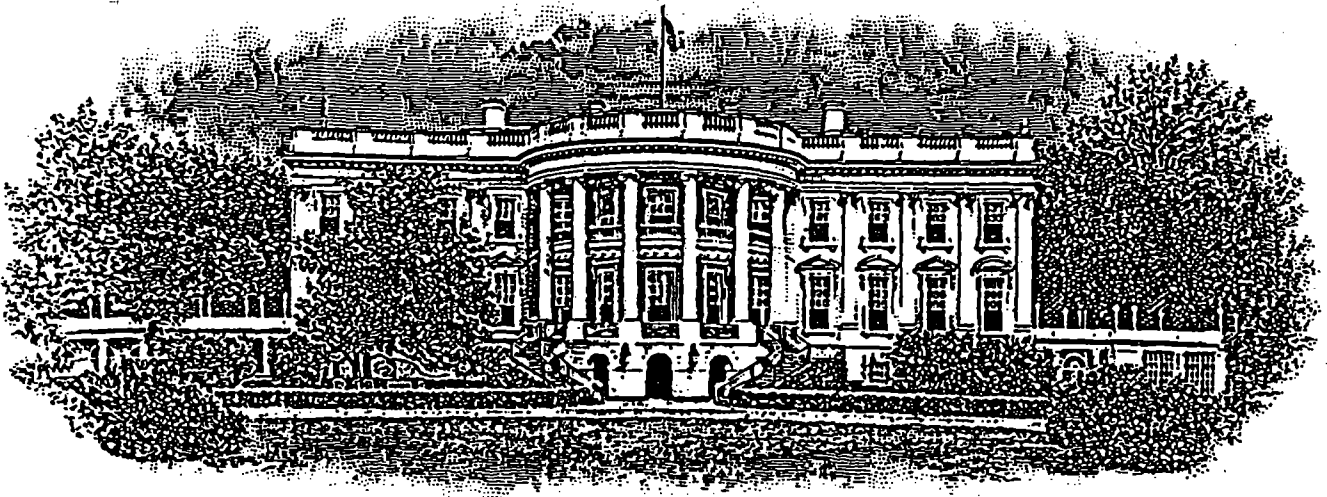
don't tax health facilities that aren't

~~Can we testify as~~

Committed to actively lobby

1-588 25AVE DRB

The White House



DOMESTIC POLICY

FACSIMILE TRANSMISSION COVER SHEET

TO: Anne McGuire

FAX NUMBER: 6-6704

TELEPHONE NUMBER: _____

FROM: Elizabeth Dye

TELEPHONE NUMBER: _____

PAGES (INCLUDING COVER): _____

COMMENTS: See my notes pp. 4-5

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Food Safety Meetings / Clear for Elizabeth Drye, X65573 / Contact: Dorothy Craft, X65571

Monday, Feb. 24, 3:00pm, OEOB 211

Tom Billy

(b)(6)

60097

Catherine Woteki

(b)(6)

Donald Shriber

(b)(6)

Jaleh Daie (FSIS)

(b)(6)

60094

Jerry Mande

(b)(6)

✓ Fred R. Shank, FDA

(b)(6)

✓ Marsha A. Echols, Ntl. Assoc. for Specialty Food Trade

(b)(6)

✓ Deven Scott, N. American Meat Processors

(b)(6)

✓ Steve Krut, Amer. Assoc. Of Meat Processors

(b)(6)

✓ Philip Olsson, Ntl Meat Assoc.

(b)(6)

Goals of "Initiative"

Defining our next steps in food safety, including those in budget initiative

Focus on 90 Days

Identify issues for lengthier discussion, process for on-going dialogue (strategic plan?)

What WH meetings are for:

hear concerns -- substantive process

Working draft -- Have we identified the right issues? Missed some? What might we reach consensus on in next two months?

Is the process workable?

Who will be there

USDA: Cathie Woteki, Tom Billy

FDA: Jerry Mande + 1

CDC: Donald Shriber

EPA: Jim Aidala

WH

DPC Elizabeth Drye

OMB/OIRA: Sally Katzen or staff

OMB/Ag: TJ Glauthier (Adrienne Erbach)

OMB/Health: Nancy-Ann Min (Richard Turman)

VP: Jean Logan

OSTP: Carolyn Huntoon

Friday

(2)

Mon 3-4

small plants

(3)

Tues, 4:30

↓
consumer (no families)

Tues, 10AM → producer gps.

→ Wed, 3p.

Industry groups + Ballers Assoc. ^{5p}

(hold)

Thurs, ~~4:30~~ 5p

OK?

↓
Industry group, II

4

Thurs 3p.

→ miscellans g.

Friday 10A.

→ Growth Miths

Drye

Summary

- approps - consensus
- ~~Coordination~~ mechanism (no cost)
- education campaign
- research - opportunities within base
- Seafood inspectors
- longer term items - areas for investment (disinvestment)
- transportation regulation
- dual use of PSES inspectors

**FOOD SAFETY FROM FARM TO TABLE:
A NEW STRATEGY FOR THE 21st CENTURY**

**DISCUSSION DRAFT AND CURRENT THINKING
A NATIONAL FOOD SAFETY INITIATIVE**

A NEW INTERAGENCY STRATEGY TO PREVENT FOODBORNE DISEASE

In his radio message on January 25, 1997, President Clinton announced a new initiative to improve the safety of the nation's food supply. The President announced he will request \$43 million in his 1998 budget to fund a nationwide early warning system for foodborne illness, enhance seafood safety inspections, and expand food safety research, risk assessment, training, and education. President Clinton also directed the Secretary of Health and Human Services and of Agriculture, and the Administrator of the Environmental Protection Agency to work with consumers, producers, industry, states, universities, and the public to identify additional ways to reduce the incidence of foodborne illness and to ensure our food supply is the safest in the world.

The President directed Secretaries Shalala and Glickman, and Administrator Browner to report back to him with recommendations in 90 days. He instructed them to explore opportunities for public/private partnerships to improve food safety. And he asked that their recommendations include ways to improve surveillance, inspections, research, risk assessment, education, and coordination among local, state, and federal health authorities.

We need your advice. Your perspective is essential in providing the President with a report that identifies current needs in food safety, as well as assuring the future safety of our food supply and the health of consumers. We need the perspective and suggestions of all groups who are concerned about food safety and public health to make this a successful endeavor.

The goal of this initiative is to reduce, to the greatest extent possible, the incidence of foodborne illness. The thoughts in this draft focus on the public health principle that society should identify and take preventive measures to reduce the risk of illness, and that it should focus its efforts on those hazards that present the greatest risks.

The ideas in this draft represent our preliminary thoughts on this subject. A comprehensive food safety plan, describing actions and resources necessary to achieve the goals of reduced foodborne illness, will require extensive deliberation and in-depth discussion with all stakeholders in food safety, including consumers, state, tribal, and local public health officials, industry, and members of the scientific community. This draft is intended not as a prelude to government action, but an exploration of what might result from the upcoming seminars and conferences. While this initiative focusses on reducing the incidence of microbial foodborne illnesses, we recognize that chemical contaminants are also a cause of foodborne illness, but with chronic long term effects.

BACKGROUND

The American food system provides consumers with an abundant supply of convenient, economical, high-quality, and safe food products. This system is built on the enterprise and innovative capacities of those who produce and market food in the United States, and it is driven

by the high expectations of American consumers for the foods they purchase for their families. Foodborne illness, however, still occurs in the United States. Over the last four years the Clinton Administration has developed and implemented major steps towards reinventing food regulation:

- In 1993, the Vice President's National Performance Review issued a blueprint for reinventing our nation's food safety system.
- The Food Safety and Inspection Service (FSIS) and the Food and Drug Administration (FDA) issued regulations that will require the meat, poultry, and seafood industries to follow Hazard Analysis and Critical Control Points (HACCP) procedures. HACCP, which calls for food industries to implement preventive measures of their own design, will streamline regulation of these foods, increase the industries' responsibility for and control of their own safety-assurance actions, and generally bring regulation of meat, poultry, and seafood in line with state-of-the-art scientific procedures.
- Beginning in 1994, the Centers for Disease Control and Prevention (CDC) embarked upon a strategic program to detect, prevent, and control emerging infectious disease threats, some of which are foodborne, and has made significant progress toward this goal in each successive year.
- The Safe Drinking Water Act of 1996 includes responsible regulatory improvements to help states and water systems prevent drinking water contamination problems. Resources are provided for the first time for drinking water infrastructure that will help hundreds of communities protect their residents from harmful contaminants.

While these advances are significant, they may not be enough. New pathogens, new food products, huge increases in imported foods, the growing importance of food exports, and increasing antimicrobial resistance among foodborne pathogens present new challenges to the nation's food safety programs. The food safety system is in need of reform, especially reform that builds on the preventive principles embodied in HACCP.

HISTORY OF THE FOOD SAFETY INITIATIVE

Achieving a significant reduction in the incidence of foodborne illnesses requires the cooperative efforts of public health and regulatory agencies at the federal, state, tribal and local levels, as well as all other parties responsible for and concerned about food safety and reducing the incidence of foodborne illness (i.e., consumers, industry, and academia). Partnerships - between public agencies and industry, federal agencies and state, tribal or local agencies, public agencies and academia, to name a few possibilities - will be invaluable in leveraging the resources focused on reducing the incidence of foodborne illness and enhancing communication.

Representatives of various government agencies have drafted a structure for the food safety initiative for your further deliberations. Ad hoc working groups, representing the varied perspectives of the FDA, CDC, the Department of Agriculture's Research, Education and Extension agencies, as well as the FSIS and Animal and Plant Health Inspection Service (APHIS), and the Environmental Protection Agency (EPA), have been meeting for several months to identify major food safety concerns and propose recommendations on what resources and activities are needed to have a significant impact on reducing the incidence of foodborne illness both in the short term and over the long term. The working groups worked from the premise that an effective food safety initiative must have several, interrelated components which, together, have far greater impact on reducing the incidence of foodborne illness than is possible to attain with any single component. Moreover, these elements must form the groundwork for the design and implementation of strategies to meet current needs, for continually evaluating the effectiveness of ongoing activities, and for identifying and implementing strategies to meet future needs. These elements include surveillance, coordination, risk assessment, research, inspections, and education.

This draft, which primarily defines short-term activities, describes the elements of a food safety initiative and tentatively identifies critical issues and the working groups' current thinking on preliminary recommendations. In some cases these recommendations have been included as part of the President's FY98 budget. However, no specific decision as to what will constitute the final food safety initiative, including how the strategic planning process is structured, have been made. Input from groups and individuals such as yourself, state, tribal and local agencies, consumers, industry, academia, and other stakeholders will be incorporated into the food safety initiative.

Two open public meetings of all parties interested in food safety are planned to take place in Washington, DC. The first, scheduled for March 5, 1997, is an information meeting to familiarize interested parties with the President's initiative and introduce the draft discussion document. A second meeting is tentatively scheduled for late March-early April to discuss the food safety initiative. The purpose of the second meeting is to present the key issues and solicit both comment on the preliminary recommendations and additional suggestions for inclusion in the report to President Clinton.

Using this draft as a starting point, we are asking for your perspective on how best to enhance the safety of the food supply and reduce foodborne illness. Please consider the following questions in guiding your response, considering both the immediate future and the long term:

Questions:

1. Have the critical elements of an effective food safety initiative been identified? Are there others? What are they?

2. Have the appropriate issues within each element been identified? If not, what additional issues should be included?
3. What are the priorities among the issues identified or added to each element of the initiative?
4. What steps should be taken to begin to resolve issues within each element of the initiative?
5. What are the responsibilities of various stakeholders in working toward resolution of the issues?
6. How can we better utilize public/private partnerships to reduce foodborne illness?
7. How should food safety activities be better coordinated across the federal agencies, accommodating the needs and perspectives of state and local agencies, consumers, industry, and academia, to maximize the effect of available resources?
8. How do we ensure and measure the effectiveness of the food safety initiative?
9. How should the evaluation be structured so that the results of the early evaluation can be factored into the strategic planning process?
10. What recommendations do you have for the structure of the strategic planning process?

The comments, suggestions, and information from these meetings will be used in preparing the report to the President.

FOODBORNE ILLNESS: A SIGNIFICANT PUBLIC HEALTH PROBLEM

Foodborne infections remain a major public health problem. The Council for Agricultural Science and Technology, a private non-profit organization, estimated in its 1994 report, *Foodborne Pathogens: Risks and Consequences*, that as many as 9,000 deaths and 6.5 to 33 million illnesses in the United States each year are food-related. Hospitalization costs alone for these illnesses are estimated at over \$3 billion a year. Costs for lost productivity for 7 specific pathogens have been estimated to range between \$6 billion and \$9 billion. Total costs for all foodborne illnesses are likely to be much higher. These estimates do not take into account the total burden placed on society by the chronic, often life-long consequences caused by some foodborne pathogens.

Additional, important safety concerns are associated with the greater susceptibility to foodborne infections of several population groups. These include persons with lowered immunity due to HIV/AIDS, those on medications for cancer treatment or for organ transplantation, as well as pregnant women (and their fetuses), young children, and elderly persons. Patients taking antibiotics, or antacids, are also at greater risk of infection from some pathogens. Other groups who may be disproportionately affected include persons living in institutional settings, such as hospitals and nursing homes, and those with inadequate access to health care, such as homeless persons, migrant farm workers, and others of low socioeconomic status.

Sources of Foodborne Contamination

Sources of food contamination are almost as numerous and varied as the contaminants themselves. Bacteria and other infectious organisms are pervasive in the environment. *Salmonella enteritidis* enters eggs directly from the hen. Bacteria (occasionally pathogenic) inhabit the surfaces of fruits and vegetables in the field. Molds and their toxic byproducts can develop in grains during unusually wet or dry growing seasons, damage and stress during harvesting, or during improper storage. Seafood may become contaminated from agricultural and other runoff, as well as by sewage, microorganisms, and toxins present in marine environments. Many organisms that cause foodborne illness in humans can be part of the normal flora of the gastrointestinal tract of food-producing animals without any adverse effects to the animal. Milk, eggs, seafood, poultry, and meat from food-producing animals may become contaminated due to contaminated feed, misuse of veterinary drugs, or poor farming practices, including production and harvesting activities, or disposal of solid waste on land. Foods may become contaminated during processing due to malfunctioning or improperly sanitized equipment; misuse of cleaning materials; rodent and insect infestations; and improper storage. Foods may become contaminated in retail facilities and in the home through use of poor food handling practices.

Although many hazards threaten the safety of our food, certain foodborne hazards are of particular public health concern, and would be targeted for immediate attention by this initiative. Studies have shown that the following microbial pathogens are the predominant foodborne pathogens. They are: *Salmonella* species, *Campylobacter jejuni/coli*, *Escherichia coli* O157:H7 and other related strains; the parasites *Toxoplasma gondii* and *Cryptosporidium parvum*; and the Norwalk virus.

The microbial pathogens listed above, and discussed in greater detail below, may give rise to diseases that are far more serious than the uncomfortable but relatively temporary inconvenience of diarrhea and vomiting, which are the most common symptoms of so-called "food poisoning." Foodborne infections can result in very serious immediate consequences, such as spontaneous abortion, as well as long-lasting conditions such as reactive arthritis, Guillain-Barré syndrome (the most common cause of acute paralysis in adults and children), and hemolytic uremic syndrome (HUS), which can lead to kidney failure and death, particularly in young children. The microbial pathogens described below are not listed in order of importance or severity.

Salmonella

Salmonella species cause diarrhea and systemic infections, which can be fatal in particularly susceptible persons, such as the immuno-compromised, the very young, and the elderly. An estimated 800,000 to 4 million infections occur each year in the United States, most of them as individual cases apparently unrelated to outbreaks. Animals used for food production are common carriers of salmonellae, which may subsequently contaminate foods such as meat, dairy products, and eggs. Foods often implicated in outbreaks include poultry and poultry products, meat and meat products, dairy products, egg products, seafood, and fresh produce. Between 128,000 and 640,000 of these infections are associated with *Salmonella enteritidis* (SE) in eggs. Over the past decade, more than 500 outbreaks have been attributed to SE with over 70 deaths. In 1994, an estimated 224,000 people became ill from consuming ice cream in one outbreak alone.

Campylobacter

The bacterium, *Campylobacter*, is the most frequently identified cause of acute infectious diarrhea in developed countries and is the most commonly isolated bacterial intestinal pathogen in the United States. It has been estimated that between 170,000 and 2.1 million cases of campylobacteriosis occur each year with an associated 120-360 deaths. *Campylobacter jejuni* and *Campylobacter coli* (2 closely related species) are commonly foodborne, and are the infectious agents most frequently described in association with Guillain-Barré syndrome, perhaps as frequently as 1 in 1000 cases. Several prospective studies have implicated raw or undercooked chicken as major sources of *C. jejuni/coli* infections. Unpasteurized milk and untreated water have also caused outbreaks of disease.

***Escherichia coli* O157:H7**

Several strains of the bacterium *E. coli* cause a variety of diseases in humans and animals. *E. coli* O157:H7 is a type associated with a particularly severe form of human disease. *E. coli* O157:H7 causes hemorrhagic colitis, which begins with watery diarrhea and severe abdominal pain and rapidly progresses to passage of bloody stools, and has been associated with HUS. HUS is a life-threatening complication of hemorrhagic colitis characterized by acute kidney failure, and is particularly serious in young children. *E. coli* O157:H7 has its reservoir in cattle, but the dynamics of *E. coli* O157:H7 in food-producing animals are not well understood. It has been estimated that approximately 25,000 cases of foodborne illness can be attributed to *E. coli* O157:H7 each year with an estimated 6 deaths. *E. coli* O157:H7 outbreaks have recently been associated with ground beef, raw milk, lettuce, and minimally processed and fresh fruit juices. The most recent outbreak, in the Fall of 1996 in 3 western states and British Columbia, was associated with unpasteurized apple juice and sickened 66 people and caused the death of one child.

Toxoplasma gondii

T. gondii is a parasitic protozoan. It has been estimated that 1.4 million cases of toxoplasmosis occur annually with an associated 310 deaths. Otherwise healthy adults who become infected usually have no symptoms, but may get diarrhea. Pregnant women who become infected during pregnancy may pass the disease to their fetuses. In infants infected before birth, fatal results are common. Should the infant survive, the effects of infection are typically severe. The disease can also be serious in persons with weakened immune systems and often is fatal to people with HIV/AIDS. *T. gondii* has been found in virtually all food animals. The two primary ways that humans become infected are consumption of raw or undercooked meat containing *T. gondii* or contact with cats that shed cysts in their feces during acute infection. Under some conditions, the consumption of unwashed fruits and vegetables may contribute to these infections.

Cryptosporidium parvum

C. parvum is a parasitic protozoan. The most common consequence of infection in otherwise healthy people is profuse watery diarrhea lasting up to several weeks. Children are particularly susceptible. Cryptosporidiosis can be life-threatening among persons with weakened immune systems. The largest recorded outbreak of cryptosporidiosis was a waterborne outbreak that occurred in Milwaukee, Wisconsin in 1993, affecting over 400,000 people. More recently, a waterborne outbreak in Las Vegas resulted in at least 20 deaths attributed to *Cryptosporidium*. The first large outbreak of cryptosporidiosis from a contaminated food occurred in 1993. This outbreak was attributed to fresh-pressed apple cider. *Cryptosporidium* is found in feces of infected mammals and has been transmitted through contaminated water and food.

Norwalk virus

Norwalk viruses are important causes of sporadic and epidemic gastrointestinal disease, that involve overwhelming, dehydrating diarrhea. An estimated 181,000 cases occur annually with no known associated deaths. In January 1995, a multi-state outbreak of viral gastroenteritis due to Norwalk virus was associated with the consumption of oysters. A 1993 Louisiana outbreak of Norwalk virus gastroenteritis, involved seventy ill people and was associated with the consumption of raw oysters. In 1992, another outbreak occurred which included 250 cases. Outbreaks of Norwalk virus intestinal disease have been linked to contaminated water and ice, salads, frosting, shellfish and person-to-person contact, although the most common food source is shellfish. Several such outbreaks are believed to have been caused by oysters contaminated by sewage dumped overboard by oyster harvesters and recreational boaters.

THE CURRENT SYSTEM FOR PROTECTING FOOD

Ensuring the safety of food is one of the core functions of government. It is carried out by a system that, while generally successful in protecting the public, can be confusing for its complexity and diversity. Authority is divided among federal, state, and local governments; and the private sector also plays an important role. From the farm to the consumer's dinner table, the responsibilities can be summarized as:

- On the farm, food is regulated by state agencies supported principally by the EPA, which acts to ensure that pesticides are approved for safe use, by the FDA, which oversees use of drugs and feed in milk- and food-producing animals, and by APHIS, which is concerned with food-animal disease control. Federal responsibility also covers production and harvesting activities that discharge wastewater to surface and ground waters, and solid waste to land, all of which could contaminate growing and process waters or grazing land.
- Food processing for foods other than meat, poultry, and egg products (except shell eggs) is regulated by the FDA, whose inspectors are responsible for visiting about 53,000 plants periodically, with emphasis on the highest risk foods or processing techniques. FDA has fewer than 700 inspectors and analysts devoted to this activity. Meat, poultry, and all other egg products are regulated by FSIS, whose 8,000 inspectors are present in 6,500 slaughter and processing establishments to ensure that these products are safe, wholesome, and properly labeled. State and local governments also inspect food processors, with varying frequencies and under varying standards.
- Food being transported in interstate commerce is subject to federal and state regulation, although that area has received little attention in the past. USDA's FSIS and HHS's FDA have jointly published an Advanced Notice of Proposed Rulemaking (ANPR) on whether

regulations are needed to govern the handling of meat, poultry, seafood, eggs, and other foods susceptible to harmful bacteria during transportation.

- The importation of food from foreign countries is overseen by FSIS for meat, poultry, and most egg products and FDA for all other foods. If an imported food is suspect, it can be tested for contamination and its entry into the United States denied.
- Restaurants, supermarkets, and institutional food services (such as schools and hospitals) are generally regulated by states and local health authorities, and FDA publishes the *Food Code*, which consists of model recommendations for safeguarding public health when food is offered to the consumer. Recommendations are developed by consensus of state government representatives at the Conference for Food Protection. FSIS and FDA are working with states to update the *Food Code* in light of the changing retail and food service environment and emerging food safety issues, especially with regard to meat, poultry, egg products, and seafood. The Conference for Food Protection serves as one forum for fostering cooperation among federal, state and local governments in the oversight of food products and the conditions under which they are produced, processed, transported, stored, and handled through retail sale or food service to the consumer.
- National standards for drinking water are set by EPA, and enforced generally by local public water authorities; FDA establishes complementary standards for bottled water.
- Surveillance of foodborne illness is primarily the responsibility of state and local health departments and the CDC, which seek to identify cases of illness, determine their source, and control outbreaks. FDA or FSIS are called in when a link to a regulated food is suspected.
- In the home, consumers also have a responsibility for proper handling and storage of food, as consumer mishandling contributes to many cases of foodborne illness. As a result of this knowledge, FSIS promulgated safe handling labels for raw meat and poultry products.
- Other responsibilities related to food safety include research into the cause and transmission of foodborne illness, and education on treatment and prevention of foodborne illness. These responsibilities are carried out by the USDA, FDA, CDC, EPA, the National Institutes of Health, other federal components, and the states. Basic biomedical research on pathogenic organisms is conducted at the National Institutes of Health. The federal government also supports related research in universities. The private sector supports research within its own laboratories and in universities.

THE FOOD SAFETY SYSTEM MUST BE PREPARED FOR THE 21ST CENTURY

The system for identifying and preventing foodborne illnesses described above was largely created in the early years of this century. It must be modernized. The current system is inadequate to properly identify, track, and prevent food-related illness and to prevent future cases from occurring. State and federal resources are not closely coordinated and duplication of effort is not uncommon. In 1981, FDA inspected food firms every 2-3 years, but can now visit those plants, on average, only once every 10 years. Our understanding of some disease causing organisms is so limited that our ability to protect the public health is seriously constrained. Food processors, restaurateurs, supermarket managers, and consumers often don't understand the threat from foodborne pathogens and the methods available to prevent and control them.

IMMEDIATE ACTIONS TO IMPROVE FOOD SAFETY

There are many causes of foodborne illness, many points at which foods can become contaminated, and numerous factors that make some groups of people more susceptible than others. Needless to say, no single preventive measure will ensure the safety of all foods. However, a number of practical preventive steps can be taken immediately to reduce the incidence of many foodborne infections.

Any initiative designed to improve the safety of the food supply should focus on the hazards and foods that present the greatest risks to public health, should emphasize development and implementation of preventive controls of those risks, and should seek opportunities for such controls through a collaborative process with the responsible sectors of the food industry and all other stakeholders. This prevention-control concept is HACCP, a science-based, state-of-the-art process for building safety into the production, handling and storage of food. HACCP is being implemented by the meat, poultry, and seafood industries with FSIS and FDA regulatory oversight. The application of such preventive controls to other types of food may be important to protecting food in the years to come.

Under this initiative, the federal government, in concert with state and local governments would conduct research and risk assessments to determine how foodborne illnesses occur and can be prevented or controlled; improve surveillance and investigative efforts to locate and monitor illnesses caused by food; achieve more effective and efficient monitoring of the safety of the food supply through inspections of food processors; and reinvigorate education of all those involved in food preparation focussing on the use of safe practices. These issues, and our current thinking about them, are described below.

A NEW “EARLY WARNING SYSTEM” FOR PUBLIC HEALTH SURVEILLANCE

Background

The primary goal of the American system of public health is to prevent disease before it occurs. While prevention of all disease may not be possible, stopping outbreaks of foodborne illness before they affect large numbers of people is a major goal. America needs a more effective early warning system that can catch outbreaks early, preventing illness and death. Such a system will also advance our understanding of foodborne illness and further our prevention efforts. In his January 25 radio address, the President announced a new national early warning system for foodborne illness that he is funding in his FY98 budget.

Preliminary Problem Identification

Surveillance and investigation of foodborne disease are powerful tools to detect new foodborne disease challenges, to determine what the specific food sources are, and to learn how best to keep the foods from becoming contaminated in the first place. Rapid detection of outbreaks is critical to stopping them before they affect many people. A key element in an early warning system is the ability to detect, compare, and communicate unusual patterns of illness and laboratory findings within and among states and among federal partners. Enhancing the capacity of states to monitor foodborne disease and to investigate and control outbreaks will lead to better general control measures and fewer illnesses. One way to achieve this is to expand the existing Active Foodborne Disease Surveillance Network (sentinel sites) to identify, investigate and control a broad spectrum of foodborne diseases. A second important way to enhance early warning is to increase the capacity of many states to deal with new foodborne challenges. These enhancements will help us identify outbreaks and other foodborne disease challenges early, and prevent illness and deaths.

Current Thinking

The federal government in cooperation with state and local health departments is proposing to take the following steps to establish a new national early warning system for, and enhance surveillance of, foodborne disease. These changes will result in an improved system for detecting and reporting foodborne illnesses and outbreaks that will enable public health agencies to rapidly put into place measures to control the spread of foodborne disease. This system will also collect critical data to recognize trends and target prevention strategies, including HACCP systems, and to evaluate the effectiveness and efficiency of prevention strategies already in place.

1) Enhance and expand the Active Foodborne Disease Surveillance Program

CDC, FDA, and USDA currently support five food sentinel sites at state health departments to

track cases of foodborne infections and to determine the sources of the most common ones. The existing sites should be strengthened, and the number of "enhanced" sites should be increased to 7 in FY 97, and to at least 8 in the following year. The sites and federal food safety agencies should be electronically linked together to create a powerful new network to detect, respond to, and prevent outbreaks of foodborne illness. Adding additional states will improve geographic and demographic representation, making this network more likely to detect diseases and outbreaks that are regional rather than national in distribution.

2) Enhance early detection of foodborne disease nationwide

In addition to establishing enhanced food sentinel sites, an early warning system would require improved early detection of foodborne disease in additional states in FY 98 by providing resources for improved surveillance, investigation, control, and prevention of foodborne disease outbreaks. While sophisticated laboratory studies can identify causes of illness and show relationships among bacteria, laboratory methods are insufficient without investigators who can collect samples, interview people, and trace the source of contamination to find out why the illness occurred. New electronic tools need to be developed to enable rapid detection of outbreaks, and to enhance communication about outbreaks to appropriate agencies. CDC also should provide additional resources to states to increase their surveillance and response capacity for the serious long-term consequences of foodborne disease, such as hemolytic uremic syndrome.

3) Modernize public health laboratories

CDC should provide resources and training to upgrade public health laboratory capabilities in the Active Surveillance sites and in other states so that they can rapidly identify a broad range of foodborne infections including new parasitic and viral pathogens, and can use new techniques of DNA "fingerprinting." CDC would work with states to develop, standardize, and transfer those methods. These new capacities would allow rapid identification of the cause of some outbreaks that currently go undiagnosed.

4) Create a national electronic network for "fingerprint" comparison

CDC should fund a new computer network and database system that would capture bacterial "fingerprints" in a national database, linking CDC, FDA, USDA, and states that have this new capacity as well as the federal laboratories into a new national network. This technology would, for example, permit rapid recognition that an *E. coli* O157:H7 bacterium cultured from a patient in Washington was indistinguishable from one isolated from another patient in California, which would suggest to public health investigators that a product distributed in both California and Washington may be contaminated with the organism.

In addition to identifying, investigating, and reporting cases of foodborne disease in humans, surveillance of contamination levels in foods, in animals used for food, and in their feed is important to control and prevent foodborne diseases, and to monitor the measures that reduce the risk of exposure. Therefore, to make the "early warning system" fully operational, and to translate its findings into long-term improvements in the safety of the food supply, additional surveillance activities would be required.

5) Increase national surveillance for antimicrobial resistance of foodborne pathogens

CDC should expand surveillance for antimicrobial resistance in *Campylobacter*, *Salmonella*, and *E. coli* O157:H7 isolated in humans, and FDA and USDA should take similar steps for bacterial samples from food-producing animals and food products, in a way that permits these data to be compared. CDC, FDA and USDA should develop standard procedures for sharing necessary information, and for responding to increases in resistance, or other "red flag events" such as the discovery of an important new resistant bacterium.

6) Enhance oversight of animal feeds and feedstuffs for the impact of drugs and other therapies in food animal populations and pathogens

FDA may consider increasing monitoring of animal feed processing to determine the nature and extent of pathogen contamination and the impact of control strategies on pathogen reduction in animals.

COORDINATION

Background

At the federal level, there are four agencies charged with responding to outbreaks of foodborne illness (including waterborne illness): FDA and CDC at HHS, FSIS at USDA, and EPA. While CDC's primary responsibility is to work with state and local health departments to identify and investigate sporadic cases and outbreaks of illness, FDA, FSIS, and EPA have the additional responsibility of taking regulatory action against the suspect products, or those who contaminate the air, land, or waters used to produce the food product. Which regulatory agency gets involved depends on the type of food involved, with FSIS having primary jurisdiction over meat, poultry, and egg products, FDA over all other foods including shell eggs and EPA over water and pesticides. While each agency has clearly defined areas of responsibility, most outbreaks of foodborne illness involve more than one agency.

In addition, investigations of foodborne illness usually begin at the community or state level. These illnesses may cross jurisdictional boundaries and may be linked to foods or food ingredients that were processed or produced in another state or by international trading partners, necessitating the involvement of federal agencies. Federal involvement is also necessary when contaminated foods from the same sources may be in grocery stores, restaurants, and homes in other parts of the country. Companies responsible for affected products also have a critical role to play as many product recalls are voluntary.

In most outbreaks of foodborne illness, federal agencies work with state and local health authorities in their investigations and implementation of control measures through consultation, diagnostic assistance, and recommendations for control measures. In some instances on-site assistance is requested by the local and state authorities. For large or multi-state outbreaks, federal agencies play a critical coordination role to assure consistency of approach and implementation of needed control measures.

Preliminary Problem Identification

Although significant coordination already occurs among the federal and state agencies, the mere fact that more than one agency is involved in any one outbreak of foodborne illness can cause some confusion. Many times a joint effort is hindered by a lack of communication or a misunderstanding of each agency's role in a particular situation.

Current Thinking

Improved coordination among the federal agencies, between federal and state agencies, and

among the various state agencies would enhance the level of public health protection, make the best use of interagency collaboration, and avoid duplication of effort.

1) Improve federal/state coordination in the management of response to foodborne illness

A Foodborne Outbreak Response Coordinating Group made up of representatives of the federal and state agencies charged with responding to outbreaks of foodborne illness should be created to coordinate the investigation and response to significant outbreaks of foodborne illness. The overall goal of this group should be to ensure that a coordinated and professional response, with all governmental resources pulling together, is undertaken to effectively investigate and respond to foodborne illness. The group should determine jointly each agency's responsibilities during the various phases of outbreak investigations, and who would play the role of spokesperson for each phase or component of an outbreak. In addition, the group should coordinate communications and decisions about appropriate actions during outbreaks and appropriate follow-up to prevent similar outbreaks. The coordinating group should also meet several times a year to review its work and the response to outbreaks.

Each participating agency could fund and enhance programs that provide opportunities to exchange employees, on a temporary basis, among federal agencies and between federal and state agencies. Such an exchange would facilitate coordination by sharing expertise and providing an opportunity to better understand the various roles each agency plays in an investigation of a foodborne illness.

2) Improve federal/state coordination in the management and response to foodborne illness

Better coordination between federal and state agencies and among the various state agencies would speed the identification and subsequent control of foodborne illness and the removal of the contaminated foods from the distribution chain.

In order to improve coordination, the federal agencies can sponsor a national meeting with state and local officials to develop recommendations on how to better coordinate the overall government response to foodborne illness.

For example, one specific issue that is discussed in FDA's FY98 budget is the occurrence of *Salmonella enteritidis* in layer hens and improved monitoring of the hens and liquid bulk egg products (before pasteurization) for contamination. The federal agencies should work to establish a federal/state cooperative program to solve this problem.

3) **Enhance the basic infrastructure for foodborne illness surveillance and coordination at state health departments**

The epidemiology offices and laboratories within state health departments are charged with the surveillance of infectious and non-infectious conditions, and, along with other state officials, with the investigation of outbreaks. They collect surveillance data from physicians, laboratories, local health departments and other sources. Yet, the resources available in many states for the surveillance and investigation of foodborne diseases are limited and decreasing, thereby limiting the states' effectiveness. As a result, outbreaks may go undetected or are never investigated.

This problem could be rectified by making sure that, given an assessment and cataloguing of available state resources, states are provided support for foodborne disease surveillance programs and assistance to better investigate outbreaks of foodborne illness.

RISK ASSESSMENT

Background

It is a basic public health tenet that public resources devoted to reducing risks should be in proportion to the toll they take on human health. Risk assessment is the tool best suited to set priorities among public health risks. Furthermore, risk assessment is a requirement for any science-based system of preventive controls. Indeed, risk assessments and evaluations of alternative risk management strategies are often carried out for major federal regulations. Pursuant to the USDA's Reorganization Act of 1994, USDA is required to conduct risk analyses for all major regulations. Such evaluations ensure that risk reduction strategies are cost effective and promote the maximum net benefit to society of efforts to reduce foodborne illness. Sound risk assessments, including bacterial, parasitic, and viral food contaminants, are also critical to World Trade Organization treaty negotiations, which require that U.S. food safety standards be based on scientifically valid measures derived through risk assessment.

Preliminary Problem Identification

Risk assessment's objective is to characterize the nature and size of the risk to human health associated with hazards, and to make clear the degree of scientific certainty of the data and the assumptions used to develop the estimates. Risk assessments require a substantial amount of specific information on the hazard and on the exposed population to provide meaningful information for those making risk management decisions. Even for chemical hazards, for which risk assessment methods have been most thoroughly developed, data gaps force the use of assumptions about exposure, hazard potency, and characteristics of the population at risk, and mathematical "models" of chemical action or of the way that the body deals with a chemical.

Risk assessment is far less developed for foodborne pathogens. Intensive commitment is necessary to develop critically needed data such as pathogen behavior in numerous foods under hundreds of conditions, and information about especially sensitive populations, such as children.

Current Thinking

This initiative's risk assessment activities would focus on developing better use of data and better models to inform surveillance plans, HACCP-based prevention strategies for process control systems and for food inspections, and research programs to fill critical food safety information gaps.

1) Establish a risk assessment consortium

All federal agencies with risk management responsibilities should establish jointly a new

consortium at which federal agencies can set collective priorities for risk assessment research and collective priorities and strategies for the further development and implementation of risk assessment and risk management. The consortium should be established at the Joint Institute for Food Safety and Applied Nutrition, a collaborative activity of FDA's Center for Food Safety and Applied Nutrition and the University of Maryland.

The consortium should focus federal research on developing data for risk assessments, focused and applied specifically to address the scientific, risk-based goal of preventive control that is the central principle of this food safety initiative.

Research supported and conducted through this initiative should cover several areas critical to developing our ability to conduct risk assessments for foodborne disease-causing organisms and to assess the effectiveness of control measures. Data and methods developed in response to the Safe Drinking Water Act Amendments of 1996, for example, will be relevant to food safety evaluations.

2) **Develop better data and modeling techniques to assess exposure to microbial and chemical contaminants, including animal drug residues, through the food supply**

Risk assessment of foodborne illness is dependent on accurately estimating the quantity of a toxin or pathogen ingested by the consumer (i.e., exposure assessment). This initiative would address the numerous data and modeling deficiencies in estimating exposure to microbial and chemical contaminants. Specifically, research should be conducted in: incidence and prevalence of microbial pathogens and chemical hazards in food; typical behaviors of commercial and home preparation operations; validation of dynamic exposure assessment models; intake data regarding food consumption patterns of the general population and sensitive subpopulations; and specific data on food vehicles of sporadic and epidemic disease. Research using biomarkers should be pursued. Biomarkers are surrogates that indicate that exposure has occurred or that some effect has occurred, particularly when actual evidence of exposure and effect are difficult or impossible to obtain.

3) **Develop dose-response assessment models for use in risk assessment**

Research is needed to estimate the relationship between the quantity of a biological agent and the frequency and magnitude of adverse human health effects in a population. Dose-response assessments typically include estimates of the rates of infection, morbidity, and mortality. For bacterial hazards, the World Health Organization's Expert Consultation on the Application of Risk Analysis to Food Standards Issues (FAO/WHO, March 1995) refers to these steps as "hazard characterization."

BIOSCIENCE RESEARCH

Background

Currently, one of the most critical needs in food safety research is for techniques to more rapidly and accurately identify and characterize foodborne hazards. FDA, CDC, EPA, and the USDA's Research, Education, and Economics agencies (the Agricultural Research Service, the Cooperative State Research, Education, and Extension Service) conduct research related to pathogenic microorganisms and other contaminants that threaten the safety of food.

Preliminary Problem Identification

New pathogens, some of them foodborne, have emerged over the last 10 years. Many of these organisms can not be easily detected, or detected at all in foods. Other microorganisms, previously thought to be innocuous, have emerged as more virulent. Just because organisms are present at levels that can not be easily detected, however, does not mean that the organisms can not cause human illness. Newly recognized pathogens are causing serious disease outbreaks. Foodborne pathogens are increasingly overcoming time-tested controls, such as heating and refrigeration, and are developing new virulence and new ways to evade our immune defenses.

Current Thinking

Effective control of foodborne pathogens requires that prevention be targeted at high-risk foods and at high-risk points in their production and distribution. These interventions ideally are guided by risk assessment, for which all too often we have insufficient data. Research is needed to support HACCP implementation, to enable verification that critical control points in HACCP systems are working, and to target the data gaps that hamper risk assessment. Among the data gaps and information needs identified here are numerous opportunities for collaboration and resource leveraging among federal agencies, the private sector, and universities.

Specific
research
steps

1) **Improved detection methods**

As stated above, many foodborne pathogens cannot be easily detected, or detected at all in foods. Methods need to be developed, validated, and implemented for rapid testing of very low levels of *Campylobacter*, *Salmonella*, *Toxoplasma*, *Vibrio*, *E. coli* O157:H7, *Cyclospora*, *Cryptosporidium*, Norwalk virus and naturally occurring toxins in food animals, in agricultural and aquaculture products, animal feeds, and processed food products. Some research efforts may initially focus on *Campylobacter*, because those foodborne infections are so prevalent and may lead to chronic diseases (Guillain-Barré syndrome); also methods to isolate and identify this pathogen are time-consuming and expensive. Research could be coordinated with EPA's efforts to develop better test methods and assessments of health effects from *Cryptosporidium* and other

contaminants in drinking water. Improved methods are needed for identifying foodborne pathogens, including emerging pathogens, in clinical specimens and to subtype known foodborne pathogens.

2) Understanding antimicrobial resistance

Microorganisms can become resistant to antimicrobial agents and conditions that have been traditionally relied on to eliminate or prevent the growth of foodborne pathogens, but have become insufficient to prevent breakthrough of newly emerging pathogens. Research is needed to determine how microorganisms associated with foodborne disease become tolerant to various types of antimicrobials and to traditional food safety safeguards such as heat or cold, low pH, high salt, and disinfectants and to elucidate factors in animal and plant production systems and processing environments that influence the development of resistance. This research will lead to the identification of food production and processing practices that are likely to permit pathogen contamination or proliferation and will provide guidance in the modification of traditional techniques or the development of new techniques to prevent or control pathogen growth.

3) Understanding antibiotic drug resistance

Pathogens in food-producing animals may become resistant to drugs partially due to improper use of the drugs, particularly antibiotic drugs, in those animals. One possible way to deal with this problem might be to adjust the required period of drug withdrawal prior to slaughter. For example, studies should be conducted to explore possible changes to "withdrawal time" requirements that could reduce transfer of resistant pathogens with minimal disruption to industry production practices. In addition, industry in collaboration with federal agencies could determine the basis for the ability of microorganisms to rapidly adapt to changing environments and, together, develop animal production and treatment mechanisms to minimize this adaptive ability.

4) Prevention techniques: Pathogen control, reduction, and elimination

Contaminants are introduced into the food supply at numerous points along the way from farm to store. Food animals may carry pathogens, but remain healthy themselves, complicating controls at the point of slaughter. Animal feed and drinking water can be "hidden" but significant sources of contamination. Possible research recommendations to address these problems for *Salmonella*, *Campylobacter*, *Toxoplasma*, *Vibrio*, *E. coli* O157:H7, *Cyclospora*, *Cryptosporidium*, and Norwalk virus in all food products are the following (to be carried out in conjunction with universities and the private sector):

- Develop drugs and other therapies to prevent initial colonization.

- Develop new methods to reduce or eliminate contaminants from animals and plants before slaughter or harvest.
- Develop new disinfection methods and equipment and systems modifications for processing and production plants, and wholesale and retail outlets.
- Develop new methods of surface decontamination of fresh fruits, vegetables, meat, poultry.
- Develop heat-based and/or other disinfection methods for seafood, meat, eggs, produce, and animal feeds.

5) **Food handling, distribution, and storage**

Food production and processing often occur thousands of miles apart. Transportation systems for live animals, fresh produce, and packaged foods offer many opportunities for contamination, such as heat, cold, and other stresses that make animals and plants more susceptible to infection, and cross-contamination from the vehicle itself. Possible research recommendations include the following:

- Investigate immune system "biomarkers" of stress that might indicate predisposition to infection during transport.
- Develop in- or on-package sensors of storage conditions to alert consumers of products not stored safely.

INSPECTIONS

Background

Inspection of commercial food processors is an integral part of the food safety assurance system. Inspections are carried out by federal, state and local authorities, with state and local officials focusing primarily on restaurants, supermarkets and other retail establishments. At the federal level, consistent with legal mandates, FSIS has carcass-by-carcass inspection in meat, poultry, and slaughter plants while they are operating, and continuous inspection in meat, poultry, and egg-product processing plants--in all, about 8,000 inspectors for 6,500 domestic plants and for all imported meat, poultry, and egg products. FDA does periodic, random inspections of all other food processing plants--less than 700 inspectors and analysts for 53,000 U.S. plants and for all other imported foods.

Preliminary Problem Identification

At FDA, the number of inspections has decreased steadily since 1981, when 21,000 inspections were conducted, so that today resources exist to carry out only about 5,000 inspections per year. The result is that an FDA-regulated plant gets inspected by FDA, on the average, only once every 10 years. FDA also relies upon the states to conduct some inspections under contract, but that number has dropped from 12,000 in 1985 to 5,000 now. Moreover, the inspectional coverage of imported foods has dropped as well, as the same number of import inspectors are now inspecting almost twice as many imports as just five years ago. Certainly FDA is finding greater problems, e.g., the number of products recalled for life-threatening microbial contamination has increased almost 5-fold since 1988 and inspectors are finding more hazardous conditions in the plants they inspect. FSIS is faced with a similar challenge of continually providing the most effective inspection program with limited resources and growing threats to food safety.

Current Thinking

Scientists and other food safety experts have concluded that the most effective and efficient mechanism for assuring that food processors identify and control hazards that could threaten food is the application of the HACCP concept of built-in preventive controls. FDA has begun to implement HACCP for the seafood industry, and FSIS for the meat and poultry industries; FSIS intends to publish an ANPR requesting comments on HACCP systems for egg processing plants, and FDA plans to work with the food industry, as it has in a pilot program over the last 2 years. To ensure that HACCP is properly implemented, and to ensure more efficient and effective monitoring of the safety of the food supply, the following preliminary recommendations are being made.

1) Enhance development of HACCP procedures

FDA is considering whether and how to implement HACCP throughout the non-meat/poultry food industry for all appropriate food commodities. It is recognized that staged implementation, by commodity, might be necessary because of resource limitations. To ensure that HACCP is being properly implemented, FDA should conduct inspections and provide necessary training and outreach activities. FSIS will continue development of a HACCP-based inspection system. FSIS plans to conduct a public meeting and then subsequent field trials to gather data to support future decisions on designing new inspection procedures in a HACCP environment.

2) Upgrade FDA's food inspection program

FDA has included implementation of seafood HACCP in its FY98 budget request. If HACCP is to be an effective program for ensuring that food processors have modern, state-of-the-art food safety procedures in effect, FDA must improve its inspection capabilities, so that the highest risk food plants (such as seafood) are inspected at least once per year. To maximize the joint federal/state role in inspections, development of new partnerships with the states may be considered, that focus on coordinating the inspection coverage and preventing duplication of effort.

FSIS and FDA may consider expanding and re-focussing existing cooperative agreements under which plants producing both meat and non-meat foods are inspected solely by FSIS inspectors, who have been trained in FDA inspectional standards. FSIS inspectors are already in these plants; their presence could be better utilized to maximize use of federal resources.

FSIS and FDA are considering whether and how to regulate the transportation of meat, poultry, seafood, eggs and other foods in order to safeguard the public from pathogenic microorganisms, as reflected in the ANPR published on November 22, 1996.

3) Enhance federal/state inspection partnerships

Additional federal/state partnerships can ensure improved coordination between the federal food safety agencies and state regulators for the training of state inspectors in federal food safety standards, as well as provide the states with equipment and technology for the rapid sharing of inspection results and for a national database for the monitoring of all food inspections. This information sharing would help both federal and state regulators make inspections more effective and efficient.

FDA may consider establishing a process for certifying private laboratories that would be authorized to test samples of food products for contaminants. This may embody a similar process currently being discussed by a coalition of industry, private laboratories, professional

associations, and accrediting bodies with input from federal agencies. Such private parties would provide a service to food firms wishing to demonstrate that their products meet applicable federal standards.

4) **Enhance inspectional coverage of imported food, to address the problem of rising imports and FDA's inability to provide adequate inspections of them**

FDA should develop more Mutual Recognition Agreements (MRAs) with foreign countries, under which both countries agree to inspect each other's food exporting firms under equivalent procedures for ensuring safety. Once such MRAs are in place, FDA could better focus its import inspections on foods coming from countries with the least reliable safety standards.

EDUCATION

Background

Educating people about steps they must take to prevent and control foodborne illness is a vital link in the food preparation chain. Educational efforts have already been made at the federal level. For example, FDA has a website which offers information on many food safety issues, has established a 24-hour seafood hotline, and has published brochures on such topics as food safety advice for persons with AIDS and posters on such topics as listeria in soft cheese. USDA has taken similar steps through its Cooperative Extension network, its Meat and Poultry Hotline, and by requiring safe handling instruction labels for meat and poultry products.

Preliminary Problem Identification

Despite these efforts, and the work that states, consumer groups and the food industry have done in this area, foodborne illness still occurs from a lack of knowledge of the risks involved at all stages of food preparation. For instance, choices consumers make about how they handle food prepared at home and whether they eat food that increases the risk of foodborne illness can have a significant impact on the incidence of foodborne illness. Studies show, for example, that 53% of the public eat food with raw eggs, 23% eat undercooked hamburger, 17% eat raw clams and oysters, and 26% do not wash their cutting boards after using them for raw meat or poultry.

Foodborne illnesses have also been traced to commercial food establishments. For example, many food establishments do not know that the pooling and undercooking of eggs can increase the risk of *Salmonella enteritidis*. Currently, a much higher percentage of those who receive their food in an institutional environment are victimized by the more serious consequences of foodborne illness. For example, during 1988 to 1992, *Salmonella* caused 69% of the 796 bacterial foodborne disease outbreaks; 60% of these *Salmonella* outbreaks were caused by *S. enteritidis*. *S. enteritidis* also resulted in more deaths than any other pathogen with 85% of these deaths occurring among residents of nursing homes.

Producers of animals used in human foods production and veterinarians treating such animals also need education in food safety practice. Drugs used to treat these animals are not always used appropriately, and can be purchased over the counter by non-veterinarians and mis-used, resulting in harmful residues in meat and milk, decreased effectiveness of these drugs, and increased antimicrobial resistance.

Finally, those responsible for the transportation of food are often unaware of unsafe practices that result in the contamination and mishandling of food during shipment.

Current Thinking

Understanding and practicing proper food handling procedures from farm to table would significantly reduce foodborne illness.

1) Improve consumer education

An alliance including industry and consumer groups should mount a comprehensive food safety awareness campaign for consumers, highly focused on messages and tactics targeted to the general public and to special populations such as high-risk consumers. The campaign should be centered around an easily recognized symbol or catch phrase and should include a national print and broadcast media campaign and incorporate food safety messages into school curricula. An emphasis should be placed on multilingual activities to ensure the widest coverage.

Innovative methods for sharing information related to food handling behaviors should be developed in order to reach larger audiences. As part of this effort, a National Food Safety Education Alliance of industry, consumer, trade, state and local food protection agencies, and academic organizations focused on changing unsafe food handling practices should be convened. Research should be conducted to determine effective methods of providing information and evaluation of educational programs. A national clearinghouse should be established to provide consumers and food safety educators with food safety information.

2) Improve retail, food service, and institutional education

A highly focused campaign should be developed to change food workers' unsafe food preparation behaviors. A multilingual approach should be developed. An alliance of federal, state, and local health agencies, as well as private parties, should be formed to develop education efforts on food safety issues. Activities of the alliance should include educating retail food service workers about the safe handling perishable food product provisions in the 1997 *Food Code*.

In addition, guidelines should be developed by USDA and the states for retail and food service operations which process meat and poultry products to train state level inspectors to identify hazards at the retail level. Efforts should also be undertaken to educate the retail, food service and institutional industries in order to increase the use of HACCP principles.

3) Improve veterinary and producer education

Development and implementation of a program could be considered to educate producers of animals for human food consumption, veterinarians, state and local regulators about proper drug use and the incorporation of HACCP principles into industry quality assurance programs. The

program could entail regularly scheduled training sessions, including satellite teleconferences, educational symposia, and presentations at producer and practitioner meetings. Guidelines and educational materials could also be developed and disseminated through a national clearinghouse to food producers and the veterinary medical community.

4) Improve industry education in the transportation area

Government agencies could form an alliance to develop educational materials and train food transportation vehicle owners and operators and food processing establishments on hazards associated with the transportation of food products, particularly hazards associated with temperature controls, prior cargoes, and sanitation methods. Training and education for state and local health and transportation authorities could also be conducted so they can apply this information during inspections of food processing facilities and transportation vehicles in their jurisdiction.

A STRATEGIC PLAN FOR REDUCING FOODBORNE ILLNESS OVER THE LONG TERM

Background

The broad issues of a sustainable safe food system include, among other issues, improving the infrastructure for rapid identification and response to outbreaks, improving coordination among all food safety participants in numerous aspects of prevention and response, and developing a strategic, long-range research agenda. Stakeholders include food producers and manufacturers, consumers, academic institutions, representatives from the food service sector, including retail, restaurant, and institutional food service settings, veterinary and medical professionals, and federal, state, and local public health and agricultural officials.

Preliminary Problem Identification

Making the necessary improvements in the food safety system will not be easy. Because so many lines of authority must be crossed, so many new working relationships established, and so many fundamental changes in infrastructure made, the current system must be “reinvented.” For example, the federal government needs to develop a long-term, coordinated research agenda to truly address research needs to support a fundamentally improved food safety system, and strategies for developing such an agenda would need to be developed through such a planning process. Extensive dialogue will be required among the many stakeholders in various regions of the country to agree upon priorities, strategies for achieving change, and a process for achieving change.

Current Thinking

A significant activity proposed as part of this food safety initiative is the creation of a process that facilitates the participation of all stakeholders in discussing the issues and setting an agenda for consideration of fundamental change in the food safety system.

A contract could be established with an independent organization to bring together all major stakeholders for discussion of fundamental changes to the present food safety system. A major purpose of this strategic planning exercise would be to identify changes that should be made to the present organizational and procedural structure that would bring about permanent improvements in efficiency and coordination. Dialogue groups could be established to develop a strategic plan. Opportunities for input could include symposia held in geographically dispersed sites to encourage stakeholder participation.

Documents developed from the deliberations and recommendations of these symposia could be the focus of further discussion during a series of open meetings. The product of this series of

dialogues, symposia, and hearings could form a report, which would provide the outline necessary for targeting needed structural changes in the federal/state food safety system.

Federal Register: March 21, 1997 (Volume 62, Number 55)

Notices

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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service
Docket No. 97-024N

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention
Food and Drug Administration
Docket No. 97N-0074

ENVIRONMENTAL PROTECTION AGENCY

President's National Food Safety Initiative

AGENCY: Food Safety and Inspection Service, USDA; Centers for Disease Control and Prevention, HHS; Food and

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Drug Administration, HHS; Environmental Protection Agency.

ACTION: Notice: Public meeting; establishment of public dockets.

SUMMARY: The United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) and Research, Education, and Economics; The Department of Health and Human Services' Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC); and the Environmental Protection Agency (EPA) will convene a meeting on March 31 to April 2, 1997, to discuss and develop for the President a comprehensive plan to reduce the annual incidence of foodborne illness by enhancing the safety of the nation's food supply. USDA and FDA are also establishing public dockets to receive comments about the President's Food Safety Initiative and the discussion draft and current thinking document made available on February 21, 1997.

DATES: The meeting will be held from 8:30 a.m. to 5:30 p.m. and 7:00 p.m. to 9:00 p.m. on March 31; 8:30 a.m. to 5:00 p.m. on April 1; and from 8:30 a.m. to 1:30 p.m. on April 2, 1997. Comments by April 4, 1997.

ADDRESSES: The meeting will be held at the Hyatt Regency Washington on Capitol Hill, 400 New Jersey Avenue, NW, Washington, DC 20001.

FOR FURTHER INFORMATION CONTACT: To register for the meeting, contact Ms. Traci Phebus at (202) 501-7138, FAX (202) 501-7642, E-mail HACCP.Confer@USDA.GOV. Participants may reserve a 5-minute public comment period when they register. Space will be allocated on a first come, first served basis. Participants should also select the breakout sessions they plan to attend when they register. For questions about the meeting or to obtain copies of the draft report, "Food Safety From Farm to Table: A New Strategy for the 21st Century, Discussion Draft and Current Thinking, A National Food Safety Initiative," contact Mr. Charles Danner, FSIS, at (202) 501-7136 or Ms. Karen Carson, FDA, at (202) 205-5140. Copies of the draft report also are available from the following: FSIS at <http://www.usda.gov/fsis> or FDA at <http://vm.cfsan.fda.gov/list.html> or CDC at <http://cdc.gov/ncidod/food.htm>.

Home

Participants who require a sign language interpreter or other special accommodations should contact Ms. Jennifer Callahan at (202) 501-7138 by March 24.

SUPPLEMENTARY INFORMATION: On January 25, 1997, the President directed the Secretaries of USDA and HHS and the Administrator of EPA to work with consumers, producers, industry, States, Tribes, universities, and the public to identify ways to further improve the safety of our food supply. The President requested that the plan focus on ``* * * further improvement of surveillance, inspection, research, risk assessment, education, and coordination among local, State, and Federal health authorities.''

On March 5, 1997, the first public meeting was held to discuss the initiative and the issues identified by food safety experts in the draft report. All attendees received a copy of the draft report and were encouraged to review the document and develop recommendations related to the seven topic areas: surveillance, risk assessment, research, inspection, education, and coordination, and strategic planning to be presented at the March 31 meeting.

The March 31 session will feature a general session with time allotted for public comment followed by concurrent breakout sessions: Bioscience Research and Coordination; and an evening session on Strategic Planning. On April 1, concurrent breakout sessions will be held in the morning on Improving Risk Assessment Tools and Improving Food Safety Education and in the afternoon on New Early Warning System for Foodborne Illness and Maximizing Inspection to Support HACCP. The April 2 session will include reports from each of the seven breakout sessions and public comment.

The agencies are also announcing the establishment of public dockets about the President's Food Safety Initiative and the discussion draft and current thinking docket made available on February 21, 1997 and are encouraging individuals to comment on the topics discussed at the March 5, 1997, meeting as well as those listed in this notice under Supplementary Information. The agencies are also urging individuals with comments on the seven topic areas of the draft report to submit these comments by March 28 to facilitate discussion in the breakout sessions. Submit written comments as follows: USDA/FSIS Hearing Clerk, Room 3806 South Building, Washington, DC 20250-3700 or Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Drive, Room 1-23, Rockville, MD 20857. Comments are to be identified with the docket number. For those comments directed to USDA use Docket No. 97-024N; for comments directed to FDA, use Docket No. 97N-0074.

Transcripts of the public meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, Room 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. The transcript of the public meeting and all submitted comments will be available for public examination at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Done at Washington, DC, on March 17, 1997.

Thomas J. Billy,
Administrator, Food Safety and Inspection Service.
Fred R. Shank,
Director, Center for Food Safety and Applied Nutrition, Food and Drug Administration.
Donald E. Shriber,
Associate Director/Washington, Centers for Disease Control and Prevention.
Dana Minerva,
Deputy Assistant Administrator for Water, Environmental Protection Agency.
FR Doc. 97-7155 Filed 3-18-97; 9:53 am
BILLING CODE 3410-DM-P

**FOOD SAFETY FROM FARM TO TABLE:
A NEW STRATEGY FOR THE 21st CENTURY**

**DISCUSSION DRAFT AND CURRENT THINKING
A NATIONAL FOOD SAFETY INITIATIVE**

A NEW INTERAGENCY STRATEGY TO PREVENT FOODBORNE DISEASE

In his radio message on January 25, 1997, President Clinton announced a new initiative to improve the safety of the nation's food supply. The President announced he will request \$43 million in his 1998 budget to fund a nationwide early warning system for foodborne illness, enhance seafood safety inspections, and expand food safety research, risk assessment, training, and education. President Clinton also directed the Secretary of Health and Human Services and of Agriculture, and the Administrator of the Environmental Protection Agency to work with consumers, producers, industry, states, universities, and the public to identify additional ways to reduce the incidence of foodborne illness and to ensure our food supply is the safest in the world.

The President directed Secretaries Shalala and Glickman, and Administrator Browner to report back to him with recommendations in 90 days. He instructed them to explore opportunities for public/private partnerships to improve food safety. And he asked that their recommendations include ways to improve surveillance, inspections, research, risk assessment, education, and coordination among local, state, and federal health authorities.

We need your advice. Your perspective is essential in providing the President with a report that identifies current needs in food safety, as well as assuring the future safety of our food supply and the health of consumers. We need the perspective and suggestions of all groups who are concerned about food safety and public health to make this a successful endeavor.

The goal of this initiative is to reduce, to the greatest extent possible, the incidence of foodborne illness. The thoughts in this draft focus on the public health principle that society should identify and take preventive measures to reduce the risk of illness, and that it should focus its efforts on those hazards that present the greatest risks.

The ideas in this draft represent our preliminary thoughts on this subject. A comprehensive food safety plan, describing actions and resources necessary to achieve the goals of reduced foodborne illness, will require extensive deliberation and in-depth discussion with all stakeholders in food safety, including consumers, state, tribal, and local public health officials, industry, and members of the scientific community. This draft is intended not as a prelude to government action, but an exploration of what might result from the upcoming seminars and conferences. While this initiative focusses on reducing the incidence of microbial foodborne illnesses, we recognize that chemical contaminants are also a cause of foodborne illness, but with chronic long term effects.

BACKGROUND

The American food system provides consumers with an abundant supply of convenient, economical, high-quality, and safe food products. This system is built on the enterprise and innovative capacities of those who produce and market food in the United States, and it is driven

by the high expectations of American consumers for the foods they purchase for their families. Foodborne illness, however, still occurs in the United States. Over the last four years the Clinton Administration has developed and implemented major steps towards reinventing food regulation:

- In 1993, the Vice President's National Performance Review issued a blueprint for reinventing our nation's food safety system.
- The Food Safety and Inspection Service (FSIS) and the Food and Drug Administration (FDA) issued regulations that will require the meat, poultry, and seafood industries to follow Hazard Analysis and Critical Control Points (HACCP) procedures. HACCP, which calls for food industries to implement preventive measures of their own design, will streamline regulation of these foods, increase the industries' responsibility for and control of their own safety-assurance actions, and generally bring regulation of meat, poultry, and seafood in line with state-of-the-art scientific procedures.
- Beginning in 1994, the Centers for Disease Control and Prevention (CDC) embarked upon a strategic program to detect, prevent, and control emerging infectious disease threats, some of which are foodborne, and has made significant progress toward this goal in each successive year.
- The Safe Drinking Water Act of 1996 includes responsible regulatory improvements to help states and water systems prevent drinking water contamination problems. Resources are provided for the first time for drinking water infrastructure that will help hundreds of communities protect their residents from harmful contaminants.

While these advances are significant, they may not be enough. New pathogens, new food products, huge increases in imported foods, the growing importance of food exports, and increasing antimicrobial resistance among foodborne pathogens present new challenges to the nation's food safety programs. The food safety system is in need of reform, especially reform that builds on the preventive principles embodied in HACCP.

HISTORY OF THE FOOD SAFETY INITIATIVE

Achieving a significant reduction in the incidence of foodborne illnesses requires the cooperative efforts of public health and regulatory agencies at the federal, state, tribal and local levels, as well as all other parties responsible for and concerned about food safety and reducing the incidence of foodborne illness (i.e., consumers, industry, and academia). Partnerships - between public agencies and industry, federal agencies and state, tribal or local agencies, public agencies and academia, to name a few possibilities - will be invaluable in leveraging the resources focused on reducing the incidence of foodborne illness and enhancing communication.

Representatives of various government agencies have drafted a structure for the food safety initiative for your further deliberations. Ad hoc working groups, representing the varied perspectives of the FDA, CDC, the Department of Agriculture's Research, Education and Extension agencies, as well as the FSIS and Animal and Plant Health Inspection Service (APHIS), and the Environmental Protection Agency (EPA), have been meeting for several months to identify major food safety concerns and propose recommendations on what resources and activities are needed to have a significant impact on reducing the incidence of foodborne illness both in the short term and over the long term. The working groups worked from the premise that an effective food safety initiative must have several, interrelated components which, together, have far greater impact on reducing the incidence of foodborne illness than is possible to attain with any single component. Moreover, these elements must form the groundwork for the design and implementation of strategies to meet current needs, for continually evaluating the effectiveness of ongoing activities, and for identifying and implementing strategies to meet future needs. These elements include surveillance, coordination, risk assessment, research, inspections, and education.

This draft, which primarily defines short-term activities, describes the elements of a food safety initiative and tentatively identifies critical issues and the working groups' current thinking on preliminary recommendations. In some cases these recommendations have been included as part of the President's FY98 budget. However, no specific decision as to what will constitute the final food safety initiative, including how the strategic planning process is structured, have been made. Input from groups and individuals such as yourself, state, tribal and local agencies, consumers, industry, academia, and other stakeholders will be incorporated into the food safety initiative.

Two open public meetings of all parties interested in food safety are planned to take place in Washington, DC. The first, scheduled for March 5, 1997, is an information meeting to familiarize interested parties with the President's initiative and introduce the draft discussion document. A second meeting is tentatively scheduled for late March-early April to discuss the food safety initiative. The purpose of the second meeting is to present the key issues and solicit both comment on the preliminary recommendations and additional suggestions for inclusion in the report to President Clinton.

Using this draft as a starting point, we are asking for your perspective on how best to enhance the safety of the food supply and reduce foodborne illness. Please consider the following questions in guiding your response, considering both the immediate future and the long term:

Questions:

1. Have the critical elements of an effective food safety initiative been identified? Are there others? What are they?

2. Have the appropriate issues within each element been identified? If not, what additional issues should be included?
3. What are the priorities among the issues identified or added to each element of the initiative?
4. What steps should be taken to begin to resolve issues within each element of the initiative?
5. What are the responsibilities of various stakeholders in working toward resolution of the issues?
6. How can we better utilize public/private partnerships to reduce foodborne illness?
7. How should food safety activities be better coordinated across the federal agencies, accommodating the needs and perspectives of state and local agencies, consumers, industry, and academia, to maximize the effect of available resources?
8. How do we ensure and measure the effectiveness of the food safety initiative?
9. How should the evaluation be structured so that the results of the early evaluation can be factored into the strategic planning process?
10. What recommendations do you have for the structure of the strategic planning process?

The comments, suggestions, and information from these meetings will be used in preparing the report to the President.

FOODBORNE ILLNESS: A SIGNIFICANT PUBLIC HEALTH PROBLEM

Foodborne infections remain a major public health problem. The Council for Agricultural Science and Technology, a private non-profit organization, estimated in its 1994 report, *Foodborne Pathogens: Risks and Consequences*, that as many as 9,000 deaths and 6.5 to 33 million illnesses in the United States each year are food-related. Hospitalization costs alone for these illnesses are estimated at over \$3 billion a year. Costs for lost productivity for 7 specific pathogens have been estimated to range between \$6 billion and \$9 billion. Total costs for all foodborne illnesses are likely to be much higher. These estimates do not take into account the total burden placed on society by the chronic, often life-long consequences caused by some foodborne pathogens.

Additional, important safety concerns are associated with the greater susceptibility to foodborne infections of several population groups. These include persons with lowered immunity due to HIV/AIDS, those on medications for cancer treatment or for organ transplantation, as well as pregnant women (and their fetuses), young children, and elderly persons. Patients taking antibiotics, or antacids, are also at greater risk of infection from some pathogens. Other groups who may be disproportionately affected include persons living in institutional settings, such as hospitals and nursing homes, and those with inadequate access to health care, such as homeless persons, migrant farm workers, and others of low socioeconomic status.

Sources of Foodborne Contamination

Sources of food contamination are almost as numerous and varied as the contaminants themselves. Bacteria and other infectious organisms are pervasive in the environment. *Salmonella enteritidis* enters eggs directly from the hen. Bacteria (occasionally pathogenic) inhabit the surfaces of fruits and vegetables in the field. Molds and their toxic byproducts can develop in grains during unusually wet or dry growing seasons, damage and stress during harvesting, or during improper storage. Seafood may become contaminated from agricultural and other runoff, as well as by sewage, microorganisms, and toxins present in marine environments. Many organisms that cause foodborne illness in humans can be part of the normal flora of the gastrointestinal tract of food-producing animals without any adverse effects to the animal. Milk, eggs, seafood, poultry, and meat from food-producing animals may become contaminated due to contaminated feed, misuse of veterinary drugs, or poor farming practices, including production and harvesting activities, or disposal of solid waste on land. Foods may become contaminated during processing due to malfunctioning or improperly sanitized equipment; misuse of cleaning materials; rodent and insect infestations; and improper storage. Foods may become contaminated in retail facilities and in the home through use of poor food handling practices.

Although many hazards threaten the safety of our food, certain foodborne hazards are of particular public health concern, and would be targeted for immediate attention by this initiative. Studies have shown that the following microbial pathogens are the predominant foodborne pathogens. They are: *Salmonella* species, *Campylobacter jejuni/coli*, *Escherichia coli* O157:H7 and other related strains; the parasites *Toxoplasma gondii* and *Cryptosporidium parvum*; and the Norwalk virus.

The microbial pathogens listed above, and discussed in greater detail below, may give rise to diseases that are far more serious than the uncomfortable but relatively temporary inconvenience of diarrhea and vomiting, which are the most common symptoms of so-called "food poisoning." Foodborne infections can result in very serious immediate consequences, such as spontaneous abortion, as well as long-lasting conditions such as reactive arthritis, Guillain-Barré syndrome (the most common cause of acute paralysis in adults and children), and hemolytic uremic syndrome (HUS), which can lead to kidney failure and death, particularly in young children. The microbial pathogens described below are not listed in order of importance or severity.

Salmonella

Salmonella species cause diarrhea and systemic infections, which can be fatal in particularly susceptible persons, such as the immuno-compromised, the very young, and the elderly. An estimated 800,000 to 4 million infections occur each year in the United States, most of them as individual cases apparently unrelated to outbreaks. Animals used for food production are common carriers of salmonellae, which may subsequently contaminate foods such as meat, dairy products, and eggs. Foods often implicated in outbreaks include poultry and poultry products, meat and meat products, dairy products, egg products, seafood, and fresh produce. Between 128,000 and 640,000 of these infections are associated with *Salmonella enteritidis* (SE) in eggs. Over the past decade, more than 500 outbreaks have been attributed to SE with over 70 deaths. In 1994, an estimated 224,000 people became ill from consuming ice cream in one outbreak alone.

Campylobacter

The bacterium, *Campylobacter*, is the most frequently identified cause of acute infectious diarrhea in developed countries and is the most commonly isolated bacterial intestinal pathogen in the United States. It has been estimated that between 170,000 and 2.1 million cases of campylobacteriosis occur each year with an associated 120-360 deaths. *Campylobacter jejuni* and *Campylobacter coli* (2 closely related species) are commonly foodborne, and are the infectious agents most frequently described in association with Guillain-Barré syndrome, perhaps as frequently as 1 in 1000 cases. Several prospective studies have implicated raw or undercooked chicken as major sources of *C. jejuni/coli* infections. Unpasteurized milk and untreated water have also caused outbreaks of disease.

***Escherichia coli* O157:H7**

Several strains of the bacterium *E. coli* cause a variety of diseases in humans and animals. *E. coli* O157:H7 is a type associated with a particularly severe form of human disease. *E. coli* O157:H7 causes hemorrhagic colitis, which begins with watery diarrhea and severe abdominal pain and rapidly progresses to passage of bloody stools, and has been associated with HUS. HUS is a life-threatening complication of hemorrhagic colitis characterized by acute kidney failure, and is particularly serious in young children. *E. coli* O157:H7 has its reservoir in cattle, but the dynamics of *E. coli* O157:H7 in food-producing animals are not well understood. It has been estimated that approximately 25,000 cases of foodborne illness can be attributed to *E. coli* O157:H7 each year with an estimated 6 deaths. *E. coli* O157:H7 outbreaks have recently been associated with ground beef, raw milk, lettuce, and minimally processed and fresh fruit juices. The most recent outbreak, in the Fall of 1996 in 3 western states and British Columbia, was associated with unpasteurized apple juice and sickened 66 people and caused the death of one child.

Toxoplasma gondii

T. gondii is a parasitic protozoan. It has been estimated that 1.4 million cases of toxoplasmosis occur annually with an associated 310 deaths. Otherwise healthy adults who become infected usually have no symptoms, but may get diarrhea. Pregnant women who become infected during pregnancy may pass the disease to their fetuses. In infants infected before birth, fatal results are common. Should the infant survive, the effects of infection are typically severe. The disease can also be serious in persons with weakened immune systems and often is fatal to people with HIV/AIDS. *T. gondii* has been found in virtually all food animals. The two primary ways that humans become infected are consumption of raw or undercooked meat containing *T. gondii* or contact with cats that shed cysts in their feces during acute infection. Under some conditions, the consumption of unwashed fruits and vegetables may contribute to these infections.

Cryptosporidium parvum

C. parvum is a parasitic protozoan. The most common consequence of infection in otherwise healthy people is profuse watery diarrhea lasting up to several weeks. Children are particularly susceptible. Cryptosporidiosis can be life-threatening among persons with weakened immune systems. The largest recorded outbreak of cryptosporidiosis was a waterborne outbreak that occurred in Milwaukee, Wisconsin in 1993, affecting over 400,000 people. More recently, a waterborne outbreak in Las Vegas resulted in at least 20 deaths attributed to *Cryptosporidium*. The first large outbreak of cryptosporidiosis from a contaminated food occurred in 1993. This outbreak was attributed to fresh-pressed apple cider. *Cryptosporidium* is found in feces of infected mammals and has been transmitted through contaminated water and food.

Norwalk virus

Norwalk viruses are important causes of sporadic and epidemic gastrointestinal disease, that involve overwhelming, dehydrating diarrhea. An estimated 181,000 cases occur annually with no known associated deaths. In January 1995, a multi-state outbreak of viral gastroenteritis due to Norwalk virus was associated with the consumption of oysters. A 1993 Louisiana outbreak of Norwalk virus gastroenteritis, involved seventy ill people and was associated with the consumption of raw oysters. In 1992, another outbreak occurred which included 250 cases. Outbreaks of Norwalk virus intestinal disease have been linked to contaminated water and ice, salads, frosting, shellfish and person-to-person contact, although the most common food source is shellfish. Several such outbreaks are believed to have been caused by oysters contaminated by sewage dumped overboard by oyster harvesters and recreational boaters.

THE CURRENT SYSTEM FOR PROTECTING FOOD

Ensuring the safety of food is one of the core functions of government. It is carried out by a system that, while generally successful in protecting the public, can be confusing for its complexity and diversity. Authority is divided among federal, state, and local governments; and the private sector also plays an important role. From the farm to the consumer's dinner table, the responsibilities can be summarized as:

- On the farm, food is regulated by state agencies supported principally by the EPA, which acts to ensure that pesticides are approved for safe use, by the FDA, which oversees use of drugs and feed in milk- and food-producing animals, and by APHIS, which is concerned with food-animal disease control. Federal responsibility also covers production and harvesting activities that discharge wastewater to surface and ground waters, and solid waste to land, all of which could contaminate growing and process waters or grazing land.
- Food processing for foods other than meat, poultry, and egg products (except shell eggs) is regulated by the FDA, whose inspectors are responsible for visiting about 53,000 plants periodically, with emphasis on the highest risk foods or processing techniques. FDA has fewer than 700 inspectors and analysts devoted to this activity. Meat, poultry, and all other egg products are regulated by FSIS, whose 8,000 inspectors are present in 6,500 slaughter and processing establishments to ensure that these products are safe, wholesome, and properly labeled. State and local governments also inspect food processors, with varying frequencies and under varying standards.
- Food being transported in interstate commerce is subject to federal and state regulation, although that area has received little attention in the past. USDA's FSIS and HHS's FDA have jointly published an Advanced Notice of Proposed Rulemaking (ANPR) on whether

regulations are needed to govern the handling of meat, poultry, seafood, eggs, and other foods susceptible to harmful bacteria during transportation.

- The importation of food from foreign countries is overseen by FSIS for meat, poultry, and most egg products and FDA for all other foods. If an imported food is suspect, it can be tested for contamination and its entry into the United States denied.
- Restaurants, supermarkets, and institutional food services (such as schools and hospitals) are generally regulated by states and local health authorities, and FDA publishes the *Food Code*, which consists of model recommendations for safeguarding public health when food is offered to the consumer. Recommendations are developed by consensus of state government representatives at the Conference for Food Protection. FSIS and FDA are working with states to update the *Food Code* in light of the changing retail and food service environment and emerging food safety issues, especially with regard to meat, poultry, egg products, and seafood. The Conference for Food Protection serves as one forum for fostering cooperation among federal, state and local governments in the oversight of food products and the conditions under which they are produced, processed, transported, stored, and handled through retail sale or food service to the consumer.
- National standards for drinking water are set by EPA, and enforced generally by local public water authorities; FDA establishes complementary standards for bottled water.
- Surveillance of foodborne illness is primarily the responsibility of state and local health departments and the CDC, which seek to identify cases of illness, determine their source, and control outbreaks. FDA or FSIS are called in when a link to a regulated food is suspected.
- In the home, consumers also have a responsibility for proper handling and storage of food, as consumer mishandling contributes to many cases of foodborne illness. As a result of this knowledge, FSIS promulgated safe handling labels for raw meat and poultry products.
- Other responsibilities related to food safety include research into the cause and transmission of foodborne illness, and education on treatment and prevention of foodborne illness. These responsibilities are carried out by the USDA, FDA, CDC, EPA, the National Institutes of Health, other federal components, and the states. Basic biomedical research on pathogenic organisms is conducted at the National Institutes of Health. The federal government also supports related research in universities. The private sector supports research within its own laboratories and in universities.

THE FOOD SAFETY SYSTEM MUST BE PREPARED FOR THE 21ST CENTURY

The system for identifying and preventing foodborne illnesses described above was largely created in the early years of this century. It must be modernized. The current system is inadequate to properly identify, track, and prevent food-related illness and to prevent future cases from occurring. State and federal resources are not closely coordinated and duplication of effort is not uncommon. In 1981, FDA inspected food firms every 2-3 years, but can now visit those plants, on average, only once every 10 years. Our understanding of some disease causing organisms is so limited that our ability to protect the public health is seriously constrained. Food processors, restaurateurs, supermarket managers, and consumers often don't understand the threat from foodborne pathogens and the methods available to prevent and control them.

IMMEDIATE ACTIONS TO IMPROVE FOOD SAFETY

There are many causes of foodborne illness, many points at which foods can become contaminated, and numerous factors that make some groups of people more susceptible than others. Needless to say, no single preventive measure will ensure the safety of all foods. However, a number of practical preventive steps can be taken immediately to reduce the incidence of many foodborne infections.

Any initiative designed to improve the safety of the food supply should focus on the hazards and foods that present the greatest risks to public health, should emphasize development and implementation of preventive controls of those risks, and should seek opportunities for such controls through a collaborative process with the responsible sectors of the food industry and all other stakeholders. This prevention-control concept is HACCP, a science-based, state-of-the-art process for building safety into the production, handling and storage of food. HACCP is being implemented by the meat, poultry, and seafood industries with FSIS and FDA regulatory oversight. The application of such preventive controls to other types of food may be important to protecting food in the years to come.

Under this initiative, the federal government, in concert with state and local governments would conduct research and risk assessments to determine how foodborne illnesses occur and can be prevented or controlled; improve surveillance and investigative efforts to locate and monitor illnesses caused by food; achieve more effective and efficient monitoring of the safety of the food supply through inspections of food processors; and reinvigorate education of all those involved in food preparation focussing on the use of safe practices. These issues, and our current thinking about them, are described below.

A NEW “EARLY WARNING SYSTEM” FOR PUBLIC HEALTH SURVEILLANCE

Background

The primary goal of the American system of public health is to prevent disease before it occurs. While prevention of all disease may not be possible, stopping outbreaks of foodborne illness before they affect large numbers of people is a major goal. America needs a more effective early warning system that can catch outbreaks early, preventing illness and death. Such a system will also advance our understanding of foodborne illness and further our prevention efforts. In his January 25 radio address, the President announced a new national early warning system for foodborne illness that he is funding in his FY98 budget.

Preliminary Problem Identification

Surveillance and investigation of foodborne disease are powerful tools to detect new foodborne disease challenges, to determine what the specific food sources are, and to learn how best to keep the foods from becoming contaminated in the first place. Rapid detection of outbreaks is critical to stopping them before they affect many people. A key element in an early warning system is the ability to detect, compare, and communicate unusual patterns of illness and laboratory findings within and among states and among federal partners. Enhancing the capacity of states to monitor foodborne disease and to investigate and control outbreaks will lead to better general control measures and fewer illnesses. One way to achieve this is to expand the existing Active Foodborne Disease Surveillance Network (sentinel sites) to identify, investigate and control a broad spectrum of foodborne diseases. A second important way to enhance early warning is to increase the capacity of many states to deal with new foodborne challenges. These enhancements will help us identify outbreaks and other foodborne disease challenges early, and prevent illness and deaths.

Current Thinking

The federal government in cooperation with state and local health departments is proposing to take the following steps to establish a new national early warning system for, and enhance surveillance of, foodborne disease. These changes will result in an improved system for detecting and reporting foodborne illnesses and outbreaks that will enable public health agencies to rapidly put into place measures to control the spread of foodborne disease. This system will also collect critical data to recognize trends and target prevention strategies, including HACCP systems, and to evaluate the effectiveness and efficiency of prevention strategies already in place.

1) Enhance and expand the Active Foodborne Disease Surveillance Program

CDC, FDA, and USDA currently support five food sentinel sites at state health departments to

track cases of foodborne infections and to determine the sources of the most common ones. The existing sites should be strengthened, and the number of “enhanced” sites should be increased to 7 in FY 97, and to at least 8 in the following year. The sites and federal food safety agencies should be electronically linked together to create a powerful new network to detect, respond to, and prevent outbreaks of foodborne illness. Adding additional states will improve geographic and demographic representation, making this network more likely to detect diseases and outbreaks that are regional rather than national in distribution.

2) Enhance early detection of foodborne disease nationwide

In addition to establishing enhanced food sentinel sites, an early warning system would require improved early detection of foodborne disease in additional states in FY 98 by providing resources for improved surveillance, investigation, control, and prevention of foodborne disease outbreaks. While sophisticated laboratory studies can identify causes of illness and show relationships among bacteria, laboratory methods are insufficient without investigators who can collect samples, interview people, and trace the source of contamination to find out why the illness occurred. New electronic tools need to be developed to enable rapid detection of outbreaks, and to enhance communication about outbreaks to appropriate agencies. CDC also should provide additional resources to states to increase their surveillance and response capacity for the serious long-term consequences of foodborne disease, such as hemolytic uremic syndrome.

3) Modernize public health laboratories

CDC should provide resources and training to upgrade public health laboratory capabilities in the Active Surveillance sites and in other states so that they can rapidly identify a broad range of foodborne infections including new parasitic and viral pathogens, and can use new techniques of DNA “fingerprinting.” CDC would work with states to develop, standardize, and transfer those methods. These new capacities would allow rapid identification of the cause of some outbreaks that currently go undiagnosed.

4) Create a national electronic network for “fingerprint” comparison

CDC should fund a new computer network and database system that would capture bacterial “fingerprints” in a national database, linking CDC, FDA, USDA, and states that have this new capacity as well as the federal laboratories into a new national network. This technology would, for example, permit rapid recognition that an *E. coli* O157:H7 bacterium cultured from a patient in Washington was indistinguishable from one isolated from another patient in California, which would suggest to public health investigators that a product distributed in both California and Washington may be contaminated with the organism.

In addition to identifying, investigating, and reporting cases of foodborne disease in humans, surveillance of contamination levels in foods, in animals used for food, and in their feed is important to control and prevent foodborne diseases, and to monitor the measures that reduce the risk of exposure. Therefore, to make the "early warning system" fully operational, and to translate its findings into long-term improvements in the safety of the food supply, additional surveillance activities would be required.

5) Increase national surveillance for antimicrobial resistance of foodborne pathogens

CDC should expand surveillance for antimicrobial resistance in *Campylobacter*, *Salmonella*, and *E. coli* O157:H7 isolated in humans, and FDA and USDA should take similar steps for bacterial samples from food-producing animals and food products, in a way that permits these data to be compared. CDC, FDA and USDA should develop standard procedures for sharing necessary information, and for responding to increases in resistance, or other "red flag events" such as the discovery of an important new resistant bacterium.

6) Enhance oversight of animal feeds and feedstuffs for the impact of drugs and other therapies in food animal populations and pathogens

FDA may consider increasing monitoring of animal feed processing to determine the nature and extent of pathogen contamination and the impact of control strategies on pathogen reduction in animals.

COORDINATION

Background

At the federal level, there are four agencies charged with responding to outbreaks of foodborne illness (including waterborne illness): FDA and CDC at HHS, FSIS at USDA, and EPA. While CDC's primary responsibility is to work with state and local health departments to identify and investigate sporadic cases and outbreaks of illness, FDA, FSIS, and EPA have the additional responsibility of taking regulatory action against the suspect products, or those who contaminate the air, land, or waters used to produce the food product. Which regulatory agency gets involved depends on the type of food involved, with FSIS having primary jurisdiction over meat, poultry, and egg products, FDA over all other foods including shell eggs and EPA over water and pesticides. While each agency has clearly defined areas of responsibility, most outbreaks of foodborne illness involve more than one agency.

In addition, investigations of foodborne illness usually begin at the community or state level. These illnesses may cross jurisdictional boundaries and may be linked to foods or food ingredients that were processed or produced in another state or by international trading partners, necessitating the involvement of federal agencies. Federal involvement is also necessary when contaminated foods from the same sources may be in grocery stores, restaurants, and homes in other parts of the country. Companies responsible for affected products also have a critical role to play as many product recalls are voluntary.

In most outbreaks of foodborne illness, federal agencies work with state and local health authorities in their investigations and implementation of control measures through consultation, diagnostic assistance, and recommendations for control measures. In some instances on-site assistance is requested by the local and state authorities. For large or multi-state outbreaks, federal agencies play a critical coordination role to assure consistency of approach and implementation of needed control measures.

Preliminary Problem Identification

Although significant coordination already occurs among the federal and state agencies, the mere fact that more than one agency is involved in any one outbreak of foodborne illness can cause some confusion. Many times a joint effort is hindered by a lack of communication or a misunderstanding of each agency's role in a particular situation.

Current Thinking

Improved coordination among the federal agencies, between federal and state agencies, and

among the various state agencies would enhance the level of public health protection, make the best use of interagency collaboration, and avoid duplication of effort.

1) Improve federal/state coordination in the management of response to foodborne illness

A Foodborne Outbreak Response Coordinating Group made up of representatives of the federal and state agencies charged with responding to outbreaks of foodborne illness should be created to coordinate the investigation and response to significant outbreaks of foodborne illness. The overall goal of this group should be to ensure that a coordinated and professional response, with all governmental resources pulling together, is undertaken to effectively investigate and respond to foodborne illness. The group should determine jointly each agency's responsibilities during the various phases of outbreak investigations, and who would play the role of spokesperson for each phase or component of an outbreak. In addition, the group should coordinate communications and decisions about appropriate actions during outbreaks and appropriate follow-up to prevent similar outbreaks. The coordinating group should also meet several times a year to review its work and the response to outbreaks.

Each participating agency could fund and enhance programs that provide opportunities to exchange employees, on a temporary basis, among federal agencies and between federal and state agencies. Such an exchange would facilitate coordination by sharing expertise and providing an opportunity to better understand the various roles each agency plays in an investigation of a foodborne illness.

2) Improve federal/state coordination in the management and response to foodborne illness

Better coordination between federal and state agencies and among the various state agencies would speed the identification and subsequent control of foodborne illness and the removal of the contaminated foods from the distribution chain.

In order to improve coordination, the federal agencies can sponsor a national meeting with state and local officials to develop recommendations on how to better coordinate the overall government response to foodborne illness.

For example, one specific issue that is discussed in FDA's FY98 budget is the occurrence of *Salmonella enteritidis* in layer hens and improved monitoring of the hens and liquid bulk egg products (before pasteurization) for contamination. The federal agencies should work to establish a federal/state cooperative program to solve this problem.

3) **Enhance the basic infrastructure for foodborne illness surveillance and coordination at state health departments**

The epidemiology offices and laboratories within state health departments are charged with the surveillance of infectious and non-infectious conditions, and, along with other state officials, with the investigation of outbreaks. They collect surveillance data from physicians, laboratories, local health departments and other sources. Yet, the resources available in many states for the surveillance and investigation of foodborne diseases are limited and decreasing, thereby limiting the states' effectiveness. As a result, outbreaks may go undetected or are never investigated.

This problem could be rectified by making sure that, given an assessment and cataloguing of available state resources, states are provided support for foodborne disease surveillance programs and assistance to better investigate outbreaks of foodborne illness.

RISK ASSESSMENT

Background

It is a basic public health tenet that public resources devoted to reducing risks should be in proportion to the toll they take on human health. Risk assessment is the tool best suited to set priorities among public health risks. Furthermore, risk assessment is a requirement for any science-based system of preventive controls. Indeed, risk assessments and evaluations of alternative risk management strategies are often carried out for major federal regulations. Pursuant to the USDA's Reorganization Act of 1994, USDA is required to conduct risk analyses for all major regulations. Such evaluations ensure that risk reduction strategies are cost effective and promote the maximum net benefit to society of efforts to reduce foodborne illness. Sound risk assessments, including bacterial, parasitic, and viral food contaminants, are also critical to World Trade Organization treaty negotiations, which require that U.S. food safety standards be based on scientifically valid measures derived through risk assessment.

Preliminary Problem Identification

Risk assessment's objective is to characterize the nature and size of the risk to human health associated with hazards, and to make clear the degree of scientific certainty of the data and the assumptions used to develop the estimates. Risk assessments require a substantial amount of specific information on the hazard and on the exposed population to provide meaningful information for those making risk management decisions. Even for chemical hazards, for which risk assessment methods have been most thoroughly developed, data gaps force the use of assumptions about exposure, hazard potency, and characteristics of the population at risk, and mathematical "models" of chemical action or of the way that the body deals with a chemical.

Risk assessment is far less developed for foodborne pathogens. Intensive commitment is necessary to develop critically needed data such as pathogen behavior in numerous foods under hundreds of conditions, and information about especially sensitive populations, such as children.

Current Thinking

This initiative's risk assessment activities would focus on developing better use of data and better models to inform surveillance plans, HACCP-based prevention strategies for process control systems and for food inspections, and research programs to fill critical food safety information gaps.

1) Establish a risk assessment consortium

All federal agencies with risk management responsibilities should establish jointly a new

consortium at which federal agencies can set collective priorities for risk assessment research and collective priorities and strategies for the further development and implementation of risk assessment and risk management. The consortium should be established at the Joint Institute for Food Safety and Applied Nutrition, a collaborative activity of FDA's Center for Food Safety and Applied Nutrition and the University of Maryland.

The consortium should focus federal research on developing data for risk assessments, focused and applied specifically to address the scientific, risk-based goal of preventive control that is the central principle of this food safety initiative.

Research supported and conducted through this initiative should cover several areas critical to developing our ability to conduct risk assessments for foodborne disease-causing organisms and to assess the effectiveness of control measures. Data and methods developed in response to the Safe Drinking Water Act Amendments of 1996, for example, will be relevant to food safety evaluations.

2) Develop better data and modeling techniques to assess exposure to microbial and chemical contaminants, including animal drug residues, through the food supply

Risk assessment of foodborne illness is dependent on accurately estimating the quantity of a toxin or pathogen ingested by the consumer (i.e., exposure assessment). This initiative would address the numerous data and modeling deficiencies in estimating exposure to microbial and chemical contaminants. Specifically, research should be conducted in: incidence and prevalence of microbial pathogens and chemical hazards in food; typical behaviors of commercial and home preparation operations; validation of dynamic exposure assessment models; intake data regarding food consumption patterns of the general population and sensitive subpopulations; and specific data on food vehicles of sporadic and epidemic disease. Research using biomarkers should be pursued. Biomarkers are surrogates that indicate that exposure has occurred or that some effect has occurred, particularly when actual evidence of exposure and effect are difficult or impossible to obtain.

3) Develop dose-response assessment models for use in risk assessment

Research is needed to estimate the relationship between the quantity of a biological agent and the frequency and magnitude of adverse human health effects in a population. Dose-response assessments typically include estimates of the rates of infection, morbidity, and mortality. For bacterial hazards, the World Health Organization's Expert Consultation on the Application of Risk Analysis to Food Standards Issues (FAO/WHO, March 1995) refers to these steps as "hazard characterization."

BIOSCIENCE RESEARCH

Background

Currently, one of the most critical needs in food safety research is for techniques to more rapidly and accurately identify and characterize foodborne hazards. FDA, CDC, EPA, and the USDA's Research, Education, and Economics agencies (the Agricultural Research Service, the Cooperative State Research, Education, and Extension Service) conduct research related to pathogenic microorganisms and other contaminants that threaten the safety of food.

Preliminary Problem Identification

New pathogens, some of them foodborne, have emerged over the last 10 years. Many of these organisms can not be easily detected, or detected at all in foods. Other microorganisms, previously thought to be innocuous, have emerged as more virulent. Just because organisms are present at levels that can not be easily detected, however, does not mean that the organisms can not cause human illness. Newly recognized pathogens are causing serious disease outbreaks. Foodborne pathogens are increasingly overcoming time-tested controls, such as heating and refrigeration, and are developing new virulence and new ways to evade our immune defenses.

Current Thinking

Effective control of foodborne pathogens requires that prevention be targeted at high-risk foods and at high-risk points in their production and distribution. These interventions ideally are guided by risk assessment, for which all too often we have insufficient data. Research is needed to support HACCP implementation, to enable verification that critical control points in HACCP systems are working, and to target the data gaps that hamper risk assessment. Among the data gaps and information needs identified here are numerous opportunities for collaboration and resource leveraging among federal agencies, the private sector, and universities.

1) Improved detection methods

As stated above, many foodborne pathogens cannot be easily detected, or detected at all in foods. Methods need to be developed, validated, and implemented for rapid testing of very low levels of *Campylobacter*, *Salmonella*, *Toxoplasma*, *Vibrio*, *E. coli* O157:H7, *Cyclospora*, *Cryptosporidium*, Norwalk virus and naturally occurring toxins in food animals, in agricultural and aquaculture products, animal feeds, and processed food products. Some research efforts may initially focus on *Campylobacter*, because those foodborne infections are so prevalent and may lead to chronic diseases (Guillain-Barré syndrome); also methods to isolate and identify this pathogen are time-consuming and expensive. Research could be coordinated with EPA's efforts to develop better test methods and assessments of health effects from *Cryptosporidium* and other

contaminants in drinking water. Improved methods are needed for identifying foodborne pathogens, including emerging pathogens, in clinical specimens and to subtype known foodborne pathogens.

2) Understanding antimicrobial resistance

Microorganisms can become resistant to antimicrobial agents and conditions that have been traditionally relied on to eliminate or prevent the growth of foodborne pathogens, but have become insufficient to prevent breakthrough of newly emerging pathogens. Research is needed to determine how microorganisms associated with foodborne disease become tolerant to various types of antimicrobials and to traditional food safety safeguards such as heat or cold, low pH, high salt, and disinfectants and to elucidate factors in animal and plant production systems and processing environments that influence the development of resistance. This research will lead to the identification of food production and processing practices that are likely to permit pathogen contamination or proliferation and will provide guidance in the modification of traditional techniques or the development of new techniques to prevent or control pathogen growth.

3) Understanding antibiotic drug resistance

Pathogens in food-producing animals may become resistant to drugs partially due to improper use of the drugs, particularly antibiotic drugs, in those animals. One possible way to deal with this problem might be to adjust the required period of drug withdrawal prior to slaughter. For example, studies should be conducted to explore possible changes to "withdrawal time" requirements that could reduce transfer of resistant pathogens with minimal disruption to industry production practices. In addition, industry in collaboration with federal agencies could determine the basis for the ability of microorganisms to rapidly adapt to changing environments and, together, develop animal production and treatment mechanisms to minimize this adaptive ability.

4) Prevention techniques: Pathogen control, reduction, and elimination

Contaminants are introduced into the food supply at numerous points along the way from farm to store. Food animals may carry pathogens, but remain healthy themselves, complicating controls at the point of slaughter. Animal feed and drinking water can be "hidden" but significant sources of contamination. Possible research recommendations to address these problems for *Salmonella*, *Campylobacter*, *Toxoplasma*, *Vibrio*, *E. coli* O157:H7, *Cyclospora*, *Cryptosporidium*, and Norwalk virus in all food products are the following (to be carried out in conjunction with universities and the private sector):

- Develop drugs and other therapies to prevent initial colonization.

- Develop new methods to reduce or eliminate contaminants from animals and plants before slaughter or harvest.
- Develop new disinfection methods and equipment and systems modifications for processing and production plants, and wholesale and retail outlets.
- Develop new methods of surface decontamination of fresh fruits, vegetables, meat, poultry.
- Develop heat-based and/or other disinfection methods for seafood, meat, eggs, produce, and animal feeds.

5) **Food handling, distribution, and storage**

Food production and processing often occur thousands of miles apart. Transportation systems for live animals, fresh produce, and packaged foods offer many opportunities for contamination, such as heat, cold, and other stresses that make animals and plants more susceptible to infection, and cross-contamination from the vehicle itself. Possible research recommendations include the following:

- Investigate immune system "biomarkers" of stress that might indicate predisposition to infection during transport.
- Develop in- or on-package sensors of storage conditions to alert consumers of products not stored safely.

INSPECTIONS

Background

Inspection of commercial food processors is an integral part of the food safety assurance system. Inspections are carried out by federal, state and local authorities, with state and local officials focusing primarily on restaurants, supermarkets and other retail establishments. At the federal level, consistent with legal mandates, FSIS has carcass-by-carcass inspection in meat, poultry, and slaughter plants while they are operating, and continuous inspection in meat, poultry, and egg-product processing plants--in all, about 8,000 inspectors for 6,500 domestic plants and for all imported meat, poultry, and egg products. FDA does periodic, random inspections of all other food processing plants--less than 700 inspectors and analysts for 53,000 U.S. plants and for all other imported foods.

Preliminary Problem Identification

At FDA, the number of inspections has decreased steadily since 1981, when 21,000 inspections were conducted, so that today resources exist to carry out only about 5,000 inspections per year. The result is that an FDA-regulated plant gets inspected by FDA, on the average, only once every 10 years. FDA also relies upon the states to conduct some inspections under contract, but that number has dropped from 12,000 in 1985 to 5,000 now. Moreover, the inspectional coverage of imported foods has dropped as well, as the same number of import inspectors are now inspecting almost twice as many imports as just five years ago. Certainly FDA is finding greater problems, e.g., the number of products recalled for life-threatening microbial contamination has increased almost 5-fold since 1988 and inspectors are finding more hazardous conditions in the plants they inspect. FSIS is faced with a similar challenge of continually providing the most effective inspection program with limited resources and growing threats to food safety.

Current Thinking

Scientists and other food safety experts have concluded that the most effective and efficient mechanism for assuring that food processors identify and control hazards that could threaten food is the application of the HACCP concept of built-in preventive controls. FDA has begun to implement HACCP for the seafood industry, and FSIS for the meat and poultry industries; FSIS intends to publish an ANPR requesting comments on HACCP systems for egg processing plants, and FDA plans to work with the food industry, as it has in a pilot program over the last 2 years. To ensure that HACCP is properly implemented, and to ensure more efficient and effective monitoring of the safety of the food supply, the following preliminary recommendations are being made.

1) Enhance development of HACCP procedures

FDA is considering whether and how to implement HACCP throughout the non-meat/poultry food industry for all appropriate food commodities. It is recognized that staged implementation, by commodity, might be necessary because of resource limitations. To ensure that HACCP is being properly implemented, FDA should conduct inspections and provide necessary training and outreach activities. FSIS will continue development of a HACCP-based inspection system. FSIS plans to conduct a public meeting and then subsequent field trials to gather data to support future decisions on designing new inspection procedures in a HACCP environment.

2) Upgrade FDA's food inspection program

FDA has included implementation of seafood HACCP in its FY98 budget request. If HACCP is to be an effective program for ensuring that food processors have modern, state-of-the-art food safety procedures in effect, FDA must improve its inspection capabilities, so that the highest risk food plants (such as seafood) are inspected at least once per year. To maximize the joint federal/state role in inspections, development of new partnerships with the states may be considered, that focus on coordinating the inspection coverage and preventing duplication of effort.

FSIS and FDA may consider expanding and re-focussing existing cooperative agreements under which plants producing both meat and non-meat foods are inspected solely by FSIS inspectors, who have been trained in FDA inspectional standards. FSIS inspectors are already in the plants; their presence could be better utilized to maximize use of federal resources.

FSIS and FDA are considering whether and how to regulate the transportation of meat, poultry, seafood, eggs and other foods in order to safeguard the public from pathogenic microorganisms, as reflected in the ANPR published on November 22, 1996.

3) Enhance federal/state inspection partnerships

Additional federal/state partnerships can ensure improved coordination between the federal food safety agencies and state regulators for the training of state inspectors in federal food safety standards, as well as provide the states with equipment and technology for the rapid sharing of inspection results and for a national database for the monitoring of all food inspections. This information sharing would help both federal and state regulators make inspections more effective and efficient.

FDA may consider establishing a process for certifying private laboratories that would be authorized to test samples of food products for contaminants. This may embody a similar process currently being discussed by a coalition of industry, private laboratories, professional

associations, and accrediting bodies with input from federal agencies. Such private parties would provide a service to food firms wishing to demonstrate that their products meet applicable federal standards.

4) **Enhance inspectional coverage of imported food, to address the problem of rising imports and FDA's inability to provide adequate inspections of them**

FDA should develop more Mutual Recognition Agreements (MRAs) with foreign countries, under which both countries agree to inspect each other's food exporting firms under equivalent procedures for ensuring safety. Once such MRAs are in place, FDA could better focus its import inspections on foods coming from countries with the least reliable safety standards.

EDUCATION

Background

Educating people about steps they must take to prevent and control foodborne illness is a vital link in the food preparation chain. Educational efforts have already been made at the federal level. For example, FDA has a website which offers information on many food safety issues, has established a 24-hour seafood hotline, and has published brochures on such topics as food safety advice for persons with AIDS and posters on such topics as listeria in soft cheese. USDA has taken similar steps through its Cooperative Extension network, its Meat and Poultry Hotline, and by requiring safe handling instruction labels for meat and poultry products.

Preliminary Problem Identification

Despite these efforts, and the work that states, consumer groups and the food industry have done in this area, foodborne illness still occurs from a lack of knowledge of the risks involved at all stages of food preparation. For instance, choices consumers make about how they handle food prepared at home and whether they eat food that increases the risk of foodborne illness can have a significant impact on the incidence of foodborne illness. Studies show, for example, that 53% of the public eat food with raw eggs, 23% eat undercooked hamburger, 17% eat raw clams and oysters, and 26% do not wash their cutting boards after using them for raw meat or poultry.

Foodborne illnesses have also been traced to commercial food establishments. For example, many food establishments do not know that the pooling and undercooking of eggs can increase the risk of *Salmonella enteritidis*. Currently, a much higher percentage of those who receive their food in an institutional environment are victimized by the more serious consequences of foodborne illness. For example, during 1988 to 1992, *Salmonella* caused 69% of the 796 bacterial foodborne disease outbreaks; 60% of these *Salmonella* outbreaks were caused by *S. enteritidis*. *S. enteritidis* also resulted in more deaths than any other pathogen with 85% of these deaths occurring among residents of nursing homes.

Producers of animals used in human foods production and veterinarians treating such animals also need education in food safety practice. Drugs used to treat these animals are not always used appropriately, and can be purchased over the counter by non-veterinarians and mis-used, resulting in harmful residues in meat and milk, decreased effectiveness of these drugs, and increased antimicrobial resistance.

Finally, those responsible for the transportation of food are often unaware of unsafe practices that result in the contamination and mishandling of food during shipment.

Current Thinking

Understanding and practicing proper food handling procedures from farm to table would significantly reduce foodborne illness.

1) Improve consumer education

An alliance including industry and consumer groups should mount a comprehensive food safety awareness campaign for consumers, highly focused on messages and tactics targeted to the general public and to special populations such as high-risk consumers. The campaign should be centered around an easily recognized symbol or catch phrase and should include a national print and broadcast media campaign and incorporate food safety messages into school curricula. An emphasis should be placed on multilingual activities to ensure the widest coverage.

Innovative methods for sharing information related to food handling behaviors should be developed in order to reach larger audiences. As part of this effort, a National Food Safety Education Alliance of industry, consumer, trade, state and local food protection agencies, and academic organizations focused on changing unsafe food handling practices should be convened. Research should be conducted to determine effective methods of providing information and evaluation of educational programs. A national clearinghouse should be established to provide consumers and food safety educators with food safety information.

2) Improve retail, food service, and institutional education

A highly focused campaign should be developed to change food workers' unsafe food preparation behaviors. A multilingual approach should be developed. An alliance of federal, state, and local health agencies, as well as private parties, should be formed to develop education efforts on food safety issues. Activities of the alliance should include educating retail food service workers about the safe handling perishable food product provisions in the 1997 *Food Code*.

In addition, guidelines should be developed by USDA and the states for retail and food service operations which process meat and poultry products to train state level inspectors to identify hazards at the retail level. Efforts should also be undertaken to educate the retail, food service and institutional industries in order to increase the use of HACCP principles.

3) Improve veterinary and producer education

Development and implementation of a program could be considered to educate producers of animals for human food consumption, veterinarians, state and local regulators about proper drug use and the incorporation of HACCP principles into industry quality assurance programs. The

program could entail regularly scheduled training sessions, including satellite teleconferences, educational symposia, and presentations at producer and practitioner meetings. Guidelines and educational materials could also be developed and disseminated through a national clearinghouse to food producers and the veterinary medical community.

4) Improve industry education in the transportation area

Government agencies could form an alliance to develop educational materials and train food transportation vehicle owners and operators and food processing establishments on hazards associated with the transportation of food products, particularly hazards associated with temperature controls, prior cargoes, and sanitation methods. Training and education for state and local health and transportation authorities could also be conducted so they can apply this information during inspections of food processing facilities and transportation vehicles in their jurisdiction.

A STRATEGIC PLAN FOR REDUCING FOODBORNE ILLNESS OVER THE LONG TERM

Background

The broad issues of a sustainable safe food system include, among other issues, improving the infrastructure for rapid identification and response to outbreaks, improving coordination among all food safety participants in numerous aspects of prevention and response, and developing a strategic, long-range research agenda. Stakeholders include food producers and manufacturers, consumers, academic institutions, representatives from the food service sector, including retail, restaurant, and institutional food service settings, veterinary and medical professionals, and federal, state, and local public health and agricultural officials.

Preliminary Problem Identification

Making the necessary improvements in the food safety system will not be easy. Because so many lines of authority must be crossed, so many new working relationships established, and so many fundamental changes in infrastructure made, the current system must be “reinvented.” For example, the federal government needs to develop a long-term, coordinated research agenda to truly address research needs to support a fundamentally improved food safety system, and strategies for developing such an agenda would need to be developed through such a planning process. Extensive dialogue will be required among the many stakeholders in various regions of the country to agree upon priorities, strategies for achieving change, and a process for achieving change.

Current Thinking

A significant activity proposed as part of this food safety initiative is the creation of a process that facilitates the participation of all stakeholders in discussing the issues and setting an agenda for consideration of fundamental change in the food safety system.

A contract could be established with an independent organization to bring together all major stakeholders for discussion of fundamental changes to the present food safety system. A major purpose of this strategic planning exercise would be to identify changes that should be made to the present organizational and procedural structure that would bring about permanent improvements in efficiency and coordination. Dialogue groups could be established to develop a strategic plan. Opportunities for input could include symposia held in geographically dispersed sites to encourage stakeholder participation.

Documents developed from the deliberations and recommendations of these symposia could be the focus of further discussion during a series of open meetings. The product of this series of

dialogues, symposia, and hearings could form a report, which would provide the outline necessary for targeting needed structural changes in the federal/state food safety system.