

Food Safety Event Meeting Agenda

Food Safety
Pulse
net

Overview

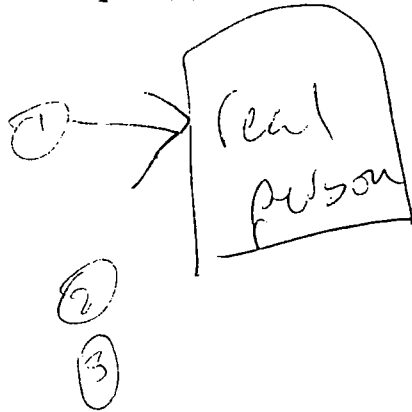
Message of the event

Elements of the event

1. *Food Safety Initiative 1999 Budget Proposal*
2. *PulseNet*
3. *ForcG*
4. *MOU*
5. *Foodborne Illness Report(?)*
6. *Other*

Players

VPOTUS
HHS
CDC
FDA
USDA
EPA
Food Safety Consumer Advocate
Other?



Sequence of event

Location

Audience

Press Strategy

Other Issues

HHS
USDA
EPA
VPOTUS

Food Safety Event --
Participants and phone numbers

Domestic Policy Council
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HHS
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USDA
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EPA
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DRAFT

SCHEDULE PROPOSAL

☐ ACCEPT	☐ REGRET	☐ PENDING
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TO: Kim Tilley, Director of Scheduling for the Vice President

FROM: Morley Winograd, Senior Policy Advisor to the Vice President

REQUEST: Vice President announces release of USDA report on food-borne illness, as well as ForcG MOU signing and initiation of PulseNet computer system.

BACKGROUND: Food-borne illnesses and the government's efforts to deal with it are frequently in the media. The National Food Safety Initiative is pending before Congress in '99 budget. The legislation would increase the budget for USDA (46 million) and HHS (55million) for food safety activities. The administration strongly supports the National Food Safety Initiative legislation.

This event would highlight three new food safety initiatives.

1. The release of a comprehensive report by the USDA, CDC and FDA on the incidence of food-borne illness in the United States.
2. The signing of an MOU between USDA, EPA, HHS (FDA, CDC) and state health associations to create "ForcG," a task force that will review food-borne illness outbreak response by Federal and state governments and, based on these findings, develop and implement accelerated response procedures.
3. The launching of "PulseNet," a web-site that will provide the DNA "fingerprints"(sequences) of foodborne illnesses-causing pathogens. This will enable state and Federal health agencies to quickly determine if the same pathogen is causing a similar outbreak in a different state or region -- also accelerating detection and response time.

PREVIOUS POTUS charged USDA, HHS, and EPA to identify specific steps to improve food safety in his radio address of January 27, 1997.

PARTICIPATION: VPOTUS has made several announcements regarding food safety initiatives..

DATE and TIME: May 21, 1998 Time: TBD

BRIEFING TIME: 10 minutes, NPR will provide information..

DURATION: c. 30 minutes

LOCATION: Roosevelt Room, or Indian Treaty or 450 in OEOP (suggested)

PARTICIPANTS: VPOTUS, Department and agency heads from HHS, USDA, EPA, 5 state association representatives, employees from the agencies, press.

OUTLINE * VPOTUS opens. Makes brief remarks (8 minutes) -- announces the release of the report on the national incidence of food-borne illness, salutes the signatories of the MOU creating ForcG, and outlines the advantages of PulseNet..

OF EVENT: .

conduct *

* VPOTUS turns on computer launching PulseNet. Then agency reps demonstration of its capabilities. (5 minutes)

* CDC, FDA, USDA (EPA?) speakers make brief remarks (4 minutes each)

* Consumer food safety advocate speaks (4 minutes)

* VPOTUS closes (1 minute)

REMARKS: Prepared by OVP speechwriters with NPR input.

MEDIA: National print, radio, TV. Local print, radio, TV. Federal government, trade press. NPR press office will coordinate with VPOTUS press.

CONTACT: Tom Flavin, 694-0032
Annetta Cheek, 694-0024

05-13-98 10:21:47 PM: USDA FSIS 04 1000000000

MEMORANDUM OF UNDERSTANDING

AMONG

THE UNITED STATES DEPARTMENT OF AGRICULTURE

AND

THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES

AND

THE ENVIRONMENTAL PROTECTION AGENCY

I. INTRODUCTION

A. Parties

The parties to this agreement are the United States Department of Agriculture (USDA), the United States Department of Health and Human Services (HHS) and the Environmental Protection Agency (EPA).

B. Background

While the American food supply is among the safest in the world, there are still millions of Americans stricken by illness every year caused by the food they consume, and some 9,000 a year — mostly the very young and elderly — die as a result. The threats are numerous and varied, ranging from *Escherichia coli* O157:H7 in meat and apple juice, to *Salmonella* in eggs and on vegetables, to *Cyclospora* on fruit, to *Cryptosporidium* in public drinking water supplies — and most recently, to hepatitis A virus in frozen, sliced and sugared strawberries.

In his January 25, 1997 radio address, President Clinton directed three Cabinet members — the Secretary of Agriculture, the Secretary of HHS, and the Administrator of the EPA — to identify specific steps to improve the safety of the food supply. Their May, 1997, report to the President identified several issues and outlined a comprehensive new initiative to address those issues and improve the safety of the Nation's food supply.

One issue addressed in the report to the President was the coordination among federal, state and local agencies in responding to interstate outbreaks of foodborne illnesses. This MOU builds on previous Administration steps to modernize our food safety system and respond to emerging challenges as well as creating partnerships and leveraging the resources of federal, state and local agencies as part of the Vice President's National Partnership for Reinventing Government.

Four federal entities are charged with responding to outbreaks of foodborne illness (for the purpose of this MOU, foodborne illness also includes waterborne illness): USDA, EPA, and the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) at HHS. Each of the four federal agencies has a critical role when a outbreaks occur. CDC's primary responsibility is to assist state and local health departments in investigating outbreaks of illness and in identifying the cause of the outbreak. FDA, the Food Safety and Inspection Service (FSIS) at USDA, and EPA also have responsibility for determining whether a product they regulate may be causing illness, and for halting the spread of illness by taking regulatory action against the suspect products, or wastes (other than animal manures) that have the potential to contaminate the air, land, or waters used to produce the food product. The food product implicated in a foodborne outbreak determines which regulatory agency has primary jurisdiction. FSIS regulates meat, poultry, and egg products; FDA regulates all other foods including game meats, bottled drinking water and shell eggs; and EPA regulates water, drinking water from public systems and pesticides, and manages organic and inorganic wastes used or disposed of on agricultural land. While each entity has clearly defined areas of responsibility, the successful containment of many outbreaks of foodborne illness involves more than one federal entity.

All states and many local governments with varying expertise and resources share responsibility with the federal agencies for response to such outbreaks and, also, have a critical role. Identification and investigations of foodborne illness often begin at the community or state level. States and local governments share with the federal government the legal responsibility for protecting the health of their residents. The majority of foodborne outbreaks occur at the local or state level, however, many outbreaks involve federal agency jurisdiction. Illnesses cross state borders, and most foods or food ingredients are processed or produced in another state or by international trading partners. Federal involvement is also necessary when contaminated food from a common source has been distributed to grocery stores, restaurants, and homes in more than one state.

When outbreaks of foodborne illness occur, federal agencies work with state and local health and agricultural authorities in their investigation and in implementation of control measures through consultation, diagnostic assistance, and by regulatory action against the products. In some instances, on-site assistance is requested by local and state authorities from the CDC to establish the cause of an outbreak, and from other agencies to help find the source of the problem. For large or multistate outbreaks, federal agencies play a critical coordination role to ensure consistency of approach and implementation of needed control measures.

C. Recognition of Need

Although significant communication already occurs among the federal agencies; among federal, state and local agencies; among the various state agencies; and between state and local agencies, better coordination is needed to meet new and growing threats to the nation's food supply, enhance the level of public health protection, provide standards for prevention of future foodborne illness outbreaks, leverage agency resources and experience, and avoid duplication of effort and move more quickly since products can be widely distributed.

Further, a critical element of an effective, rapid response to a foodborne illness outbreak is ready communication by all the involved parties. Although there are communication systems in place, the systems need to be expanded and coordinated to achieve rapid exchange of information and data between key outbreak response personnel in each agency at the federal, state and local levels and the affected food industry.

The report to the President recommended the establishment of an intergovernmental group, to be known as the Foodborne Outbreak Response Coordinating Group, to improve the approach to interstate outbreaks of foodborne illness and develop a national, coordinated outbreak response system.

II. PURPOSE

A. This memorandum of understanding ("Memorandum") among the parties is entered into in order to form the Foodborne Outbreak Response Coordinating Group ("FORCG").

B. The purpose of the FORCG is defined by the following goal, mission and objectives:

1. It is the goal of FORCG to improve the approach to interstate outbreaks of foodborne illness by federal, state and local agencies charged with responding to such outbreaks.
2. Toward this goal, it is the mission of FORCG to include federal, state and local agencies with outbreak response duties in the development of a national comprehensive and coordinated foodborne illness outbreak response system.
3. This mission will be accomplished by subscribing to the following management objectives which will, in turn, guide FORCG:
 - a. FORCG will review and evaluate outbreak response at the federal agency level (among agencies), including cooperation among federal agencies and between state and local agencies and affected industries. FORCG will identify areas where efficiency can be gained and make specific recommendations for improvement. FORCG will work with federal, state, and local governments, the food industry, health professionals, and consumer advocates to implement beneficial changes.
 - b. Standard operating procedures will be developed for the rapid exchange of data and information associated with foodborne illness outbreaks between involved agencies and for dissemination to the public. The procedures will cover the exchange of data and information associated with an outbreak and will complement systems established for exchange of information about day-to-day occurrences of foodborne illness.

c. A nationwide survey will be conducted to catalogue existing state and local food safety program infrastructures.

d. Working groups will be established to develop recommended procedures for outbreak response coordination between federal and state agencies, and between state and local agencies levels to improve the coordinated response to interstate outbreaks.

III. ORGANIZATION AND MEMBERSHIP

A. Under Title II, Section 204, Subpart (a) of the Unfunded Mandate Reform Act of 1995, Pub. L. 104-4, elected state officers, or their designated representatives with authority to act on their behalf, may meet with federal officers to exchange views, information, or advice relating to the management or implementation of federal programs established pursuant to public law that explicitly or inherently share intergovernmental responsibilities or administration. The parties, therefore, agree that all members of FORCG will be federal officials or state employees with the requisite authority.

B. FORCG will have the following members:

1. Two representatives from USDA: The Under Secretary for Food Safety and the Administrator for FSIS, or their designees.

2. Four representatives from HHS: The Assistant Secretary for Health, the Commissioner of the FDA, the Director of CFSAN and the Director of CDC, or their designees.

3. Two representatives from EPA: The Assistant Administrator for the Office of Prevention, Pesticides and Toxic Substances and the Assistant Administrator for Water, or their designees.

4. One state employee who is a representative of the Association of Food and Drug Officials.

5. One state employee who is a representative of National Association of City and County Health Officials.

6. One state employee who is a representative of the Association of State and Territorial Public Health Laboratory Directors.

7. One state employee who is a representative of the Council of State and Territorial Epidemiologists.

8. One state employee who is a representative of the National Association of State Departments of Agriculture.

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IV. RESPONSIBILITIES AND SCOPE OF WORK

- A.** FORCG will be co-chaired by the Under Secretary for Food Safety (USDA) and the Assistant Secretary for Health (HHS). His or her designee will facilitate each meeting.
- B.** One member will be designated as the outbreak response coordinator for each department or agency that has a role in an outbreak response. The duties of each outbreak response coordinator will be identified as FORCG develops the overall outbreak response system. HHS will designate the Assistant Secretary for Health as the primary person in charge of coordination for HHS. USDA will designate the Under Secretary for Food Safety as the primary person in charge of coordination for USDA. EPA will designate the Assistant Administrator for Water as the primary person in charge of coordination for EPA when drinking water is involved, and the Assistant Administrator for the Office of Prevention, Pesticides, and Toxic Substances will be the primary person when Pesticides and Toxic Substances are involved.

V. GENERAL PROVISIONS

- A.** FORCG will meet Bi-monthly.
- B.** This Memorandum may be modified with supplemental written agreements signed by the parties and can be terminated in writing, in whole or in part, by consensus of the parties.
- C.** This Memorandum will become effective on the date the final signature is affixed hereto.
- D.** This Memorandum is entered into within the limits of the statutory authority of the parties to the Memorandum.

SIGNATURES

Department of Health and Human Services
U. S. Department of Agriculture
Revised February 1998

1999 Budget Proposal for Food Safety Initiative

Backgrounder

Executive Summary

Backgrounder

U.S. Department of Agriculture

Department of Health and Human Services

Revised February 1998

1999 National Food Safety Initiative

On January 25, 1997, the President announced the National Food Safety Initiative. The initiative includes components for reducing the incidence of foodborne illness from farm-to-table. Key components include expansion of the Federal food safety surveillance system, improved coordination between Federal, State, and local health authorities, improved risk assessment capabilities, increased inspection, expanded research, consumer education, and strategic planning. Utilizing the funds provided by Congress in 1998, an increase of \$43 million, the U.S. Department of Agriculture (USDA) and Department of Health and Human Services (HHS) have initiated changes to ensure the safety of a wider variety range of food products from a broader range of hazards. In addition, USDA and HHS have identified measures that need to be taken to ensure the safety of fresh fruits and vegetables consistent with the President's directive on this issue. USDA, HHS, and other interested parties will seek input on measures that can be taken to improve food safety during production, transportation, storage, distribution, and in the home.

1999 Budget Request

For 1999, the Administration is proposing an increase of \$101 million for the National Food Safety Initiative. Of this amount, \$46 million is allocated to USDA and \$55 million to HHS. The 1999 National Food Safety Initiative builds on the successes of the 1998 initiative as well as fills the gaps that have been identified in the past year. In 1999, the focus of the initiative is on enhancing the safety of imported and domestic fruits and vegetables, targeting food safety education, implementing of Hazard Analysis and Critical Control Point (HACCP) systems in appropriate sectors of the food supply, and developing of scientific information and tools to control a greater range of food safety hazards. Funding is requested for the following activities:

Enhance surveillance and investigation to improve outbreak response (+\$7 million):

HHS (+\$6.7 million): The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) will work with States to identify potential food safety threats early. CDC and FDA will further build the capabilities and coverage of the FoodNet early-warning surveillance system and will improve monitoring of threats to food by expanding the range of pathogens under surveillance. The agencies also will improve information sharing among agencies and with the public, and provide training and technical assistance to State/local agencies for outbreak investigation.

USDA (+\$0.3 million): The Economic Research Service (ERS) will evaluate the effectiveness of food safety measures by analyzing foodborne illness surveillance data. New estimates will be developed for the national incidence of foodborne disease, distribution of illness among subpopulations, and rates of illness.

Strengthen coordination and improve efficiency (+\$0.2 million):

HHS will work with other Federal agencies and States to expand assistance to states and local governments in developing the infrastructure necessary to ensure proper detection, evaluation, and coordination in response to foodborne outbreaks. Standard operating procedures for sharing information and data among agencies and with the public on foodborne outbreaks will be developed.

Improve capability to estimate risks associated with foodborne hazards (+\$11 million):

HHS (+\$7 million): FDA will initiate a program of research in quantitative risk assessment (particularly for microbial hazards) that is targeted to address the limitations in risk assessment methodologies and available data related to 1) dose-response relations for the general population and high risk groups (e.g. neonates, elderly, immune-compromised), 2) the impact of production, processing, distribution, marketing, and preparation practices, and 3) the quantification of factors contributing to incidence and prevalence of pathogenic microorganisms in raw ingredients and finished products. FDA will continue to build the activities of the interagency Risk Assessment Consortium at the Joint Institute for Food Safety and Nutrition (JIFSAN) that provides a forum for coordination of federal microbial risk assessment research and serves as a clearinghouse for risk assessment information and expertise.

USDA (+\$4 million): The Agriculture Research Service (ARS), Cooperative State Research, Education and Extension Service (CSREES), ERS, FSIS, and the Office of the Chief Economist (OCE) will conduct quantitative risk assessments to identify food safety hazards and controls, make faster and more accurate regulatory decisions, target program resources more effectively, and facilitate the development and evaluation of surveillance plans and risk reduction strategies.

Expand inspection and compliance efforts, implement new preventive measures with a new emphasis on domestic and imported produce, and facilitate the implementation of HACCP (+\$36 million):

HHS (+\$28 million): FDA will enhance protection of American consumers by seeking legislation that would decrease the risk of importing unsafe food products from countries with food safety systems for exported products that are not on a par with the U.S. system or that refuse to allow entry of U.S. investigators into facilities producing products offered for import. FDA will verify implementation of seafood HACCP and implement HACCP for juices. FDA will provide technical assistance and educational outreach to promote the appropriate application of voluntary good agricultural practices/good manufacturing practices (GAP/GMP) guidance in the domestic fresh produce industry.

USDA (+\$8 million): The Food Safety and Inspection Service (FSIS) will provide special onetime assistance to State meat and poultry inspection programs to facilitate implementation of HACCP.

Continue to build the national food safety education campaign (+\$14 million):

USDA (+\$10 million) and HHS (+\$4 million) for the following activities:

Consumer and Food Handler Education--USDA (+\$5 million) and HHS (+4 million): Building on the national campaign launched by the public-private Partnership for Food Safety Education in 1997, FSIS, CSREES and FDA will target specific programs to change unsafe behaviors used by home food handlers, cooks and food handlers in retail settings and in congregate feeding sites. CDC, FSIS and FDA will begin development of materials to assist in educating school children about how to prevent foodborne illness. FDA will target vulnerable groups (e.g., those affected by *Vibrio* in raw oysters and pregnant women and *Listeria*) with specific food safety messages. FDA will develop multilingual training programs for food service and retail workers and provide technical assistance to domestic and foreign fresh produce industries to promote appropriate application of good agricultural and manufacturing guidance. FSIS will target vulnerable groups (e.g., senior citizens and people with compromised immune systems) and will launch a campaign to promote thorough cooking of meat and poultry products.

School Food Service Provider Education--USDA (+\$2 million): The Food and Nutrition Service (FNS) will develop and operate training workshops to educate local school food service professionals about the latest safe food handling practices specific to their needs and the updated Food Code.

Producer Education--USDA (+\$3 million): FSIS and CSREES will work with industry and academia to educate food animal producers and fruit and vegetable producers on food safety assurance practices, risk management, and risk communication.

Accelerate food safety research efforts (+\$33 million):

(USDA +\$24 million and HHS +\$9 million)

Research will be conducted to enhance understanding of pathogen growth and control and will focus in the four areas identified in interagency research planning as critical to reducing microbial risk in produce. Improved detection methods, particularly rapid tests, will be developed that identify a broader range of pathogens on food products, particularly fresh fruits and vegetables, throughout the food production, manufacturing, and distribution system. Development of prevention/intervention strategies is another area of focus, with research on development of alternative food production, processing, and handling systems that eliminate or reduce pathogen contamination. Research on identification of conditions under which food products become contaminated during food handling, distribution, and storage will play an integral role in this research. FDA and USDA will conduct research on resistance to traditional preservation techniques and antibiotic resistance. USDA will develop a microbiological baseline for pathogens on fresh fruits and vegetables utilizing existing program infrastructure.

FOOD SAFETY FROM FARM TO TABLE: A NATIONAL FOOD SAFETY INITIATIVE

EXECUTIVE SUMMARY

A Consolidated, Multi-Agency Plan for Improving Food Safety

The fiscal year (FY) 1999 integrated food safety initiative budget presents a coordinated proposal of actions to enhance the safety of the Nation's food supply by building on the accomplishments that have begun to be realized in FY 1997 and will be furthered in FY 1998. The FY 1998 budget initiative brought new resources to enhance surveillance of foodborne disease outbreaks and better coordinate our response to outbreaks, improve inspections and compliance, target important new research and risk assessment to critical scientific gaps, and expand education and training especially to promote the use of safe food handling practices. The FY 1999 initiative will build on gains made in these areas, and place increased emphasis on ensuring the safety of domestic and imported fresh produce. Our experience of working together for the past year has also helped us identify new opportunities to avoid duplication of effort and to leverage agency resources.

The Administration, through a Presidential Directive issued on October 2, 1997, is taking additional actions to improve the safety of domestic and imported fresh fruits and vegetables. The President has proposed additional funds to enable the Food and Drug Administration (FDA) to expand dramatically its coverage of imported foods and will continue to seek legislation that would enable FDA to prevent the import of fruits, vegetables, or other foods from any foreign country whose food safety systems for exported products are not on par with those of the United States. Additional funds are included in the budget for the U.S. Department of Agriculture (USDA) and FDA for research that will enhance our understanding of pathogenic contamination on fruits and vegetables and lead to improved controls for ensuring the safety of these commodities. In addition, the President has directed the Secretaries of the Department of Health and Human Services (HHS) and USDA to work together with the agricultural community to develop guidance on good manufacturing practices and good agricultural practices for fruits and vegetables as well as to accelerate food safety research, and provide education and outreach to domestic and foreign producers. FDA, working with USDA, undertook development of these guidelines and public outreach to the broad agricultural community with no new resources in FY 1998.

The impetus to focus increased Federal attention on food safety came from a number of sources. The most important of these sources is the rapidly increasing number and complexity of food safety problems (such as newly recognized pathogens and their appearance on foods, such as fresh produce, where they had not been detected before). These trends, along with the increasing number of foodborne disease outbreaks, and increasing public concern, highlighted the need for significant new resources to help the food safety agencies will not be able to meet the challenges of the 21st century. Estimates cited in the report released by the Vice President in May 1997 are that every year from 6.5 million to 33 million Americans become ill and as many as 9,000 die as a result of foodborne pathogens. These illnesses and deaths are far too many. Our challenge is to continue to build the best food safety system possible and to reduce the burden of avoidable human suffering and economic loss to the greatest extent possible.

The FY 1998 Food Safety Initiative

The increase of \$42.8 million approved by Congress for FY 1998 to support the President's National Food Safety Initiative is the first installment of a major governmentwide effort to enhance the safety of the Nation's food supply. The initiative has won wide support among industry and consumer groups and the general public.

The FY 1998 Food Safety Initiative cited seven critical elements of a comprehensive and more effectively coordinated nationwide program required to improve the safety of the food supply and, thereby reduce the possibility that consumers will suffer the adverse health and economic consequences of foodborne infections. Key components of this interagency initiative included the following activities:

- Build enhanced "early warning" and surveillance systems to help detect and respond to foodborne illness outbreaks, and to provide the data needed to prevent future outbreaks.
- Achieve better coordination of interagency responses to foodborne disease outbreaks including electronic communication and data exchange among Federal, State, and local health authorities.
- Develop and implement inspection strategies that provide greater assurance of the safety of foods, including implementation of Hazard Analysis Critical Control Point (HACCP) and other food safety control systems, and enhanced inspection coverage of food processors and imported foods.
- Improve risk assessment methods for foodborne pathogens and develop data bases needed to help food safety agencies to better characterize the nature and size of risk to humans and make decisions on how to best allocate resources to control the hazards.
- Expand food safety education and training particularly for consumers and retail food service workers to acquaint them with safe food processing, storage, and handling techniques.
- Conduct research to develop more effective methods for detecting, controlling, and preventing foodborne hazards.
- Continue long-range strategic planning for improving the food safety system.

The FY 1999 Food Safety Initiative

The FY 1999 Food Safety Initiative further reflects the coordination between the Federal food safety agencies and builds on the key components identified in the FY 1998 initiative. A new focus is being placed on enhancing the safety of domestic and imported fruits and vegetables, facilitating the adoption of HACCP systems, improving the food handling practices of school food service providers, and develop information and tools necessary to cover a broader range of food safety hazards.

Surveillance

CDC, USDA, and FDA will continue to build the capabilities of the national early-warning surveillance system to help detect and respond to outbreaks of foodborne illness earlier, and will add new emphasis on training, technical assistance, and investigations.

Enhance surveillance and investigative systems: CDC and FDA will direct additional resources to FoodNet sites and other State and local health departments to improve outbreak investigations, to expand the range of pathogens under surveillance, to begin implementing and evaluating control strategies, and to facilitate intrastate, interstate, and State-Federal information sharing. In addition, CDC will enhance foodborne disease surveillance and control activities, including standardized molecular subtyping methods for bacterial foodborne pathogens.

Epidemiologic and technical studies of emerging and drug-resistant pathogens and other contaminants: FDA will work with CDC and USDA to monitor the incidence of foodborne disease associated with emerging and drug-resistant pathogens. CDC will initiate training and technical assistance to State and local health agencies to improve diagnostic capacity for foodborne diseases and to support development of better diagnostic assays for clinical specimens.

Improve and enhance workforce competency: CDC will provide four new Epidemic Intelligence Service (EIS) officers to improve investigation of foodborne diseases, and will establish a training program in pathogen identification with an emphasis on new technologies aimed at a wide range of State Health Department professionals.

Coordination

Federal agencies and State representatives have formed an intergovernmental group, the Foodborne Outbreak Response Coordinating Group (FORCG), to evaluate and make recommendations for improving responses to interstate outbreaks of foodborne illness. This cooperative effort will be continued and expanded to provide rapid, efficient response to foodborne outbreaks and minimize their spread.

Expand assistance to State and local Governments: FDA, USDA and CDC will work with other Federal agencies to expand assistance to State and local Governments to develop the infrastructure necessary to ensure quick and accurate detection and coordination of response to outbreaks, and evaluation of those responses.

Inspections and Compliance

Monitoring the food supply to ensure its safety must occur at several levels to be effective: for example, Federal assessment of agricultural and production practices in foreign countries; Federal oversight of imported and domestic products in the

United States; local oversight of food processing and manufacturing facilities, retail food, food service, and institutional establishments such as school lunch programs. FDA, USDA, CDC and the Environmental Protection Agency (EPA) will build on and expand efforts already underway through the President's National Food Safety Initiative. These will include additional steps to ensure the safety of imported foods; development of good agricultural and good manufacturing guidance for produce; continued progress to implement HACCP for seafood, meat and poultry products; continued development of HACCP for appropriate sectors of the food industry; and additional progress toward development of partnerships among agencies at the Federal, State, and local levels.

Seek statutory authority to assure imported food safety: FDA is seeking statutory amendments to the Food, Drug and Cosmetic Act to enable the agency to assure that imported products are produced under systems that provide the same level of protection as the U.S. system.

Develop Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs) Guidance: FDA and USDA, will work with the agriculture community to develop and issue GAPs and GMPs to minimize microbial hazards in fresh produce.

Expand HACCP and HACCP training: FDA, working with industry partnerships, will expand HACCP in appropriate sectors of the food industry, such as implementing HACCP in the juice industry. USDA will provide HACCP training to State meat and poultry inspectors and provide special assistance to facilitate the transition of State programs to HACCP by 2000.

Develop assistance and outreach to State and local programs: FDA and USDA will work to expand efforts to achieve adoption of the Food Code.

Risk Assessment

Risk assessment methods help characterize the nature and magnitude of risks to human health associated with foodborne hazards and assist regulators in making decisions about where in the food chain to allocate resources to control those hazards. Risk assessment also focuses data collection and scientific research in the most critical areas. Working together, the Federal agencies with food safety and risk assessment responsibilities will build on and expand efforts already underway through the National Food Safety Initiative announced in May 1997. Intensive work is needed to develop better risk assessment methods and models to make it possible to carry out quantitative risk assessments for microbial agents.

Develop and evaluate risk-based pathogen reduction strategies for food animal producers: USDA will evaluate science-based pathogen reduction systems that are compatible with HACCP-based inspection systems. Evaluate costs and benefits of alternative pathogen control strategies using risk assessment results.

Expand activities of the Risk Assessment Consortium: In FY 1997, FDA, USDA, and EPA established an interagency risk assessment consortium at the Joint Institute of Food Safety and Applied Nutrition at the University of Maryland. The goal of the consortium is to cooperatively advance the science of microbial risk assessment. The agencies will work to further focus critical research needs and reach consensus on the priorities of those needs based on their potential to reduce the uncertainty of risk management decisions.

Develop better data on human exposures to foodborne agents: FDA, CDC, USDA, and EPA will work together to conduct several risk assessment activities including food-consumption surveys targeted to specific subpopulations, development of more effective exposure modeling techniques, and development of better animal models for infectious microorganisms.

Develop better modeling techniques: FDA, USDA, and EPA will develop more effective modeling techniques for the growth, death and adaptation of foodborne and waterborne pathogens at all points from farm to table.

Education

Food safety education is an integral part of a successful, coordinated food safety program. In FY 1997, FDA, Food Safety and Inspection Service (FSIS), Cooperative, State, Research, Education, and Extension Service (CSREES), and CDC laid the foundation for a nationwide food safety education campaign, in a new public-private partnership with industry, consumer groups, and State representatives through the Association of Food and Drug Officials. The basis of the campaign is four key food safety messages based on research to be used by educators nationwide. In FY 1998, the agencies are focussing on consumers. The goal for FY 1999 is to develop product-specific and audience-specific messages to address risks relevant to groups throughout the food chain.

Improve producer and distributor education: FDA and USDA will initiate communication about GAP and GMP guidance to appropriate audiences. USDA will continue coordination with States to educate producers, processors, and distributors on risk management, risk communication, and safety assurance.

Improve retailer and food service worker education: USDA will provide education to local school food service professionals based on the Food Code

(a 1999 revision is planned). FDA and USDA will continue training for State sanitarians on new retail and restaurant food processing techniques. Development of multilingual training programs (begun in FY 1998) will be expanded.

Develop education programs for school children: CDC, FDA, and USDA will train school teachers to teach food safety concepts to school children (in collaboration with State, territorial, local, and other relevant organizations).

Improve consumer and health professional education: FDA and USDA will continue to develop and implement research-based education materials to convey food safety information. CDC will educate and train epidemiologists and public health laboratory workers in proper detection, surveillance, and outbreak investigation of foodborne disease and, internationally, will work with the World Health Organization and other organizations to train health professionals in those settings.

Research

Food safety practices and programs must be science-based to effectively detect and identify pathogens, minimize their presence, assess risk, and respond to outbreaks. Basic research is needed to understand the ecology and etiology of foodborne pathogens, their genetic content, how they multiply, how they are transmitted, and under what conditions they grow. Applied research is then needed to develop the practices and technologies that will enable pathogen detection and control. To better coordinate food safety research, the FY 1999 food safety initiative includes development of an interagency process coordinated by the National Science and Technology Council for reviewing ongoing research and identifying basic research needs and that which is helpful to regulatory agencies. Agencies include USDA's FSIS, Agricultural Research Service (ARS), and CSREES, and HHS' FDA and CDC, and EPA.

Develop rapid, cost-effective tests for pathogens in foods: FDA, USDA, CDC, and EPA will collaborate to develop effective methods to detect, identify, and quantify pathogens, with particular emphasis on imported and domestic fresh fruits and vegetables and on pathogens in animal wastes.

Enhance understanding of how pathogens become resistant to food preservation techniques and to antibiotics: FDA and USDA will conduct research into physiological, genetic, and other factors that cause hazardous foodborne microorganisms to develop resistance to preservation techniques, and into the factors that contribute to development of drug resistance by pathogens.

Develop prevention techniques for pathogen avoidance, reduction, and elimination: USDA and FDA will work with other agencies at the Federal and State level, as well as industry and academia to identify points of contamination and to develop new production, processing, and distribution practices that avoid the introduction of contaminants into food producing animals and food, or if contamination is present, reduce levels of or eliminate the contamination. Technologies will include antimicrobial agents, and thermal and non-thermal pasteurization, including irradiation. Collaborative work will also focus on developing systems for improved sanitation of animal production facilities and for handling liquid and solid animal wastes.

Develop better food handling, distribution, and storage procedures: FDA and USDA will evaluate conditions that influence the possibility of food contamination during handling, transportation, and storage, and will develop methods to minimize those conditions.

Develop microbiological baselines for pathogens on fruits and vegetables: Utilizing existing program infrastructure, USDA will conduct a scientifically-sound microbiological survey program for foodborne pathogens on domestic and imported fruits and vegetables. Program costs will be minimized by using the existing

infrastructure of the Pesticide Data Program for statistically reliable sampling, participating laboratories, and data reporting capabilities.

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Hypertext updated by dms 1998-MAR-11

Pulse
net

What is PulseNet?

PulseNet is a national network of public health laboratories that performs DNA "fingerprinting" on foodborne pathogens and compares these patterns through an electronic database at the Centers for Disease Control and Prevention (CDC). The DNA "fingerprinting" method is called pulsed-field gel electrophoresis (PFGE).

Why did CDC create PulseNet?

CDC created PulseNet so that scientists at public health laboratories throughout the country can rapidly compare the PFGE patterns of pathogens isolated from ill persons and determine whether they are similar. Similarity of strains among ill persons suggest a common source; for example, illness among persons in different parts of the country can be caused by a widely distributed contaminated food product. Strains isolated from food products by regulatory agencies can also be compared. Identifying these connections can help to detect outbreaks and remove contaminated foods from the marketplace.

Who participates in PulseNet?

CDC began developing PulseNet in 1995 in conjunction with the public health laboratories in Massachusetts, Minnesota, Texas, and Washington (regional laboratories) and the laboratory at the US Department of Agriculture - Food Safety and Inspection Service (USDA-FSIS). The four regional laboratories perform DNA "fingerprinting" by PFGE on isolates from their state and neighboring states that do not have PFGE capability. Scientists from 16 other state public health laboratories have now been trained at CDC in PulseNet methods, and the laboratory of the Food and Drug Administration - Center for Food Safety and Applied Nutrition (FDA-CFSAN) is also joining the network. Participating laboratories will have a direct link with a central computer at CDC which holds a national database of DNA "fingerprints" for *E. coli* O157:H7 and other bacteria that cause foodborne illness. These laboratories will be able to submit new patterns to the national database and to query the database about epidemiologic information associated with patterns in the database. When matching isolates are submitted by laboratories in different locations during the same period, the CDC computer will alert those laboratories of a possible multistate outbreak.

How has DNA "fingerprinting" by PFGE been used to prevent foodborne illness?

In 1993, during a large outbreak of *E. coli* O157:H7 infections in the western United States, scientists at CDC determined that strains isolated from patients in four states and the implicated ground beef patties had matching PFGE patterns. Prompt recognition of this outbreak and its cause resulted in rapid recall of ground beef patties, with an estimated 800 illnesses prevented.

In 1996, epidemiologists traced an outbreak of *E. coli* O157:H7 infections to commercial unpasteurized apple juice. Subtyping by PFGE by the Washington State public health laboratory showed that isolates from patients and the apple juice matched. Prompt recognition of this outbreak resulted in rapid recall of the widely-distributed juice.

In 1997, the Colorado State Health Department identified a cluster of ill persons whose *E. coli* O157:H7 isolates that matched each other by PFGE. About the same time, the USDA laboratory isolated an *E. coli* O157:H7 strain from a ground beef patty from the same bag as one consumed by an ill person. The patterns were transferred electronically to CDC, and they matched. This pattern was then transmitted to PulseNet sites, which compared it with patterns from over 300 other recent *E. coli* O157:H7 isolates. No matches were found, providing strong evidence that the outbreak was not nationwide.

What is in the future for PulseNet?

Using DNA "fingerprinting," PulseNet sites will continue to help in identifying and investigating outbreaks *E. coli* O157:H7 infection, and will do the same for *Salmonella* strains. Over time, methods for DNA "fingerprinting" of more pathogens by PFGE will be added.

Recognized outbreaks are only the tip of the iceberg of foodborne illness. Most foodborne infections are "sporadic," meaning there is no link to a known outbreak. PulseNet will be an early warning system that links seemingly sporadic human illnesses together; as a result, more outbreaks will be recognized, especially those that are spread out over many states. Investigation of these outbreaks will result in identification of hazards and implementation of new measures to increase the safety of our food supply.

MEMORANDUM OF UNDERSTANDING
AMONG
THE UNITED STATES DEPARTMENT OF AGRICULTURE
AND
THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
THE ENVIRONMENTAL PROTECTION AGENCY

I. INTRODUCTION

A. Parties

The parties to this agreement are the United States Department of Agriculture (USDA), the United States Department of Health and Human Services (HHS) and the Environmental Protection Agency (EPA).

B. Background

While the American food supply is among the safest in the world, there are still millions of Americans stricken by illness every year caused by the food they consume, and some 9,000 a year — mostly the very young and elderly — die as a result. The threats are numerous and varied, ranging from *Escherichia coli* O157:H7 in meat and apple juice, to *Salmonella* in eggs and on vegetables, to *Cyclospora* on fruit, to *Cryptosporidium* in public drinking water supplies — and most recently, to hepatitis A virus in frozen, sliced and sugared strawberries.

In his January 25, 1997 radio address, President Clinton directed three Cabinet members — the Secretary of Agriculture, the Secretary of HHS, and the Administrator of the EPA — to identify specific steps to improve the safety of the food supply. Their May, 1997, report to the President identified several issues and outlined a comprehensive new initiative to address those issues and improve the safety of the Nation's food supply.

One issue addressed in the report to the President was the coordination among federal, state and local agencies in responding to interstate outbreaks of foodborne illnesses. This MOU builds on previous Administration steps to modernize our food safety system and respond to emerging challenges as well as creating partnerships and leveraging the resources of federal, state and local agencies as part of the Vice President's National Partnership for Reinventing Government.

Four federal entities are charged with responding to outbreaks of foodborne illness (for the purpose of this MOU, foodborne illness also includes waterborne illness): USDA, EPA, and the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) at HHS. Each of the four federal agencies has a critical role when a outbreaks occur. CDC's primary responsibility is to assist state and local health departments in investigating outbreaks of illness and in identifying the cause of the outbreak. FDA, the Food Safety and Inspection Service (FSIS) at USDA, and EPA also have responsibility for determining whether a product they regulate may be causing illness, and for halting the spread of illness by taking regulatory action against the suspect products, or wastes (other than animal manures) that have the potential to contaminate the air, land, or waters used to produce the food product. The food product implicated in a foodborne outbreak determines which regulatory agency has primary jurisdiction: FSIS regulates meat, poultry, and egg products; FDA regulates all other foods including game meats, bottled drinking water and shell eggs; and EPA regulates water, drinking water from public systems and pesticides, and manages organic and inorganic wastes used or disposed of on agricultural land. While each entity has clearly defined areas of responsibility, the successful containment of many outbreaks of foodborne illness involves more than one federal entity.

All states and many local governments with varying expertise and resources share responsibility with the federal agencies for response to such outbreaks and, also, have a critical role. Identification and investigations of foodborne illness often begin at the community or state level. States and local governments share with the federal government the legal responsibility for protecting the health of their residents. The majority of foodborne outbreaks occur at the local or state level, however, many outbreaks involve federal agency jurisdiction. Illnesses cross state borders, and most foods or food ingredients are processed or produced in another state or by international trading partners. Federal involvement is also necessary when contaminated food from a common source has been distributed to grocery stores, restaurants, and homes in more than one state.

When outbreaks of foodborne illness occur, federal agencies work with state and local health and agricultural authorities in their investigation and in implementation of control measures through consultation, diagnostic assistance, and by regulatory action against the products. In some instances, on-site assistance is requested by local and state authorities from the CDC to establish the cause of an outbreak, and from other agencies to help find the source of the problem. For large or multistate outbreaks, federal agencies play a critical coordination role to ensure consistency of approach and implementation of needed control measures.

C. Recognition of Need

Although significant communication already occurs among the federal agencies; among federal, state and local agencies; among the various state agencies; and between state and local agencies, better coordination is needed to meet new and growing threats to the nation's food supply, enhance the level of public health protection, provide standards for prevention of future foodborne illness outbreaks, leverage agency resources and experience, and avoid duplication of effort and move more quickly since products can be widely distributed.

Further, a critical element of an effective, rapid response to a foodborne illness outbreak is ready communication by all the involved parties. Although there are communication systems in place, the systems need to be expanded and coordinated to achieve rapid exchange of information and data between key outbreak response personnel in each agency at the federal, state and local levels and the affected food industry.

The report to the President recommended the establishment of an intergovernmental group, to be known as the Foodborne Outbreak Response Coordinating Group, to improve the approach to interstate outbreaks of foodborne illness and develop a national, coordinated outbreak response system.

II. PURPOSE

A. This memorandum of understanding ("Memorandum") among the parties is entered into in order to form the Foodborne Outbreak Response Coordinating Group ("FORCG").

B. The purpose of the FORCG is defined by the following goal, mission and objectives:

1. It is the goal of FORCG to improve the approach to interstate outbreaks of foodborne illness by federal, state and local agencies charged with responding to such outbreaks.
2. Toward this goal, it is the mission of FORCG to include federal, state and local agencies with outbreak response duties in the development of a national comprehensive and coordinated foodborne illness outbreak response system.
3. This mission will be accomplished by subscribing to the following management objectives which will, in turn, guide FORCG:
 - a. FORCG will review and evaluate outbreak response at the federal agency level (among agencies), including cooperation among federal agencies and between state and local agencies and affected industries. FORCG will identify areas where efficiency can be gained and make specific recommendations for improvement. FORCG will work with federal, state, and local governments, the food industry, health professionals, and consumer advocates to implement beneficial changes.
 - b. Standard operating procedures will be developed for the rapid exchange of data and information associated with foodborne illness outbreaks between involved agencies and for dissemination to the public. The procedures will cover the exchange of data and information associated with an outbreak and will complement systems established for exchange of information about day-to-day occurrences of foodborne illness.

c.. A nationwide survey will be conducted to catalogue existing state and local food safety program infrastructures.

d. Working groups will be established to develop recommended procedures for outbreak response coordination between federal and state agencies, and between state and local agencies levels to improve the coordinated response to interstate outbreaks.

III. ORGANIZATION AND MEMBERSHIP

A. Under Title II, Section 204, Subpart (a) of the Unfunded Mandate Reform Act of 1995, Pub. L. 104-4, elected state officers, or their designated representatives with authority to act on their behalf, may meet with federal officers to exchange views, information, or advice relating to the management or implementation of federal programs established pursuant to public law that explicitly or inherently share intergovernmental responsibilities or administration. The parties, therefore, agree that all members of FORCG will be federal officials or state employees with the requisite authority.

B. FORCG will have the following members:

1. Two representatives from USDA: The Under Secretary for Food Safety and the Administrator for FSIS, or their designees.

2. Four representatives from HHS: The Assistant Secretary for Health, the Commissioner of the FDA, the Director of CFSAN and the Director of CDC, or their designees.

3. Two representatives from EPA: The Assistant Administrator for the Office of Prevention, Pesticides and Toxic Substances and the Assistant Administrator for Water, or their designees.

4. One state employee who is a representative of the Association of Food and Drug Officials.

5. One state employee who is a representative of National Association of City and County Health Officials.

6. One state employee who is a representative of the Association of State and Territorial Public Health Laboratory Directors.

7. One state employee who is a representative of the Council of State and Territorial Epidemiologists.

8. One state employee who is a representative of the National Association of State Departments of Agriculture.

IV. RESPONSIBILITIES AND SCOPE OF WORK

A. FORCG will be co-chaired by the Under Secretary for Food Safety (USDA) and the Assistant Secretary for Health (HHS). His or her designee will facilitate each meeting.

B. One member will be designated as the outbreak response coordinator for each department or agency that has a role in an outbreak response. The duties of each outbreak response coordinator will be identified as FORCG develops the overall outbreak response system. HHS will designate the Assistant Secretary for Health as the primary person in charge of coordination for HHS. USDA will designate the Under Secretary for Food Safety as the primary person in charge of coordination for USDA. EPA will designate the Assistant Administrator for Water as the primary person in charge of coordination for EPA when drinking water is involved, and the Assistant Administrator for the Office of Prevention, Pesticides, and Toxic Substances will be the primary person when Pesticides and Toxic Substances are involved.

V. GENERAL PROVISIONS

A. FORCG will meet Bi-monthly.

B. This Memorandum may be modified with supplemental written agreements signed by the parties and can be terminated in writing, in whole or in part, by consensus of the parties.

C. This Memorandum will become effective on the date the final signature is affixed hereto.

D. This Memorandum is entered into within the limits of the statutory authority of the parties to the Memorandum.

SIGNATURES