



United States Department of Agriculture
Food Safety and Inspection Service

FAX

To:

Elizabeth Dnye

Fax #:

456-5581

Subject:

Cover letter for report

Date:

Pages:

3 including this cover sheet.

COMMENTS:

From the desk of

Tom M

Thomas J. Billy

Administrator

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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 the many stakeholders in food safety, presents specific recommendations for action in the following areas:

- Surveillance and "Early Warning"--Preventing the occurrence or mitigating the extent and severity of foodborne illness;
- Outbreak Response--Improving Interstate Outbreak Containment and Response Coordination;
- Risk Assessment--Improving risk assessment tools and interagency coordination in risk assessment;
- Bioscience 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 inspecting a larger percentage of imported foods;
- Education--Expanding and improving food safety education for food production workers and processors, retailers, restaurateurs, food service workers, veterinarians and health professionals, and consumers; 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 presented in the enclosed report.

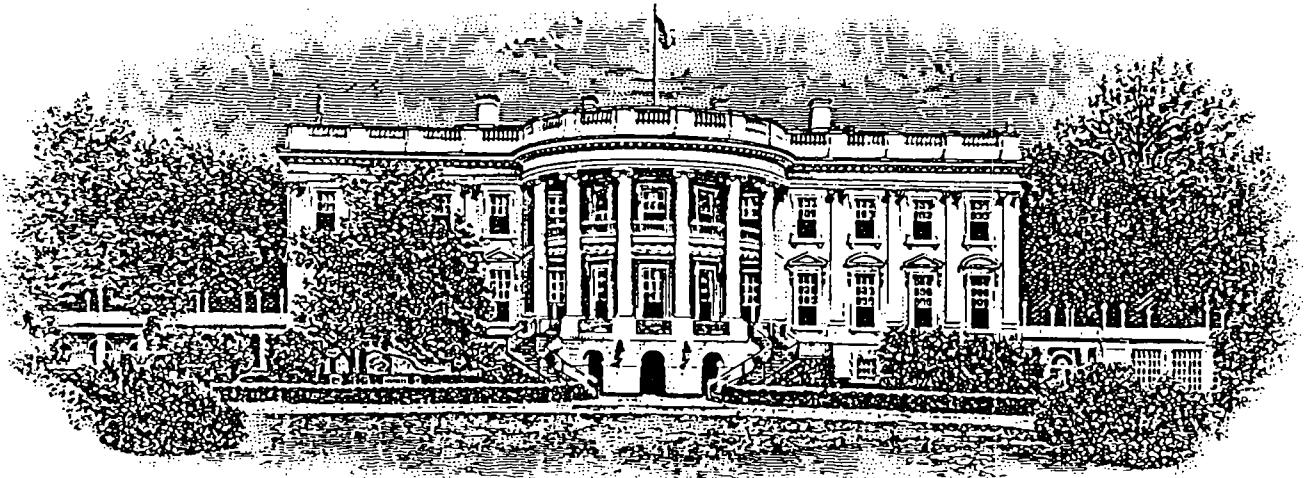
Sincerely,

DAN GLICKMAN
Secretary of Agriculture

DONNA E. SHALALA
Secretary of Health
And Human Services

CAROL M. BROWNER
Administrator
Environmental Protection Agency

The White House



DOMESTIC POLICY

FACSIMILE TRANSMISSION COVER SHEET

TO: Jean Mondshein 690-0530 / Karen Hulebale
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FAX NUMBER: _____

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594-6777

FROM: Elizabeth Dwyer

TELEPHONE NUMBER: _____

PAGES (INCLUDING COVER): 6

COMMENTS: My comments as coordination —
I have now shown to OMB. It's
better, but needs substantial editing.

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. drop minor details about current system.

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, 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 of FoodNet and the strengthening of state surveillance capacity and federal-state communications will enhance appropriate involvement of federal agencies in the investigation of foodborne disease outbreaks. ~~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.~~

other The agencies must also improve

write as recommendations

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. *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 agency 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. 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.~~

is this new?
Topic Sentence
No Topic Sentence - need one for this paragraph
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.

out of order shouldn't this be para 2
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.

also
~~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 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. 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.

new?
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.

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

old?
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

Why 3 free-standing sentences? drop or put elsewhere

Too internal

how many times do we need to say this?

in [scribble]

as part of this initiative?

may be (A)
out of order shouldn't this be para 2
do you describe new system

conference calls in outbreak settings.

To further strengthen our outbreak response systems

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 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.

FY97 Activities

- 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 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 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 a group of representatives from each federal agency and 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.

Who? will develop

How does this relate to discussion above?
Is it for US?

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.

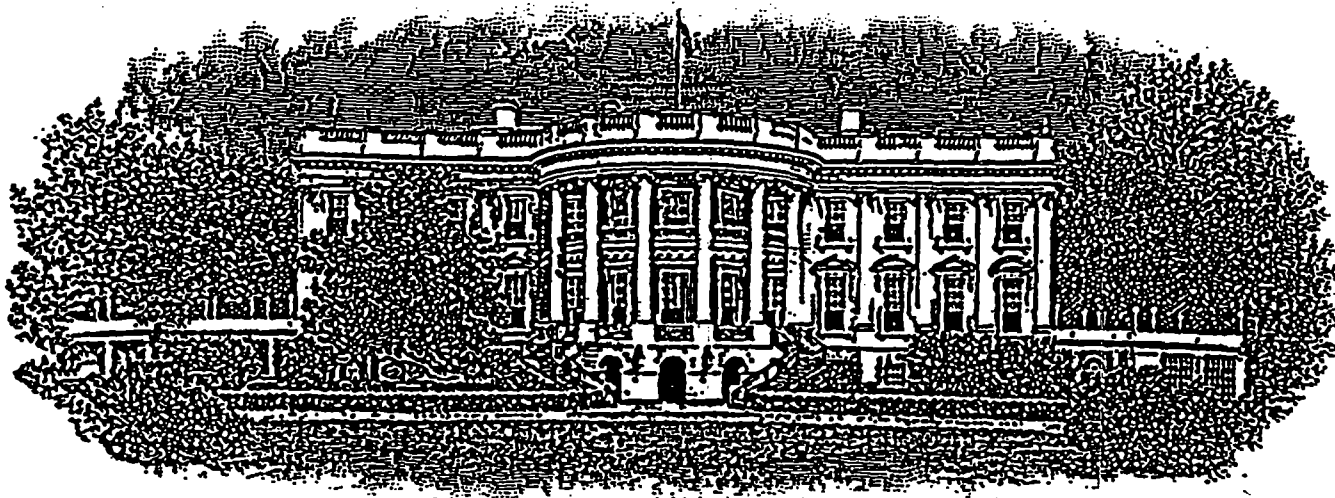
FY97 Activities

- 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.

The White House



DOMESTIC POLICY

FACSIMILE TRANSMISSION COVER SHEET

TO: Eric Olsen

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FROM: Elizabeth Dye

TELEPHONE NUMBER: 486-5573

PAGES (INCLUDING COVER): _____

COMMENTS: Here are OMB (budget) and
DPC comments. OMB/OIRA comments
went to Joan Mondshain. Thanks
for your help.

April 22, 1997 DRAFT

ORR Ag Branch
CONTENTS

4/25

FOOD SAFETY FROM FARM TO TABLE:
~~A NEW STRATEGY FOR THE 21st CENTURY~~
National Food Safety Initiative
REPORT TO THE PRESIDENT

April / May 1997

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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.

As part of the
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?*

Encouraged *The agencies have*
~~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 (A²) 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? AE
unbold
I 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 mo? AE

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 Sub 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 40 km*

*children feeding
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

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
easier to read
- AE

per JE - more 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.

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

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 many provisions of the Admin's bill*
- *last year* ~~The President signed~~ *Clinton* 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 33% 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 to serve as networks for federal agencies,~~ *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 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~~ *9* 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. *Cost? AE*

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. *whose budget is this?*

Long-term Activities

- *Evaluate program and those AE*
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

- 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. *will? AE*

Improve Industry Education in the Transportation Area

Long-term Activities

- ~~FDA and USDA should~~ ^F 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. *(FDA and USDA)*
- 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. *will* 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 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

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.

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

JK - 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

- per our meeting, Name the ASST. See and Under GC. as leads. AF*
- 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.

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.

*who define? what is risk analysis?
what does this sentence add?
RE*

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 A

- 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 -AE

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 changed with this role AE

to link research with the activities and needs of the arm agencies AE

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 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.

NOAA says OK JE

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

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 system 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 Inability to Provide Adequate Coverage**

✓ to improve

AE

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.~~ *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.

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. 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.
- 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.
- Exchange of information about foodborne disease outbreaks.
- Best approaches to prevention, intervention, and control.

in general

on

too broad?

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

AE

Move to end of section

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)

OPTIONAL FORM 99 (7-90)

FAX TRANSMITTAL

of pages ▶

To: <u>Elizabeth Dye</u>	From:
Dept./Agency:	Phone #:
Fax # <u>456-5581</u>	Fax #:

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

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. In addition to inspection of production and processing facilities, and warehouses, ~~with~~ state and local officials also have primary responsibility for inspection of ~~focusing primarily on~~ restaurants, supermarkets and other retail establishments. At the federal level, consistent with legal mandates, FSIS has responsibility for ~~carcass by carcass inspection in~~ meat and poultry, ~~and slaughter plants while they are operating, and continuous inspection in~~ meat, poultry, and egg-product processing plants--in all, about 8,000 inspectors for ~~6,500~~ 6,200 domestic plants and for all imported meat, poultry, and egg products. FDA, on the other hand, does periodic, random inspections of all other food processing plants--less than 700 inspectors and analysts for 53,000 U.S. plants and for all other imported foods.

Problem

~~At FDA,~~ 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. The result is that an FDA-regulated plant gets inspected by FDA, on the average, only once every 10 years. FDA also relies upon the states to conduct some inspections under contract, but that number has dropped from 12,000 in 1985 to 5,000 now. States are also faced with declining resources for inspections and cannot meet the need for increased coverage triggered by FDA's decreased resources for inspections without cooperative efforts such as federal/state partnerships. ~~Moreover, the inspectional coverage of imported foods has dropped as well, as the same number of import inspectors are now inspecting almost twice as many imports as just five years ago.~~ Moreover, since the number of imports has doubled in five years, but the number of inspectors has not increased, a smaller percentage of imports are inspected at entry.

Certainly, FDA is finding greater problems, e.g., the number of products recalled for life-threatening microbial contamination has increased almost 5-fold since 1988. ~~and inspectors are finding more hazardous conditions in the plants they inspect.~~ FSIS is faced with a similar challenge of continually providing the most effective ~~inspection~~ food safety and consumer protection program with limited resources and increasingly complex public health concerns related ~~and growing increasing threats~~ to food safety.

Increasingly, foods prepared in retail food establishments are becoming an integral part of consumers' daily diets. Recognizing

that illnesses associated with retail foods may be reported more frequently, these foods accounted for 37% of the foodborne illnesses reported to CDC in 1992.

Recommendations

Scientists and other food safety experts have concluded that the most effective and efficient mechanism for assuring that food processors identify and control hazards that could threaten food is the application of the HACCP concept of built-in preventive controls. This conclusion has been borne out by industry, academic, and consumer participants in the public meetings on the food safety initiative and in comments received on the initiative. The seafood HACCP regulations go into effect in December 1997; a strong federal inspection capability is necessary to maintain domestic and international credibility for the U.S. food safety system, the safety of U.S. foods, and to ensure that HACCP is implemented properly. FSIS begins to implement HACCP for the meat and poultry industries in 1998 with phase-in completed in 2000. ~~FSIS intends to publish an ANPR requesting comments on HACCP based systems for egg processing plants and FDA plans to work with the food industry, as it has in a pilot program over the last 2 years.~~

To ensure that HACCP is properly implemented, and to ensure more efficient and effective monitoring of the safety of the food supply, ~~the following preliminary~~ recommendations are being made in the following areas. These areas are in the order of priority designated by participants in the Inspections session at the March 31-April 2 public meeting on the food safety initiative and also reflect comments received to the discussion draft. Within each prioritized area, are listed specific activities agencies are either doing or planning to do, based on suggestions and comments from participants in the public process.

Enhance development of HACCP procedures

FY97 Activities:

- FDA will publish a proposed regulation for use of HACCP in the manufacture of juice products.
- FSIS will publish a proposed regulation for use of HACCP in the manufacture of egg products.
- FDA will evaluate ~~considering~~ whether and how to implement HACCP ~~throughout the non meat/poultry food industry for all other appropriate food commodities and animal feeds. It is recognized that staged implementation, by commodity, might be necessary because of resource limitations.~~
- FDA will ~~conduct inspections and~~ 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 ~~under which~~ so that plants producing both meat and non-meat foods are inspected ~~solely~~ by FSIS inspectors, ~~who have been~~ trained in FDA inspectional standards. Without these cooperative agreements, both FSIS inspectors and FDA inspectors inspect the plants. With FSIS inspectors ~~are already in these plants on a continual basis~~, their presence could be better utilized to maximize use of federal resources without loss of inspectional coverage for FSIS-regulated foods.
- FSIS plans to conduct a series of public meetings to discuss:
 - How HACCP requirements will be implemented in slaughter plants consistent with the legal mandate of carcass-by-carcass inspection and how the roles and responsibilities of inspection personnel will change with that implementation, and
 - The design and testing of new concepts consistent with HACCP principles, for achieving food safety and other consumer protection objectives in the inspection of meat and poultry products, during production, and through distribution 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 would implement seafood HACCP and conduct inspections to ensure proper implementation. FDA would acquire approximately 80 new investigators to implement seafood HACCP and expend approximately \$ 6.4 million.
- ~~FDA will also continue HACCP training for federal, and state regulatory officials and industry.~~
- A Performance-Based Organization (PBO), located at and operating as part of FDA, would be created as the organizational structure for seafood inspectors currently located at the Department of Commerce's National Marine Fisheries Service. These inspectors would be integrated into the seafood HACCP program. This would provide additional resources to implement seafood HACCP and consolidate voluntary and mandatory seafood programs within one agency, assuring consistency and better utilization of resources. ~~that HACCP is being properly implemented, FDA should conduct inspections and provide necessary training and outreach activities. FSIS will continue development of~~

~~a HACCP based inspection system.~~

- FDA and FSIS would cooperate in evaluating the feasibility of HACCP for commodities such as fresh fruits and vegetables.

Longterm Activities

- FDA should implement HACCP procedures, as appropriate, for other foods, using risk assessment techniques where possible.

Enhance safety of foods produced in retail food establishments

More than 3,000 state and local regulatory agencies have primary responsibility for monitoring retail food establishments to assure that the consumer is protected. There are approximately 785,000 commercial and institutional food establishments, 128,000 grocery and convenience stores, and 1.5 million vending operations in the U.S. employing workers with backgrounds as diverse as high school students and non-English speaking individuals, to highly trained food service workers. The nature of the food service industry presents unique challenges to assuring the safety of the food produced.

FY97 Activities

- FDA and FSIS will hold a series of grassroots meetings with state and local regulators in 5 regions to establish retail program standards in accordance with the 1997 Food Code to enhance national uniformity.

FY98 Activities with Food Safety Initiative Funds

- FDA and USDA would enter into public/private partnerships to develop and initiate implementation of a national food safety education program for all segments of the retail food industry using concepts in the 1997 Food Code.
- FDA and USDA would form an alliance, joining expertise of federal, state, and local agencies, industry, and professional and trade associations to promote and implement the Food Code and develop communication techniques targeted to specific groups (e.g., non-English speaking individuals) to overcome barriers to communicating appropriate food safety behaviors to food service workers.
- FSIS would provide HACCP training to state and local inspectors to improve the safety of meat and poultry products processed in retail establishments. This training, at a funding level of \$565,000, would augment the training program for federal inspection personnel, more fully covering the farm-to-table continuum.

Longterm Activities

- Achieve adoption of the Food Code, particularly the HACCP provisions, by all 50 states.

Enhance federal/state inspection partnerships

~~FDA has included implementation of seafood HACCP in its FY98 budget request.~~ If HACCP is to be an effective program for ensuring that food processors have modern, state-of-the-art food safety procedures in effect, FDA must improve its inspection capabilities, so that the highest risk food plants (such as seafood) are inspected at least once per year. Maximizing the ~~To maximize the~~ joint federal/state role in inspections through development of new federal/state partnerships ~~would be considered that focussed on coordinating the inspection coverage and preventing duplication of effort, particularly between FDA and the states, is a major step in this direction.~~ FDA would expend approximately \$1.25 million of food safety initiative funding in this effort.

FY98 Activities with Food Safety Initiative Funds

- FDA would develop additional federal/state partnerships to ~~Federal/state partnerships can~~ ensure improved coordination between the federal food safety agencies and state regulators for the training of state inspectors in federal food safety standards applicable at all levels, including retail.
- FDA would expand the number of federal/state partnerships to include more extensive HACCP training of state inspectors, the seafood industry, and the retail food industry.

Longterm Activities

- FDA and USDA should work more closely with industry, professional and trade associations, and academia to assure effective implementation of HACCP, 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 and for a national database for the monitoring of all food inspections. ~~This information sharing would help both federal and state regulators make inspections more effective and efficient.~~

Enhance inspectional coverage of imported foods regulated by FDA, to address the problem of rising imports and FDA's inability to

provide adequate coverage ~~inspections of them~~

FY98 Activities with Food Safety Initiative Funds

- FDA would expand its program to develop MRAs with trading partners ~~foreign countries under which both countries agree to inspect each other's food exporting firms under equivalent procedures for ensuring safety.~~
- FDA would also initiate a federal/state communication system through which states can inform federal agencies of problems found with imported products in their jurisdictions.
- FDA would initiate a system for certifying/accrediting private laboratories, including use of a quality assurance procedure, that would be authorized to test samples of food products for contaminants.. ~~This~~The lab certification process may embody a similar process currently being discussed by a coalition of industry, private laboratories, professional associations, and accrediting bodies with input from federal agencies. FDA anticipates that this effort would require approximately \$200,000 to initiate. Such private parties would provide a service to food firms wishing to demonstrate that their products meet applicable federal standards.

Longterm Activities

- FSIS should verify foreign government inspection progress for conformance with the new HACCP and pathogen regulation requirements; this 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 this expansion, FDA should evaluate the feasibility of combining this communication system with the federal/state inspection data system discussed above, making the data and information more widely accessible.

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, FSIS and FDA published an ANPR on November 22, 1996. ~~are considering whether and how to regulate the transportation of meat, poultry, seafood, eggs and~~

~~other foods in order to safeguard the public from pathogenic microorganisms, as reflected in the ANPR published on November 22, 1996.~~

FY98 Activities with Food Safety Initiative Funds

- FDA and USDA would establish guidelines for the safe transportation of high-risk food and establish performance standards, including elements such as temperature maintenance, prior cargo and cleaning information for the food shipper's use, to ensure safety of the food at its destination.

Longterm Activities

- FDA and USDA, through the partnerships with states, should provide training and training materials to the transportation industry on safe food transportation.

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; food transportation workers and vehicle owners. The challenge is to target educational messages that address the risks relevant to each audience throughout the food chain. Realizing that educational efforts are cost-effective investments, the federal government in cooperation with state, local and private organizations, consumer groups and the industry has been fostering educational programs to address foodborne illness.

The Problem

Despite these educational efforts, foodborne illness is still 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 handling practices. Without food safety knowledge and proper food handling procedures practiced by those involved from farm to table, foodborne illness will not be significantly reduced. Individuals at each stage along the farm to table continuum need to be targeted for the appropriate food safety message.

Research to determine the most effective ways to overcome barriers and to insure safe food handling practices is needed for each specific audience. Consumers' food handling practices will

either increase or decrease the chances of foodborne illness. Studies show, for example, that 53% of the public eat raw eggs, 23% eat undercooked hamburger, 17% eat raw clams and oysters, and 26% do not wash their cutting boards after using them for raw meat or poultry.

Similarly, food preparers in the retail sector must be made aware of how they can prevent food contamination and reduce pathogen growth. For example, during 1988 to 1992, *Salmonella* caused 69% of the 796 bacterial foodborne disease outbreaks; 60% of these *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.

In addition, health professionals and physicians need knowledge to better detect and treat foodborne illnesses. Producers of animals used in human food production and veterinarians treating such animals must be made aware of food safety implications related to drugs and 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, especially those providing food to populations at high risk in hospitals, nursing homes, assisted living facilities, child day care, and senior day care. Objectives include conducting the appropriate research to identify barriers to safe food handling and the design of persuasive messages to foster behavior change. To address this goal, FDA, USDA, and CDC will develop, through research, effective food safety education materials and services for consumers and for food service operations. Also, the development of a national food safety education program for consumers, retail and other food handlers, will be initiated through new public/private partnerships and existing networks to maximize resources and develop effective, consistent educational messages, campaigns and training programs.

It is anticipated that implementation of the education goals and objectives of the initiative, along with the other elements of the initiative, will result in a significant increase in the number of consumers, and a large portion of the 12 million food service workers, being reached with effective and persuasive food safety messages. Improved safe food handling resulting in a reduction of foodborne illness would be the desired outcome.

Improve education of all target audiences

FY97 Activities, USDA, FDA and CDC will:

Expand existing information systems such as the Foodborne Illness Education Information Center while creating a national clearinghouse to provide consumers and educators with food safety information.

Develop innovative methods for sharing food safety information in order to reach larger audiences, such as the use of electronic communications technology and the consolidation of government food safety internet sites. . Establish a National Food Safety Education Council. The Council, through an independent scientific review board, would establish longterm goals and objectives for food safety education and changing unsafe food handling practices.

Convene broad alliances that network federal government agencies, industry, consumer, trade, state and local food protection agencies, and academic organizations to share and conduct food safety education activities.

Improve Consumer Education

Consumer education will be conducted in several phases. Phase one, to begin immediately, has the goal of raising awareness of the general public to the need for safe food handling practices. A second phase will build a long-term education program designed to effectively change consumer food handling behavior.

FY97 Activities: USDA, FDA, CDC will:

Form a partnership with private-sector organizations, through a *Memorandum of Understanding*, to conduct a public food safety awareness education campaign, with a logo and key basic messages, to emphasize the need for safe food handling. Specific audiences such as high-risk consumers, minorities and non-English speaking populations will be targeted.

Conduct a conference on food safety education, *Changing Strategies; Changing Behaviors*, scheduled for June 12-13, 1997. The conference will be a forum to introduce plans for the national food safety awareness campaign.

Promote September as National Food Safety Education Month. The kick-off of the national awareness campaign will begin this month.

FY98 Activities with Food Safety Initiative Funds, USDA, FDA and CDC will:

Develop national "safe food handling" guidelines like the Dietary Guidelines. Under the auspices of the National Council, convene the scientific review board to determine guidelines and review them periodically. The board would also identify at-risk audiences for targeted food safety education programs.

Conduct research necessary to determine effective methods of fostering behavior change in targeted consumer audiences and methods to evaluate effectiveness of educational methods and programs.

Consider use of food labels to convey food safety information.

Expand the capacity of the clearinghouse for food safety information.

Continue work to promote food safety messages and personal hygiene in elementary and secondary schools and to incorporate food safety education into school curricula.

Sponsor journalists' conferences on food safety issues to inform the media.

Long-term Activities, USDA, FDA and CDC should:

Conduct research necessary to develop a visual communication tool to convey food safety principles, like the food guide pyramid.

Implement, through partnerships and alliances, a massive education campaign to encourage the use of the new educational tools developed, especially targeted to school curricula and specific at-risk audiences.

Continue to promote the National Food Safety Education Council and to expand capacity of the clearinghouse for food safety information.

Improve Retail, Food Service, and Institutional Education

FY 97 Activities, USDA, CDC, and FDA will:

Form an alliance of federal, state, and local health agencies, as well as private parties, to promote education efforts on food safety issues, using existing training programs and networks to strengthen the programs.

Encourage multilingual training programs and educational materials that include educating retail food service workers about the safe handling provisions in the 1997 Food Code and HACCP principles.

Promote state adoption of 1997 Food Code and support handler certification requirements.

FY98 Activities with Food Safety Initiative Funds, USDA, FDA

Develop guidelines for retail and food service operations that process meat, poultry and seafood products to train state-level inspectors to identify hazards at the retail level.

Initiate a program to educate retail, food service and institutional industries to increase the use of HACCP principles.

Promote accredited industry management certification programs.

Provide training to state and local regulators and the retail food industry in the 1997 Food Code, as well as implementation of HACCP.

Longterm Activities, USDA, FDA and CDC will:

Continue to support alliances in the development of a food safety agenda in their respective areas.

Continue to provide training to state and local regulators and the retail food industry in the 1997 Food Code, as well as implementation of HACCP.

Improve Veterinarian and Producer Education

FY98 Activities with Food Safety Initiative Funds, USDA, FDA and CDC will:

Use existing mechanisms such as the Cooperative Extension and professional associations to strengthen and implement programs to educate producers, veterinarians, state and local regulators about proper drug use and the incorporation of HACCP principles to reduce foodborne pathogens into industry quality assurance programs.

Encourage the improvement of veterinary and producer education at veterinary and agriculture colleges to address foodborne pathogens in animals.

Longterm Activities, USDA, FDA and CDC will:

Continue to expand educational programs for producers of animals for human food consumption, veterinarians, state and local regulators about proper drug use and the incorporation of HACCP principles into quality assurance programs. Continue to schedule regular training sessions, including satellite teleconferences, educational symposia, and presentations at producer and practitioner meetings. Guidelines and educational materials will be developed and disseminated through existing networks to food producers and the veterinary medical community.

Improve Health Professional Education**Longterm Activities:**

CDC, in cooperation with FDA and USDA, should train public health professionals on foodborne disease and clinical microbiology and foodborne illnesses with non-traditional symptoms by using multimedia and distance learning techniques and the National Laboratory Training Network

Improve Industry Education in the Transportation Area**FY97 Activities:**

USDA and FDA may establish final regulations for safe transportation and enforcement procedures.

Longterm Activities:

FDA and USDA should form an alliance among government agencies to develop educational materials and train food-transportation vehicle owners and operators and food processing establishments on hazards associated with the transportation of food products, particularly hazards associated with temperature controls, prior cargoes, and sanitation methods.

FDA and USDA should conduct training and education for state and local health transportation authorities so they can apply HACCP information during inspections of food processing facilities and transportation vehicles in their jurisdiction.

A BLUEPRINT FOR A BETTER FOOD SAFETY SYSTEM

Background

A comprehensive strategic plan for food safety is needed to reduce foodborne illness over the long term. The plan would be used to help set priorities. A strategic planning process would also help to improve coordination and efficiency to make the best use of limited resources.

Elements of the strategic plan might include: Improving coordination among all food safety participants in numerous aspects of prevention and response; improving the infrastructure for rapid identification and response to outbreaks; and developing a strategic, long-range research agenda.

The Challenge

A major challenge will be obtaining consensus on priorities within a food safety system that is extremely complex and for which there are many competing interests. Since authority for regulating food safety is fragmented among several federal agencies and state and local jurisdictions, there are often conflicting priorities and disagreement on priorities. This is compounded by differences between the scientific community and the public regarding the nature and extent of the risks associated with various foods and foodborne pathogens. Such issues include: the structure of a coordinated, strategic plan for food safety research; policy and technical issues associated with agricultural manures; policy and technical issues associated with food irradiation; issues associated with exchange of information about foodborne disease outbreaks; and best approaches to prevention, intervention, and control.

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

Identify an appropriate mechanism for developing a strategic planning process

While there is agreement among all sectors that improvements can be made in the food safety system to enhance its effectiveness, there are various opinions on how to reach this 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, there are several essential elements that 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 prior to 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. It is recognized that it is unlikely that there will be unanimous agreement, therefore, a general consensus will be used as the foundation upon which the planning processes is built.

Identify essential participants and selection criteria for participation

Participation in any strategic planning process can be accomplished in a number of ways. Open sector and regional meetings provide a means of reaching 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.

Prepare a three- to five-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 two years to determine the strategic plan's impact 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 outbreaks, more effective prevention and intervention programs, more rapid responses to foodborne illness outbreaks, changes in behavior, and better detection and quantification methodologies.

new ed Section
4/11

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; food transportation workers and vehicle owners. The challenge is to target educational messages that address the risks relevant to each audience throughout the food chain. Realizing that educational efforts are cost-effective investments, the federal government, state and local governments, private organizations, consumer groups and the industry has been fostering educational programs to address foodborne illness.

The Problem

Despite these educational efforts, foodborne illness is still 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 handling practices. Without food safety knowledge and proper food handling procedures practiced by those involved from farm to table, foodborne illness will not be significantly reduced. Individuals at each stage along the farm to table continuum need to be targeted for the appropriate food safety message.

Research to determine the most effective ways to overcome barriers and to insure safe food handling practices is needed for each specific audience. Consumers' food handling practices will either increase or decrease the chances of foodborne illness. Studies show, for example, that 53% of the public eat raw eggs, 23% eat undercooked hamburger, 17% eat raw clams and oysters, and 26% do not wash their cutting boards after using them for raw meat or poultry.

Similarly, food preparers in the retail sector must be made aware of how they can prevent food contamination and reduce pathogen growth. For example, during 1988 to 1992, *Salmonella* caused 69% of the 796 bacterial foodborne disease outbreaks; 60% of these *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.

In addition, health professionals and physicians need knowledge to better detect and treat foodborne illnesses. Producers of animals used in human food production and veterinarians treating such animals must be made aware of food safety implications related to drugs and 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, especially those providing food to populations at high risk in hospitals, nursing homes, assisted living facilities, child day care, and senior day care. Objectives include conducting the appropriate research to identify barriers to safe food handling and the design of persuasive messages to foster behavior change. To address this goal, FDA, USDA, and CDC will develop, through research, effective food safety education materials and services for consumers and for food service operations. Also, the development of a national food safety education program for consumers, retail and other food handlers, will be initiated through new public/private partnerships and existing networks to maximize resources and develop effective, consistent educational messages, campaigns and training programs.

It is anticipated that implementation of the education goals and objectives of the initiative, along with the other elements of the initiative, will result in a significant increase in the number of consumers, and a large portion of the 12 million food service workers, being reached with effective and persuasive food safety messages. Improved safe food handling resulting in a reduction of foodborne illness would be the desired outcome.

Improve education of all target audiences

FY97 Activities

USDA, FDA and CDC will:

- Expand existing information systems such as the Foodborne Illness Education Information Center while laying the groundwork for a national clearinghouse to provide consumers and educators with food safety information.

- Initiate innovative methods for sharing food safety information in order to reach larger audiences, such as the use of electronic communications technology and the consolidation of government food safety internet sites. Begin a process to establish a National Food Safety Education Council. The Council, through an independent scientific review board, would establish longterm goals and objectives for food safety education and changing unsafe food handling practices.

- Convene broad alliances that network federal government agencies, industry, consumer, trade, state and local food protection agencies, and academic organizations to share and conduct food safety education activities.

Improve Consumer Education

Consumer education will be conducted in several phases. Phase one, to begin immediately, has the goal of raising awareness of the general public to the need for safe food handling practices. A second phase will build a long-term education program designed to effectively change consumer food handling behavior.

FY97 Activities

USDA, FDA, CDC will:

Form a partnership with private-sector organizations, through a *Memorandum of Understanding*, to conduct a public food safety awareness education campaign, with a logo and key basic messages, to emphasize the need for safe food handling. Specific audiences will include high-risk consumers, minorities and non-English speaking populations.

Conduct a conference on food safety education, *Changing Strategies; Changing Behaviors*, scheduled for June 12-13, 1997. The conference will be a forum to introduce plans for the national food safety awareness campaign.

Promote September as National Food Safety Education Month, which was established two years ago by the National Restaurant Association. The kick-off of the national awareness campaign will begin this month.

FY98 Activities with Food Safety Initiative Funds

USDA, FDA and CDC would:

Develop national "safe food handling" guidelines like the Dietary Guidelines. Under the auspices of the National Council, convene the scientific review board to determine guidelines and review them periodically. The board would also identify at-risk audiences for targeted food safety education programs.

Conduct research necessary to determine effective methods of fostering behavior change in targeted consumer audiences and methods to evaluate effectiveness of educational methods and programs. Consider use of food labels to convey food safety information.

Expand the capacity of the clearinghouse for food safety information.

Continue work to promote food safety messages and personal hygiene in schools and to incorporate food safety education into school curricula.

Sponsor journalists' conferences on food safety issues to inform the media.

Long-term Activities

USDA, FDA and CDC should:

Conduct research necessary to develop a visual communication tool to convey food safety principles, like the food guide pyramid.

Implement, through partnerships and alliances, a massive education campaign to encourage the use of the new educational tools developed, especially targeted to school curricula and specific at-risk audiences.

Continue to promote the National Food Safety Education Council and to expand capacity of the clearinghouse for food safety information.

Improve Retail, Food Service, and Institutional Education

FY 97 Activities

USDA, CDC, and FDA will:

Form an alliance of federal, state, and local health agencies, as well as private parties, to promote education efforts on retail and food service food safety issues, using existing networks to strengthen the programs, including a multilingual approach to include safe food handling provisions in the 1997 Food Code and HACCP principles.

FY98 Activities with Food Safety Initiative Funds

USDA, FDA and CDC would:

Develop and initiate a highly focused program to change food workers' unsafe food preparation behaviors and include a multilingual approach. Programs will address the high turnover in foodservice workers and target teenage workers, small businesses, and new entrepreneurs.

Develop guidelines for retail and food service processing operations for meat, poultry and seafood to train state and local inspectors to identify hazards at the retail level.

Provide training to state and local regulators as well as retail, food service and institutional industries to increase the use of HACCP principles and provisions in the 1997 Food Code.

Long-term Activities

USDA, FDA and CDC should:

Continue to support alliances in the development of a food safety agenda in their respective areas.

Continue to provide training to state and local regulators and the retail food industry in the 1997 Food Code, as well as implementation of HACCP.

Improve Veterinarian and Producer Education

FY98 Activities with Food Safety Initiative Funds

USDA, FDA and CDC would:

Use existing mechanisms such as the Cooperative Extension and professional associations to strengthen and implement programs to educate producers, veterinarians, state and local regulators about proper drug use and the incorporation of HACCP principles to reduce foodborne pathogens into industry quality assurance programs.

Encourage the improvement of veterinary and producer education at veterinary and agriculture colleges to address foodborne pathogens in animals and their manures so produced.

Long-term Activities

USDA, FDA and CDC should:

Continue to expand educational programs for producers of animals for human food consumption, veterinarians, state and local regulators about proper drug use and the incorporation of HACCP principles into quality assurance programs.

Continue to schedule regular training sessions, including satellite teleconferences, educational symposia, and presentations at producer and practitioner meetings. Guidelines and educational materials will be developed and disseminated through existing networks to food producers and the veterinary medical community.

Improve Health Professional Education

Long-term Activities

CDC, in cooperation with FDA and USDA, should train public health professionals on foodborne disease and clinical microbiology and foodborne illnesses with non-traditional symptoms by using multimedia and distance learning techniques and the National Laboratory Training Network.

Improve Industry Education in the Transportation Area

FY97 Activities

USDA and FDA may establish final regulations for safe transportation and enforcement procedures.

Long-term Activities

FDA and USDA should form an alliance among government agencies to develop educational materials and train food-transportation vehicle owners and operators and food processing establishments on hazards associated with the transportation of food products, particularly hazards associated with temperature controls, prior cargoes, and sanitation methods.

FDA and USDA should conduct training and education for state and local health transportation authorities so they can apply HACCP information during inspections of food processing facilities and transportation vehicles in their jurisdiction.

FY99-2001 Activities

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



DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20250

456-5581

April 24, 1997

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(Including cover sheet)

/ Elizabeth / John

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72
5043

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 the many stakeholders in food safety, presents specific recommendations for action in the following areas:

- **Surveillance and "Early Warning"**—Preventing the occurrence or mitigating the extent and severity of foodborne illness;
- **Improving Interstate Outbreak Containment and Response Coordination;**
- **Risk Assessment**—Improving risk assessment tools and interagency coordination in risk assessment;
- **Bioscience 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 inspecting a larger percentage of imported foods;

- **Education**—Expanding and improving food safety education for food production workers and processors, retailers, restaurateurs, food service workers, veterinarians and health professionals, and consumers; 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 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

USDA ADDITION, 5/8/97 -- INSERT ON PAGE 8 OF Q's & A's:

How frequently do you inspect imports?

All shipments of meat and poultry imports undergo USDA reinspection at their point-of-entry into the United States. Import reinspection is an additional check on the effectiveness of foreign inspection systems in ensuring that products from foreign countries meet U.S. standards for safety, wholesomeness, and accurate labeling. About 78 import inspection personnel carried out import reinspection during 1995 at 157 official establishments. As part of reinspection procedures, inspection certificates are verified and imported products are sampled for food chemistry, microbiological hazards, and drug residues.

The amount of meat and poultry we import is relatively stable -- between 2.4 and 2.6 billion pounds annually -- less than eight percent of the domestic supply. Only countries with inspection controls equivalent to those of the United States are eligible to export to this country. Exporting countries must undergo a rigorous review by USDA to gain this eligibility.

Research and risk assessment paragraph:

Increase research on pathogen detection, prevention techniques, and risk assessment. \$16.5 million will be used to provide fast, new methods of detecting foodborne pathogens, preservation techniques to prevent and control pathogens, and improving methods to assess risks, particularly from foodborne pathogens, in the food supply. Many pathogens - such as hepatitis A virus and *Cyclospora* - cannot now be detected in many foods. Others have developed resistance to traditional preservation methods such as heat and refrigeration. Data and information from this research will factor into improving assessment of risks in the food supply.

website address: <http://vm.cfsan.fda.gov/list.html>

**FOOD AND DRUG ADMINISTRATION
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MESSAGE: Elizabeth: Since I've already corrected my copy I'm sending it, noting how it read before correction was made. Call me if there's a problem.

TOTAL PAGES: 3

DATE: 5-8-97

(ADDITIONAL MATERIAL)

Sources of food contamination are almost as numerous and varied as the contaminants themselves. These include preharvest/slaughter conditions to contamination introduced during processing and preparation. Bacteria and other infectious organisms are pervasive in the environment. It is not unusual for raw fruits and vegetables to have bacteria on their surface prior to harvest.

-- 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. Misuse of pesticides, herbicides, and other chemicals may result in unacceptably high levels of these chemicals in various foods.

-- Seafood may become contaminated from agricultural, animal manure, and other runoff, sewage, accidental spills of hazardous substances, or microorganisms and toxins which naturally occur in marine environments.

-- Milk, eggs, and meat from food-producing animals may become contaminated due to contaminated feed, contact from animal manure the misuse of veterinary drugs, or poor farming practices, including production and harvesting activities, disposal of solid waste (including animal manure on land, or toxic emissions to air.

-- Foods may become contaminated during processing due to malfunctioning or improperly sanitized equipment; misuse of cleaning materials; rodent and insect infestations; chemical spills during transportation; and improper storage. Foods may become contaminated in retail facilities and in the home through poor food safety practices.

*Before correction
this was
"waste"*

*Before
correction
this was
"waste"*

Q. What foodborne hazards are targeted by this initiative?

A. The primary focus of the initiative is on bacteria, parasites, and viruses that can cause serious diarrheal disease, not just the relatively short term, unpleasant intestinal distress usually thought of as "food poisoning". We are also targeting organisms that can cause death, spontaneous abortion, birth defects, and long-lasting illness such as reactive arthritis, and life-threatening paralysis. Other contaminants, such as mycotoxins and marine toxins found in seafood are included in some activities in the initiative.

strategies can be determined.

- It recommends USDA and FDA long-term research to develop new decontamination methods for Hepatitis A and other contaminants on fresh produce.

This bullet was added [-- Education programs under the initiative would help assure adequate training in hygiene for farm and food plant workers and the proper management of animal manures on the farm.

Hepatitis A infections usually result from fecal-oral contamination, and food-related hepatitis A cases in the U.S. are usually associated with foods contaminated by an infected food worker during preparation. Educating more consumers and workers on proper handwashing techniques could reduce the number of foodborne hepatitis A cases.

II. COORDINATION QUESTIONS

Q. Are you doing anything to better coordinate the federal government's response to outbreaks of foodborne illness?

- A. Federal agencies work together (along with state and local governments) to assure food safety through research and prevention activities, such as inspection and enforcement, and to respond to outbreaks when they occur. Nevertheless, we need to do a better job to reduce redundancies and more intelligently target our use of resources.

An interagency coordination group is being created by FDA, CDC, USDA and EPA to improve communication among the agencies in response to outbreaks of foodborne illness. An improved communication system will be established between federal, state, and local authorities to assist in more rapid identification and control of outbreaks.

Q. Is anything being done to encourage coordination between federal and state officials who are responding to outbreaks of foodborne illness?

- A. Yes. State agencies will be included in the interagency coordination group and communication network.

III. INSPECTION HACCP QUESTIONS

Q. How frequently should inspections be conducted to assure food safety?

April 15, 1997 DRAFT

Coordination - substantive
Education - more up
- starts, identify
Strategic Plan new
country, HS
responsibilities

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

NATIONAL FOOD SAFETY INITIATIVE

REPORT TO THE PRESIDENT

Editorial

No passive voice

- why highlight 6 contaminants?
link to policies?

97 - activities -
- in process/new
commitments

- HACCP
principles

- HACCP rules

Surveillance - how you
inf. researchers. -

- Paradigm shift -
- HACCP
- Coordinated response
science-based monitoring and strategies
- process
- science-based risk-based inspection system
- setting priorities
- coordination
- leveraging resources -

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EXECUTIVE SUMMARY

Ensuring the safety of the food supply is one of government's most enduring and important functions. However, federal, state and local governments face many challenges in maintaining and improving food safety. Indeed, disease-causing microorganisms (pathogens) threaten the public health, and in some cases the threat is growing and becoming more deadly. To address this concern, on January 25, 1997, President Clinton asked the Secretaries of Agriculture and Health and Human Services and the Administrator of the Environmental Protection Agency to report recommendations in ninety days for improving the safety of the American food supply. To prepare this report, the three departments carried out an intensive dialogue with the many "stakeholders" in food safety, including food producers and processors, consumers, restaurateurs, states, and academia.

This report outlines new, and in some cases innovative, ways of doing things, to get the diverse talents and resources in the federal government pulling together--in partnership with state and local officials, the food industry, academic scientists, and consumer groups--to identify and act against threats to the safety of the food supply. The report identifies specific steps that should be taken in the coming months to reduce the incidence of food-related disease in the coming months, as well as build a foundation for improved food safety for years to come.

The primary problem is evident. Every day, thousands of Americans are stricken by illness caused by the food they consume, and up to 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 on frozen strawberries. Our understanding of many of these pathogens and how they contaminate food is limited; for some, we do not even 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 limited means 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 go 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.

The problems identified above do not mean that the U.S. food supply is unsafe; it is one of the world's safest and most wholesome. However, drawing on the substantial medical and scientific talent in the public agencies responsible for food safety, new scientific understanding, preventive controls, coordination and education can be brought to bear on the problem. Working with the food industry, for example, the Clinton Administration has devised a safety assurance system for the harvesting, processing, transportation, handling, and storage of food. That system, which relies upon preventing the contamination of food, must be put into place at every step of

the food delivery process--from the farm to the consumer's dinner table. Known as Hazard Analysis Critical Control Points, or "HACCP," it represents a paradigm that better allocates responsibility between government and the private sector.

This report builds on this paradigm, and presents recommendations in seven areas, which are summarized below:

1) **Surveillance/"Early Warning" -- Prevent the occurrence or mitigate the extent and severity of foodborne illness outbreaks.** Americans need a more effective early warning system that can detect outbreaks sooner. A key element in such a system is an increased ability to detect, compare and communicate unusual patterns of illness and utilization of laboratory findings within and among states and their federal partners. Improvements that will be implemented to accomplish that goal include:

- Expanding and enhancing the foodborne disease active surveillance network (FoodNet), by adding new "sentinel sites" that collect outbreak data, and by strengthening existing surveillance sites.
- Improving early detection of foodborne disease nationwide by funding state efforts to gather epidemiologic data, developing electronic capability to collect and share data on outbreaks, and creating a national electronic network for bacterial "fingerprints" to help identify the source and cause of outbreaks.

2) **Interstate Outbreak Containment and Response Coordination -- Improve overall efficiency and emergency response coordination for outbreaks.** At the federal level, there are four agencies charged with responding to outbreaks of food- and waterborne illness: the Department of Health and Human Services's Centers for Disease Control and Prevention and the Food and Drug Administration, the U.S. Department of Agriculture's Food Safety and Inspection Service, and the Environmental Protection Agency. But the current system is characterized by inadequate communication, poor data sharing, and a lack of understanding of each others' roles. These problems will be fixed by:

- Establishing an intergovernmental group to coordinate investigations and responses to outbreaks that would ensure that outbreak causes are identified quickly and accurately, to coordinate decisions about government response to outbreaks, and to ensure that one person speaks for all during each phase of the outbreak.
- Enhancing the basic infrastructure for surveillance of foodborne illness and coordination at state health departments.

3) **Risk Assessment -- Improve risk assessment tools and interagency coordination in risk assessment.** Risk assessment's objective is to characterize the nature and size of the risk to human health associated with hazards, which in turn can lead regulators to more informed

decisions about controlling those hazards. Risk assessment activities will be improved by:

- Establishing a risk assessment consortium of the various agencies, to set priorities and guide overarching federal risk assessment research.
- Develop better data and modeling techniques to assess exposure to microbial contaminants in the food supply.
- Develop simulations of microbial variability under specific environmental conditions existing from farm to table.

4) **Bioscience Research -- Expand research to develop new methods for identifying and controlling foodborne pathogens.** Today, many pathogens in food or animal feed cannot even be identified, and others have developed resistance to time-tested controls such as heating and refrigeration. Research will begin 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 technologies and antibiotics.
- Develop technologies for prevention and control of pathogens.



5) **Inspections -- Improve FDA's inspectional process with more resources, expanded use of HACCP and partnerships with the States, and increased coverage of imported foods.** Although meat and poultry are inspected continuously by FSIS, and HACCP rules for those foods are being implemented, other foods, which are subject to FDA inspection, are much less frequently inspected (as FDA has only 700 inspectors and analysts to cover 53,000 U.S. food plants and 3 million annual imports). The most efficient mechanism for insuring that inspections are effective is by having food processors use HACCP preventive controls. Thus, recommendations are to :

- Implement the HACCP requirements for seafood by adding new seafood inspectors, and -- transferring the Commerce Department's voluntary seafood inspection program to FDA as a "Performance-Based Organization."
- Expand HACCP to other foods and animal feeds, as appropriate, beginning immediately with fruit juices and egg products; help retailers implement HACCP-type controls in restaurants and supermarkets.
- Improve coverage of imported foods via agreements with foreign countries to ensure that such foods produced under a food safety system equivalent to the U.S. system.

6) **Education -- Expand and improve food safety education for food producers and processors, retailers, restaurateurs, food service workers, veterinarians and health professionals, and consumers.** Everyone producing and handling food needs to be better educated about how to safely do so, and health professionals need better training in their knowledge of foodborne disease detection and treatment. Understanding and practicing proper food safety techniques from farm to table would significantly reduce foodborne illness, and the food industry is eager to work collaboratively to carry out such efforts as:

- Establishing a formal public/private partnership for food safety education.
- Training state and local regulators, as well as retail, food service, and institutional industries in the Food Code.
- Designing food handling guidelines similar to U.S. Dietary Guidelines.
- Using technology to spread information, such as consolidating various government Internet sites.
- Training health professionals in detection and treatment.

7) **Strategic Planning -- Develop a strategic plan and a shared long-term agenda for an improved food safety system.** Many of the above recommendations can be immediately implemented to improve food safety. These next steps do not constitute a comprehensive, strategic plan for improving the nation's food safety system. Even these immediate steps need to be harmonized with ongoing activities and longer term needs. Therefore, a long-term planning exercise is necessary to develop a knowledge base that would identify and attack foodborne illness over the coming decades and to identify systemic changes (including organizational, procedural, and structural changes) that would lead to lasting improvements.

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 Health and Human Services and of Agriculture, and the Administrator of the Environmental Protection Agency to work with consumers, producers, industry, states, universities, and the public to identify additional ways to reduce the incidence of foodborne illness and to ensure our food supply is the safest in the world. The President directed Secretaries Shalala and Glickman, and Administrator Browner to report back to him with recommendations in 90 days. He instructed them to explore opportunities for public/private partnerships to improve food safety. And he asked that their recommendations include ways to improve surveillance, inspections, research, risk assessment, education, and coordination among local, state, and federal health authorities. ~~This report is the result of the 90-day process of deliberation and discussion among all stakeholders in the nation's food safety system, including federal, state, and local agencies, consumers, universities, food producers, manufacturers, distributors, representatives of the retail and restaurant sectors, veterinarians and health professionals, and many others.~~ *Over the past 90 days 7/5/97 (A) p. 9 (B) p. 8*

Emergency changes
~~The goal of this initiative is to reduce, to the greatest extent possible, the incidence of foodborne illness. 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 those hazards that present the greatest risks.~~ *← move to p. 147*

BACKGROUND

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

Foodborne illness, however, still occurs in the United States. Over the last four years the Clinton Administration has developed and implemented major steps towards reinventing food regulation:

- In 1993, the Vice President's National Performance Review issued a blueprint for reinventing our nation's food safety system.
- The Food Safety and Inspection Service (FSIS) and the Food and Drug Administration (FDA) issued regulations that will require the meat, poultry, and seafood industries to follow Hazard Analysis and Critical Control Points (HACCP) procedures. HACCP, which calls for food industries to implement preventive measures of their own design, will streamline regulation of these foods, increase the industries' responsibility for and control

of their own safety-assurance actions, and generally bring regulation of meat, poultry, and seafood in line with state-of-the-art scientific procedures.

- Beginning in 1994, the Centers for Disease Control and Prevention (CDC) embarked upon a strategic program to detect, prevent, and control emerging infectious disease threats, some of which are foodborne, and has made significant progress toward this goal in each successive year.
- The 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.
- The Safe Drinking Water Act of 1996 includes responsible regulatory improvements to help states and water systems prevent drinking water contamination problems. Resources are provided for the first time for drinking water infrastructure that will help hundreds of communities protect their residents from harmful contaminants.

relevant

While these advances are significant, 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.

HOW THIS REPORT WAS PRODUCED

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

As noted above, this report is the final product of the 90-day process of discussion among all stakeholders that President Clinton called for in his January 25 radio address. The basis for discussion was a draft document that summarized the thinking of the federal agencies. That draft presented the agencies' "current thinking" about the resources and activities needed to have a significant impact on reducing the incidence of foodborne illness. The draft was based on the premise that an effective food safety initiative must have several, interrelated components which, together, have far greater impact on reducing the incidence of foodborne illness than is possible to attain with any single component. Moreover, these elements must form the groundwork for the design and implementation of strategies to meet current needs, for continually evaluating the effectiveness of ongoing activities, and for identifying and implementing strategies to meet future needs. These interrelated elements include surveillance, coordination, risk assessment, research, inspections, and education, and strategic planning.

starting point

8

drop*

The Agencies held two major public meetings on March 5th and March 31-April 2--and established a public docket for written comments. *two major public meetings*

~~In order to maximize opportunities for dialogue and feed back during the 90 day period, a number of meetings were held and written comments were received into public dockets. Several meetings of major stakeholders were held with Executive Office staff, and two major public meetings were held on March 5 and on March 31 through April 2. These meetings presented opportunities for stakeholders to comment on the preliminary recommendations presented in the discussion draft and to provide additional suggestions for improving food safety. This report and its recommendations reflect comments and suggestions from participants in the public discussion process of the past 90 days.~~ *including*

FOODBORNE ILLNESS: A SIGNIFICANT PUBLIC HEALTH PROBLEM

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

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

Sources of Foodborne Contamination

Sources of food contamination are almost as numerous and varied as the contaminants themselves. Bacteria and other infectious organisms are pervasive in the environment. *Salmonella* 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 may become contaminated from agricultural animal manures and animal 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 animal. Milk, eggs, seafood, poultry, and meat may become contaminated due to contaminated feed, misuse of veterinary drugs, or poor farming practices, in particular, the mis-management of animal manures, including production and harvesting activities. Foods may become contaminated during processing due to malfunctioning or improperly sanitized equipment;

misuse of cleaning materials; rodent and insect infestations; and improper storage. Foods may become contaminated in retail facilities and in the home through use of poor food handling practices.

Although many hazards threaten the safety of our food, certain microbial hazards are of particular public health concern, and are targeted for immediate risk reduction by this initiative. Studies have shown that the following microorganisms are common, serious foodborne pathogens: *Salmonella* species, *Campylobacter jejuni/coli*, toxin-producing strains of *Escherichia coli*, including O157:H7; the parasites *Toxoplasma gondii* and *Cryptosporidium parvum*; and the Norwalk virus. ✓

The microbial pathogens listed above, and discussed in greater detail below, may give rise to diseases that are far more serious than the uncomfortable but relatively temporary inconvenience of diarrhea and vomiting, which are the most common symptoms of so-called "food poisoning." Foodborne infections can result in very serious immediate consequences, such as spontaneous abortion, as well as long-lasting conditions such as reactive arthritis, Guillain-Barré syndrome (the most common cause of acute paralysis in adults and children), and hemolytic uremic syndrome (HUS), which can lead to kidney failure and death, particularly in young children. The pathogens described below are not listed in order of importance or severity. They are not alone: Other foodborne pathogens, such as the hepatitis A virus and *Vibrio vulnificus*, also are important causes of foodborne disease. However, focusing first on the most frequent causes of serious foodborne disease creates the greatest opportunity for immediate public health benefits.

Mix of
Contaminants
Microbes

are we
really "poisoning"
where do we
say no?
long.

Intent

Salmonella

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

Campylobacter

The bacterium, *Campylobacter*, is the most frequently identified cause of acute infectious diarrhea in developed countries and is the most commonly isolated bacterial intestinal pathogen in the United States. It has been estimated that between 2 and 4 million cases of campylobacteriosis occur each year with an associated 120-360 deaths. *Campylobacter jejuni* and *Campylobacter coli* (2 closely related species) are commonly foodborne, and are the infectious agents most frequently described in association with Guillain-Barré

syndrome, perhaps as frequently as 1 in 1000 cases. Several prospective studies have implicated raw or undercooked chicken as major sources of *C. jejuni/coli* infections. Unpasteurized milk and untreated water have also caused outbreaks of disease.

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, and has been associated with HUS. HUS is a life-threatening complication of hemorrhagic colitis characterized by acute kidney failure, and is particularly serious in young children. *E. coli* O157:H7 has its reservoir in cattle, but the dynamics of *E. coli* O157:H7 in food-producing animals are not well understood. It has been estimated that approximately 25,000 cases of foodborne illness can be attributed to *E. coli* O157:H7 each year with as many as 100 deaths. *E. coli* O157:H7 outbreaks have recently been associated with ground beef, raw milk, lettuce, and minimally processed and fresh fruit juices. The most recent outbreak, in the Fall of 1996 in 3 western states and British Columbia, was associated with unpasteurized apple juice and sickened 66 people and caused the death of one child.

Toxoplasma gondii

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

Cryptosporidium parvum

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

manures) and has been transmitted through contaminated water and food.

Norwalk virus

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

Other pathogens and contaminants

Many other foodborne pathogens also cause illness and death in the United States, and efforts are underway to address these threats as well. These include *Listeria*, *Vibrio* species, especially *Vibrio vulnificus*, Shiga toxin-producing *E. coli* other than serotype O157:H7, other *E. coli* groups, *Shigella*, hepatitis A virus, *Bacillus cereus*, *Clostridium botulinum*, *Clostridium perfringens*, *Staphylococcus aureus*, the agents of ciguatera and scombroid poisoning, mycotoxins, and others known or yet to be identified.

THE CURRENT SYSTEM FOR PROTECTING FOOD

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

- On the farm, food is regulated by state agencies supported principally by the EPA, which acts to ensure that pesticides are approved for safe use, by the FDA, which oversees use of drugs and feed in milk- and food-producing animals, and by Animal and Plant Health Inspection Service, which is concerned with food-animal disease control. Federal responsibility also covers production and harvesting activities that discharge wastewater to surface and ground waters, and solid waste to land, all of which could contaminate growing and process waters or grazing land. 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. The EPA Office of Water is reviewing options for expanding the coverage of permit requirements for animal feeding operations in order to better protect water quality. *edit*

- Food processing for foods other than meat, poultry, and egg products (except shell eggs) is regulated by the FDA, whose inspectors are responsible for visiting about 53,000 plants periodically, with emphasis on the highest risk foods or processing techniques. FDA ~~has~~ *about* ~~fewer than~~ 700 inspectors and analysts ~~devoted~~ to this activity. Meat, poultry, and all other egg products are regulated by FSIS, whose 8,000 inspectors are present in 6,200 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. *Current*

- Food being transported in interstate commerce is subject to federal and state regulation, although that area has received little attention in the past. In 1996, USDA's FSIS and HHS's 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. *foods?*

- The importation of food from foreign countries is overseen by FSIS for meat, poultry, and most egg products and FDA for all other foods. If an imported food is suspect, it can be tested for contamination and its entry into the United States denied. *yn*

- Restaurants, supermarkets, and institutional food services (such as schools and hospitals) are generally regulated by state and local authorities, and FDA publishes the *Food Code*, which consists of model recommendations for safeguarding public health when food is offered to the consumer. Recommendations are developed by consensus of state government representatives at the Conference for Food Protection. FSIS and FDA have worked with states to update the *Food Code* in light of the changing retail and food service environment and emerging food safety issues, especially with regard to meat, poultry, egg products, and seafood. ~~The Conference for Food Protection serves as one forum for fostering cooperation among federal, state and local governments in the oversight of food products and the conditions under which they are produced, processed, transported, stored, and handled through retail sale or food service to the consumer.~~ *explicit that FDA jurisdiction - limited*

- 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 source, and control outbreaks. FDA or FSIS are called in when a link to a regulated food is suspected. FDA is charged with ensuring that disease is not spread interstate. *within their jurisdiction depends on one who is called in*

- In the home, consumers also have a responsibility for proper handling and storage of food, as consumer mishandling contributes to many cases of foodborne illness. ~~As a result of this knowledge~~ *In 19xx to improve food handling improve consumer safety.* FSIS promulgated safe handling labels for raw meat and poultry products.
- Research ~~Other responsibilities~~ related to food safety include research into the cause and transmission of foodborne illness, and education on treatment and prevention of foodborne illness. ~~These responsibilities are carried out by the~~ USDA, FDA, CDC, EPA, the National Institutes of Health (NIH), other federal components, and the states. Basic research, conducted largely in university laboratories, on the biology, genetics, pathogenesis, natural history, and epidemiology of microorganisms implicated in foodborne disease is actively supported by the NIH, and in particular, by the National Institute of Allergy and Infectious Diseases. Research efforts are focused on understanding the disease process and using this information to design effective prevention and treatment strategies aimed at reducing human disease. Other agencies of the federal government also support related research in universities. The private sector supports research within its own laboratories and in universities.

State
Education

Make
Propanade

Recent Improvements in Federal Administration Actions to Modernize Food Safety

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

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

Delayed
? benches
whining

IMMEDIATE ACTIONS TO IMPROVE FOOD SAFETY

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

The recommendations in this report focus

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

edit.

oversight. The application of such preventive controls to other types of food, including animal feeds, may be important to protecting food in the years to come.

Under this initiative, the federal government, in concert with state and local governments, industry and academia, would: conduct research and risk assessments to determine how foodborne illnesses occur and can be prevented or controlled; improve surveillance and investigative efforts to locate and monitor illnesses caused by food; achieve more effective and efficient monitoring of the safety of the food supply through inspections of food processors; and reinvigorate education of all those involved in food preparation focusing on the use of safe practices. These issues, and our recommendations for addressing them, are described below. Because the components of the food safety initiative are interrelated, throughout this report, overlapping activities will be noted (for example, among research and risk assessment, and education and inspection).

Process
8/1/07

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

ADD BUDGET FIGURES TO ABOVE PARAGRAPH.

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 increases 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. 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 the specific food sources are, and to learn how best to keep the foods from becoming contaminated in the first place. Rapid detection of outbreaks is critical to stopping them before they affect many people. A key element in an early warning system is the ability to detect, compare, and communicate unusual patterns of illness and laboratory findings within and among states and 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 coupled with the other elements of this initiative, prevent illness and premature deaths related to foodborne diseases.

Further, responsibility for surveillance is shared among Fed., states, local agencies, limiting communication. ... Limited capacity in some States.

Recommendations

The federal government, in cooperation with state and local health departments, is proposing to take the following steps to establish a national early warning system for, and enhance surveillance of, foodborne 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 appropriate 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 HACCP systems, and to evaluate the effectiveness and efficiency of prevention strategies already in place.

Enhance and Expand Foodborne Diseases Active Surveillance

CDC, FDA, and USDA currently 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 7 in FY97, and to at least 8 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.

FY97 Activities

- Two new FoodNet sites, encompassing several counties in New York State 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 other 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.

support

hire and train people

Enhance early detection of foodborne disease nationwide

In addition to establishing enhanced sentinel sites, an early warning system would require 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. While 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 hemolytic uremic syndrome.

26

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 hemolytic uremic syndrome.

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 improve 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 optimal control strategies can be determined.
- ^{CDC} Scope of 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.

- Gulf Coast *Vibrio* surveillance ~~will be strengthened by CDC, FDA, and states.~~ ^{and will work with to strengthen}

Long-term Activities

- Continue to enhance surveillance and investigative systems 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 other states so they 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." These new capacities would allow rapid identification of the cause of

Can you do this - be clear about money

Ward

full-time permanent unit 18

CDC & FDA, state initiative -
FDA liaison at CDC - Hire a
staff person to run that
program. ?

some outbreaks that currently go undiagnosed.

FY97 Activities

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

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* because they 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 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 these pathogens.

Long-term Activities

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

Why here?

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 this 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, which would suggest to public health investigators that a product distributed in both California and Washington may be contaminated with the organism.

In addition to identifying, investigating, and reporting cases of foodborne disease in humans, microbiological surveillance of pathogens in foods, in food animals and their manures so produced, 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

- Continue to expand the national electronic database of DNA “fingerprint” patterns.
- CDC, in collaboration with participating state health department laboratories, FDA and USDA, 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 USDA will set up centralized national electronic databases of DNA “fingerprint” patterns of *Salmonella* serotypes Typhimurium and Enteritidis.

Long-term Activities

- CDC should continue to develop standardized DNA “fingerprinting” methods for other foodborne disease-causing bacteria as appropriate and will 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

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

FY97 Activities

? words

Antimicrobial resistance?
How do we use information to reduce incidence?

- 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 to assess the impact of antimicrobial drug use on resistance patterns and prevalence to guide regulatory policy and educational campaigns.
- FDA should assist the World Health Organization 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 Impact 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 would increase the monitoring of animal feed processing to determine the nature and extent of pathogen contamination and the impact of control strategies on pathogen reduction in animals.

INTERSTATE OUTBREAK CONTAINMENT AND RESPONSE COORDINATION

TO BE SUBMITTED

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. The President's budget includes \$3.95 million for this activity. Risk assessment provides a strong foundation upon which efficient allocation of scarce food safety resources can be made. Furthermore, risk assessment is a requirement for 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 and evaluations of alternative risk management strategies are required for economically significant 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 which govern standards for food safety, among other issues. Carefully formulated risk assessments based on high quality data and scientific information generated from bioscience 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.

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 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 food borne 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.

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, HACCP-based prevention strategies for process control systems and for food inspections, 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.

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 should guide and conduct federal food safety research for developing methods and models for risk assessments, to address the scientific, risk-based goal of preventive control that is the central principle of this food safety initiative.
- The consortium should be inclusive in its risk assessment activities, seeking expertise from assessment professionals and scientists from public and private sources as well as industry and consumer groups. The initial focus of the initiative will be on pathogenic microorganisms. [A compilation of current ongoing microbial risk assessment research will be used to evaluate developing methodologies and models for algorithms and to guide microbial for risk assessment.] [USDA, PLEASE CLARIFY] Also in 1997, the consortium would begin the process of establishing a clearing house that will collect and catalog 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 interagency meetings will be scheduled in 1997 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

Internal meeting 5/6

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.

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

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 food borne 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 and effect are difficult or impossible to obtain.

FY98 Activities with Food Safety Initiative Funds

Research projects to be considered and prioritized by the consortium in 1998 include developing methods and models to:

- Address the dynamics of foodborne pathogens in agricultural environments (e.g. feed, animal manure)

- Quantify effects of key processing steps on levels of pathogens
- Quantify effects of key commercial food service preparation procedures, marketing facilities, and home food handling practices
- Design and propose 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 and emerging food safety needs. 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. In addition, in order to reduce uncertainties in exposure estimates, the consortium will work with researchers who are conducting focused food-consumption surveys that target food 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

Research projects to be considered and prioritized by the consortium in 1998 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

As stated previously, risk assessment research priorities will be collectively established by the 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 toxicoinfectious microorganisms. Further research is also needed into the use of biomarkers of susceptibility, chronic sequelae, microbiological toxicokinetics, and infectious dose.

BIOSCIENCE RESEARCH

*Budget
table
Coordination*

Background

Food safety research is critically needed to develop the means to more rapidly and accurately identify and characterize 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 in the continuum from production to consumption. FDA, CDC, EPA, NIH, and the USDA's Research, Education, and Economics agencies (i.e., Agricultural Research Service and Cooperative State Research, Education, and Extension Service) conduct research related to pathogenic microorganisms and other contaminants that threaten the safety of food. This 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 last 10 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 these organisms cannot be detected readily due to either a lack of suitable methods or their sporadic occurrence in foods, however, this does not mean that the organisms cannot cause human illness. Certain foodborne pathogens are increasingly being associated with resistance to time-tested controls, such as heating, refrigeration, and acid. In some cases, this ability appears to be linked with increased virulence or new ways to evade our immune defenses. Food safety research covering the production to consumption continuum is needed to provide solutions.

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 biological agent. Selection of target pathogens and foods ideally are guided by risk assessment. Research is also needed to support HACCP implementation to enable verification that critical control points in HACCP systems are working, and to target the data gaps that hamper both HACCP and risk assessment. Among the information needs and data gaps identified, there are numerous opportunities for collaboration and the development of research partnerships among federal and state agencies, the private sector, and academia. Among these recognized data gaps, the following areas were identified as priority research needs. In conducting research in these areas, USDA will expend \$8 million and FDA will expend \$3.9 million in FY98 food safety initiative funds. (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 the rapid, cost-effective testing for a number of pathogens in food animals and their manures, in agriculture and aquaculture products, animal feeds, and processed food products. For these pathogens in particular, methods development must address their low level, sporadic incidence 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 a methods to detect *Cyclospora* and to develop control measures.

FY98 Activities with Food Safety Initiative Funds

- USDA, FDA, and EPA will enhance on-going research to develop test methods for *Campylobacter*, *Salmonella*, *Toxoplasma*, *E. coli* O157:H7 and other shiga toxin-producing *E. coli*, *Cryptosporidium*, hepatitis A and Norwalk viruses, and naturally-occurring mycotoxins and marine toxins in foods.
- FDA will expand its on-going 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 conditions that have been traditionally relied on to eliminate or prevent the growth of foodborne pathogens have become increasingly important as 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. There is insufficient understanding of the physiological and genetic basis of resistance to prevent breakthrough of newly emerging pathogens. This research will help identify food production, processing, and handling practices that are likely to contribute to pathogen contamination or proliferation. It 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 may be to modify drug withdrawal periods. Such an approach requires the development of scientific data on how the animals' microbial populations resistance profile changes in response to the elimination of the drug. Work involving resistance to traditional preservation technologies and antibiotic drug resistance must be based on a sound understanding of microbial physiological and genetic adaptive mechanisms.

Long-term Activities

- FDA and USDA should 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 should 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 non-resistance. Research will emphasize competitive exclusion techniques (probiotics) and the use of extended drug withdrawal periods.

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 may carry human pathogens, without any clinical manifestations. Likewise, fresh fruits, fresh vegetables, and grains may 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 for the prevention or control of the pathogens listed below in raw agricultural commodities and seafood. It is anticipated that developments in this area will also 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 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 of 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/harvest, including the use of probiotics.
- Develop new methods to reduce or eliminate pathogenic microorganisms 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 *Vibrio* and Norwalk virus on/in marine-harvested and aquaculture-reared seafood, and for *Cyclospora* and hepatitis A virus on fresh produce. [such as]
- USDA (ARS, CREES) and FDA, working with industry and academia, should develop new techniques for eliminating pathogens that provide alternatives to traditional thermal processing. and speed consideration of emerging technologies
- FDA and USDA (FSIS) should work with industry 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 may 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, working with industry and academia, should develop and assess the effectiveness of in- or on-package sensors of storage conditions to alert consumers of products not stored safely.

INSPECTIONS

Background

Inspection of commercial food processors is an integral part of the food safety assurance system. Inspections are carried out by federal, state and local authorities. State and local officials also have primary responsibility for inspection of focusing primarily on restaurants, supermarkets and other retail establishments. At the federal level, consistent with legal mandates, FSIS has responsibility for meat, poultry, and egg-product and processing plants--in all, about 8,000 inspectors for 6,200 domestic plants and for all imported meat, poultry, and egg products. FDA, on the other hand, has responsibility for and conducts periodic, random inspections of all other food processing plants--about 700 inspectors and analysts 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. The result is that an FDA-regulated plant gets inspected by FDA, on the average, only once every 10 years. FDA also relies upon the states to conduct some inspections under contract, but that number has dropped from 12,000 in 1985 to 5,000 now. Moreover, since the number of imports has doubled in five years, with no real increase in inspectors, a smaller percentage of imports are inspected at entry.

As FDA's inspections have dropped, FDA is finding greater problems, e.g., the number of products recalled for life-threatening microbial contamination has increased almost 5-fold since 1988. FSIS is faced with a similar challenge of continually providing the most effective food safety and consumer protection program with limited resources and increasingly complex public health concerns related to food safety.

Recommendations

Scientists and other food safety experts have concluded that the most effective and efficient mechanism for assuring that food processors identify and control hazards that could threaten food is the application of the HACCP concept of built-in preventive controls. FDA's seafood HACCP regulations go into effect in December 1997. FSIS begins to implement HACCP for the meat and poultry industries in 1998 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:

- The Administration will publish proposed regulations for use of HACCP in the manufacture of juice products (by FDA) and egg products (by FSIS). ✓
- 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 plants. ✓
- FSIS and FDA will evaluate expanding existing cooperative agreements so that plants producing both meat and non-meat foods are inspected by FSIS inspectors trained in FDA inspectional standards. Without these cooperative agreements, both FSIS inspectors and FDA inspectors would inspect the same plants. With FSIS inspectors already in these plants, their presence could be better utilized to maximize use of federal resources without loss of inspectional coverage for FSIS-regulated foods. ✓
- ~~FSIS plans to conduct a series of public meetings to discuss:~~
 - ~~How HACCP requirements will be implemented in slaughter plants consistent with~~ *is evaluating* *are consistent with* the legal mandate of carcass-by-carcass inspection and how the roles and responsibilities of inspection personnel will change with that implementation, and
 - ~~The design and testing of~~ new concepts consistent with HACCP principles, for achieving food safety and other consumer protection objectives in the inspection of meat and poultry products.
- 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 and will expend approximately \$6.4 million to hire approximately 80 investigators to conduct inspections to ensure proper implementation of seafood HACCP.
- A Performance-Based Organization (PBO), located at FDA, 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. This will 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.

36
Evaluation of how FSIS allocates inspectors
now - doing pilots. - veg. implement.

ANRM
FDA
safe egg
including whether or how

- processing inspectors working the plant

} pilots

Long-term Activities

- FDA should implement HACCP procedures, as appropriate, for other foods, including animal feeds, using risk assessment techniques where possible.
- FDA should evaluate the voluntary fee-for-service seafood program and the operational functioning of the seafood PBO.

vague
pilot
project?

neutral
reference?

the Administration

Enhance safety of foods produced in retail food establishments

More than 3,000 state and local regulatory agencies have primary responsibility for monitoring retail food establishments to assure that the consumer is protected. There are approximately 785,000 commercial and institutional food establishments, 128,000 grocery and convenience stores, and 1.5 million vending operations in the U.S. employing workers with highly diverse backgrounds and training.

FY97 Activities

- FDA and FSIS will hold a series of grassroots meetings with state and local regulators in 5 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

- FDA and USDA will form an alliance, joining expertise of federal, state, and local agencies, industry, and professional and trade associations to promote and develop communication techniques targeted to specific groups (e.g., non-English speaking individuals) to overcome barriers to communicating appropriate food safety behaviors to food service workers. (See "Education: Improve retail food service and institutional education.")
- FDA and USDA will enter into public/private partnerships to develop a national food safety education program for state and local regulators using concepts in the 1997 Food Code. (See "Education: Improve retail food service and institutional education.")
- FSIS will provide HACCP training to state and local inspectors to improve the safety of meat and poultry products processed in retail establishments. This training will augment the training program for federal inspection personnel, more fully covering the farm-to-table continuum.

involve
minorities
on board?

Long-term Activities

contact
establishment?

Not -

- Achieve adoption of the Food Code, particularly the HACCP provisions, by all 50 states.

Enhance federal/state inspection partnerships

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. Maximizing the joint federal/state role in inspections through development of new federal/state partnerships focused on coordinating inspection coverage and preventing duplication of effort, particularly between FDA and the states, is a major step in this direction. FDA will expend approximately \$1.25 million of food safety initiative funding in this effort.

Seafood only?

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 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.

Long-term Activities

- FDA and USDA should work more closely with industry, professional and trade associations, and academia to assure effective implementation of HACCP, 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.

prevention and control -
Good reports

Enhance inspectional coverage of imported foods regulated by FDA, to address the problem of rising imports and FDA's inability to provide adequate coverage

problem defined

FY98 Activities with Food Safety Initiative Funds

- FDA will expand its program to develop mutual recognition agreements (MRAs) with trading partners.
- FDA will also 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/accrediting private laboratories, including use of a

?

✓

Sense not
to import plants

* → Integrate - shipment of state³⁸ - inspected meat - - USDA's inspection activities

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.

Long-term Activities

- FSIS should verify foreign government inspection progress for conformance with the new HACCP and pathogen regulation requirements; this 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 this expansion, FDA should evaluate the feasibility of combining this communication system with the federal/state inspection data system discussed above, making the data and information more widely accessible.

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, FSIS and FDA published an ANPR on November 22, 1996.

FY98 Activities with Food Safety Initiative Funds

- FDA and USDA would establish guidelines for the safe transportation of high-risk food and establish performance standards, including elements such as temperature maintenance, prior cargo and cleaning information for the food shipper's use, to ensure 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.")

mention
ANPRM
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Such efforts
ast

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 for which research and risk assessment are important components. Realizing that educational efforts are cost-effective investments, federal, state and local governments, private organizations, consumer groups and the industry have been fostering educational programs to address foodborne illness.

Problem

Despite these educational efforts, foodborne illness is still 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 handling practices. Without food safety knowledge and proper food handling procedures practiced by those involved from farm to table, foodborne illness will not be significantly reduced. Individuals at each stage along the farm to table continuum need to be targeted with the appropriate food safety messages.

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

Similarly, food preparers in the retail sector must be made aware of how they can prevent food contamination and reduce pathogen growth. For example, during 1988 to 1992, *Salmonella* caused 69% of the 796 bacterial foodborne disease outbreaks; 60% of these *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.

In addition, health professionals and physicians need more knowledge to better detect and treat foodborne illnesses. Producers of animals used in human food production and veterinarians treating such animals must be made aware of food safety implications related to drugs and 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, especially those providing food to populations at high risk in hospitals, nursing homes, assisted living facilities, child day care, and senior day care. Objectives include conducting the appropriate research to identify barriers to safe food handling and the design of persuasive messages to foster behavior change. To address this goal, FDA, USDA, and CDC will develop, through research, effective food safety education materials and services for consumers and for food service operations. Also, the development of a national food safety education program for consumers, retail and other food handlers, will be initiated through new public/private partnerships and existing networks to maximize resources and develop effective, consistent educational messages, campaigns and training programs. *launch*

through these and other activities
~~It is anticipated that implementation of the education goals and objectives of the initiative, along with the other elements of the initiative, will result in a significant increase in the number of consumers, and a large portion of the 12 million food-service workers, being reached with effective and persuasive food safety messages. Improved safe food handling resulting in a reduction of foodborne illness is the desired outcome.~~ *will reach*
reaction significant

Improve education of all target audiences

FY97 Activities

USDA, FDA and CDC will:

- Expand existing information systems such as the Foodborne Illness Education Information Center while laying the groundwork for a national clearinghouse to provide consumers and educators with food safety information.
 - Initiate innovative methods for sharing food safety information in order to reach larger audiences, such as the use of electronic communications technology and the consolidation of government food safety Internet sites.
 - Begin a process to establish a National Food Safety Education Council. The Council, through an independent scientific review board, will establish longterm goals and objectives for food safety education and changing unsafe food handling practices.
 - Convene broad alliances that network federal government agencies, industry, consumer, trade, state and local food protection agencies, and academic organizations to share food safety materials and conduct joint food safety education activities.
- Describe*

Improve Consumer Education

Consumer education will be conducted in several phases. Phase one, to begin immediately, has the goal of raising awareness of the general public to the need to use safe food handling *leads to*

practices. A second phase will build a long-term education program designed to effectively change consumers' unsafe food handling behaviors, based on research.

FY97 Activities

USDA, FDA, CDC will:

- Form a partnership with private-sector organizations, through a *Memorandum of Understanding*, to conduct a public food safety awareness education campaign, with a logo and basic key messages, to emphasize the need for safe food handling. Specific audiences will include high-risk consumers, minorities and non-English speaking populations. ✓

- Conduct a conference on food safety education, "*Changing Strategies; Changing Behaviors*," scheduled for June 12-13, 1997. *Propose* The conference will be a forum to introduce plans for national food safety awareness campaign and the conduct a conference. ✓

- Promote September as National Food Safety Education Month, which was established two years ago by the National Restaurant Association. The kick-off of the national awareness campaign will begin this month.

FY98 Activities with Food Safety Initiative Funds

USDA, FDA and CDC will:

- Conduct research necessary to determine effective methods of fostering behavior change in targeted consumer audiences and methods to evaluate effectiveness of educational methods and programs.
- Develop national "safe food handling" guidelines like the Dietary Guidelines. Under the auspices of the National Council, convene the scientific review board to determine guidelines and review them periodically. Risk assessment will be used to identify at-risk audiences for targeted food safety education programs.
- Consider use of food labels and other educational materials to convey food safety information (for example, for microorganisms in shellfish for at-risk groups). ✓
- Expand the capacity of the national clearinghouse for food safety information.
- Promote food safety messages in schools and incorporate food safety education into school programs.
- Sponsor journalists' conference on food safety issues.

Long-term Activities

USDA, FDA and CDC should:

- Conduct research necessary to develop a visual communication tool to convey food safety principles, like the food guide pyramid does for nutrition principles.
- Implement, through partnerships and alliances, a massive education campaign to encourage the use of the new educational tools developed, especially targeted to school programs and specific at-risk audiences.
- Continue to promote the National Food Safety Education Council and expand capacity of the national clearinghouse for food safety information.

Improve Retail, Food Service, and Institutional Education

FY97 Activities

- 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 Food Code and develop communication techniques targeted to specific groups (e.g., non-English speaking individuals) to overcome barriers to communicating appropriate food safety behaviors to food service workers. (See “Inspections: Enhance safety of foods produced in retail food establishments.”)

FY98 Activities with Food Safety Initiative Funds

USDA and FDA will:

- Develop and initiate a highly focused program to change food workers' unsafe food preparation behaviors and include a multilingual approach. Programs will address the high turnover in food service workers and target teenage workers, small businesses, and new entrepreneurs. (See “Inspections: Enhance safety of foods produced in retail food establishments.”)
- Develop guidelines for retail and food service processing operations for meat, poultry and seafood to train state and local inspectors to identify hazards at the retail level.
- Provide training to state and local regulators as well as retail, food service and institutional industries to increase the use of HACCP principles and provisions in the 1997 Food Code.
- Form an alliance of federal, state, and local health agencies, as well as private parties, to promote education efforts on retail and food service food safety issues, using existing networks to strengthen the programs, including a multilingual approach to include safe food handling provisions in the 1997 Food Code and HACCP principles. (See “Inspections: Enhance safety of food produced in retail food establishments.”)

Long-term Activities

USDA, FDA and CDC should:

- Continue to support alliances in the development of a food safety agenda in their respective areas.
- Continue to provide training to state and local regulators and the retail food industry in the 1997 Food Code, as well as implementation of HACCP.

Improve Veterinarian and Producer Education

FY98 Activities with Food Safety Initiative Funds

USDA, FDA and CDC would:

- 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.
- Encourage the improvement of veterinary and producer education at veterinary and agriculture colleges to address foodborne pathogens in animals and their manures so produced.

Long-term Activities

USDA, FDA and CDC should:

- Continue to expand educational programs for producers of animals for human food consumption, veterinarians, state and local regulators about proper drug use and the incorporation of HACCP principles into quality assurance programs.
- Continue to schedule regular training sessions, including satellite teleconferences, educational symposia, and presentations at producer and practitioner meetings. Guidelines and educational materials will be developed and disseminated through existing networks to food producers and the veterinary medical community.
- Guidelines and educational materials will be developed and disseminated through existing networks to food producers and the veterinary medical community.

Improve Health Professional Education

Long-term Activities

- CDC, in cooperation with FDA and USDA, should train public health professionals on foodborne disease and clinical microbiology and foodborne illnesses with non-traditional symptoms by using multimedia and distance learning techniques and the National Laboratory Training Network

Improve Industry Education in the Transportation Area

Long-term Activities

- FDA and USDA should form an alliance among government agencies to develop educational materials and train food-transportation vehicle owners and operators and food processing establishments on hazards associated with the transportation of food products, particularly hazards associated with temperature controls, prior cargoes, and sanitation methods. (See “Inspections: Enhance safety of foods during transportation.”)
- FDA and USDA should conduct training and education for state and local health transportation authorities so they can apply HACCP information during inspections of food processing facilities and transportation vehicles in their jurisdiction.

A BLUEPRINT FOR A BETTER FOOD SAFETY SYSTEM

TEXT TO BE SUBMITTED