

April 22, 1997 DRAFT

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EXECUTIVE SUMMARY

In his January 25, 1997 radio address, President Clinton launched a new initiative to improve the safety of the nation's food supply. The President announced he would request \$43 million in his 1998 budget to fund a nation-wide early-warning system for foodborne illness, increase seafood-safety inspections, and expand food-safety research, training, and education. The President also directed three Cabinet members--the Secretary of Agriculture, the Secretary of Health and Human Services, and the Administrator of the Environmental Protection Agency--to identify further steps to improve the safety of the food supply. He directed them to develop these next steps working with consumers, producers, industry, states, universities, and the public, and to report back to him in 90 days.

The goal of this initiative is to further reduce the incidence of foodborne illness to the greatest extent feasible. The recommendations presented in this report are based on the public health principles that we should identify and take preventive measures to reduce risk of illness, should focus our efforts on hazards that present the greatest risk, and should make the best use of public and private resources. The initiative also seeks to further collaboration between public and private organizations and to improve coordination within the government as we work toward our common goal of improving the safety of the nation's food supply.

Four agencies in the federal government have primary responsibility for food safety: two agencies under the Department of Health and Human Services (HHS)--the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC); the Department of Agriculture (USDA); and the Environmental Protection Agency (EPA). Over the last 90 days, these agencies have worked with the many constituencies interested in food safety to identify the greatest public health risks and design strategies to reduce these risks. USDA, FDA, CDC, and EPA have worked to build consensus and to identify opportunities to better use their collective resources and expertise, and to strengthen partnerships with private organizations. As directed by the President, the agencies have explored ways to strengthen systems of coordination, surveillance, inspections, research, risk assessment and education.

This report presents the results of that consultative process. It outlines steps USDA, HHS, and EPA will take this year to reduce foodborne illness, and spells out in greater detail how agencies will use the \$43 million in new funds requested for fiscal year 1998. It also identifies issues the agencies plan to consider further through a public-planning process.

The actions in this report build on previous Administration steps to modernize our food safety programs and respond to emerging challenges. As part of the Vice President's National Performance Review the agencies have encouraged the wide-spread adoption of preventive

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controls. Specifically, the report urged implementation of hazard analysis and critical control point (HACCP) systems to ensure food manufacturers identified points where contamination is likely to occur and implement process controls to prevent it.

The Administration has put in place science-based HACCP regulatory programs for seafood, meat, and poultry. In late 1995 the Administration issued new rules to ensure seafood safety. In July, 1996 President Clinton announced new regulation to modernize the nation's meat and poultry inspection system for the first time in 90 years. The Early-Warning System the President announced in January will gather critical scientific data to further improve these prevention systems. And additional actions outlined in this report will expand the use of HACCP principles throughout the food industry.

KEY ADMINISTRATION ACTIONS

Enhance Surveillance and Build an Early-Warning System

As the President announced in January, the Administration will build a new national early-warning system to help detect and respond to outbreaks of foodborne illness earlier, and to give us the data we need to prevent future outbreaks. For example, with FY 98 funds, the Administration will:

Enhance Surveillance. The Administration will expand from 5 to 8 the number of FoodNet active surveillance sentinel sites. Existing sites are in Oregon, Northern California, Minnesota, Connecticut, and metropolitan Atlanta. New sites will be in New York and in Maryland, with an eighth site to be identified. CDC will also increase surveillance activities for certain specific contaminants. For example, CDC will begin a case-control study of hepatitis A virus to determine the proportion of cases due to food contamination and strengthen surveillance for *Vibrio* in Gulf Coast oysters.

Equip FoodNet sites and other state health departments with state-of-the-art technology, including DNA fingerprinting to identify the source of infectious agents and additional epidemiologist and food safety scientists to trace outbreaks to their source.

Create a national electronic network for rapid fingerprint comparison. Agencies will equip the sentinel sites and other state health departments with DNA fingerprinting technology, and will link sites together to allow the rapid sharing of information and to quickly determine whether outbreaks in different states have a common source.

Further Food Safety Education

Foodborne illness remains prevalent throughout the United States, in part because food preparers and handlers at each point of the food chain are not fully informed of risks and related safe-handling practices. Understanding and practicing proper food safety techniques from farm to

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table would significantly reduce foodborne illness. The Administration--working in partnership with the private sector--will use FY98 funds to, among other things:

Establish a Public-Private Partnership for Food Safety Education. FDA, USDA, and CDC will work with the food industry, consumer groups and the states to launch a food-safety public awareness and education campaign. The Partnership will develop, disseminate, and evaluate a single food-safety slogan and several standard messages. Industry has pledged \$500,000 to date to support the partnership's activities and plans to raise additional funds.

Educate professionals and high risk groups. Agencies will better educate physicians to diagnose and treat foodborne illness; strengthen efforts to educate producers, veterinarians, and state and local regulators about proper animal drug use and HACCP principles; and work with the Partnership to better train retail- and food-service workers in safe handling practices and to inform high risk groups about how to avoid foodborne illness, e.g., illness that may be caused by consuming raw oysters containing *Vibrio vulnificus*.

Improve Responses to Foodborne Outbreaks

At the federal level, four agencies are charged with responding to outbreaks of foodborne and waterborne illness: CDC, FDA, and USDA's Food Safety and Inspection Service (FSIS) and EPA. States and many local governments with widely varying expertise and resources also share responsibility for outbreak response. The current system does not assure a well-coordinated, rapid response to interstate outbreaks. To more quickly identify an outbreak's cause and ensure a rapid response, agencies will:

Establish an intergovernmental Foodborne Outbreak Response Coordinating Group
[still under discussion]

Strengthen the infrastructure for surveillance and coordination at state health departments

Improve Risk Assessment

Risk-assessment methods help characterize the nature and size of the risk to human health associated with foodborne hazards and assist regulators in making decisions about controlling those hazards. To improve risk-assessment capabilities, agencies will:

Establish an interagency risk-assessment consortium to set priorities and guide overarching federal risk-assessment research related to food safety.

Develop better data and modeling techniques to assess exposure to microbial contaminants, and simulate microbial variability from farm to table.

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Develop New Research Methods

Today, many pathogens in food or animal feed cannot be identified, and others have developed resistance to time-tested controls such as heating and refrigeration. The agencies will focus research immediately to:

Develop rapid, cost-effective tests for the presence of pathogens, such as *Salmonella*, *Cryptosporidium*, *E.coli* O157:H7, and hepatitis A virus.

Enhance understanding of how pathogens become resistant to food-preservation techniques and antibiotics.

Develop technologies for prevention and control of pathogens.

~~**Increase and Improve Effectiveness of Inspections.**~~ *Improving Inspections and Compliance*
The agencies will pursue several strategies to increase inspections for higher-risk foods; the agencies will, among other things:

Implement seafood HACCP. FDA will add seafood inspectors using new FY98 funds to implement new seafood HACCP regulations, and will work with the Commerce Department to better integrate the Department's voluntary seafood-inspection program with FDA's program.

Propose new regulations for fruit juices. FDA will also propose, among other things, to require the use of HACCP for juice products.

Propose HACCP regulatory options for egg products. FSIS will propose HACCP regulatory options for egg products.

- **Identify preventive measures to address public health problems associated with fresh produce, such as hepatitis A associated with frozen strawberries.**

Improve coverage of imported foods. FDA will develop additional mutual recognition agreements (MRAs) with trading partners, initiate a federal-state communication system covering imported foods, and FDA and FSIS will provide technical assistance to countries whose products are implicated in a foodborne illness.

Enhance federal-state inspection partnerships

Continue the long-range planning process

actions

Espinoza 7002
Friedrich 8013
Roscher 10202

4/25/97 - added in Kaye's paragraph on FSIS activities in emergency response area

INTERSTATE OUTBREAK CONTAINMENT AND RESPONSE COORDINATION

Background

Four federal agencies are charged with responding to outbreaks of foodborne illness (including waterborne illness): FDA and CDC (at HHS), FSIS (at USDA), and EPA. All states, and many local governments, with widely varying expertise and resources, share responsibility with the federal government for response to such outbreaks. When an outbreak occurs, all of the relevant entities must work together to efficiently and effectively prevent deaths and minimize the number of illnesses. The better coordinated the response, the more quickly the outbreak will be contained.

Each of the four federal agencies has a potentially critical role when an outbreak occurs. 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, FSIS, and EPA also have responsibility for determining whether a product they regulate may be causing illness, and of 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 type of food affected determines which regulatory agency has primary jurisdiction: FSIS regulates meat, poultry, and egg products; FDA regulates all other foods including shell eggs; and EPA regulates water and pesticides and manages organic and inorganic wastes used or disposed of on agricultural land. While each agency has clearly defined areas of responsibility, the successful containment of many outbreaks of foodborne illness involves more than one agency.

The states and many local governments also have a critical role. Identification and investigations of foodborne illness often begin at the community or state level. States share with the federal government the legal responsibility for protecting the health of their residents. Although food outbreaks are sometimes local because of improper processing or handling, most outbreaks implicate 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.

In many outbreaks of foodborne illness, federal agencies work with state and local health authorities in their investigations 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 the 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.

Companies responsible for affected products also have a critical role to play. Food companies are sometimes the first to recognize that their product is causing illness. In addition, most food-product recalls are voluntary. Federal and state agencies can benefit from industry's expertise about food products and their distribution patterns.

Problem

Although significant coordination already occurs among federal, state, and local agencies, better coordination is needed to meet new and growing threats to the nation's food supply. More than one agency is involved in virtually every large foodborne outbreak. Joint efforts are often hindered by a lack of communication or a misunderstanding of each agency's role in a particular situation.

Recommendations

Federal, state, and local governments should improve the coordinated management of interstate outbreaks. Improved coordination among the federal agencies, among federal, state, and local agencies, among the various state agencies, and between state and local agencies would enhance the level of public-health protection, leverage agency resources and experience, and avoid duplication of effort.

The early warning capability of FoodNet and the strengthening of state surveillance capacity and federal-state communications will enhance ^{appropriate} early involvement of federal agencies in the investigation of foodborne disease outbreaks. ~~It is critical for responsible agencies to be aware of the developing situation when a food vehicle is suspected.~~ An essential factor in effective response to foodborne outbreaks is rapid communication and exchange of information among the appropriate federal, state, and local government agencies.

Improve Outbreak Containment Through Better Federal-State-Local Coordination of the Evaluation of and Response to Foodborne Illness

There are probably hundreds of times a year when at least one federal agency, working with state and local agencies, plays a role in detection, investigation, and containment of illnesses that may be caused by contamination of food. Occasionally (typically once or twice a year) the outbreak is sufficiently significant and complex to require the involvement of the highest level officials in the responsible federal agencies. When this occurs, it is essential that federal agencies speak with one voice. ~~The agencies that typically will be involved will be CDC and USDA (if the outbreak involves meat and poultry), FDA (if the outbreak involves any other food product), or EPA (if the outbreak involves drinking water).~~

The lead department in any foodborne illness outbreak will be determined by regulatory jurisdiction over the food products implicated in the outbreak. FSIS has regulatory responsibility for meat, poultry, and egg products, so USDA will be the lead when these

The staff will tell the Coordinator who will then coord the response among federal and state agencies.

products are involved. Since FDA has regulatory responsibility for all other foods, HHS will be the lead when any other food product is involved. Where there is overlap, both HHS and USDA will have leadership responsibility. EPA will continue to be the lead agency for outbreaks traced to drinking water. Each agency will designate a Coordinator.

State

This new management system will provide a common set of objectives and strategies and one spokesperson that will speak on behalf of the federal government. Coordination and communication of the outbreak by the Coordinator to appropriate staff (agency and field) Once there are indications of a large-scale problem by federal or state agencies, notification to the appropriate Cabinet-level official and ongoing communication with Cabinet Affairs in the White House will be part of the continuing role of the Coordinator.

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§ INSERT A as designate a person with responsibility for coordinating its activities for any significant and complex outbreak, and a single official will be placed in charge of the federal government's role in managing the outbreak.

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after

c1

In addition, CDC, EPA, FDA, and FSIS will establish an intergovernmental group, the Foodborne Outbreak Response Coordinating Group (FORCG), to improve the approach to interstate outbreaks of foodborne illness. FORCG will ~~include~~ include representatives of state and local agencies charged with responding to outbreaks of foodborne illness. This group will also review ways to more effectively involve the appropriate state agencies when there is a foodborne outbreak.

c2

FORCG will review and evaluate outbreak response. FORCG will undertake these reviews after appropriate consultation with industry and consumer representatives. Based on these deliberations, FORCG will assess the infrastructure for outbreak response, make recommendations for improving the current system, and work with federal, state, and local governments, the food industry, health professionals, and consumer advocates to implement beneficial changes. FORCG will meet several times a year for this purpose.

sheng

B1

A critical element of an effective, rapid response to a foodborne illness outbreak is ready communication, by all the involved parties at the federal, state, and local level. ~~must be identified and put in place for~~ the rapid exchange of information and data between key outbreak response personnel in each agency at the federal, state, and local levels. This system will complement the data and information exchange systems described in the "Early Warning for Foodborne Disease Surveillance" section of this report.

B2

Rapid communication of data and information about foodborne illness outbreaks is an essential factor in preventing and controlling outbreaks. In order to improve communications with state agencies, FDA has adopted a fax-on-demand and fax broadcast system. The fax broadcast system, containing a database of more than 900 state officials, permits messages to be sent any time day or night to any list of state contacts, providing an early alert or update to foodborne illness investigations. The fax-on-demand system provides access to press releases from Federal agencies, press releases from firms about their recall, as well as other information. FDA has also instituted a 50-state conference call

system to keep all state agencies up-to-date on major foodborne outbreaks. This system was first used for the outbreak involving *E. coli* O157:H7 in apple juice and was most recently used for the hepatitis A outbreak associated with frozen strawberries. FDA and CDC jointly participate in these calls to assure more effective follow up and control of outbreaks.

B3

FDA will modify the conference call system to involve appropriate states in the very early stages of any multistate outbreak, as well as continuing the 50-state update conference calls, in order to ensure better communication among state and federal agencies.

~~That FDA activities are coordinated by the agency's Division of Emergency~~

FSIS has established an Emergency Response Program to prevent and control foodborne disease outbreaks involving meat, poultry, and egg products. The program has Field Epidemiology Officers throughout the country who maintain a liaison with state public health officials and assist states in outbreak investigations. These activities are coordinated by the Emergency Response Division at headquarters, where the Division maintains an 800 number with a 24-hour answering service used by state and federal health officials, consumers, and the industry.

FDA's Division of Emergency and Investigational Operations serves this function for all other food products. The Division maintains 24-hour telephone service (800 number) 301 443 1240 staffed with individuals trained to respond to emergencies and ongoing illnesses, including foodborne illness and outbreaks. DEIO has immediate access to emergency personnel throughout the agency, as well as with emergency contacts in other agencies, including CDC, USDA, and EPA. This Division will serve to coordinate with other agencies (this is a new function).

FSIS communicates with state departments of health and coordinates outbreak response through CDC WONDER (Internet) and both FDA and USDA maintain liaisons at CDC to facilitate food safety activities, including outbreak investigations.

FY97 Activities

- For outbreaks that fall within the purview of CDC and FDA, HHS will identify the official with lead responsibility for managing the outbreak. HHS and USDA will identify the individual responsible for managing any significant and complex outbreak that falls within the jurisdiction of both Departments.
- Under the new initiative there will be one person/position designated as the outbreak coordinator for each department or agency. This position will be established as a formal institutional position, with appropriate backup designees. For outbreaks that fall within the purview of CDC and FDA, HHS will designate [the Assistant Secretary for Health] to be the primary person in charge of coordination. For outbreaks that fall with the purview of USDA, the Under Secretary for Food Safety will coordinate. Both the [Assistant Secretary for Health] and the Under Secretary for Food Safety will

manage outbreak responses that fall within the jurisdiction of both agencies. EPA will designate the [_____] as the primary person in charge of coordination when drinking water is involved.

- CDC, EPA, FDA, and FSIS, in consultation with representatives of state and local governments, will establish the Foodborne Outbreak Response Coordinating Group.
- 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 SOPs will be developed by a group of representatives from each federal agency and from the appropriate state agencies. The SOPs 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. (See "Early Warning for Foodborne Illness Surveillance" section.) The SOPs will also provide for rapid dissemination of accurate information to the public by the agency spokesperson.

Enhance State and Local Infrastructure for Foodborne Outbreak Detection, Evaluation, and Response Coordination

The epidemiology offices and laboratories within state and local health departments are charged with the surveillance of infectious and non-infectious conditions, and, along with other state and local 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 and communities for the surveillance and investigation of foodborne diseases are limited and decreasing, thereby limiting the effectiveness of their response. As a result, outbreaks may go undetected or are never investigated.

CDC, EPA, FDA, and FSIS will address the problem first by assessing and cataloguing available state resources, and then by working with states and providing support for foodborne-disease-surveillance programs and assistance to better investigate outbreaks of foodborne illness.

FY97 Activities

- FORCG, with assistance from the Association of Food and Drug Officials, the Association of State and Territorial Health Officials, the Association of State and Territorial Public Health Laboratory Directors, the Council of State and Territorial Epidemiologists, and the National Association of State Departments of Agriculture, will begin a nationwide audit to catalogue the existing state and local food-safety program infrastructure.

- **FORCG, in consultation with the appropriate outside organizations, will establish working groups consisting of federal, state, and local officials to develop recommended procedures for outbreak response coordination at the state and local level.**

FY98 Activities with Food-Safety Initiative Funds

- **CDC, EPA, FDA, and FSIS will assist states and local governments in developing the infrastructure necessary to ensure proper detection, evaluation, and coordinated response to foodborne outbreaks.**



United States Department of Agriculture
Food Safety and Inspection Service

FAX

To: LISA GROVE

Fax #: 395-7285

Subject: Change in Language

Date: 4/24/97

Pages: 3 including this cover sheet.

COMMENTS:

LISA -

I have changed the language in the Executive Summary and in the inspection section on "egg products." This should address your concerns - Please let me know if there is a problem with this new language.

Joan Mondsheen

tel - 720-4150

From the desk of

Thomas J. Billy
Administrator
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C.C. Elizabeth Prye

11. Under

Improve Risk Assessment

Risk-assessment methods help characterize the nature and size of the risk to human health associated with foodborne hazards and assist regulators in making decisions about controlling those hazards. To improve risk-assessment capabilities, agencies will:

Establish an interagency risk-assessment consortium to set priorities and guide overarching federal risk-assessment research related to food safety.

Develop better data and modeling techniques to assess exposure to microbial contaminants, and simulate microbial variability from farm to table.

Develop New Research Methods

Today, many pathogens in food or animal feed cannot be identified, and others have developed resistance to time-tested controls such as heating and refrigeration. The agencies will focus research immediately to:

Develop rapid, cost-effective tests for the presence of pathogens, such as *Salmonella*, *Cryptosporidium*, *E.coli* O157:H7, and hepatitis A virus.

Enhance understanding of how pathogens become resistant to food-preservation techniques and antibiotics.

Develop technologies for prevention and control of pathogens.

Increase Inspections

The agencies will pursue several strategies to increase inspections for higher-risk foods; the agencies will, among other things:

Implement seafood HACCP. FDA will add seafood inspectors using new FY98 funds to implement new seafood HACCP regulations, and will work with the Commerce Department to better integrate the Department's voluntary seafood-inspection program with FDA's program.

Propose new regulations for fruit juices. FDA will also propose, among other things, to require the use of HACCP for juice products.

Propose HACCP regulatory options for egg products. FSIS will ~~consider whether to propose HACCP~~ regulatory options, including HACCP for egg products. *Based on the best science* *Prop. 10/01*

Improve coverage of imported foods. FDA will develop additional mutual recognition agreements (MRAs) with trading partners,

*change
in language*

FY97 Activities:

- FDA will publish proposed regulations for the use of HACCP in the manufacture of juice products.
- FSIS and FDA will jointly publish an ANPR in which they will evaluate the public-health, food technology, and regulatory issues involved in reducing the risk of human illness from *Salmonella Enteritidis* in shell eggs. The ANPR will solicit information and comment on all elements of risk in the farm-to-table chain to ensure any resulting regulatory actions will be both reasonable and effective in reducing risk. *FSIS will propose HACCP regulatory options for egg products. Based on the best science available, FSIS will propose regulatory options, including HACCP, for egg products.*
- FDA will evaluate whether and how to propose to require the use of HACCP in other appropriate food commodities and animal feeds.
- FDA and USDA will immediately identify preventive measures to address public-health problems, such as those recently associated with fruits and vegetables, e.g., hepatitis A associated with frozen strawberries. This will be accomplished through a comprehensive review of current production and food-safety programs including inspection, sampling, and analytic methods.
- FDA will provide additional training in seafood HACCP and FSIS will complete HACCP training of inspectors in large plants.
- FSIS and FDA will evaluate expanding existing cooperative agreements so that plants producing meat and nonmeat foods are inspected by FSIS inspectors trained in FDA inspectional standards. FSIS inspectors are already in these plants, and their presence could be better used to maximize use of federal resources without loss of inspectional coverage for FSIS-regulated foods.
- FSIS will conduct a series of public meetings to discuss:
 - How HACCP requirements will be implemented in slaughter plants and how the roles and responsibilities of inspection personnel will change with that implementation.
 - The design and testing of new inspection concepts consistent with HACCP principles to achieve food-safety and other consumer-protection objectives through distribution and retail channels to consumers.
- FSIS and state associations will complete development of HACCP-based control measures for meat and poultry processing

*change
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language
same as
Exec.
Summary*



**Executive Office of the President
Office of Management and Budget
Office of Information and Regulatory Affairs
New Executive Office Building
Washington, DC 20503**

FAX TRANSMITTAL

DATE: April 24, 1997
TO: Elizabeth Drye
Karen Hulebak
Joan Mondschein
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Number of pages (including transmittal sheet): 4

Recipient's fax number: 456-7028
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690-0550

Remarks: Enclosed are proposed language changes for the Risk Assessment section of the
the Food Safety Initiative report. I tried to use as much of the existing language
as possible. The underlined text is either added or reworded.

Background

...Carefully formulated risk assessments based on high-quality data and scientific information generated from research lead to more informed risk management and better decisions.

Risk assessment also provides essential information for estimating and analyzing the costs and benefits of policy alternatives. Risk estimates are used to characterize the state of the world in the baseline and the alternative states expected to occur after taking action, whether that through regulation, guidelines, or education campaigns. Ideally, risk estimates are in the form of distributions which capture the scientific uncertainty and population variability, but where that is not possible, point estimates of risk need to reflect the impact on the entire population.

Risk management and risk assessment must mutually inform each other but must remain separate and independent entities...

Problem

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 assumptions used to develop the estimates. Risk assessments require 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, hazards potency, and characteristics of the population at risk.

Risk assessment is far less developed for foodborne pathogens. Intensive commitment is necessary to develop critically needed methods of analyzing the available data and addressing its uncertainty; methods that account for variability, specifically of living microbial pathogens, are essential. Chemical and radiological risks do not pose these special challenges, so extending these established methods to microbial risk is not sufficient.

Economic research into the value that people place on avoiding foodborne illness is necessary to extend the results of microbial risk assessment into regulatory analysis. Various types of illness are not valued equally, and a better understanding of this issue will help target limited resources on the problems which people feel are the most important.

The research needed to develop improved methods and models that will make it possible to perform quantitative microbial risk assessments...

Recommendations

This initiative emphasizes the development, testing, and validation of microbial risk assessment and foodborne illness valuation methods. These efforts are prerequisites for effective and efficient public response to foodborne illness concerns, whether the response is improved

want

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summit

surveillance plans, better prevention strategies, or stronger inspection models. The recommendations fall into three areas.

Establish a Food Safety Risk Assessment Consortium

All federal agencies with risk management responsibilities for food safety will establish jointly a consortium at which federal agencies can collectively advance the science of microbial risk assessment. The consortium would be inclusive in its risk assessment activities, seeking expertise from risk assessment professionals and scientists from public and private sources as well as industry and consumer groups. The goal of this consortium would be to improve the quality of risk assessment research by coordinating research priorities, eliminating redundancies of effort, and encouraging multidisciplinary research efforts. The consortium will have three primary functions:

1. Develop a scheme for setting methodological research priorities based upon the value of information expected from each research activity.
2. Serve as a clearinghouse for information about current and planned research projects pertinent to microbial risk-assessment techniques.
3. Foster and, where possible, augment the research activities of the member agencies to accelerate particularly critical research projects.

FY97 Activities

- The consortium, which will include all interagency partners, will be established in 1997 as part of the Joint Institute for Food Safety and Applied Nutrition, a collaborative activity of FDA's Center for Food Safety and Applied Nutrition and Center for Veterinary Medicine and the University of Maryland. The initial focus of the consortium will be on pathogenic microorganisms.
- The consortium will begin to establish a clearinghouse that will collect and catalogue available methodology, specifically simulations necessary to assess microbial growth and death variables offered by the private sector, trade associations, federal and state agencies, and international sources.

FY98 Activities with Food-Safety Initiative Funds

- A series of public meetings...
- Begin a comprehensive review of existing data and federal information collection programs to determine the extent to which they may fill existing data gaps, and suggest changes to those collections which could be used to perform risk assessments.

Long-term Activities

- The consortium...

Develop and Validate Exposure Assessment Models based on Probabilistic Safety Analysis

Risk assessment of foodborne illness is dependent on estimating the probability that a various quantities of a toxin or pathogen will be ingested by a consumer. This initiative addresses the numerous data and modeling deficiencies in estimating exposure to microbial contaminant. Specifically, research will be conducting into the development of models and simulations based on Probabilistic Safety Analysis (PSA) for the occurrence of microbial pathogens in food at all stages of the food chain;...

Develop and Validate Dose-Response Assessment Models for Use in Risk Assessment



Executive Office of the President
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FAX TRANSMITTAL

DATE: April 25, 1997

TO: Elizabeth Drye
Karen Carson
Karen Hulebak
Joan Mondschein (c/o Judy Riggins)

FROM: David Rostker
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Fax: (202) 395-7285

Number of pages (including transmittal sheet): 3

Recipient's fax number: 456-7028
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Remarks: Enclosed are my requested changes to the Food Safety Initiative Report. I look
forward to discussing them with you on Monday.

Executive Summary

¶5, last sentence: And additional actions outlined in this report will ~~expand~~ encourage use of HACCP principles throughout the food industry.

KEY ADMINISTRATION ACTIONS

Increase Inspections (Use similar language in the body of the report.)

Propose new ~~regulations~~ policies for fruit juices. FDA will also propose, among other things, policy options, including mandatory and voluntary HACCP schemes, to address the hazards in to require the use of HACCP for juice products.

Propose ~~HACCP regulatory options~~ new policies for egg products. Based on the best science available, FSIS will ~~consider whether to propose HACCP regulatory~~ policy options, including possible HACCP regulations, for egg products.

A New Interagency Strategy to Prevent Foodborne Disease

¶4, first sentence: The goal of this initiative is to reduce the incidence of foodborne illness to the greatest extent possible without unduly limiting the abundant variety and innovation in our food supply.

Foodborne Illness: A Significant Public Health Problem

¶1, last sentence: Those estimates do not take into account the total burden places on society by the chronic, often lifelong, consequences caused by some foodborne pathogens in rare instances.

¶2, second sentence: "as are people living in institutional settings, such as hospitals and nursing homes" Are these people inherently more at risk than the rest of the populations, like the others listed in this paragraph? Or do we mean to say that institutional food, because of the conditions during preparation and consumption, is riskier? If the latter, remove this clause and add a sentence at the end of the paragraph: People living in institutional settings, such as hospitals, nursing homes, and prisons, are also at greater risk because the shared food supply make contamination easier.

Sources of Foodborne Contamination

¶1, last sentence: ~~Foods can become contaminated~~ Pathogens can be spread from food to food in retail facilities and in homes through poor food-handling practices.

¶2, second sentence: In rare cases, foodborne infections can result in very serious...

The Current System for Protecting Food

- In the home, consumers have a responsibility for proper handling and storage of food. Because ~~consumer mishandling contributes to many cases~~ proper food handling practices can prevent a majority of foodborne illness, FSIS ~~promulgated~~ issued rules requiring the use of a safe-handling labels for raw meat and poultry products.

The Food Safety System Must Be Prepared for the 21st Century

Second bullet, last sentence: ~~These HACCP rules calls for~~ require food industries to design and implement preventive measures, ~~streamlines regulation of foods,~~ and increase the industries' responsibility for control of their safety-assurance actions. FSIS and FDA will streamline their current regulations as part of their conversion to HACCP.

April 24, 1997



Health Division



Office of Management and Budget
Executive Office of the President
Washington, D.C. 20503

Please route to:

Richard Turman
Barry Clendenin
Nancy-Ann Min
Elizabeth Drye

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Comment

ACTION REQUESTED:

☐ Decision or Approval
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☐ For your information

TIME SENSITIVITY:

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☒ ASAP

Time Action Requested by 4/25/97

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With informational copies for:

GW, HPS chiron, H2 Clenn
Sarah Laskin

Subject: Draft Food Safety Report to
the President

From: Jim Esquea

JE

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We have reviewed the draft food safety report and have made various edits (see attached).

General Comments

- The report is very "slow going" and can use some streamlining. To that end, we recommend moving the descriptions of the various types of contaminants on pages 8 through 11 to the Appendix. In addition the description of the current system for protecting food on pages 11 through 13 should also be moved to the Appendix.
- In the "Interstate Outbreak Containment and Response Coordination" section, there is a description of how a single official will be placed in charge of the federal government's role in "managing" the outbreak (pages 29 & 30). We should state explicitly what "managing" the outbreak means. Does "managing" also include coordinating the flow of information to the White House and the public? How does this recommendation satisfy Kitty Higgins's concern about having one "go to" person in each department who can manage/coordinate the flow of information to the White House and the public about the federal response to an outbreak?

- The OMB Commerce branch examiner advises that it is “ok” to include the language on page 44 of the report about the **possible** relocation of the proposed Commerce seafood inspection performance-based organization to HHS/FDA. However, the recommendation that the Administration should evaluate the voluntary fee-for-service seafood program and the operational functioning of the seafood PBO should be stricken from the report (page 44).
- Finally, the last section of the report contains a recommendation for the development of a long-term food safety strategic plan but nothing is said about who would be the recipient of the plan. Will this strategic plan be presented to the President for approval or will the agencies develop the strategic plan for incorporation into their agency strategic plans?

Please let us know if you have any questions about our comments or edits.

Attachments

April 22, 1997 DRAFT

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

REPORT TO THE PRESIDENT

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This will be
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report

EXECUTIVE SUMMARY

In his January 25, 1997 radio address, President Clinton launched a new initiative to improve the safety of the nation's food supply. The President announced he would request \$43 million in his 1998 budget to fund a nation-wide early-warning system for foodborne illness, increase seafood-safety inspections, and expand food-safety research, training, and education. The President also directed three Cabinet members--the Secretary of Agriculture, the Secretary of Health and Human Services, and the Administrator of the Environmental Protection Agency--to identify further steps to improve the safety of the food supply. He directed them to develop these next steps working with consumers, producers, industry, states, universities, and the public, and to report back to him in 90 days.

Food Safety & Insp Service (FSIS)

Four agencies in the federal government have primary responsibility for food safety: two agencies under the Department of Health and Human Services (HHS)--the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC); the Department of Agriculture (USDA); and the Environmental Protection Agency (EPA). Over the last 90 days, these agencies have worked with the many constituencies interested in food safety to identify the greatest public health risks and design strategies to reduce these risks. USDA, FSIS, FDA, CDC, and EPA have worked to build consensus and to identify opportunities to better use their collective resources and expertise, and to strengthen partnerships with private organizations. As directed by the President, the agencies have explored ways to strengthen systems of coordination, surveillance, prevention, inspections, research, risk assessment and education.

This report presents the results of that consultative process. It outlines the steps USDA, HHS, and EPA will take this year to reduce foodborne illness, and spells out in greater detail how agencies will use the \$43 million in new funds requested for fiscal year 1998. It also identifies issues the agencies plan to consider further through a public-planning process.

The actions in this report build on previous Administration steps to modernize our food safety programs and respond to emerging challenges. In 1993, the Vice President's National Performance Review issued a strategy for reinventing food safety. The report noted that our inspections system had a limited ability to detect microbial contaminants. As a key recommendation, the report urged the wide-spread adoption of preventive controls. Specifically, the report urged implementation of hazard analysis and critical control point (HACCP) systems to ensure food manufacturers identified points where contamination is likely to occur and implement process controls to prevent it.

Acting on this recommendation, the Administration has put in place science-based HACCP regulatory programs for seafood, meat, and poultry. In late 1995 the Administration issued new rules to ensure seafood safety. In July, 1996 President Clinton announced new regulation to

Number Key Administrative Actions.

modernize the nation's meat and poultry inspection system for the first time in 90 years. The Early-Warning System the President announced in January will gather critical scientific data to further improve these prevention systems. And additional actions outlined in this report will expand the use of HACCP principles throughout the food industry.

KEY ADMINISTRATION ACTIONS

I Enhance Surveillance and Build an Early-Warning System

As the President announced in January, the Administration will build a new national 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. For example, the Administration will:

Enhance Surveillance, expand from 5 to 8 the number of FoodNet active surveillance sentinel sites. Existing sites are in Oregon, Northern California, Minnesota, Connecticut, and metropolitan Atlanta. New sites will be in New York and in Maryland. CDC will also increase surveillance activities for certain specific contaminants. For example, CDC will begin a case-control study of hepatitis A virus to determine the proportion of cases due to food contamination and strengthen surveillance for *Vibrio* in Gulf Coast oysters.

Equip FoodNet sites and other state health departments with state-of-the-art technology, including DNA fingerprinting to identify the source of infectious agents and with additional epidemiologist and food safety scientists to trace outbreaks to their source.

Create a national electronic network for rapid fingerprint comparison. Agencies will equip the sentinel sites and other state health departments with DNA fingerprinting technology, and will link sites together to allow the rapid sharing of information and to quickly determine whether outbreaks in different states have a common source.

II

Further Food Safety Education

Foodborne illness remains prevalent throughout the United States, in part because food preparers and handlers at each point of the food chain are not fully informed of risks and related safe-handling practices. Understanding and practicing proper food safety techniques from farm to table would significantly reduce foodborne illness. The Administration--working in partnership with the private sector--will, among other things:

Establish a Public-Private Partnership for Food Safety Education. FDA, USDA, and CDC will work with the food industry, consumer groups and the states to launch a food-safety public awareness and education campaign. The Partnership will develop, disseminate, and evaluate a single food-safety slogan and several standard messages. Industry has pledged \$500,000 to date to support the partnership's activities and plans to raise additional funds.

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Report

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Educate professionals and high risk groups. Agencies will better educate physicians to diagnose and treat foodborne illness; strengthen efforts to educate producers, veterinarians, and state and local regulators about proper animal drug use and HACCP principles; and work with the Partnership to better train retail- and food-service workers in safe handling practices.

III Improve Responses to Foodborne Outbreaks

At the federal level, four agencies are charged with responding to outbreaks of foodborne and waterborne illness: CDC, FDA, and USDA's ~~Food Safety and Inspection Service (FSIS)~~ and EPA. States and many local governments with widely varying expertise and resources also share responsibility for outbreak response. The current system does not assure a well-coordinated, rapid response to interstate outbreaks. To more quickly identify an outbreak's cause and ensure a rapid response, agencies will:

- ★ **Establish an intergovernmental Foodborne Outbreak Response Coordinating Group**
[still under discussion]

Strengthen the infrastructure for surveillance and coordination at state health departments

IV Improve Risk Assessment

Risk-assessment methods help characterize the nature and size of the risk to human health associated with foodborne hazards and assist regulators in making decisions about controlling those hazards. To improve risk-assessment capabilities, agencies will:

Establish an interagency risk-assessment consortium to set priorities and guide overarching federal risk-assessment research related to food safety.

Develop better data and modeling techniques to assess exposure to microbial contaminants, and simulate microbial variability from farm to table.

V Develop New Research Methods

Today, many pathogens in food or animal feed cannot be identified, and others have developed resistance to time-tested controls such as heating and refrigeration. The agencies will focus research immediately to:

Develop rapid, cost-effective tests for the presence of pathogens, such as *Salmonella*, *Cryptosporidium*, *E.coli* O157:H7, and hepatitis A virus.

Enhance understanding of how pathogens become resistant to food-preservation techniques and antibiotics.

5
Have we kept
this?

Develop technologies for prevention and control of pathogens.

VI Increase Inspections

The agencies will pursue several strategies to increase inspections for higher-risk foods; the agencies will, among other things:

Implement seafood HACCP. FDA will add seafood inspectors using new FY98 funds to implement new seafood HACCP regulations, and will work with the Commerce Department to integrate the Department's voluntary seafood-inspection program with FDA's program.

Propose new regulations for fruit juices. FDA will also propose, among other things, to require the use of HACCP for juice products.

Propose HACCP regulatory options for egg products. FSIS will ~~consider whether to~~ propose HACCP regulatory options for egg products.

Improve coverage of imported foods. FDA will develop additional mutual recognition agreements (MRAs) with trading partners, initiate a federal-state communication system covering imported foods, and FDA and FSIS will provide technical assistance to countries whose products are implicated in a foodborne illness.

with lowered immunity due to HIV/AIDS and those on medications for cancer treatment or for organ transplantation, as well as pregnant women and their fetuses, young children, and the elderly. Patients taking antibiotics or antacids are also at greater risk of infection from some pathogens, as are people living in institutional settings, such as hospitals and nursing homes, and those with inadequate access to health care, such as homeless people, migrant farm workers, and others of low socioeconomic status.

Sources of Foodborne Contamination

Bacteria and other infectious organisms are pervasive in the environment. *Salmonella* serotype Enteritidis enters eggs directly from the hen. Bacteria (occasionally pathogenic) inhabit the surfaces of fruits and vegetables. 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 can become contaminated from agricultural animal manures and wastes 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 animals. Milk, eggs, seafood, poultry, and meat can become contaminated due to contaminated feed, misuse of veterinary drugs, or poor farming practices, in particular, mismanagement of animal manures, including production and harvesting activities. Foods can become contaminated during processing due to malfunctioning or improperly sanitized equipment, misuse of cleaning materials, rodent and insect infestations, and improper storage. Foods can become contaminated in retail facilities and in homes through poor food-handling practices.

Some microbial pathogens 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. Some of the most serious contaminants are described below. *in the Appendix.*

Salmonella

Salmonella species cause diarrhea and systemic infections, which can be fatal in particularly susceptible persons, such as the immunocompromised, the very young, and the elderly. Animals used for food production are common carriers of salmonellae, which can 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. 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. Between 128,000 and 640,000 of those infections are associated with *Salmonella* Enteritidis in eggs. Over the past decade,

*move descriptions of contaminants to the Appendix
(pages 8 - 11)*

more than 500 outbreaks have been attributed to *S. Enteritidis* with more than 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 2 and 4 million cases of campylobacteriosis occur each year with an associated 120-360 deaths.

Campylobacter jejuni and *Campylobacter coli* (two closely related species) are commonly foodborne, and are the infectious agents most frequently described in association with Guillain-Barré syndrome, 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.

Shiga-like toxin-producing *Escherichia coli*

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. It has been associated with HUS, a life-threatening complication of hemorrhagic colitis characterized by acute kidney failure that is particularly serious in young children. *E. coli* O157:H7 is found in cattle, but there may be other reservoirs; the dynamics of *E. coli* O157:H7 in food-producing animals are not well understood. Approximately 25,000 cases of foodborne illness can be attributed to *E. coli* O157:H7 each year with as many as 100 deaths resulting. *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 three western states and British Columbia was associated with unpasteurized apple juice, sickened 66 people, and caused the death of one child.

Toxoplasma gondii

T. gondii is a parasitic protozoan. Some 1.4 million cases of toxoplasmosis occur annually with an associated 310 deaths. Healthy adults who become infected usually have no symptoms but might get diarrhea. Pregnant women who become infected can pass the disease to their fetuses. In infants infected before birth, fatality is common. Should the infant survive, the effects of infection are typically severe (i.e., mental retardation). The disease can be life-threatening 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 can contribute to infections.

Cryptosporidium parvum

C. parvum is a parasitic protozoan. The most common consequence of infection in healthy people is profuse watery diarrhea lasting up to several weeks. Children are particularly susceptible. Cryptosporidiosis can be life-threatening among people with weakened immune systems. The largest recorded outbreak of cryptosporidiosis was a waterborne outbreak in Milwaukee, Wisconsin, in 1993, affecting more than 400,000 people. More recently, a waterborne outbreak in Las Vegas resulted in at least 20 deaths. The first large outbreak of cryptosporidiosis from a contaminated food occurred in 1993. That outbreak was attributed to fresh-pressed apple cider. *Cryptosporidium* also is found in animal manures.

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 multistate outbreak of viral gastroenteritis due to Norwalk virus was associated with the consumption of oysters. A 1993 Louisiana outbreak of Norwalk virus gastroenteritis involved 70 ill people and was associated with the consumption of raw oysters. In 1992, another outbreak resulted in 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.

Vibrio vulnificus

Vibrio species are gram-negative bacteria most commonly associated with seafood-containing dishes. *Vibrio parahaemolyticus* is the species that is most commonly reported as a cause of foodborne disease; it generally causes watery diarrhea and abdominal pain lasting 1-7 days, and commonly follows consumption of improperly handled cold-seafood salads. *V. vulnificus* is one of the most severe foodborne pathogens, with a case-fatality rate for invasive disease that exceeds 50%. Most cases of foodborne *V. vulnificus* infections occur in persons with underlying illness, particularly liver disorders, who eat raw molluscan shellfish. Since the late 1980s, CDC, FDA, and the Gulf Coast states have intensified efforts to collect information on *Vibrio* infections, and on the microorganisms' ecology, to improve our ability to prevent foodborne infections.

Hepatitis A virus

Hepatitis A virus (HAV) is a picornavirus that infects the liver and causes hepatitis A, an illness with an abrupt onset that can include fever, malaise, nausea, abdominal discomfort, dark urine, and jaundice after a prolonged incubation period. In children less than 6 years old, most (70%) infections are asymptomatic, but in older children and adults, infection is usually symptomatic, with jaundice occurring in more than 70% of patients. Signs and symptoms of hepatitis A usually last more than 2 months. About

10% of persons require hospitalization, and death from hepatitis A is uncommon. About 130,000 infections with HAV and 100 deaths occur each year in the United States. There are no chronic consequences of HAV infection. The primary mode of transmission for HAV is person-to-person by the fecal-oral route. Recognized foodborne hepatitis A outbreaks account for only 2% to 5% of hepatitis A cases reported in the United States each year. These outbreaks are usually associated with foods contaminated by an infected food worker during preparation. Outbreaks due to foods contaminated prior to preparation, while uncommon, have been associated with widely distributed products such as shellfish, lettuce, frozen raspberries, and frozen strawberries. Hepatitis A can be prevented before exposure by hepatitis A vaccine, and after exposure by immune globulin, if given within 14 days of exposure.

THE CURRENT SYSTEM FOR PROTECTING FOOD

Our food-safety system, although generally successful in protecting the public, is characterized by complexity and diversity. Regulatory authority is divided among federal, state, and local governments. The private sector has the primary responsibility for ensuring the safety of the food that it produces. From the farm to the consumer's dinner table, the responsibilities can be summarized as follows:

- Consumer education on food handling and storage in the home is the primary responsibility of FSIS, CSREES, FDA, and CDC. FSIS, with responsibility for meat, poultry and most egg products, FDA, with jurisdiction over all other foods, and CDC, with epidemiological capabilities, all produce educational materials. FDA and FSIS staff consumer hotlines, and all agencies have web sites. CSREES has an enormous network of extension agents across the country, and FDA has Public Affairs Specialists in offices around the country to respond to inquiries and conduct safe handling programs for consumers, health professionals, and the media.
- In the home, consumers have a responsibility for proper handling and storage of food. Because consumer mishandling contributes to many cases of foodborne illness, FSIS promulgated safe-handling labels for raw meat and poultry products.
- On the farm, food is regulated by state agencies supported principally by the Environmental Protection Agency (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 the Animal and Plant Health Inspection Service (APHIS) in the U.S. Department of Agriculture (USDA), which is concerned with food-animal-disease control. Federal responsibility also covers production and harvesting activities that discharge wastewater to surface and to ground waters and solid waste to land, all of which could contaminate growing and processing waters or grazing land. Animal manures are excluded from the definition of solid waste under EPA's solid-waste-disposal regulation, and therefore, an EPA regulatory mechanism does not exist for these

Move Description of Current System to the Appendix (pages 11-13)

materials. The ecology of human pathogens in food animals and in their manures produced on farms and ranches, in wild animals, in slaughter operations, and in processing facilities has received little attention in the past. Regulations under the Clean Water Act require large animal-feeding operations to obtain a discharge permit.

- Food processing for foods other than meat, poultry, and egg products (except shell eggs) is regulated by FDA, whose inspectors are responsible for visiting about 53,000 plants periodically, with emphasis on the highest risk foods or processing techniques. FDA devotes about 700 inspectors and laboratory personnel to this activity. Meat, poultry, and all other egg products are regulated by FSIS, whose inspectors are present in 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. In 1996, FSIS and FDA 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 microbial contamination during transportation. FDA and USDA will evaluate the comments and information received in response to the ANPR as a basis for determining what, if any, regulatory approach to take, including development of guidelines. These guidelines may include such elements as suggested performance standards for temperature control, providing information on prior cargo, and cleaning information for the food-shipper's use, to ensure the safety of the food at its destination.
- Importation of food from foreign countries is overseen by FSIS for meat, poultry, and most egg products and by 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) fall under the FDA's retail food-protection program, a cooperative federal-state food-safety effort operated under the Public Health Service Act. FDA has regulatory authority under the Federal Food, Drug, and Cosmetic Act over retail establishments because the food used in these establishments traveled in interstate commerce, however, the PHS Act provides the means for more efficient regulation and use of available resources, as well as broader inspection coverage. FDA publishes the Food Code, which consists of model recommendations that states and local authorities adopt and use to regulate retail food establishments. FDA, along with FSIS and CDC, work with states biennially to update the Food Code.
- National standards for drinking water and criteria for surface waters 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 sources, and control outbreaks. CDC conducts field investigations of foodborne diseases only at the request of state health departments, which have the authority to implement outbreak control measures. FDA, FSIS, or both are called in when food within their jurisdiction is suspected. FDA is charged with ensuring that foods implicated in a foodborne illness outbreak and traveling in interstate commerce are removed from the market.
- Research serves many purposes in reducing the incidence of foodborne illness and is integral to the programs of all public-health agencies. Research is essential to evaluate effectiveness of surveillance initiatives, control and prevention strategies, conduct risk assessments, and verify effectiveness of preventive techniques such as HACCP. Research into the cause and transmission of foodborne illness is the primary responsibility of CDC, FDA, USDA, and EPA. The development of screening and analytic methods to rapidly and accurately identify and characterize foodborne hazards, identifying and tracking to the source the causes of foodborne illness, is the responsibility of FDA, USDA, EPA, and CDC. Research to develop preventive technologies, ranging from new production techniques, to disinfection and food-processing techniques to reduce levels of pathogens, is the primary responsibility of USDA, FDA, and industry. Basic research is conducted largely in university laboratories on the biology, genetics, pathogenesis, natural history, and epidemiology of microorganisms implicated in foodborne disease and is actively supported by the NIH, and in particular, by the National Institute of Allergy and Infectious Diseases. These efforts are focused on understanding the disease process and designing prevention and treatment strategies. Other agencies of the federal government also support 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

in Re Appendix

The system for identifying and preventing foodborne illnesses described ~~above~~ was largely created in the early 1900s. It must be modernized. The system cannot properly identify, track, control, or and prevent food-related illness or prevent future cases from occurring. In 1981, FDA inspected food firms every 2-3 years, but can now visit those firms, on average, only once every 10 years (although some plants that produce higher-risk foods may be inspected more frequently). State and federal resources are not closely coordinated. Our understanding of some disease-causing organisms is so limited that our ability to protect the public health is seriously constrained.

The Clinton Administration has already taken a number of steps to improve the safety of the food supply.

- In 1993, the Vice President's National Performance Review issued a blueprint for reinventing our nation's food-safety system. A major recommendation of the report was

are sometimes the first to recognize that their product is causing illness. In addition, most food-product recalls are voluntary. Federal and state agencies can benefit from industry's expertise about food products and their distribution patterns.

Problem

Although significant coordination already occurs among federal, state, and local agencies, better coordination is needed to meet new and growing threats to the nation's food supply. More than one agency is involved in virtually every large foodborne outbreak. Joint efforts are often hindered by a lack of communication or a misunderstanding of each agency's role in a particular situation.

Recommendations

Federal, state, and local governments should improve the coordinated management of interstate outbreaks. Improved coordination among the federal agencies, among federal, state, and local agencies, among the various state agencies, and between state and local agencies would enhance the level of public-health protection, leverage agency resources and experience, and avoid duplication of effort.

Improve Outbreak Containment Through Better Federal-State-Local Coordination of the Evaluation of and Response to Foodborne Illness

There are probably hundreds of times a year when at least one federal agency, working with state and local agencies, plays a role in detection, investigation, and containment of illnesses that may be caused by contamination of food. Occasionally (typically once or twice a year) the outbreak is sufficiently significant and complex to require the involvement of the highest level officials in the responsible federal agencies. The agencies that typically will be involved will be CDC and USDA (if the outbreak involves meat and poultry), FDA (if the outbreak involves any other food product), or EPA (if the outbreak involves drinking water).

Each agency should designate a person with responsibility for coordinating its activities for any significant and complex outbreak, and a single official will be placed in charge of the federal government's role in managing the outbreak.

In addition, CDC, EPA, FDA, and USDA will establish an intergovernmental group, the Foodborne Outbreak Response Coordinating Group (FORCG), to improve the approach to interstate outbreaks of foodborne illness. FORCG will provide for appropriate participation by representatives of state and local agencies charged with responding to outbreaks of foodborne illness.

FORCG will review and evaluate outbreak response. FORCG will undertake these reviews after

what does managing²⁹ mean? Managing flow of information? Resources? Managing communication w/ White House & the public?

appropriate consultation with industry and consumer representatives. Based on these deliberations, FORCG will assess the infrastructure for outbreak response, make recommendations for improving the current system, and work with federal, state, and local governments, the food industry, health professionals, and consumer advocates to implement beneficial changes. FORCG will meet several times a year for this purpose.

FY97 Activities

- For outbreaks that fall within the purview of CDC and FDA, HHS will identify the official with lead responsibility for managing the outbreak. HHS and USDA will identify the individual responsible for managing any significant and complex outbreak that falls within the jurisdiction of both Departments. → state what this means!
- CDC, EPA, FDA, and USDA, in consultation with representatives of state and local governments, will establish the Foodborne Outbreak Response Coordinating Group.

Enhance State and Local Infrastructure for Foodborne Outbreak Detection, Evaluation, and Response Coordination

The epidemiology offices and laboratories within state and local health departments are charged with the surveillance of infectious and non-infectious conditions, and, along with other state and local 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 and communities for the surveillance and investigation of foodborne diseases are limited and decreasing, thereby limiting the effectiveness of their response. As a result, outbreaks may go undetected or are never investigated.

CDC, EPA, FDA, and USDA will address the problem first by assessing and cataloguing available state resources, and then by working with states and providing support for foodborne-disease-surveillance programs and assistance to better investigate outbreaks of foodborne illness.

FY97 Activities

- FORCG, with assistance from the Association of Food and Drug Officials, the Association of State and Territorial Health Officials, the Association of State and Territorial Public Health Laboratory Directors, the Council of State and Territorial Epidemiologists, and the National Association of State Departments of Agriculture, will begin a nationwide audit to catalogue the existing state and local food-safety program infrastructure.
- FORCG, in consultation with the appropriate outside organizations, will establish working groups consisting of federal, state, and local officials to develop recommended procedures for outbreak response coordination at the state and local level.

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. State and local officials also have primary responsibility for inspecting restaurants, supermarkets, and other retail establishments. At the federal level, FSIS has responsibility for continuous meat- and poultry-inspection in slaughter and processing plants and egg-product processing plants, and for all imported meat, poultry, and egg products. FDA conducts periodic, random inspections of all other food-processing plants; that entails fewer than 700 inspectors and laboratory personnel for 53,000 U.S. plants and for all other imported foods.

Problem

The number of inspections conducted by FDA 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. An FDA-regulated plant is inspected by FDA, on 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, because the number of imports has doubled over 5 years, with no real increase in inspectors, a smaller percentage of imports are inspected at entry.

Given the limited inspection coverage,
As FDA's inspections have dropped, FDA is finding an increasing number of problems--the number of products recalled for life-threatening microbial contamination has increased almost five-fold since 1988. ✓

Recommendations

Scientists and other food-safety experts have concluded that the most effective and efficient mechanism to ensure that food processors identify and control hazards that could threaten food is the application of HACCP principles. FDA's seafood HACCP regulations go into effect in December 1997. FSIS began to implement its HACCP and Pathogen Reduction Requirements for the meat and poultry industries in 1997 with phase-in completed in 2000.

To ensure that HACCP is properly implemented, and to ensure more efficient and effective monitoring of the safety of the food supply, recommendations are being made in the following areas.

Enhance Development of HACCP Procedures

FY97 Activities:

NOAA says
ok.

- FDA will implement seafood HACCP by hiring approximately 80 investigators to conduct inspections to ensure proper implementation of seafood HACCP. ↓
- A performance-based organization (PBO), will be created, with Congressional approval, as the organizational structure for the voluntary fee-for-service seafood program currently located at the Department of Commerce's National Marine Fisheries Service. The Departments of Commerce and Health and Human Services will consider whether to locate the PBO at FDA, which would consolidate voluntary and mandatory seafood programs within one agency and provide limited additional resources for implementation of seafood HACCP, while continuing the voluntary fee-for-service program.
- FDA and USDA will cooperate in evaluating the feasibility of HACCP for commodities such as fresh fruit and vegetables. The process could also consider whether it is appropriate to use USDA inspectors to inspect plants that manufacture products regulated by both agencies, such as fresh produce used in the school lunch program.

Long-term Activities

- FDA should further the use of HACCP principles, as appropriate, for other foods, including animal feeds, and use risk-assessment techniques where possible.
- ~~The Administration should evaluate the voluntary fee-for-service seafood program and the operational functioning of the seafood PBO.~~

NOAA wants this
deleted!!

Enhancing the Safety of Foods Produced in Retail Food Establishments Particularly at State and Local Levels

More than 3,000 state and local regulatory agencies have primary responsibility for monitoring retail food establishments to ensure that consumers are protected. U.S. retail establishments include approximately 785,000 commercial- and institutional-food establishments, 128,000 grocery and convenience stores, and 1.5 million vending operations. Workers in these establishments have highly diverse backgrounds and training.

FY97 Activities

- FDA and FSIS will hold a series of meetings with state and local regulators in five regions to establish retail program standards in accordance with the 1997 model state code (the Food Code") to enhance national uniformity.

FY98 Activities with Food-Safety Initiative Funds

- FSIS and FDA will provide HACCP training to state and local inspectors that will

sharing of inspection results.

**Enhance Coverage of Imported Foods
with Specific Attention to Foods Regulated by FDA
To Address the Problem of Rising Imports
and ~~FDA's Inability to Provide Adequate Coverage~~**

Limited Inspection Coverage

Wharf examinations and sampling of foods being offered for import into the United States have dropped by 50% in just the past four years. Today, FDA is responsible for about 2.2 million import food entries (i.e., shipments), an increase from 1.5 million entries just 5 years ago, with the same number of staff.

FY98 Activities with Food-Safety Initiative Funds

- FDA will expand its program to develop mutual recognition agreements (MRAs) with trading partners. Under MRAs, the trading countries ensure that food is produced and manufactured under equivalent systems that provide a comparable level of safety.
- FDA will initiate a federal-state communication system through which states can inform federal agencies of problems found with imported products in their jurisdictions.
- FDA will initiate a system for certifying and accrediting private laboratories, including use of a quality-assurance procedure, that will be authorized to test samples of food products for contaminants. Such private parties would provide a service to food firms wishing to demonstrate that their products meet applicable federal standards.
- When FDA and FSIS become aware of possible public-health problems associated with a regulated food product (e.g., through occurrence of foodborne illness outbreaks, sample analysis, or inspections), the agencies will provide technical assistance to the foreign country importing the product.

Long-term Activities

- FSIS should continue to verify foreign government-inspection progress for conformance with the new HACCP and Pathogen Reduction Requirements; that activity will begin in 1997 and should be completed in 2000.
- The laboratory-certification process should be extended to include assessing the utility of existing accrediting bodies with FDA providing performance standards and oversight to the process.
- FDA should expand the federal-state communication system states use to inform federal agencies of problems found with imported products in their jurisdictions. As part of that

A BLUEPRINT FOR A BETTER FOOD SAFETY SYSTEM

Background

Several components of USDA, HHS, and EPA have responsibilities for ensuring the safety of the U.S. food supply. USDA also has ancillary responsibilities for the quality of our food. These responsibilities include the grading of agricultural commodities and grain by the Agricultural Marketing Service and the Grain Inspection Service, the importation of foreign plants and animals by the Animal and Plant Health Inspection Service, and the quality and wholesomeness of food purchased by the federal school lunch program. Regulatory requirements applicable to food products are largely established by FSIS for meat, poultry and egg products, and by FDA for all other products.

The programs in the two agencies have very different histories. Because meat and poultry have historically been considered to have the greatest risk, these products have been regulated under a separate regulatory program administered by FSIS. Under that program, at least one USDA official is present in every meat- and poultry-slaughter plant and is responsible for continuously inspecting meat and poultry products. FDA, on the other hand, regulates products that have historically been considered less risky. For these reasons, historically the two agencies have taken very different approaches to food regulation, with FSIS relying on continuous inspection and FDA relying on periodic inspections.

These old assumptions are no longer valid. In recent years, it has been increasingly argued that foodborne diseases can be caused by microbial contamination in seafood, fresh fruits, vegetables, and other products. Moreover, during the Clinton Administration, both agencies have adopted a new and similar approach to food regulation. USDA has adopted HACCP for the products that it regulates and FDA has adopted HACCP for seafood products, and is considering the HACCP approach for other products. During the next few years, these HACCP regulations will go into effect. One function of the strategic-planning process is to consider how ~~to make the best use of each agency's limited resources~~ *to leverage each agency's resources for the best public health impact.*

Recommendations

The process for preparing a comprehensive long-term food safety strategic plan should facilitate the participation of all interested parties. Extensive dialogue will be needed to build trust in the process, obtain agreement on the priorities, strategies for achieving change, and a process for measuring progress.

Another mechanism that could be used to facilitate a strategic planning process would be to have the food safety agencies overseeing the process and then incorporating appropriate elements of the strategic planning process into their individual agency strategic plans. As with the other suggested approaches, a process would be developed for selecting a constituent committee which would receive suggestions and recommendations from a series of public meetings, focus groups

This is confusing. I'm assuming that the recommendation is that there needs to be a long-term food safety strategic plan.

Prepare a 3- to 5-Year Strategic Plan

Participants in the planning process would be charged with developing a strategic long-range agenda that could be used to help set priorities, improve coordination and efficiency, identify gaps in the current system, and enhance and strengthen prevention and intervention strategies, and identify measures to show progress.

Measure Progress to Evaluate the Effectiveness of the Plan in Reducing the Annual Incidence of Foodborne Illness

Progress would be reviewed after 2 years to determine the strategic plan's effect on reducing the annual incidence of foodborne illness. Measurable goals and objectives would provide a basis for establishing progress. Measurements could be based on a decline in the number of foodborne illnesses and deaths, a decline in the number of outbreaks, more effective prevention and intervention programs, more rapid responses to foodborne illness outbreaks, increases in inspection coverage for domestic and imported products, changes in behavior, and better detection and quantification methodologies.

Who would be the recipient of the
strategic plan? Pres? Congress? or
just the Departments?

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Roster 10 202

4/25/97 - added in Kaye's paragraph on FSIS activities in emergency response area

INTERSTATE OUTBREAK CONTAINMENT AND RESPONSE COORDINATION

Background

Four federal agencies are charged with responding to outbreaks of foodborne illness (including waterborne illness): FDA and CDC (at HHS), FSIS (at USDA), and EPA. All states, and many local governments, with widely varying expertise and resources, share responsibility with the federal government for response to such outbreaks. When an outbreak occurs, all of the relevant entities must work together to efficiently and effectively prevent deaths and minimize the number of illnesses. The better coordinated the response, the more quickly the outbreak will be contained.

Each of the four federal agencies has a potentially critical role when an outbreak occurs. 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, FSIS, and EPA also have responsibility for determining whether a product they regulate may be causing illness, and of 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 type of food affected determines which regulatory agency has primary jurisdiction: FSIS regulates meat, poultry, and egg products; FDA regulates all other foods including shell eggs; and EPA regulates water and pesticides and manages organic and inorganic wastes used or disposed of on agricultural land. While each agency has clearly defined areas of responsibility, the successful containment of many outbreaks of foodborne illness involves more than one agency.

The states and many local governments also have a critical role. Identification and investigations of foodborne illness often begin at the community or state level. States share with the federal government the legal responsibility for protecting the health of their residents. Although food outbreaks are sometimes local because of improper processing or handling, most outbreaks implicate 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.

In many outbreaks of foodborne illness, federal agencies work with state and local health authorities in their investigations 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 the 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.

Companies responsible for affected products also have a critical role to play. Food companies are sometimes the first to recognize that their product is causing illness. In addition, most food-product recalls are voluntary. Federal and state agencies can benefit from industry's expertise about food products and their distribution patterns.

Problem

Although significant coordination already occurs among federal, state, and local agencies, better coordination is needed to meet new and growing threats to the nation's food supply. More than one agency is involved in virtually every large foodborne outbreak. Joint efforts are often hindered by a lack of communication or a misunderstanding of each agency's role in a particular situation.

Recommendations

Federal, state, and local governments should improve the coordinated management of interstate outbreaks. Improved coordination among the federal agencies, among federal, state, and local agencies, among the various state agencies, and between state and local agencies would enhance the level of public-health protection, leverage agency resources and experience, and avoid duplication of effort.

The early warning capability of FoodNet and the strengthening of state surveillance capacity and federal-state communications will enhance ^{appropriate} early involvement of federal agencies in the investigation of foodborne disease outbreaks. ~~It is critical for responsible agencies to be aware of the developing situation when a food vehicle is suspected.~~ An essential factor in effective response to foodborne outbreaks is rapid communication and exchange of information among the appropriate federal, state, and local government agencies.

Improve Outbreak Containment Through Better Federal-State-Local Coordination of the Evaluation of and Response to Foodborne Illness

There are probably hundreds of times a year when at least one federal agency, working with state and local agencies, plays a role in detection, investigation, and containment of illnesses that may be caused by contamination of food. Occasionally (typically once or twice a year) the outbreak is sufficiently significant and complex to require the involvement of the highest level officials in the responsible federal agencies. When this occurs, it is essential that federal agencies speak with one voice. ~~The agencies that typically will be involved will be CDC and USDA (if the outbreak involves meat and poultry), FDA (if the outbreak involves any other food product), or EPA (if the outbreak involves drinking water).~~

The lead department in any foodborne illness outbreak will be determined by regulatory jurisdiction over the food products implicated in the outbreak. FSIS has regulatory responsibility for meat, poultry, and egg products, so USDA will be the lead when these

system to keep all state agencies up-to-date on major foodborne outbreaks. This system was first used for the outbreak involving *E. coli* O157:H7 in apple juice and was most recently used for the hepatitis A outbreak associated with frozen strawberries. FDA and CDC jointly participate in these calls to assure more effective follow up and control of outbreaks.

B3

FDA will modify the conference call system to involve appropriate states in the very early stages of any multistate outbreak, as well as continuing the 50-state update conference calls, in order to ensure better communication among state and federal agencies.

~~These FDA activities are coordinated by the agency's Division of Emergency~~

FSIS has established an Emergency Response Program to prevent and control foodborne disease outbreaks involving meat, poultry, and egg products. The program has Field Epidemiology Officers throughout the country who maintain a liaison with state public health officials and assist states in outbreak investigations. These activities are coordinated by the Emergency Response Division at headquarters, where the Division maintains an 800 number with a 24-hour answering service used by state and federal health officials, consumers, and the industry.

FDA's Division of Emergency and Investigational Operations serves this function for all other food products. The Division maintains 24-hour telephone service (~~800 number~~) 301 443 1240 staffed with ^{a duty officer} individuals trained to respond to emergencies and ongoing illnesses, including foodborne illness and outbreaks. DEIO has immediate access to emergency personnel throughout the agency, as well as with emergency contacts in other agencies, including CDC, USDA, and EPA. This Division will serve to coordinate with other agencies (this is a new function).

EMERGENCY

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A2

301 443 1240

B4

FSIS communicates with state departments of health and coordinates outbreak response through CDC WONDER (Internet) and both FDA and USDA maintain liaisons at CDC to facilitate food safety activities, including outbreak investigations.

Force G here
FY97 Activities

- For outbreaks that fall within the purview of CDC and FDA, HHS will identify the official with lead responsibility for managing the outbreak. HHS and USDA will identify the individual responsible for managing any significant and complex outbreak that falls within the jurisdiction of both Departments.

- Under the new initiative there will be one person/position designated as the outbreak coordinator for each department or agency. This position will be established as a formal institutional position, with appropriate backup designees. For outbreaks that fall within the purview of CDC and FDA, HHS will designate [the Assistant Secretary for Health] to be the primary person in charge of coordination. For outbreaks that fall with the purview of USDA, the Under Secretary for Food Safety will coordinate. Both the [Assistant Secretary for Health] and the Under Secretary for Food Safety will

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manage outbreak responses that fall within the jurisdiction of both agencies. EPA will designate the [_____] as the primary person in charge of coordination when drinking water is involved.

- CDC, EPA, FDA, and FSIS, in consultation with representatives of state and local governments, will establish the Foodborne Outbreak Response Coordinating Group.
- 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 SOPs will be developed by a group of representatives from each federal agency and from the appropriate state agencies. The SOPs 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. (See "Early Warning for Foodborne Illness Surveillance" section.) The SOPs will also provide for rapid dissemination of accurate information to the public by the agency spokesperson.

Enhance State and Local Infrastructure for Foodborne Outbreak Detection, Evaluation, and Response Coordination

The epidemiology offices and laboratories within state and local health departments are charged with the surveillance of infectious and non-infectious conditions, and, along with other state and local 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 and communities for the surveillance and investigation of foodborne diseases are limited and decreasing, thereby limiting the effectiveness of their response. As a result, outbreaks may go undetected or are never investigated.

CDC, EPA, FDA, and FSIS will address the problem first by assessing and cataloguing available state resources, and then by working with states and providing support for foodborne-disease-surveillance programs and assistance to better investigate outbreaks of foodborne illness.

FY97 Activities

- FORCG, with assistance from the Association of Food and Drug Officials, the Association of State and Territorial Health Officials, the Association of State and Territorial Public Health Laboratory Directors, the Council of State and Territorial Epidemiologists, and the National Association of State Departments of Agriculture, will begin a nationwide audit to catalogue the existing state and local food-safety program infrastructure.

- **FORCG, in consultation with the appropriate outside organizations, will establish working groups consisting of federal, state, and local officials to develop recommended procedures for outbreak response coordination at the state and local level.**

FY98 Activities with Food-Safety Initiative Funds

- **CDC, EPA, FDA, and FSIS will assist states and local governments in developing the infrastructure necessary to ensure proper detection, evaluation, and coordinated response to foodborne outbreaks.**

Possible VP Statement

Good Morning.

Over the past few weeks, schoolchildren and parents across the nation have been frightened about eating that most quintessential of children's food--strawberries. But the outbreak in Michigan of Hepatitis A in strawberries is only the latest in the all-too-frequent cases of foodborne illness. Every year, thousands of Americans are stricken by illness caused by the food they consume, and it is estimated that 9,000 a year--mostly the very young and the elderly--die as a result.

Although we as Americans are rightfully proud that our food supply is among the safest in the world, there are real threats out there--ranging from *E.Coli* in meat and apple juice, to *Salmonella* in eggs, to *Cyclospora* on fruit, to *Cryptosporidium* in drinking water. We as a society must fight these threats, and this Administration will lead the way.

In January, President Clinton announced that we were launching a new nationwide early warning system for foodborne illness. Under that system, disease "detectives" will track down these illnesses, stop them in their tracks, and work to prevent their recurrence. He also asked the Secretaries of Agriculture and Health and Human Services, and the Administrator of the Environmental Protection Agency, to report back to us within 90 days on further ways to protect the public from these deadly diseases.

Well, they have delivered that report, and it provides the first comprehensive set of recommendations for improving food safety since the current system was created in 1906. It was done through intensive consultations with the many groups concerned about our food supply--food producers, manufacturers, consumer groups, academia and our colleagues in the states. The report is a plan that, when implemented, will make our food supply significantly safer. I won't take the time to discuss all of the proposals now. But let me give you a few highlights.

First, we're going to follow through on the President's January announcement of a new early warning system. New "FoodNet" sites will be added in New York, Maryland and the desert southwest to help catch and respond to outbreaks of food poisoning. We're also going to help our friends in the states develop the kind of state-of-the-art technology, including DNA fingerprinting, that will enable us to track these diseases to their source. And we're going to better coordinate these outbreaks when they occur. When there is an outbreak, it will be clear to the states, the press, and the public that one person is in charge and knows what's going on.

NO

Next, we're going to apply the latest science to these problems. Where we can't even determine if a microbe is on a food today, we'll do the research to learn how to find it. Where these "pathogens" can defeat our food preservation technology, we'll develop new technology. And where they resist our efforts to control them, we'll develop measures to stamp them out before they can attack our families.

We're also announcing today a major new public-private partnership for food safety education. One of the most effective ways of preventing foodborne illness is by making sure that restaurant and cafeteria workers, and ordinary citizens, know such simple techniques as washing hands and food preparation surfaces and cooking certain foods at high enough temperatures. Secretaries Glickman and Shalala today signed a new agreement under which the Federal government and a wide array of food manufacturers and retailers will develop a nationwide education campaign. Industry has pledged \$500,000 to this effort and plans to raise additional funds.

And lastly, we're going to upgrade our regulatory program. Over the past two years, we have developed new safety control procedures for meat, poultry, and seafood processors that uses state-of-the-art science in protecting those foods from contamination. Next year, we will expand those procedures to fruit juices and eggs. And over the next few months, HHS and USDA will work together to determine how they can better coordinate their many food safety efforts to ensure that such state-of-the-art scientific principles are used across the food supply.

No one of the action I've outlined today will ensure safe food, nor can any government effort guarantee that. But these actions collectively form a real plan for reducing the risk to our parents, our children and ourselves. The President's 1998 budget asks Congress for funds to begin this journey. I urge members to seriously consider our request. The modest funds we're seeking can go a long way toward helping our food producers make the best food possible and our citizens live longer, healthier lives.



United States Department of Agriculture
Food Safety and Inspection Service

FAX

To:

Elizabeth Dye

Fax #:

456-5581

Subject:

Cover letter for report

Date:

Pages:

3 including this cover sheet.

COMMENTS:

Revised

From the desk of

Tom M
Thomas J. Billy

Administrator

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

202-720-7025

or 720-8217

Fax 205-0158

OK-MB
4/30/97

DRAFT

MEMORANDUM FOR THE PRESIDENT

We are pleased to provide you with the report on improving the safety of the nation's food supply that you requested on January 25, 1997. As you stated in that request, the American food supply is unmatched in quality and quantity, and Americans can be confident that their food supply is one of the most wholesome in the world. However, Federal, State, and local food safety authorities face many challenges in maintaining and improving these high food safety standards that we all expect. Our report, prepared after an intensive dialogue with constituent groups outlines action items that USDA, HHS and EPA will take this year to reduce foodborne illness and explains in greater detail how the agencies will use the 43 million in new funds requested for fiscal year 1998.

Key Administration actions outlined in this report are:

- Surveillance and "Early Warning"-- A national early warning system to help catch and respond to outbreaks of foodborne illness earlier, preventing the occurrence or mitigating the extent and severity of foodborne illness;
- Outbreak Response-- A new management system that will direct all operations in coordination with representatives of states and local agencies charged with responding to outbreaks--this new system will provide a common set of objectives and strategies to improve the approach to interstate outbreaks of foodborne illness;
- Risk Assessment-- A new risk assessment consortium to set priorities and guide overarching federal risk-assessment research related to food safety;
- Research-- Expanding research to develop new methods for identifying and controlling foodborne pathogens;

- **Inspections--Improving the Federal inspection process through expanding the use of modern technology, forging stronger partnerships with the States, and enhancing development of Haccp systems to allow the government to focus on the points of greatest risk;**
- **Education--an unprecedented new partnership between the private sector and government agencies including industry, consumer groups, USDA, HHS and the Department of Education that will center on key food safety messages; and**
- **Strategic Planning--Developing a strategic plan and a shared long-term agenda for a continually improving food safety system.**

We look forward to working together under your leadership to make the food safety infrastructure improvements outlined in the enclosed report.

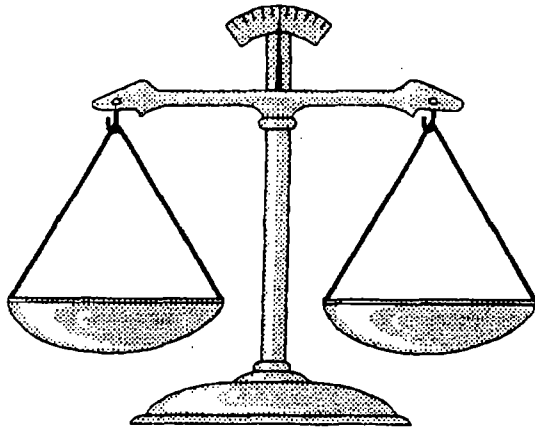
Sincerely,

DAN GLICKMAN
Secretary of Agriculture

DONNA E. SHALALA
Secretary of Health
And Human Services

CAROL M. BROWNER
Administrator
Environmental Protection Agency

FOOD AND DRUG ADMINISTRATION



OFFICE OF POLICY

REGULATIONS POLICY
AND
MANAGEMENT STAFF

FACSIMILE NUMBER: FTS: 443-2946
COMMERCIAL: 301-443-2946

DATE: 5-2-97

TO: Elizabeth Dye
fax: 202-456-5581

FROM: Robin Johnson
FDA
301-443-3480

Requested by Bill Hubbard

Number of Pages

COVER + 1

FOOD AND DRUG ADMINISTRATION
5600 FISHERS LANE, HF-26
ROOM 12A-17
ROCKVILLE, MD 20857

MESSAGE: Attached is the discussion for HACCP as it relates to the processing of juice in the Unified Agenda. The Agenda published in the Federal Register of April 25, 1997 (62 FR 21702).

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by telephone at 301-443-3480 and return it to us at the above address by mail, HF-26. THANK YOU!!

21702

Federal Register / Vol. 62, No. 80 / Friday, April 25, 1997 / Unified Agenda

HHS—FDA

Long-Term Actions

Small Entities Affected: Businesses**Government Levels Affected:** State, Federal**Additional Information:** Previously reported under RIN 0905-AD89.**ABSTRACT CONT:** nutrition labeling for raw produce and fish.

Agency Contact: F. Edward Scarbrough, Director, Office of Food Labeling, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS-150), 200 C Street SW., Washington, DC 20204
Phone: 202 205-4561
Fax: 202 205-4594

RIN: 0910-AA19

1002. CLASSIFICATION OF COMPUTER SOFTWARE PROGRAMS THAT ARE MEDICAL DEVICES**Priority:** Other Significant. Major status under 5 USC 801 is undetermined.**Unfunded Mandates:** Undetermined**Legal Authority:** 21 USC 321(h); 21 USC 351; 21 USC 352; 21 USC 360(c)**CFR Citation:** None**Legal Deadline:** None

Abstract: FDA is considering whether it can or should classify stand-alone computer software products that fit the definition of a medical device under the Federal Food, Drug, and Cosmetic Act. The Secretary has made no decision regarding whether or not to initiate such a program. The Agency anticipates classifying these devices by using a risk-based approach as required under the Medical Device Amendments to the act. In addition, the agency will use existing exemptions from regulation where appropriate. Under this approach low risk medical software devices would be subject only to the adulteration and misbranding provisions of the act. Moderate risk devices would additionally be subject to the registration, listing, and good manufacturing practice requirements for adverse events and complaints. High risk devices would be the only products to require premarket submissions or premarket approval. FDA is also seeking comment on potential criteria related to the intended uses of medical software devices that might be used in determining the level of risk.

Timetable:

Action	Date	FR Cite
NPRM	00/00/00	

Small Entities Affected: Undetermined**Government Levels Affected:** None**Additional Information:** Previously reported under RIN 0905-AE58.

Agency Contact: Chuck Furfine, Regulatory Review Scientist/Software Expert, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health (HFZ-84), 2098 Galther Road, Rockville, MD 20850
Phone: 301 594-4765

RIN: 0910-AA41

1003. DEVELOPMENT OF HAZARD ANALYSIS CRITICAL CONTROL POINTS FOR THE FOOD INDUSTRY; REQUEST FOR COMMENTS; PROPOSED RULE**Priority:** Economically Significant. Major under 5 USC 801.**Legal Authority:** 21 USC 321 et seq; 21 USC 342(a)(4); 21 USC 371(a); 42 USC 264**CFR Citation:** 21 CFR 120**Legal Deadline:** None

Abstract: FDA announced on August 4, 1994, its plans to consider developing regulations that would establish requirements for a new comprehensive food safety assurance program for both domestically produced and imported foods that would be based on the principles of Hazard Analysis Critical Control Points (HACCP). The new food safety program would respond to new challenges, such as new food processing and packaging technologies, new food distribution and consumption patterns, exposure to industrial chemicals and chemical waste, the increasing importation of foods, new microbial pathogens, and resource constraints. The most serious of these challenges is presented by food pathogens. The number of recognized food-borne pathogens has broadened considerably, as has the awareness of long-term complications from certain food-borne illnesses—such as arthritis, heart disease, and kidney and neurological damage. To meet such challenges, FDA intends to shift the focus of its food safety assurance program away from periodic visual inspection and end-product testing and

toward prevention of food safety risks and problems, utilizing the HACCP state-of-the-art preventive approach. A first step was taken when FDA published a HACCP regulation for fish and fishery products on December 18, 1995. In addition, USDA published a HACCP regulation for meat and poultry on July 25, 1996. As a further step in response to comments on the ANPR, FDA proposes to publish a HACCP regulation for all foods that FDA regulates, with implementation first for processing of juice. In preparation of this document, FDA is also considering information obtained during HACCP pilot activities, and comments and scientific and technological information relating to fresh juices provided during and after the public meeting on juice held on December 16 and 17, 1996.

Timetable:

Action	Date	FR Cite
ANPRM	08/04/94	59 FR 39888
ANPRM Comment Period End	12/02/94	
NPRM	00/00/00	
NPRM Comment Period End	00/00/00	

Small Entities Affected: Businesses**Government Levels Affected:** Undetermined**Additional Information:** Previously reported under RIN 0905-AE60.

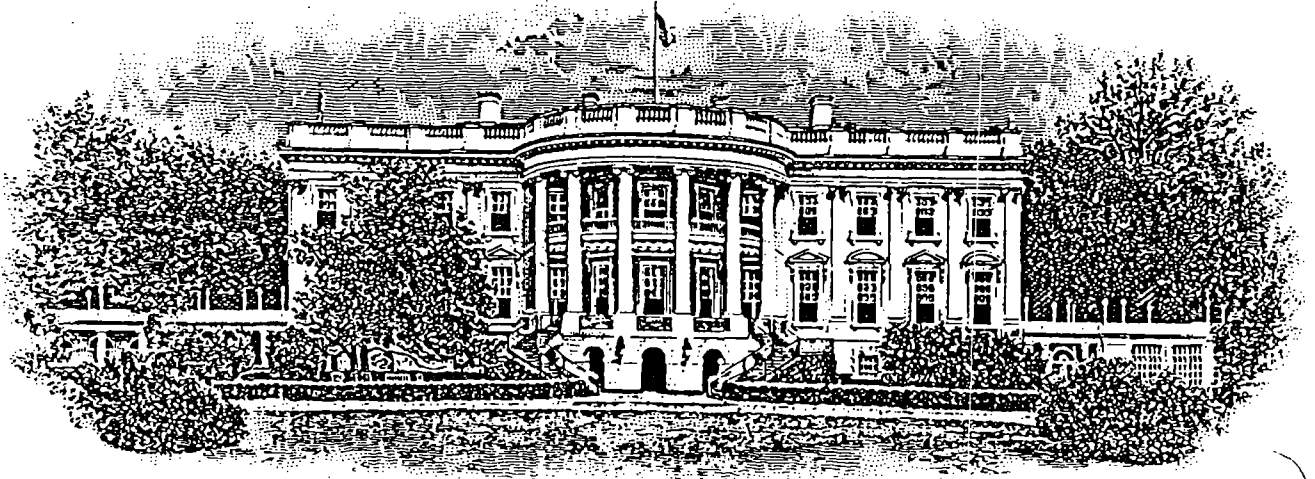
Agency Contact: John E. Kvenberg, Strategic Manager, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS-10), 200 C Street SW., Washington, DC 20204
Phone: 202 205-4020
Fax: 202 205-4018
Email: John.Kvenberg@bangate.fda.gov
RIN: 0910-AA43

1004. HABIT FORMING DRUGS**Priority:** Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.**Unfunded Mandates:** Undetermined

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 371

The White House



DOMESTIC POLICY

FACSIMILE TRANSMISSION COVER SHEET

TO: Karen Hulebak Joan Mondsheen
201-443-6906 201-459-0550
FAX NUMBER: 690

TELEPHONE NUMBER: _____

FROM: Elizabeth Dwyer

TELEPHONE NUMBER: 456-5573

PAGES (INCLUDING COVER): 2 ~~1~~ (4)

COMMENTS: My comments on weekend draft.

A BLUEPRINT FOR A BETTER FOOD-SAFETY SYSTEM

Background

As discussed throughout this report, ~~multiple departments and agencies~~ USDA, HHS, and EPA
Several components of USDA, HHS, and EPA have responsibilities for ensuring the safety of the U.S. food supply. USDA also has ancillary responsibilities for the quality of our food. These responsibilities include the grading of agricultural commodities and grain by the Agricultural Marketing Service and the Grain Inspection Service, the importation of foreign plants and animals by APHIS, and the quality and wholesomeness of food purchased by the federal school lunch program. Regulatory requirements applicable to food products are largely established by FSIS for meat, poultry and egg products, and by FDA for all other products.

The programs in USDA and HHS have very different histories. Because meat and poultry have historically been considered to have the greatest risk, these products have been regulated under separate regulatory program administered by FSIS. Under that program, at least one USDA official is present in every meat- and poultry-slaughter plant and is responsible for continuously inspecting meat and poultry products. FDA, on the other hand, regulates products that have historically been considered less risky. For these reasons, historically the two agencies have taken very different approaches to food regulation, with FSIS relying on continuous inspection and FDA relying on periodic inspections.

These old assumptions are no longer valid. In recent years, it has been increasingly argued that foodborne diseases can be caused by microbial contamination in seafood, fresh fruits, vegetables, and other products. Moreover, during the Clinton Administration, both agencies have adopted a new and similar approach to food regulation. FSIS has adopted HACCP for the products that it regulates and FDA has adopted HACCP for seafood products, and is considering the HACCP approach for other products. During the next few years, these HACCP regulations will go into effect. One function of the strategic-planning process is to consider how to make the best use of each agency's limited resources.

The actions described in this report will significantly improve the safety of the nation's food supply, but the agencies recognize that this 90-day report does not address a number of critical issues facing our food-safety programs. The agencies recommend a longer-term strategic planning effort--involving all public and private stakeholders--to consider how to best address important challenges and make the best use of the agencies' limited resources.

Through this initiative, and previous activities, we have laid the groundwork for a strategic planning effort. For example, the government, consumer groups, industry and federal agencies have worked together to incorporate HACCP into meat, poultry, and seafood regulatory programs. And there is now a broad recognition of the need to carefully implement these programs, and to consider how to apply preventive measures in other areas of concern. A strategic-planning effort could build on this common ground, and tackle some of the difficult public-health, resource, and management questions facing federal food-safety agencies.

This is totally redundant of the first 48 pages of the report. Every time I read it, I feel like we're wasting their time.

Developing a Strategic Plan

to develop a strategic plan for improving the food safety system.

Over the past 90 days, the federal food-safety agencies have engaged a wide range of stakeholders in discussions about food-safety issues through a series of public meetings and through written comments to public dockets. Although these discussions have identified some ideas for approaches to strategic planning, they have more clearly established the need for continuing discussions about the process for developing a strategic plan. ~~The federal food-safety agencies are committed to continuing to meet with stakeholders; the product of these meetings will be a strategic plan for improving the food-safety system.~~

Therefore, the agencies will initiate a long-term strategic planning process.
The process for developing a food-safety strategic plan should facilitate the participation of all interested parties. Extensive, structured discussions will be needed to build trust in the process, and to obtain agreement on the priorities, strategies for achieving change, and ways for measuring progress.

The agencies will provide the agencies will give all
Because it is critical that the process be inclusive and equitable, interested parties should be given an opportunity to comment on the possible approaches for structuring the dialogue before its implementation. Specific information will be provided regarding the general objective, scope, and conduct of the dialogue and strategic-planning process, management of the process, selection criteria for participants, and other relevant factors. Unanimous agreement is unlikely. *Therefore, The agencies will use* A general consensus ~~will be used, therefore, as the foundation upon which the planning processes is built.~~

The agencies will hold to shape the
Broad participation of stakeholders is central to the success of the discussions. The achievement of such broad participation can be accomplished in a number of ways. Meetings will involve multiple sectors to ensure broad and balanced participation of all stakeholders in the food-safety system. Meetings will be held in various regions of the United States, which will also ensure broad participation. Meetings will be open and their proceedings, products, and the process for producing those products transparent. *These means* *move this sentence below*

Issues for Consideration

A major challenge in developing a strategic plan will be attaining consensus on priorities for action to enhance food safety within the highly complex food-safety oversight system. Reaching agreement on priorities is compounded by the complexity of the food supply and the different perspectives of the various oversight agencies and groups. Federal and state agencies have established programs in research, risk assessment, education, and inspection and, ~~to a certain degree, the activities within these programs are coordinated between agencies.~~ Nevertheless, a better system of identifying and setting priorities within these areas is essential to maximizing the use and effect of limited agency resources in reducing the incidence of foodborne illness and enhancing the safety of the food supply.

agencies are working to better coordinate the

During the course of the stakeholder discussions, a variety of issues, ranging from specific to broad, surfaced as priority topics for discussion. A number of stakeholders suggested the need to

consider such broad policy questions as:

- Structure of strategic, coordinated, long-range risk-assessment and research agendas.
- Consideration of improvements for coordination and planning of food-safety regulation to optimize federal and state prevention, intervention, and control actions.

• Key public health, resource, and management questions

More focused, technical issues were also suggested for consideration, among them:

- Technical and policy issues associated with agricultural manures. Animal manures are currently excluded from regulation. Therefore, an EPA regulatory mechanism to control human health impacts that result from improper application or burial of manures to farm and other lands does not exist.

- Technical and policy issues associated with food irradiation.

- Developing a global approach to evaluating new, emerging, and potential foodborne diseases such as Transmissible (Bovine) Spongiform Encephalopathy--T(B)SE--and a process for responding to prevent the spread of such diseases.

- Means to improve exchange of information about foodborne disease outbreaks.

Prepare a 3- to 5-Year Strategic Plan

Participants in the planning process would be charged with developing a strategic long-range agenda that could be used to help set priorities, improve coordination and efficiency, identify gaps in the current system, and enhance and strengthen prevention and intervention strategies, and identify measures to show progress.

Measure Progress to Evaluate the Effectiveness of the Plan in Reducing the Annual Incidence of Foodborne Illness

After the plan's implementation, progress would be reviewed to determine the strategic plan's effect on reducing the annual incidence of foodborne illness. Measurable goals and objectives would provide a basis for establishing progress. Measurements could be based on a decline in the number of foodborne illnesses and deaths, a decline in the number of outbreaks, more effective prevention and intervention programs, more rapid responses to foodborne illness outbreaks, increases in inspection coverage for domestic and imported products, changes in behavior, and better detection and quantification methodologies.

A 1293
The actions in this report build on previous Administration steps to modernize our food-safety programs and respond to emerging challenges. As part of the Vice President's National Performance Review (NPR), the agencies have encouraged the widespread adoption of preventive controls. ~~Specifically, the NPR report urged implementation of Hazard Analysis and Critical Control Point (HACCP) systems to ensure food manufacturers identified points where~~ contamination is likely to occur and implement process controls to prevent it. Under HACCP-based there is a clear delineation of responsibilities between industry and regulatory agencies: industry ensures the safety of the food it produces and distributes and government verifies that industry is carrying out its responsibility, initiating appropriate action if necessary. *regulatory programs* *good*

The Administration has put in place science-based HACCP ^(S) regulatory programs for seafood, meat, and poultry. In late 1995 the Administration issued new rules to ensure seafood safety. In July 1996, President Clinton announced new regulation to modernize the nation's meat and poultry inspection system for the first time in 90 years. The Early-Warning System the President announced in January will gather critical scientific data to further improve these prevention systems. Additional actions outlined in this report will expand the use of HACCP principles throughout the food industry.

The need for further action is clear. ^{contaminants} Our understanding of many pathogens and how they contaminate food is limited; for some, we do not know how much must be present in food for there to be a risk of illness. The public-health system in this country has had a limited ability to identify and track the causes of foodborne illness; and federal, state, and local food-safety agencies need to improve coordination for more efficient and effective response to outbreaks of illness. Resource problems increasingly limit the ability of federal and state agencies to inspect food processing facilities (e.g., years can to by before some plants receive a federal inspection.) Increasing quantities of imported foods flow into this country daily with little scrutiny. Some food processors, restaurateurs, food-service workers, supermarket managers, and consumers are unaware of the threat of foodborne contaminants and how to protect food. These deficiencies will be addressed by key Administration actions outlined in this report and described below. *limited? scrutiny?* *and other(?)*

KEY ADMINISTRATION ACTIONS

Enhance Surveillance and Build an Early-Warning System

As the President announced in January, the Administration will build a new national early-warning system to help detect and respond to outbreaks of foodborne illness earlier, and to give us the data we need to prevent future outbreaks. For example, with FY98 funds, the Administration will:

Enhance Surveillance. The Administration will expand from 5 to 8 the number of FoodNet active surveillance sentinel sites. Personnel at sentinel sites actively look for foodborne diseases. Existing sites are in Oregon, Northern California, Minnesota, Connecticut, and metropolitan Atlanta. New sites will be in New York and in Maryland,

overarching federal risk-assessment research related to food safety.

Develop better data and modeling techniques to assess exposure to microbial contaminants, and simulate microbial variability from farm to table. Such techniques will help scientists estimate, for example, how many bacteria are likely to be present on a food at the point that it is eaten (the end of the food chain), given an initial level of bacteria on that food as it entered the food chain.

Develop New Research Methods

Today, many pathogens in food or animal feed cannot be identified; for example, there is currently no method for detecting hepatitis A virus on strawberries. Other pathogens have developed resistance to time-tested controls such as heat and refrigeration. The agencies will focus research immediately to:

Develop rapid, cost-effective tests for the presence in foods of pathogens such as *Salmonella*, *Cryptosporidium*, *E. coli* O157:H7, and hepatitis A virus in a variety of foods, especially foods associated with foodborne illness.

Enhance understanding of how pathogens become resistant to food-preservation techniques and antibiotics.

Develop technologies for prevention and control of pathogens, such as by developing new methods of decontamination of meat, poultry, seafood, fresh produce, and eggs.

Improve Inspections and Compliance

The agencies will pursue several strategies to increase inspections for higher-risk foods; the agencies will, among other things:

Implement seafood HACCP. FDA will add seafood inspectors using new FY98 funds to implement new seafood HACCP regulations, and will work with the Commerce Department to integrate Commerce's voluntary seafood-inspection program with FDA's program.

Propose HACCP regulations for fresh fruit and vegetable juices. FDA will publish proposed regulations for the use of HACCP in the manufacture of fruit and vegetable juice products.

Propose appropriate regulatory options for egg products. Based on the best science available, FSIS will propose appropriate regulatory and non-regulatory options, including HACCP, for egg products.

Identify preventive measures to address public-health problems associated with fresh produce to address public-health problems such as those recently associated with

9
hepatitis A in frozen strawberries and *E. coli* O157:H7 on lettuce. These measures will be identified through a comprehensive review of current production and food-safety programs including inspection, sampling, and analytic methods.

Improve coverage of imported foods. FDA will develop additional mutual recognition agreements (MRAs) with trading partners, initiate a federal-state communication system covering imported foods, and FDA and FSIS will provide technical assistance to countries whose products are implicated in a foodborne illness.

Further Food-Safety Education

Foodborne illness remains prevalent throughout the United States, in part because food preparers and handlers at each point of the food chain are not fully informed of risks and related safe-handling practices. Understanding and practicing proper food-safety techniques, such as thoroughly washing hands and cooking foods to proper temperatures, could significantly reduce foodborne illness. The Administration--working in partnership with the private sector--will use FY98 funds to, among other things:

Establish a Public-Private Partnership for Food-Safety Education. FDA, USDA, and CDC will work with the food industry, consumer groups and the states to launch a food-safety public awareness and education campaign. The Partnership will develop, disseminate, and evaluate a single food-safety slogan and several standard messages. Industry has pledged \$500,000 to date to support the partnership's activities and plans to raise additional funds.

Educate professionals and high-risk groups. Agencies will better educate physicians to diagnose and treat foodborne illness; strengthen efforts to educate producers, veterinarians, and state and local regulators about proper animal drug use and HACCP principles; and work with the Partnership to better train retail- and food-service workers in safe handling practices and to inform high-risk groups about how to avoid foodborne illness, e.g., illness that may be caused by consuming raw oysters containing *Vibrio vulnificus*.

Enhance federal-state inspection partnerships. New federal-state partnerships focused on coordinating inspection coverage (particularly between FDA and the states) will be undertaken, in an important step towards ensuring the effectiveness of HACCP and ensuring that the highest-risk food plants are inspected at least once per year.

Continue the long-range planning process

Through this initiative, and through previous activities, we have laid the groundwork for a strategic planning effort. There is a broad recognition of the need to carefully implement the initiative's programs, and to consider how to apply preventive measures in other areas of concern. A strategic-planning effort is needed to build on this common ground, and to tackle some of the difficult public-health, resource, and management questions facing federal food-safety agencies.

The Clinton Administration has already taken a number of steps to improve the safety of the food supply.

- In 1993, the Vice President's National Performance Review issued a report recommending that the government and industry should move toward a system of preventive controls.
- FSIS and FDA issued regulations that will require the meat, poultry, and seafood industries to follow HACCP procedures. HACCP calls for food industries to design and implement preventive measures, streamlines regulation of foods, and increases the industries' responsibility for and control of their safety assurance actions. FSIS and FDA will streamline their current regulations as part of their conversion to HACCP.
- In 1994, 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 Food Quality Protection Act of 1996, including many provisions of the Administration's bill, streamlined regulation of pesticides by FDA and EPA and put important new public-health protections in place, especially for children.
- Last year, the President signed the Safe Drinking Water Act of 1996, which includes regulatory improvements to help states and water-utility managers 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.

How measured?
for Q and A

These advances are significant, but they are not 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 change, especially change that builds on the preventive principles embodied in HACCP.

IMMEDIATE ACTIONS TO IMPROVE FOOD SAFETY

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

The Administration's food-safety efforts focus on the hazards and foods that present the greatest risks to public health and impose the greatest economic burden on the nation, emphasize development and implementation of preventive controls of those risks, and seek to ensure that preventive controls are cost-effective. The Administration is emphasizing the use of HACCP

principles, and seeks opportunities for such controls through a collaborative process with the responsible sectors of the food industry and all other stakeholders.

Under this initiative, the federal government, in concert with state and local governments, industry and academia, would conduct research and risk assessments and cost-benefit analyses to determine how foodborne illnesses occur and can be prevented or controlled in the most efficient and cost-effective manner; 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 focusing on the use of safe practices. ~~Those~~ issues, and actions and recommendations for addressing them are described below. Because the components of the food-safety initiative are interrelated, overlapping activities will be noted throughout this report (for example, among research and risk assessment, and education and inspection).

These



A NEW EARLY-WARNING SYSTEM FOR FOODBORNE DISEASE SURVEILLANCE

Background

The primary objective of the American system of public health is to prevent disease before it occurs. Although prevention of all disease might not be possible, stopping outbreaks of foodborne illness before they affect large numbers of people is a major goal. America needs an effective early-warning system that can detect and stop outbreaks before they spread. Such a system will also advance understanding of foodborne illness and further prevention efforts. In his January 25 radio address, the President announced a new national early-warning system for foodborne illness for which he is requesting funds in his FY98 budget.

Problem

The current public-health system in the United States has limited means to identify and track the causes of foodborne illness. A more effective early-warning system is needed to detect and stop outbreaks early before they spread. Also, the national and global increase in antimicrobial resistance is a compelling public-health problem. Human infections caused by resistant pathogens increase morbidity and mortality and increase health care costs as newer, more expensive antibiotics are needed to treat common infections.

Recommendations

Surveillance and investigation are powerful tools to detect new foodborne disease challenges, to determine what specific food sources are, and to learn how best to keep foods from becoming contaminated in the first place. Surveillance for antimicrobial resistance will allow early detection of resistance and containment of its spread. 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 federal partners. ✓

Enhancing ^{enhance and} 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 Foodborne Disease Active Surveillance Network (FoodNet) to identify, investigate, and control a broad spectrum of foodborne diseases. A second important way to ^{improve} 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 premature deaths related to foodborne diseases.

In cooperation with state and local health departments, the federal government is proposing to take the following steps to establish a national early-warning system for foodborne diseases, and

to enhance surveillance of such disease. These changes will result in an improved system for promptly and accurately detecting and reporting foodborne illnesses and outbreaks so public-health agencies can rapidly institute appropriately and correctly focused measures to control the spread of foodborne disease. This system will also collect critical data to recognize trends and target prevention strategies, including systems based on HACCP principles, and to evaluate the effectiveness and efficiency of prevention strategies already in place.

Enhance and Expand Foodborne Disease Active Surveillance

CDC, FDA, and USDA support five FoodNet sites at state health departments to track cases of foodborne infections and to determine the sources of the most common ones. The existing sites will be strengthened, and their number increased to seven in FY97, and to at least eight in the following year. The sites and federal food-safety agencies will be electronically linked to create a powerful new network to detect, respond to, and prevent outbreaks of foodborne illness. Adding additional sites will improve geographic and demographic representation, making this network more likely to detect diseases and outbreaks that are regional rather than national in distribution.

FY97 Activities

- Two new active surveillance sites, in New York and Maryland, will begin FoodNet activities.

FY98 Activities with Food-Safety Initiative Funds

- CDC, FDA, FSIS, and the Council of State and Territorial Epidemiologists (CSTE) will add at least one site to FoodNet, and CDC will enhance personnel resources at all sites to improve surveillance, analysis of data, and timely and appropriate release of information.
- CDC and the FoodNet sites will develop and conduct case-control studies of *Campylobacter* and *Cryptosporidium* infections to guide control efforts.

Enhance Early Detection of Foodborne Disease Nationwide

The early-warning system will enhance improved early detection of foodborne disease in additional states in FY98 by providing resources for improved surveillance, investigation, control, and prevention of foodborne disease outbreaks. Although sophisticated laboratory studies can identify causes of illness and show relationships among pathogens, 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 HUS.

spell-out.

appropriate states in the very early stages of any multistate outbreak, as well as continuing the 50-state update conference calls, in order to ensure better communication among state and federal agencies.

FY97 Activities

- To further strengthen our outbreak-response systems, CDC, EPA, FDA, and FSIS will establish an intergovernmental group, the Foodborne Outbreak Response Coordinating Group (FORCG), to improve the approach to interstate outbreaks of foodborne illness. FORCG will provide for appropriate participation by representatives of state and local agencies charged with responding to outbreaks of foodborne illness. This group will also review ways to more effectively involve the appropriate state agencies when there is a foodborne outbreak.
- FORCG will review and evaluate outbreak response. FORCG will undertake these reviews after appropriate consultation with industry and consumer representatives. Based on these deliberations, FORCG will assess the infrastructure for outbreak response, make recommendations for improving the current system, and work with federal, state, and local governments, the food industry, health professionals, and consumer advocates to implement beneficial changes. FORCG will meet several times a year for this purpose.
- Under the new initiative there will be one person/position designated as the outbreak coordinator for each department or agency. This position will be established as a formal institutional position, with appropriate backup designees. For outbreaks that fall within the purview of CDC and FDA, HHS will designate the Assistant Secretary for Health to be the primary person in charge of coordination. For outbreaks that fall within the purview of USDA, the Under Secretary for Food Safety will coordinate. Both the Assistant Secretary for Health and the Under Secretary for Food Safety will manage outbreak responses that fall within the jurisdiction of both departments. EPA will designate the Assistant Secretary for Water as the primary person in charge of coordination when drinking water is involved.
Administrator
- Standard 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 be developed by FORCG and representatives from the appropriate state agencies. 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. (See “Early Warning for Foodborne Illness Surveillance” section.) The procedures will also provide for rapid dissemination of accurate information to the public by the agency spokesperson.

Enhance State and Local Infrastructure for Foodborne

- ARS, CSREES, and FDA should undertake research to identify factors that contribute to the spread of microorganisms during transportation of live animals and fresh produce and develop techniques for eliminating cross-contamination.
- FDA, ARS, and CSREES should work with industry and academia to develop and assess the effectiveness of in- or on-package sensors of storage conditions to alert consumers of products not stored safely.

**Charge an Interagency Committee Convened
by the Office of Science and Technology Policy (OSTP)
to Coordinate Federal Research Priorities and Planning**

~~Among the information needs and data gaps identified,~~ ^N numerous opportunities ^{exist} arise for collaboration and the development of research partnerships among federal and state agencies, the private sector, and academia. A mechanism is needed to coordinate food-safety research among federal agencies, to link research with the activities and needs of the agencies, to better leverage agency resources and experience, and avoid duplication of effort. Such a coordination mechanism could be provided by an OSTP-convened interagency committee. That committee would review food-safety responsibilities and research programs of the various agencies with a view to recommending direction of research funds and programs in accordance with those responsibilities.

Are
we
doing
this
or
just
considering
it?
Reads like
the latter.

- FDA will publish proposed regulations for the use of HACCP in the manufacture of fruit and vegetable juice products.
- Based on the best science available, FSIS will propose appropriate regulatory and non-regulatory options, including HACCP, for egg products.
- FDA and USDA will immediately identify preventive measures to address public-health problems, such as those recently associated with fruits and vegetables, e.g., hepatitis A associated with frozen strawberries. This will be accomplished through a comprehensive review of current production and food-safety programs including inspection, sampling, and analytic methods.
- FSIS and FDA will jointly publish an ANPR *spell out* in which they will evaluate the public-health, food-technology, and regulatory issues involved in reducing the risk of human illness from *Salmonella* Enteritidis in shell eggs. The ANPR will solicit information and comment on all elements of risk in the farm-to-table chain to ensure any resulting regulatory actions will be both reasonable and effective in reducing risk.
- FDA will evaluate whether and how to propose to require the use of HACCP in other appropriate food commodities and animal feeds.
- FDA will provide additional training in seafood HACCP and FSIS will complete HACCP training of inspectors in large meat and poultry plants.
- FSIS and FDA will evaluate expanding existing cooperative agreements so that plants producing meat and nonmeat foods are inspected by FSIS inspectors trained in FDA inspection standards. FSIS inspectors are already in these plants, and their presence could be better used to maximize use of federal resources without loss of inspection coverage for FSIS-regulated foods.
- FSIS will conduct a series of public meetings to discuss:
 - How HACCP requirements will be implemented in slaughter plants and how the roles and responsibilities of inspection personnel will change with that implementation.
 - The design and testing of new inspection concepts consistent with HACCP principles to achieve food-safety and other consumer-protection objectives through distribution and retail channels to consumers.
- FSIS and state associations will complete development of HACCP-based control measures for meat and poultry processing at the retail level.

SOME IMPORTANT?

APPENDIX B
MICROBIAL PATHOGENS ASSOCIATED
WITH FOODBORNE ILLNESS

✓

Bacteria

Salmonella

Salmonella species cause diarrhea and systemic infections, which can be fatal in particularly susceptible persons, such as the immunocompromised, the very young, and the elderly. Animals used for food production are common carriers of salmonellae, which can 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. 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. Between 128,000 and 640,000 of those infections are associated with *Salmonella* Enteritidis in eggs. Over the past decade, more than 500 outbreaks have been attributed to *S. Enteritidis* with more than 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 2 and 4 million cases of campylobacteriosis occur each year with an associated 120-360 deaths. *Campylobacter jejuni* and *Campylobacter coli* (two closely related species) are commonly foodborne, and are the infectious agents most frequently described in association with Guillain-Barré syndrome, 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.

Shiga-like toxin-producing *Escherichia coli*

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. It has been associated with HUS, a life-threatening complication of hemorrhagic colitis characterized by acute kidney failure that is particularly serious in young children. *E. coli* O157:H7 is found in cattle, but there may be other reservoirs; the dynamics of *E. coli* O157:H7 in food-producing animals are not well understood. Approximately 25,000 cases of foodborne illness can be attributed to *E. coli* O157:H7 each year with as many as 100 deaths resulting. *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 three western states and British Columbia was associated with unpasteurized apple juice, sickened 66 people, and caused the death of one child.

EDUCATION

Background

An integral part of the overall food-safety initiative is providing food-safety education to a variety of audiences: consumers (the general public and specific groups at risk for foodborne illness); public-health professionals and physicians; retail, food-service, and institutional food preparers; veterinarians, animal and other food producers; and food-transportation workers. The challenge is to create educational messages that address the risks relevant to each audience throughout the food chain. Research and risk assessment are important elements in identifying these risks and devising appropriate messages. Realizing that educational efforts are cost-effective investments, federal, state and local governments, private organizations, consumer groups, and industry have fostered educational programs to address foodborne illness.

Problem

Despite educational efforts, ~~foodborne~~ foodborne illness remains prevalent throughout the United States. For example, from 1988 to 1992, *Salmonella* caused 69% of the 796 bacterial foodborne disease outbreaks; 60% of those *Salmonella* outbreaks were caused by *Salmonella* Enteritidis. *S.* Enteritidis also resulted in more deaths than any other pathogen, with 85% of these deaths occurring among residents of nursing homes.

One reason is that food preparers and handlers at each stage of the food chain lack the knowledge of risks involved and the related safe food-handling practices. Food preparers in the retail sector must be made aware of how they can prevent food contamination and reduce pathogen growth, particularly by preventing cross-contamination with other foods and by properly cooking foods such as eggs. Without the practice of food-safety knowledge and proper food-handling procedures, foodborne illness cannot be significantly reduced. Food-safety messages should be developed to reach individuals at each stage from the farm to the table.

Risk assessment and research are needed to determine the most effective ways to overcome barriers to use of safe food-handling practices and to ensure use of safe food-handling practices by specific audiences. For example, consumers' food-handling practices and the choices they make in the foods they eat will either increase or decrease the chances of foodborne illness. Studies show that more than 50% of the public eat raw or undercooked eggs, 23% eat undercooked hamburger, 17% eat raw clams and oysters, and 26% do not wash cutting boards after using them for raw meat or poultry.

Health professionals and physicians also need specific knowledge about causes and effects of foodborne illness to more effectively detect and treat the illnesses. Producers of animals used in human food production and veterinarians treating such animals must be made aware of food-safety aspects of drugs and drug residues. Finally, those responsible for the transportation of food are often unaware that mishandling of food during shipment can result in contamination.

Recommendations

of foodborne illness

The goal of this initiative is to target and change unsafe food-handling practices by people throughout the food chain, including food-service workers, and especially those providing food to populations at high risk. Objectives include: 1) forming partnerships and alliances to maximize resources and broaden the impact and scope of educational efforts; 2) designing messages by conducting research to identify barriers to safe food handling, upon which educational programs will be centered; and 3) expanding the use of innovative outreach methods, including the use of new technologies.

Implementation of the education goals and objectives of the initiative combined with the other elements of the initiative will significantly increase the number of consumers and food-service workers being reached with effective and persuasive food-safety messages.

Improve Consumer, Retail, and Food Service Education

FY97 Activities

The 1997 Consumer Food Safety Education Partnership

A memorandum of understanding was signed in May 1997, formalizing a food-safety education partnership that includes industry, consumer groups, HHS, USDA, and the Department of Education. Participants in the partnership will launch a nationwide food-safety education campaign for the general public. The campaign will center on four key food-safety concepts tested for maximum consumer understanding and will include a slogan, logo or identifiable character. At present, the Partnership is reviewing proposals from national public-relations and communications firms to conduct a public awareness and education campaign. The industry groups have contributed almost \$500,000 to date. Plans for the nationwide campaign will be announced at the food-safety education conference, "*Changing Strategies: Changing Behaviors*," sponsored by USDA, FDA, and CDC to be held June 12-13 in Washington, DC. The partnership will promote September as National Food Safety Month, as already designated by industry, and launch the food-safety message campaign during the month.

Identify key food-safety education principles through establishment of an expert council

Convene the National Food Safety Education Council, an independent scientific review board to periodically review food-safety education messages. The Council, which will include food scientists and educators, will serve to identify emerging food-safety risks that require public education. Risk assessment will be used to identify at-risk audiences for targeted food-safety education programs.

Cost?
for
QA
Who
Comments?

May 2, 1997 DRAFT

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

**REPORT TO THE PRESIDENT
MAY 1997**

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EXECUTIVE SUMMARY

Every day, thousands of Americans are stricken by illness 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* (*E. coli*) O157:H7 in meat and apple juice, to *Salmonella* in eggs and on vegetables, to *Cyclospora* on fruit, to *Cryptosporidium* in drinking water--and most recently, to hepatitis A virus in frozen strawberries.

In his January 25, 1997 radio address, President Clinton launched a new initiative to improve the safety of the nation's food supply. The President announced he would request \$43 million in his 1998 budget to fund a nationwide early-warning system for foodborne illness, increase seafood safety inspections, and expand food-safety research, training, and education. The President also directed three Cabinet members--the Secretary of Agriculture, the Secretary of Health and Human Services, and the Administrator of the Environmental Protection Agency--to identify further steps to improve the safety of the food supply. He directed them to develop these next steps working with consumers, producers, industry, states, universities, and the public, and to report back to him in 90 days.

The goal of this initiative is to further reduce the incidence of foodborne illness to the greatest extent feasible. The recommendations presented in this report are based on the public-health principles that we should identify and take preventive measures to reduce risk of illness, should focus our efforts on hazards that present the greatest risk, and should make the best use of public and private resources. The initiative also seeks to further collaboration between public and private organizations and to improve coordination within the government as we work toward our common goal of improving the safety of the nation's food supply.

Six agencies in the federal government have primary responsibility for food safety: two agencies under the Department of Health and Human Services (HHS)--the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC); three agencies under the Department of Agriculture (USDA)--the Food Safety and Inspection Service (FSIS), the Agricultural Research Service (ARS), and the Cooperative State Research, Education, and Extension Service (CSREES); and the Environmental Protection Agency (EPA). Over the last 90 days, these agencies have worked with the many constituencies interested in food safety to identify the greatest public-health risks and design strategies to reduce these risks. USDA, FDA, CDC, and EPA have worked to build consensus and to identify opportunities to better use their collective resources and expertise, and to strengthen partnerships with private organizations. As directed by the President, the agencies have explored ways to strengthen systems of coordination, surveillance, inspections, research, risk assessment, and education.

This report presents the results of that consultative process. It outlines steps USDA, HHS, and EPA will take this year to reduce foodborne illness, and spells out in greater detail how agencies will use the \$43 million in new funds requested for fiscal year 1998. It also identifies issues the agencies plan to consider further through a public planning process.

with an eighth site to be identified. CDC will also increase surveillance activities for certain specific diseases. For example, CDC will begin a case-control study of hepatitis A to determine the proportion of cases due to food contamination, FDA will strengthen surveillance for *Vibrio* in Gulf Coast oysters, and CDC will strengthen surveillance for *Vibrio* in people.

Equip FoodNet sites and other state health departments with state-of-the-art technology, including DNA fingerprinting, to identify the source of infectious agents and additional epidemiologists and food-safety scientists to trace outbreaks to their source.

Create a national electronic network for rapid fingerprint comparison. CDC will equip the sentinel sites and other state health departments with DNA fingerprinting technology, and will link states together to allow the rapid sharing of information and to quickly determine whether outbreaks in different states have a common source.

Improve Responses to Foodborne Outbreaks

At the federal level, four agencies are charged with responding to outbreaks of foodborne and waterborne illness: CDC, FDA, FSIS, and EPA. States and many local governments with widely varying expertise and resources also share responsibility for outbreak response. The current system does not assure a well-coordinated, rapid response to interstate outbreaks. To ensure a rapid and appropriate response, agencies will:

Establish an intergovernmental Foodborne Outbreak Response Coordinating Group Federal agencies will form an intergovernmental group, the Foodborne Outbreak Response Coordinating Group (FORCG), to improve the approach to interstate outbreaks of foodborne illness. FORCG will provide for appropriate participation by representatives of state and local agencies charged with responding to outbreaks of foodborne illness. This group will also review ways to more effectively involve the appropriate state agencies when there is a foodborne outbreak.

Strengthen the infrastructure for surveillance and coordination at state health departments. CDC, EPA, FDA, and FSIS will assess and catalogue available state resources, provide support for foodborne-disease-surveillance programs, and assistance to better investigate foodborne-disease outbreaks.

Improve Risk Assessment

Risk assessment is the process of determining the likelihood that exposure to a hazard, such as a foodborne pathogen, will result in harm or disease. Risk-assessment methods help characterize the nature and size of risks to human health associated with foodborne hazards and assist regulators in making decisions about controlling those hazards. To improve risk-assessment capabilities, agencies will:

Establish an interagency risk assessment consortium to set priorities and guide

The federal food-safety agencies are committed to continuing to meet with stakeholders, ultimately to produce a strategic plan for improving the food-safety system.

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 would 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 Agriculture, the Secretary of Health and Human Services, 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 Glickman and Shalala and Administrator Browner to report to him with recommendations in 90 days. He instructed them to consult with a broad range of stakeholders in the food-safety system and 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.

To start the discussion, the agencies issued a draft document summarizing their initial ideas. Subsequently, the agencies held two public meetings on March 5 and March 31-April 2, and established public dockets for written comments.

This report is the result of that 90-day process of deliberation and discussion among all stakeholders in the nation's food-safety system, including federal, state, and local agencies, consumers, academia, food producers, manufacturers, distributors, representatives of the retail and restaurant sectors, veterinarians and health professionals, and many others.

The goal of this initiative is to reduce the incidence of foodborne illness to the extent possible. The recommendations presented in this report are based on the public-health principles that society should identify and take preventive measures to reduce the risk of illness and that it should focus its efforts on hazards that present the greatest risks.

FOODBORNE ILLNESS: A SIGNIFICANT PUBLIC-HEALTH PROBLEM

The Council for Agricultural Science and Technology, a private nonprofit 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. The Department of Agriculture (USDA) estimates that medical costs and productivity losses for seven specific pathogens in food have been estimated to range between \$6.5 billion and \$34.9 billion annually.

Total costs for all foodborne illnesses are likely to be much higher. Those estimates do not take into account the total burden placed on society by the chronic, often lifelong consequences caused by some foodborne pathogens.

Several population groups have increased susceptibility to foodborne infections, such as persons with lowered immunity due to HIV/AIDS and those on medications for cancer treatment or for organ transplantation, as well as pregnant women and their fetuses, young children, and the elderly. Patients taking antibiotics or antacids are also at greater risk of infection from some pathogens. The consequences of foodborne disease are particularly serious for those with inadequate access to health care, such as homeless people, migrant farm workers, and others of low socioeconomic status.

Sources of Foodborne Contamination

Bacteria and other infectious organisms are pervasive in the environment.

- *Salmonella* serotype Enteritidis enters eggs directly from the hen.
- Bacteria (occasionally pathogenic) inhabit the surfaces of fruits and vegetables.
- 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 can become contaminated from agricultural animal manures and wastes 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 animals.
- Milk, eggs, seafood, poultry, and meat can become contaminated from contaminated feed, misuse of veterinary drugs, or poor farming practices, in particular, mismanagement of animal manures, including production and harvesting activities.
- Foods can become contaminated during processing due to malfunctioning or improperly sanitized equipment, misuse of cleaning materials, rodent and insect infestations, and improper storage.
- Foods can become contaminated in retail facilities and in homes through poor food-handling practices.

Some microbial pathogens 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. Some of the microbial pathogens that have been the source of foodborne illness cases and outbreaks recently include, *Salmonella*, *Campylobacter*, Shiga-like toxin-producing *Escherichia coli*, *Vibrio*, *Toxoplasma gondii*, *Cryptosporidium parvum*, Norwalk virus, hepatitis A virus. A full description of these pathogens, the foodborne illnesses they cause, and frequently implicated foods may be found in Appendix B. In addition to microbial pathogens, other substances may contaminate foods and cause foodborne illness. Among these are naturally occurring mycotoxins and marine toxins.

THE CURRENT SYSTEM FOR PROTECTING FOOD

Our food-safety system, although generally successful in protecting the public, is characterized by complexity and diversity. Regulatory authority is divided among federal, state, and local governments. The private sector has the primary responsibility for ensuring the safety of the food that it produces. From the farm to the consumer’s dinner table, the responsibilities can be summarized as follows:

- Consumer education on food handling and storage in the home is the primary responsibility of USDA’s Cooperative State Research, Education, and Extension Service (CSREES), FSIS, FDA, and CDC. FSIS, with responsibility for meat, poultry and most egg products, FDA, with jurisdiction over all other foods, and CDC, with epidemiological capabilities, all produce educational materials. FDA and FSIS staff consumer hotlines, and all agencies have web sites. CSREES has an enormous network of extension agents across the country, and FDA has Public Affairs Specialists in offices around the country to respond to inquiries and conduct safe handling programs for consumers, health professionals, and the media.
- In the home, consumers have a responsibility for proper handling and storage of food. Because consumer use of proper food-handling practices can prevent many cases of foodborne illness, FSIS issued rules requiring the use of safe-handling labels on raw meat and poultry products.
- On the farm, food is regulated by state agencies supported principally by the Environmental Protection Agency (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 USDA’s Animal and Plant Health Inspection Service (APHIS), which is concerned with food-animal-disease control. Federal responsibility also covers production and harvesting activities that discharge wastewater to surface and to

ground waters and solid waste to land, all of which could contaminate growing and processing waters or grazing land. Animal manures are currently excluded from the definition of solid waste under EPA's solid-waste-disposal regulation, and therefore, an EPA regulatory mechanism does not exist for these materials. The ecology of human pathogens in food animals and in their manures produced on farms and ranches, in wild animals, in slaughter operations, and in processing facilities has received little attention in the past. Regulations under the Clean Water Act require large animal-feeding operations to obtain a discharge permit.

- Food processing for foods other than meat, poultry, and egg products (except shell eggs) is regulated by FDA, whose inspectors are responsible for visiting about 53,000 plants periodically, with emphasis on the highest risk foods or processing techniques. FDA devotes about 700 inspectors and laboratory personnel to this activity. Meat, poultry, and all other egg products are regulated by FSIS, whose inspectors are present in 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. In 1996, FSIS and FDA 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 microbial contamination during transportation. FDA and FSIS will evaluate the comments and information received in response to the ANPR as a basis for determining what, if any, regulatory approach to take, including development of guidelines. These guidelines may include such elements as suggested performance standards for temperature control, providing information on prior cargo, and cleaning information for the food-shipper's use, to ensure the safety of the food at its destination.
- Importation of food from foreign countries is overseen by FSIS for meat, poultry, and most egg products and by 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) fall under the FDA's retail food-protection program, a cooperative federal-state food-safety effort operated under the Public Health Service Act. FDA has regulatory authority under the Federal Food, Drug, and Cosmetic Act over retail establishments because the food used in these establishments traveled in interstate commerce, however, the PHS Act provides the means for more efficient regulation and use of available resources, as well as broader inspection coverage. FDA publishes the Food Code, which consists of model recommendations that states and local authorities adopt and use to regulate retail food establishments. FDA, along with FSIS and CDC, work with states biennially to update the Food Code.

- National standards for drinking water and criteria for surface waters 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 sources, and control outbreaks. CDC conducts field investigations of foodborne diseases only at the request of state health departments, which have the authority to implement outbreak control measures. FDA, FSIS, or both are called in when food within their jurisdiction is suspected. FDA is charged with ensuring that foods implicated in a foodborne illness outbreak and traveling in interstate commerce are removed from the market.
- Research serves many purposes in reducing the incidence of foodborne illness and is integral to the programs of all public-health agencies. Research is essential to evaluate effectiveness of surveillance initiatives, control and prevention strategies, conduct risk assessments, and verify effectiveness of preventive techniques such as HACCP. Research into the cause and transmission of foodborne illness is the primary responsibility of CDC, FDA, ARS, CSREES, and EPA. The development of screening and analytic methods to rapidly and accurately identify and characterize foodborne hazards, identifying and tracking to the source the causes of foodborne illness, is the responsibility of FDA, ARS, CSREES, EPA, and CDC. Research to develop preventive technologies, ranging from new production techniques, to disinfection and food-processing techniques to reduce levels of pathogens, is the primary responsibility of ARS, CSREES, FDA, and industry. Basic research is conducted largely in university laboratories on the biology, genetics, pathogenesis, natural history, and epidemiology of microorganisms implicated in foodborne disease and is actively supported by the NIH, and in particular, by the National Institute of Allergy and Infectious Diseases. These efforts are focused on understanding the disease process and designing prevention and treatment strategies. Other agencies of the federal government also support 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 1900s. It must be modernized. The system cannot properly identify, track, and control food-related illness, or prevent, to the extent possible, future cases from occurring. In 1981, FDA inspected food firms every 2-3 years, but can now visit those firms, on average, only once every 10 years (although some plants that produce higher-risk foods may be inspected more frequently). State and federal resources are not closely coordinated. Our understanding of some disease-causing organisms is so limited that our ability to protect the public health is seriously constrained.

FY97 Activities

- CSTE and CDC, in conjunction with FDA and FSIS, will develop a protocol for evaluating epidemiologic outbreak data. The group will also develop criteria for local and state health officials to provide information on outbreaks to federal authorities for review and necessary action.
- FoodNet sites will gather epidemiologic data on cases of HUS.

FY98 Activities with Food-Safety Initiative Funds

- CSTE and CDC, in conjunction with FDA and FSIS, will define critical capacity elements that state and local health departments require to conduct surveillance, investigation, control, and prevention of foodborne illnesses; CDC will help states remedy identified deficiencies.
- CDC and CSTE will develop an electronic module for collecting and transmitting data to CDC on outbreaks of foodborne illness.
- CDC will begin a case-control study of hepatitis A to determine the proportion of cases due to contamination of food so that optimal control strategies could be determined. Recognized foodborne outbreaks account for about 2 to 5% of annually reported hepatitis A cases and are usually caused by an infected food handler.
- Epidemic assistance for outbreaks of foodborne disease will be expanded when states request direct CDC participation in investigations.
- CDC and, where appropriate FDA and FSIS, will collaborate with state health departments to improve diagnostics, outbreak detection, and electronic communications.
- *Vibrio* surveillance will be strengthened by CDC, FDA, and states by increasing personnel, epidemiologic, and laboratory resources devoted to the Gulf Coast *Vibrio* surveillance program.

Long-term Activities

- Surveillance and investigative systems should continue to be enhanced to improve the ability of state and local health departments to promptly and accurately identify foods that are the source of foodborne illness.

Modernize Public-Health Laboratories

CDC should provide resources and training to upgrade public-health laboratory capabilities in

FoodNet sites and in states without those sites so the laboratories can rapidly identify a broad range of foodborne pathogens, including parasites and viruses, and can use new techniques of DNA fingerprinting. The new capacities would allow rapid identification of the cause of some outbreaks that currently go undiagnosed.

FY97 Activities

- CDC will collaborate with FoodNet sites to determine serotypes of *E. coli* other than O157:H7 that cause HUS in children.

FY98 Activities with Food-Safety Initiative Funds

- The Association of State and Territorial Public Health Laboratory Directors (ASTPHLD) and CDC will improve diagnostic assays and provide additional resources to improve the capacity of state laboratories to detect foodborne pathogens, including selected viruses and parasites.
- CDC will provide sufficient funds to states to support the production of serotyping reagents for *Salmonella*, which are critical for outbreak identification.
- CDC will develop DNA amplification-based tests for foodborne pathogenic bacteria that are difficult to detect by culture (e.g., Shiga-like toxin-producing *E. coli* other than *E. coli* O157:H7 and other disease-causing *E. coli*) and will provide resources and technical assistance to states to improve their capacity in diagnosing those pathogens.

Long-term Activities

- CDC should begin developing molecular alternatives to serotyping for *Salmonella*.

Create a National Electronic Network for Fingerprint Comparison

CDC should fund a new computer network and database system that would capture fingerprints of pathogens in a national database, linking CDC, FDA, FSIS, and states that have that new capacity into a 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. That might suggest to public-health investigators that a product distributed in California and Washington was contaminated with the same organism.

In addition to identifying, investigating, and reporting cases of foodborne disease in humans, microbiological surveillance of pathogens in foods, in food animals and their manures, and in animal feed, is important to control and prevent foodborne diseases and to evaluate 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.

FY97 Activities

- CDC will provide resources and technical assistance to state health departments for DNA fingerprinting of *E. coli* O157:H7, and begin to establish a centralized national electronic database of DNA fingerprint patterns.

FY98 Activities with Food-Safety Initiative Funds

- The national electronic database of DNA fingerprint patterns of *E. coli* O157:H7 will continue to be expanded.
- In collaboration with participating state health department laboratories, FDA and FSIS, CDC will develop standardized methods for DNA fingerprinting of *Salmonella* serotypes Typhimurium and Enteritidis and will transfer the techniques to selected state health departments.
- CDC, ASTPHLD, and CSTE will develop guidelines for maximizing the utility of DNA fingerprinting at state health departments in foodborne disease surveillance and outbreak investigations.
- CDC, FDA, and FSIS will set up centralized national electronic databases of DNA fingerprint patterns of *S. Typhimurium* and Enteritidis.

Long-term Activities

- CDC should continue to develop standardized DNA fingerprinting methods for other foodborne disease-causing bacteria as appropriate and should transfer the standardized methods to state health departments and appropriate federal laboratories.
- CDC should begin implementing automated foodborne disease outbreak detection algorithms based on the DNA fingerprint patterns submitted by state health department laboratories.

Increase National Surveillance for Antimicrobial Resistance of Foodborne Pathogens

The problem of foodborne disease is increasing, in part, because foodborne infections are becoming more serious. One of the ways foodborne pathogens become more virulent is by acquiring resistance to antimicrobial agents, making such infections very difficult to treat.

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

FY97 Activities

- CDC, FDA, and FSIS will conduct surveillance of antimicrobially resistant *Salmonella* and *E. coli* O157:H7 isolates.

FY98 Activities with Food-Safety Initiative Funds

- CDC, FDA, and FSIS will initiate surveillance of antimicrobial resistance in isolates of *Campylobacter* from humans and animals, including poultry.
- FDA and CDC will conduct surveillance and epidemiologic studies to monitor and reduce the incidence of foodborne disease associated with emerging and drug-resistant pathogens.

Long-term Activities

- CDC, FDA, and FSIS should continue monitoring and comparing the antimicrobial resistance of *E. coli* O157:H7, *Salmonella*, and *Campylobacter* strains in humans and animals.
- FDA and CDC should conduct physician and veterinary drug-prescribing surveys, including patients and animal producers, to assess the effect of antimicrobial drug use on resistance patterns and prevalence to guide regulatory policy and educational campaigns.
- FDA should assist the World Health Organization (WHO) in the development of a veterinary database within the WHONET system. (WHONET is a system for standardized international reporting of antimicrobial resistance to WHO.)

Conduct Surveillance of Human Pathogens in Food-Animal Populations and Enhance Oversight of Animal Feedstuffs, Feeds, and Manures for the Effect of Drugs and Other Therapies

FY98 Activities with Food-Safety Initiative Funds

- USDA, CDC, FDA, and EPA will convene a working group to discuss how to conduct surveillance of human pathogens in food animals and their manures, and should target one pathogen on which to begin surveillance in FY99.

Long-term Activities

- FDA should increase the monitoring of animal-feed processing to determine the nature and extent of pathogen contamination and the effect of control strategies on pathogen reduction in animals.

INTERSTATE OUTBREAK CONTAINMENT AND RESPONSE COORDINATION

Background

Four federal agencies are charged with responding to outbreaks of foodborne illness (including waterborne illness): FDA and CDC (at HHS), FSIS (at USDA), and EPA. All states, and many local governments, with widely varying expertise and resources, share responsibility with the federal government for response to such outbreaks. When an outbreak occurs, all of the relevant entities must work together to efficiently and effectively prevent deaths and minimize the number of illnesses. The better coordinated the response, the more quickly the outbreak will be contained.

Each of the four federal agencies has a potentially critical role when an outbreak occurs. 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, FSIS, and EPA also have responsibility for determining whether a product they regulate may be causing illness, and of 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 type of food affected determines which regulatory agency has primary jurisdiction: FSIS regulates meat, poultry, and egg products; FDA regulates all other foods including shell eggs; and EPA regulates water and pesticides and manages organic and inorganic wastes used or disposed of on agricultural land. While each agency has clearly defined areas of responsibility, the successful containment of many outbreaks of foodborne illness involves more than one agency.

The states and many local governments also have a critical role. Identification and investigations of foodborne illness often begin at the community or state level. States share with the federal government the legal responsibility for protecting the health of their residents. Although foodborne outbreaks are sometimes local, most outbreaks implicate 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.

In many outbreaks of foodborne illness, federal agencies work with state and local health authorities in their investigations 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 the 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.

Companies responsible for affected products also have a critical role to play. Food companies are sometimes the first to recognize that their product is causing illness. In addition, food-product

recalls are voluntary, although FDA may request a company to recall products. Federal and state agencies can benefit from industry's expertise about food products and their distribution patterns.

Problem

Although significant coordination already occurs among federal, state, and local agencies, better coordination is needed to meet new and growing threats to the nation's food supply. More than one agency is involved in virtually every large foodborne outbreak. Joint efforts are often hindered by a lack of communication or a misunderstanding of each agency's role in a particular situation.

Recommendations

Federal, state, and local governments should improve the coordinated management of interstate outbreaks. Improved coordination among the federal agencies, among federal, state, and local agencies, among the various state agencies, and between state and local agencies would enhance the level of public health protection, leverage agency resources and experience, and avoid duplication of effort.

The early-warning capability, comprised of FoodNet and strengthened state-surveillance capacity, and improved federal-state communications will enhance appropriate involvement of federal agencies in the investigation of foodborne disease outbreaks. Communication and exchange of information among the appropriate federal, state, and local government agencies must be improved.

Improve Outbreak Containment Through Better Federal-State-Local Coordination of the Evaluation of and Response to Foodborne Illness

There are probably hundreds of times a year when at least one federal agency, working with state and local agencies, plays a role in detection, investigation, and containment of illnesses that may be caused by contamination of food. Occasionally (typically once or twice a year) the outbreak is sufficiently significant and complex to require the involvement of the highest level officials in the responsible federal agencies. When this occurs, it is essential that federal agencies speak with one voice.

A critical element of an effective, rapid response to a foodborne illness outbreak is ready communication by all the involved parties at the federal, state, and local level. Although there are communication systems in place, they 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. This strengthened system will complement the data and information exchange systems described in the "Early Warning for Foodborne Disease Surveillance" section of this report.

As part of this initiative, the agencies have streamlined their outbreak-response procedures. The lead department in any foodborne illness outbreak will be determined by regulatory jurisdiction over the food products implicated in the outbreak. FSIS has regulatory responsibility for meat, poultry, and egg products, so USDA will be the lead when these products are involved. Since FDA has regulatory responsibility for all other foods, HHS will be the lead when any other food product is involved. Where there is overlap, both HHS and USDA will have leadership responsibility. EPA will continue to be the lead agency for outbreaks traced to drinking water. Each department will designate a Coordinator.

This new management system will provide a common set of objectives and strategies and one spokesperson that will speak on behalf of the federal government. Once there are indications to federal or state agencies of a large-scale problem, the staff will tell the Coordinator who will then coordinate the response among federal and state agencies.

Each agency has specific mechanisms in place to aid in this effort. FSIS has established an Emergency Response Program to prevent and control foodborne disease outbreaks involving meat, poultry, and egg products. Likewise, FDA's Division of Emergency and Investigational Operations serves this function for all other food products. Both FDA and FSIS maintain 24-hour telephone service staffed with a duty officer trained to respond to emergencies and ongoing illnesses, including foodborne illness and outbreaks, who have access to emergency personnel throughout the agency, as well as with emergency contacts in other agencies. FDA's Division of Emergency and Investigational Operations will serve to coordinate with other agencies. CDC provides 24-hour emergency consultation for botulism and other foodborne disease clinical emergencies and stations Epidemic Intelligence Service officers in 15-20 states each year to support surveillance and emergency response at the state level.

In order to improve communications with state agencies, FDA has adopted a fax-on-demand and fax broadcast system. The fax broadcast system, containing a database of more than 900 state officials, permits messages to be sent any time of day or night to any list of state contacts, providing an early alert or update to foodborne illness investigations. The fax-on-demand system provides access to press releases from federal agencies, press releases from firms about their recall, as well as other information. FSIS communicates with state departments of health and coordinates outbreak response through CDC WONDER (Internet) and both FDA and USDA maintain liaisons at CDC to facilitate food-safety activities, including outbreak investigations. CDC has established rapid communication links with all state and territorial epidemiologists and public health laboratory directors providing rapid group electronic mail and group fax links, and conference calls in outbreak settings.

FDA has also instituted a 50-state conference call system to keep all state agencies up-to-date on major foodborne outbreaks. This system was first used for the outbreak involving *E. coli* O157:H7 in apple juice and was most recently used for the hepatitis A outbreak associated with frozen strawberries. FDA and CDC jointly participate in these calls to assure more effective follow up and control of outbreaks. FDA will modify the conference call system to involve

Outbreak Detection, Evaluation, and Response Coordination

The epidemiology offices and laboratories within state and local health departments are charged with the surveillance of infectious and non-infectious conditions, and, along with other state and local 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 and communities for the surveillance and investigation of foodborne diseases are limited and decreasing, thereby limiting the effectiveness of their response. As a result, outbreaks may go undetected or are never investigated.

CDC, EPA, FDA, and FSIS will address the problem first by assessing and cataloguing available state resources, and then by working with states and providing support for foodborne-disease-surveillance programs and assistance to better investigate outbreaks of foodborne illness.

FY97 Activities

- FORCG, with assistance from the Association of Food and Drug Officials, the Association of State and Territorial Health Officials, the Association of State and Territorial Public Health Laboratory Directors, the Council of State and Territorial Epidemiologists, and the National Association of State Departments of Agriculture, will begin a nationwide audit to catalogue the existing state and local food-safety program infrastructure.
- FORCG, in consultation with the appropriate outside organizations, will establish working groups consisting of federal, state, and local officials to develop recommended procedures for outbreak-response coordination at the state and local level.

FY98 Activities with Food-Safety Initiative Funds

- CDC, EPA, FDA, and FSIS will assist states and local governments in developing the infrastructure necessary to ensure proper detection, evaluation, and coordinated response to foodborne outbreaks.

RISK ASSESSMENT

Background

The impact of increased funding for development of methods and models directed at improving risk assessments will be to focus public resources on reducing those risks that have the greatest consequences for human health. Risk assessment provides a strong foundation upon which efficient allocation of scarce food-safety resources can be made. While obvious severe hazards in the food supply will be addressed through the larger food-safety initiative, risk assessment provides an objective foundation upon which efficient allocation of scarce food-safety resources can be established. Furthermore, risk assessment often plays a central role in the development of any science-based system of preventive controls.

There has been a long history of performing safety assessments or risk assessments for foods, particularly chemicals and drug residues. Risk assessments, cost-benefit analyses, and evaluations of alternative risk-management strategies are required for all major regulations in USDA, a requirement imposed by the Federal Crop Insurance Reform and Reorganization Act of 1994 (P.L. 103-354). EPA is developing methods for required risk assessments under the Safe Drinking Water Amendments of 1996, including both microbial and chemical hazards. Sound risk assessments are important in various aspects of international trade, including the provisions of Codex Alimentarius and the World Trade Organization, the international bodies that govern standards for food safety, among other issues. Carefully formulated risk assessments based on high-quality data and scientific information generated from research lead to more informed risk management and better decisions.

Risk assessment also provides essential information for estimating and analyzing the costs and benefits of policy alternatives. Risk estimates are used to characterize the state of the world in the baseline and the alternative states expected to occur after taking action, whether through regulation, guidelines, or education campaigns. Ideally, results of risk estimates are in the form of distributions that capture the scientific uncertainty and population variability, but where that is not possible, point estimates of risk need to reflect the impact on the entire population.

Risk management and risk assessment must mutually inform each other but must remain separate and independent entities. Risk communication must be an integral part of all risk-related activities, including the public, industry, and all affected parties.

Good risk assessment requires good risk communication. Participation from industry, academia, and private risk organizations will be ensured in the interagency consortium's risk-assessment activities. Good risk communication must be ensured by interfacing with educators. Active communication between the risk assessment consortium and the research community is crucial to a successful initiative.

Risk assessment characterizes 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 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.

Problem

Risk assessment is far less developed for foodborne pathogens. Intensive commitment is necessary to develop critically needed methods of analyzing the available data and addressing its uncertainty; methods that account for variability, specifically of living microbial pathogens, are essential. Chemical and radiological risks do not pose these special challenges, so extending these established methods to microbial risk is not sufficient.

The research needed to develop improved methods and models that will make it possible to perform quantitative microbial risk assessments to the degree of complexity required for most food-safety issues will require the integration of work in biological sciences, predictive microbiology, and applied mathematics. In some instances, the research needs overlap with those identified in the bioresearch section of this document. However, to reflect the multidisciplinary nature of the needed research programs and to highlight the critical nature of the research needs, research needs related to risk assessment are being presented as a separate item for consideration.

Recommendations

This initiative's activities focus on developing models for improving risk assessment, thereby more precisely targeting the prevention of foodborne disease by informing surveillance plans, prevention strategies for process-control systems and for food inspections based on HACCP principles, and research programs to fill critical food-safety information gaps. Recommendations are being made in three areas.

Establish a Risk Assessment Consortium

All federal agencies with risk-management responsibilities for food safety will establish jointly a consortium at which federal agencies can collectively advance the science of microbial risk assessment to further develop and implement risk assessment, and to assist agencies in fulfilling their specific food-safety regulatory mandates. The consortium should be inclusive in its risk-assessment activities, seeking expertise from risk-assessment professionals and scientists from public and private sources, as well as industry and consumer groups. The goal of the consortium would be to improve the quality of risk-assessment research by coordinating research priorities, eliminating redundancies of effort, and encouraging multidisciplinary research efforts. The consortium will have three primary functions:

- Develop a scheme for setting methodological research priorities based upon the value of information expected from each research activity.
- Serve as a clearinghouse for information about current and planned research projects pertinent to microbial risk-assessment techniques.
- Foster and, where possible, augment the research activities of the member agencies to accelerate particularly critical research projects.

FY97 Activities

- The consortium, which will include all interagency partners, will be established in 1997 as part of the Joint Institute for Food Safety and Applied Nutrition, a collaborative activity of FDA's Center for Food Safety and Applied Nutrition and Center for Veterinary Medicine and the University of Maryland. The consortium will have three primary functions. The first will be to provide a means for identifying priority research needs in microbial risk-assessment methodology and modeling (e.g., predictive microbiology). Such methodologies are needed to enable mathematical description of the behavior and fate of foodborne pathogens at points along the farm-to-consumption chain. Second, the consortium will serve as a clearinghouse for information about current and planned research projects pertinent to microbial risk-assessment techniques, helping to prevent redundancies of effort and helping to identify scientists and applied mathematicians who could contribute to multidisciplinary research efforts. Third, the consortium will foster, and where possible, augment the research activities of member agencies in order to accelerate research projects of a particularly critical nature.
- The consortium will be inclusive in its risk-assessment activities, seeking expertise from risk-assessment professionals and scientists from public and private sources, and industry and consumer groups. The initial focus of the initiative will be on pathogenic microorganisms. The consortium will work with its member agencies to catalogue their microbial risk-assessment-research advances and identify data sets that would provide the scientific data needed to develop new models. The consortium will begin the process of establishing a clearinghouse that will collect and catalogue available methodology, specifically simulations necessary to address microbial growth and death variables offered by the private sector, trade associations, federal and state agencies, and international sources.

FY98 Activities with Food-Safety Initiative Funds

- A series of public meetings will be held to develop a strategy to address long-term research needs for the analysis of farm-to-table scenarios, including potential pathogen introduction at each level (e.g. farm, processing, transportation, home, restaurant, and retail food handling), food-consumption data, and computer modeling. A strategic plan

will be developed for research into dose-response calculations, chronic sequelae, biomarkers, and adapting surveillance data. This process will include a broad spectrum of academic, industry and government expertise that will be obtained through an acceptable process such as an advisory committee.

- Begin a comprehensive review of existing data and federal information-collection programs to determine the extent to which they may fill existing data gaps, and suggest additional data needs to better support risk assessments.

Long-term Activities

- The consortium will continue to collectively identify critical research needs, propose effective research on analytical approaches and methods, and reach consensus on the priority of these needs based on their potential to reduce the uncertainty of risk-management decisions in food safety and provide the greatest positive impact. Research supported and conducted through this initiative would 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.

Develop and Validate Exposure Assessment Models Based on Probabilistic Methodology

Risk assessment of foodborne illness is dependent on accurately estimating the probability that various quantities of a toxin or pathogen will be ingested by the consumer (i.e., exposure assessment). This initiative addresses numerous data and modeling deficiencies in estimating exposure to microbial and chemical contaminants. Specifically, research will be conducted into the development of models and simulations based on probabilistic methods for the occurrence of microbial pathogens and chemical hazards in food at all stages of the food chain; typical behaviors of commercial and home preparation operations; validation of dynamic exposure assessment models; evaluation of intake data regarding food-consumption patterns of the general population and sensitive subpopulations; and specific data on microbial behavior in food vehicles of sporadic and epidemic disease. Research on how to incorporate data related to 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 or effect is difficult or impossible to obtain.)

FY98 Activities with Food-Safety Initiative Funds

Working with FDA, EPA, and USDA, the consortium will identify priority research programs in two areas that are in need of augmentation: exposure assessment methods, and techniques for acquisition and analysis of experimental data for model development. Initial areas identified include:

- Addressing the dynamics of foodborne pathogens in agricultural environments (e.g. pathogen reservoirs, feed, and animal manure).
- Quantifying effects of key processing steps on levels of pathogens.
- Quantifying effects of key commercial food service preparation procedures, marketing facilities, and home food-handling practices.
- Designing and proposing ways to integrate the collection of exposure and dose-response data into outbreak investigation.

Long-term Activities

Future initiatives would be fluid to adjust to results of short-term research, emerging food-safety needs, and changes in the direction of research programs within individual agencies. Additional research would likely include the development of modeling techniques to assess human exposure resulting from the subtherapeutic use of veterinary antibiotics in food-producing animals. To reduce uncertainties in exposure estimates, the consortium will work with researchers who are conducting focused food-consumption surveys targeting foods consumed by a variety of subpopulations (e.g., the elderly, children).

Develop and Validate 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.

FY98 Activities with Food-Safety Initiative Funds

Working with FDA, EPA, and USDA, the consortium will identify priority research programs in dose-response-assessment methods and models that need to be augmented. Initial areas identified include:

- Methodology to incorporate the use of biomarkers in exposed populations into risk-assessment models.
- Identification and development of criteria for objective models that permit high-to-low-dose extrapolation.
- Development of criteria that will be used to select or weight alternative models (theories) for extrapolating from empirical data to quantitative descriptions of risk.

Long-term Activities

Risk-assessment research priorities in this area will be collectively established by the interagency consortium. Additional research includes studying whether threshold or non-threshold models for infectivity are more appropriate for describing low-dose infectivity rates for infectious and toxico-infectious microorganisms. Further research is also needed into the use of biomarkers of susceptibility, chronic sequelae, microbiological toxicokinetics, and infectious dose.

RESEARCH

Background

Food-safety research is critically needed to develop the means to identify and characterize more rapidly and accurately foodborne hazards, to provide the tools for regulatory enforcement, and to develop effective interventions that can be used as appropriate to prevent hazards at each step from production to consumption. FDA, CDC, EPA, NIH, ARS, and CSREES, conduct research related to pathogenic microorganisms and other contaminants that threaten the safety of food. That research supports the needs of both the federal and state food-safety agencies and the many food industries.

Problem

New foodborne pathogens have emerged over the past ten years. Other microorganisms, previously thought to be innocuous, have been linked to life-threatening diseases after acquiring new virulence genes and antimicrobial resistance. Many of those organisms cannot be detected readily due to either a lack of suitable methods or their sporadic occurrence in foods. Certain foodborne pathogens are increasingly associated with resistance to time-tested controls, such as heating, refrigeration, and acid. In some cases, that ability appears to be linked with increased virulence or new ways to evade our immune defenses. The various research programs of FDA, ARS, CSREES, CDC, EPA, and NIH need to better coordinate their research efforts on the highest-priority issues and work together more effectively to leverage each other's resources.

Recommendations

Prevention of foodborne pathogens in foods requires an understanding of how foods become contaminated during their production, processing, and distribution, and the availability of practical interventions to control or eliminate the biologic agent. Selection of target pathogens and foods ideally are guided by risk assessment. Research is also needed to support HACCP implementation to verify that critical control points in HACCP systems are working, and to target the data gaps that hamper HACCP and risk assessment. Among the recognized data gaps, the following areas were identified as priority research needs. (Research activities listed for FY97 and FY98 are not necessarily completed in those years. Therefore, activities listed as long-term are additional activities.)

Improved Detection Methods

Many pathogens cannot be easily detected in foods, e.g., hepatitis A virus on strawberries. Among the needs for improved diagnostics, methods are needed for rapid, cost-effective testing for pathogens in food animals and their manures, in agriculture and aquaculture products, animal feeds, and processed food products. Methods development must address the low-level, sporadic incidence of many pathogens in foods. Research will be coordinated with EPA's efforts to

develop better test methods for *Cryptosporidium* and other pathogens in water and drinking water. Improved methods are needed for the identification and subtyping of foodborne pathogens in human and animal clinical specimens. The development of effective sampling plans and enrichment techniques are vital parts of detection methodology.

FY97 Activities

- EPA, CDC, ARS, CSREES, and FDA, in conjunction with states and academia, will conduct research to develop detection methods and control measures for *Cyclospora*.

FY98 Activities with Food-Safety Initiative Funds

- ARS, FDA, and EPA will enhance ongoing research to develop test methods for *Campylobacter*, *Salmonella*, *Toxoplasma*, *E. coli* O157:H7 and other Shiga-like toxin-producing *E. coli*, *Cryptosporidium*, hepatitis A and Norwalk viruses, and naturally occurring mycotoxins and marine toxins in foods.
- FDA will expand its ongoing research on the development of methods for detecting foodborne pathogens in animal feeds.

Long-term Activities

- FDA, ARS, CSREES, and EPA should undertake research to develop test methods for *Vibrio vulnificus* in foods.

Understanding Resistance to Traditional Preservation Technologies

Microorganisms that are resistant to antimicrobial agents and processing techniques that have been relied on traditionally to eliminate or prevent the growth of foodborne pathogens have become increasingly important causes of serious foodborne disease. 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. The physiological and genetic bases of resistance are not understood well enough to prevent breakthrough of newly emerging pathogens. Such research will help identify food production, processing, and handling practices that are likely to contribute to pathogen contamination or proliferation. That research is also needed to guide improvement of traditional techniques and the development of new interventions.

Long-term Activities

- ARS, CSREES, and FDA should undertake research into physiological, genetic, and other

factors that cause foodborne-disease-causing microorganisms to develop resistance to preservation technologies.

Understanding Antibiotic Drug Resistance

Pathogens in food-producing animals and their manures may become resistant to antibiotics and drugs, particularly when used improperly. One possible solution might be to modify drug withdrawal periods. Such an approach would require scientific data to be developed on how the resistance profiles of microbial populations in animals changes in response to the elimination of a drug. Work involving resistance to traditional preservation technologies and antibiotic drug resistance must be based on a sound understanding of microbial, physiologic, and genetic adaptive mechanisms.

FY98 Activities with Food-Safety Initiative Funds

- FDA and ARS will conduct research to identify and characterize the factors that lead to the development of multiple drug (antibiotic) resistance in foodborne pathogens in farm and aquaculture animals, including establishing the gene-transfer mechanisms and selective pressures.
- ARS and FDA will investigate techniques for manipulating the microbial ecology of the intestinal tract of agricultural and aquaculture animals to prevent the development of antibiotic resistance or select for nonresistance. Research should emphasize competitive exclusion techniques (probiotics) and the use of extended drug-withdrawal periods. Probiotics are benign bacteria that can be used to out-compete pathogenic bacteria.

Prevention Techniques: Pathogen Avoidance, Reduction, and Elimination

Contaminants are introduced into the food supply at numerous points along the way from farm to table. Food animals and their manures can carry human pathogens, without any clinical manifestations. Likewise, fresh fruits, fresh vegetables, and grains can harbor pathogens or mycotoxins without any discernable loss of quality. In such cases, traditional approaches of segregating contaminated foods are ineffective, and active interventions are needed. In particular, new interventions are needed to prevent and control the pathogens listed below in raw agricultural commodities and seafood. Developments in this area would be expected to provide new approaches for controlling a variety of other foodborne contaminants.

FY98 Activities with Food-Safety Initiative Funds

For *Campylobacter*, *Salmonella*, *Toxoplasma*, *E. coli* O157:H7, and other Shiga-like toxin-producing *E. coli*, and *Cryptosporidium*, FDA and ARS, often in partnership with universities and industry, will:

- Expand research into the microbial ecology of foodborne pathogens and how initial colonization in plants and animals can be prevented.
- Expand research on new methods to reduce or eliminate pathogenic microorganisms and mycotoxins from agricultural and aquaculture animals before slaughter or harvest, including the use of probiotics.
- Develop new methods to reduce or eliminate pathogenic microorganisms and mycotoxins from plants before harvest.
- Develop new disinfection methods and systems for improved sanitation of production (including on-farm) processing and marketing equipment and facilities.
- Expand research on new methods of decontamination of meat, poultry, seafood, fresh produce, and eggs.
- Initiate research to develop new techniques for eliminating animal feeds as a source of foodborne pathogens.

Long-term Activities

- ARS, CSREES, and FDA should undertake research to develop new decontamination methods for contaminants such as *Vibrio* and Norwalk virus on or in marine-harvested and aquaculture-reared seafood, and for *Cyclospora* and hepatitis A virus on fresh produce.
- ARS, CREES, and FDA should work with industry and academia to develop new techniques that provide alternatives to traditional thermal processing for eliminating pathogens. Collaboration among these parties, particularly with industry participation, will facilitate rapid evaluation of the safety and effectiveness of new technologies, and ultimately, approval of processes.
- FDA, FSIS, and EPA should work with industry and academia to develop criteria for evaluating the efficacy and safety of the new intervention technologies.

Food Handling, Distribution, and Storage

Food production, processing, and consumption often occur thousands of miles apart. Stresses associated with the transportation of live animals and fresh produce can contribute to the dissemination of foodborne pathogens. Effective packaging and proper food-storage conditions are critical to maintaining the level of safety achieved by processing.

Long-term Activities

IMPROVING INSPECTIONS AND COMPLIANCE

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. State and local officials also have primary responsibility for inspecting restaurants, supermarkets, and other retail establishments. At the federal level, FSIS has responsibility for continuous meat and poultry inspection in slaughter and processing plants and egg-product-processing plants, and for all imported meat, poultry, and egg products. FDA conducts periodic, random inspections of all other food-processing plants; that entails fewer than 700 inspectors and laboratory personnel for 53,000 U.S. plants and for all other imported foods.

Problem

The number of inspections conducted by FDA 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. An FDA-regulated plant is inspected by FDA, on 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, because the number of imports has doubled over 5 years, with no real increase in inspectors, a smaller percentage of imports are inspected at entry.

Given the limited inspection coverage, FDA is finding an increasing number of problems--the number of products recalled for life-threatening microbial contamination has increased almost five-fold since 1988. Federal budget constraints will likely prohibit significant funding increases in the future, so FDA must find new ways to provide adequate inspection coverage.

Recommendations

Scientists and other food-safety experts have concluded that the most effective and efficient mechanism to ensure that food processors identify and control hazards that could threaten food is the application of HACCP principles. FDA's seafood HACCP regulations go into effect in December 1997. FSIS began to implement its HACCP and Pathogen Reduction Requirements for the meat and poultry industries in 1997 with phase-in to be completed in 2000. HACCP programs allow government and industry resources to be used more appropriately, allowing the government to focus on the greatest risks. To ensure that HACCP is properly implemented, and to ensure more efficient and effective monitoring of the safety of the food supply, recommendations are being made in the following areas.

Enhance Development of HACCP Procedures

FY97 Activities:

FY98 Activities with Food-Safety Initiative Funds

- FDA and USDA will cooperate in evaluating the feasibility of HACCP for commodities such as fresh fruit and vegetables. The process could also consider whether it is appropriate to use USDA inspectors to inspect plants that manufacture products regulated by both agencies or even products that must meet different regulatory requirements from the two agencies, such as fresh produce used in the school lunch program.
- FDA will implement seafood HACCP by hiring approximately 80 investigators to conduct inspections to ensure proper implementation of seafood HACCP.
- A performance-based organization (PBO), will be created, with Congressional approval, as the organizational structure for the voluntary fee-for-service seafood program currently located at the Department of Commerce's National Marine Fisheries Service. The Departments of Commerce and Health and Human Services will consider whether to locate the PBO at FDA, which would consolidate voluntary and mandatory seafood programs within one agency and provide limited additional resources for implementation of seafood HACCP, while continuing the voluntary fee-for-service program.
- FSIS will continue to propose changes to current regulations to harmonize with HACCP.

Long-term Activities

- FDA should further the use of HACCP principles, as appropriate, for other foods, including animal feeds, and use risk-assessment techniques where possible.

Enhancing the Safety of Foods Produced in Retail Food Establishments Particularly at State and Local Levels

More than 3,000 state and local regulatory agencies have primary responsibility for monitoring retail food establishments to ensure that consumers are protected. U.S. retail establishments include approximately 785,000 commercial and institutional food establishments, 128,000 grocery and convenience stores, and 1.5 million vending operations. Workers in these establishments have highly diverse backgrounds and training.

FY97 Activities

- FDA and FSIS will hold a series of meetings with state and local regulators in five regions to establish retail program standards in accordance with the 1997 model state code (the Food Code) to enhance national uniformity.

FY98 Activities with Food-Safety Initiative Funds

- FSIS and FDA will provide HACCP training to state and local inspectors that will augment the training program for federal inspection personnel, more fully covering the farm-to-table process.
- See also “Education: Improve Retail Food-Service and Institutional Education.”

Long-term Activities

- The Food Code should be adopted by all 50 states.

Enhance Federal-State Inspection Partnerships

State inspection programs are an important component of the nation’s food-safety inspection system. The move toward HACCP will pose a challenge to the states that federal agencies can help the state system to meet. 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 are inspected at least once per year. New federal-state partnerships focused on coordinating inspection coverage (particularly between FDA and the states), are major steps in this direction.

FY97 Activities

- FSIS will be holding two public meetings on the issue of interstate distribution of state-inspected meat and poultry products. The purpose of these public meetings is to obtain information and comment from all stakeholders on this issue.

FY98 Activities with Food-Safety Initiative Funds

- FDA will develop additional federal-state partnerships to improve coordination between the federal food-safety agencies and state regulators for the training of state inspectors in food-safety standards applicable at all levels, including retail. FDA is currently involved in 92 partnerships with states; approximately 30 of those deal with inspection activities.
- FDA will expand the number of federal-state partnerships to include more extensive HACCP training of state inspectors, the seafood industry, and the retail food industry.
- FSIS will initiate HACCP training for state inspectors with respect to meat and poultry products.

Long-term Activities

- FDA and FSIS should work more closely with industry, professional and trade associations, and academia to ensure effective implementation of HACCP principles,

particularly at the production, processing, and retail levels.

- FDA should create a data system to compile inspection data from federal and state inspections, as well as provide the states with equipment and technology for the rapid sharing of inspection results.

Enhance Coverage of Imported Foods with Specific Attention to Foods Regulated by FDA

Wharf examinations and sampling of foods being offered for import into the United States have dropped by 50% in just the past four years. Today, FDA is responsible for about 2.2 million import food entries (i.e., shipments), an increase from 1.5 million entries just 5 years ago, with the same number of staff.

FY98 Activities with Food-Safety Initiative Funds

- FDA will increase the number of mutual recognition agreements (MRAs) with trading partners. Under MRAs, the trading countries ensure that food is produced and manufactured under equivalent systems that provide a comparable level of safety.
- FDA will initiate a federal-state communication system through which states can inform federal agencies of problems found with imported products in their jurisdictions.
- FDA will initiate a system for certifying and accrediting private laboratories, including use of a quality-assurance procedure, that will be authorized to test samples of food products for contaminants. Such private parties would provide a service to food firms wishing to demonstrate that their products meet applicable federal standards.
- When FDA and FSIS become aware of possible public-health problems associated with a regulated food product (e.g., through occurrence of foodborne illness outbreaks, sample analysis, or inspections), the agencies will provide technical assistance to the foreign country importing the product.

Long-term Activities

- FSIS should continue to verify foreign government-inspection progress for conformance with the new HACCP and Pathogen Reduction Requirements; that activity will begin in 1997 and should be completed in 2000.
- The laboratory-certification process should be extended to include assessing the utility of existing accrediting bodies with FDA providing performance standards and oversight to the process.

- FDA should expand the federal-state communication system states use to inform federal agencies of problems found with imported products in their jurisdictions. As part of that expansion, FDA should evaluate the feasibility of combining the communication system with the federal-state inspection data system discussed above, making the data and information more widely accessible.
- FDA should review and evaluate ways to increase coverage of imports through such means as increased personnel, increased partnerships, or innovative information-sharing with the states.

Enhance Safety of Foods During Transportation

In considering whether and how to regulate the transportation of meat, poultry, seafood, eggs, and other foods to safeguard the public from pathogenic microorganisms and other hazards, FSIS and FDA published an ANPR on November 22, 1996.

FY98 Activities with Food-Safety Initiative Funds

- FDA and FSIS will evaluate the comments and information received in response to the ANPR as a basis for determining what, if any, regulatory approach to take, including development of guidelines. These guidelines may include such elements as suggested performance standards for temperature control, providing information on prior cargo, and cleaning information for the food-shipper's use, to ensure the safety of the food at its destination.

Long-term Activities

- FDA and FSIS, through partnerships with states, should provide training and training materials to the transportation industry on safe food transportation. (See "Education: Improve Industry Education in the Transportation Area.")

APPENDIX A

FY98 Budget -- Food Safety Initiative

HHS:

Food and Drug Administration

Foods:

Surveillance	1,660,000
Monitoring pathogen levels	
Support sentinel sites	
Coordination	550,000
Risk Assessment	3,950,000
Risk assessment consortium	
Exposure assessment	
Research	3,900,000
Analytical Methods	
Pathogen Control	
Food Handling	
Inspections	7,870,000
Implement seafood HACCP	
State partnerships	
Lab certification	
Education	<u>2,070,000</u>
Consumer/retail education	
Total Foods	20,000,000

Animal Drugs and Feeds:

Surveillance	1,500,000
Research	<u>2,500,000</u>
Total Animal Drugs & Feeds	4,000,000

Centers for Disease Control:

Surveillance	<u>10,000,000</u>
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Total, HHS **34,000,000**

USDA:

Agricultural Research Service

Research	<u>4,114,000</u>
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Cooperative State Research, Education and Extension Service

Research	2,000,000
Education	<u>2,000,000</u>
Total, CSREES	4,000,000

Food Safety and Inspection Service

Surveillance	500,000
Inspections	<u>565,000</u>
Total, FSIS	1,065,000

Total, USDA **9,179,000**

Total Initiative **43,179,000**

Vibrio

Vibrio species are gram-negative bacteria most commonly associated with seafood-containing dishes. *Vibrio parahaemolyticus* is the species that is most commonly reported as a cause of foodborne disease; it generally causes watery diarrhea and abdominal pain lasting 1-7 days, and commonly follows consumption of improperly handled cold-seafood salads. *V. vulnificus* is one of the more serious foodborne pathogens, with a case-fatality rate for invasive disease that exceeds 50%. Most cases of foodborne *V. vulnificus* infections occur in persons with underlying illness, particularly liver disorders, who eat raw molluscan shellfish. Since the late 1980s, the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and the Gulf Coast states have intensified efforts to collect information on *Vibrio* infections, and on the microorganisms' ecology, to improve our ability to prevent foodborne infections.

Protozoa

Toxoplasma gondii

T. gondii is a parasitic protozoan. Some 1.4 million cases of toxoplasmosis occur annually with an associated 310 deaths. Healthy adults who become infected usually have no symptoms but might get diarrhea. Pregnant women who become infected can pass the disease to their fetuses. In infants infected before birth, fatality is common. Should the infant survive, the effects of infection are typically severe (i.e., mental retardation). The disease can be life-threatening 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 can contribute to infections.

Cryptosporidium parvum

C. parvum is a parasitic protozoan. The most common consequence of infection in healthy people is profuse watery diarrhea lasting up to several weeks. Children are particularly susceptible. Cryptosporidiosis can be life-threatening among people with weakened immune systems. The largest recorded outbreak of Cryptosporidiosis was a waterborne outbreak in Milwaukee, Wisconsin, in 1993, affecting more than 400,000 people. More recently, a waterborne outbreak in Las Vegas resulted in at least 20 deaths. The first large outbreak of cryptosporidiosis from a contaminated food occurred in 1993. That outbreak was attributed to fresh-pressed apple cider. *Cryptosporidium* also is found in animal manures.

Viruses

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 multistate outbreak of

viral gastroenteritis due to Norwalk virus was associated with the consumption of oysters. A 1993 Louisiana outbreak of Norwalk virus gastroenteritis involved 70 ill people and was associated with the consumption of raw oysters. In 1992, another outbreak resulted in 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.

Hepatitis A virus

Hepatitis A virus (HAV) is a virus that infects the liver and causes hepatitis A, an illness with an abrupt onset that can include fever, malaise, nausea, abdominal discomfort, dark urine, and jaundice after a prolonged incubation period (e.g, more than 2 months). In children less than 6 years old, most (70%) infections are asymptomatic, but in older children and adults, infection is usually symptomatic, with jaundice occurring in more than 70% of patients. Signs and symptoms of hepatitis A usually last more than 2 months, and there are no chronic consequences. About 130,000 infections with HAV and 100 deaths occur each year in the United States. The primary mode of transmission for HAV is person-to-person by the fecal-oral route. Recognized foodborne hepatitis A outbreaks account for only 2% to 5% of hepatitis A cases reported in the United States each year, most of which are caused by an infected food handler. Outbreaks due to foods contaminated before preparation, while uncommon, have been associated with widely distributed products such as shellfish, lettuce, frozen raspberries, and frozen strawberries. Hepatitis A can be prevented by good personal hygiene and safe food-handling practices. It can also be prevented before exposure by hepatitis A vaccine, and after exposure by immune globulin, if given within 14 days of exposure.

Other FY97 Activities

- The agencies will form alliances with industry, consumer, trade, state and local food-protection agencies, and academic organizations to share food-safety education materials and conduct joint food-safety education activities in order to leverage resources and expand the reach of the alliances. For example, FDA, FSIS, and CSREES will form an alliance, joining expertise of federal, state and local agencies, industry, and professional and trade associations to promote and implement the 1997 Food Code and develop multilingual communication techniques targeted to specific groups to overcome communication barriers.
- See “Inspections: Enhance Safety of Foods Produced in Retail Food Establishments.”

FY98 Activities with Food-Safety Initiative Funds

- FDA, CDC, FSIS, and CSREES will promote and incorporate food-safety education into school programs.

Conduct Research to Identify Barriers to Safe Food-handling, Upon Which Educational Programs Will Be Centered

FY97 Activities

Under the auspices of the National Food Safety Education Council:

- HHS and USDA will develop national safe-food-handling guidelines like the Dietary Guidelines and review them periodically.

FY98 Activities with Food-Safety Initiative Funds

- Conduct additional research necessary to determine the best way to communicate key food-safety principles in order to achieve behavior change.
- Conduct research necessary to develop a visual communication tool that conveys food-safety principles, as the food guide pyramid does for nutrition principles.

Long-term Activities

- Through partnerships and alliances, implement an education campaign to use the new educational tools especially targeted to school programs and specific at-risk audiences.

Expand Existing Information Systems

FY97 Activities

- Expand existing information systems, such as the existing Foodborne Illness Education Information Center, while laying the groundwork for a National Clearinghouse for Food Safety Education. Innovative methods for sharing food-safety information will be explored, including the consolidation of government food-safety Internet sites to reach larger audiences and provide easier access to information through a single site.

FY98 Activities with Food-Safety Initiative Funds

- Establish the National Clearinghouse for Food Safety Education.
- Consider use of food labels and other point-of-sale materials to convey food-safety information.
- In food service, develop and initiate a highly focused multilingual program to change food workers' unsafe food-preparation behaviors. The programs will address the impact of the high turnover in food-service workers and target teenage workers, small businesses, and new entrepreneurs.

Long-term Activities

- Evaluate program and continue to support those programs initiated in FY97 and FY98.

Improve Veterinarian and Producer Education

Long-term Activities

- Use existing mechanisms, such as the Cooperative Extension Service and professional associations, to strengthen and implement programs to educate producers, veterinarians, and state and local regulators about proper drug use and the incorporation of HACCP principles into industry quality-assurance programs to reduce foodborne pathogens.
- Encourage the evaluation and improvement of veterinary and producer education at veterinary and agriculture colleges to address foodborne pathogens in animals and their manures.
- Develop and disseminate guidelines and educational materials through existing networks to food producers and the veterinary medical community.

Improve Health-Professional Education

Long-term Activities

- In cooperation with FDA , FSIS, and CSREES, CDC should train public-health professionals on foodborne disease and clinical microbiology and foodborne illnesses with nontraditional symptoms by using multimedia and distance-learning techniques and the National Laboratory Training Network.

Improve Industry Education in the Transportation Area

Long-term Activities

- Form an alliance among government agencies and the private sector 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 control, prior cargo, and sanitation methods.
- See also: "Inspections: Enhance Safety of Foods During Transportation."

THE WHITE HOUSE
WASHINGTON

- NOTE - HACCP gives industry
~~enhancing~~ responsibilities

ensuring compliance?

improve inspection and compliance.

April 22, 1997 DRAFT

Next Steps

- Don't take my edits as last word
- transmittal, press release
 - tell a clear story
 - how you'd want it reported if we could get press interested
- Get it out

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

REPORT TO THE PRESIDENT

③ Show responsiveness - acknowledge what we learned from groups in problem statements

OMB / Rosler

- R.A. - add

- Exec Sum highlights

- USDA - add #'s of inspectors.

- Inspection - fruit juice - guidelines

- Adeline's comments

- Mike's comments

- To Jerry

- Set up 4:00 message

- Agency

- Elena - objective

Call to ask questions.

Wed. 10:00 am copy

⑥ Not "Strategy for 21st Century"

EXEC SUMMARY P. 14

① Goals start exec sum
Not beg 1P report? Add produce?

② Strategic planning - write in a coherent way -
- don't repeat content
- Separate big picture from minute
- process at end.

Strategic Planning - add comments at work

P. 14 - add PERUS

P. 14 AE?

P. 17 MOW signed?

P. 44

- Title

- NAS report

- P. 44 -

- Problem section
- explicitly identify
in others.
- states
- industry
- consumers

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This will be
the order
of the
report

EXECUTIVE SUMMARY

Highlight
FY98?
Funds?

In his January 25, 1997 radio address, President Clinton launched a new initiative to improve the safety of the nation's food supply. The President announced he would request \$43 million in his 1998 budget to fund a nation-wide early-warning system for foodborne illness, increase seafood-safety inspections, and expand food-safety research, training, and education. The President also directed three Cabinet members--the Secretary of Agriculture, the Secretary of Health and Human Services, and the Administrator of the Environmental Protection Agency--to identify further steps to improve the safety of the food supply. He directed them to develop these next steps working with consumers, producers, industry, states, universities, and the public, and to report back to him in 90 days.

Insert
A

Food Safety & Inspect Service (FSIS)

Four agencies in the federal government have primary responsibility for food safety: two agencies under the Department of Health and Human Services (HHS)--the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC); the Department of Agriculture (USDA); and the Environmental Protection Agency (EPA). Over the last 90 days, these agencies have worked with the many constituencies interested in food safety to identify the greatest public health risks and design strategies to reduce these risks. USDA, FSIS, FDA, CDC, and EPA have worked to build consensus and to identify opportunities to better use their collective resources and expertise, and to strengthen partnerships with private organizations. As directed by the President, the agencies have explored ways to strengthen systems of coordination, surveillance, prevention, inspections, research, risk assessment and education.

This report presents the results of that consultative process. It outlines the steps USDA, HHS, and EPA will take this year to reduce foodborne illness, and spells out in greater detail how agencies will use the \$43 million in new funds requested for fiscal year 1998. It also identifies issues the agencies plan to consider further through a public-planning process.

The actions in this report build on previous Administration steps to modernize our food safety programs and respond to emerging challenges. In 1993, the Vice President's National Performance Review issued a strategy for reinventing food safety. The report noted that our inspections system had a limited ability to detect microbial contaminants. As a key recommendation, the report urged the wide-spread adoption of preventive controls. Specifically, the report urged implementation of hazard analysis and critical control point (HACCP) systems to ensure food manufacturers identified points where contamination is likely to occur and implement process controls to prevent it. *Note - industry responsibility?*

As part of the

encouraged

Acting on this recommendation, the Administration has put in place science-based HACCP regulatory programs for seafood, meat, and poultry. In late 1995 the Administration issued new rules to ensure seafood safety. In July, 1996 President Clinton announced new regulation to

Insert (A⁹) p.

The goal of this initiative is to further reduce the incidence of foodborne illness to the greatest extent feasible. The recommendations presented in this report are based on the public-health principles that we should identify and take preventive measures to reduce risk of illness, should focus our efforts on hazards that present the greatest risk, and should make the best use of public and private resources. The initiative also seeks to further collaboration between public and private organizations and to improve coordination within the government as we work toward our common goal of improving the safety of the nation's food supply.

Number items (JE)

modernize the nation's meat and poultry inspection system for the first time in 90 years. The Early-Warning System the President announced in January will gather critical scientific data to further improve these prevention systems. And additional actions outlined in this report will expand the use of HACCP principles throughout the food industry.

KEY ADMINISTRATION ACTIONS

Enhance Surveillance and Build an Early-Warning System

As the President announced in January, the Administration will build a new national 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. For example, the Administration will:

Should we indicate w/ FY 98 funds? JE
unbold
I
The Administration will
Enhance Surveillance, expand from 5 to 8 the number of FoodNet active surveillance sentinel sites. Existing sites are in Oregon, Northern California, Minnesota, Connecticut, and metropolitan Atlanta. New sites will be in New York and in Maryland. CDC will also increase surveillance activities for certain specific contaminants. For example, CDC will begin a case-control study of hepatitis A virus to determine the proportion of cases due to food contamination and strengthen surveillance for *Vibrio* in Gulf Coast oysters. *third site?*
third one? JE

0
Equip FoodNet sites and other state health departments with state-of-the-art technology, including DNA fingerprinting to identify the source of infectious agents and with additional epidemiologist and food safety scientists to trace outbreaks to their source.

Create a national electronic network for rapid fingerprint comparison. Agencies will equip the sentinel sites and other state health departments with DNA fingerprinting technology, and will link sites together to allow the rapid sharing of information and to quickly determine whether outbreaks in different states have a common source.

Further Food Safety Education

Restate to order of Draft Report
Foodborne illness remains prevalent throughout the United States, in part because food preparers and handlers at each point of the food chain are not fully informed of risks and related safe-handling practices. Understanding and practicing proper food safety techniques from farm to table would significantly reduce foodborne illness. The Administration--working in partnership with the private sector--will, among other things:

Establish a Public-Private Partnership for Food Safety Education. FDA, USDA, and CDC will work with the food industry, consumer groups and the states to launch a food-safety public awareness and education campaign. The Partnership will develop, disseminate, and evaluate a single food-safety slogan and several standard messages. Industry has pledged \$500,000 to date to support the partnership's activities and plans to raise additional funds. *move to end*

children folding or high impact? AE
food handlers?

Educate professionals and high risk groups. Agencies will better educate physicians to diagnose and treat foodborne illness; strengthen efforts to educate producers, veterinarians, and state and local regulators about proper animal drug use and HACCP principles; and work with the Partnership to better train retail- and food-service workers in safe handling practices.

Improve Responses to Foodborne Outbreaks

At the federal level, four agencies are charged with responding to outbreaks of foodborne and waterborne illness: CDC, FDA, and USDA's ~~Food Safety and Inspection Service (FSIS)~~ and EPA. States and many local governments with widely varying expertise and resources also share responsibility for outbreak response. The current system does not assure a well-coordinated, rapid response to interstate outbreaks. To more quickly identify an outbreak's cause and ensure a rapid response, agencies will:

Establish an intergovernmental Foodborne Outbreak Response Coordinating Group

[still under discussion]

Strengthen the infrastructure for surveillance and coordination at state health departments

Improve Risk Assessment

Risk-assessment methods help characterize the nature and size of the risk to human health associated with foodborne hazards and assist regulators in making decisions about controlling those hazards. To improve risk-assessment capabilities, agencies will:

Establish an interagency risk-assessment consortium to set priorities and guide overarching federal risk-assessment research related to food safety.

Develop better data and modeling techniques to assess exposure to microbial contaminants, and simulate microbial variability from farm to table.

Develop New Research Methods

Today, many pathogens in food or animal feed cannot be identified, and others have developed resistance to time-tested controls such as heating and refrigeration. The agencies will focus research immediately to:

Develop rapid, cost-effective tests for the presence of pathogens, such as *Salmonella*, *Cryptosporidium*, *E.coli* O157:H7, and hepatitis A virus.

STET **Enhance understanding of how pathogens become resistant** to food-preservation techniques and antibiotics. *AE*

and improve effectiveness of
Develop technologies for prevention and control of pathogens.

Increase Inspections

The agencies will pursue several strategies to increase inspections for higher-risk foods; the agencies will, among other things:

Implement seafood HACCP. FDA will add seafood inspectors using new FY98 funds to implement new seafood HACCP regulations, and will work with the Commerce Department to integrate the Department's voluntary seafood-inspection program with FDA's program.

Propose new regulations for fruit juices. FDA will also propose, among other things, to require the use of HACCP for juice products.

Propose HACCP regulatory options for egg products. FSIS will ~~consider whether to~~ propose HACCP regulatory options for egg products.

Improve coverage of imported foods. FDA will develop additional mutual recognition agreements (MRAs) with trading partners, initiate a federal-state communication system covering imported foods, and FDA and FSIS will provide technical assistance to countries whose products are implicated in a foodborne illness.

Enhance Federal-State Inspection Partnerships AE

Add: Continue Planning Process . . .

*Consumers will be pleased w/work on produce — can we add a bullet highlighting research/HACCP work?
better*

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 would 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 Agriculture, the Secretary of Health and Human Services, 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 Glickman and Shalala and Administrator Browner to report 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.

This report is the result of that 90-day process of deliberation and discussion among all stakeholders in the nation's food-safety system, including federal, state, and local agencies, consumers, academia, food producers, manufacturers, distributors, representatives of the retail and restaurant sectors, veterinarians and health professionals, and many others.

To start the discussion, the agencies issued a draft document summarizing their initial ideas. Subsequently, the agencies held two public meetings on March 5 and March 31-April 2, and established public dockets for written comments.

The goal of this initiative is to reduce the incidence of foodborne illness to the greatest extent possible. The recommendations presented in this report are based on the public-health principles that society should identify and take preventive measures to reduce the risk of illness and that it should focus its efforts on hazards that present the greatest risks.

FOODBORNE ILLNESS: A SIGNIFICANT PUBLIC HEALTH PROBLEM

The Council for Agricultural Science and Technology, a private nonprofit 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. USDA estimates that medical costs and productivity losses for seven specific pathogens in food have been estimated to range between \$6.5 billion and \$34.9 billion annually. Total costs for all foodborne illnesses are likely to be much higher. Those estimates do not take into account the total burden placed on society by the chronic, often lifelong consequences caused by some foodborne pathogens.

Several population groups have increased susceptibility to foodborne infections, such as persons

Move to
Appendix
AE

with lowered immunity due to HIV/AIDS and those on medications for cancer treatment or for organ transplantation, as well as pregnant women and their fetuses, young children, and the elderly. Patients taking antibiotics or antacids are also at greater risk of infection from some pathogens, as are people living in institutional settings, such as hospitals and nursing homes, and those with inadequate access to health care, such as homeless people, migrant farm workers, and others of low socioeconomic status.

because they are
in institution or sick?
AE

Sources of Foodborne Contamination

Bacteria and other infectious organisms are pervasive in the environment. *Salmonella* serotype Enteritidis enters eggs directly from the hen. Bacteria (occasionally pathogenic) inhabit the surfaces of fruits and vegetables. 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 can become contaminated from agricultural animal manures and wastes 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 animals. Milk, eggs, seafood, poultry, and meat can become contaminated due to contaminated feed, misuse of veterinary drugs, or poor farming practices, in particular, mismanagement of animal manures, including production and harvesting activities. Foods can become contaminated during processing due to malfunctioning or improperly sanitized equipment, misuse of cleaning materials, rodent and insect infestations, and improper storage. Foods can become contaminated in retail facilities and in homes through poor food-handling practices.

Some microbial pathogens 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. Some of the most serious contaminants are described below.

in the appendix (JE)

Bacteria Salmonella

Salmonella species cause diarrhea and systemic infections, which can be fatal in particularly susceptible persons, such as the immunocompromised, the very young, and the elderly. Animals used for food production are common carriers of salmonellae, which can 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. 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. Between 128,000 and 640,000 of those infections are associated with *Salmonella* Enteritidis in eggs. Over the past decade,

Bullets?
Table? would be easier to read - AE

per JE - move description of contaminants to the appendix pp. 8-11

more than 500 outbreaks have been attributed to *S. Enteritidis* with more than 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 2 and 4 million cases of campylobacteriosis occur each year with an associated 120-360 deaths.

Campylobacter jejuni and *Campylobacter coli* (two closely related species) are commonly foodborne, and are the infectious agents most frequently described in association with Guillain-Barré syndrome, 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.

Shiga-like toxin-producing *Escherichia coli*

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. It has been associated with HUS, a life-threatening complication of hemorrhagic colitis characterized by acute kidney failure that is particularly serious in young children. *E. coli* O157:H7 is found in cattle, but there may be other reservoirs; the dynamics of *E. coli* O157:H7 in food-producing animals are not well understood. Approximately 25,000 cases of foodborne illness can be attributed to *E. coli* O157:H7 each year with as many as 100 deaths resulting. *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 three western states and British Columbia was associated with unpasteurized apple juice, sickened 66 people, and caused the death of one child.

Protozoa

Toxoplasma gondii

T. gondii is a parasitic protozoan. Some 1.4 million cases of toxoplasmosis occur annually with an associated 310 deaths. Healthy adults who become infected usually have no symptoms but might get diarrhea. Pregnant women who become infected can pass the disease to their fetuses. In infants infected before birth, fatality is common. Should the infant survive, the effects of infection are typically severe (i.e., mental retardation). The disease can be life-threatening 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 can contribute to infections.

Cryptosporidium parvum

C. parvum is a parasitic protozoan. The most common consequence of infection in healthy people is profuse watery diarrhea lasting up to several weeks. Children are particularly susceptible. Cryptosporidiosis can be life-threatening among people with weakened immune systems. The largest recorded outbreak of cryptosporidiosis was a waterborne outbreak in Milwaukee, Wisconsin, in 1993, affecting more than 400,000 people. More recently, a waterborne outbreak in Las Vegas resulted in at least 20 deaths. The first large outbreak of cryptosporidiosis from a contaminated food occurred in 1993. That outbreak was attributed to fresh-pressed apple cider. *Cryptosporidium* also is found in animal manures.

Viruses

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 multistate outbreak of viral gastroenteritis due to Norwalk virus was associated with the consumption of oysters. A 1993 Louisiana outbreak of Norwalk virus gastroenteritis involved 70 ill people and was associated with the consumption of raw oysters. In 1992, another outbreak resulted in 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.

Bacteria

Vibrio vulnificus

Vibrio species are gram-negative bacteria most commonly associated with seafood-containing dishes. *Vibrio parahaemolyticus* is the species that is most commonly reported as a cause of foodborne disease; it generally causes watery diarrhea and abdominal pain lasting 1-7 days, and commonly follows consumption of improperly handled cold-seafood salads. *V. vulnificus* is one of the most severe foodborne pathogens, with a case-fatality rate for invasive disease that exceeds 50%. Most cases of foodborne *V. vulnificus* infections occur in persons with underlying illness, particularly liver disorders, who eat raw molluscan shellfish. Since the late 1980s, CDC, FDA, and the Gulf Coast states have intensified efforts to collect information on *Vibrio* infections, and on the microorganisms' ecology, to improve our ability to prevent foodborne infections.

Hepatitis A virus

Hepatitis A virus (HAV) is a picornavirus that infects the liver and causes hepatitis A, an illness with an abrupt onset that can include fever, malaise, nausea, abdominal discomfort, dark urine, and jaundice after a prolonged incubation period. In children less than 6 years old, most (70%) infections are asymptomatic, but in older children and adults, infection is usually symptomatic, with jaundice occurring in more than 70% of patients. Signs and symptoms of hepatitis A usually last more than 2 months. About

10% of persons require hospitalization, and death from hepatitis A is uncommon. About 130,000 infections with HAV and 100 deaths occur each year in the United States. There are no chronic consequences of HAV infection. The primary mode of transmission for HAV is person-to-person by the fecal-oral route. Recognized foodborne hepatitis A outbreaks account for only 2% to 5% of hepatitis A cases reported in the United States each year. These outbreaks are usually associated with foods contaminated by an infected food worker during preparation. Outbreaks due to foods contaminated prior to preparation, while uncommon, have been associated with widely distributed products such as shellfish, lettuce, frozen raspberries, and frozen strawberries. Hepatitis A can be prevented before exposure by hepatitis A vaccine, and after exposure by immune globulin, if given within 14 days of exposure.

Appendix
AF.

THE CURRENT SYSTEM FOR PROTECTING FOOD

} Move pp. 11-13 describing
current system to
the appendix
JE.

Our food-safety system, although generally successful in protecting the public, is characterized by complexity and diversity. Regulatory authority is divided among federal, state, and local governments. The private sector has the primary responsibility for ensuring the safety of the food that it produces. From the farm to the consumer's dinner table, the responsibilities can be summarized as follows:

- Consumer education on food handling and storage in the home is the primary responsibility of FSIS, CSREES, FDA, and CDC. FSIS, with responsibility for meat, poultry and most egg products, FDA, with jurisdiction over all other foods, and CDC, with epidemiological capabilities, all produce educational materials. FDA and FSIS staff consumer hotlines, and all agencies have web sites. CSREES has an enormous network of extension agents across the country, and FDA has Public Affairs Specialists in offices around the country to respond to inquiries and conduct safe handling programs for consumers, health professionals, and the media.
- In the home, consumers have a responsibility for proper handling and storage of food. Because consumer mishandling contributes to many cases of foodborne illness, FSIS promulgated safe-handling labels for raw meat and poultry products.
- On the farm, food is regulated by state agencies supported principally by the Environmental Protection Agency (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 the Animal and Plant Health Inspection Service (APHIS) in the U.S. Department of Agriculture (USDA), which is concerned with food-animal-disease control. Federal responsibility also covers production and harvesting activities that discharge wastewater to surface and to ground waters and solid waste to land, all of which could contaminate growing and processing waters or grazing land. Animal manures are excluded from the definition of solid waste under EPA's solid-waste-disposal regulation, and therefore, an EPA regulatory mechanism does not exist for these

materials. The ecology of human pathogens in food animals and in their manures produced on farms and ranches, in wild animals, in slaughter operations, and in processing facilities has received little attention in the past. Regulations under the Clean Water Act require large animal-feeding operations to obtain a discharge permit.

- Food processing for foods other than meat, poultry, and egg products (except shell eggs) is regulated by FDA, whose inspectors are responsible for visiting about 53,000 plants periodically, with emphasis on the highest risk foods or processing techniques. FDA devotes about 700 inspectors and laboratory personnel to this activity. Meat, poultry, and all other egg products are regulated by FSIS, whose inspectors are present in 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. In 1996, FSIS and FDA 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 microbial contamination during transportation. FDA and USDA will evaluate the comments and information received in response to the ANPR as a basis for determining what, if any, regulatory approach to take, including development of guidelines. These guidelines may include such elements as suggested performance standards for temperature control, providing information on prior cargo, and cleaning information for the food-shipper's use, to ensure the safety of the food at its destination.
- Importation of food from foreign countries is overseen by FSIS for meat, poultry, and most egg products and by 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) fall under the FDA's retail food-protection program, a cooperative federal-state food-safety effort operated under the Public Health Service Act. FDA has regulatory authority under the Federal Food, Drug, and Cosmetic Act over retail establishments because the food used in these establishments traveled in interstate commerce, however, the PHS Act provides the means for more efficient regulation and use of available resources, as well as broader inspection coverage. FDA publishes the Food Code, which consists of model recommendations that states and local authorities adopt and use to regulate retail food establishments. FDA, along with FSIS and CDC, work with states biennially to update the Food Code.
- National standards for drinking water and criteria for surface waters 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 sources, and control outbreaks. CDC conducts field investigations of foodborne diseases only at the request of state health departments, which have the authority to implement outbreak control measures. FDA, FSIS, or both are called in when food within their jurisdiction is suspected. FDA is charged with ensuring that foods implicated in a foodborne illness outbreak and traveling in interstate commerce are removed from the market.
- Research serves many purposes in reducing the incidence of foodborne illness and is integral to the programs of all public-health agencies. Research is essential to evaluate effectiveness of surveillance initiatives, control and prevention strategies, conduct risk assessments, and verify effectiveness of preventive techniques such as HACCP. Research into the cause and transmission of foodborne illness is the primary responsibility of CDC, FDA, USDA, and EPA. The development of screening and analytic methods to rapidly and accurately identify and characterize foodborne hazards, identifying and tracking to the source the causes of foodborne illness, is the responsibility of FDA, USDA, EPA, and CDC. Research to develop preventive technologies, ranging from new production techniques, to disinfection and food-processing techniques to reduce levels of pathogens, is the primary responsibility of USDA, FDA, and industry. Basic research is conducted largely in university laboratories on the biology, genetics, pathogenesis, natural history, and epidemiology of microorganisms implicated in foodborne disease and is actively supported by the NIH, and in particular, by the National Institute of Allergy and Infectious Diseases. These efforts are focused on understanding the disease process and designing prevention and treatment strategies. Other agencies of the federal government also support related research in universities. The private sector supports research within its own laboratories and in universities.

Very long paragraph

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

The system for identifying and preventing foodborne illnesses described ^{in the appendix} ~~above~~ was largely created in the early 1900s. It must be modernized. The system cannot properly identify, track, control, or and prevent food-related illness or prevent future cases from occurring. In 1981, FDA inspected food firms every 2-3 years, but can now visit those firms, on average, only once every 10 years (although some plants that produce higher-risk foods may be inspected more frequently). State and federal resources are not closely coordinated. Our understanding of some disease-causing organisms is so limited that our ability to protect the public health is seriously constrained.

The Clinton Administration has already taken a number of steps to improve the safety of the food supply.

- In 1993, the Vice President's National Performance Review issued a blueprint for reinventing our nation's food-safety system. A major recommendation of the report was

that the government and industry should move toward a system of preventive controls.

- The Food Safety 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 calls for food industries to design and implement preventive measures, streamlines regulation of foods, and increases the industries' responsibility for and control of their safety-assurance actions.
- 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 Food Quality Protection Act of 1996 streamlined regulation of pesticides by FDA and EPA and put important new public-health protections in place, especially for children. *- which included major provisions of the Admin's bill*
- *Last year* ~~The President signed~~ *for* The Safe Drinking Water Act of 1996 includes regulatory improvements to help states and water-utility managers 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.

These advances are significant, but they are not 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. *← AE? can't read*

IMMEDIATE ACTIONS TO IMPROVE FOOD SAFETY

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

The Administration's food-safety efforts focus on the hazards and foods that present the greatest risks to public health and impose the greatest economic burden on the nation, emphasize development and implementation of preventive controls of those risks, and seek to ensure that preventive controls are cost-effective. The Administration is emphasizing the use of HACCP principles, and seeks opportunities for such controls through a collaborative process with the responsible sectors of the food industry and all other stakeholders.

Under this initiative, the federal government, in concert with state and local governments, industry and academia, would conduct research and risk assessments and cost-benefit analyses to determine how foodborne illnesses occur and can be prevented or controlled in the most efficient and cost-effective manner; 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 focusing on the use of safe practices. Those issues, and *actions and* recommendations for addressing them are described below. ~~Because the components of the food safety initiative are interrelated, overlapping activities will be noted throughout this report (for example, among research and risk assessment, and education and inspection).~~ ✓

EDUCATION

Background

An integral part of the overall food-safety initiative is providing food-safety education to a variety of audiences: consumers (the general public and specific groups at risk for foodborne illness); public-health professionals and physicians; retail, food-service, and institutional food preparers; veterinarians, animal and other food producers; and food transportation workers. The challenge is to create educational messages that address the risks relevant to each audience throughout the food chain. Research and risk assessment are important elements in identifying these risks and devising appropriate messages. Realizing that educational efforts are cost-effective investments, federal, state and local governments, private organizations, consumer groups, and industry have fostered educational programs to address foodborne illness.

Problem

Despite educational efforts, foodborne illness remains prevalent throughout the United States. One reason is that food preparers and handlers at each stage of the food chain lack the knowledge of risks involved and the related safe food handling practices. Without the practice of food-safety knowledge and proper food-handling procedures, foodborne illness cannot be significantly reduced. Food-safety messages should be developed to reach individuals at each stage from the farm to the table.

Risk assessment and research to determine the most effective ways to overcome barriers to use of safe food handling and to ensure use of safe food-handling practices are needed for specific audiences. For example, consumers' food-handling practices and the choices they make in the foods they eat will either increase or decrease the chances of foodborne illness. Studies show that 53% of the public eats raw eggs, 23% eats undercooked hamburger, 17% eats raw clams and oysters, and 26% do not wash cutting boards after using them for raw meat or poultry.

Similarly, food preparers in the retail sector must be made aware of how they can prevent food contamination and reduce pathogen growth. For example, from 1988 to 1992, *Salmonella* caused 69% of the 796 bacterial foodborne disease outbreaks; 60% of those *Salmonella* outbreaks were caused by *Salmonella* Enteritidis. *S. Enteritidis* also resulted in more deaths than any other pathogen, with 85% of these deaths occurring among residents of nursing homes.

Health professionals and physicians need specific knowledge about causes and effects of foodborne illness to more effectively detect and treat the illnesses. Producers of animals used in human food production and veterinarians treating such animals must be made aware of food safety aspects of drugs and drug residues. Finally, those responsible for the transportation of food are often unaware that mishandling of food during shipment can result in contamination.

Recommendations

The goal of this initiative is to target and change unsafe food-handling practices by people throughout the food chain, including food-service workers, and especially those providing food to populations at high risk. Objectives include: 1) forming partnerships and alliances to maximize resources and broaden the impact and scope of educational efforts; 2) designing messages by conducting research to identify barriers to safe food handling, upon which educational programs will be centered; and 3) expanding the use of innovative outreach methods, including the use of new technologies.

Implementation of the education goals and objectives of the initiative combined with the other elements of the initiative will significantly increase the number of consumers and 12 million food-service workers being reached with effective and persuasive food safety messages.

Improve Consumer, Retail, and Food-Service Education

FY97 Activities

The 1997 Consumer Food-Safety Education Partnership

New paragraph
A memorandum of understanding was signed in April 1997, formalizing a food-safety education partnership that includes industry, consumer groups, FDA, USDA, CDC, [and the Department of Education]. Participants in the partnership will launch a nationwide food-safety education campaign for the general public. The campaign will center on four key food-safety concepts tested for maximum consumer understanding and will include a slogan, logo or identifiable character. At present, the Partnership is reviewing proposals from national public-relations and communications firms to conduct a public awareness and education campaign. The industry groups have contributed almost \$500,000 to date. Plans for the nationwide campaign will be announced at the food-safety education conference, "Changing Strategies: Changing Behaviors," sponsored by USDA, FDA, and CDC to be held June 12-13 in Washington, DC. The partnership will promote September as National Food Safety Month, as already designated by industry, and launch the food-safety message campaign during the month.

Identify key food-safety education principles through establishment of an expert council

Convene the National Food-Safety Education Council, an independent scientific review board to periodically review food-safety education messages. The Council, which will include food scientists and educators, will serve to identify emerging food-safety risks that require public education. Risk assessment will be used to identify at-risk audiences for targeted food-safety education programs.

Other FY97 Activities

- The agencies will form*
- Multiple alliances ~~will be formed~~ *with* to serve as networks for federal agencies, industry, consumer, trade, state and local food-protection agencies, and academic organizations to share food-safety education materials and conduct joint food-safety education activities in order to leverage resources and expand the reach of the alliances. For example, FDA and USDA will form an alliance, joining expertise of federal, state and local agencies, industry, and professional and trade associations to promote and implement the 1997 Food Code and develop multilingual communication techniques targeted to specific groups to overcome communication barriers.
 - See "Inspections: Enhance Safety of Foods Produced in Retail Food Establishments."

FY98 Activities with Food-Safety Initiative Funds

- FDA, CDC, and USDA will promote and incorporate food-safety education into school programs.

Conduct Research to Identify Barriers to Safe Food Handling, Upon Which Educational Programs Will Be Centered

FY97 Activities

Under the auspices of the National Food-Safety Education Council, ~~the following activities will be coordinated:~~

- USDA and HHS will develop - AE*
- ~~Develop~~ national safe-food-handling guidelines like the Dietary Guidelines and review them periodically.

FY98 Activities with Food-Safety Initiative Funds

- Conduct additional research necessary to determine effective messages and methods to foster behavior change. Determine the best way to communicate the key food-safety principles.
- Conduct research necessary to develop a visual communication tool to convey food-safety principles, as the food guide pyramid does for nutrition principles.

Long-term Activities

- Through partnerships and alliances, implement a ~~massive~~ education campaign to use the new educational tools especially targeted to school programs and specific

Seems backward to have occur in 98 when Partnership is to develop logo in 97

at-risk audiences.

Expand Existing Information Systems

FY97 Activities

- Expand existing information systems, such as the existing Foodborne Illness Education Information Center, while laying the groundwork for a National Clearinghouse for Food Safety Education. Innovative methods for sharing food-safety information will be explored, including the consolidation of government food-safety Internet sites to reach larger audiences and provide easier access to information through a single site.

FY98 Activities with Food-Safety Initiative Funds

- Establish the National Clearinghouse for Food Safety Education.
- Consider use of food labels and other point-of-sale materials to convey food-safety information.
- In food service, develop and initiate a highly focused multilingual program to change food workers' unsafe food-preparation behaviors. The programs will address the impact of the high turnover in food-service workers and target teenage workers, small businesses, and new entrepreneurs.

Long-term Activities

- Evaluate program and those ~~Continue to expand and support~~ programs initiated in FY97 and FY98.

Improve Veterinarian and Producer Education

Long-term Activities

- Use existing mechanisms, such as the Cooperative Extension and professional associations, to strengthen and implement programs to educate producers, veterinarians, and state and local regulators about proper drug use and the incorporation of HACCP principles into industry quality-assurance programs to reduce foodborne pathogens.
- the evaluation and Encourage the improvement of veterinary and producer education at veterinary and agriculture colleges to address foodborne pathogens in animals and their manures.

- Develop and disseminate (AE)*
- ~~guidelines and educational materials should be developed and disseminated~~ through existing networks to food producers and the veterinary medical community.

Improve Health-Professional Education

Long-term Activities

- will? AE*
- In cooperation with FDA and USDA, CDC should train public-health professionals on foodborne disease and clinical microbiology and foodborne illnesses with nontraditional symptoms by using multimedia and distance-learning techniques and the National Laboratory Training Network.

Improve Industry Education in the Transportation Area

Long-term Activities

- F* *(FDA and USDA)*
- ~~FDA and USDA should~~ form an alliance among government agencies and the private sector 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 control, prior cargo, and sanitation methods.
 - See also: "Inspections: Enhance Safety of Foods During Transportation."

A NEW EARLY WARNING SYSTEM FOR FOODBORNE DISEASE SURVEILLANCE

Background

The primary objective of the American system of public health is to prevent disease before it occurs. Although prevention of all disease might not be possible, stopping outbreaks of foodborne illness before they affect large numbers of people is a major goal. America needs an effective early-warning system that can detect outbreaks before they cause illness and death. Such a system will also advance understanding of foodborne illness and further prevention efforts. In his January 25 radio address, the President announced a new national early-warning system for foodborne illness for which he is requesting funds in his FY98 budget.

Problem

The current public health system in the United States has limited means to identify and track the causes of foodborne illness. A more effective early warning system is needed to catch outbreaks early and prevent illness and death. Also, the national and global increase in antimicrobial resistance is a compelling public health problem. Human infections caused by resistant pathogens result in increased morbidity and mortality from treatment failures and increased health care costs as newer, more expensive antibiotics are needed to treat common infections.

Recommendations

AE [Surveillance for antimicrobial resistance will allow early detection of resistance and containment of its spread. Surveillance and investigation are powerful tools to detect new foodborne disease challenges, to determine what specific food sources are, and to learn how best to keep 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 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 Foodborne Disease Active Surveillance Network (FoodNet) 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 premature deaths related to foodborne diseases.

In cooperation with state and local health departments, the federal government is proposing to take the following steps to establish a national early-warning system for foodborne diseases, and

to enhance surveillance of such disease. These changes will result in an improved system for promptly and accurately detecting and reporting foodborne illnesses and outbreaks so public-health agencies can rapidly institute appropriately and correctly focused measures to control the spread of foodborne disease. This system will also collect critical data to recognize trends and target prevention strategies, including systems based on HACCP principles, and to evaluate the effectiveness and efficiency of prevention strategies already in place.

Enhance and Expand Foodborne Disease Active Surveillance

will CDC, FDA, and USDA support five FoodNet 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 their number ~~should be~~ increased to seven in FY97, and to at least eight in the following year. The sites and federal food-safety agencies ~~should~~ be electronically linked to create a powerful new network to detect, respond to, and prevent outbreaks of foodborne illness. Adding additional sites will improve geographic and demographic representation, making this network more likely to detect diseases and outbreaks that are regional rather than national in distribution. ✓ will

FY97 Activities

- Two new FoodNet sites that encompass several counties in New York and Maryland will begin FoodNet activities.

FY98 Activities with Food-Safety Initiative Funds

- CDC, FDA, USDA, and the Council of State and Territorial Epidemiologists (CSTE) will add at least one site to FoodNet, and CDC will enhance personnel resources at all sites to improve surveillance, analysis of data, and timely and appropriate release of information.
- CDC and the FoodNet sites will develop and conduct case-control studies of *Campylobacter* and *Cryptosporidium* infections to guide control efforts.

Enhance early detection of foodborne disease nationwide

The will
~~An~~ early-warning system ~~would~~ enhance improved early detection of foodborne disease in additional states in FY98 by providing resources for improved surveillance, investigation, control, and prevention of foodborne disease outbreaks. Although sophisticated laboratory studies can identify causes of illness and show relationships among pathogens, 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 HUS.

FY97 Activities

- CSTE and CDC, in conjunction with FDA and USDA, will develop a protocol for evaluating epidemiologic outbreak data. The group will also develop criteria for local and state health officials to provide information on outbreaks to federal authorities for review and necessary action.
- FoodNet sites will gather epidemiologic data on cases of HUS.

FY98 Activities with Food-Safety Initiative Funds

- CSTE and CDC, in conjunction with FDA and USDA, will define critical capacity elements that state and local health departments require to conduct surveillance, investigation, control, and prevention of foodborne illnesses; CDC will help states remedy identified deficiencies.
- CDC and CSTE will develop an electronic module for collecting and transmitting data to CDC on outbreaks of foodborne illness.
- CDC will begin a case-control study of hepatitis A virus to determine the proportion of cases due to contamination of food so that optimal control strategies could be determined.
- Epidemic assistance for outbreaks of foodborne disease will be expanded when states request direct CDC participation in investigations.
- CDC and, where appropriate FDA and USDA, will collaborate with state health departments to improve diagnostics, outbreak detection, and electronic communications.
- *Vibrio* surveillance will be strengthened by CDC, FDA, and states by increasing personnel, epidemiologic, and laboratory resources devoted to the Gulf Coast *Vibrio* surveillance program.

Long-term Activities

- Surveillance and investigative systems should continue to be enhanced to improve the ability of state and local health departments to promptly and accurately identify foods that are the source of foodborne illness.

Modernize Public-Health Laboratories

CDC should provide resources and training to upgrade public-health laboratory capabilities in

FoodNet sites and in states without those sites so the laboratories can rapidly identify a broad range of foodborne infections, including those caused by parasitic and viral pathogens, and can use new techniques of DNA fingerprinting. The new capacities would allow rapid identification of the cause of some outbreaks that currently go undiagnosed.

FY97 Activities

- CDC will collaborate with FoodNet sites to determine serotypes of *E. coli* other than O157:H7 that cause HUS in American children.

FY98 Activities with Food-Safety Initiative Funds

- The Association of State and Territorial Public Health Laboratory Directors (ASTPHLD) and CDC will improve diagnostic assays and provide additional resources to improve the capacity of state laboratories to detect foodborne pathogens, including selected viruses and parasites.
- CDC will provide sufficient funds to states to support the production of serotyping reagents for *Salmonella*, which are critical for outbreak identification.
- CDC will develop DNA amplification-based tests for foodborne pathogenic bacteria that are difficult to detect by culture (e.g., Shiga-like toxin-producing *E. coli* other than *E. coli* O157:H7 and other disease-causing *E. coli*) and will provide resources and technical assistance to states to improve their capacity in diagnosing those pathogens.

Long-term Activities

- CDC should begin developing molecular alternatives to serotyping for *Salmonella*.

Create a National Electronic Network for Fingerprint Comparison

CDC should fund a new computer network and database system that would capture fingerprints of pathogens in a national database, linking CDC, FDA, USDA, and states that have that new capacity 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. That might suggest to public-health investigators that a product distributed in California and Washington was contaminated with the organism.

In addition to identifying, investigating, and reporting cases of foodborne disease in humans, microbiological surveillance of pathogens in foods, in food animals and their manures, and in animal feed, is important to control and prevent foodborne diseases and to evaluate 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.

FY97 Activities

- CDC will provide resources and technical assistance to state health departments for DNA fingerprinting of *E. coli* O157:H7, and begin to establish a centralized national electronic database of DNA fingerprint patterns.

FY98 Activities with Food-Safety Initiative Funds

- The national electronic database of DNA fingerprint patterns of *E. coli* O157:H7 will continue to be expanded.
- In collaboration with participating state health department laboratories, FDA and USDA, CDC will develop standardized methods for DNA fingerprinting of *Salmonella* serotypes Typhimurium and Enteritidis and will transfer the techniques to selected state health departments.
- CDC, ASTPHLD, and CSTE will develop guidelines for maximizing the utility of DNA fingerprinting at state health departments in foodborne disease surveillance and outbreak investigations. ? AE
- CDC, FDA, and USDA will set up centralized national electronic databases of DNA fingerprint patterns of *S. Typhimurium* and Enteritidis.

Long-term Activities

- CDC should continue to develop standardized DNA fingerprinting methods for other foodborne disease-causing bacteria as appropriate and would transfer the standardized methods to state health departments and appropriate federal laboratories.
- CDC should begin implementing automated foodborne disease outbreak detection algorithms based on the DNA fingerprint patterns submitted by state health department laboratories.

Increase National Surveillance for Antimicrobial Resistance of Foodborne Pathogens

The problem of foodborne disease is increasing, in part, because foodborne infections are becoming more serious. One of the ways foodborne pathogens become more virulent is by acquiring resistance to antimicrobial agents, making such infections very difficult to treat.

Therefore, 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 those bacteria isolated from food-producing animals and their manures and from food products in a way that permits those data to be compared. CDC, FDA and USDA should develop standard procedures for sharing information and for responding to increases in resistance or other red flag events such as the discovery of an important new resistant bacterium.

FY97 Activities

- CDC, FDA, and USDA will conduct surveillance of antimicrobially resistant *Salmonella* and *E. coli* O157:H7 isolates.

FY98 Activities with Food Safety Initiative Funds

- CDC, FDA, and USDA will initiate surveillance of antimicrobial resistance in isolates of *Campylobacter* from humans and animals, including poultry.
- FDA and CDC will conduct surveillance and epidemiologic studies to monitor and reduce the incidence of foodborne disease associated with emerging and drug-resistant pathogens.

Long-term Activities

- CDC, FDA, and USDA should continue monitoring and comparing the antimicrobial resistance of *E. coli* O157:H7, *Salmonella*, and *Campylobacter* strains in humans and animals.
- FDA and CDC should conduct physician and veterinary drug-prescribing surveys, including patients and animal producers, to assess the effect of antimicrobial drug use on resistance patterns and prevalence to guide regulatory policy and educational campaigns.
- FDA should assist the World Health Organization (WHO) in the development of a veterinary database within the WHONET system. (WHONET is a system for standardized reporting of antimicrobial resistance to WHO.)

Conduct Surveillance of Human Pathogens in Food Animal Populations and Enhance Oversight of Animal Feedstuffs, Feeds, and Manures for the Effect of Drugs and Other Therapies

FY98 Activities with Food-Safety Initiative Funds

- USDA, CDC, FDA, and EPA will convene a working group to discuss how to conduct surveillance of human pathogens in food animals and their manures, and should target

one pathogen on which to begin surveillance in FY99.

Long-term Activities

- FDA should increase the monitoring of animal-feed processing to determine the nature and extent of pathogen contamination and the effect of control strategies on pathogen reduction in animals.

INTERSTATE OUTBREAK CONTAINMENT AND RESPONSE COORDINATION

Background

Four federal agencies are charged with responding to outbreaks of foodborne illness (including waterborne illness): FDA and CDC (at HHS), FSIS (at USDA), and EPA. All states, and many local governments, with widely varying expertise and resources, share responsibility with the federal government for response to such outbreaks. When an outbreak occurs, all of the relevant entities must work together to efficiently and effectively prevent deaths and minimize the number of illnesses. The better coordinated the response, the more quickly the outbreak will be contained.

Each of the four federal agencies has a potentially critical role when an outbreak occurs. 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, FSIS, and EPA also have responsibility for determining whether a product they regulate may be causing illness, and of 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 type of food affected determines which regulatory agency has primary jurisdiction: FSIS regulates meat, poultry, and egg products; FDA regulates all other foods including shell eggs; and EPA regulates water and pesticides and manages organic and inorganic wastes used or disposed of on agricultural land. While each agency has clearly defined areas of responsibility, the successful containment of many outbreaks of foodborne illness involves more than one agency.

The states and many local governments also have a critical role. Identification and investigations of foodborne illness often begin at the community or state level. States share with the federal government the legal responsibility for protecting the health of their residents. Although food outbreaks are sometimes local because of improper processing or handling, most outbreaks implicate 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.

In many outbreaks of foodborne illness, federal agencies work with state and local health authorities in their investigations 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 the 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.

Companies responsible for affected products also have a critical role to play. Food companies

are sometimes the first to recognize that their product is causing illness. In addition, most food-product recalls are voluntary. Federal and state agencies can benefit from industry's expertise about food products and their distribution patterns.

Problem

Although significant coordination already occurs among federal, state, and local agencies, better coordination is needed to meet new and growing threats to the nation's food supply. More than one agency is involved in virtually every large foodborne outbreak. Joint efforts are often hindered by a lack of communication or a misunderstanding of each agency's role in a particular situation.

Recommendations

Federal, state, and local governments should improve the coordinated management of interstate outbreaks. Improved coordination among the federal agencies, among federal, state, and local agencies, among the various state agencies, and between state and local agencies would enhance the level of public-health protection, leverage agency resources and experience, and avoid duplication of effort.

Improve Outbreak Containment Through Better Federal-State-Local Coordination of the Evaluation of and Response to Foodborne Illness

There are probably hundreds of times a year when at least one federal agency, working with state and local agencies, plays a role in detection, investigation, and containment of illnesses that may be caused by contamination of food. Occasionally (typically once or twice a year) the outbreak is sufficiently significant and complex to require the involvement of the highest level officials in the responsible federal agencies. The agencies that typically will be involved will be CDC and USDA (if the outbreak involves meat and poultry), FDA (if the outbreak involves any other food product), or EPA (if the outbreak involves drinking water).

Each agency should designate a person with responsibility for coordinating its activities for any significant and complex outbreak, and a single official will be placed in charge of the federal government's role in managing the outbreak.

In addition, CDC, EPA, FDA, and USDA will establish an intergovernmental group, the Foodborne Outbreak Response Coordinating Group (FORCG), to improve the approach to interstate outbreaks of foodborne illness. FORCG will provide for appropriate participation by representatives of state and local agencies charged with responding to outbreaks of foodborne illness.

FORCG will review and evaluate outbreak response. FORCG will undertake these reviews after

JE - What does ²⁹managing mean? Managing flow of information? Resources? Managing communication with WH and the public?

appropriate consultation with industry and consumer representatives. Based on these deliberations, FORCG will assess the infrastructure for outbreak response, make recommendations for improving the current system, and work with federal, state, and local governments, the food industry, health professionals, and consumer advocates to implement beneficial changes. FORCG will meet several times a year for this purpose.

FY97 Activities

- For outbreaks that fall within the purview of CDC and FDA, HHS will identify the official with lead responsibility for managing the outbreak. ~~HHS and USDA will identify the individual responsible for managing any significant and complex outbreak that falls within the jurisdiction of both Departments.~~ ? state what this means. - LE
- CDC, EPA, FDA, and USDA, in consultation with representatives of state and local governments, will establish the Foodborne Outbreak Response Coordinating Group.

Enhance State and Local Infrastructure for Foodborne Outbreak Detection, Evaluation, and Response Coordination

The epidemiology offices and laboratories within state and local health departments are charged with the surveillance of infectious and non-infectious conditions, and, along with other state and local 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 and communities for the surveillance and investigation of foodborne diseases are limited and decreasing, thereby limiting the effectiveness of their response. As a result, outbreaks may go undetected or are never investigated.

CDC, EPA, FDA, and USDA will address the problem first by assessing and cataloguing available state resources, and then by working with states and providing support for foodborne-disease-surveillance programs and assistance to better investigate outbreaks of foodborne illness.

FY97 Activities

- FORCG, with assistance from the Association of Food and Drug Officials, the Association of State and Territorial Health Officials, the Association of State and Territorial Public Health Laboratory Directors, the Council of State and Territorial Epidemiologists, and the National Association of State Departments of Agriculture, will begin a nationwide audit to catalogue the existing state and local food-safety program infrastructure.
- FORCG, in consultation with the appropriate outside organizations, will establish working groups consisting of federal, state, and local officials to develop recommended procedures for outbreak response coordination at the state and local level.

Per our meeting, Name the Asst. Sec. and Under Sec. as leads. AF

FY98 Activities with Food-Safety Initiative Funds

- CDC, EPA, FDA, and USDA will assist states and local governments in developing the infrastructure necessary to ensure proper detection, evaluation, and coordinated response to foodborne outbreaks.

RISK ASSESSMENT

Background

The impact of increased funding for development of methods and models directed at improving risk assessments will be to focus public resources on reducing those risks that have the greatest consequences for human health. Risk assessment provides a strong foundation upon which efficient allocation of scarce food safety resources can be made. While obvious severe hazards in the food supply will be addressed through the larger food-safety initiative, risk assessment provides an objective foundation upon which efficient allocation of scarce food-safety resources can be established. Furthermore, risk assessment often plays a central role in the development of any science-based system of preventive controls.

There has been a long history of performing safety assessments or risk assessments for foods, particularly chemicals and drug residues. Risk assessments, cost-benefit analyses, and evaluations of alternative risk management strategies are required for all major regulations in USDA, a requirement imposed by the Federal Crop Insurance Reform and Reorganization Act of 1994 (P.L. 103-354). EPA is developing methods for required risk assessments under the Safe Drinking Water Amendments of 1996, including both microbial and chemical hazards. Sound risk assessments are important in various aspects of international trade, including the provisions of Codex Alimentarius and the World Trade Organization, the international bodies that govern standards for food safety, among other issues. Carefully formulated risk assessments based on high-quality data and scientific information generated from research lead to more informed risk management and better decisions.

Risk management and risk assessment must mutually inform each other but must remain separate and independent entities. Risk communication must be an integral part of all risk-related activities, including the public, industry, and all affected parties. Risk assessment, risk management, and risk communication constitute risk analysis.

Why define? What is risk analysis? what does this sentence add? AE

Good risk assessment requires good risk communication. Participation from industry, academia, and private risk organizations will be ensured in the interagency consortium's risk-assessment activities. Good risk communication must be ensured by interfacing with educators (see Education section in this report). Active communication between the risk assessment consortium and the research community is crucial to a successful initiative.

Problem

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 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

This paragraph doesn't belong in Problem Section AE

been most thoroughly developed, data gaps force the use of assumptions about exposure, hazard potency, and characteristics of the population at risk.

Risk assessment is far less developed for foodborne pathogens. Intensive commitment is necessary to develop critically needed methods of analyzing the available data and addressing its uncertainty; methods that account for variability, specifically of living microbial pathogens, are essential.

The research needed to develop improved methods and models that will make it possible to perform quantitative microbial risk assessments to the degree of complexity required for most food safety issues will require the integration of work in biological sciences, predictive microbiology, and applied mathematics. In some instances, the research needs overlap with those identified in the bioresearch section of this document. However, to reflect the unique multi-disciplinary nature of the needed research programs and highlight the critical nature of the research needs, research needs related to risk assessment are being presented as a separate item for consideration.

Recommendations

This initiative's activities focus on developing models for improving risk assessment, thereby more precisely targeting the prevention of foodborne disease by informing surveillance plans, prevention strategies for process-control systems and for food inspections based on HACCP principles, and research programs to fill critical food safety information gaps. Recommendations are being made in three areas.

Establish a Risk Assessment Consortium

All federal agencies with risk management responsibilities for food safety will establish jointly a consortium at which federal agencies can collectively advance the science of microbial risk assessment to further develop and implement risk assessment, and to assist agencies in fulfilling their specific food safety regulatory mandates. The consortium should be inclusive in its risk assessment activities, seeking expertise from risk assessment professionals and scientists from public and private sources as well as industry and consumer groups.

FY97 Activities

- The consortium, which will include all interagency partners, will be established in 1997 as part of the Joint Institute for Food Safety and Applied Nutrition, a collaborative activity of FDA's Center for Food Safety and Applied Nutrition and Center for Veterinary Medicine and the University of Maryland. The consortium will have three primary functions. The first will be to provide a means for identifying priority research needs in microbial risk assessment methodology and modeling (e.g., predictive microbiology). Such methodologies are needed to enable mathematical description of the behavior and

fate of foodborne pathogens at points along the farm-to-consumption chain. Second, the consortium will serve as a clearinghouse for information about current and planned research projects pertinent to microbial risk-assessment techniques, helping to prevent redundancies of effort and helping to identify scientists and applied mathematicians who could contribute to multidisciplinary research efforts. Third, the consortium will foster, and where possible, augment the research activities of member agencies in order to accelerate research projects of a particularly critical nature.

- The consortium will be inclusive in its risk-assessment activities, seeking expertise from risk assessment professionals and scientists from public and private sources, and industry and consumer groups. The initial focus of the initiative will be on pathogenic microorganisms. The consortium will work with its member agencies to catalogue their microbial risk-assessment research advances and identify data sets that would provide the scientific data needed to develop new models. The consortium will begin the process of establishing a clearinghouse that will collect and catalogue available methodology, specifically simulations necessary to address microbial growth and death variables offered by the private sector, trade associations, federal and state agencies, and international sources.

FY98 Activities with Food-Safety Initiative Funds

- A series of public meetings will be held to develop a strategy to address long-term research needs for the analysis of farm-to-table scenarios including potential pathogen introduction at each level, e.g. farm, processing, transportation, home/restaurant/retail food handling, food consumption data, and computer modeling. A strategic plan will be developed for research into dose-response calculations, chronic sequelae, biomarkers, and adapting surveillance data. This process will include a broad spectrum of academic, industry and government expertise that will be obtained through an acceptable process such as an advisory committee.

Long-term Activities

- The consortium will continue to collectively identify critical research needs, propose effective research on analytical approaches and methods, and reach consensus on the priority of these needs based on their potential to reduce the uncertainty of risk-management decisions in food safety and provide the greatest positive impact. Research supported and conducted through this initiative would 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.

**Develop Better Modeling Techniques and Better Use of Data
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 addresses numerous data and modeling deficiencies in estimating exposure to microbial and chemical contaminants. Specifically, research will be conducted into the development of models and simulations for the occurrence of microbial pathogens and chemical hazards in food at all stages of the food chain; typical behaviors of commercial and home preparation operations; validation of dynamic exposure assessment models; evaluation of intake data regarding food consumption patterns of the general population and sensitive subpopulations; and specific data on microbial behavior in food vehicles of sporadic and epidemic disease. Research on how to incorporate data related to 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 or effect is difficult or impossible to obtain.)

FY98 Activities with Food-Safety Initiative Funds

Working with FDA, EPA, and USDA, the consortium will identify priority research programs in two areas that are in need of augmentation: exposure assessment methods, and techniques for acquisition and analysis of experimental data for model development. Initial areas identified include:

- Addressing the dynamics of foodborne pathogens in agricultural environments (e.g. pathogen reservoirs, feed, and animal manure).
- Quantifying effects of key processing steps on levels of pathogens.
- Quantifying effects of key commercial food service preparation procedures, marketing facilities, and home food handling practices.
- Designing and proposing ways to integrate the collection of exposure and dose-response data into outbreak investigation.

Long-term Activities

Future initiatives would be fluid to adjust to results of short-term research, emerging food-safety needs, and changes in the direction of research programs within individual agencies. Additional research would likely include the development of modeling techniques to assess human exposure resulting from the subtherapeutic use of veterinary antibiotics in food-producing animals. To reduce uncertainties in exposure estimates, the consortium will work with researchers who are conducting focused food-consumption surveys targeting foods consumed by a variety of subpopulations (e.g., children).

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.

FY98 Activities with Food-Safety Initiative Funds

Working with FDA, EPA, and USDA, the consortium will identify priority research programs in dose-response-assessment methods and models that need to be augmented. Initial areas identified include:

- Methodology to incorporate the use of biomarkers in exposed populations into risk assessment models.
- Identification and development of criteria for objective models that permit high to low-dose extrapolation.
- Development of criteria that will be used to select or weight alternative models (theories) for extrapolating from empirical data to quantitative descriptions of risk.

Long-term Activities

Risk assessment research priorities in this area will be collectively established by the interagency consortium. Additional research includes studying whether threshold or non-threshold models for infectivity are more appropriate for describing low dose infectivity rates for infectious and toxico-infectious microorganisms. Further research is also needed into the use of biomarkers of susceptibility, chronic sequelae, microbiological toxicokinetics, and infectious dose.

RESEARCH

Background

Food-safety research is critically needed to develop the means to identify and characterize more rapidly and accurately foodborne hazards, to provide the tools for regulatory enforcement, and to develop effective interventions that can be used as appropriate to prevent hazards at each step from production to consumption. FDA, CDC, EPA, NIH, and the USDA's Research, Education, and Economics agencies (i.e., the Agricultural Research Service (ARS) and the Cooperative State Research, Education, and Extension Service (CREES)) conduct research related to pathogenic microorganisms and other contaminants that threaten the safety of food. That research supports the needs of both the federal and state food safety agencies and the many food industries.

Problem

New foodborne pathogens have emerged over the past ten years. Other microorganisms, previously thought to be innocuous, have been linked to life-threatening diseases after acquiring new virulence genes and antimicrobial resistance. Many of those organisms cannot be detected readily due to either a lack of suitable methods or their sporadic occurrence in foods. Certain foodborne pathogens are increasingly associated with resistance to time-tested controls, such as heating, refrigeration, and acid. In some cases, that ability appears to be linked with increased virulence or new ways to evade our immune defenses. The various research programs of FDA, USDA, CDC, EPA, and NIH need to better coordinate their research efforts on the highest priority issues and work together more effectively to leverage each other's resources.

Recommendations

Prevention of foodborne pathogens in foods requires an understanding of how foods become contaminated during their production, processing, and distribution, and the availability of practical interventions to control or eliminate the biologic agent. Selection of target pathogens and foods ideally are guided by risk assessment. Research is also needed to support HACCP implementation to verify that critical control points in HACCP systems are working, and to target the data gaps that hamper HACCP and risk assessment. Among the recognized data gaps, the following areas were identified as priority research needs. (Research activities listed for FY97 and FY98 are not necessarily completed in those years. Therefore, activities listed as long-term are additional activities.)

Improved Detection Methods

Many pathogens cannot be easily detected in foods, e.g., hepatitis A virus on strawberries. Among the needs for improved diagnostics, methods are needed for rapid, cost-effective testing for pathogens in food animals and their manures, in agriculture and aquaculture products, animal feeds, and processed food products. Methods development must address the low-level, sporadic

incidence of many pathogens in foods. Research will be coordinated with EPA's efforts to develop better test methods for *Cryptosporidium* and other pathogens in water and drinking water. Improved methods are needed for the identification and subtyping of foodborne pathogens in human and animal clinical specimens. The development of effective sampling plans and enrichment techniques are vital parts of detection methodology.

FY97 Activities

- EPA, CDC, USDA, and FDA, in conjunction with states and academia, will conduct research to develop detection methods and control measures for *Cyclospora*.

FY98 Activities with Food-Safety Initiative Funds

- USDA, FDA, and EPA will enhance ongoing research to develop test methods for *Campylobacter*, *Salmonella*, *Toxoplasma*, *E. coli* O157:H7 and other Shiga-like toxin-producing *E. coli*, *Cryptosporidium*, hepatitis A and Norwalk viruses, and naturally occurring mycotoxins and marine toxins in foods.
- FDA will expand its ongoing research on the development of methods for detecting foodborne pathogens in animal feeds.

Long-term Activities

- FDA, USDA, and EPA should undertake research to develop test methods for *Vibrio vulnificus* in foods.

Understanding Resistance to Traditional Preservation Technologies

Microorganisms that are resistant to antimicrobial agents and processing techniques that have been relied on traditionally to eliminate or prevent the growth of foodborne pathogens have become increasingly important causes of serious foodborne disease. 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. The physiological and genetic bases of resistance are not understood well enough to prevent breakthrough of newly emerging pathogens. Such research will help identify food production, processing, and handling practices that are likely to contribute to pathogen contamination or proliferation. That research is also needed to guide improvement of traditional techniques and the development of new interventions.

Long-term Activities

- USDA and FDA should undertake research into physiological, genetic, and other factors that cause foodborne-disease-causing microorganisms to develop resistance to preservation technologies.

Understanding Antibiotic Drug Resistance

Pathogens in food-producing animals and their manures may become resistant to antibiotics and drugs, particularly when used improperly. One possible solution might be to modify drug withdrawal periods. Such an approach would require scientific data to be developed on how the resistance profiles of microbial populations in animals changes in response to the elimination of a drug. Work involving resistance to traditional preservation technologies and antibiotic drug resistance must be based on a sound understanding of microbial physiologic and genetic adaptive mechanisms.

FY98 Activities with Food-Safety Initiative Funds

- FDA and USDA will conduct research to identify and characterize the factors that lead to the development of multiple drug (antibiotic) resistance in foodborne pathogens in farm and aquaculture animals, including establishing the gene-transfer mechanisms and selective pressures.
- USDA and FDA will investigate techniques for manipulating the microbial ecology of the intestinal tract of agricultural and aquaculture animals to prevent the development of antibiotic resistance or select for nonresistance. Research should emphasize competitive exclusion techniques (probiotics) and the use of extended drug-withdrawal periods. Probiotics are benign bacteria that can be used to out-compete pathogenic bacteria.

Prevention Techniques: Pathogen Avoidance, Reduction, and Elimination

Contaminants are introduced into the food supply at numerous points along the way from farm to table. Food animals and their manures can carry human pathogens, without any clinical manifestations. Likewise, fresh fruits, fresh vegetables, and grains can harbor pathogens or mycotoxins without any discernable loss of quality. In such cases, traditional approaches of segregating contaminated foods are ineffective, and active interventions are needed. In particular, new interventions are needed to prevent and control the pathogens listed below in raw agricultural commodities and seafood. Developments in this area would be expected to provide new approaches for controlling a variety of other foodborne contaminants.

FY98 Activities with Food-Safety Initiative Funds

For *Campylobacter*, *Salmonella*, *Toxoplasma*, *E. coli* O157:H7, and other Shiga-like toxin-producing *E. coli*, and *Cryptosporidium*, FDA and USDA, often in partnership with universities and industry, will:

- Expand research into the microbial ecology of foodborne pathogens and how initial colonization in plants and animals can be prevented.
- Expand research on new methods to reduce or eliminate pathogenic microorganisms and mycotoxins from agricultural and aquaculture animals before slaughter or harvest, including the use of probiotics.
- Develop new methods to reduce or eliminate pathogenic microorganisms and mycotoxins from plants before harvest.
- Develop new disinfection methods and systems for improved sanitation of production (including on-farm) processing and marketing equipment and facilities.
- Expand research on new methods of decontamination of meat, poultry, seafood, fresh produce, and eggs.
- Initiate research to develop new techniques for eliminating animal feeds as a source of foodborne pathogens.

Long-term Activities

- USDA and FDA should undertake research to develop new decontamination methods for contaminants such as *Vibrio* and Norwalk virus on or in marine-harvested and aquaculture-reared seafood, and for *Cyclospora* and hepatitis A virus on fresh produce.
- ARS, CREES, and FDA should work with industry and academia to develop new techniques that provide alternatives to traditional thermal processing for eliminating pathogens. Collaboration among these parties, particularly with industry participation, will facilitate rapid evaluation of the safety and effectiveness of new technologies, and ultimately, approval of processes.
- FDA, FSIS, and EPA should work with industry and academia to develop criteria for evaluating the efficacy and safety of the new intervention technologies.

Food handling, Distribution, and Storage

Food production, processing, and consumption often occur thousands of miles apart. Stresses associated with the transportation of live animals and fresh produce might contribute to the dissemination of foodborne pathogens. Effective packaging and proper food-storage conditions are critical to maintaining the level of safety achieved by processing.

Long-term Activities

- USDA and FDA should undertake research to identify factors that contribute to the spread of microorganisms during transportation of live animals and fresh produce and develop techniques for eliminating cross-contamination.
- FDA and USDA should work with industry and academia to develop and assess the effectiveness of in- or on-package sensors of storage conditions to alert consumers of products not stored safely.

Charge the President's National Science and Technology Council's (NSTC) Committee on Health, Safety, and Food R&D to ~~Coordinate Federal Research Priorities and Planning~~

Develop a research program for food safety -AF

Among the information needs and data gaps identified, numerous opportunities arise for collaboration and the development of research partnerships among federal and state agencies, the private sector, and academia. A mechanism is needed to coordinate food-safety research among federal agencies, to better leverage agency resources and experience, and avoid duplication of effort. Such a coordination mechanism could be provided by The NSTC's Committee on Health, Safety, and Food Research and Development. The Committee would review food-safety responsibilities and research programs of the various agencies with a view to recommending direction of research funds and programs in accordance with those responsibilities.

will be charged with this role AF

to link research with the activities and needs of the various agencies AF

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. State and local officials also have primary responsibility for inspecting restaurants, supermarkets, and other retail establishments. At the federal level, FSIS has responsibility for continuous meat- and poultry-inspection in slaughter and processing plants and egg-product processing plants, and for all imported meat, poultry, and egg products. FDA conducts periodic, random inspections of all other food-processing plants; that entails fewer than 700 inspectors and laboratory personnel for 53,000 U.S. plants and for all other imported foods.

Problem

The number of inspections conducted by FDA 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. An FDA-regulated plant is inspected by FDA, on 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, because the number of imports has doubled over 5 years, with no real increase in inspectors, a smaller percentage of imports are inspected at entry.

JE - given the limited inspection coverage

~~As FDA's inspections have dropped,~~ FDA is finding an increasing number of problems--the number of products recalled for life-threatening microbial contamination has increased almost five-fold since 1988. *Federal budget constraints will likely prohibit significant funding increases in the future, so FDA must find new ways to provide adequate inspection coverage (AE)*

Recommendations

Scientists and other food-safety experts have concluded that the most effective and efficient mechanism to ensure that food processors identify and control hazards that could threaten food is the application of HACCP principles. FDA's seafood HACCP regulations go into effect in December 1997. FSIS began to implement its HACCP and Pathogen Reduction Requirements for the meat and poultry industries in 1997 with phase-in completed in 2000. *HACCP programs allow governmental and industry resources to be more appropriately*
To ensure that HACCP is properly implemented, and to ensure more efficient and effective monitoring of the safety of the food supply, recommendations are being made in the following areas.

Enhance Development of HACCP Procedures

FY97 Activities:

distributed allowing the government to focus on the points of greatest risk.

- FDA will publish proposed regulations for the use of HACCP in the manufacture of juice products.
- FSIS and FDA will jointly publish an ANPR in which they will evaluate the public-health, food technology, and regulatory issues involved in reducing the risk of human illness from *Salmonella* Enteritidis in shell eggs. The ANPR will solicit information and comment on all elements of risk in the farm-to-table chain to ensure any resulting regulatory actions will be both reasonable and effective in reducing risk. FSIS will propose HACCP regulatory options for egg products.
- FDA will evaluate whether and how to propose to require the use of HACCP in other appropriate food commodities and animal feeds.
- FDA and USDA will immediately identify preventive measures to address public-health problems, such as those recently associated with fruits and vegetables, e.g., hepatitis A associated with frozen strawberries. This will be accomplished through a comprehensive review of current production and food-safety programs including inspection, sampling, and analytic methods.
- FDA will provide additional training in seafood HACCP and FSIS will complete HACCP training of inspectors in large plants.
- FSIS and FDA will evaluate expanding existing cooperative agreements so that plants producing meat and nonmeat foods are inspected by FSIS inspectors trained in FDA inspection standards. FSIS inspectors are already in these plants, and their presence could be better used to maximize use of federal resources without loss of inspection coverage for FSIS-regulated foods.
- FSIS will conduct a series of public meetings to discuss:
 - How HACCP requirements will be implemented in slaughter plants and how the roles and responsibilities of inspection personnel will change with that implementation.
 - The design and testing of new inspection concepts consistent with HACCP principles to achieve food-safety and other consumer-protection objectives through distribution and retail channels to consumers.
- FSIS and state associations will complete development of HACCP-based control measures for meat and poultry processing at the retail level.

FY98 Activities with Food-Safety Initiative Funds

- FDA will implement seafood HACCP by hiring approximately 80 investigators to conduct inspections to ensure proper implementation of seafood HACCP. NOAA says OK JE
- A performance-based organization (PBO), will be created, with Congressional approval, as the organizational structure for the voluntary fee-for-service seafood program currently located at the Department of Commerce's National Marine Fisheries Service. The Departments of Commerce and Health and Human Services will consider whether to locate the PBO at FDA, which would consolidate voluntary and mandatory seafood programs within one agency and provide limited additional resources for implementation of seafood HACCP, while continuing the voluntary fee-for-service program.
- FDA and USDA will cooperate in evaluating the feasibility of HACCP for commodities such as fresh fruit and vegetables. The process could also consider whether it is appropriate to use USDA inspectors to inspect plants that manufacture products regulated by both agencies, such as fresh produce used in the school lunch program.

Long-term Activities

- FDA should further the use of HACCP principles, as appropriate, for other foods, including animal feeds, and use risk-assessment techniques where possible.
- The Administration should evaluate the voluntary fee-for-service seafood program and the operational functioning of the seafood PBO. NOAA wants dropped

Enhancing the Safety of Foods Produced in Retail Food Establishments Particularly at State and Local Levels

More than 3,000 state and local regulatory agencies have primary responsibility for monitoring retail food establishments to ensure that consumers are protected. U.S. retail establishments include approximately 785,000 commercial- and institutional-food establishments, 128,000 grocery and convenience stores, and 1.5 million vending operations. Workers in these establishments have highly diverse backgrounds and training.

FY97 Activities

- FDA and FSIS will hold a series of meetings with state and local regulators in five regions to establish retail program standards in accordance with the 1997 model state code (the Food Code") to enhance national uniformity.

FY98 Activities with Food-Safety Initiative Funds

- FSIS and FDA will provide HACCP training to state and local inspectors that will

(44)

AE - From attached guidance - harmonization activities w/ reg - part of product guidance

augment the training program for federal inspection personnel, more fully covering the farm-to-table process.

- See also "Education: Improve Retail Food-Service and Institutional Education."

Long-term Activities

- The Food Code should be adopted by all 50 states.

Enhance Federal-State Inspection Partnerships

State inspection programs are an important component of the nation's food safety inspection system.

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 are inspected at least once per year. New federal-state partnerships focused on coordinating inspection coverage (particularly between FDA and the states), is a major step in this direction.

FY97 Activities

- FSIS will be holding two public meetings on the issue of interstate distribution of state-inspected meat and poultry products. The purpose of these public meetings is to obtain information and comment from all stakeholders on this issue.

The move toward HACCP will pose a challenge to the states that federal agencies can help the state systems to meet.

FY98 Activities with Food-Safety Initiative Funds

Is this a specific program? What is it? Explain!

- FDA will develop additional federal-state partnerships to improve coordination between the federal food-safety agencies and state regulators for the training of state inspectors in food-safety standards applicable at all levels, including retail.
- FDA will expand the number of federal-state partnerships to include more extensive HACCP training of state inspectors, the seafood industry, and the retail-food industry.
- FSIS will initiate HACCP training for state inspectors with respect to meat and poultry products.

Long-term Activities

- FDA and USDA should work more closely with industry, professional and trade associations, and academia to ensure effective implementation of HACCP principles, particularly at the production, processing, and retail levels.
- FDA should create a data system to compile inspection data from federal and state inspections, as well as provide the states with equipment and technology for the rapid

sharing of inspection results.

**Enhance Coverage of Imported Foods
with Specific Attention to Foods Regulated by FDA
To Address the Problem of Rising Imports
and FDA's ^{AE}Liability to Provide Adequate Coverage**

to improve

Wharf examinations and sampling of foods being offered for import into the United States have dropped by 50% in just the past four years. Today, FDA is responsible for about 2.2 million import food entries (i.e., shipments), an increase from 1.5 million entries just 5 years ago, with the same number of staff.

FY98 Activities with Food-Safety Initiative Funds

- FDA will expand its program to develop mutual recognition agreements (MRAs) with trading partners. Under MRAs, the trading countries ensure that food is produced and manufactured under equivalent systems that provide a comparable level of safety.
- FDA will initiate a federal-state communication system through which states can inform federal agencies of problems found with imported products in their jurisdictions.
- FDA will initiate a system for certifying and accrediting private laboratories, including use of a quality-assurance procedure, that will be authorized to test samples of food products for contaminants. Such private parties would provide a service to food firms wishing to demonstrate that their products meet applicable federal standards.
- When FDA and FSIS become aware of possible public-health problems associated with a regulated food product (e.g., through occurrence of foodborne illness outbreaks, sample analysis, or inspections), the agencies will provide technical assistance to the foreign country importing the product.

Long-term Activities

- FSIS should continue to verify foreign government-inspection progress for conformance with the new HACCP and Pathogen Reduction Requirements; that activity will begin in 1997 and should be completed in 2000.
- The laboratory-certification process should be extended to include assessing the utility of existing accrediting bodies with FDA providing performance standards and oversight to the process.
- FDA should expand the federal-state communication system states use to inform federal agencies of problems found with imported products in their jurisdictions. As part of that

expansion, FDA should evaluate the feasibility of combining the communication system with the federal-state inspection data system discussed above, making the data and information more widely accessible.

- FDA should review and evaluate ways to increase coverage of imports through such means as increased personnel, increased partnerships, or innovative information-sharing with the states.

Enhance Safety of Foods During Transportation

In considering whether and how to regulate the transportation of meat, poultry, seafood, eggs, and other foods to safeguard the public from pathogenic microorganisms and other hazards, FSIS and FDA published an ANPR on November 22, 1996.

FY98 Activities with Food-Safety Initiative Funds

- FDA and USDA will evaluate the comments and information received in response to the ANPR as a basis for determining what, if any, regulatory approach to take, including development of guidelines. These guidelines may include such elements as suggested performance standards for temperature control, providing information on prior cargo, and cleaning information for the food-shipper's use, to ensure the safety of the food at its destination.

Long-term Activities

- FDA and USDA, through partnerships with states, should provide training and training materials to the transportation industry on safe food transportation. (See "Education: Improve Industry Education in the Transportation Area.")

→ Introduce with (B) (see insert)

A BLUEPRINT FOR A BETTER FOOD SAFETY SYSTEM

Redundant.

Background

Several components of USDA, HHS, and EPA have responsibilities for ensuring the safety of the U.S. food supply. USDA also has ancillary responsibilities for the quality of our food. These responsibilities include the grading of agricultural commodities and grain by the Agricultural Marketing Service and the Grain Inspection Service, the importation of foreign plants and animals by the Animal and Plant Health Inspection Service, and the quality and wholesomeness of food purchased by the federal school lunch program. Regulatory requirements applicable to food products are largely established by FSIS for meat, poultry and egg products, and by FDA for all other products.

The programs in the two agencies have very different histories. Because meat and poultry have historically been considered to have the greatest risk, these products have been regulated under a separate regulatory program administered by FSIS. Under that program, at least one USDA official is present in every meat- and poultry-slaughter plant and is responsible for continuously inspecting meat and poultry products. FDA, on the other hand, regulates products that have historically been considered less risky. For these reasons, historically the two agencies have taken very different approaches to food regulation, with FSIS relying on continuous inspection and FDA relying on periodic inspections.

Statistically determined AE

USDA and HHS have seen an increase in AE

These old assumptions are no longer valid. In recent years, it has been increasingly argued that foodborne diseases ~~can be~~ caused by microbial contamination in seafood, fresh fruits, vegetables, and other products. Moreover, during the Clinton Administration, both agencies have adopted a new and similar approach to food regulation. USDA has adopted HACCP for the products that it regulates and FDA has adopted HACCP for seafood products, and is considering the HACCP approach for other products. During the next few years, these HACCP regulations will go into effect. One function of the strategic-planning process is to consider how to ~~make the best use of each agency's limited resources.~~ Leverage each agency's resources for the best public health impact. JE

Recommendations

Long-term strategic plan

The process for preparing a comprehensive long-term food safety strategic plan should facilitate the participation of all interested parties. Extensive dialogue will be needed to build trust in the process, obtain agreement on the priorities, strategies for achieving change, and a process for measuring progress.

what process? unclear.

Another mechanism that could be used to facilitate a strategic planning process would be to have the food safety agencies overseeing the process and then incorporating appropriate elements of the strategic planning process into their individual agency strategic plans. As with the other suggested approaches, a process would be developed for selecting a constituent committee which would receive suggestions and recommendations from a series of public meetings, focus groups

required by the GPR

This is confusing. You need to state here that the agencies will work with groups to prepare long-term strategic plan

Insert
(B)

The actions described in this report will significantly improve the safety of the nation's food supply, but the agencies recognize that this 90-day report does not address a number of critical issues facing our food safety programs. The agencies recommend a longer-term strategic planning effort -- involving all public and private stakeholders -- to consider how to best address important challenges and make the best use of the agencies' limited resources.

Through this initiative, and previous activities, we have laid the groundwork for a strategic planning effort. For example, the government, consumer groups, and industry have worked together to incorporate HACCP into meat, poultry, and seafood regulatory programs. And there is now a broad recognition of the need to carefully implement these programs, and to consider how to apply preventive measures in other areas of concern. A strategic planning effort could build on this common ground, and tackle some of the difficult public health, resource and management questions facing the federal food safety agencies.

break out small, narrow issues from big issues

and a public-comment process that would be used to develop the strategic plan.

The strategic-planning process will consider how to make best use of the limited resources that each agency has. Among the issues that the strategic-planning process could consider are:

- Developing a strategic, long-range risk assessment and research agenda.
- The structure of a coordinated, strategic plan for food-safety regulation.
- Policy and technical issues associated with agricultural manures. Animal manures are currently excluded from regulation. Therefore, an EPA regulatory mechanism to control human health and environmental impacts from improper application or burial of manures to farm and other lands does not exist. *- impacts*
- Policy and technical issues associated with food irradiation.
- Developing a global approach to evaluating new, emerging, and potential foodborne diseases such as Transmissible (Bovine) Spongiform Encephalopathy--T(B)SE-- and a process for responding to prevent the spread of such diseases. *- on*
- Exchange of information about foodborne disease outbreaks.
- Best approaches to prevention, intervention, and control. *too broad?*

Move to end of section

Identify an Appropriate Mechanism for Developing a Strategic-Planning Process

Although all sectors agree that improvements can be made in the food-safety system to enhance its effectiveness, opinions vary on how to reach that overall goal. Developing a long-range strategic-planning process which includes maximum participation provides such a mechanism. Various strategic-planning models could be used. Whichever model is selected, several essential elements should be considered in designing the optimal mechanism. Because it is critical that the process be perceived as inclusive and equitable, interested parties should be given an opportunity to comment on the recommended approach before its implementation. Specific information would be provided regarding the general objective, scope, and conduct of the planning process, management of the process, selection criteria for participants, and other relevant factors. Unanimous agreement is unlikely. A general consensus will be used, therefore, as the foundation upon which the planning processes is built.

The achievement of broad participation in any strategic-planning process can be accomplished in a number of ways. Open-sector and regional meetings reach the largest number of people. The process must be open, transparent, and capable of including broad and balanced participation involving all stakeholders in the food-safety system.

The best organizational structure⁴⁹ for the Federal food safety activities

5

AE

Prepare a 3- to 5-Year Strategic Plan

Participants in the planning process would be charged with developing a strategic long-range agenda that could be used to help set priorities, improve coordination and efficiency, identify gaps in the current system, and enhance and strengthen prevention and intervention strategies, and identify measures to show progress.

Measure Progress to Evaluate the Effectiveness of the Plan in Reducing the Annual Incidence of Foodborne Illness.

Progress would be reviewed after 2 years to determine the strategic plan's effect on reducing the annual incidence of foodborne illness. Measurable goals and objectives would provide a basis for establishing progress. Measurements could be based on a decline in the number of foodborne illnesses and deaths, a decline in the number of outbreaks, more effective prevention and intervention programs, more rapid responses to foodborne illness outbreaks, increases in inspection coverage for domestic and imported products, changes in behavior, and better detection and quantification methodologies.

→ who is audience for strategic plan?
President? Congress? or just departments? JE

President's Food Safety Initiative
FY98 Budget Request
(in Millions)

<u>Activity</u>	<u>FDA</u>	<u>USDA</u>	<u>CDC</u>	<u>EPA</u>	<u>Total</u>
Education	\$ 2.0	\$ 2.0	\$ 0	-	\$ 4.0
Surveillance	3.2	0.5	10.0	-	13.7
Coordination	0.5	0	0	-	0.5
Risk Assessment	4.0	0	0	-	4.0
Research	6.4	6.1	0	-	12.5
Inspections	<u>7.9</u>	<u>0.6</u>	<u>0</u>	<u>-</u>	<u>8.5</u>
Total	\$ 24.0	\$ 9.2	\$ 10.0	0	\$ 43.2

Add Key Actions (so we have case for '98 funds made concisely in one place)

End of Day - ONE PAGE

- Education
- # box

with 3-4 things

Elena -

- Status Food Safety Report
- Presidential Event
- Paper - release -
good so