

- Conflicts of interest -
↳

Deves
Bruce Bulger

Device approval stands
ok

Drug - think ok

Animal drugs - working w/ and - may go
on separate track

Manufacturing changes

- bio/pharma - have a disagreement
on products that are not well
characterized

- hoping it gets worked out w/ind

device product mod

- with us on language we gave them.

health claims -

- Anne/Harker - intended official stmt.
for govt agency

- Anne will get back to us on whether
making resolution a priority -
process changes. -

Med Guides - not sure what problems they're
trying to address - ^{will consult} Gregg's person -

- we're working to drop hammer,

- consult on goals.

- FDA wants ability to right guidance
~~- drops~~

- codifies reg

- drops final reg hammer. -

AEIR

Device changes - no Third Party on drugs
- other device changes

- mtg. w/ greenwood, moderate
D's on mtg. - List of
remaining concerns

- Drafts in circulation tomorrow or Monday
- Markup in subcommittee week of 17th
- Not clear they want a bipartisan bill -
- Greenwood called David -

Senate - Rich took hard line on hammer and
Glas 3

- Jane Williams - CBO can't do interstate
cause FDA is holding back it's.

- Met w/ 4 D's 5/31 - full alternative
for Coates - they could carry water -
Want our taking ownership -
Class I, II, III -

- Meeting w/ Jane, 4 Dems, Vince (Coates)
Tomorrow 3/15 -

- Schuler - health claims -

Good about our positioning - FDA reform,

Susan Conley
Director
Food Safety Education and Communications Staff
FSIS

April 17, 1997

TO: Greg Frazier, Chief of Staff
Eric Olsen, Special Assistant
Secretary of Agriculture

Tom Billy, Administrator
Food Safety and Inspection Service

RE: Attached MOU on Food Safety Education Partnership

Attached is the draft *Memorandum of Understanding* between the Industry Partnership for Food Safety Education and USDA, FDA and CDC to conduct joint food safety education projects targeted to consumers. This document reflects comments and revisions made by the industry partners at the CEO level, FDA and USDA general counsel, FDA and USDA procurement and contracts staffs and by comparable representatives at CDC. It has also been reviewed by CSREES management.

Sections that are underlined show areas where the most recent changes have been made. The only area of contention has been section #4, item e. We hope the changed wording will address industry concerns that the word "approve" is used. FDA and USDA counsel feels strongly that the government must retain approval or consensus rights, or not be a part of the Partnership.

Also attached is a draft description of the Partnership and the current status of work and organizational progress.

Please review these documents. We need comments and clearance by COB Monday, April 21, if this document is to be signed before the Presidential Initiative report goes forward to the White House.

The question has been raised as to who will sign the document for USDA and FDA or HHS. The industry signatories will be the respective CEO. Industry has suggested the government should sign at the Secretary level. Please let me know the decision on this. FDA has indicated they will take our lead and have the comparable appropriate person sign for them.

✓ CC: Joan Mondschein

FAX TRANSMITTAL FROM:

SUSAN CONLEY
DIRECTOR

FOOD SAFETY EDUCATION AND COMMUNICATIONS STAFF
Food Safety and Inspection Service

DATE: 4/17

TO: **Elizabeth Drye**
Associate Director
Domestic Policy Council
White House

FAX NUMBER: 456-5581

NUMBER OF PAGES 6

COMMENTS: RE: **Attached MOU on Food Safety Education Partnership**
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This revision will now be reviewed one more time (hopefully) by industry CEOs and Government officials.

USDA
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*Comments by COL
Monday
to S Conley*

MEMORANDUM OF UNDERSTANDING
AMONG
THE U.S. DEPARTMENT OF AGRICULTURE
THE FOOD AND DRUG ADMINISTRATION
THE CENTERS FOR DISEASE CONTROL AND PREVENTION
and
THE PARTNERSHIP FOR FOOD SAFETY EDUCATION

This Memorandum of Understanding (MOU) is made and entered into among the U.S. Department of Agriculture, the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and the Partnership for Food Safety Education, hereinafter referred to as the Partnership.

1. PURPOSE

The purpose of the MOU is to provide a framework for cooperation among the parties as each develops science-based consumer-oriented messages to promote safe food handling practices.

2. IDENTITY AND BACKGROUND OF PARTIES

The U.S. Department of Agriculture (USDA) is responsible for ensuring that the nation's commercial supply of meat, poultry and egg products are safe, wholesome, and correctly labeled as required by the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act. USDA provides information on food safety to every county in the Nation, offering education that links research, science, and technology to people where they live and work. The Food and Drug Administration and the Centers for Disease Control and Prevention are agencies within the U.S. Department of Health and Human Services. FDA is the lead agency responsible for promoting and protecting the public health by ensuring that the food is safe and wholesome under the Federal Food, Drug, and Cosmetic Act. CDC is the lead agency responsible for promoting health and quality of life by preventing and controlling disease.

The Partnership for Food Safety Education is comprised of food industry groups, and others interested in promoting safe food handling behavior to prevent foodborne illness.

3. BACKGROUND

Food borne infections remain a major public health problem. The council for Agricultural Science and Technology, a private non-profit organization, estimated in its 1994 report, **FOODBORNE PATHOGENS: RISKS AND CONSEQUENCES**, that as many as 9,000 deaths and 6.5 to 33 million illnesses in the United States each year are food related. Hospitalization costs alone for these illnesses are estimated at over \$3 billion a year. Costs for lost productivity for 7 specific pathogens have been estimated to range between 6

billion and \$9 billion. 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. Total costs for all foodborne illnesses are likely to be much higher.

As a result, new food industry regulations have been recently introduced to improve food safety. These new regulations require food manufacturers to use a science-based system of hazard identification and control measures called Hazard Analysis Critical Control Point (HACCP). Using the HACCP system, a food manufacturer analyzes the production system, identifies where a hazard may enter the food, implements a control measure to prevent the hazard from occurring, then constantly monitors the system to assure that the control is effective in producing a safe product.

While this new system will reduce harmful contamination and reduce the risk of illness for consumers it can not eliminate harmful bacteria. Consumers play an essential role in foodborne illness prevention. How they prepare and handle food at home and the decision to eat foods that may increase the risk of foodborne illness can have a significant impact on public health.

Recent survey research shows a decline in consumer knowledge about safe food handling. Moreover, recent focus group research shows that many consumers do not understand the basic safe food handling messages that have been in use by government and industry for years. Newly designed messages are needed for the consumers of the 21st century.

While the general public needs to understand safe food handling and its role in preventing illness, current campaigns are diverse and often complex. A unify theme and basic set of simple, common and meaningful messages is needed to raise consumers' consciousness and motivate them to pay attention and improve their food handling behavior.

No single private or public entity commands the creative, human and financial resources to mount a major, high-impact safe food handling campaign. A partnership between the private and public sectors will bring together the necessary resources to create, launch and maintain such a broad food safety educational effort.

3. STATEMENT OF MUTUAL INTERESTS AND BENEFIT

The signatory parties recognize a mutual interest in improving the health of Americans by changing their unsafe food handling practices. The parties propose to carry out this common objective by developing accurate, science-based, and consumer-oriented messages to promote safe handling behaviors. In undertaking their independent projects, the parties will share information and serve as technical resources, with each other.

4. STATEMENT OF RESPONSIBILITIES

The Partnership for Food Safety Education and USDA, FDA and CDC will work together, to develop one overarching theme or slogan akin to "Five A Day" or "Only You Can Prevent Forest Fires." Key educational messages will be channeled through existing networks of each signator and the outlets such as the media; local, state and federal governments; public health officials; consumer-based organizations; and private sector businesses.

In consideration of the above state mutual interests and objectives, the parties agree to do the following:

USDA, FDA, and CDC shall:

- a. Provide liaison to the Partnership
- b. Coordinate communication between the Partnership and other government agencies;
- c. Provide such technical assistance and support to the Partnership, as may be agreed upon, and document in writing, where practical, projects for the development, implementation, and evaluation of science-based and consumer-oriented messages to promote safe food handling practices;
- d. Share information with the Partnership, including consumer-based market research promoting the Partnership and the safe food handling messages; and
- e. Provide opportunities, as appropriate, to communicate Partnership messages through USDA, FDA, and CDC publications, programs, and activities.

The Partnership shall:

- a. Request that USDA, FDA, and CDC identify contact persons to serve as liaisons to the Partnership;
- b. Ensure that membership of the Partnership fairly reflects the broad spectrum of stakeholders in the food, food safety and health community;
- c. Develop science-based and consumer-oriented messages that promote safe food handling practices utilizing technical assistance and other support, as may be agreed upon from USDA, FDA, and CDC;
- d. Share useful consumer research and other information generated by members of the Partnership with USDA, FDA, and CDC for promotion of and education about safe food handling;
- e. Ensure that all Partnership-developed messages to be released as a part of this MOU receive approval by USDA, FDA, and CDC;
- f. Provide opportunities for USDA, FDA, and CDC to utilize

Partnership-developed messages and materials through their respective publications, programs, and activities.

5. STATEMENT OF APPLICATION AND LIMITATIONS

It is mutually agreed and understood by and among the said parties that:

a. They will meet at least annually to review implementation of this MOU and to recommend any appropriate modifications;

b. This MOU shall not restrict the parties from participating in similar activities or arrangements with other public or private agencies, organizations, or individuals;

c. The MOU does not obligate any funds. Any joint endeavors involving reimbursement of funds among the parties to this MOU will be handled in accordance with applicable laws and regulations and will be subject to a supplemental agreement which shall be effected in writing by the parties;

d. The parties agree to review and assess the effectiveness of the science-based, consumer oriented safe food handling messages developed pursuant to the efforts carried out under this MOU, on a periodic basis; and

e. The principal contacts for the MOU are:

April 17, 1997 DRAFT

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

REPORT TO THE PRESIDENT

10/1/97

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EXECUTIVE SUMMARY

Every day, thousands of Americans are stricken by illness caused by the food they consume, and some 9,000 a year--mostly the very young and elderly--die as a result. The threats are numerous and varied, ranging from *Escherichia coli* (*E. coli*) O157:H7 in meat and apple juice, to *Salmonella* in eggs and on vegetables, to *Cyclospora* on fruit, to *Cryptosporidium* in drinking water--and most recently, to hepatitis A virus on frozen strawberries.

Ensuring and improving the safety of the food supply is one of government's most enduring and important functions. It is also one of the most challenging areas facing federal, state and local governments. Disease-causing microorganisms (pathogens) threaten the public health, and in some cases, the threat is growing and becoming more deadly. To address that concern, on January 25, 1997, President Clinton asked the Secretary of Agriculture and the Secretary of Health and Human Services, and the Administrator of the Environmental Protection Agency to report recommendations in 90 days for improving the safety of the American food supply.

Our understanding of many pathogens and how they contaminate food is limited; for some, we do not know how much must be present in food for there to be a risk of illness. The public-health system in this country has had a limited ability to identify and track the causes of foodborne illness; and federal, state and local food-safety agencies need to improve coordination for more efficient and effective response to outbreaks of illness. Resource problems increasingly limit the ability of federal and state agencies to inspect food processing facilities (e.g., years can 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 U.S. food supply is among 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 is putting in place a safety assurance system for the harvesting, processing, transportation, handling, and storage of food. That system, which relies upon preventing food contamination, should be put into place at every step of the food-delivery process--from the farm to the dinner table. Known as Hazard Analysis Critical Control Points (HACCP), it represents a model that better allocates responsibility between government and the private sector.

To prepare this report, USDA, HHS, and EPA conducted extensive discussions and deliberations 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 working

in partnership with state and local officials, the food industry, animal-health experts, 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 to build a foundation for improved food safety for years to come.

This report builds on this model, and presents recommendations in seven areas:

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” to 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, four agencies are charged with responding to outbreaks of foodborne and waterborne illness: the Department of Health and Human Services’s Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA), the U.S. Department of Agriculture’s Food Safety and Inspection Service (FSIS), and the Environmental Protection Agency (EPA). But the current system needs significant improvements in communication, data sharing, and understanding of agency roles. These problems will be fixed by:

- Establishing an intergovernmental group to coordinate the federal responses to outbreaks, and ensure that one person speaks for all during each phase of an outbreak.
- Enhancing the 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.** The objective of risk assessment is to characterize the nature and size of a risk to human health associated with hazards, which in turn can aid regulators in making decisions about controlling those hazards. Risk-assessment activities will be improved by:

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

4) **Research -- Expand research to develop new methods for identifying and controlling foodborne pathogens.** 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. Research will immediately focus on:

- Developing rapid, cost-effective tests for the presence of pathogens, such as *Salmonella*, *Cryptosporidium*, *E. coli* O157:H7, and hepatitis A virus.
- Enhancing understanding of how pathogens become resistant to food preservation techniques and antibiotics.
- Developing technologies for prevention and control of pathogens.

5) **Inspections -- Increase the frequency of FDA's inspections with more resources, expanded use of HACCP and partnerships with the states, and increased coverage of imported foods.** Foods subject to FDA inspection are much less frequently inspected than they should be, as FDA has only 700 inspectors and laboratory personnel to cover 53,000 U.S. food plants and 3 million annual imports. Furthermore, significant numbers of new inspectors are needed to implement HACCP. The most efficient mechanism for ensuring that inspections are effective is by having food processors use HACCP preventive controls. Thus, recommendations are to :

- Implement HACCP requirements for seafood by adding new seafood inspectors, and transferring the Department of Commerce 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 imported foods are 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 do so safely, and health professionals need better training for 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 recommendations above can be immediately implemented to improve food safety. These next steps, however, do not constitute a comprehensive, strategic plan for improving the nation's food safety system. And 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 will identify and attack foodborne illness over the coming decades and identify systemic changes (including organizational, procedural, and structural changes) that will 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 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. ^{subsequently} 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, universities, food producers, manufacturers, distributors, representatives of the retail and restaurant sectors, veterinarians and health professionals, and many others. ~~Over the past 90 days,~~ ^{The} agencies held two public meetings on March 5th and March 31-April 2, ^{and established} The goal of the initiative announced by the President is to reduce the incidence of foodborne illness to the greatest extent possible. The recommendations presented in this report are based on ^a the public-health principles that society should identify and take preventive measures to reduce ^{public} the risk of illness and that it should focus its efforts on hazards that present the greatest risks.

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. Despite our best measures, foodborne illness still occurs in the United States. Over the past four years, the Clinton Administration has developed and implemented major steps towards improving food regulation:

- 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 ~~over~~ the government and industry}
 - 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, and will streamline regulation of foods, increase the industries' responsibility for and control of their safety-}
- ^{These new regulations will} ^{should move toward a system of preventive controls (describe HACCP.)}

To start the discussion, the agencies issued a draft document summarizing their initial ideas.

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written comments

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

- 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 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.

HOW THIS REPORT WAS PRODUCED

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 that summarized the current thinking of the federal agencies about the resources and activities needed to significantly reducing the incidence of foodborne illness. The draft was based on the premise that an effective food-safety initiative must have several interrelated components that together could achieve greater reductions in the incidence of foodborne illness than any single component could. Moreover, those components 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. Those interrelated components include surveillance, coordination, risk assessment, research, inspections, and education, and strategic planning.

Achieving a significant reduction in the incidence of foodborne illnesses requires cooperative efforts of public-health and regulatory agencies at the federal, state, tribal, and local levels, as well as all other responsible and concerned parties. 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. Dialogue among these parties was an essential part of

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completing this report.

To maximize opportunities for dialogue and feedback, several 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 - April 2. Those meetings presented opportunities for stakeholders to comment on the preliminary recommendations 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 90-day public discussion process.

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.

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.

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 can 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 also not the only pathogens. Other foodborne pathogens, such as the hepatitis A virus and *Vibrio vulnificus*, also are important causes of foodborne disease. However, focusing on the most frequent causes of serious foodborne disease creates the greatest opportunity for immediate public health benefits.~~ Some of the most serious contaminants are described below ---

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 (SE) in eggs. Over the past decade, more than 500 outbreaks have been attributed to SE with more than 70 deaths. In 1994, an estimated 224,000 people became ill from consuming ice cream in one outbreak alone.

Campylobacter

The bacterium *Campylobacter* is the most frequently identified cause of acute infectious diarrhea in developed countries and is the most commonly isolated bacterial intestinal pathogen in the United States. It has been estimated that between 2 and 4 million cases of campylobacteriosis occur each year with an associated 120-360 deaths.

Campylobacter jejuni and *Campylobacter coli* (two closely related species) are

commonly foodborne, and are the infectious agents most frequently described in association with Guillain-Barré syndrome, as frequently as 1 in 1000 cases. Several prospective studies have implicated raw or undercooked chicken as major sources of *C. jejuni/coli* infections. Unpasteurized milk and untreated water have also caused outbreaks of disease.

Shiga-like toxin-producing *Escherichia coli*

Several strains of the bacterium *E. coli* cause a variety of diseases in humans and animals. *E. coli* O157:H7 is a type associated with a particularly severe form of human disease. *E. coli* O157:H7 causes hemorrhagic colitis, which begins with watery diarrhea and severe abdominal pain and rapidly progresses to passage of bloody stools. It has been associated with HUS, a life-threatening complication of hemorrhagic colitis characterized by acute kidney failure that is particularly serious in young children. *E. coli* O157:H7 is found in cattle, but there may be other reservoirs; the dynamics of *E. coli* O157:H7 in food-producing animals are not well understood. Approximately 25,000 cases of foodborne illness can be attributed to *E. coli* O157:H7 each year with as many as 100 deaths resulting. *E. coli* O157:H7 outbreaks have recently been associated with ground beef, raw milk, lettuce, and minimally processed and fresh fruit juices. The most recent outbreak in the Fall of 1996 in three western states and British Columbia was associated with unpasteurized apple juice, sickened 66 people, and caused the death of one child.

Toxoplasma gondii

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

Cryptosporidium parvum

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

in animal manures.

Norwalk virus

Norwalk viruses are important causes of sporadic and epidemic gastrointestinal disease that involve overwhelming, dehydrating diarrhea. An estimated 181,000 cases occur annually with no known associated deaths. In January 1995, a multistate outbreak of viral gastroenteritis due to Norwalk virus was associated with the consumption of oysters. A 1993 Louisiana outbreak of Norwalk virus gastroenteritis involved 70 ill people and was associated with the consumption of raw oysters. In 1992, another outbreak resulted in 250 cases. Outbreaks of Norwalk virus intestinal disease have been linked to contaminated water and ice, salads, frosting, shellfish, and person-to-person contact, although the most common food source is shellfish. Several such outbreaks are believed to have been caused by oysters contaminated by sewage dumped overboard by oyster harvesters and recreational boaters.

Other pathogens and contaminants

Many other foodborne pathogens 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-like 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

our food safety "system"
~~The safety of food is ensured a system that,~~ 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:

- 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. 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. ✓

- 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 ~~has~~ ^{devotes} ~~fewer than~~ ^{about} 700 inspectors and laboratory personnel ~~devoted~~ 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. *Status? Next step?* ✓
- 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) 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*, 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.~~ *too detailed*
- 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.

be explicit about FDA responsibility

discuss limits of authority?

Research describe base education describe separately

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. 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~~ ^{or both}

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. Those responsibilities are carried out by USDA's Agricultural Research Service, FDA, CDC, EPA, the National Institutes of Health (NIH), other federal components, and the states. 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. 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.

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

The system for identifying and preventing foodborne illnesses described above was largely created in the early 1900s. It must be modernized. The system cannot properly identify, track, control, or and prevent food-related illness or prevent future cases from occurring. In 1981, FDA inspected food firms every 2-3 years; plants now are visited, on average, only once every 10 years (although some plants that produce higher-risk foods may be visited 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.

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~~
~~The actions and recommendations in this report~~
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 and impose the greatest economic burden on the nation, ~~should~~ ^{should} emphasize development and implementation of preventive controls of those risks, ~~should~~ ^{seek to} ensure that preventive controls are cost-effective, and ~~should~~ ^{seek} opportunities for such controls through a collaborative process with the responsible sectors of the food industry and all other stakeholders. That ~~prevention-control~~ ^{prevention} concept is HACCP, a science-based, state-of-the-art process for building safety into the production, handling, and storage of food. HACCP is

The Administration

define HACCP in one place above

The Clinton Administration ¹⁴ has already taken a number of steps to modernize the food supply (A)

And The Administration is emphasizing the use of HACCP principles.

already said
~~being implemented by the meat, poultry, and seafood industries with FSIS and FDA regulatory oversight. Applying HACCP to other types of food, including animal feeds, could 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 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 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).

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 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.

Recommendations

Surveillance for antimicrobial resistance will allow early detection or 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} ~~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. ✓

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

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.
- provide*
hire and train personnel, at
to

Enhance early detection of foodborne disease nationwide

An early-warning system would enhance improved early detection of foodborne disease in additional states in FY98 by providing resources for improved surveillance, investigation, control, and prevention of foodborne disease outbreaks. Although sophisticated laboratory studies can identify causes of illness and show relationships among pathogens, laboratory methods are insufficient without investigators who can collect samples, interview people, and trace the source of contamination to find out why the illness occurred. New electronic tools need to be developed to enable rapid detection of outbreaks and to enhance communication about outbreaks to appropriate agencies. CDC also should provide additional resources to states to increase their surveillance and response capacity for the serious long-term consequences of foodborne disease, such as HUS.

FY97 Activities

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

FY98 Activities with Food-Safety Initiative Funds

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

Long-term Activities

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

Modernize Public-Health Laboratories

CDC should provide resources and training to upgrade public-health laboratory capabilities in FoodNet sites and in states without those sites so the laboratories can rapidly identify a broad range of foodborne infections, including those caused by parasitic and viral pathogens, and can use new techniques of DNA fingerprinting. The new capacities would allow rapid identification

of the cause of some outbreaks that currently go undiagnosed.

FY97 Activities

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

FY98 Activities with Food-Safety Initiative Funds

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

Long-term Activities

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

Is this
better
placed
under
research?

Create a National Electronic Network for Fingerprint Comparison

CDC should fund a new computer network and database system that would capture fingerprints of pathogens in a national database, linking CDC, FDA, USDA, and states that have that new capacity into a new national network. This technology would, for example, permit rapid recognition that an *E. coli* O157:H7 bacterium cultured from a patient in Washington was indistinguishable from one isolated from another patient in California. That might suggest to public-health investigators that a product distributed in California and Washington was contaminated with the organism.

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

FY97 Activities

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

FY98 Activities with Food-Safety Initiative Funds

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

per our discussion, explain how we will use this information to reduce illness

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

FY97 Activities

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

FY98 Activities with Food Safety Initiative Funds

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

Long-term Activities

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

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

FY98 Activities with Food-Safety Initiative Funds

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

Long-term Activities

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

INTERSTATE OUTBREAK CONTAINMENT AND RESPONSE COORDINATION

Background

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

Each of the four federal agencies has a potentially critical role when an outbreak occurs. CDC's primary responsibility is to assist state and local health departments in investigating outbreaks of illness and in identifying the cause of the outbreak. FDA, FSIS, and EPA also have responsibility for determining whether a product they regulate may be causing illness, and of halting the spread of illness by taking regulatory action against the suspect products, or wastes (other than animal manures) that have the potential to contaminate the air, land, or waters used to produce the food product. The type of food affected determines which regulatory agency has primary jurisdiction: FSIS regulates meat, poultry, and egg products; FDA regulates all other foods including shell eggs; and EPA regulates water and pesticides and manages organic and inorganic wastes used or disposed of on agricultural land. While each agency has clearly defined areas of responsibility, the successful containment of many outbreaks of foodborne illness involves more than one agency.

The states and many local governments also have a critical role. Identification and investigations of foodborne illness often begin at the community or state level. States share with the federal government the legal responsibility for protecting the health of their residents. Although food outbreaks are sometimes local because of improper processing or handling, most outbreaks implicate federal agency jurisdiction. Illnesses cross state borders, and most foods or food ingredients are processed or produced in another state or by international trading partners. Federal involvement is also necessary when contaminated foods from the same sources have been distributed to grocery stores, restaurants, and homes in more than one state.

*legal
authorities*

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

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

product recalls are voluntary. Federal and state agencies can benefit from industry's expertise about food products and their distribution patterns.

Problem

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

Recommendations

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

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

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

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

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

FORCG will review and evaluate outbreak response. FORCG will undertake these reviews after appropriate consultation with industry and consumer representatives. Based on these

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

FY97 Activities

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

FY98 Activities with Food-Safety Initiative Funds

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

RISK ASSESSMENT

Background

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

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

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

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 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

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

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

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. The consortium should be inclusive in its risk assessment activities, seeking expertise from risk assessment professionals and scientists from public and private sources as well as industry and consumer groups.

FY97 Activities

- The consortium, which will include all interagency partners, will be established in 1997 as part of the Joint Institute for Food Safety and Applied Nutrition, a collaborative activity of FDA's Center for Food Safety and Applied Nutrition and Center for Veterinary Medicine and the University of Maryland. The consortium 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 will be inclusive in its risk-assessment activities, seeking expertise from risk assessment professionals and scientists from public and private sources, and industry and consumer groups. The initial focus of the initiative will be on pathogenic microorganisms. A compilation of current ongoing microbial risk assessment research will be used to evaluate developing methodologies and models to develop algorithms and guidelines for microbial risk assessment. The consortium will begin the process of establishing a clearinghouse that will collect and catalogue available methodology, specifically simulations necessary to address microbial growth and death variables

offered by the private sector, trade associations, federal and state agencies, and international sources.

FY98 Activities with Food-Safety Initiative Funds

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

is this internal only?

Long-term Activities

- The consortium will continue to collectively identify critical research needs, propose effective research on analytical approaches and methods, and reach consensus on the priority of these needs based on their potential to reduce the uncertainty of risk-management decisions in food safety and provide the greatest positive impact. Research supported and conducted through this initiative would cover several areas critical to developing our ability to conduct risk assessments for foodborne disease-causing organisms and to assess the effectiveness of control measures.

Develop Better Modeling Techniques and Better Use of Data to Assess Exposure to Microbial and Chemical Contaminants, Including Animal Drug Residues, through the Food Supply

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

FY98 Activities with Food-Safety Initiative Funds

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

- Address the dynamics of foodborne pathogens in agricultural environments (e.g. feed and 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. To reduce uncertainties in exposure estimates, the consortium will work with researchers who are conducting focused food-consumption surveys targeting foods consumed by a variety of subpopulations (e.g., children).

Develop Dose-Response Assessment Models for Use in Risk Assessment

Research is needed to estimate the relationship between the quantity of a biological agent and the frequency and magnitude of adverse human health effects in a population. Dose-response assessments typically include estimates of the rates of infection, morbidity, and mortality.

FY98 Activities with Food-Safety Initiative Funds

Research projects to be considered and prioritized by the consortium include:

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

Long-term Activities

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

RESEARCH

*Need coordination
mechanism for
research*

Background

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

Problem

New foodborne pathogens have emerged over the past ten years. Other microorganisms, previously thought to be innocuous, have been linked to life-threatening diseases after acquiring new virulence genes and antimicrobial resistance. Many of those organisms cannot be detected readily due to either a lack of suitable methods or their sporadic occurrence in foods. Certain foodborne pathogens are increasingly associated with resistance to time-tested controls, such as heating, refrigeration, and acid. In some cases, that ability appears to be linked with increased virulence or new ways to evade our immune defenses.

Recommendations

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

Improved Detection Methods

Many pathogens cannot be easily detected in foods, e.g., hepatitis A virus on strawberries. Among the needs for improved diagnostics, methods are needed for rapid, cost-effective testing for pathogens in food animals and their manures, in agriculture and aquaculture products, animal feeds, and processed food products. For those pathogens, 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 detection methods and control measures for *Cyclospora*.

FY98 Activities with Food-Safety Initiative Funds

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

Long-term Activities

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

Understanding Resistance to Traditional Preservation Technologies

Microorganisms that are resistant to antimicrobial agents and conditions that have been relied on traditionally to eliminate or prevent the growth of foodborne pathogens have become increasingly important causes of serious foodborne disease. Research is needed to determine how microorganisms associated with foodborne disease become tolerant to various types of antimicrobials and to traditional food-safety safeguards, such as heat or cold, low pH, high salt, and disinfectants, and to elucidate factors in animal- and plant-production systems and processing environments that influence the development of resistance. The physiological and genetic bases of resistance are not understood well enough to prevent breakthrough of newly emerging pathogens. Such research will help identify food production, processing, and handling practices that are likely to contribute to pathogen contamination or proliferation. That research is also needed to guide improvement of traditional techniques and the development of new interventions.

Long-term Activities

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

Understanding Antibiotic Drug Resistance

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

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 nonresistance. Research should emphasize competitive exclusion techniques (probiotics) and the use of extended drug-withdrawal periods. Probiotics are benign bacteria that can be used to out-compete pathogenic bacteria.

Prevention Techniques: Pathogen Avoidance, Reduction, and Elimination

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

FY98-Activities with Food Safety Initiative Funds

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

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

Long-term Activities

- *Such as* USDA and FDA should undertake research to develop new decontamination methods for *Contaminant* *Vibrio* and Norwalk virus on or in marine-harvested and aquaculture-reared seafood, and *for Cyclospora* and hepatitis A virus on fresh produce.
- ARS, CREES, and FDA should work with industry and academia to develop new techniques that provide alternatives to traditional thermal processing for eliminating pathogens. *[anything we can say about speeding consideration of emerging technologies?]*
- FDA and 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 might contribute to the dissemination of foodborne pathogens. Effective packaging and proper food-storage conditions are critical to maintaining the level of safety achieved by processing.

Long-term Activities

- USDA and FDA should undertake research to identify factors that contribute to the spread of microorganisms during transportation of live animals and fresh produce and

develop techniques for eliminating cross-contamination.

- FDA and USDA should work with industry and academia to develop and assess the effectiveness of in- or on-package sensors of storage conditions to alert consumers of products not stored safely.

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 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.

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. FSIS is faced with a similar challenge of continually providing the most effective food-safety and consumer-protection program 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 to ensure that food processors identify and control hazards that could threaten food is the application of the HACCP concept. 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 meat and nonmeat foods are inspected by FSIS inspectors trained in FDA inspectional standards. Without such cooperative agreements, both FSIS inspectors and FDA inspectors could inspect these plants. FSIS inspectors already are in these plants, and their presence could be better used to maximize use of federal resources without loss of inspectional coverage for FSIS-regulated foods.
- FSIS ^{is evaluating and} will conduct a series of public meetings to discuss:
 - How HACCP requirements ^{will be} implemented in slaughter plants consistent with carcass-by-carcass inspection and how the roles and responsibilities of inspection personnel will change with that implementation.
 - The design and testing of new inspection concepts consistent with HACCP principles to achieve food-safety and other consumer-protection objectives through distribution and retail channels to consumers.
- FSIS and state associations will complete development of HACCP-based control measures for meat and poultry processing at the retail level.

FY98 Activities with Food-Safety Initiative Funds

- FDA will implement seafood HACCP by hiring approximately 80 investigators to conduct inspections to ensure proper implementation of seafood HACCP.
- 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. That 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.

Add discussion

37

of new FSIS ~~evaluators~~ pilots evaluating allocation of inspectors

regulatory options ~~from~~ to reduce risks in the

Can this be done with FDA

shell egg rule, including whether

or how to require HACCP for those foods.

Long-term Activities

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

- The Administration*
- ~~FDA~~ should evaluate the voluntary fee-for-service seafood program and the operational functioning of the seafood PBO.

Aid States in **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 ensure that consumers are protected. U.S. retail establishments include 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

- FDA and USDA will join the expertise of federal, state, and local agencies, industry, and professional and trade associations in an alliance 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. That training will augment the training program for federal inspection personnel, more fully covering the farm-to-table process.

- *(See also "Education")*

Long-term Activities

- The Food Code, particularly the HACCP provisions, should be adopted 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. New federal-state partnerships focused on coordinating inspection coverage (particularly between FDA and the states), is a major step in this direction.

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.
- (Mentioning on interstate shipment of meat?)

Long-term Activities

- FDA and USDA should work more closely with industry, professional and trade associations, and academia to ensure effective implementation of HACCP, particularly at the production, processing, and retail levels. principles
- 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 Inspection Coverage of Imported Foods

Regulated by FDA To Address the Problem of Rising Imports and FDA's Inability to Provide Adequate Coverage

FDA will pursue strategies to enhance inspection of imported foods...

define problem; describe current activity briefly.

FY98 Activities with Food-Safety Initiative Funds

- FDA will expand its program to develop mutual recognition agreements (MRAs) with trading partners. *explain*
- 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.

Long-term Activities

- FSIS should continue to verify foreign government-inspection progress for conformance with the new HACCP and pathogen-regulation requirements; that activity will begin in 1997 and should be completed in 2000.
- The laboratory-certification process should be extended to include assessing the utility of existing accrediting bodies with FDA providing performance standards and oversight to the process.
- FDA should expand the federal-state communication system states use to inform federal agencies of problems found with imported products in their jurisdictions. As part of that expansion, FDA should evaluate the feasibility of combining the communication system with the federal-state inspection data system discussed above, making the data and information more widely accessible.

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

- ^{jointly} ~~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.~~

performance standards,

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.")

Is this regulatory? How does it relate to ANPRM mentioned earlier. Isn't it funded by base?

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 industry have been fostering 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-handling practices. Without the practice of food-safety knowledge and proper food-handling procedures, foodborne illness will not be significantly reduced. Individuals at each stage from the farm to table 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. For example, consumers' food-handling practices will either increase or decrease the chances of foodborne illness. Studies show that 53% of the public eats raw eggs, 23% eats undercooked hamburger, 17% eats raw clams and oysters, and 26% do not wash cutting boards after using them for raw meat or poultry.

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

Health professionals and physicians need more knowledge to detect and treat foodborne illnesses better. 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 daycare, and senior daycare. 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 research and develop effective food-safety education materials and services for consumers and for food-service operations. A national food-safety-education program for consumers, retail workers 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.

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

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, such as using electronic communications technology and consolidating government food-safety Internet sites to reach larger audiences.
- Begin a process to establish a national food safety education council. The council, through an independent scientific-review board, will establish long-term 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.

Improve Consumer Education

Consumer education will be conducted in several phases. The first phase will begin immediately and has the goal of raising awareness of the general public to the need to use safe food-handling practices. A second phase will build a long-term education program designed to 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 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 national food-safety awareness.
- Promote September as National Food Safety Education Month, which was established 2 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 food safety education council, a scientific-review board would be convened 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, as the food guide pyramid does for nutrition principles.
- Through partnerships and alliances, implement a massive education campaign to encourage the use of the new educational tools 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 people) 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 multilingual program to change food workers' unsafe food-preparation behaviors. The 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, and private parties, to promote multilingual education efforts on retail and food-service food-safety issues. Use existing networks to strengthen education programs 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.

Long-term Activities

USDA, FDA and CDC should:

- Continue to expand educational programs for producers of animals for human food consumption, veterinarians, and 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 should be developed and disseminated through existing networks to food producers and the veterinary medical community.
- 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.

Improve Industry Education in the Transportation Area

Long-term Activities

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

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.

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.

The strategic-planning process will consider how to make best use of the limited resources that each agency has. For example, 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 which manufacture products regulated by both agencies, or even products which must meet different regulatory requirements from the two agencies (such as fresh produce used in the school lunch program). The strategic-planning process will also consider how scarce research dollars in each agency can best be utilized. In addition, the strategic-planning process could consider:

- Improving coordination among all food safety participants in numerous aspects of prevention and response.
- Improving the infrastructure for rapid identification and response to outbreaks.
- Developing a strategic, long-range risk assessment and research agenda.
- The structure of a coordinated, strategic plan for food-safety regulation and research.
- Policy and technical issues associated with agricultural manures.
- Policy and technical issues associated with food irradiation.
- Exchange of information about foodborne disease outbreaks.
- Best approaches to prevention, intervention, and control.

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.

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.

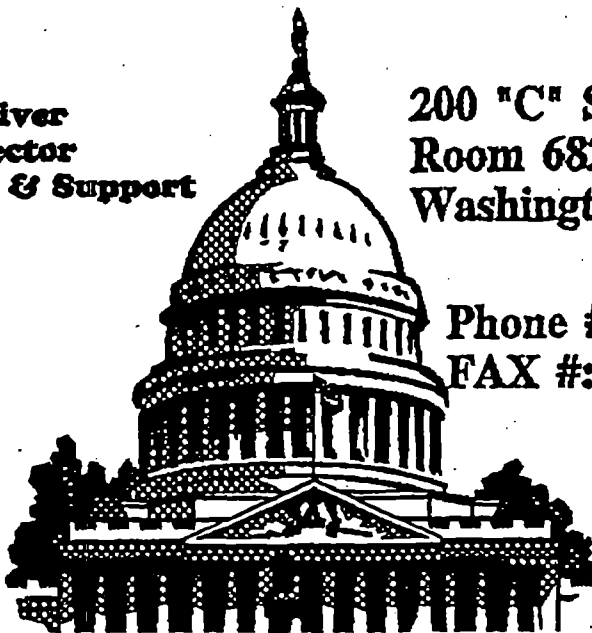
Budget Request for Food Safety Initiative Activities: FY98

Food Safety Initiative Activity	Budget Request			
	FDA	USDA	CDC	EPA
Coordination	\$ 0.550	\$ -	- -	- -
Surveillance	3.160	0.500	\$ 10.000	- -
Inspections	7.870	0.565	- -	- -
Education	2.070	2.000	- -	- -
Risk Assessment	3.950	- -	- -	- -
Research	6.400	6.114	- -	- -
Total	\$24.000	\$ 9.179	\$ 10.000	\$ 0

FDA/CFSAN

Janice F. Oliver
Deputy Director
for Systems & Support

200 "C" ST., SW/HFS-3
Room 6820
Washington, DC 20204



Phone #: (202) 205-4307
FAX #: (202) 205-5025

TO:

Elizabeth Drye
456-5581
Joan Mondschein
720-9600

FAX NO.

Margarie Davidson
720-9063

NO. OF PAGES

9

FROM:

Janice Oliver

DATE:

4/18/97

Comments: _____

This document is intended for the use of the party to whom it is addressed and may contain information that is privileged, confidential and protected from disclosure under applicable law. If you are not the addressee, or a person authorized to deliver the document to the addressee and received this document in error, please immediately notify us by telephone and return it to us as soon as possible. Thank You.

BACKGROUND BULLETS

PARTNERSHIP FOR FOOD SAFETY EDUCATION

- FDA, USDA, and CDC are in the process of finalizing a public private partnership through a memorandum of understanding with industry on food safety education for consumers.
- Interested members of the food industry, government agencies, and consumer groups are joining together to form a coalition with the primary goal of changing consumer unsafe food handling behavior through a new, widely promoted public awareness and education campaign.
- The partnership will work together to develop one overarching theme or slogan and key educational messages to be part of the foundation of the educational efforts.
- Research/consumer focus groups will be used.
- The theme and messages will be channeled through outlets such as the media; local, state and federal governments; public health officials; consumer based organizations; and the private sector.
- At the present time, the industry members have pledged approximately \$500,000 toward the development and production of the educational campaign. They have the goal of raising \$1 million the first year of the partnership.
- The government agencies have agreed to provide technical assistance and support, where practical, for the development, implementation, and evaluation of the educational projects; to share information including consumer-based market research; and provide opportunities, as appropriate, to communicate the messages through publications, programs and activities.
- The industry group with input from FDA has already submitted 4 concepts in food handling behaviors to 19 separate PR firms which have independently developed programs which are currently under review.
- Contracts with these PR firms involve developing slogans, specific messages on food safety education and conducting research on both before an educational program/campaign would begin.
- Progress on these messages and this program will be discussed at the June 12/13, 1997, Food Safety Education Conference being sponsored by USDA, FDA, and CDC (possibly Department of Education).

- Current members of the expanding partnership are:

From the Government:

Food and Drug Administration
U.S. Department of Agriculture
Centers for Disease Control and Prevention
[U.S. Department of Education]?

Representing the States:

Association of Food and Drug Officials

From the Industry:

American Meat Institute
Food Marketing Institute
Produce Marketing Association
Industry Council on Food Safety/National Restaurant
Association
American Egg Board
Grocery Manufacturers of America

Representing Consumers:

Coalition for Safe Food
Consumer Federation of America

- Meetings held with industry on April 14 and 17, 1997, and has been reviewed by HHS and USDA attorneys.
- The MOU should be finalized for signature by the government and industry on Monday, April 21, 1997. At this point the President and CEO of industry organizations have been designated to sign for industry. We have not yet finalized who will sign for the government departments or agencies.

April 18, 1997

Draft

PARTNERSHIP FOR FOOD SAFETY EDUCATION

Representatives of the food industry, government agencies, and consumer groups have joined together to form a coalition with the primary goal of changing consumer unsafe food handling behavior through a new, widely-promoted public awareness and education campaign. The partnership will work together to develop one overarching theme or slogan and key educational messages to be part of the foundation of the educational effort. The theme and messages will be channeled through outlets such as the media; local, state and federal governments; public health officials; consumer-based organizations; and the private sector.

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Industry Council on Food Safety/National Restaurant Association
American Egg Board
Grocery Manufacturers of America

Representing Consumers:

Coalition for Safe Food
Consumer Federation of America

At the present time, the industry members have pledged approximately \$500,000 toward the development and production of the educational campaign. They have the goal of raising \$1 million the first year of the partnership and are actively promoting the partnership to other associations. The government agencies have agreed to provide technical assistance and support, where practical, for the development, implementation, and evaluation of the educational projects; to share information including consumer-based market research; and provide opportunities, as appropriate, to communicate the messages through publications, programs and activities.

Currently, the Partnership has solicited proposals from 19 public relations firms to develop educational campaigns using the four safe food handling concepts that will be the core messages of the nation-wide effort. On April 24, four selected firms will present their proposals for a coordinated campaign to include a slogan, a logo, a character, consumer friendly messages, a massive awareness effort, and a targeted educational effort to reach special populations. All the messages will be evaluated for consumer acceptance through public marketing research. The Partnership will be highlighted at the USDA/FDA/CDC June 12 Food Safety Education Conference in Washington, D.C., and attendees will be invited to join an overarching alliance, of which this Partnership is one part.

DRAFT

MEMORANDUM OF UNDERSTANDING
among
THE U.S. DEPARTMENT OF AGRICULTURE
THE FOOD AND DRUG ADMINISTRATION
THE CENTERS FOR DISEASE CONTROL AND PREVENTION
and
THE PARTNERSHIP FOR FOOD SAFETY EDUCATION

This Memorandum of Understanding (MOU) is made and entered into among the U.S. Department of Agriculture, the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and the Partnership for Food Safety Education, hereinafter referred to as the Partnership.

1. PURPOSE

The purpose of the MOU is to provide a framework for cooperation among the parties as each develops science-based consumer-oriented messages to promote safe food handling practices.

2. IDENTITY AND BACKGROUND OF PARTIES

The U.S. Department of Agriculture (USDA) is responsible for ensuring that the nation's commercial supply of meat, poultry and egg products are safe, wholesome, and correctly labeled as required by the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act. USDA provides information on food safety to every county in the Nation, offering education that links research, science, and technology to people where they live and work. The Food and Drug Administration and the Centers for Disease Control and Prevention are agencies within the U.S. Department of Health and Human Services. FDA is the lead agency responsible for promoting and protecting the public health by ensuring that the food is safe and wholesome under the Federal Food, Drug, and Cosmetic Act. CDC is the lead agency responsible for promoting health and quality of life by preventing and controlling disease.

The Partnership for Food Safety Education is comprised of food industry groups, and others interested in promoting safe food handling behavior to prevent foodborne illness.

3. BACKGROUND

Food borne infections remain a major public health problem. The council for Agricultural Science and Technology, a private non-profit organization, estimated in its 1994 report, **FOODBORNE PATHOGENS: RISKS AND CONSEQUENCES**, that as many as 9,000 deaths and 6.5 to 33 million illnesses in the United States each year are food related. Hospitalization costs alone for these illnesses are estimated at over \$3 billion a year. Costs for lost productivity for 7 specific pathogens have been estimated to range between 6 billion and \$9 billion. 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. Total costs for all foodborne illnesses are likely to be much higher.

As a result, new food industry regulations have been recently introduced to improve food safety. These new regulations require food manufacturers to use a science-based system of hazard identification and control measures called Hazard Analysis Critical Control Point (HACCP). Using the HACCP system, a food manufacturer analyzes the production system, identifies where a hazard may enter the food, implements a control measure to prevent the hazard from occurring, then constantly monitors the system to assure that the control is effective in producing a safe product.

While this new system will reduce harmful contamination and reduce the risk of illness for consumers it can not eliminate harmful bacteria. Consumers play an essential role in foodborne illness prevention. How they prepare and handle food at home and the decision to eat foods that may increase the risk of foodborne illness can have a significant impact on public health.

Recent survey research shows a decline in consumer knowledge about safe food handling. Moreover, recent focus group research shows that many consumers do not understand the basic safe food handling messages that have been in use by government and industry for years. Newly designed messages are needed for the consumers of the 21st century.

While the general public needs to understand safe food handling and its role in preventing illness, current campaigns are diverse and often complex. A unify theme and basic set of simple, common and meaningful messages is needed to raise consumers' consciousness and motivate them to pay attention and improve their food handling behavior.

No single private or public entity commands the creative, human and financial resources to mount a major, high-impact safe food handling campaign. A partnership between the private and public sectors will bring together the necessary resources to create, launch and maintain such a broad food safety educational effort.

3. STATEMENT OF MUTUAL INTERESTS AND BENEFIT

The signatory parties recognize a mutual interest in improving the health of Americans by changing their unsafe food handling practices. The parties propose to carry out this common objective by developing accurate, science-based, and consumer-oriented messages to promote safe handling behaviors. In undertaking their independent projects, the parties will share information and serve as technical resources, with each other.

4. STATEMENT OF RESPONSIBILITIES

The Partnership for Food Safety Education and USDA, FDA and CDC will work together, to develop one overarching theme or slogan akin to "Five A Day" or "Only You Can Prevent Forest Fires." Key educational messages will be channeled through existing networks of each signator and the outlets such as the media; local, state and federal governments; public health officials; consumer-based organizations; and private sector businesses.

In consideration of the above state mutual interests and objectives, the parties agree to do the following:

USDA, FDA, and CDC shall:

- a. Provide liaison to the Partnership
- b. Coordinate communication between the Partnership and other government agencies;
- c. Provide such technical assistance and support to the Partnership, as may be agreed upon, and document in writing, where practical, projects for the development, implementation, and evaluation of science-based and consumer-oriented messages to promote safe food handling practices;
- d. Share information with the Partnership, including consumer-based market research promoting the Partnership and the safe food handling messages; and
- e. Provide opportunities, as appropriate, to communicate Partnership messages through USDA, FDA, and CDC publications, programs, and activities.

The Partnership shall:

- a. Request that USDA, FDA, and CDC identify contact persons to serve as liaisons to the Partnership;
- b. Ensure that membership of the Partnership fairly reflects the broad spectrum of stakeholders in the food, food safety and health community;
- c. Develop science-based and consumer-oriented messages that promote safe food handling practices utilizing technical assistance and other support, as may be agreed upon from USDA, FDA, and CDC;
- d. Share useful consumer research and other information generated by members of the Partnership with USDA, FDA, and CDC for promotion of and education about safe food handling;
- e. Ensure that all Partnership-developed messages to be released as a part of this MOU receive approval by USDA, FDA, and CDC;
- f. Provide opportunities for USDA, FDA, and CDC to utilize Partnership-developed messages and materials through their respective publications, programs, and activities.

5. STATEMENT OF APPLICATION AND LIMITATIONS

It is mutually agreed and understood by and among the said parties that:

- a. They will meet at least annually to review implementation of this MOU and to recommend

any appropriate modifications;

b. This MOU shall not restrict the parties from participating in similar activities or arrangements with other public or private agencies, organizations, or individuals;

c. The MOU does not obligate any funds. Any joint endeavors involving reimbursement of funds among the parties to this MOU will be handled in accordance with applicable laws and regulations and will be subject to a supplemental agreement which shall be effected in writing by the parties;

d. The parties agree to review and assess the effectiveness of the science-based, consumer oriented safe food handling messages developed pursuant to the efforts carried out under this MOU, on a periodic basis; and

e. The principal contacts for the MOU are:

J. Patrick Boyle, President and CEO
American Meat Institute

Tim Hammonds, President and CEO
Food Marketing Institute

Herman Kane, President and CEO
National Restaurant Association

John Farquharson, President
Industry Council on Food Safety
National Restaurant Association

Louis B. Raffel, President
American Egg Board

Bryan Silbermann, President
Produce Marketing Association

For the Government

For the Partnership for Food Safety

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.

*nature of - requires higher intensity inspection.
operational - careful scrutiny by gov't inspectors
to insure that diseased animals*

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.

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

- What it is about: is a mystery.
- Reduction of foodborne illness.
- Mgmt's resources 9's from a fragmented system.

*There is a
current
retention*

*1/3 of consumer
spending on
USDA products*

*Veterinary
inspection
program*

become clear

*in the context of
HACCP-based programs*

*Very
different
in terms
of
inspection.*

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. For example, 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 which manufacture products regulated by both agencies, or even products which must meet different regulatory requirements from the two agencies (such as fresh produce used in the school lunch program). The strategic-planning process will also consider how scarce research dollars in each agency can best be utilized. In addition, the strategic-planning process could consider:

- Improving coordination among all food safety participants in numerous aspects of prevention and response.
- Improving the infrastructure for rapid identification and response to outbreaks.
- Developing a strategic, long-range risk assessment and research agenda. *introduce problem*
- The structure of a coordinated, *comprehensive* strategic plan for food-safety regulation and research.
- Policy and technical issues associated with agricultural manures.
- Policy and technical issues associated with food irradiation. *food safety technologies*
- Exchange of information about foodborne disease outbreaks. *?*
- Best approaches to prevention, intervention, and control.

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.

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 inspectional coverage for domestic and imported products, changes in behavior, and better detection and quantification methodologies.

703-671-2928

Food Safety - 4/8

Dennis Lang. NIH

Steve Schab EPA

Forest Service Command Center.

Greg Olsen - -

Approx 1 million in industry -
- food safety;

Should be ready to

- Carol Tucker Foreman

- Good govt / good industry

labeling consider

- CDC - Physician education. - Under
consideration

- NAS/NRC; Keystone -

- Coordination -

- research -

- Irradiation -

NATIONAL SCIENCE AND TECHNOLOGY COUNCIL

CONCURRENCE SHEET

RETURN BY TUESDAY, APRIL 15, 1997

Please check the applicable box and sign in space provided.

**COMMITTEE ON ENVIRONMENT AND NATURAL RESOURCES : FY 1998
EDITION OF THE U.S. GLOBAL CHANGE RESEARCH PROGRAM'S *OUR
CHANGING PLANET***

- ☐ a. I approve publication of the report.
- ☐ b. I approve publication of the report with editing (attach comments).
- ☐ c. I do not approve and request to have further discussion with the Committee on
Environment and Natural Resources

Signature

Agency

Date

Telephone Number

Return by FAX to:
Angela Phillips Diaz
(202) 456-6026

KEY AGENCY: _____

NON-KEY AGENCY: _____ **X**

Management and Resource

Allocation problem

Options for solving, including
an independent food agency.

Specific Change. — look 10 long-term future —
identify —

Statutory change — req FSIS send
inspectors to every plant every
day.

— Pepperoni pizza plants. —

Food Safety - NOTES / Questions

- high cost of food borne illness
- optimal inspection system is one with different levels of intensity, consistent w/ degree of risk
- reliable monitoring system and accurate compliance history for each food establishment.
- FDA's enforcement strategy emphasizes end-product testing
- periodic inspections provide only snapshot
- FDA can't adequately cover universe of food processors
- process controls must be a priority (HACCP)
- FDA's assignment of priority is not based on P.A.
- FDA inspects once every 3-5 years (contrast: FSIS once / yr) ^{1/10}
- FDA lacks ^{necessary} enforcement powers to ensure a safe food supply.
 - lacks recall / seizure authority (p. 43) ?
 - little incentive for food establishments to exceed minimum requirements
 - food research is duplicative, driven by missions at 21 agencies (\$200 million annually)
diet; nutrients, pesticide/drug residues / infectious disease agents.

Recommendations

- specifically sound, risk based inspection system
- automated reporting system on inspection frequencies
- uniform regulator action to give inspectors enforcement authority
- administer all research funding

USDA - 6,000 Plants 1,000 inspectors
FDA - 53,000 Plants 700 inspectors

THE WHITE HOUSE
Office of the Press Secretary

For Immediate Release

January 25, 1997

January 25, 1997

MEMORANDUM FOR THE SECRETARY OF AGRICULTURE
SECRETARY OF HEALTH AND HUMAN SERVICES
ADMINISTRATOR OF THE ENVIRONMENTAL
PROTECTION AGENCY

SUBJECT: Improving the Safety of the Nation's Food Supply

Americans rightly expect to have the world's safest food supply. Although our food is unmatched in quantity and quality, we can do better in our efforts to eliminate disease caused by microorganisms and other contaminants. Americans still suffer thousands of food-related deaths and millions of food-related illnesses.

The 21st century will present new and greater challenges in this area. Novel pathogens are emerging. Long-understood pathogens are growing resistant to treatment. Americans eat more foods prepared outside the home, and we consume record levels of imported food -- some of which moves across the globe overnight. These changing circumstances require greatly strengthened systems of coordination, surveillance, prevention, research, and education.

My Administration has already taken a number of steps to improve food safety. We modernized the meat, poultry, and seafood safety systems. I signed into law new legislation to keep harmful pesticides off our fruits and vegetables -- and legislation that keeps our drinking water safe and pure. Today, I announced a new national early warning system for food-borne illness. The system will allow us to respond more quickly to disease outbreaks and to better prevent them in the future.

But we need to do more. Government, consumers, and industry must work together to further reduce food-borne disease and to ensure our food supply is the safest in the world.

I hereby direct that you work with consumers, producers, industry, States, universities, and the public to identify additional ways to improve the safety of our food supply through government and private sector action, including public-private partnerships. Your recommendations should identify steps to further improve surveillance, inspections, research, risk assessment, education, and coordination among local, State, and Federal health authorities. You should report back to me within 90 days with your recommendations.

WILLIAM J. CLINTON

#

AGENDA

1. Message Content

a) National early warning system (increase sentinel sites; link together electronically; DNA fingerprinting; disease detectives).

Issue: What's funded in base?

b) Other FY98 budget pieces -- seafood inspectors, research, education.

Issue: Add EPA \$ for Food Quality Protection Act

c) Directive -- work w/industry and consumers and report back in 90 days.

Issues: Specific language on scope, reference to 98 budget, reference to Food Quality Protection Act.

2. Potential Participants:

Administration:

POTUS

VPOTUS

Shalala, Kessler, Satcher

Glickman, ?

Browner, ?

Families of victims:

Industry

States

3. Program

POTUS remarks (no Q & A)

VPOTUS remark (no Q & A)

Secretaries?

4. Press

5. Outreach

Industry, Families, States

TO BE PREPARED/CIRCULATED

Fact Sheet 1-page

Other background (optional)

Q&A

Press release

Talking Points

Event Memo

Remarks

April 16, 1997

NOTE TO: Carolyn Huntoon 432 OEOB
Anne McGuire 160 OEOB
Lisa Grove 10202 NEOB
David Rostker 10202 NEOB
Adrienne Erbach 8013 NEOB
Jim Esquea 7002 NEOB
Sara Laskin 9215 NEOB

FROM: Elizabeth Drye

SUBJECT: Draft food safety report

Attached are five of the seven draft chapters for the food safety report for staff-level review. The Departments have not transmitted the report formally to the White House, this draft has not been cleared by Department heads, and I have not yet reviewed it. I asked agencies to share a copy with us so we could give them initial feedback this week.

I would like to meet with you tomorrow morning, **Thursday, 10:00 - 11:30 am, room 211 OEOB**, to share initial questions and concerns. Specifically, I'd like to identify recommendations on which we all agree and those that need further consideration. That should give us all a better idea of how much work we have to do and how fast we'll be able to do it.

Please call me if you have questions or cannot make the meeting. Thanks

April 15, 1997 DRAFT

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

NATIONAL FOOD SAFETY INITIATIVE

REPORT TO THE PRESIDENT

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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 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, universities, food producers, manufacturers, distributors, representatives of the retail and restaurant sectors, veterinarians and health professionals, and many others.

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

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.

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.

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.

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.

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.

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.

- Food processing for foods other than meat, poultry, and egg products (except shell eggs) is regulated by the FDA, whose inspectors are responsible for visiting about 53,000 plants periodically, with emphasis on the highest risk foods or processing techniques. FDA has fewer than 700 inspectors and analysts devoted to this activity. Meat, poultry, and all other egg products are regulated by FSIS, whose 8,000 inspectors are present in 6,200 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.
- 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.
- The importation of food from foreign countries is overseen by FSIS for meat, poultry, and most egg products and FDA for all other foods. If an imported food is suspect, it can be tested for contamination and its entry into the United States denied.
- Restaurants, supermarkets, and institutional food services (such as schools and hospitals) are generally regulated by 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.
- 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.

- In the home, consumers also have a responsibility for proper handling and storage of food, as consumer mishandling contributes to many cases of foodborne illness. As a result of this knowledge, FSIS promulgated safe handling labels for raw meat and poultry products.
- Other responsibilities related to food safety include research into the cause and transmission of foodborne illness, and education on treatment and prevention of foodborne illness. These responsibilities are carried out by the USDA, FDA, CDC, EPA, the National Institutes of Health (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.

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.

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.

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

oversight. The application of such preventive controls to other types of food, 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).

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 or 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.

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.

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.

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.
- 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.

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

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*.

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

- 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

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 toxico-infectious microorganisms. Further research is also needed into the use of biomarkers of susceptibility, chronic sequelae, microbiological toxicokinetics, and infectious dose.

BIOSCIENCE RESEARCH

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.
- USDA (ARS, CREES) and FDA, working with industry and academia, should develop new techniques for eliminating pathogens that provide alternatives to traditional thermal processing.
- 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 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.

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.

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.

Long-term Activities

- 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.

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.

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

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

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.")

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.

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.

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.

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

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. The conference will be a forum to introduce plans for national food safety awareness.
- 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