

BACKGROUND:
FOOD SAFETY

PHOTOCOPY
PRESERVATION



Richard Durbin

UNITED STATES SENATOR ■ ILLINOIS

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 June 24, 1999

**DURBIN, COLLEAGUES PROPOSE BIPARTISAN BILL TO IMPROVE
 FOOD SAFETY; CURRENT SYSTEM IS JUMBLE OF DIFFERENT AGENCIES**

Washington, D.C. — Saying the nation's current food safety system is a federal food fight that fails to adequately protect America's families, U.S. Sen. Dick Durbin (D-IL) today proposed bipartisan legislation to create a single, independent food safety agency to replace a system that involves as many as 12 different federal agencies and 35 different laws.

Joined by colleagues, consumer advocates and families at a news conference, Durbin said today's food safety system is a hodgepodge of programs created in response to individual outbreaks of foodborne illnesses over the years.

Noting there were more than 515 confirmed cases and five fatalities due to two deadly foodborne pathogens (*Salmonella enteritidis* and *E. coli* O157:H7) in Illinois last year, Durbin said the current food safety and inspection system would be more effective and consistent if federal resources were concentrated under one roof.

"Our current food safety system is a food fight among federal agencies playing by 35 different rule books," said Durbin, who serves on the Senate Governmental Affairs Committee and the Senate Appropriations Subcommittee on Agriculture. "We have politics at their worst in an area where American families rightfully demand our best."

Durbin is introducing his bipartisan legislation with U.S. Reps. Rosa DeLauro (D-CT) and Tom Latham (R-IA). Other cosponsors include U.S. Sens. Robert Torricelli (D-NJ) and Barbara Mikulski (D-MD) and U.S. Reps. Nita Lowey (D-NY), Tim Roemer (D-IN) and Lucille Roybal-Allard (D-CA).

The Durbin-DeLauro-Latham legislation would consolidate all food safety, inspection and labeling functions into one independent agency funded by the combined budgets of the current programs. Right now, such functions are spread throughout 12 agencies, with the following having the majority of jurisdiction: the U.S. Department of Agriculture (USDA) oversees meat, poultry and egg products; the Food and Drug Administration (FDA) oversees most other food products; and the Commerce Department's National Marine Fisheries Service inspects fish.

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Durbin said the involvement of so many agencies can result in duplication of responsibilities, service gaps and inconsistencies and confusion about which agency oversees different types of food.

He noted that while FDA — which has jurisdiction over frozen cheese pizza — inspects cheese pizza processors once every 10 years on average, USDA — with responsibility over frozen pepperoni pizza — inspects such processors daily. In another example, shell eggs are under the jurisdiction of FDA, while USDA takes over once the eggs are broken.

"The challenge to Congress is to summon the political will to protect America's families with a modern, coordinated food safety agency," Durbin said. "Make no mistake — our nation is blessed with the safest and most abundant food supply in the world. But with 21 million people sick and 9,000 people dying every year as a result of food poisoning, we can — and should — do better."

Durbin said the non-partisan General Accounting Office (GAO) has been unwavering in its recommendation of the consolidation of federal food safety programs for more than two decades. In addition, the GAO recently released a report that pointed to the lack of coordination of federal food safety efforts as an example of government waste, among other programs.

Durbin has worked for a number of years on food safety issues with a Chicago mother whose six-year-old son died after eating contaminated hamburger. That mother, Nancy Donley, now president of Safe Tables Our Priority (S.T.O.P.), today said, "Nothing is more important than the safety of the food we feed our families. Too many lives have been destroyed because of a fragmented and inconsistent food safety program across multiple agencies. We deserve the protection that an independent food safety agency will bring."

The Durbin-DeLauro-Latham legislation has been endorsed by S.T.O.P.; the Consumer Federation of America; the Center for Science in the Public Interest; Consumers Union; the National Consumers League; and the Association for Professionals in Infection Control and Epidemiology.

SAFE FOOD ACT OF 1999

- This legislation would replace the current fragmented federal food safety system with a single, independent agency food safety and inspection agency— the Food Safety Administration.
- It would combine the functions of USDA's Food Safety and Inspection Service, FDA's Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine, the Department of Commerce's Seafood Inspection Program, and the food safety functions of other federal agencies.
- The new, independent agency would be funded with the combined budgets from the above mentioned agencies.
- In a study commissioned by Congress and published last August, the National Academy of Sciences (NAS) recommended the establishment of a unified and central framework for managing federal food safety programs. "Many members of the committee are of the view that the most viable means of achieving these goals would be to create a single, unified agency headed by a single administrator."
- The General Accounting Office has been unequivocal in its recommendation for consolidation of federal food safety programs. GAO's April 1998 report states that "since 1992, we have frequently reported on the fragmented and inconsistent organization of food safety responsibilities in the federal government." In a May 25, 1994 report, GAO cites that its "testimony is based on over 60 reports and studies issued over the last 25 years by GAO, agency Inspectors General, and others." The Appendix to the 1994 GAO report lists: 49 reports since 1977, 9 USDA Office of Inspector General reports since 1986, 1 HHS Office of Inspector General report in 1991, and 15 reports and studies by Congress, scientific organizations, and others since 1981.
- Over 20 years ago, the Senate Committee on Governmental Affairs advised that consolidation is essential to avoid conflicts of interest and overlapping jurisdictions. This 1977 report stated, "While we support the recent efforts of FDA and USDA to improve coordination between the agencies, periodic meetings will not be enough to overcome [these] problems." In June 1992 GAO, referencing this recommendation, said "This argument has become even more convincing since 1977."
- With overlapping jurisdictions, federal agencies many times lack accountability on food safety-related issues. There are simply too many cooks in the kitchen. A single, independent agency would help focus our policy and improve enforcement of food safety and inspection laws.

- A single, independent agency with uniform food safety standards and regulations based on food hazards would provide an easier framework for implementing U.S. standards in an international context. When our own agencies don't have uniform safety and inspection standards for all potentially hazardous foods, the establishment of uniform international standards will be next to impossible.
- Research could be better coordinated within a single agency than among multiple programs. Currently, federal funding for food safety research is spread over at least 20 federal agencies, and coordination among those agencies is ad hoc at best.
- New technologies to improve food safety could be approved more rapidly with one food safety agency. Currently, food safety technologies must go through multiple agencies for approval, often adding years of delay.
- With the incidence of food recalls on the rise, it is important to move beyond short-term solutions to major food safety problems. A single, independent food safety and inspection agency could more easily work toward long-term solutions to the frustrating and potentially life-threatening issue of food safety.
- At a time of government downsizing and reorganization, the U.S. simply can't afford to continue to operate multiple systems. In order to achieve a more effective and efficient food safety and inspection system, a single agency with uniform standards is needed.
- The concept is supported by the Safe Food Coalition; Consumer Federation of America; Center for Science in the Public Interest; Consumers Union; National Consumers League; S.T.O.P. — Safe Tables Our Priority; and the Association for Professionals in Infection Control and Epidemiology.

Statement of U.S. Senator Richard J. Durbin

June 24, 1999

Introduction of the Safe Food Act

Mr. President, today I am reintroducing legislation that would replace the current fragmented federal food safety system with a single, independent agency responsible for all federal food safety activities — the Safe Food Act of 1999 (S. 1281). I am pleased to be joined by Senators Torricelli, Mikulski, and Cleland in this important effort.

Make no mistake, our country has been blessed with one of the safest and most abundant food supplies in the world. However, we can do better. Foodborne illness is a significant problem.

The safety of our nation's food supply is facing tremendous pressures with regard to emerging pathogens, an aging population with a growing number of people at high risk for foodborne illnesses, broader food distribution patterns, an increasing volume of food imports, and changing consumption patterns.

The General Accounting Office (GAO) estimates that as many as 81 million people will suffer food poisoning this year and more than 9,000 will die. Children and the elderly are especially vulnerable. In terms of medical costs and productivity losses, foodborne illness costs the nation up to \$37 billion annually. The situation is not likely to improve without decisive action. The Department of Health and Human Services predicts that foodborne illnesses and deaths will increase 10-15 percent over the next decade.

In 1997, a Princeton Research survey found that 44 percent of Americans believe the food supply in this country is less safe than it was 10 years ago. American consumers spend more than \$617 billion annually on food, of which about \$511 billion is spent on foods grown on U.S. farms. Our ability to assure that the safety of our food and to react rapidly to potential threats to food safety is critical not only for public health, but also to the vitality of both domestic and rural economies and international trade.

Many of you are probably following the dioxin crisis in Belgium. Days before the national elections poultry, eggs, pork, beef, and dairy products were withdrawn from supermarket shelves. Butcher shops closed and livestock farms were quarantined. Since then countries, worldwide, have restricted imports of eggs, chickens, and pork from the European Union. Public outrage in Belgium over the dioxin scandal led to a disastrous showing by the ruling party in the national and European elections on June 14, and the government was forced to resign. Food safety concerns and fears are global.

Today, food moves through a global marketplace. This was not the case in the early

1900's when the first federal food safety agencies were created. Throughout this century, Congress responded by adding layer upon layer—agency upon agency—to answer the pressing food safety needs of the day. That's how the federal food safety system got to the point where it is today. And again as we face increasing pressures on food safety, the federal government must respond. But we must respond not only to these pressures but also to the very fragmented nature of the federal food safety structure.

Fragmentation of our food safety system is a burden that must be changed to protect the public health from these increasing pressures. Currently, there are at least 12 different federal agencies, 35 different laws governing food safety, and 28 House and Senate subcommittees with food safety oversight. With overlapping jurisdictions, federal agencies often lack accountability on food safety-related issues.

Last August, the National Academy of Sciences (NAS) released a report recommending the establishment of a "unified and central framework" for managing federal food safety programs, "one that is headed by a single official and which has the responsibility and control of resources for all federal food safety activities." I agree with this conclusion.

The Administration has stepped forward on the issue of food safety — the President's Food Safety Initiatives and the President's Council on Food Safety have focused efforts to track and prevent microbial foodborne illnesses. I commend President Clinton and Secretaries Glickman and Shalala for their commitment to improving our nation's food safety and inspection systems. Earlier this year in response to the NAS report, the President's Council on Food Safety stated its support for the NAS recommendation calling for a new statute that establishes a unified framework for food safety programs with a single official with control over all federal food safety resources.

An independent single food safety agency is needed to replace the current, fragmented system. My proposed legislation would combine the functions of USDA's Food Safety and Inspection Service, FDA's Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine, the Department of Commerce's Seafood Inspection Program, and the food safety functions of other federal agencies. This new, independent agency would be funded with the combined budgets from these consolidated agencies.

With overlapping jurisdictions, federal agencies many times lack accountability on food safety-related issues. There are simply too many cooks in the kitchen. A single, independent agency would help focus our policy and improve enforcement of food safety and inspection laws.

The General Accounting Office has been unequivocal in its recommendation for consolidation of federal food safety programs. GAO's April 1998 report states that "since 1992, we have frequently reported on the fragmented and inconsistent organization of food safety responsibilities in the federal government." In a May 25, 1994 report, GAO cites that its "testimony is based on over 60 reports and studies issued over the last 25 years by GAO, agency

Inspectors General, and others." The Appendix to the 1994 GAO report lists: 49 reports since 1977, 9 USDA Office of Inspector General reports since 1986, 1 HHS Office of Inspector General report in 1991, and 15 reports and studies by Congress, scientific organizations, and others since 1981.

Again, earlier this year, GAO in its 21-volume report on government waste, pointed to the lack of coordination of the federal food safety efforts as an example. "So many cooks are spoiling the broth," says the GAO while highlighting the absurdity of having one federal agency inspecting frozen meat pizza and another inspecting frozen cheese pizza.

Over 20 years ago, the Senate Committee on Governmental Affairs advised that consolidation is essential to avoid conflicts of interest and overlapping jurisdictions. In a 1977 report the committee stated, "While we support the recent efforts of FDA and USDA to improve coordination between the agencies, periodic meetings will not be enough to overcome [these] problems." This statement is just as true today as it was then.

It's time to move forward. Let us stop using multiple federal agencies to inspect pizza. Instead let us "deliver" what makes sense — a single, independent food safety agency.

A single, independent agency with uniform food safety standards and regulations based on food hazards would provide an easier framework for implementing U.S. standards in an international context. When our own agencies don't have uniform safety and inspection standards for all potentially hazardous foods, the establishment of uniform international standards will be next to impossible.

Research could be better coordinated within a single agency than among multiple programs. Currently, federal funding for food safety research is spread over at least 20 federal agencies, and coordination among those agencies is ad hoc at best.

New technologies to improve food safety could be approved more rapidly with one food safety agency. Currently, food safety technologies must go through multiple agencies for approval, often adding years of delay.

In this era of limited budgets, it is our responsibility to modernize and streamline the food safety system. The U.S. simply cannot afford to continue operating multiple systems. This is not about more regulation, a super agency, or increased bureaucracy, it's about common sense and more effective marshaling of our existing federal resources.

With the incidence of food recalls on the rise, it is important to move beyond short-term solutions to major food safety problems. A single, independent food safety and inspection agency could more easily work toward long-term solutions to the frustrating and potentially life-threatening issue of food safety.

Mr. President, together, we can bring the various agencies together to eliminate the overlap and confusion that have, unfortunately, at times characterized our food safety efforts. We need action, not simply reaction. I encourage my colleagues to join me in this effort to consolidate the food safety and inspection functions of numerous agencies and offices into a single, independent food safety agency.

106TH CONGRESS
1ST SESSION

S. 1281

IN THE SENATE OF THE UNITED STATES

Mr. DURBIN (for himself, Mr. TORRICELLI, Ms. MIKULSKI, and Mr. CLELAND) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To consolidate in a single independent agency in the executive branch the responsibilities regarding food safety, labeling, and inspection currently divided among several Federal agencies.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) **SHORT TITLE.**—This Act may be cited as the
5 “Safe Food Act of 1999”.

6 (b) **TABLE OF CONTENTS.**—The table of contents of
7 this Act is as follows:

- Sec. 1. Short title; table of contents.
- Sec. 2. Findings and purposes.
- Sec. 3. Definitions.

- Sec. 4. Establishment of independent Food Safety Administration.
- Sec. 5. Consolidation of separate food safety and inspection services and agencies.
- Sec. 6. Additional authorities of the Administration.
- Sec. 7. Limitation on authorization of appropriations.
- Sec. 8. Effective date.

1 **SEC. 2. FINDINGS AND PURPOSES.**

2 (a) FINDINGS.—Congress finds the following:

3 (1) The safety and security of the food supply
4 of the United States requires efficient and effective
5 management of food safety regulations.

6 (2) The safety of the food supply of the United
7 States is facing tremendous pressures with regard to
8 the following issues:

9 (A) Emerging pathogens and the ability to
10 detect them.

11 (B) An aging population with a growing
12 number of people at high risk for foodborne ill-
13 nesses.

14 (C) An increasing volume of imported
15 foods, without adequate monitoring and inspec-
16 tion.

17 (D) Maintenance of adequate inspection of
18 the domestic food processing and food service
19 industry.

20 (2) Federal food safety inspection, enforcement,
21 and research efforts should be based on scientifically
22 supportable assessments of risks to public health.

1 (4) The Federal food safety system is frag-
2 mented, with at least 12 primary Federal agencies
3 governing food safety.

4 (b) PURPOSES.—It is the purpose of this Act—

5 (1) to establish a single agency, the Food Safe-
6 ty Administration, that will be responsible for the
7 regulation of food safety and labeling and for con-
8 ducting food safety inspections to ensure, with rea-
9 sonable certainty, that no harm will result from the
10 consumption of food, by preventing food-borne ill-
11 nesses due to microbial, natural, or chemical hazards
12 in food; and

13 (2) to transfer to the Food Safety Administra-
14 tion the food safety, labeling, and inspection func-
15 tions currently performed by other Federal agencies,
16 to achieve more efficient management and effective
17 application of Federal food safety laws for the pro-
18 tection and improvement of public health.

19 **SEC. 3. DEFINITIONS.**

20 For purposes of this Act:

21 (1) ADMINISTRATION.—The term “Administra-
22 tion” means the Food Safety Administration estab-
23 lished under section 4.

1 (2) ADMINISTRATOR.—The term “Adminis-
2 trator” means the Administrator of Food Safety ap-
3 pointed under section 4.

4 (3) FOOD SAFETY LAWS.—The term “food safe-
5 ty laws” means the following:

6 (A) The Federal Meat Inspection Act (21
7 U.S.C. 601 et seq.).

8 (B) The Poultry Products Inspection Act
9 (21 U.S.C. 451 et seq.).

10 (C) The Egg Products Inspection Act (21
11 U.S.C. 1031 et seq.).

12 (D) The Federal Food, Drug, and Cos-
13 metic Act (21 U.S.C. 301 et seq.), with regard
14 to food safety, labeling, and inspection under
15 that Act.

16 (E) Such other laws and portions of laws
17 regarding food safety, labeling, and inspection
18 as the President may designate by Executive
19 order as appropriate to consolidate under the
20 administration of the Administration.

21 **SEC. 4. ESTABLISHMENT OF INDEPENDENT FOOD SAFETY**
22 **ADMINISTRATION.**

23 (a) ESTABLISHMENT OF ADMINISTRATION; ADMINIS-
24 TRATOR.—There is established in the executive branch an
25 agency to be known as the “Food Safety Administration”.

1 The Administration shall be an independent establish-
2 ment, as defined in section 104 of title 5, United States
3 Code. The Administration shall be headed by the Adminis-
4 trator of Food Safety, who shall be appointed by the Presi-
5 dent, by and with the advice and consent of the Senate.

6 (b) RESPONSIBILITIES.—The Administrator shall ad-
7 minister and enforce the food safety laws for the protec-
8 tion of the public health and shall oversee the following
9 functions of the Administration:

10 (1) Implementation of Federal food safety in-
11 spection, enforcement, and research efforts, based on
12 scientifically supportable assessments of risks to
13 public health.

14 (2) Development of consistent and science-
15 based standards for safe food.

16 (3) Coordination and prioritization of food safe-
17 ty research and education programs with other Fed-
18 eral agencies.

19 (4) Coordination of the Federal response to
20 foodborne illness outbreaks with other Federal agen-
21 cies and State agencies.

22 (5) Integration of Federal food safety activities
23 with State and local agencies.

1 **SEC. 5. CONSOLIDATION OF SEPARATE FOOD SAFETY AND**
2 **INSPECTION SERVICES AND AGENCIES.**

3 (a) **TRANSFER OF FUNCTIONS.**—For each Federal
4 agency specified in subsection (b), there are transferred
5 to the Administration all functions that the head of the
6 Federal agency exercised on the day before the effective
7 date specified in section 8 (including all related functions
8 of any officer or employee of the Federal agency) that re-
9 late to administration or enforcement of the food safety
10 laws, as determined by the President.

11 (b) **COVERED AGENCIES.**—The Federal agencies re-
12 ferred to in subsection (a) are the following:

13 (1) The Food Safety and Inspection Service of
14 the Department of Agriculture.

15 (2) The Center for Food Safety and Applied
16 Nutrition of the Food and Drug Administration.

17 (3) The Center for Veterinary Medicine of the
18 Food and Drug Administration.

19 (4) The National Marine Fisheries Service of
20 the National Oceanic and Atmospheric Administra-
21 tion of the Department of Commerce as it relates to
22 the Seafood Inspection Program.

23 (5) Such other offices, services, or agencies as
24 the President may designate by Executive order to
25 further the purposes of this Act.

1 (c) TRANSFER OF ASSETS AND FUNDS.—Consistent
2 with section 1531 of title 31, United States Code, the per-
3 sonnel, assets, liabilities, contracts, property, records, and
4 unexpended balances of appropriations, authorizations, al-
5 locations, and other funds that relate to the functions
6 transferred under subsection (a) from a Federal agency
7 shall be transferred to the Administration. Unexpended
8 funds transferred pursuant to this subsection shall be used
9 by the Administration only for the purposes for which the
10 funds were originally authorized and appropriated.

11 (d) REFERENCES.—After the transfer of functions
12 from a Federal agency under subsection (a), any reference
13 in any other Federal law, Executive order, rule, regulation,
14 document, or other material to that Federal agency or the
15 head of that agency in connection with the administration
16 or enforcement of the food safety laws shall be deemed
17 to be a reference to the Administration or the Adminis-
18 trator, respectively.

19 (e) SAVINGS PROVISIONS.—The transfer of functions
20 from a Federal agency under subsection (a) shall not af-
21 fect—

22 (1) an order, determination, rule, regulation,
23 permit, agreement, grant, contract, certificate, li-
24 cense, registration, privilege, or other administrative
25 action issued, made, granted, or otherwise in effect

1 or final with respect to that agency on the day be-
2 fore the transfer date with respect to the transferred
3 functions; or

4 (2) any suit commenced with regard to that
5 agency, and any other proceeding (including a notice
6 of proposed rulemaking), or any application for any
7 license, permit, certificate, or financial assistance
8 pending before that agency on the day before the
9 transfer date with respect to the transferred func-
10 tions.

11 **SEC. 6. ADDITIONAL AUTHORITIES OF THE ADMINISTRA-**
12 **TION.**

13 (a) **OFFICERS AND EMPLOYEES.**—The Administrator
14 may appoint officers and employees for the Administration
15 in accordance with the provisions of title 5, United States
16 Code, relating to appointment in the competitive service,
17 and fix the compensation of the officers and employees
18 in accordance with chapter 51 and with subchapter III of
19 chapter 53 of such title, relating to classification and Gen-
20 eral Schedule pay rates.

21 (b) **EXPERTS AND CONSULTANTS.**—The Adminis-
22 trator may procure the services of experts and consultants
23 as authorized by section 3109 of title 5, United States
24 Code, and pay in connection with the services travel ex-
25 penses of individuals, including transportation and per

1 diem in lieu of subsistence while away from the homes or
2 regular places of business of the individuals, as authorized
3 by section 5703 of such title.

4 (c) BUREAUS, OFFICES, AND DIVISIONS.—The Ad-
5 ministrator may establish within the Administration such
6 bureaus, offices, and divisions as the Administrator may
7 determine to be necessary to discharge the responsibilities
8 of the Administration.

9 (d) RULES.—The Administrator may prescribe, in ac-
10 cordance with chapters 5 and 6 of title 5, United States
11 Code, such rules as the Administrator determines to be
12 necessary or appropriate to administer and manage the
13 functions of the Administrator.

14 **SEC. 7. LIMITATION ON AUTHORIZATION OF APPROPRIA-**
15 **TIONS.**

16 For the fiscal year that includes the effective date
17 of this Act, the amount authorized to be appropriated to
18 carry out this Act shall not exceed—

19 (1) the amount appropriated for that fiscal year
20 for the Federal agencies described in section 5(h) for
21 the purpose of administering or enforcing the food
22 safety laws; or

23 (2) the amount appropriated for these agencies
24 for such purpose for the preceding fiscal year, if, as
25 of the effective date of this Act, appropriations for

1 these agencies for the fiscal year that includes the
2 effective date have not yet been made.

3 **SEC. 8. EFFECTIVE DATE.**

4 This Act shall take effect on the earlier of—

5 (1) the date that is 180 days after the date of
6 the enactment of this Act; and

7 (2) such date during that 180-day period as the
8 President may direct in an Executive order.

FOOD SAFETY FACTS

- Today, fifty cents of every food dollar is spent on food prepared outside the home. This includes ready-to-eat foods from restaurants and supermarkets. There are also a large number of Americans who have their meals prepared and served in hospitals, nursing homes, and day care and senior centers.
- The number of people that are considered at higher risk for foodborne illness has also increased. Today, nearly twenty-five percent of people in the United States fall into this category: the elderly, young children, pregnant women and the immuno-compromised. Moreover, the size of the vulnerable population is growing. Due to increased longevity, the senior population is now the fastest growing sector of society.
- Fifty years ago scientists had identified four foodborne pathogens; today five times that number have been identified.
- The General Accounting Office (GAO) estimates that as many as 81 million people will suffer food poisoning this year and more than 9,000 will die.
- In terms of medical costs and productivity losses, foodborne illness costs the nation up to \$37 billion annually.
- The Department of Health and Human Services predicts that foodborne illnesses and deaths will increase 10-15 percent over the next decade.
- In 1997, a Princeton Research survey found that 44 percent of Americans believe the food supply in this country is less safe than it was 10 years ago.
- American consumers spend more than \$617 billion annually on food, of which about \$511 billion is spent on foods grown on U.S. farms.
- Since 1990, more than 40 outbreaks of foodborne illness have been linked to fresh fruit, vegetable and juice products consumed in the United States. More than 6300 illnesses were reported, with victims in almost all-50 states. (Harkin Testimony 4/99).
- In 1998, we had a record of 13 recalls for deadly E. coli 0157:H7, involving more than 2 million pounds of meat products. (Harkin Testimony 01/99).
- Over the 1998 holidays, a nationwide outbreak of Listeria was recognized, leading to the massive recall of hotdogs and cold cuts. At least a dozen people lost their lives during that outbreak just over the recent holiday season.

- The bulk of the illnesses from foodborne pathogens happen to children younger than 6 years of age--kids have not built up the immunity that they need get the sickest from these foodborne pathogens, such as Salmonella, E. coli, and Campylobacter.
- Currently (May, 1999), one-half of all the seafood and one-third of all the fresh fruit consumed in the U.S. comes from overseas. In fact, since the 1980's food imports to the U.S. have doubled, but federal inspections by Food and Drug Administration have dropped by 50 percent. (Testimony of Senator Frist, May 1999).
- Over the years there have been foodborne pathogen outbreaks involving raspberries from Guatemala, strawberries from Mexico, scallions, parsley and cantaloupes from Mexico, carrots from Peru, coconut milk from Thailand, canned mushrooms from China and others. These outbreaks have serious consequences. The Mexican frozen strawberries I have just noted were distributed in the school lunch programs in several states, including my home state of Tennessee, were attributed to causing an outbreak of Hepatitis A in **March of 1997**. (Testimony of Senator Frist, May 1999).
- In the past seven years, the amount of food imported into the U.S. has more than doubled. Out of all the produce we eat, 40% of it is imported. (Testimony of Sen. Mikulski May, 1999).
- Michigan schoolchildren were contaminated with Hepatitis A from imported strawberries in 1997, Americans were put on alert. Thousands of cases of cyclospora infection from imported raspberries--resulting in severe, prolonged diarrhea, weight loss, vomiting, chills and fatigue were also reported that year. Imported cantaloupe eaten in Maryland sickened 25 people. As much as \$663 million was spent on food borne illness in Maryland alone. Overall, as many as 33 million people per year become ill and over 9000 die as a result of food borne illness. (Testimony of Sen. Mikulski May, 1999).
- In 1998, there was a 50 percent increase in outbreaks and a record number of recalls for the deadly E.Coli 0157-H7 in ground beef. (Testimony of Harkin 01/99).
- Between 1992-1997, for foods regulated by FDA, the number of imported food entries more than doubled from 1.1 million to 2.7 million (GAO Report 04/98).
- Between 1992-1997, as workloads increased for FDA regulated foods, resources devoted to inspecting imported foods declined by 22 percent--- from 328 staff years for inspectors in 1992 to 257 staff years for inspectors in 1997.
- This decrease meant that the average number of annual food shipments each inspector was responsible for increased from about 3,350 to about 10,500.

THE FOOD SAFETY INITIATIVE

On January 25, 1997, President Clinton announced a Food Safety Initiative (FSI) to reduce the incidence of foodborne illness to the greatest extent possible.

SCIENCE-BASED FOOD SAFETY SYSTEM

- Together, FDA, USDA, CDC and EPA laid the foundation for a state-of-the-art science-based food safety system combating foodborne illness on two major strategic fronts:

- 1. Prevention Strategies**
- 2. Strong Outbreak Response System**

PREVENTION, EDUCATION, and VERIFICATION

- Hazard Analysis and Critical Control Point (HACCP).
- Model Prevention Programs (such as the 1999 Food Code, a model code of food safety guidelines for food service establishments).
- Prevention programs are supported by education and verification--by educating producers, processors, distributors, food service workers, and consumers in how to use prevention techniques correctly, and by verifying, through inspections at business establishments, that prevention techniques are being applied properly.

OUTBREAK RESPONSE

- Food Net, the Foodborne Diseases Active Surveillance Network: sites throughout the country actively track laboratory-confirmed cases of foodborne disease in their nearby population centers and share findings among sites and with the CDC.
- PulseNet: A computerized database that matches the DNA fingerprint of foodborne diseases to accelerate traceback to the source of the contamination.
- The Epidemiology Rapid Assessment Team: available 24 hours a day to review incoming reports of foodborne disease and to coordinate traceback and containment efforts rapidly.
- FORCE-G, the Foodborne Outbreak Response Coordinating Group: links federal, state and local government agencies to enhance coordination and communication in responding to outbreaks and emerging threats to the food supply.

THE PRODUCE SAFETY INITIATIVE

President Clinton introduced the Produce Safety Initiative (PSI) in the fall of 1997 that is part of the FSI, addressing entire food chain.

VOLUNTARY GUIDANCE

- The Guide to Minimize Microbial Food Safety Hazards For Fresh Fruits and Vegetables: Identifies broad microbial hazards, the scientific basis for the hazard, and good agricultural practices and good management practices that can be used to reduce the risk of microbial contamination in produce. It addresses:
 1. Water quality
 2. Manure and municipal biosolids
 3. Worker health and hygiene
 4. Sanitation, including fields and packing facilities
 5. Transportation

The recommendations also establish traceback procedures to safeguards further contamination.

THE IMPORTED FOOD SAFETY INITIATIVE

In July 1999 President Clinton directed the Secretary of Health and Human Services (HHS) and the Secretary of the Treasury to report back within 90 days on the available steps they will take to:

- (1) Prevent distribution of imported unsafe food by means such as requiring food to be held until reviewed by FDA. Requiring food to be held in a secure storage facility until released by FDA will prevent "bad actor" importers from distributing and selling potentially unsafe imported food before FDA has completed its review.
- (2) Destroy imported food that poses a serious public health threat. Requiring destruction of such food will protect American consumers by removing the goods from commerce (thus preventing their re-entry at another port) and will also protect consumers around the world by preventing importers from exporting the contaminated foods to other countries.
- (3) Prohibit "port shopping"-- in which importers whose cargo is denied entry at one port try to introduce it at another -- though a new FDA requirement to mark shipping containers and/or papers of imported food that is denied admission for safety reasons. The unsafe food will be clearly marked, "Refused U.S.".
- (4) Set standards for private laboratories for the collection and analysis of samples of imported food for the purpose of gaining entry into the United States.

- (5) Increase the amount of the bond posted for imported foods when necessary to deter premature and illegal entry into the United States. Increasing the bond amount will prevent unscrupulous importers from forfeiting the bond amount (which is currently based only on the wholesale value of the shipment), selling the shipment before FDA completes its review, and turning a significant profit anyway.
- (6) Enhance enforcement for violations of United States laws related to the importation of foods, including the imposition of civil monetary penalties. Food Safety Initiative and Legislation.

The President also called on Congress to provide full funding for his requested \$72 million increase for the Food Safety Initiative, which supports:

- (1) Enabling FDA to hire new inspectors to inspect at least annually every domestic manufacturer of high-risk food products.
- (2) Permitting USDA to assist states in order to create a seamless national inspection program; enabling FDA to more than double the number of inspections conducted of foreign food processors.
- (3) Allowing the agencies to expand research to develop more effective ways of testing for and identifying dangerous contaminants such as Salmonella and Cyclospora.

The House-passed Agricultural Appropriations bill fails to fund \$27 million of the much-needed requested increase, and the Senate Appropriations Committee bill fails to fund \$18 million of the requested increase.

The President also called on Congress to pass two pieces of legislation that:

- Ensures that imports of fruits, vegetables, and other food products meet U.S. food safety requirements or provide the same level of protection as is required for U.S. products. (Sponsored by **Senators Mikulski, Kennedy, Durbin** and **Representative Eshoo**).
- Will give USDA the authority to issue mandatory recalls and impose civil penalties for unsafe meat and poultry. (Sponsored by **Senator Harkin**).

**Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are
Inconsistent and Unreliable**
(Chapter Report, 04/30/98, GAO/RCED-98-103).

EXECUTIVE SUMMARY

Concerned about the safety of imported foods, the Chairman of the Permanent Subcommittee on Investigations, Senate Committee on Governmental Affairs, asked GAO to review the efforts of federal programs to ensure the safety of food imports.

PURPOSE:

To discuss:

1. the differences in the agencies' authorities and approaches for ensuring the safety of imported foods.
2. the agencies' efforts to target their resources on foods posing risks and the weaknesses in the controls over imported foods.

BACKGROUND:

- The primary responsibility for ensuring the safety of imported foods is split between **USDA's Food Safety and Inspection Service (FSIS)** and **FDA**.
- Jurisdiction:
FSIS: Meat, poultry, and some egg products.
FDA: All other foods.
- FSIS and FDA work closely with **Customs** and **CDC**.

Role:

CUSTOMS: Refers imported foods to FSIS or FDA for review before releasing the shipment into U.S. commerce.

CDC: Monitors the incidence of foodborne illness, works with state and local health departments to investigate outbreaks, and collaborates with FSIS, FDA, and others to conduct research.

- FSIS and FDA require imported foods to meet the same standards as domestic foods, but their approaches to enforcing these requirements differ:
 - *By law, FSIS* places the principal responsibility of safety to the exporting countries by allowing imports only from countries with food safety systems deemed equivalent to the U.S.
 - **FDA**, lacks this legal authority and allows food imports from almost any country, taking on the burden of ensuring the safety of imported foods as they arrive at U.S. ports of entry.

RESULTS:

1. LACK OF EQUIVALENCY AUTHORITY DIMINISHES FDA'S ABILITY TO PROTECT U.S. CONSUMERS.

Relying on port-of-entry inspections to detect and prevent unsafe foods is ineffective:

- It does not ensure that foods are produced under adequately controlled conditions.
- FDA currently inspects less than 2 percent of all foreign shipments.
- Inspection will not detect some organisms, such as Cyclospora, for which visual inspections and laboratory tests are inadequate.

2. AGENCIES COULD MORE EFFECTIVELY TARGET RESOURCES ON UNSAFE FOODS.

Federal agencies cannot ensure that imported foods are safe for consumers because FSIS and FDA are not deploying their inspection resources to maximum advantage:

- FSIS focuses on exporting firms with a history of non-health related violations (processing defects, incorrect shipping labels, etc...), yet using available data on exports with a history of health-related violations would allow inspectors to focus on imports posing the greater risks.
- FDA does not make health risk data readily available to guide inspectors' selections and when making deciding on which shipments to inspect, they rely on importers' descriptions of shipments' contents, which are often incorrect. As a result, the agency's resources may not be focused on imported foods posing the greater safety risk.

3. WEAKNESSES IN IMPORT CONTROLS ALLOW ENTRY OF UNSAFE PRODUCTS.

The Food and Drug Administration's procedures for ensuring that unsafe imported foods do not reach U.S. consumers are vulnerable to abuse by unscrupulous importers:

- Because FDA does not have the explicit authority to require importers to use certain laboratories, importers can choose the laboratories that select the samples and perform the tests to prove compliance.
- FDA has often found discrepancies between their test results and those from private laboratories for the same shipment.
- Customs and FDA inspectors have also found that importers substitute safe products for inspection, rather than the imported products FDA wanted to inspect.

RECOMMENDATIONS:

- (1) That the Congress require all foods eligible for import to the United States, not just meat and poultry, be produced under equivalent food safety systems.

Agency Response: FDA agreed that it needs equivalency authority to control the safety of imported foods, but it did not agree that equivalence should be a requirement for the entry of imported foods. FDA believes that the authority should be discretionary, not mandatory, so that equivalency could be applied where it is most appropriate without disrupting trade.

- (2) The Secretary of Health and Human Services and the Secretary of Agriculture improve the effectiveness and efficiency of their import review systems and procedures by targeting inspection resources on foods posing greater health risks.

The report recommends that the Secretary of Agriculture improve the Automated Import Information System's usefulness so that the system can identify patterns between laboratory test results and specific foods, foreign firms and exporting countries.

The report recommends to the Secretary of HHS to direct the Commissioner, FDA, to:

- Clarify the guidance inspectors should use when making decisions on which shipments to inspect and test.
- Modify the Operational and Administrative System for Import Support (OASIS) System.
- Ensure that the field offices are taking the appropriate corrective action, when warranted, against importers that repeatedly enter incorrect shipping information into the OASIS database.

Agency Response: FSIS agreed with GAO's recommendation, and that it will be evaluating its port-of-entry inspection procedures and consider GAO's recommendations.

FDA agreed with GAO's recommendation to link three databases (the Import Alert database, the Low-Acid Canned Food database, and the laboratory database) to the Operational and Administrative System for Import Support for use by inspectors when choosing shipments for inspections and tests.

FDA also agreed generally with other specific recommendations regarding its import screening system.

- (3) No Recommendation for the third result.

Imported Food Safety Improvement Act

May 26, 1999

TITLE: Cited as the 'Imported Food Safety Improvement Act of 1999'.

TITLE I: IMPROVEMENTS TO THE FOOD SAFETY IMPORT SYSTEM.

SPONSORS: Senators Mikulski, Kennedy and Durbin

PURPOSES: To amend the Federal Food, Drug, and Cosmetic Act to improve the safety of imported food, and for other purposes.

- (1) It requires that FDA make equivalence determinations on imported food. Senator Kennedy and Senator Mikulski developed this with the FDA in consultation with the consumer groups.
 - It will allow FDA to look at the production at its source and take preventive measures.
 - FDA will be able to be proactive, rather than just reactive.
- (2) It covers emergency situations by allowing FDA to ban imported food that has been connected to outbreaks of food borne illness and grants the Secretary of Health and Human Services the authority to issue an emergency ban.
- (3) It enhances enforcement measures through the creation of additional employment positions for laboratory, inspection, and compliance personnel.

THE SAFE FOOD ACT
1999

TITLE: The Safe Food Act of 1999 (S. 1281)

SPONSOR (S): Senators Durbin, Toricelli, Mikulski and Cleland.

A BILL

To consolidate in a single independent agency in the executive branch the responsibilities regarding food safety, labeling, and inspection currently divided among several Federal agencies.

PURPOSES:

- (1) To establish a single agency, the Food Safety Administration, that will be responsible for the regulation of food safety and labeling and for conducting food safety inspections to ensure, with reasonable certainty, that no harm will result from the consumption of food, by preventing food-borne illnesses due to microbial, natural, or chemical hazards in food; and
- (2) To transfer to the Food Safety Administration the food safety, labeling, and inspection functions currently performed by other Federal agencies, to achieve more efficient management and effective application of Federal food safety laws for the protection and improvement of public health.

SAFE AND FAIR ENFORCEMENT AND RECALL FOR MEAT AND POULTRY ACT
(SAFER Meat and Poultry Act)
1999

TITLE(S):

- SHORT TITLE(S) AS INTRODUCED:
Safe and Fair Enforcement and Recall for Meat and Poultry Act
Safer Meat and Poultry Act
- OFFICIAL TITLE AS INTRODUCED:
A bill to amend the Federal Meat Inspection Act and the Poultry Products Inspection Act to provide for improved public health and food safety through enhanced enforcement.

SPONSOR(S): Senators Harkin, Daschle, Mikulski, Torricelli, Leahy, Johnson, Kennedy, Durbin and Boxer.

PURPOSE:

- A. To amend the Federal Meat Inspection Act and the Poultry Products Inspection Act to provide for improved public health and food safety through enhanced enforcement.
- B. Safe and Fair Enforcement and Recall for Meat and Poultry Act (SAFER Meat and Poultry Act) - Amends the Federal Meat Inspection Act and the Poultry Products Inspection Act to:
 - Provide the Secretary with authority for voluntary and mandatory non-distribution and recall, withdrawal of inspectors from violating facilities, and civil penalties.
 - Require that someone who knows about a contaminated food product, other than a consumer, must notify the Secretary of Agriculture.

THE FRUIT AND VEGETABLE SAFETY ACT
1999 (S. 823)

PURPOSE: To establish a program to assure the safety of processed produce intended for human consumption, and for other purposes.

SPONSOR (S): Senators Harkin, Durbin and Kerry.

PURPOSE: This bill establishes that:

- Persons who process produce for human consumption have the responsibility to prevent or minimize food safety hazards related to their products.
- Consumption of fresh fruits and vegetables can promote health and prevent disease, and should be encouraged.
- Rising consumer demand for processed produce, the growing market for various kinds of domestic and imported processed produce, and the increasing variety of processing techniques for produce, are causing newly recognized or unpredicted safety hazards.
- Uniform sanitation practices, applied to processing of produce, will minimize these hazards.

Biotechnology

Release No. 0285.99

Remarks

As Prepared for Delivery
by

Secretary of Agriculture Dan Glickman
before the National Press Club on

New Crops, New Century, New Challenges:

How Will Scientists, Farmers, And Consumers Learn to Love Biotechnology
And What Happens If They Don't? Washington, D.C. - July 13, 1999

"Good afternoon. Thank you for coming.

"Let's think about this hypothetical situation for a moment: Let's suppose that today's salad was made with the new carrot from Press Club Farms, Inc. Farmers grow the new carrot on fewer acres because it yields more, and it's less expensive because it does not require any fertilizers or pesticides and can be harvested totally mechanically. In addition, it has more vitamin A & C than traditional varieties and stays crisper longer and keeps its fresh taste longer.

"But, because this carrot does not require as much labor, the farmers have had to lay off hundreds of employees. While it does not require any chemicals to flourish, this new carrot does affect the environment by making it difficult for other crops or plants in close proximity to survive. And though it's cheaper to begin with, it's only available from one company, which could result in a considerable premium over regular carrot seed.

"And what's the secret to this hypothetical new carrot? It's the latest advance from biotechnology -- produced with a gene from kudzu, an invasive weed.

"Sound far-fetched? It probably shouldn't: Remember the flavor-saver tomato? How many of you have heard of the so-called terminator gene which can keep a plant from reproducing? Today, nearly half the soybeans in the U.S. the stuff that is crushed and made into salad and cooking oil and that feeds most of the livestock we grow are produced from a variety that increases the plant's resistance to certain pesticides. Genetically-engineered corn with certain pest resistant characteristics is also rapidly displacing more traditional varieties. And, it gets even more interesting when you consider that researchers are looking at genetically-modified mosquitoes that cannot carry malaria.

"So, what do we think about this new carrot? Are we concerned about the environmental effects we still don't fully understand? What about the farm workers who are now unemployed? Should one company have a monopoly on it? And finally, are you concerned about these issues and about how it is produced? Would you still have eaten it if you knew about the kudzu gene? Should you have been told? Would you buy it?

"Folks, this is the tip of the biotechnology iceberg. There are many more questions that haven't yet been thought of, much less answered. But first of all, and if you come away with a dominant point from my remarks, it is that I want you to know that biotechnology has enormous potential.

"Biotechnology is already transforming medicine as we know it. Pharmaceuticals such as human insulin for diabetes, interferon and other cancer medications, antibiotics and vaccines are all products of genetic engineering. Just yesterday I read that scientists at Virginia Polytechnic Institute will process drugs from milk from genetically altered cows. One new drug has the potential to save hemophiliacs from bleeding to death. Scientists are also looking at bananas that may one day deliver vaccines to children in developing countries.

"Agricultural biotechnology has enormous potential to help combat hunger. Genetically modified plants have the potential to resist killer weeds that are, literally, starving people in Africa and other parts of the developing world.

"Biotechnology can help us solve some of the most vexing environmental problems: It could reduce pesticide use, increase yields, improve nutritional content, and use less water. We're employing bioengineered fungi to remove ink from pulp in a more environmentally sensitive manner.

"But, as with any new technology, the road is not always smooth. Right now, in some parts of the world there is great consumer resistance and great cynicism toward biotechnology. In Europe protesters have torn up test plots of biotechnology-derived crops and some of the major food companies in Europe have stopped using GMOs genetically-modified organisms in their products.

"Yesterday's news was that the WTO affirmed our view that the EU is unjustifiably blocking US ranchers from selling beef produced with completely tested and safe growth hormones. Today we're seeing that the G-8 agreed to a new review of food safety issues and, having myself just come back from France a couple of weeks ago, I can assure you that trade in GMOs is looming larger over US-EU trade relations in all areas.

"Now, more than ever, with these technologies in their relative infancy, I think it's important that, as we encourage the development of these new food production systems, we cannot blindly embrace their benefits. We have to ensure public confidence in general, consumer confidence in particular, and assure farmers the knowledge that they will benefit.

"The important question is not, do we accept the changes the biotechnology revolution can bring, but are we willing to heed the lessons of the past in helping us to harness this burgeoning technology. The promise and potential are enormous, but so too are the questions many of which are completely legitimate. Today, on the threshold of this revolution, we have to grapple with and satisfy those questions so we can in fact fulfill biotechnology's awesome potential.

"To that end, today I am laying out 5 principles I believe should guide us in our approach to biotechnology in the 21st century. They are:

1. An Arm's Length Regulatory Process. Government regulators must continue to stay an arm's length, dispassionate distance from the companies developing and promoting these products; and continue to protect public health, safety and the environment.

2. Consumer Acceptance. Consumer acceptance is fundamentally based on an arm's length regulatory process. There may be a role for information labeling, but fundamental questions to acceptance will depend on sound regulation.

3. Fairness to Farmers. Biotechnology has to result in greater, not fewer options for farmers. The industry has to develop products that show real, meaningful results for farmers, particularly small and medium size family farmers.

4. Corporate Citizenship. In addition to their desire for profit, biotechnology companies must also understand and respect the role of the arm's length regulator, the farmer, and the consumer.

5. Free and Open Trade. We cannot let others hide behind unfounded, unwarranted scientific claims to block commerce in agriculture.

Arm's Length Regulatory Process

"When I was a school board member in Wichita, Kansas, one of my tasks was to study the level of student participation in the school lunch program. I quickly learned if the food didn't taste or look good, no matter how nutritious it was, the kids wouldn't eat it.

"With all that biotechnology has to offer, it is nothing if it's not accepted. This boils down to a matter of trust -- trust in the science behind the process, but particularly trust in the regulatory process that ensures thorough review -- including complete and open public involvement. The process must stay at arm's length from any entity that has a vested interest in the outcome.

"By and large the American people have trust and confidence in the food safety efforts of USDA, the FDA, EPA, CDC and others because these agencies are competent and independent from the industries they regulate, and are viewed as such. That kind of independence and confidence will be required as we deal with biotechnology.

"The US regulatory path for testing and commercializing biotechnology products as they move from lab to field to marketplace is over a decade old. We base decisions on rigorous analysis and sound scientific principles. Three federal agencies -- USDA, FDA, and EPA -- each play a role in determining the use of biotechnology products in the United States: USDA evaluates products for potential risk to other plants and animals. FDA reviews biotechnology's effect on food safety. And the EPA examines any products that can be classified as pesticides.

"Right now, there are about 50 genetically altered plant varieties approved by USDA. And so far, thanks to the hard work and dedication of our scientists, the system is keeping pace. But, as I said, the system is tried and tested, but not perfect and not inviolate and should be improved where and when possible.

"To meet the future demand of the thousands of products in the pipeline will require even greater resources, and a more unified approach and broader coordination.

"When I chaired the US delegation to the World Food Conference in Rome in 1996, I got pelted with genetically modified soybeans by naked protesters. I began to realize the level of opposition and distrust in parts of Europe to biotechnology for products currently on the market or in the pipeline.

"I believe that distrust is scientifically unfounded. It comes in part from the lack of faith in the EU to assure the safety of their food. They have no independent regulatory agencies like the FDA, USDA or EPA. They've had many food scares in recent years -- mad-cow disease, and in just the last several weeks, dioxin-tainted chicken -- that have contributed to a wariness of any food that is not produced in a traditional manner notwithstanding what the science says. Ironically they do not share that fear as it relates to genetically modified pharmaceuticals.

"But, GMO foods evoke in many circles a very volatile reaction. And that has created a serious problem for the U.S. and other countries as we try to sell our commodities in international markets.

"We need to make sure our regulatory system has the foresight to begin addressing issues even before they arise. So to keep pace with the accelerating growth of agricultural biotechnology, I am taking several additional steps to ensure we are fully prepared to meet the regulatory challenges of this new technology.

"Today I'm announcing that I will be asking for an independent

scientific review of USDA's biotech approval process. The purpose of this review will be to ensure that, as we are faced with increasingly complex issues surrounding biotechnology, our scientists have the best information and tools to ensure our regulatory capabilities continue to evolve along with advances in the new technology. And to address complex issues like pharmaceutical producing plants or genetically modified livestock we will need to consult the experts, many of whom are outside USDA.

"Two of the more significant challenges we face are grower and consumer awareness, and improving monitoring on a long term basis. We do not have evidence the heavily publicized Monarch butterfly lab study appears to be happening in the field. But, the resulting attention to the reports and ensuing debate underscore the need to develop a comprehensive approach to evaluating long-term and secondary effects of biotech products.

"So, USDA will propose the establishment of regional centers around the country to evaluate biotech products over a long period of time and to provide information on an ongoing basis to growers, consumers, researchers and regulators.

"To strengthen biotechnology guidelines to ensure we can stay on top of any unforeseen adverse effects after initial market approval, I am requesting all developers of biotech products to report any unexpected or potentially adverse effects to the Department of Agriculture immediately upon discovery.

"Finally, we need to ensure that our regulators just regulate and only regulate. A few years ago, we created a food safety agency separate and distinct from any and all marketing functions to ensure that no commercial interests have even the appearance of influence on our decisions regarding food safety. It needs to be the same with biotechnology. The scientists who evaluate and approve biotech products for the market must be free of any hint of influence from trade support and other non-regulatory areas within USDA.

"We at USDA will undertake a review to reinforce the clear line between our regulatory functions and those that promote and support trade. This reaffirms our basic principle that we will remain scrupulously rigid in maintaining an arm's length regulatory process.

Consumer Acceptance

"However strong our regulatory process is, it is of no use if consumer confidence is low and if consumers cannot identify a direct benefit to them.

"I have felt for some time that when biotechnology products from agriculture hit the market with attributes that, let's say, reduce cholesterol, increase disease resistance, grow hair, lower pesticide and herbicide use, and are truly recognized as products that create more specific public benefits, consumer acceptance will rise dramatically.

"There's been a lot of discussion as to whether we should label GMO products. There are clearly trade and domestic implications to labeling to be considered in this regard. I know many of us in this room are sorting out these issues. At the end of the day many observers, including me, believe some type of informational labeling is likely to happen. But, I do believe that it is imperative that such labeling does not undermine trade and this promising new technology.

"The concept of labeling particular products for marketing purposes is not a radical one. For example, USDA has already decided that for a product to be certified as organic under our pending organic agriculture rules, a GMO product would not qualify. And that does not mean that USDA believes organic is safer or better than non-organic all approved foods are safe it just means that consumers are given this informed choice.

"There clearly needs to be a strong public education effort to show

consumers the benefits of these products and why they are safe. Not only will this be the responsibility of private industry and government, but I think the media will play a vital role. It's important that the media treat this subject responsibly and not sensationalize or fan consumer fears. That's what we're seeing happen in the EU and the outcome is fear, doubt and outright opposition.

"What we cannot do is take consumers for granted. I cannot stress that enough. A sort of if-you-grow-it-they-will-come mentality. I believe farmers and consumers will eventually come to see the economic, environmental, and health benefits of biotechnology products, particularly if the industry reaches out and becomes more consumer accessible.

"But, to build consumer confidence, it is just like it is with the way we regulate our airlines, our banks and the safety of our food supply consumers must have trust in the regulatory process. That trust is built on openness. Federal agencies have nothing to hide. We work on behalf of the public interest. Understanding that will go a long way to solving the budding controversy over labeling and ensuring that consumers will have the ability to make informed choices.

Fairness to Farmers

"Like consumers, farmers need to have adequate choices made available to them. But today, American agriculture is at a crossroads. Farmers are currently facing extremely low commodity prices and are rightfully asking what will agriculture look like in the years to come and what will their roles be.

"That also means they have more responsibility and more pressure. And much of the pressure they face originates from sources beyond their control. We are seeing social and economic trends that have a powerful effect on how farmers do business. We are seeing increased market concentration, a rise in contracting, rapidly evolving technologies such as information power and precision agriculture in addition to biotechnology. We are seeing different marketing techniques such as organics, direct marketing, coops and niche markets, and an expansion of non-agricultural industrial uses for plants.

"One of my biggest concerns is what biotechnology has in store for family farmers. Consolidation, industrialization and proprietary research can create pitfalls for farmers. It threatens to make them servants to bigger masters, rather than masters of their own domains. In biotechnology, we're already seeing a heated argument over who owns what. Companies are suing companies over patent rights even as they merge. Farmers have been pitted against their neighbors in efforts to protect corporate intellectual property rights.

"We need to ensure that biotechnology becomes a tool that results in greater -- not fewer -- options for farmers. For example, we're already hearing concerns from some farmers that to get some of the more highly desirable non-GMO traits developed over the years, they might have to buy biotechnology seeds. For some, that's like buying the car of your dreams but only if you get it in yellow. On the other hand, stress-tolerant plants are in the pipeline which could expand agricultural possibilities on marginal lands which could be a powerful benefit to poor farmers.

"The ability of farmers to compete on a level playing field with adequate choices available to them and without undue influence or impediments to fair competition must be preserved. As this technology develops, we must achieve a balance between fairness to farmers and corporate returns.

"We need to examine all of our laws and policies to ensure that, in the rush to bring biotech products to market, small and medium family farmers are not simply plowed under. We will need to integrate issues like privatization of genetic resources, patent holders rights and public research to see if our approach is helping or harming the public good and family farmers.

"It is not the government who harnesses the power of the airwaves, but it is the government who regulates it. That same principle might come to apply to discoveries in nature as well. And that debate is just getting started.

Corporate Citizenship

"If the promises hold true, biotechnology will bring revolutionary benefits to society. But that very promise means that industry needs to be guided by a broader map and not just a compass pointing toward the bottom line.

"Product development to date has enabled those who oppose this technology to claim that all the talk about feeding the world is simply cover for corporate profit-making. To succeed in the long term, industry needs to act with greater sensitivity and foresight.

"In addition, private sector research should also include the public interest, with partnerships and cooperation with non-governmental organizations here and in the developing world ensuring that the fruits of this technology address the most compelling needs like hunger and food security.

"Biotechnology developers must keep farmers informed of the latest trends, not just in research but in the marketplace as well. Contracts with farmers need to be fair and not result in a system that reduces farmers to mere serfs on the land or create an atmosphere of mistrust among farmers or between farmers and companies.

"Companies need to continue to monitor products, after they've gone to market, for potential danger to the environment and maintain open and comprehensive disclosure of their findings.

"We don't know what biotechnology has in store for us in the future, good and bad, but if we stay on top of developments, we're going to make sure that biotechnology serves society, not the other way around.

"These basic principles of good corporate citizenship really just amount to good long-term business practices. As in every other sector of the economy, we expect responsible corporate citizenship and a fair return. For the American people, that is the bottom line.

Free and Open Trade

"The issues I have raised have profound consequences in world trade. Right now, we are fighting the battles on ensuring access to our products on many fronts. We are not alone in these battles. Canada, Australia, Mexico, many Latin American, African and Asian nations, agree with us that sound science ought to establish whether biotech products are safe and can move in international commerce.

"These are not academic problems. For 1998 crops 44% of our soybeans and 36% of our corn are produced from genetically modified seeds. While only a few varieties of GMO products have been approved for sale and use in Europe, many more have been put on hold by a de facto European moratorium on new GMO products.

"Two weeks ago I went to France and met with the French Agriculture Minister at the request of the US ambassador there, Felix Rohatyn, to see if we can break this logjam which directly threatens US-EU relations at a delicate time when we are commencing the next WTO round in Seattle.

"Quite frankly the food safety and regulatory regimes in Europe are so

split and divided among the different countries that I am extremely concerned that failure to work out these biotech issues in a sensible way could do deep damage to our next trade round and effect both agricultural and non-agricultural issues. For that reason, the French Minister's agreement to have a short-term working group with USDA on biotech approval issues, and his willingness to come to the US in the fall to further discuss the situation, is encouraging.

"To forestall a major US-EU trade conflict, both sides of the Atlantic must tone down the rhetoric, roll up our sleeves and work toward conflict resolution based on open trade, sound science and consumer involvement. I think this can be done if the will is there.

"However, I should warn our friends across the Atlantic that, if these issues cannot be resolved in this manner, we will vigorously fight for our legitimate rights.

Conclusion

"Finally, I've established a Secretary's Advisory Committee on Agricultural Biotechnology -- a cross-section of 25 individuals from government, academia, production agriculture, agribusiness, ethicists, environmental and consumer groups. The committee, which will hold its first meeting in the fall, will provide me with advice on a broad range of issues relating to agricultural biotechnology and on maintaining a flexible policy that evolves as biotechnology evolves.

"Public policy must lead in this area and not merely react. Industry and government cannot engage in hedging or double talking as problems develop, which no doubt they will.

"At the same time, science will march forward, and especially in agriculture, that science can help to create a world where no one needs to go hungry, where developing nations can become more food self-sufficient and thereby become freer and more democratic, where the environmental challenges and clean water, clean air, global warming and climate change, must be met with sound and modern science and that will involve biotechnological solutions.

"Notwithstanding my concerns raised here today, I would caution those who would be too cautious in pursuing the future. As President Kennedy said, "We should not let our fears hold us back from pursuing our hopes."

"So let us continue to move forward thoughtfully with biotechnology in agriculture but with a measured sense of what it is and what it can be. We will then avoid relegating this promising new technology to the pile of what-might-have-beens, and instead realize its potential as one of the tools that will help us feed the growing world population in a sustainable manner.

"Thank you."

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THE FOOD SAFETY
INITIATIVE

PHOTOCOPY
PRESERVATION

THE FOOD SAFETY INITIATIVE

On January 25, 1997, President Clinton announced a Food Safety Initiative (FSI) to reduce the incidence of foodborne illness to the greatest extent possible.

SCIENCE-BASED FOOD SAFETY SYSTEM

- Together, FDA, USDA, CDC and EPA laid the foundation for a state-of-the-art science-based food safety system combating foodborne illness on two major strategic fronts:

- 1. Prevention Strategies**
- 2. Strong Outbreak Response System**

PREVENTION, EDUCATION, and VERIFICATION

- Hazard Analysis and Critical Control Point (HACCP).
- Model Prevention Programs (such as the 1999 Food Code, a model code of food safety guidelines for food service establishments).
- Prevention programs are supported by education and verification--by educating producers, processors, distributors, food service workers, and consumers in how to use prevention techniques correctly, and by verifying, through inspections at business establishments, that prevention techniques are being applied properly.

OUTBREAK RESPONSE

- Food Net, the Foodborne Diseases Active Surveillance Network: sites throughout the country actively track laboratory-confirmed cases of foodborne disease in their nearby population centers and share findings among sites and with the CDC.
- PulseNet: A computerized database that matches the DNA fingerprint of foodborne diseases to accelerate traceback to the source of the contamination.
- The Epidemiology Rapid Assessment Team: available 24 hours a day to review incoming reports of foodborne disease and to coordinate traceback and containment efforts rapidly.
- FORCE-G, the Foodborne Outbreak Response Coordinating Group: links federal, state and local government agencies to enhance coordination and communication in responding to outbreaks and emerging threats to the food supply.

THE PRODUCE SAFETY INITIATIVE

President Clinton introduced the Produce Safety Initiative (PSI) in the fall of 1997 that is part of the FSI, addressing entire food chain.

VOLUNTARY GUIDANCE

- The Guide to Minimize Microbial Food Safety Hazards For Fresh Fruits and Vegetables: Identifies broad microbial hazards, the scientific basis for the hazard, and good agricultural practices and good management practices that can be used to reduce the risk of microbial contamination in produce. It addresses:
 1. Water quality
 2. Manure and municipal biosolids
 3. Worker health and hygiene
 4. Sanitation, including fields and packing facilities
 5. Transportation

The recommendations also establish traceback procedures to safeguards further contamination.

THE IMPORTED FOOD SAFETY INITIATIVE

In July 1999 President Clinton directed the Secretary of Health and Human Services (HHS) and the Secretary of the Treasury to report back within 90 days on the available steps they will take to:

- (1) Prevent distribution of imported unsafe food by means such as requiring food to be held until reviewed by FDA. Requiring food to be held in a secure storage facility until released by FDA will prevent "bad actor" importers from distributing and selling potentially unsafe imported food before FDA has completed its review.
- (2) Destroy imported food that poses a serious public health threat. Requiring destruction of such food will protect American consumers by removing the goods from commerce (thus preventing their re-entry at another port) and will also protect consumers around the world by preventing importers from exporting the contaminated foods to other countries.
- (3) Prohibit "port shopping"-- in which importers whose cargo is denied entry at one port try to introduce it at another -- though a new FDA requirement to mark shipping containers and/or papers of imported food that is denied admission for safety reasons. The unsafe food will be clearly marked, "Refused U.S.".
- (4) Set standards for private laboratories for the collection and analysis of samples of imported food for the purpose of gaining entry into the United States.

- (5) Increase the amount of the bond posted for imported foods when necessary to deter premature and illegal entry into the United States. Increasing the bond amount will prevent unscrupulous importers from forfeiting the bond amount (which is currently based only on the wholesale value of the shipment), selling the shipment before FDA completes its review, and turning a significant profit anyway.
- (6) Enhance enforcement for violations of United States laws related to the importation of foods, including the imposition of civil monetary penalties. Food Safety Initiative and Legislation.

The President also called on Congress to provide full funding for his requested \$72 million increase for the Food Safety Initiative, which supports:

- (1) Enabling FDA to hire new inspectors to inspect at least annually every domestic manufacturer of high-risk food products.
- (2) Permitting USDA to assist states in order to create a seamless national inspection program; enabling FDA to more than double the number of inspections conducted of foreign food processors.
- (3) Allowing the agencies to expand research to develop more effective ways of testing for and identifying dangerous contaminants such as Salmonella and Cyclospora.

The House-passed Agricultural Appropriations bill fails to fund \$27 million of the much-needed requested increase, and the Senate Appropriations Committee bill fails to fund \$18 million of the requested increase.

The President also called on Congress to pass two pieces of legislation that:

- Ensures that imports of fruits, vegetables, and other food products meet U.S. food safety requirements or provide the same level of protection as is required for U.S. products. (Sponsored by **Senators Mikulski, Kennedy, Durbin and Representative Eshoo**).
- Will give USDA the authority to issue mandatory recalls and impose civil penalties for unsafe meat and poultry. (Sponsored by **Senator Harkin**).

**U.S. Food & Drug Administration
Center for Food Safety & Applied Nutrition
The Food Safety Initiative
April 1999**

The Food Safety Initiative

On January 25, 1997, President Clinton announced a Food Safety Initiative (FSI) with a single mission--to reduce the incidence of foodborne illness to the greatest extent possible.

The President took this action as a result of major changes in the food system and consumer lifestyles that were placing Americans at greater risk from foodborne illness. While recognizing that, in general, the American food supply is safe, the FSI acknowledges that these changes place increasing challenges to the nation's food safety system.

FOOD SAFETY IN A CHANGING WORLD

What are the changes that affect the food system? People are eating a greater variety of foods and foods no longer need to be seasonal or locally grown. Food is often transported over long distances, domestically and internationally. This combination of new sources and wide distribution of food poses new safety challenges.



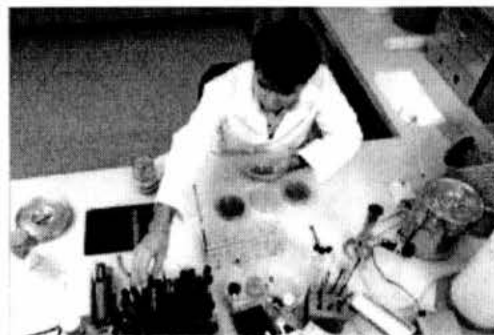
People are also eating more food prepared by others. In the past, most food was prepared in the home. Today, fifty cents of every food dollar is spent on food prepared outside the home. This includes ready-to-eat foods from restaurants and supermarkets. There are also a large number of Americans who have their meals prepared and served in hospitals, nursing homes, and day care and senior centers.

The number of people considered to be at higher risk for foodborne illness has also increased. Today, nearly twenty-five percent of people in the United States fall into this category: the elderly, young children, pregnant women and the immuno-compromised. Moreover, the size of the vulnerable population is growing. Due to increased longevity, the senior population is now the fastest growing sector of society.

Finally and most importantly, resistance trends in pathogenic bacteria, as well as new and more deadly pathogens, have emerged in the food supply. Fifty years ago scientists had identified four foodborne pathogens; today five times that number have been identified.

SCIENCE-BASED FOOD SAFETY SYSTEM

Working together, the federal government's food safety agencies, the Food and Drug Administration, the U.S. Department of Agriculture, the Centers for Disease Control and Prevention, (CDC) and the Environmental Protection Agency have responded to these changes by laying the foundation for the creation of a state-of-the-art science-based food safety system. This system focuses on combating foodborne illness on two major strategic fronts:



- Through the development of prevention strategies, programs that will keep pathogens out of the food, throughout the food chain from farm to table. These prevention programs are

supported by education and verification--by educating producers, processors, distributors, food service workers, and consumers in how to use prevention techniques correctly, and by verifying, through inspections at business establishments, that prevention techniques are being applied properly; and

- Through the development of a strong outbreak response capability that provides for the early detection and containment of foodborne hazards before they become widespread and helps develop the knowledge to prevent future outbreaks.

PREVENTION, EDUCATION, and VERIFICATION

Prevention is the key to reducing foodborne illness. Scientific risk assessment programs identify threats to the public health from the environment, from processing systems, from food handlers and other sources in the nation's food system. This information is used to identify the most effective techniques to prevent pathogens from entering the food supply.

Regulatory prevention programs such as the Hazard Analysis and Critical Control Point (HACCP) system, look for places where contamination is likely to occur as a way to reduce risk. Mandated at seafood, meat and poultry production and processing facilities, HACCP programs identify and document methods to prevent contamination.

Development and adoption of model prevention programs is another technique to advance food safety. An example is the 1999 Food Code, a model code of food safety guidelines for food service establishments that promotes food safety by serving as a reference for more than 3,000 state and local regulatory agencies that oversee food safety in restaurants, grocery stores, nursing homes, and other institutional and retail settings. Working together with food industries to establish voluntary guidelines, such as the good agricultural and good manufacturing practices for raw fruits and vegetables, also help prevent pathogens from entering the food supply.



Education about food safety practices for food handlers along the farm to table continuum is an effective prevention program as well. Programs to teach good agricultural practices to domestic and international growers, development of knowledge and skill competencies for food service managers and food safety regulators assigned to inspect retail food service establishments, school-based education programs to instill in young people life long safe food handling practices, and media and community-based public information campaigns to reach at-risk populations are all part of FSI.

Verification of the effectiveness of the prevention programs is achieved through varying types and frequencies of inspection procedures at domestic food production and processing facilities, at international borders, and at foreign locations of producers and processors who export food to the United States.

OUTBREAK RESPONSE

Fast and effective response to emerging pathogens in the food supply is essential to preventing widespread illness. FSI's outbreak response program uses scientific research as the foundation for a multi-faceted program that includes:

- Scientists at the Foodborne Diseases Active Surveillance Network (FoodNet) sites located throughout the country who actively track laboratory-confirmed cases of foodborne disease in their nearby population centers. Findings are shared among

HACCP

The Federally mandated, science-based Hazard Analysis and Critical Control Point (HACCP) system is a critical prevention program under the Food Safety Initiative. This program identifies points where contamination

sites and with the CDC to gain a more accurate picture of the number of possible foodborne disease cases annually;

- A computerized database, PulseNet, that matches the DNA fingerprint of foodborne diseases accelerating the traceback process to the source of the contamination;
- The Epidemiology Rapid Assessment Team available 24 hours a day to provide a rapid review of incoming reports of foodborne disease and to coordinate traceback and containment efforts; and
- FORCE-G, the Foodborne Outbreak Response Coordinating Group, that links federal, state and local government agencies to enhance coordination and communication in responding to outbreaks, use resources efficiently and prepare for new and emerging threats to the food supply.

is likely to occur and puts in place appropriate process controls to prevent contamination during production and processing at seafood, meat and poultry facilities.

With HACCP regulatory programs, there is a clear delineation of responsibilities between industry and the regulatory agencies. Industry has the primary responsibility for the safety of the food it produces and distributes. The government's principle role is to verify that industry is carrying out its responsibility, and to initiate appropriate regulatory action if necessary. Technical assistance is provided to facilities implementing HACCP plans.

The Produce Safety Initiative

Fresh fruits and vegetables are important to the health and well being of the American consumer. However, in recent years the detection of outbreaks of foodborne illness associated with both domestic and imported fresh fruits and vegetables has increased. As a result, President Clinton introduced the Produce Safety Initiative in the fall of 1997. Like the FSI, of which it is a part, the PSI addresses the entire produce food chain from grower to table.

VOLUNTARY GUIDANCE

To minimize microbial hazards in the production, packing and transport of fresh fruits and vegetables, voluntary guidance has been developed that represents generally accepted, safe science-based agricultural practices. Published in the Guide to Minimize Microbial Food Safety Hazards For Fresh Fruits and Vegetables, the recommendations identify critical control points where contamination is likely to happen and outlines steps that can be taken to minimize the risk of that occurring. Developed in consultation with consumers, growers packers and shippers, these recommendations are designed to be tailored to the needs of individual facilities and farms.

The Guide identifies broad microbial hazards, the scientific basis for the hazard, and good agricultural practices and good management practices that can be used to reduce the risk of microbial contamination in fresh and minimally processed produce. Five areas of concern are addressed in the Guide:

- Water quality
- Manure and municipal biosolids
- Worker health and hygiene
- Sanitation, including fields and packing facilities
- Transportation

The recommendations also establish traceback procedures so that the sources of bacteria can be identified and safeguards put in place to prevent further contamination.

IMPORTS

On the premise that the safety of imported foods can be better monitored where foods are produced rather than as they cross the U.S. border, new programs are being designed to prevent contamination in countries that export to the United States. Assessment of foreign controls over food products exported to the United States are underway and technical assistance is being provided to foreign countries.

Foreign inspections of food establishments that produce food products at high risk for microbial contamination will be conducted and conventional surveillance of imported food products at U.S. borders will be increased. When foodborne illness outbreaks associated with imported foods occur, follow up investigations in the exporting countries will be conducted.

The Future of Food Safety

Although it is among the best in the world, the nation's food safety system can and will be improved. Illnesses due to contaminated food, while preventable, continue to occur. The Food Safety Initiative is establishing a strong foundation for creating the safest science-based food system possible.

For further information about the Food Safety Initiative check the U.S. Government's website, www.FoodSafety.gov.

Home

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FOOD SAFETY FROM
FARM TO TABLE

PHOTOCOPY
PRESERVATION

Food and Drug Administration
U. S. Department of Agriculture
U. S. Environmental Protection Agency
Centers for Disease Control and Prevention
May 1997

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

REPORT TO THE PRESIDENT MAY 1997

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EXECUTIVE SUMMARY

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

In his January 25, 1997 radio address, President Clinton announced he would request \$43.2 million in

his 1998 budget to fund a nationwide early-warning system for foodborne illness, increase seafood safety inspections, and expand food-safety research, training, and education. The President also directed three Cabinet members--the Secretary of Agriculture, the Secretary of Health and Human Services, and the Administrator of the Environmental Protection Agency--to identify specific steps to improve the safety of the food supply. He directed them to consult with consumers, producers, industry, states, universities, and the public, and to report back to him in 90 days. This report responds to the President's request and outlines a comprehensive new initiative to improve the safety of the nation's food supply.

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

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

This report presents the results of that consultative process. It outlines steps USDA, HHS, and EPA will take this year to reduce foodborne illness, and spells out in greater detail how agencies will use the \$43.2 million in new funds requested for fiscal year 1998. It also identifies issues the agencies plan to consider further through a public planning process.

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

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

The need for further action is clear. Our understanding of many pathogens and how they contaminate food is limited; for some contaminants, we do not know how much must be present in food for there

to be a risk of illness; for others, we do not have the ability to detect their presence in foods. 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 constraints 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 limited scrutiny. Some food processors, restaurateurs, food-service workers, supermarket managers, and consumers are unaware of how to protect food from the threat of foodborne contaminants. These and other deficiencies will be addressed by key Administration actions outlined in this report and described below.

Enhance Surveillance and Build an Early-Warning System

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

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

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

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

Improve Responses to Foodborne Outbreaks

At the federal level, four agencies are charged with responding to outbreaks of foodborne and waterborne illness: CDC, FDA, FSIS, and EPA. States and many local governments with widely varying expertise and resources also share responsibility for outbreak response. The current system does not assure a well-coordinated, rapid response to interstate outbreaks. To ensure a rapid and appropriate response, with FY98 funds, agencies will:

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

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

Improve Risk Assessment

Risk assessment is the process of determining the likelihood that exposure to a hazard, such as a

foodborne pathogen, will result in harm or disease. Risk-assessment methods help characterize the nature and size of risks to human health associated with foodborne hazards and assist regulators in making decisions about where in the food chain to allocate resources to control those hazards. To improve risk-assessment capabilities, with FY98 funds, the agencies will:

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

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

Develop New Research Methods

Today, many pathogens in food or animal feed cannot be identified. Other pathogens have developed resistance to time-tested controls such as heat and refrigeration. With FY98 funds, the agencies will focus research immediately to:

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

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

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

Improve Inspections and Compliance

With FY98 funds, the agencies will pursue several strategies to increase inspections for higher-risk foods; the agencies will, among other things:

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

Propose preventive measures for fresh fruit and vegetable juices. Based on the best science available, FDA will propose appropriate regulatory and non-regulatory options, including HACCP, for the manufacture of fruit and vegetable juice products.

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

Identify preventive measures to address public-health problems associated with produce such as those recently associated with hepatitis A virus in frozen strawberries and *E. coli* O157:H7 on lettuce. These measures will be identified through a comprehensive review of current production and food-safety programs including inspection, sampling, and analytical methods.

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

whose products are implicated in a foodborne illness.

Further Food-Safety Education

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

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

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

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

Continue the Long-Range Planning Process

Through this initiative, and through previous activities, HHS, USDA, and EPA have laid the groundwork for a strategic planning effort. There is a broad recognition of the need to carefully implement the initiative's programs, and to consider how to apply preventive measures in other areas of concern. A strategic-planning effort is needed to build on this common ground, and to tackle some of the difficult public-health, resource, and management questions facing federal food-safety agencies. The federal food-safety agencies are committed to continuing to meet with stakeholders, ultimately to produce a strategic plan for improving the food-safety system.

A NEW INTERAGENCY STRATEGY TO PREVENT FOODBORNE DISEASE

In his radio message on January 25, 1997, President Clinton announced a new initiative to improve the safety of the nation's food supply. The President announced he would request \$43.2 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 (see Appendix A). President Clinton also directed the Secretary of Agriculture, the Secretary of Health and Human Services, and the Administrator of the Environmental Protection Agency to work with consumers, producers, industry, states, universities, and the public to identify additional ways to reduce the incidence of foodborne illness and to ensure our food supply is the safest in the world. The President directed Secretaries Glickman and Shalala and Administrator Browner to report to him with recommendations in 90 days. He instructed them to consult with a broad range of stakeholders in the food-safety system and to explore opportunities for public-private partnerships to improve food safety. And he asked that their recommendations include ways to improve surveillance, inspections,

research, risk assessment, education, and coordination among local, state, and federal health authorities.

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

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

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

FOODBORNE ILLNESS: A SIGNIFICANT PUBLIC-HEALTH PROBLEM

The Council for Agricultural Science and Technology, a private nonprofit organization, estimated in its 1994 report, *Foodborne Pathogens: Risks and Consequences*, that as many as 9,000 deaths and 6.5 to 33 million illnesses in the United States each year are food-related. The Department of Agriculture (USDA) estimates that medical costs and productivity losses for 7 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 include the total burden placed on society by the chronic illness caused by some foodborne pathogens.

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

Sources of Foodborne Contamination

Bacteria and other infectious organisms are pervasive in the environment.

- *Salmonella* serotype Enteritidis enters eggs directly from the hen.
- Bacteria (occasionally pathogenic) inhabit the surfaces of fruits and vegetables.
- Molds and their toxic byproducts can develop in grains during unusually wet or dry growing seasons, damage and stress during harvesting, or during improper storage.
- Seafood can become contaminated from agricultural animal manures and wastes and other runoff, as well as by sewage, microorganisms, and toxins present in marine environments.
- Many organisms that cause foodborne illness in humans can be part of the normal flora of the gastrointestinal tract of food-producing animals without any adverse effects to the animals.

- Milk, eggs, seafood, poultry, and meat can become contaminated from contaminated feed, misuse of veterinary drugs, or poor farming practices, in particular, mismanagement of animal manures, including production and harvesting activities.
- Foods can become contaminated during processing due to malfunctioning or improperly sanitized equipment, misuse of cleaning materials, rodent and insect infestations, and improper storage.
- Foods can become contaminated in retail facilities and in homes through poor food-handling practices.

Some microbial pathogens give rise to diseases that are far more serious than the uncomfortable but relatively temporary inconvenience of diarrhea and vomiting, which are the most common symptoms of so-called "food poisoning." Foodborne infections can result in very serious immediate consequences, such as spontaneous abortion, as well as long-lasting conditions, such as reactive arthritis, Guillain-Barré syndrome (the most common cause of acute paralysis in adults and children), and hemolytic uremic syndrome (HUS), which can lead to kidney failure and death, particularly in young children. Some of the microbial pathogens that have been the source of foodborne illness cases and outbreaks recently include, *Salmonella*, *Campylobacter*, Shiga-like toxin-producing *Escherichia coli*, *Vibrio*, *Toxoplasma gondii*, *Cryptosporidium parvum*, Norwalk virus, and hepatitis A. A full description of these pathogens, the foodborne illnesses they cause, and frequently implicated foods may be found in Appendix B. In addition to microbial pathogens, other substances may contaminate foods and cause foodborne illness. Among these are naturally occurring mycotoxins and marine toxins.

THE CURRENT SYSTEM FOR PROTECTING FOOD

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

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

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

- Food processing for foods other than meat, poultry, and egg products (except shell eggs) is regulated by FDA, whose inspectors are responsible for visiting about 53,000 plants periodically, with emphasis on the highest risk foods or processing techniques. FDA devotes about 700 inspectors and laboratory personnel to this activity. Meat, poultry, and all other egg products are regulated by FSIS, whose inspectors are present in slaughter and processing establishments to ensure that these products are safe, wholesome, and properly labeled. State and local governments also inspect food processors, with varying frequencies and under varying standards.
- Food being transported in interstate commerce is subject to federal and state regulation. In 1996, FSIS and FDA jointly published an Advanced Notice of Proposed Rulemaking (ANPR) on whether regulations are needed to govern the handling of meat, poultry, seafood, eggs, and other foods susceptible to microbial contamination during transportation. FDA and FSIS will evaluate the comments and information received in response to the ANPR as a basis for determining what, if any, regulatory approach to take, including development of guidelines. These guidelines may include such elements as suggested performance standards for temperature control, providing information on prior cargo, and cleaning information for the food-shipper's use, to ensure the safety of the food at its destination.
- Importation of food from foreign countries is overseen by FSIS for meat, poultry, and most egg products and by FDA for all other foods. If an imported food is suspect, it can be tested for contamination and its entry into the United States denied.
- Restaurants, supermarkets, and institutional food services (such as schools and hospitals) fall under the FDA's retail food-protection program, a cooperative federal-state food-safety effort operated under the Public Health Service Act. FDA has regulatory authority under the Federal Food, Drug, and Cosmetic Act over retail establishments because the food used in these establishments traveled in interstate commerce, however, the PHS Act provides the means for more efficient regulation and use of available resources, as well as broader inspection coverage. FDA publishes the Food Code, which consists of model recommendations that states and local authorities adopt and use to regulate retail food establishments. FDA, along with FSIS and CDC, work with states biennially to update the Food Code.
- National standards for drinking water and criteria for surface waters are set by EPA and enforced generally by local public-water authorities; FDA establishes complementary standards for bottled water.
- Surveillance of foodborne illness is primarily the responsibility of state and local health departments and the CDC, which seek to identify cases of illness, determine their sources, and control outbreaks. CDC conducts field investigations of foodborne diseases only at the request of state health departments, which have the authority to implement outbreak control measures. FDA, FSIS, or both are called in when food within their jurisdiction is suspected. FDA and FSIS are charged with ensuring that foods implicated in a foodborne illness outbreak and traveling in interstate commerce are removed from the market.
- Research serves many purposes in reducing the incidence of foodborne illness and is integral to the programs of all public-health agencies. Research is essential to evaluate effectiveness of

surveillance initiatives, control and prevention strategies, conduct risk assessments, and verify effectiveness of preventive techniques such as HACCP. Research into the cause and transmission of foodborne illness is the primary responsibility of CDC, FDA, ARS, CSREES, and EPA. The development of screening and analytic methods to rapidly and accurately identify and characterize foodborne hazards, identifying and tracking to the source the causes of foodborne illness, is the responsibility of FDA, ARS, CSREES, EPA, and CDC. Research to develop preventive technologies, ranging from new production techniques, to disinfection and food-processing techniques to reduce levels of pathogens, is the primary responsibility of ARS, CSREES, FDA, and industry. Basic research is conducted largely in university laboratories on the biology, genetics, pathogenesis, natural history, and epidemiology of microorganisms implicated in foodborne disease and is actively supported by the NIH, and in particular, by the National Institute of Allergy and Infectious Diseases. These efforts are focused on understanding the disease process and designing prevention and treatment strategies. Other agencies of the federal government also support related research in universities. The private sector supports research within its own laboratories and in universities.

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

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

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

- In 1993, the Vice President's National Performance Review issued a report recommending that the government and industry should move toward a system of preventive controls.
- FSIS and FDA issued regulations that will require the meat, poultry, and seafood industries to follow HACCP procedures. These HACCP rules require food industries to design and implement preventive measures and increase the industries' responsibility for and control of their safety-assurance actions. FSIS and FDA will streamline their current regulations as part of their conversion to HACCP.
- In 1994, CDC embarked upon a strategic program to detect, prevent, and control emerging infectious disease threats, some of which are foodborne, and has made significant progress toward this goal in each successive year.
- The Food Quality Protection Act of 1996, including many provisions of the Administration's bill, streamlined regulation of pesticides by FDA and EPA and put important new public-health protections in place, especially for children.
- Last year, the President signed the Safe Drinking Water Act of 1996, which includes regulatory improvements to help states and water-utility managers prevent drinking-water contamination problems. Resources are provided for the first time for drinking-water infrastructure that will help hundreds of communities protect their residents from harmful contaminants.

These advances are significant, but they are not enough. New pathogens, new food products, huge

increases in imported foods, the growing importance of food exports, and increasing antimicrobial resistance among foodborne pathogens present new challenges to the nation's food-safety programs. The food-safety system is in need of change, especially change that builds on the preventive principles embodied in HACCP.

IMMEDIATE ACTIONS TO IMPROVE FOOD SAFETY

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

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

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

A NEW EARLY-WARNING SYSTEM FOR FOODBORNE DISEASE SURVEILLANCE

Background

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

Problem

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

Recommendations

Surveillance and investigation are powerful tools to detect new foodborne disease challenges, to determine what specific food sources are implicated in foodborne illness, and to learn how best to keep foods from becoming contaminated in the first place. Surveillance for antimicrobial resistance will allow early detection of resistance and containment of its spread. Rapid detection of outbreaks is critical to stopping them before they affect many people. A key element in an early-warning system is the ability to detect, compare, and communicate unusual patterns of illness and laboratory findings within and among states and federal partners.

Enhancing 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 enhance and expand the existing Foodborne Disease Active Surveillance Network (FoodNet) to identify, investigate, and control a broad spectrum of foodborne diseases. A second important way to enhance early warning is to increase the capacity of many states to deal with new foodborne challenges. These enhancements will help us identify outbreaks and other foodborne disease challenges early, and prevent illness and premature deaths related to foodborne diseases.

In cooperation with state and local health departments, the federal government is proposing to take the following steps to establish a national early-warning system for foodborne diseases, and to enhance surveillance of such disease. These changes will result in an improved system for promptly and accurately detecting and reporting foodborne illnesses and outbreaks so public-health agencies can rapidly institute appropriately and correctly focused measures to control the spread of foodborne disease. This system will also collect critical data to recognize trends and target prevention strategies, including systems based on HACCP principles, and to evaluate the effectiveness and efficiency of prevention strategies already in place.

Enhance and Expand Foodborne Disease Active Surveillance

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

FY97 Activities

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

FY98 Activities with Food-Safety Initiative Funds

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

Enhance Early Detection of Foodborne Disease Nationwide

The early-warning system will enhance improved early detection of foodborne disease in additional states in FY98 by providing resources for improved surveillance, investigation, control, and

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

FY97 Activities

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

FY98 Activities with Food-Safety Initiative Funds

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

Long-term Activities

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

Modernize Public-Health Laboratories

CDC should provide resources and training to upgrade public-health laboratory capabilities in FoodNet sites and in states without those sites so the laboratories can rapidly identify a broad range of foodborne pathogens, including parasites and viruses, and can use new techniques like DNA

fingerprinting. The new capacities would allow rapid identification of the cause of some outbreaks that currently go undiagnosed.

FY97 Activities

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

FY98 Activities with Food-Safety Initiative Funds

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

Long-term Activities

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

Create a National Electronic Network for Fingerprint Comparison

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

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

FY97 Activities

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

FY98 Activities with Food-Safety Initiative Funds

- The national electronic database of DNA fingerprint patterns of *E. coli* O157:H7 will continue to be expanded.

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

Long-term Activities

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

Increase National Surveillance for Antimicrobial Resistance of Foodborne Pathogens

The problem of foodborne disease is increasing, in part, because foodborne infections are becoming more serious. One of the ways foodborne pathogens become more virulent is by acquiring resistance to antimicrobial agents, making such infections very difficult to treat. Therefore, CDC should expand surveillance for antimicrobial resistance in *Campylobacter*, *Salmonella*, and *E. coli* O157:H7 isolated in humans, and FDA and FSIS should take similar steps for those bacteria isolated from food-producing animals and their manures and from food products in a way that permits those data to be compared. CDC, FDA and FSIS should develop standard procedures for sharing information and for responding to increases in resistance or other "red-flag events" such as the discovery of an important new resistant bacterium.

FY97 Activities

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

FY98 Activities with Food-Safety Initiative Funds

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

Long-term Activities

- CDC, FDA, and FSIS should continue monitoring and comparing the antimicrobial resistance of *E. coli* O157:H7, *Salmonella*, and *Campylobacter* strains in humans and animals.

- FDA and CDC should conduct physician and veterinary drug-prescribing surveys, including patients and animal producers, to assess the effect of antimicrobial drug use on resistance patterns and prevalence to guide regulatory policy and educational campaigns.
- FDA should assist the World Health Organization (WHO) in the development of a veterinary database within the WHONET system. (WHONET is a system for standardized international reporting of antimicrobial resistance to WHO.)

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

FY98 Activities with Food-Safety Initiative Funds

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

Long-term Activities

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

INTERSTATE OUTBREAK CONTAINMENT AND RESPONSE COORDINATION

Background

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

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

The states and many local governments also have a critical role. Identification and investigations of foodborne illness often begin at the community or state level. States share with the federal government the legal responsibility for protecting the health of their residents. Although foodborne outbreaks are sometimes local, most outbreaks implicate federal agency jurisdiction. Illnesses cross state borders, and most foods or food ingredients are processed or produced in another state or by

international trading partners. Federal involvement is also necessary when contaminated food from a common source has been distributed to grocery stores, restaurants, and homes in more than one state.

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

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

Problem

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

Recommendations

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

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

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

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

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

As part of this initiative, the agencies have streamlined their outbreak-response procedures. The departments with a role in any foodborne illness outbreak will be determined by public-health responsibility and regulatory jurisdiction over the food products (or water) implicated in the outbreak. Each department with public-health responsibility and regulatory jurisdiction over food products (or water) implicated in an outbreak will designate a Coordinator responsible for that Department's activities related to the outbreak.

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

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

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

FDA has also instituted a 50-state conference call system to keep all state agencies up-to-date on major foodborne outbreaks. This system was first used for the outbreak involving *E. coli* O157:H7 in apple juice and was most recently used for the hepatitis A outbreak associated with frozen strawberries. FDA and CDC jointly participate in these calls to assure more effective follow up and control of outbreaks. FDA will modify the conference call system to involve appropriate states in the very early stages of any multistate outbreak, as well as continuing the 50-state update conference calls, in order to ensure better communication among state and federal agencies.

FY97 Activities

- To further strengthen our outbreak-response systems, CDC, EPA, FDA, and FSIS will establish an intergovernmental group, the Foodborne Outbreak Response Coordinating Group (FORCG), to improve the approach to interstate outbreaks of foodborne illness. FORCG will provide for appropriate participation by representatives of state and local agencies charged with responding to outbreaks of foodborne illness. This group will also review ways to more effectively involve the appropriate state agencies when there is a foodborne outbreak.
- FORCG will review and evaluate outbreak response. FORCG will undertake these

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

- Under the new initiative there will be one person/position designated as the outbreak coordinator for each department or agency that has a role in the outbreak response. This position will be established as a formal institutional position, with appropriate backup designees. For outbreaks that fall within the purview of HHS, HHS will designate the Assistant Secretary for Health to be the primary person in charge of coordination for HHS. For outbreaks that fall within the purview of USDA, the Under Secretary for Food Safety will coordinate for USDA. EPA will designate the Assistant Administrator for Water as the primary person in charge of coordination for EPA when drinking water is involved.
- Standard procedures will be developed for the rapid exchange of data and information associated with foodborne illness outbreaks between involved agencies and for dissemination to the public. The procedures will be developed by FORCG and representatives from the appropriate state agencies. The procedures will cover the exchange of data and information associated with an outbreak and will complement systems established for exchange of information about day-to-day occurrences of foodborne illness. (See "A New Early-Warning System for Foodborne Disease Surveillance" section.) The procedures will also provide for rapid dissemination of accurate information to the public by the agency spokesperson.

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

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

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

FY97 Activities

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

FY98 Activities with Food-Safety Initiative Funds

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

RISK ASSESSMENT**Background**

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

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

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

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

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

Risk assessment characterizes the nature and size of the risk to human health associated with hazards, and to make clear the degree of scientific certainty of the data and the assumptions used to develop the estimates. Risk assessments require specific information on the hazard and on the exposed population to provide meaningful information for those making risk-management decisions. Even for chemical hazards, for which risk-assessment force the use of assumptions about exposure, hazard potency, and characteristics of the population at risk.

Problem

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

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

Recommendations

This initiative emphasizes the development, testing, and validation of microbial risk assessment and foodborne illness valuation methods. These efforts should support effective and efficient public response to foodborne illness concerns, whether the response is improved surveillance plans, better prevention strategies, or stronger inspection models. The initiative's activities focus on developing models for improving risk assessment, thereby more precisely targeting the prevention of foodborne disease by informing surveillance plans, prevention strategies for process-control systems and for food inspections based on HACCP principles, and research programs to fill critical food-safety information gaps. Recommendations are being made in three areas.

Establish a Risk Assessment Consortium

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

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

FY97 Activities

- The consortium, which will include all interagency partners, will be established in 1997 as part of the Joint Institute for Food Safety and Applied Nutrition, a collaborative activity of FDA's Center for Food Safety and Applied Nutrition and Center for Veterinary Medicine and the University of Maryland. The initial focus of the initiative

will be on pathogenic microorganisms.

- 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. The consortium will work with its member agencies to catalogue their microbial risk-assessment-research advances and identify data sets that would provide the scientific data needed to develop new models. The consortium will 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.

FY98 Activities with Food-Safety Initiative Funds

- A series of public meetings will be held to develop a strategy to address long-term research needs for the analysis of farm-to-table scenarios, including potential pathogen introduction at each level (e.g. farm, processing, transportation, home, restaurant, and retail food handling), food-consumption data, and computer modeling. A strategic plan will be developed for research into dose-response calculations, chronic sequelae, biomarkers, and adapting surveillance data. This process will include a broad spectrum of academic, industry and government expertise that will be obtained through an acceptable process such as an advisory committee.
- Begin a comprehensive review of existing data and federal information-collection programs to determine the extent to which they may fill existing data gaps, and suggest additional data needs to better support risk assessments.

Long-term Activities

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

Develop and Validate Exposure Assessment Models Based on Probabilistic Methodology

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

FY98 Activities with Food-Safety Initiative Funds

Working with FDA, EPA, and USDA, the consortium will identify priority research programs

in two areas that are in need of augmentation: exposure assessment methods, and techniques for acquisition and analysis of experimental data for model development. Initial areas identified include:

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

Long-term Activities

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

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

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

FY98 Activities with Food-Safety Initiative Funds

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

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

Long-term Activities

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

RESEARCH

Background

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

Problem

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

Recommendations

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

Improved Detection Methods

Many pathogens cannot be easily detected in foods, e.g., *Cyclospora* in raspberries. Among the needs for improved diagnostics, methods are needed for rapid, cost-effective testing for pathogens in food animals and their manures, in agriculture and aquaculture products, animal feeds, and processed food products. Methods development must address the low-level, sporadic incidence of many pathogens in foods. Research will be coordinated with EPA's efforts to develop better test methods for *Cryptosporidium* and other pathogens in water and drinking water. Improved methods are needed for the identification and subtyping of foodborne pathogens in human and animal clinical specimens. The development of effective sampling plans and enrichment techniques are vital parts of detection methodology.

FY97 Activities

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

FY98 Activities with Food-Safety Initiative Funds

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

Long-term Activities

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

Understanding Resistance to Traditional Preservation Technologies

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

Long-term Activities

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

Understanding Antibiotic Drug Resistance

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

FY98 Activities with Food-Safety Initiative Funds

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

Probiotics are benign bacteria that can be used to out-compete pathogenic bacteria.

Prevention Techniques: Pathogen Avoidance, Reduction, and Elimination

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

FY98 Activities with Food-Safety Initiative Funds

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

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

Long-term Activities

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

Food Handling, Distribution, and Storage

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

Long-term Activities

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

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

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

IMPROVING INSPECTIONS AND COMPLIANCE

Background

Inspection of commercial food processors is an integral part of the food-safety assurance system. Inspections are carried out by federal, state and local authorities. In addition to other food-inspection responsibilities, state and local officials also have primary responsibility for inspecting restaurants, supermarkets, and other retail establishments. At the federal level, FSIS has responsibility for meat and poultry inspection in slaughter and processing plants and egg-product-processing plants, and for all imported meat, poultry, and egg products. FDA conducts periodic, random inspections of all other food-processing plants; that entails fewer than 700 inspectors and laboratory personnel for 53,000 U.S. plants and for all other imported foods.

Problem

The number of inspections conducted by FDA has decreased steadily since 1981, when 21,000 inspections were conducted, so that today resources exist to carry out only about 5,000 inspections per year. An FDA-regulated plant is inspected by FDA, on average, only once every 10 years. FDA also relies upon the states to conduct some inspections under contract, but that number has dropped from 12,000 in 1985 to 5,000 now. Moreover, because the number of imports has doubled over 5 years, with no real increase in inspectors, a smaller percentage of imports are inspected at entry.

Given the limited inspection coverage, FDA is finding an increasing number of problems--the number of products recalled for life-threatening microbial contamination has increased almost five-

fold since 1988. Federal budget constraints will likely prohibit significant funding increases in the future, so FDA must find new ways to provide adequate inspection coverage.

Recommendations

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

Enhance Development of HACCP Procedures

FY97 Activities:

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

implementation.

- The design and testing of new inspection concepts consistent with HACCP principles to achieve food-safety and other consumer-protection objectives through distribution and retail channels to consumers.
- FSIS and state associations will complete development of HACCP-based control measures for meat and poultry processing at the retail level.

FY98 Activities with Food-Safety Initiative Funds

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

Long-term Activities

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

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

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

FY97 Activities

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

FY98 Activities with Food-Safety Initiative Funds

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

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

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

Long-term Activities

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

Enhance Federal-State Inspection Partnerships

State inspection programs are an important component of the nation's food-safety inspection system. The move toward HACCP will pose a challenge to the states that federal agencies can help the state system to meet. If HACCP is to be an effective program for ensuring that food processors have modern, state-of-the-art food-safety procedures in effect, FDA must improve its inspection capabilities, so that the highest-risk food plants are inspected at least once per year. New federal-state partnerships focused on coordinating inspection coverage (particularly between FDA and the states), are major steps in this direction.

FY97 Activities

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

FY98 Activities with Food-Safety Initiative Funds

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

Long-term Activities

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

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

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

number of staff.

FY98 Activities with Food-Safety Initiative Funds

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

Long-term Activities

- FSIS should continue to verify foreign government-inspection progress for conformance with the new HACCP and Pathogen Reduction Requirements; that activity will begin in 1997 and should be completed in 2000.
- The laboratory-certification process should be extended to include assessing the utility of existing accrediting bodies with FDA providing performance standards and oversight to the process.
- FDA should expand the federal-state communication system states use to inform federal agencies of problems found with imported products in their jurisdictions. As part of that expansion, FDA should evaluate the feasibility of combining the communication system with the federal-state inspection data system discussed above, making the data and information more widely accessible.
- FDA should review and evaluate ways to increase coverage of imports through such means as increased personnel, increased partnerships, or innovative information-sharing with the states.

Enhance Safety of Foods During Transportation

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

FY98 Activities with Food-Safety Initiative Funds

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

destination.

Long-term Activities

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

EDUCATION

Background

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

Problem

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

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

Risk assessment and research are needed to determine the most effective ways to overcome barriers to use of safe food-handling practices and to ensure use of safe food-handling practices by specific audiences. Consumers' food-handling practices and the choices they make in the foods they eat will either increase or decrease the chances of foodborne illness. Studies show that more than 50% of the public eats raw or undercooked 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.

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

Recommendations

The goal of this initiative is to target and change unsafe food-handling practices by people throughout

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

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

Improve Consumer, Retail, and Food Service Education

FY97 Activities

The 1997 Consumer Food-Safety Education Partnership

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

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

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

Other FY97 Activities

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

FY98 Activities with Food-Safety Initiative Funds

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

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

FY97 Activities

Under the auspices of the National Food Safety Education Council:

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

FY98 Activities with Food-Safety Initiative Funds

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

Long-term Activities

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

Expand Existing Information Systems

FY97 Activities

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

FY98 Activities with Food-Safety Initiative Funds

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

Long-term Activities

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

Improve Veterinarian and Producer Education

Long-term Activities

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

Improve Health-Professional Education

Long-term Activities

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

Improve Industry Education in the Transportation Area

Long-term Activities

- Form an alliance among government agencies and the private sector to develop educational materials and train food-transportation vehicle owners and operators and food-processing establishments on hazards associated with the transportation of food products, particularly hazards associated with temperature control, prior cargo, and sanitation methods.
- See also: "Inspections: Enhance Safety of Foods During Transportation."

A BLUEPRINT FOR A BETTER FOOD-SAFETY SYSTEM

Background

The actions described in this report will significantly improve the safety of the nation's food supply, but the agencies recognize that this 90-day report does not address a number of critical issues facing our food-safety programs. The agencies recommend a longer-term strategic planning effort to consider how to best address important challenges and make the best use of the agencies' limited resources. This process will involve all public and private stakeholders, including consumer groups, affected families, state and local governments, and industry. One function of the strategic-planning process is to consider how to make the best use of each agency's limited resources.

Through this initiative, and previous activities, we have laid the groundwork for a strategic planning effort. For example, federal agencies, consumer groups, and industry have worked together to incorporate HACCP into meat, poultry, and seafood regulatory programs. And there is now a broad

recognition of the need to carefully implement these programs, and to consider how to apply preventive measures in other areas of concern. A strategic-planning effort could build on this common ground, and tackle some of the difficult public-health, resource, and management questions facing federal food-safety agencies.

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

In recent years, there has been increasing evidence 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 looked to a new and similar approach to food regulation. FSIS has adopted HACCP for the products that it regulates and FDA has adopted HACCP for seafood products, and is considering the HACCP approach for other products. During the next few years, the HACCP regulations that these agencies have adopted will go into effect, and more may well follow.

Developing a Strategic Plan

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

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

Because it is critical that the process be inclusive and equitable, the agencies will give interested parties an opportunity to comment on the possible approaches for structuring the dialogue before its implementation. The agencies will provide specific information regarding the general objective, scope, and conduct of the dialogue and strategic-planning process, management of the process, selection criteria for participants, and other relevant factors. Unanimous agreement is unlikely. Therefore, the agencies will use a general consensus to shape the planning process.

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

Issues for Consideration

A major challenge in developing a strategic plan will be attaining consensus on priorities for action to enhance food safety within the highly complex food-safety oversight system. Reaching agreement on priorities is compounded by the complexity of the food supply and the different perspectives of the various oversight agencies and groups. Federal and state agencies have established programs in

research, risk assessment, education, surveillance, and inspection, and agencies are working to better coordinate activities within these programs. Nevertheless, a better system of identifying and setting priorities within these areas is essential to maximizing the use and effect of limited agency resources in reducing the incidence of foodborne illness and enhancing the safety of the food supply.

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

- Key public-health, resource, and management questions facing federal food-safety agencies.
- Structure of strategic, coordinated, long-range risk-assessment and research agendas.
- Consideration of improvements for coordination and planning of food-safety regulation to optimize federal and state prevention, intervention, and control actions.
- Means to improve exchange of information about foodborne disease outbreaks.

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

- Technical and policy issues associated with agricultural manures (important potential sources of microbial contaminants of foods). Animal manures are currently excluded from regulation. Therefore, an EPA regulatory mechanism to control human health impacts resulting from improper application to or burial of manures in farm and other lands does not exist.
- Technical and policy issues associated with microbial-control technologies, including food irradiation.
- Developing a global approach to evaluating new, emerging, and potential foodborne diseases such as Transmissible (Bovine) Spongiform Encephalopathy--T(B)SE--and a process for responding to prevent the spread of such diseases.

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. Each agency will incorporate the relevant parts of the strategic plan into its Government Performance and Results Act (GPRA) strategic plan, commensurate with its budget.

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

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

APPENDIX A

FY98 Budget -- Food Safety Initiative

HHS:**Food and Drug Administration****Foods:**

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

Animal Drugs and Feeds:

Surveillance	1,500,000
Research	2,500,000
Total Animal Drugs & Feeds	4,000,000

Centers for Disease Control:

Surveillance	10,000,000
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Total, HHS **34,000,000**

USDA:**Agricultural Research Service**

Research	4,114,000
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**Cooperative State Research, Education
and Extension Service**

Research	2,000,000
Education	2,000,000
Total, CSREES	4,000,000

Food Safety and Inspection Service

Surveillance	500,000
Inspections	565,000
Total, FSIS	1,065,000

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

Total Initiative **43,179,000**

APPENDIX B

SOME IMPORTANT MICROBIAL PATHOGENS ASSOCIATED WITH FOODBORNE ILLNESS

Bacteria

Salmonella

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

Campylobacter

The bacterium *Campylobacter* is the most frequently identified cause of acute infectious diarrhea in developed countries and is the most commonly isolated bacterial intestinal pathogen in the United States. It has been estimated that between 2 and 4 million cases of campylobacteriosis occur each year with an associated 120-360 deaths. *Campylobacter jejuni* and *Campylobacter coli* (two closely related species) are commonly foodborne, and are the infectious agents most frequently described in association with Guillain-Barré syndrome, as frequently as 1 in 1000 cases. Several prospective studies have implicated raw or undercooked chicken as major sources of *C. jejuni/coli* infections. Unpasteurized milk and untreated water have also caused outbreaks of disease.

Shiga-like toxin-producing Escherichia coli

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

Vibrio

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

Protozoa

Toxoplasma gondii

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

Cryptosporidium parvum

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

Viruses**Norwalk virus**

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

Hepatitis A

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

Hypertext updated by dms/ear 5/12/97

PHOTOCOPY
PRESERVATION

FORC-G

U. S. Food and Drug Administration
FDA Backgrounder
September 24, 1998

Food Safety: A Team Approach

September 24, 1998

The United States maintains one of the world's safest food supplies, thanks in large part to an interlocking monitoring system that watches over food production and distribution at every level—locally, statewide and nationally.

Continual monitoring is provided by food inspectors, microbiologists, epidemiologists, and other food scientists working for city and county health departments, state public health agencies, and various federal departments and agencies. Their precise duties are dictated by local, state and national laws, guidelines and other directives. Some monitor only one kind of food, such as milk or seafood. Others work strictly within a specified geographic area. Others are responsible for only one type of food establishment, such as restaurants or meat-packing plants. Together they make up the U.S. food safety team.

The Clinton administration's Food Safety Initiative, begun in 1997, strengthens the efforts of all the members of the nation's food safety team in the fight against food-borne illness, which afflicts between 6.5 million and 33 million Americans every year. One of the initiative's major programs got under way in May 1998 when the Department of Health and Human Services (which includes FDA), the U.S. Department of Agriculture, and the Environmental Protection Agency signed a memorandum of understanding to create a Food Outbreak Response Coordinating Group, or FORC-G. The new group will:

- increase coordination and communication among federal, state and local food safety agencies
- guide efficient use of resources and expertise during an outbreak
- prepare for new and emerging threats to the U.S. food supply.

Besides federal officials, members of FORC-G include the Association of Food and Drug Officials, National Association of City and County Health Officials, Association of State and Territorial Public Health Laboratory Directors, Council of State and Territorial Epidemiologists, and National Association of State Departments of Agriculture.

The following table offers a closer look at the nation's food safety lineup. The agencies listed in the table also work with other government agencies, such as the Consumer Product Safety Commission to enforce the Poison Prevention Packaging Act, the FBI to enforce the Federal Anti-Tampering Act, the Department of Transportation to enforce the Sanitary Food Transportation Act, and the U.S. Postal Service to enforce laws against mail fraud.

U.S. Department of Health and Human Services *

Food and Drug Administration

Oversees

- All domestic and imported food sold in interstate commerce, including shell eggs, but not meat and poultry
- Bottled water
- Wine beverages with less than 7 percent alcohol

Food Safety Role

Enforces food safety laws governing domestic and imported food, except meat and poultry, by:

- Inspecting food production establishments and food warehouses and collecting and analyzing samples for physical, chemical and microbial contamination
- Reviewing safety of food and color additives before marketing
- Reviewing animal drugs for safety to animals that receive them and humans who eat food produced from the animals
- Monitoring safety of animal feeds used in food-producing animals
- Developing model codes and ordinances, guidelines and interpretations and working with states to implement them in regulating milk and shellfish and retail food establishments, such as restaurants and grocery stores. An example is the model Food Code, a reference for retail outlets and nursing homes and other institutions on how to prepare food to prevent food-borne illness.
- Establishing good food manufacturing practices and other production standards, such as plant sanitation, packaging requirements, and Hazard Analysis and Critical Control Point programs
- Working with foreign governments to ensure safety of certain imported food products
- Requesting manufacturers to recall unsafe food products and monitoring those recalls
- Taking appropriate enforcement actions
- Conducting research on food safety
- Educating industry and consumers on safe food handling practices

For More Information

Consumers:
FDA Headquarters
Office of Consumer Affairs
HFE-88
5600 Fishers Lane
Rockville, MD 20857

Regional FDA offices, listed in the blue pages of the phone book under U.S. Government

Media inquiries: 202-205-4144

Consumers:
FDA's Food Information and Seafood Hotline
1-800-FDA-4010 (1-800-332-4010),
202-205-4314 in the Washington, D.C., area

www.cfsan.fda.gov/list.html
www.fda.gov/cvm/default.htm

Centers for Disease Control and Prevention

Oversees

- All foods

Food Safety Role

- Investigates with local, state and other federal officials sources of food-borne disease outbreaks
- Maintains a nationwide system of food-borne disease surveillance: Designs and puts in place rapid, electronic systems for reporting food-borne infections. Works with other federal and state agencies to monitor rates of and trends in food-borne disease outbreaks. Develops state-of-the-art techniques for rapid identification of food-borne pathogens at the state and local levels.
- Develops and advocates public health policies to prevent food-borne diseases
- Conducts research to help prevent food-borne illness
- Trains local and state food safety personnel

For More Information

Centers for Disease Control and Prevention
1600 Clifton Rd., N.E.
Atlanta, GA 30333

Media inquiries: 404-639-3286

General public: 404-639-3311

www.cdc.gov

* Also, HHS's National Institutes of Health conduct food safety research.

U.S. Department of Agriculture **

Food Safety and Inspection Service

Oversees

- Domestic and imported meat and poultry and related products, such as meat- or poultry-containing stews, pizzas and frozen foods
- Processed egg products (generally liquid, frozen and dried pasteurized egg products)

Food Safety Role

Enforces food safety laws governing domestic and imported meat and poultry products by:

- Inspecting food animals for diseases before and after slaughter
- Inspecting meat and poultry slaughter and processing plants
- With USDA's Agricultural Marketing Service, monitoring and inspecting processed egg products
- Collecting and analyzing samples of food products for microbial and chemical contaminants and infectious and toxic agents
- Establishing production standards for use of food additives and other ingredients in preparing and packaging meat and poultry products, plant sanitation, thermal processing, and other processes
- Making sure all foreign meat and poultry processing plants exporting to the United States meet U.S. standards
- Seeking voluntary recalls by meat and poultry processors of unsafe products
- Sponsoring research on meat and poultry safety
- Educating industry and consumers on safe food-handling practices

For More Information

FSIS Food Safety Education and Communications Staff
Room 1175, South Building,
1400 Independence Ave., S.W.
Washington, DC 20250

Media inquiries: 202-720-9113

Consumers:
The Meat and Poultry Hotline, 1-800-535-4555
(In Washington, D.C., area, call 202-720-3333.)
TDD/TTY: 1-800-256-7072

www.fsis.usda.gov

Cooperative State Research, Education, and Extension Service

Oversees

- All domestic foods, some imported

Food Safety Role

- With U.S. colleges and universities, develops research and education programs on food safety for farmers and consumers

For More Information

Local cooperative extension services, listed in the blue pages of the phone book under county government

Cooperative State Research, Education and Extension Service
U.S. Department of Agriculture
Washington, DC 20250-0900
202-720-3029

www.reeusda.gov

National Agricultural Library USDA/FDA Foodborne Illness Education Information Center

Oversees

- All foods

Food Safety Role

- Maintains a database of computer software, audiovisuals, posters, games, teachers' guides and other educational materials on preventing food-borne illness
- Helps educators, food service trainers and consumers locate educational materials on preventing food-borne illness

For More Information

USDA/FDA Foodborne Illness Education Information Center
Food and Nutrition Information Center
National Agricultural Library/USDA
Beltsville, MD 20705-2351

301-504-5719

www.nal.usda.gov/fnic/

**** Also, a number of other USDA agencies conduct food safety activities.**

U.S. Environmental Protection Agency

Oversees

- Drinking water

Food Safety Role

Foods made from plants, seafood, meat and poultry

- Establishes safe drinking water standards

- Regulates toxic substances and wastes to prevent their entry into the environment and food chain
- Assists states in monitoring quality of drinking water and finding ways to prevent contamination of drinking water
- Determines safety of new pesticides, sets tolerance levels for pesticide residues in foods, and publishes directions on safe use of pesticides

For More Information

Environmental Protection Agency
401 M St., S.W.
Washington, DC 20460

202-260-2090

Regional EPA offices, listed in the blue pages of the phone book under U.S. Government

www.epa.gov

U.S. Department of Commerce

National Oceanic and Atmospheric Administration

Oversees

- Fish and seafood products

Food Safety Role

- Through its fee-for-service Seafood Inspection Program, inspects and certifies fishing vessels, seafood processing plants, and retail facilities for federal sanitation standards

For More Information

Seafood Inspection Program
1315 East-West Highway
Silver Spring, MD 20910

1-800-422-2750

www.nmfs.gov/iss/services.html

U.S. Department of the Treasury

Bureau of Alcohol, Tobacco and Firearms

Oversees

- Alcoholic beverages except wine beverages containing less than 7 percent alcohol

Food Safety Role

- Enforces food safety laws governing production and distribution of alcoholic beverages
- Investigates cases of adulterated alcoholic products, sometimes with help from FDA

For More Information

Bureau of Alcohol, Tobacco and Firearms
Market Compliance Branch
650 Massachusetts Ave., N.W.
Room 5200
Washington, DC 20226

202-927-8130

www.atf.treas.gov/core/alcohol/alcohol.htm

U.S. Customs Service

Oversees

- Imported foods

Food Safety Role

- Works with federal regulatory agencies to ensure that all goods entering and exiting the United States do so according to U.S. laws and regulations

For More Information

U.S. Customs Service
P.O. Box 7407
Washington, DC 20044

Media inquiries: 202-927-1770

General public: Contact local ports of entry, listed in the blue pages of the phone book under U.S. Government, Customs Services

www.customs.ustreas.gov

U.S. Department of Justice

Oversees

- All foods

Food Safety Role

- Prosecutes companies and individuals suspected of violating food safety laws
- Through U.S. Marshals Service, seizes unsafe food products not yet in the marketplace, as ordered by courts

For More Information

U.S. attorneys' offices in blue pages of phone book under U.S. Government

www.usdoj.gov

Federal Trade Commission

Oversees

- All foods

Food Safety Role

- Enforces a variety of laws that protect consumers from unfair, deceptive or fraudulent practices, including deceptive and unsubstantiated advertising.

For More Information

FTC (Federal Trade Commission)
Consumer Response Center, CRC-240
Washington, DC 20580

Media inquiries: 202-326-2180
TDD: 202-326-2502

Consumers: 202-FTC-HELP
(202-382-4357)

www.ftc.gov

State and Local Governments

Oversees

- All foods within their jurisdictions

Food Safety Role

- Work with FDA and other federal agencies to implement food safety standards for fish, seafood, milk, and other foods produced within state borders
- Inspect restaurants, grocery stores, and other retail food establishments, as well as dairy farms and milk processing plants, grain mills, and food manufacturing plants within local jurisdictions
- Embargo (stop the sale of) unsafe food products made or distributed within state borders

For More Information

City, county and state health, agriculture and environmental protection agencies, listed in the blue pages of the phone book under city, county and state government

This is a mirror of the page at <http://www.fda.gov/opacom/backgrounders/foodteam.html>

www.FoodSafety.gov - Gateway to Government Food Safety Information

Home

PHOTOCOPY
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THE PRESIDENT'S COUNCIL
ON SAFETY

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. 98-045N]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Food and Drug Administration

[Docket No. 97N-0074]

ENVIRONMENTAL PROTECTION AGENCY

[Docket No. OPP-00550B; FRL-6087-7]

President's Council on Food Safety; Notice of Meeting

AGENCY: Food Safety and Inspection Service, USDA; Research, Education, and Economics, USDA; Centers for Disease Control and Prevention, HHS; Food and Drug Administration, HHS; Environmental Protection Agency.

ACTION: Notice of public meeting.

SUMMARY: The President's Council on Food Safety was established in August 1998 under Executive Order 13 100 to strengthen and focus our efforts to coordinate food safety policy and resources. The Council was directed to develop a comprehensive national food safety strategic plan. The United States Department of Agriculture (USDA), the Department of Health and Human Services (HHS), and the Environmental Protection Agency (EPA) are announcing a public meeting to discuss development of the plan. The purpose of the strategic plan is to reduce the annual incidence of acute and chronic foodborne and waterborne illness by further enhancing the safety of the nation's food supply. USDA, the Food and Drug Administration (FDA), and EPA have established public dockets to receive comments about the President's Council on Food Safety strategic planning process and the plan.

DATES: The meeting will be held on July 15, 1999, from 8:30 a.m. to 5 p.m. Comments should be submitted by September 1, 1999.

ADDRESSES: The meeting will be held at: The Washington Plaza Hotel, 10 Thomas Circle, Massachusetts Avenue and 14th Street, Washington, DC.

FOR FURTHER INFORMATION CONTACT: To register for this meeting, call Ms. Sheila Johnson on (202) 501-7305. Persons requiring a sign language interpreter or other special accommodations should notify Ms. Johnson by July 7, 1999.

For further information about the meeting, call Mr. Robert Tynan, of USDA, on (202) 205-393 or e-mail: robert.tynan@usda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On January 25, 1997, the President issued a directive to the Secretaries of USDA and HHS and the Administrator of EPA to work with consumers, producers, industry, States, Tribes, universities, and the public to identify ways to further improve the safety of our food supply, and report back to him in 90 days. The Federal food safety agencies, working with their colleagues in the States, in the food industries, in academia, and with consumers, initially focused on the goal of reducing illness caused by microbial contamination of food and water. This goal was to be reached through systematic improvements in six key components of the food safety system: Foodborne outbreak response coordination, surveillance, inspections, research, risk assessment, and education. The plan for meeting this goal was presented to the President in May 1997, in "Food Safety from Farm to Table: A National Food Safety Initiative."

In less than 2 years, the agencies have taken significant strides forward in building a strengthened national food safety system. Building blocks for the infrastructure are in place: Increased targeted surveillance through FoodNet and PulseNet; coordination of Federal, State, and local responses to outbreaks by the Foodborne Outbreak Response Coordinating Group (FORCG); expanded reliance on preventive controls (such as the Hazard Analysis and Critical Control Point (HACCP) based inspection systems for meat, poultry, and seafood, and Good Agricultural and Good Manufacturing Practices guidance for produce); coordination of Federal food safety research; cooperation on risk assessment through the interagency Risk Assessment Consortium; leveraging inspection resources; and innovative public and private partnerships. These efforts provide a common ground for moving forward.

In the May 1997 report, the food safety agencies made a commitment to prepare a 5-year comprehensive strategic plan, with the participation of all concerned parties. By Executive Order 13100, the President established the President's Council on Food Safety that will be responsible for development of a comprehensive strategic Federal food safety plan. A coordinated food safety strategic planning effort is needed to tackle some of the difficult public health, resource, and management questions facing Federal food safety agencies. Although microbial contamination will remain an area of emphasis, the strategic plan will address the full range of issues (e.g., chemical contamination, pesticides, food additives, and physical hazards) and actions necessary to ensure the safety of the food and water Americans use and consume. The charge is to develop a strategic long-range plan that can be used to help set priorities, improve coordination and efficiency, identify gaps in the current system and how to fill those gaps, enhance and strengthen prevention and intervention strategies and identify measures to show progress. In developing the plan, the agencies will consider the conclusions and recommendations of the National Academy of Sciences Report on "Ensuring Safe Food from Production to Consumption" and the review of Federal food safety research and the research plan currently being developed by an interagency working group under the auspices of the National Science and Technology Council.

The food safety agencies, as part of their work on the President's Council on Food Safety, have already taken the first steps to lay the groundwork for the development of the strategic plan by participating in interagency strategic planning sessions. The agencies also engaged consumers, producers, industry, food service providers, retailers, health professionals, State and local governments, Tribes, academia, and the public in the strategic planning process through a series of public meetings beginning in October 1998. The purpose of those meetings was to obtain the public's view on a long-term vision for food safety in the U.S. and to identify a strategic planning process that involves interested parties, addresses the important food safety challenges, and makes

the best use of agency resources. As a result of those public meetings, a vision statement is currently being revised. The revised vision statement will be available at the July meeting.

The Council has also developed a series of five draft food safety goals that create the framework for the food safety strategic plan. Each draft goal is accompanied by broad objectives designed to achieve that goal. The Council has chosen a twofold process using internal agency resources and external public comment involving all interested parties to review and refine the goals and objectives as well as to add more specific action items to the objectives.

First, the Council has designated five government agency planning workgroups to assist in the development of a final strategic plan. Each Workgroup will be responsible for the further development of one of the goals and its objectives within the plan. Under the guidance and direction of the Council, each Workgroup will perform the following tasks for its assigned goal statement and objectives:

- Refine the goals and objectives provided by the Council.
- Develop the next level of action items for the plan.
- Assist in the preparation and presentation of public and stakeholder meetings related to the planning process by: Developing appropriate discussion questions related to the goal; participating in breakout sessions concerning the goal; and reviewing and incorporating appropriate public comments into the plan.

Second, the Council wants to engage all interested stakeholders in the development of the actual plan as it did in the earlier dialogue surrounding the agencies' vision for the U.S. food safety system and the roles of all those involved. The Council is planning two public meetings during the summer and fall of 1999 to share the draft plan and obtain public input. In addition, the Council is considering engaging in a series of three to five stakeholder meetings to take place in conjunction with scientific or professional conferences scheduled over the next 6 to 9 months.

The first public meeting is scheduled for July 15, 1999, at the Washington Plaza Hotel in Washington, DC. The purpose of the July 15th meeting is to obtain the public's input on the draft goals and objectives, as well as to provide comments and suggestions on specific action items for inclusion in the plan. The meeting is intended to be a working meeting; therefore, the agenda will follow almost exclusively a breakout session format. The breakout sessions will be organized around the goals and objectives and include members of the agency planning workgroups to lead and facilitate discussions. The workgroups are currently developing several illustrative action items and questions concerning the goals and objectives to encourage and focus participant comments during the breakout sessions. The agenda will be designed to obtain the maximum input from the participants with a minimum of reporting during the meeting from the breakout groups. Summaries of all discussions will be available within 30 days from the end of the public meeting. The second fall public meeting will be announced in the **Federal Register** prior to the date of the meeting. This meeting will obtain public input on a more refined draft of the strategic plan.

The draft goals and objectives to be discussed at the meeting are as follows:

Draft Inter-Agency Food Safety Strategic Plan--Goals and Objectives

Overarching Goal: To protect public health by significantly reducing the number of foodborne illnesses through science-based and coordinated regulation, inspection, enforcement, research, and education programs.

Goal 1: Ensure the development and use of a comprehensive scientific and technological food safety knowledge base to support prevention, regulation, inspection, surveillance, and education programs.

Objectives:

- Develop a national food safety research and technology infrastructure.
- Develop and improve data, methods, models, and measures to assess health effects, including a better understanding of the factors that affect sensitivity to foodborne illness (e.g., age and health status).
- Develop new and improve existing data, methods, models, and measures to assess exposure, including improved analytical and surveillance methods.
- Develop better, integrated (uniform) national and international risk assessment capability and conduct risk assessments.
- Develop and improve prevention/control methods and risk management practices through better integration of research.
- Coordinate and evaluate research on the highest priority food safety issues and efficiently leverage Federal agencies' research resources.
- Develop adequate technological support, including advanced modeling technology, for risk assessment and risk management.

Goal 2: Improve the effectiveness of surveillance, outbreak investigation, and response.

Objectives:

- Enhance and expand foodborne disease and hazard monitoring and surveillance systems.
- Identify, investigate, and track the causes of foodborne infections to determine sources and exposed populations.
- Provide better information to health professionals and physicians about the causes and effects of foodborne illness to more effectively detect and treat these illnesses.
- Improve outbreak coordination and investigation amongst Federal, State, and local agencies for more efficient, effective responses to foodborne contamination and illness.
- Strengthen and expand traceback, intervention, and recall capability; improve coordination on tracebacks and recalls.

Goal 3: Identify and manage food safety risks through protective standards, inspection, and enforcement from farm to table.

Objectives:

- Improve the safety of the nation's food supply to protect public health to the greatest extent possible through priority- and science-based standards, guidance, and other measures, including effective food safety management strategies by processors and providers.
- Develop and implement preventive techniques and controls.
- Ensure priority-based effective and efficient monitoring and inspection of the food supply.
- Protect our food supply in accordance with U.S. statutes and where appropriate internationally recognized science-based standards.
- Ensure contaminated water will not contaminate food during its production, processing, or reconstitution.

Goal 4: Ensure that all people who come into contact with food from farm to table are fully informed of the risks and measures to prevent or reduce foodborne illnesses.

Objectives:

- Foster basic understanding of food safety principles.
- Enhance the public's timely accessibility to accurate information that will help them make informed decisions about their food and the risks.
- Provide education and information to eliminate unsafe food handling practices at each point in the food chain (producers, processors, transporters, preparers, retailers, and consumers).
- Improve communication and information to the public so that they are informed about foodborne illness incidences, but are not unduly alarmed.

Goal 5: Create a national and to the extent possible an international seamless food safety system from farm to table.

Objectives:

- Ensure a complete set of Federal statutory authorities for an effective, prevention-based food safety system, including authorities for information collection and dissemination, rulemaking, inspection, enforcement, and expedited review of food safety technologies.
- Develop and implement a seamless Federal food safety system that supports effective regulation and administration of food safety programs.
- Coordinate and integrate Federal, State, and local actions to provide efficient, effective, and timely protection of the food supply and eliminate gaps by focusing and delivering resources where they are needed.
- Optimize use of available food safety resources at all levels of government to carry out the monitoring, inspections, outbreak response, traceback, and training necessary for an appropriate level of public protection nationwide.
- Enhance international understanding and acceptance of food safety standards that are in accordance with U.S. statutes and international trade agreements.

The workgroups are continuing to refine these goals, objectives, and action items in preparation for the July 15th meeting. Therefore, the material distributed at the meeting may differ slightly from the information provided in this Notice.

II. Public Dockets and Submission of Comments

The Agencies have established public dockets for the President's Council on Food Safety Strategic Plan. Comments submitted to the dockets are to be identified with the appropriate docket number. For those comments directed to USDA, use Docket No. 98-045N, and for comments directed to FDA, use Docket No. 97N-0074. Commenters are encouraged to submit a disk with their written comments in WordPerfect 5.1/6.1 or ASCII file format. Submit written comments (in triplicate) to:

USDA/FSIS

USDA/FSIS Hearing Clerk, 300 12th Street, SW., Rm. 102 Cotton Annex, Washington, DC 20250-3700.

FDA

FDA/Dockets Management Branch (HFA-305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Electronic Comments

Comments may also be submitted electronically to: oppts.homepage@epa.gov. All comments and data in an electronic format must be identified by the docket number OPP-00550. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

Meeting Summaries

Summaries of the public meeting will be posted on the Internet at: www.foodsafety.gov. This website is a joint FDA, USDA, and EPA food safety homepage. It is linked to each agency for persons seeking additional food safety information. Summaries of the public meeting may also be requested in writing from the Dockets Management Branch (HFA-305), FDA, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, approximately 15 business days after the meeting at a cost of 10 cents per page. The summaries of the public meeting will be available for public examination at the above-mentioned office between the hours of 9 a.m. and 4 p.m., Monday through Friday, excluding legal holidays.

The public docket in its entirety will be available on the Internet at: <http://www.epa.gov/opptsfrs/home/rules.htm#docket>.

List of Subjects

Environmental protection, Food safety.

List of Subjects

Environmental protection, Food safety.

Dated: June 14, 1999

Catherine E. Woteki

Catherine E. Woteki,

Undersecretary for Food Safety, United States Department of Agriculture.

Dated: June 14, 1999

James A. O'Hara

James A. O'Hara,

Deputy Assistant Secretary for Health, Department of Health and Human Services.

Dated: 6/14/99

Susan H. Wayland

Susan H. Wayland,

*Acting Assistant Administrator for Prevention, Pesticides and Toxic Substances,
Environmental Protection Agency.*

President's Council on Food Safety



U.S. Department
of Agriculture



Department of Health
and Human Services



Environmental
Protection Agency



Department
of Commerce

"Food Safety Strategic Plan" PUBLIC MEETING AGENDA Thursday, July 15, 1999

Washington Plaza Hotel
10 Thomas Circle
Washington, DC

8:30 a.m. Welcome & Purpose of Meeting (Federal Hall Room)

Dr. Catherine Woteki
Under Secretary for Food Safety
Department of Agriculture

Dr. Neal Lane
Director, Office of Science and Technology Policy
(Co-Chair, President's Council on Food Safety)

Dan Glickman
Secretary, Department of Agriculture
(Co-Chair, President's Council on Food Safety)

Donna Shalala
Secretary, Department of Health and Human Services
(Co-Chair, President's Council on Food Safety)

Susan Wayland
Acting Assistant Administrator for Prevention, Pesticides, and Toxic Substances
Environmental Protection Agency

Dr Jane Henney
Commissioner, Food and Drugs
Department of Health and Human Services

9:30 a.m. Survey Instrument

9:45 a.m. Break

10:00 a.m. Break Out Sessions (Goals 1-5)

12:00 a.m. Lunch

1:30 p.m. Break Out Sessions (Goals 1-5)

3:30 p.m. Break

3:45 p.m. Plenary Session (Dr Jane Henney/Dr Catherine Woteki)

5:00 p.m. Adjourn



Webmaster | Last updated on 1999-JUL-14 by dms

PHOTOCOPY
PRESERVATION

FSI FACT SHEET +
ADMINISTRATION HISTORY

THE FOOD SAFETY INITIATIVE

HISTORY

- December 1995:** The Administration issued new rules to ensure seafood safety, which utilized HACCP regulatory programs to require food industries to design and implement preventive measures and increased the industries' responsibility for and control of their safety assurance actions.
- July 1996:** President Clinton announced new regulations to modernize the nation's meat and poultry inspection system for the first time in 90 years, setting new standards help prevent E. coli bacteria contamination in meat.
- August 1996:** President Clinton signed the Safe Drinking Water Act of 1996. The law required drinking water systems to protect against dangerous contaminants like cryptosporidium, and gave people the right to know about contaminants in their tap water.
- August 1996:** President Clinton signed the Food Quality Protection Act of 1996, which streamlined the regulation of pesticides by FDA and EPA and put important new public-health protections in place, especially for children.
- January 1997:** President Clinton announced a Food Safety Initiative (FSI).
Mission: To reduce the incidence of foodborne illness.
- President Clinton directed the Secretary of Agriculture, the Secretary of Health and Human Services, and the Administrator of the Environmental Protection Agency to identify specific steps to improve the safety of the food supply.
- May 1997:** HHS and USDA collaborated on a report to President Clinton entitled Food Safety from Farm to Table: A National Food Safety Initiative.
- October 1997:** President Clinton expanded the initiative to provide special emphasis on the safety of domestic and imported fruits and vegetables.
- July 1998:** President Clinton announced the creation of a Joint Institute for Food Safety Research (JIFSR) to develop a strategic plan for conducting food safety research and efficiently coordinating all Federal food safety research.
- August 1998:** President Clinton issued an Executive order to create the President's Council on Food Safety, which is charged with (1) developing a comprehensive plan for all Federal food safety activities, (2) advising agencies of food safety priorities and developing coordinated food safety budgets, and (3) overseeing the JIFSR.

July 1999:

President Clinton announced new measures to prevent unsafe food from entering U.S. borders. The President:

- Directed the Departments of Health and Human Services (HHS) and the Treasury to take several steps to: (1) prevent "port shopping," in which importers whose cargo is denied entry at one port try to introduce the unsafe food at another port; (2) require the destruction of imported food that poses a serious public health threat; and (3) increase the bond that importers must post, as a way to deter illegal imports of unsafe food.
- Called on Congress to: (1) fund his food safety initiative budget request; (2) support legislation, sponsored by **Senator Harkin**, to give the Department of Agriculture (USDA) the power to recall tainted foods and impose civil penalties; and (3) pass a comprehensive imported food safety bill introduced by **Senators Mikulski, Kennedy, and Durbin** and **Representative Eshoo**, which would increase the Food and Drug Administration's (FDA) authority to prevent unsafe food from ever reaching U.S. borders.

Food Safety Initiative Fact Sheet

May 12, 1997

"We have built a solid foundation for the health of America's families. But clearly we must do more. No parent should have to think twice about the juice they pour their children at breakfast, or a hamburger ordered during dinner out."

--President Bill Clinton, Radio Address, January 25, 1997

Today, Vice President Al Gore announced a five-point Administration plan to strengthen and improve food safety for the American people. The plan sets forth new steps the Administration will take this year to strengthen food safety and details how we will use \$43.2 million in new funds the President has requested in his fiscal year 1998 budget. The plan is outlined in a report presented to the Vice President today by Health and Human Services Secretary Donna E. Shalala, Department of Agriculture Secretary Dan Glickman, and Environmental Protection Agency Administrator Carol M. Browner. The President requested the report in January.

Working with consumers, producers, industry, states, universities, and the public, the Administration has developed measures to reduce foodborne illness from microbial contaminants; the Administration will:

- Improve inspections and expand preventive safety measures: FDA will use \$8.5 million of the new funds, in part, to hire additional Food and Drug Administration (FDA) inspectors for seafood plants and to expand the Hazard Analysis and Critical Control Point (HACCP) approach to the fruit and vegetable juice industries. U.S. Department of Agriculture (USDA) will propose preventive measures, including HACCP, this year for egg products.
- Increase research to develop new tests to detect foodborne pathogens and to assess risks in the food supply: The agencies will target \$16.5 million to critical research needs, such as giving federal, state and local food safety officials new tools to detect these pathogens, some of which -- like the Hepatitis A virus and cyclospora -- cannot now be detected in many foods.
- Build a national Early Warning System to detect and respond to outbreaks of foodborne illness earlier, and to give us the data we need to prevent future outbreaks: With \$13.7 million of the new funds, USDA, FDA, and Centers for Disease Control and Prevention will increase the number of active "sentinel sites" across the country from 5 to 8 (current sites are in Northern California, Oregon, Minnesota, Georgia and Connecticut; new sites added this year are in New York and Maryland, and the eighth will open next year) and will equip these sites with new technology to identify the diseases and their sources and to communicate these findings nationwide rapidly.
- Establish a national education campaign that will improve food handling in homes and retail outlets. FDA, USDA, CDC, and the Department of Education will launch a new public-private partnership with industry, producer and consumer groups, and states to raise public awareness of safe food practices. Using public and private funds, the partnership will develop, disseminate, and evaluate a single food-safety slogan and several standard messages. USDA and FDA will use \$4 million of the new 1998 funds to support this and other education activities.
- Strengthen coordination and improve efficiency: USDA, CDC, FDA and EPA will form a new intergovernmental group to improve federal, state and local responses to outbreaks of foodborne illnesses. Working with all stakeholders, the agencies will develop a strategic plan to further improve coordination, use resources more efficiently, and measure progress toward our common goal of reducing foodborne illness.

Building on Our Accomplishments

Food safety is a major public health challenge: millions of foodborne illnesses and thousands of food-related deaths occur annually. From the beginning, the Administration has made improving the safety of the nation's food supply a top public health priority.

- Building on the recommendations of the Vice President's National Performance Review, the President put in place new science-based, hazard prevention systems for seafood, meat, and poultry. In late 1995 the Administration issued new rules to ensure seafood safety. In July 1996, President Clinton announced new regulations to modernize the nation's meat and poultry inspection system for the first time in 90 years. The new Early Warning System will gather critical scientific data to further improve these prevention systems
- In August, 1996 President Clinton signed the Food Quality Protection Act -- a comprehensive overhaul of our laws that regulate pesticides in food putting in place reforms that the Administration had urged since 1993. These reforms will ensure health and safety for American families through a more protective, more stringent health-based standard plus special new provisions to protect the health of infants and children from pesticide risks.
- Last August, President Clinton also signed a new safe drinking water law that strengthens protections to ensure that American families have clean safe tap water -- improvements that the Administration has called for since September 1993.

More information on the National Food Safety Initiative Program is available at <http://vm.cfsan.fda.gov/~dms/fs-toc.html>.

Executive Office of the President
May 12, 1997

This is a mirror of the page at <http://www.fda.gov/opacom/foodsafety/fsfact.htm>

Home | [Food Safety Initiative](#)

**Office of the White House
Briefing Handout
October 2, 1997**

Clinton Administration Accomplishments in Improving Food Safety

The President's announcement builds on a strong record of food safety initiatives, ensuring that Americans eat the safest possible food. The Administration has put into place improved safety standards for meat, poultry and seafood products, and has begun the process of developing enhanced standards for fruit and vegetable juices. The Administration also has expanded research, education and surveillance activities throughout the food safety system.

- October, 1997. President announces new initiative to enhance FDA oversight over imported foods and develop guidance on good agricultural and manufacturing practices for fruits and vegetables.
- May, 1997. Administration announces comprehensive new initiative to improve the safety of nation's food supply--"Food Safety from Farm to Table"--detailing a \$43 million food safety program, including measures to improve surveillance, outbreak response, education, and research.
- January, 1997. President announces new Early-Warning System to gather critical scientific data to help stop food borne disease outbreaks quickly and to improve prevention systems further.
- August, 1996. President signs Safe Drinking Water Act of 1996. The law requires drinking water systems to protect against dangerous contaminants like cryptosporidium, and gives people the right to know about contaminants in their tap water.
- August, 1996. President signs Food Quality Protection Act of 1996, which streamlines regulation of pesticides by FDA and EPA and puts important new public-health protections in place, especially for children.
- July, 1996. President Clinton announces new regulations that modernize the nation's meat and poultry inspection system for the first time in 90 years. New standards help prevent E. coli bacteria contamination in meat.
- December, 1995. Administration issues new rules to ensure seafood safety. Utilizes HACCP regulatory programs to require food industries to design and implement preventive measures and increase the industries' responsibility for and control of their safety assurance actions.
- 1994. CDC embarks on strategic program to detect, prevent, and control emerging infectious disease threats, some of which are food borne, making significant progress toward this goal in each successive year.
- 1993. Vice-President's National Performance Review issues report recommending government and industry move toward a system of preventive controls.

Department of Health and Human Services
U.S. Department of Agriculture
February 25, 1999

Background

2000 President's Food Safety Initiative

For the third consecutive year, the Department of Health and Human Services (HHS) and the Department of Agriculture (USDA) have coordinated a multi-agency effort to protect the health of the American public by improving the safety of the Nation's food supply. Through joint planning, agencies can maximize the use of their resources and achieve the greatest improvements in food safety. This process began with the May 1997 report to the President, entitled, Food Safety from Farm-to-Table: A National Food Safety Initiative. The report recognized foodborne illness as an emerging public health hazard that required aggressive government action, identified critical gaps in the food safety system for controlling or eliminating foodborne pathogens from the food supply, and proposed a strategy for closing those gaps.

1998 and 1999 Activities

The 1998 budget initiative brought much-needed new resources to enhance surveillance of foodborne disease and outbreaks and better coordinate our response to outbreaks, improve inspections and compliance-particularly seafood HACCP inspections, target important new research and risk assessment to critical scientific gaps, and strengthen education and training especially of those who handle food at critical points from the retail setting to the home. The 1999 initiative built on science-based gains made in these areas, and placed increased emphasis on ensuring the safety of domestic and imported fresh produce and imported foods; targeted retail food safety education; transformed traditional meat and poultry inspection systems to science-based HACCP systems; and developed scientific information and tools to control a greater range of food safety hazards.

2000 Budget Request

For 2000, the Administration is proposing an increase of \$74.8 million for the President's Food Safety Initiative. Of this amount, \$40 million is allocated to HHS and \$34.8 million to USDA. The 2000 President's Food Safety Initiative builds on the foundation established in 1998 and 1999. Additional resources will be targeted to: (1) further develop a nationally integrated, seamless, and science-based food safety system, (2) enhance public health surveillance and increase the speed and efficiency of responses to outbreaks of foodborne illness, and (3) place greater emphasis on the control of foodborne hazards in the pre-harvest phase of the farm-to-table continuum. Funding is requested for the following activities:

Enhance Surveillance and Investigation to Improve Outbreak Response (+\$16.4 million):

HHS (+\$16.4 million): The Food and Drug Administration (FDA), working through the Centers for Disease Control and Prevention (CDC) will expand its access to PulseNet and increase outbreak response and associated traceback activities. FDA will begin initial development of electronic communication and data sharing systems for use in Federal-State monitoring and traceback activities. FDA, working with CDC, will also expand and increase the overall capacity of the National Antimicrobial Resistance Monitoring System (NARMS) and the number of States covered to assure a

higher probability of detecting emerging resistant pathogens capable of animal to human transmission and to minimize the occurrence of foodborne outbreaks including those from outside of the United States. CDC will identify foodborne hazards and characterize the risk posed by those hazards, increase the speed with which the presence of hazards in foods can be determined and controlled, and improve the accuracy and timeliness of public health data that justify food safety control programs and evaluate their effectiveness. CDC will also work with the States to improve diagnostic capacity for viruses and parasites, and expand the network of States with capacity to interact electronically with CDC to evaluate and improve diagnostic practices.

Strengthen Coordination and Improve Efficiency (+\$0.5 million):

USDA (+\$0.5 million): The Food Safety and Inspection Service (FSIS) will assign district epidemiologists to work with State Departments of Agriculture and Public Health to better coordinate responses to foodborne disease outbreaks and recalls. Efforts will be directed at increasing the speed and efficiency of responding to outbreaks of foodborne illness and to prevent further outbreaks. Funds will provide the specialized training, supplies, technology, and equipment for district epidemiology officers. This effort will further assist Federal, State, and Local integration in support of a seamless national food safety program.

Expand Inspection and Compliance Efforts with Additional Emphasis on High Risk Foods, Imported Produce, and Enhancing Federal-State Partnerships (+\$19.3 million):

HHS (+\$16.9 million): FDA will increase inspection coverage and frequency of coverage of domestic firms, with the highest risk firms being inspected once per year beginning in FY 2001. FDA will increase the number of inspections of foreign processors and will conduct evaluations of foreign food productions systems. FDA will continue to provide training to State and local food safety officials and industry in the effective use of preventive control systems, such as hazard analysis and critical control point (HACCP) systems-especially seafood HACCP systems, and to perform inspections of HACCP systems. FDA will provide States resources and "hands-on" training to promote the adoption of the Food Code by retail establishments.

USDA (+\$2.4 million): In 2000, all State meat and poultry establishments will be required to have implemented hazard analysis and critical control point (HACCP) systems. By that time, the 26 State meat and poultry inspection programs will be required to amend their regulations to make them equal to Federal regulations. To facilitate this transition, FSIS will conduct the pathogen testing required by the HACCP rule of State inspected meat and poultry products in FSIS laboratories. In addition, FSIS will conduct comprehensive reviews of State laboratories to validate the ability of these laboratories to meet HACCP testing requirements. Demonstrating compliance with pathogen testing requirements of the HACCP rule will be a major prerequisite for permitting interstate shipment of State inspected product. Assisting States will integrate and unify efforts to create a seamless national inspection program.

Improve Capability to Estimate Risks Associated with Foodborne Hazards (+\$7.9 million):

HHS (+\$1.5 million): FDA will develop methods for predicting the risk associated with foodborne pathogens and will develop partnerships with government, industry, and academic scientists to conduct studies that demonstrate comparability of disease across species. FDA will continue a program of research in quantitative risk assessment (particularly for microbial hazards) that is targeted to address the limitations in risk assessment methodologies. FDA will continue to build the activities of the interagency Risk Assessment Consortium that provides a forum for coordination of Federal microbial risk assessment research. FDA through the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) will continue development of a risk assessment clearinghouse to better establish government, industry, and academic partnerships.

USDA (+\$6.4 million): The Agricultural Research Service (ARS), the Cooperative State Research,

Education, and Extension Service (CSREES), the Economic Research Service (ERS), and the National Agricultural Statistics Service (NASS) will extend risk assessment modeling and data collection to include the pre-harvest phase for all foods. Previous risk assessment activities have focused on post-harvest operations. This pre-harvest modeling is necessary to determine the effects of various production practices, processing, and transportation systems on the behavior and subsequent contamination of poultry, beef, and swine as they are presented for slaughter. A Nationwide survey of fruit and vegetable producers and packinghouses will be conducted to establish a baseline of agricultural handling practices related to food safety. Data from the survey would be used to target food safety education materials and to conduct economic analyses concerning food safety related agricultural practices.

Continue to Develop and Disseminate Targeted Food Safety Education Materials (+ \$2.4 million):

HHS (+\$1.5 million): FDA, in cooperation with USDA and other Federal, State, and local agencies, will develop multi-lingual education programs for food service workers and will implement a National education and training program to ensure greater safety in retail food preparation practices, including the use of HACCP principles in retail establishments. Efforts will focus on the development of education materials for educating and training relating to proper storage, handling, and transportation practices identified in the Food Code. In addition, FDA will develop educational messages for using antimicrobial drugs for use in animal foods.

USDA (+\$0.9 million): CSREES, will develop educational programs that target high-risk, underserved populations who are at increased risk from developing foodborne illnesses, such as the elderly, children, and immuno-compromised individuals. Food safety education materials will also be provided to very small retailers and distributors to increase their awareness of their food safety responsibilities as part of a Nationwide education and training program. In addition CSREES will develop and implement training programs for producers, veterinarians, and crop consultants on good manufacturing and agricultural practices that can minimize microbial contamination of their products.

Accelerate Food Safety Research (+\$28.2 million):

USDA (+\$24.5 million): ARS and CSREES will support research projects that will contribute to the development of effective methods of handling and treating agricultural products to minimize microbiological contamination. Control of animal production practices, including manure management, will prevent possible distribution of pathogens to crops or other animals from surface runoff and irrigation waters. In addition, improved detection methodologies will be developed to enable producers to monitor their production processes for contamination. Research will also be supported to develop the knowledge necessary to prevent the development of antibiotic drug resistance. Research results will be used to develop strategies to prevent both the emergence and the maintenance in food producing animals of pathogenic and non-pathogenic antibiotic resistant bacteria. The Agricultural Marketing Service (AMS) will establish microbiological baselines for pathogens on fruits and vegetables. This information will contribute to the identification of microbiological hazards and the development of intervention strategies to reduce the food safety risks posed by these products.

HHS (+\$3.7 million): FDA will expand research on methods development and prevention technologies. FDA will collaborate with other Federal agencies and the private sector at the National Center for Food Safety and Technology (NCFST) and with academia to translate preventive technologies and techniques into appropriate versions for use by small firms and consumers. FDA and USDA will expand mechanisms to transfer technologies to States, small and large firms, foreign governments, consumers, and others. FDA will expand its ongoing research on the development of methods for detecting foodborne pathogens in animal feeds.

PRESIDENT'S FOOD SAFETY INITIATIVE FY 2000 BUDGET					
ACTIVITY	1997	1998	1999	2000 Budget	IncreaseOver 1999
	Dollars in Thousands				
SURVEILLANCE:					
USDA:					
Food Safety and Inspection Service	\$1,000	\$1,500	\$1,500	\$1,500	\$0
Economic Research Service	32	32	282	285	3
Subtotal, USDA	1,032	1,532	1,782	1,785	3
HHS:					
Food and Drug Administration	737	3,897	3,897	10,297	6,400
Centers for Disease Control and Prevention	4,500	14,500	19,000	29,000	10,000
Subtotal, HHS	5,237	18,397	22,897	39,297	16,400
Subtotal, Surveillance	6,269	19,929	24,679	41,082	16,403
COORDINATION:					
USDA:					
Food Safety and Inspection Service	0	0	0	500	500
HHS:					
Food and Drug Administration	7,173	7,723	7,723	7,723	0
Subtotal, Coordination	7,173	7,723	7,723	8,223	500
INSPECTIONS:					
USDA:					
Food Safety and Inspection Service	0	565	10,113	12,513	2,400
HHS:					
	73,244	81,114	105,614	122,514	16,900

Food and Drug Administration					
Subtotal, Inspections	73,244	81,679	115,727	135,027	19,300
RISK ASSESSMENT:					
USDA:					
Agricultural Research Service	5,461	4,498	4,909	7,309	2,400
Cooperative State Research, Education, and Extension Service	145	150	2,612	3,702	1,090
Food Safety and Inspection Service	0	0	3,260	3,260	0
Economic Research Service	33	33	236	686	450
National Agricultural Statistics Service	0	0	0	2,500	2,500
Office of the Chief Economist	62	60	158	158	0
Subtotal, USDA	5,701	4,741	11,175	17,615	6,440
HHS:					
Food and Drug Administration	2,589	6,539	6,539	8,039	1,500
Subtotal, Risk Assessment	8,290	11,280	17,714	25,654	7,940
EDUCATION:					
USDA:					
Cooperative State Research, Education, and Extension Service	2,365	2,365	7,365	8,287	922
Food Safety and Inspection Service	0	0	3,659	3,659	0
Food And Nutrition Service	0	0	2,000	2,000	0
Office of the Chief Economist	27	38	38	38	0
Economic Research Service	420	420	420	420	0
Subtotal, USDA	2,812	2,823	13,482	14,404	922
HHS:					
Food and Drug Administration	4,800	6,870	6,870	8,370	1,500
Centers for Disease Control and	0	0	476	476	0

Prevention					
Subtotal, HHS	4,800	6,870	7,346	8,846	1,500
Subtotal, Education	7,612	9,693	20,828	23,250	2,422
RESEARCH:					
USDA:					
Agricultural Research Service	44,186	50,351	64,959	74,279	9,320
Cooperative State Research, Education, and Extension Service	3,724	6,250	14,788	23,799	9,011
Agricultural Marketing Service	0	0	112	6,297	6,185
Subtotal, USDA	47,910	56,601	79,859	104,375	24,516
HHS:					
Food and Drug Administration	20,793	27,193	27,693	31,393	3,700
Subtotal, Research	68,703	83,794	107,552	135,768	28,216
TOTAL, INITIATIVE	171,291	214,098	294,223	369,004	74,781

PRESIDENT'S FOOD SAFETY INITIATIVE FY 2000 PROPOSAL					
	1997	1998	1999	2000 Budget	Increase Over 1999
TOTAL INITIATIVE	Dollars in Thousands				
USDA:					
Agricultural Research Service	\$49,647	\$54,849	\$69,868	\$81,588	\$11,720
Cooperative State Research, Education, and Extension Service	6,234	8,765	24,765	35,788	11,023
Agricultural Marketing Service	0	0	112	6,297	6,185
Food Safety and Inspection Service	1,000	2,065	18,532	21,432	2,900
Economic Research Service	485	485	938	1,391	453
Office of the Chief Economist	89	98	196	196	0

National Agricultural Statistics Service	0	0	0	2,500	2,500
Food and Consumer Service	0	0	2,000	2,000	0
Subtotal, USDA	57,455	66,262	116,411	151,192	34,781
HHS:					
Food and Drug Administration	109,336	133,336	158,336	188,336	30,000
Centers for Disease Control and Prevention	4,500	14,500	19,476	29,476	10,000
Subtotal, HHS	113,836	147,836	177,812	217,812	40,000
TOTAL, INITIATIVE	171,291	214,098	294,223	369,004	74,781

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**THE WHITE HOUSE
The Roosevelt Room
Saturday, July 3, 1999**

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RADIO ADDRESS OF THE PRESIDENT TO THE NATION

THE PRESIDENT: Good morning. This Independence Day at backyard barbecues and picnics in local parks, Americans celebrate the spirit of patriotism that has strengthened our nation for 223 years now. Today, I want to talk about what we must do to ensure that the food we serve at those gatherings is as safe as we can possibly make it, to keep our nation growing healthy, as well as strong.

Our food supply is the most bountiful in the world. And for six and a half years, our administration has been committed to making it the safest in the world -- from establishing a nationwide early warning system for food-borne illness, to expanding food safety research and public education programs, to increasing inspections of food at every point in the chain of production.

Last year, I established a Joint Institute for Food Safety Research and appointed the first-ever President's Council on Food Safety to coordinate and expand food safety efforts at every level of the federal government. I'm proud of the progress we're making, but when it comes to keeping our families safe, we can always do more -- and we must.

Today, Americans eat more imported food than ever before, and they have more choices than ever. Think of it: Thirty years ago, just a dozen kinds of fruits and vegetables were available year-round. Today, you could buy a different kind of fruit or vegetable every day of the year, and many were grown on the other side of the world. There's no evidence that these fruits and vegetables are less safe than those grown here in the United States. But some recent outbreaks of food-borne illness have been traced in imported foods.

Our import laws are very clear: We will not allow unsafe food to enter the United States. But a recent GAO report showed that some importers are sidestepping our laws and getting contaminated food across our borders and onto our kitchen tables. While most importers comply with our regulations, it only takes one bad apple to spoil the whole bunch, only one shipment of contaminated food to threaten hundreds, even thousands of Americans.

That is why today, consistent with our international obligations, I'm directing the Treasury Department and the Health and Human Services Department to take immediate action to keep unsafe food from crossing our borders. First, we will take new steps to stop port shopping -- preventing importers whose unsafe food has been turned away at one U.S. port from slipping their goods in at another. To make sure this unsafe food can be easily spotted, we will stamp all rejected food with the clear label, "Refused U.S."

Second, Customs and the FDA will rigorously enforce and expand our policy of destroying imported food that poses a serious health threat rather than risk letting it reach our grocery stores or the global market.

Third, we'll do more to deter dishonest importers by increasing the bond they must post while food is being inspected for safety. Too many importers forfeit their bonds as a simple cost of doing business. That's wrong and we should stop it. These steps will help us to close the gaps in our food safety system.

But Congress must also act. I'm grateful for the presence here today of Congressman Dingell and Congressman Brown. Congress should start by passing comprehensive food safety legislation that would increase the FDA's authority to turn away imported food that does not meet our high safety standards. And Congress should grant USDA the authority to impose civil penalties and to order mandatory recalls of unsafe meat and poultry.

Finally, Congress should fully fund my \$72-million Food Safety Initiative to increase the number of agents and inspections of high-risk food products right here at home, and increase the number of inspections of foreign food processors around the world.

Americans have a right to know that the food they serve their families is safe -- whether it comes from the far corners of the world or the corner produce stand. I'm pleased that so many members of Congress are committed to giving them that security. I appreciate the initiatives, especially, of Senator Durbin and Representatives Dingell and Brown, along with Senators Mikulski, Kennedy, Harkin, Collins, and Representatives Eshoo and Waxman. I look forward to working with all members of Congress of both parties to build a stronger nation with a healthier food supply for the 21st century.

Have a happy and healthy 4th of July, and thanks for listening.

This is a mirror of the White House radio address, July 3, 1999, from the White House Briefing Room

The President Announces New Measures to Prevent Unsafe Food From Entering Our Borders July 3, 1999

Food Safety Initiative

President's Council on Food Safety

Home



Food Safety and Inspection Service
United States Department of Agriculture
Washington, D.C. 20250-3700

Key Facts: HACCP Final Rule

July 1996

Key Facts: USDA's Food Safety Accomplishments Since 1993

Since a major outbreak of foodborne illness in several western states in 1993 attributed to the presence of the pathogenic bacterium *E. coli* O157:H7 in ground beef, the Clinton administration, through USDA's Food Safety and Inspection Service (FSIS), has focused on the design and implementation of a science-based food safety strategy to reduce the risk of illness caused by bacterial contamination of meat and poultry products.

USDA actions since the outbreak of foodborne illness in western states in January 1993 include the following:

- Initiated unannounced reviews at 1,000 meat and poultry plants nationwide to enforce intensified zero tolerance requirements for fecal contamination on beef products.
- Required safe handling and cooking instructional labels on raw meat and poultry products.
- Introduced a strategy to change meat and poultry inspection from command and control supervision of industry to system that prevents hazards to the food supply from the farm to the table.
- Declared the bacterium *E. coli* O157:H7 an adulterant in raw ground beef and initiated a nationwide sampling program in federally inspected plants and retail stores that process ground beef.
- Prepared a regulation to overhaul the USDA food safety system by requiring the mandatory implementation of Hazard Analysis and Critical Control Point systems and testing for bacteria in plants that slaughter and grind meat and poultry for distribution as raw product.
- Accelerated the review of requests for trials of technologies designed to improve food safety in meat and poultry plants.
- Initiated review of process controls used for fermented dry sausage and recommended revisions to industry's Good Manufacturing Practices following an outbreak of *E. coli* O157:H7 linked to the product.
- Increased funding for food safety research, including the development of methods to detect and enumerate *E. coli* O157:H7.
- Elevated food safety responsibilities in a new sub-Cabinet Office of the Under Secretary for Food Safety.
- Established an FSIS liaison at the Centers for Disease Control and Prevention in Atlanta to assist in tracking foodborne illness trends and causes and established an Epidemiology and Emergency Response Program to investigate foodborne illness outbreaks in conjunction with CDC and the states.
- Initiated an agreement with the Centers for Disease Control and Prevention and the Food and Drug Administration to conduct sentinel site surveys at five locations in the United States. The study will provide much needed baseline data regarding the incidence of foodborne illness, attributable to consumption of meat, poultry and other foods. The study will provide measures for better estimates of the incidence of foodborne illness and provide a baseline to assess the impact of new food safety initiatives.
- Developed public information programs and educational materials such as videos and compact discs for radio stations about safe food handling, targeting specific audiences such as school children, day care centers, pediatricians, fast food restaurant workers, senior citizens, and state

and local health departments. Also provided information kits to food and health page editors, magazine editors throughout the country.

- Identified more than 400 pages of burdensome and unnecessary regulations as candidates for elimination or change so that inspectors and plants could focus resources on food safety.

For Further Information Contact:

FSIS Food Safety Education and Communications Staff
Room 2932-South Building; 1400 Independence Ave. S.W.
Washington, D.C. 20250
Phone: (202) 720-7943
Fax: (202) 720-1843

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PHOTOCOPY
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HACCP

U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition

Hazard Analysis Critical Control Point

Backgrounder

- [Overview on HACCP](#)

HACCP for Land Foods

- **Juice Products** HACCP Proposed Rule April 24, 1998 and Press Release April 21, 1998
- [Report of 1997 Inspections of Fresh, Unpasteurized Apple Cider Manufacturers](#) January 1999
- [Apple Cider Food Safety Control Workshop - July 15, 1999](#) NEW
- [Food Safety Pilot Program](#) May 8, 1995 Press Release
- [Interim Report of Observations and Comments](#), June 19, 1996 HACCP Pilot Program for Selected Food Manufacturers
- [Second Interim Report of Observations and Comments](#), October 31, 1997 HACCP Pilot Program for Selected Food Manufacturers

HACCP for Seafoods

- [Critical Steps Toward Safer Seafood](#)
- [Domestic Seafood HACCP Report: Revised Instructions for FDA Form 3501](#) March 1999
- [Seafood HACCP Transition Guidance; Request for Comment](#) March 26, 1999
- **Seafood HACCP Regulation: Final Rule** - December 12, 1995
(Regulation Title: Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products)
 - [Press Release](#) December 1995
 - [Summary of Provisions](#)
 - [Summary Section of Seafood HACCP Federal Register Document](#)
 - [Seafood Final Rule Full Text \(800 Kbytes\)](#)
Full Text in three parts
 - [Part I, Preamble \(424 Kbytes\)](#)
 - [Part II, Preamble \(340 Kbytes\)](#)
 - [Part III, Regulation \(37 Kbytes\)](#)
 - [Seafood: Regulatory Impact Analysis](#) December 1995
 - [Testimony](#) May 22, 1996 before Subcommittee on Livestock, Dairy and Poultry, Committee on Agriculture, US House of Representatives
 - [Fish and Fishery Products Hazards and Control Guide](#)
 - [Seafood HACCP Implementation Timeline Presentation](#) (September 1996)
 - [HACCP Regulation for Fish and Fishery Products: Questions and Answers](#)
- **Seafood HACCP Regulation: Proposal**
 - [Press Release](#) January 1994

- [Regulatory Impact Analysis December 1993 \(168 Kbytes\)](#)

HACCP for Retail

- [FDA's Application of HACCP to Retail Food Systems](#)
- [Managing Food Safety: A HACCP Principles Guide for Operators of Food Establishments at the Retail Level](#)

National Food Safety Initiative

[Food Safety Initiative Web Pages](#) including:

- [Report to the President: From Farm to Table](#)
- [Produce & Import Safety Initiative](#)
- [Fruit and Vegetable Juices](#)
- [Food Safety Initiative Strategic Plan](#)
- [Presidential Council on Food Safety](#)
- [Food Safety Research](#)

Training and Education

- [HACCP Training Programs and Resource Materials Database](#)
 - [Video Teleconference](#): to get copy of past FDA broadcasts
-

Information from Other Federal Government Agencies

- [Food Safety and Inspection Service, USDA](#)
 - [HACCP/Pathogen Reduction](#)
 - [U.S. Department of Commerce, National Marine Fisheries Service](#)
 - [HACCP Workshops for the Seafood Industry](#)
 - [Seafood Inspection Program Publications](#) including HACCP
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Information from Non-Government Sources

- [Seafood Network Information Center, UC Davis](#)
 - [National Seafood HACCP Alliance](#) for Training and Education
 - [Seafood Network](#)
 - [Seafood HACCP Information](#)
 - [Seafood HACCP Training Schedule](#)
 - [National Center for Food Safety & Technology: Generic HACCP Plans for the Food Industry](#)
 - [International Meat and Poultry HACCP Alliance](#)
 - [Food Institute of Canada & Agriculture & Agri-Food Canada HACCP Manual](#)
 - [Conference of Research Workers in Animal Diseases HACCP Symposium Proceedings \(November 1995\)](#)
-

U. S. Food and Drug Administration
FDA Backgrounder
August 12, 1997

HACCP: A State-of-the-Art Approach to Food Safety

Space-age technology designed to keep food safe in outer space may soon become standard here on Earth.

The Food and Drug Administration is adapting a food safety program developed nearly 30 years ago for astronauts for much of the U.S. food supply. The program for the astronauts focuses on preventing hazards that could cause food-borne illnesses by applying science-based controls, from raw material to finished products. FDA's new system would do the same.

Traditionally, industry and regulators have depended on spot-checks of manufacturing conditions and random sampling of final products to ensure safe food. This system, however, tends to be reactive, rather than preventive, and can be less efficient than the new system.

The new system is known as Hazard Analysis and Critical Control Point, or HACCP (pronounced hassip). Many of its principles already are in place in the FDA-regulated low-acid canned food industry and have been incorporated into FDA's Food Code. The Food Code serves as model legislation for state and territorial agencies that license and inspect food service, retail food stores, and food vending operations in the United States.

In December 1995, FDA issued a final rule establishing HACCP for the seafood industry. Those regulations take effect Dec. 18, 1997.

The U.S. Department of Agriculture also has established HACCP for the meat and poultry industry. Larger establishments will be required to start using HACCP by Jan. 26, 1998. Smaller companies have until Jan. 25, 1999, and very small plants until Jan. 25, 2000. (USDA regulates meat and poultry; FDA all other foods.)

In August 1997, FDA was considering whether to require HACCP for fruit and vegetable juices.

In fact, FDA is considering developing HACCP regulations as a standard throughout much of the rest of the U.S. food supply. The regulations would cover both domestic and imported foods.

To help determine the degree to which such regulations would be feasible, the agency is now conducting a pilot HACCP program with volunteer food companies that make cheese, frozen dough, breakfast cereals, salad dressing or other products.

HACCP has been endorsed by the National Academy of Sciences, the Codex Alimentarius Commission (an international food standard-setting organization), and the National Advisory Committee on Microbiological Criteria for Foods.

A number of U.S. food companies already use the system in their manufacturing processes, and it is

in use in other countries, including Canada.

What is HACCP?

HACCP involves seven steps:

- **Analyze hazards.** Potential hazards associated with a food and measures to control those hazards are identified. The hazard could be biological, such as a microbe; chemical, such as a pesticide; or physical, such as ground glass or metal fragments.
- **Identify critical control points.** These are points in a food's production--from its raw state through processing and shipping to consumption by the consumer--at which the potential hazard can be controlled or eliminated. Examples are cooking, cooling, packaging, and metal detection.
- **Establish preventive measures with critical limits for each control point.** For a cooked food, for example, this might include setting the minimum cooking temperature and time required to ensure the elimination of any microbes.
- **Establish procedures to monitor the critical control points.** Such procedures might include determining how and by whom cooking time and temperature should be monitored.
- **Establish corrective actions to be taken when monitoring shows that a critical limit has not been met--**for example, reprocessing or disposing of food if the minimum cooking temperature is not met.
- **Establish procedures to verify that the system is working properly--**for example, testing time-and-temperature recording devices to verify that a cooking unit is working properly.
- **Establish effective recordkeeping to document the HACCP system.** This would include records of hazards and their control methods, the monitoring of safety requirements and action taken to correct potential problems.

Each of these steps would have to be backed by sound scientific knowledge: for example, published microbiological studies.

Need for HACCP

New challenges to the U.S. food supply have prompted FDA to consider adopting a HACCP-based food safety system. One of the most important challenges is the increasing number of new food pathogens. For example, between 1973 and 1988, bacteria not previously recognized as important causes of food-borne illness--such as *Escherichia coli* O157:H7 and *Salmonella enteritidis*--became more widespread.

There also is increasing public health concern about chemical contamination of food: for example, the effects of lead on the nervous system.

Another important factor is that the size of the food industry and the diversity of products and processes have grown tremendously--in the amount of domestic food manufactured and the number and kinds of foods imported. At the same time, FDA and state and local agencies have the same limited level of resources to ensure food safety.

Advantages

HACCP offers a number of advantages over the current system. Most importantly, HACCP:

- focuses on identifying and preventing hazards from contaminating food
- is based on sound science
- permits more efficient and effective government oversight, primarily because the

recordkeeping allows investigators to see how well a firm is complying with food safety laws over a period of time rather than how well it is doing on any given day

- places responsibility for ensuring food safety appropriately on the food manufacturer or distributor
- helps food companies compete more effectively in the world market.

BG 97-11

(This document replaces BG 95-19, printed Dec. 5, 1995)

More information about HACCP is available from FDA's Center for Food Safety and Applied Nutrition.

This is a mirror of the page at <http://www.fda.gov/opacom/backgrounders/haccp.html>

Home



**Food Safety and Inspection Service
United States Department of Agriculture
Washington, D.C. 20250-3700**

Key Facts: HACCP Final Rule

Revised January 1998

Key Facts: The Seven HACCP Principles

Hazard Analysis and Critical Control Points (HACCP) is a process control system designed to identify and prevent microbial and other hazards in food production. It includes steps designed to prevent problems before they occur and to correct deviations as soon as they are detected. Such preventive control systems with documentation and verification are widely recognized by scientific authorities and international organizations as the most effective approach available for producing safe food.

Under the Pathogen Reduction and HACCP Systems regulations, USDA is requiring that all meat and poultry plants design and implement HACCP systems. Plants will be required to develop HACCP plans to monitor and control production operations.

HACCP was implemented first in the largest meat and poultry plants, with 75 percent of slaughter production under HACCP-based process control systems on January 26, 1998. HACCP will be phased in throughout the regulated industry over a 2-year period. Very small plants will be phased in during the final stage, by January 25, 2000.

HACCP is endorsed by such scientific and food safety authorities as the National Academy of Sciences and the National Advisory Committee on Microbiological Criteria for Foods (NACMCF), and by such international organizations as the Codex Alimentarius Commission and the International Commission on Microbiological Specifications for Foods.

HACCP systems must be based on the *seven principles* articulated by the NACMCF. The seven principles are: (1) hazard analysis, (2) critical control point identification, (3) establishment of critical limits, (4) monitoring procedures, (5) corrective actions, (6) record keeping, and (7) verification procedures.

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The Seven HACCP Principles

Principle 1: *Conduct a hazard analysis.*

- Plants determine the food safety hazards identify the preventive measures the plant can apply to control these hazards.

Principle 2: *Identify critical control points.*

- A critical control point (CCP) is a point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to an acceptable level. A food safety hazard is any *biological, chemical, or physical* property that may cause a food to be unsafe for human consumption.

Principle 3: *Establish critical limits for each critical control point.*

- A *critical limit* is the maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level.

Principle 4: *Establish critical control point monitoring requirements.*

- Monitoring activities are necessary to ensure that the process is under control at each critical control point. FSIS is requiring that each monitoring procedure and its frequency be listed in the HACCP plan.

Principle 5: *Establish corrective actions.*

- These are actions to be taken when monitoring indicates a deviation from an established critical limit. The final rule requires a plant's HACCP plan to identify the corrective actions to be taken if a critical limit is not met. Corrective actions are intended to ensure that no product injurious to health or otherwise adulterated as a result of the deviation enters commerce.

Principle 6: *Establish record keeping procedures.*

- The HACCP regulation requires that all plants maintain certain documents, including its hazard analysis and written HACCP plan, and records documenting the monitoring of critical control points, critical limits, verification activities, and the handling of processing deviations.

Principle 7: *Establish procedures for verifying the HACCP system is working as intended.*

- *Validation* ensures that the plans do what they were designed to do; that is, they are successful in ensuring the production of safe product. Plants will be required to validate their own HACCP plans. FSIS will not approve HACCP plans in advance, but will review them for

conformance with the final rule.

- Verification ensures the HACCP plan is adequate, that is, working as intended. Verification procedures may include such activities as review of HACCP plans, CCP records, critical limits and microbial sampling and analysis. FSIS is requiring that the HACCP plan include verification tasks to be performed by plant personnel. Verification tasks would also be performed by FSIS inspectors. Both FSIS and industry will undertake microbial testing as one of several verification activities. the occurrence of the identified food safety hazard.

For Further Information Contact:

FSIS Food Safety Education and Communications Staff

Public Outreach and Communications

Phone: (202) 720-9352

Fax: (202) 720-9063

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PHOTOCOPY
PRESERVATION

SEAFOOD SAFETY
REGULATION ACT 1995

HHS NEWS

U.S. Department of Health and Human Services

P95-9
FOR IMMEDIATE RELEASE
Dec. 5, 1995

Food and Drug Administration
Judith Foulke (202) 205-4144
Home (703) 451-8132

SEAFOOD SAFETY REGULATIONS ANNOUNCED

The Clinton Administration today moved to increase the safety of the U.S. food supply by requiring that seafood processors use preventive controls to keep unsafe products from reaching consumers. The new Food and Drug Administration regulations represent a revolution in the way food is protected. The regulations -- based on principles of a system called Hazard Analysis Critical Control Point (HACCP) -- replace the approach adopted in the early 1900s that addressed safety problems after the fact with new procedures under which food processors will take greater responsibility for preparing safe food, and government and industry will work more closely together to protect public health. It is estimated that these regulations will prevent 20,000 to 60,000 seafood poisonings a year, which cost consumers up to \$116 million annually. The regulations lead the way toward a 21st century food safety system; they will be followed next year by Department of Agriculture rules for meat and poultry and in subsequent years by additional FDA regulations covering other segments of the food supply. -more- Page 2, P95-9, HACCP "Many Americans are making an effort to eat healthier and are including seafood in their diet," said Health and Human Services Secretary Donna E. Shalala. "A system that will ensure the safety of seafood products, regardless of what country or environment they come from, is a high public health priority. These changes also represent another step in the Clinton administration's continuing effort to protect the public health through smart, state-of-the-art regulations." The key HACCP components of the system are identification of potential problems that could make seafood hazardous; establishment and monitoring of targeted control points to minimize such risks; and keeping a record of the results. Under the FDA rule, seafood processors will have to identify hazards that, without preventive controls, are reasonably likely to affect the safety of the products. If at least one such hazard can be identified, the firm will be required to adopt and implement an appropriate HACCP plan. For example, a highly mechanized processing line would be checked regularly for metal fragments in the food and records kept of those checks. In addition to helping ensure that the food is free of such contaminants, this process also helps manufacturers who subsequently have problems with their food determine how and when those problems could have occurred. Seafood processors using the HACCP system will continue to be monitored under FDA surveillance and inspection programs. HACCP -more- Page 3, P95-9 HACCP record keeping will enable FDA regulators to monitor product safety more closely and on a more continuous basis than through spot checks. "Our safety inspections should focus on preventing problems rather than chasing the horses after they're out of the barn," said FDA Commissioner David A. Kessler, M.D. "HACCP is a system that will make that possible." While the HACCP rules do not apply to fishing vessels or transporters, processors of imported as well as domestic seafood must take responsibility for incoming materials. If the supplier does not provide satisfactory information about the area where the fish were caught or how they were handled, the HACCP plan will strengthen the processor's position in refusing to accept the shipment. The HACCP regulations contain special provisions to protect the safety of certain types of products. For instance, processors of raw molluscan shellfish (oysters, clams and mussels) must specify in their plans, among other things, that they will accept only molluscan shellfish that have been harvested from approved waters. In the case of smoked fish, HACCP controls call for procedures that will provide safety from *Clostridium botulinum* toxin through the shelf life of the product. Retail seafood operations, while exempt from the FDA rule, are regulated by state and/or local authorities with training and other -more- Page 4, P95-9, HACCP technical assistance from FDA. The HACCP regulations for seafood processors will be published in the Federal Register shortly. The rule will be fully implemented over

the next two years and the agency anticipates being able to perform HACCP inspections beginning in 1996. ####

This is a mirror of the page at <http://www.fda.gov/bbs/topics/NEWS/NEW00520.html>

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Federal Register 60 FR 65095 December 18, 1995
Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products; Final Rule

21 CFR 123 and 1240

Part I, Preamble, pp. 65095-65152 | **Part II, Preamble, pp. 65152-65197** | **Part III, Regulation, pp. 65197-65202**

Federal Register: December 18, 1995 (Volume 60, Number 242)
Rules and Regulations
Page 65095-65202
From the Federal Register Online via GPO Access wais.access.gpo.gov

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Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 123 and 1240

Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products; Final Rule

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 123 and 1240

Docket No. 93N-0195
RIN 0910-AA10

Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is adopting final regulations to ensure the safe and sanitary processing of fish and fishery products (hereinafter referred to as seafood), including imported seafood. The regulations mandate the application of Hazard Analysis Critical Control Point (HACCP) principles to the processing of seafood. HACCP is a preventive system of hazard control that can be used by processors to ensure the safety of their products to consumers.

FDA is issuing these regulations because a system of preventive controls is the most effective and efficient way to ensure that these products are safe.

DATES: Effective December 18, 1997. Submit written comments on the information collection requirements by February 16, 1996.

ADDRESSES: Submit written comments on the information collection requirements to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Philip C. Spiller, Center for Food Safety and Applied Nutrition (HFS-401), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3133.

For further information concerning the guidance entitled ``Fish and Fishery Products Hazards and Controls Guide,`` contact: Donald W. Kraemer (address above).

SUPPLEMENTARY INFORMATION: The contents of this preamble are listed in the following outline:

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 - 17. Shellfish Control Authority
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I. Background

A. The Proposal

In the Federal Register of January 28, 1994 (59 FR 4142), FDA published a proposed rule to establish requirements relating to the processing and importing of seafood for commercial distribution in the United States. The requirements involved the application of HACCP principles by processors and importers to ensure food safety to the maximum extent practicable. HACCP is a system by which food processors evaluate the kinds of hazards that could affect their products, institute controls to keep these hazards from occurring or to significantly minimize their occurrence, monitor the performance of those controls, and maintain records of this monitoring as a matter of routine practice.

In addition to publishing the proposed rule, FDA published in the Federal Register of April 7, 1994 (59 FR 16655), a notice of availability of draft guidelines, primarily directed toward processors, on how to develop HACCP controls for specific types of processing operations. The notice of availability requested comments on the draft. Among other things, these draft guidelines, which were titled the "Fish and Fishery Products Hazards and Controls Guide" (the Guide), inventoried known likely food safety hazards associated with many species of seafood and many processing methods and made recommendations on ways to control those hazards. Comments received by FDA on the draft Guide are under review. The agency intends to publish the first edition of the Guide before the effective date of these regulations.

FDA established on the proposed rule a comment period of 90 days, to end on April 28, 1994. The agency also asked for comment on the draft guidelines by the same date. During that comment period, FDA held public meetings in nine cities to help ensure that the public was aware of the proposal, to answer questions about its contents, and to encourage participation in the rulemaking process through the submission of comments. In addition, at these meetings, FDA staff explained to the public how to use the draft guidelines to develop HACCP controls in specific processing operations.

The agency received several written requests for an extension of the comment period. After considering these requests, FDA published a notice in the Federal Register on April 7, 1994 (59 FR 16578), announcing a 30-day extension of the comment period to May 31, 1994, for both the proposed rule and the draft guidelines.

PATHOGEN REDUCTION 7
HACCP SYSTEMS: MEAT & POULTRY

PHOTOCOPY
PRESERVATION



Food Safety and Inspection Service
United States Department of Agriculture
Washington, D.C. 20250-3700

Backgrounders

July 1996

Contact Information Updated 10/21/98

The Final Rule on Pathogen Reduction and Hazard Analysis and Critical Control Point (HACCP) Systems

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SUMMARY

The Food Safety and Inspection Service (FSIS) is establishing new requirements for all meat and poultry plants to improve food safety and begin the long-awaited modernization of USDA's meat and poultry inspection system.

All slaughter and processing plants will be required to adopt the system of process controls to *prevent* food safety hazards known as Hazard Analysis and Critical Control Points (HACCP). To verify that HACCP systems are effective in reducing contamination with harmful bacteria, FSIS is setting pathogen reduction performance standards for *Salmonella* that slaughter plants and plants that produce raw, ground meat and poultry will have to meet. In addition, slaughter plants will be required to conduct microbial testing for generic *E. coli* to verify that their process control systems are working as intended to prevent fecal contamination, the primary avenue of contamination for harmful bacteria. FSIS is also requiring plants to adopt and follow written Standard Operating Procedures for sanitation to reduce the likelihood that harmful bacteria will contaminate the finished product.

FSIS expects this combination of HACCP-based process control, microbial testing, pathogen reduction performance standards, and sanitation standard operating procedures to significantly reduce contamination of meat and poultry with harmful bacteria and reduce the risk of foodborne illness.

This new food safety system will also enable USDA to modernize its inspection program by focusing its attention on the most significant food safety hazards and on ensuring that all plants have systems in place that are effectively preventing food safety problems.

The new requirements are summarized as follows.

Hazard Analysis and Critical Control Points (HACCP)

All plants must develop, adopt and implement a HACCP plan for each of their processes. Under HACCP, plants identify critical control points during their processes where hazards such as microbial contamination can occur, establish controls to prevent or reduce those hazards, and maintain records documenting that the controls are working as intended. FSIS believes that HACCP-based process control, combined with appropriate food safety performance standards, is the most effective means available for ensuring the safety of food, including controlling and reducing harmful bacteria on raw meat and poultry products.

Implementation dates for HACCP are based on plant size; the largest plants are being required to have their HACCP systems in place first. Implementation dates range from 18 months to 42 months after publication of the final rule.

Pathogen Reduction and Microbial Testing

To be effective, HACCP-based process control must be combined with objective means of verifying that meat and poultry plants are achieving acceptable levels of food safety performance. FSIS will require all slaughter plants to conduct microbial testing for generic *E. coli*, a species of *E. coli* that is commonly found in the intestinal tract of food animals. Generic *E. coli* is an excellent indicator of fecal contamination, which is the primary pathway for contamination of meat and poultry with bacteria such as *E. coli* O157:H7, *Salmonella*, and *Campylobacter* that can cause illness. The testing requirement, which will be effective 6 months after publication of the final rule, will assist plants in maintaining adequate process control for fecal contamination. FSIS is establishing verification performance criteria that reflect the prevalence and levels of contamination of carcasses with *E. coli* as determined by FSIS baseline surveys.

In addition, FSIS is establishing pathogen reduction performance standards for *Salmonella* that slaughter plants and plants that produce raw ground products will be required to meet to verify that their HACCP systems are effective in reducing contamination with that pathogenic microorganism. The standards will provide incentives for innovation to improve food safety, and FSIS will conduct testing to verify compliance with the standards. Implementation dates for the standards are based on plant size and will coincide with those for HACCP. Prior to the implementation dates, FSIS will begin *Salmonella* testing to provide plants with information regarding their current level of performance relative to the pathogen reduction performance standard.

Standard Operating Procedures for Sanitation

All plants must prepare and implement plant-specific standard operating procedures (SOPs) for sanitation to ensure they are meeting their responsibility to keep their facilities and equipment clean. This requirement will become effective 6 months after publication of the final rule.

Safe Handling Beyond the Plant

These new requirements--mandatory HACCP, pathogen reduction performance standards and testing procedures, and SOPs for sanitation--are designed to reduce contamination of meat and poultry products with harmful bacteria when they leave the meat or poultry slaughter or processing plant. However, distributors, employees in retail stores and restaurants, and consumers must continue to store, handle, and prepare meat and poultry products carefully to keep food safe.

FSIS is working with the Food and Drug Administration (FDA) to adopt standards to control growth of harmful bacteria during transportation and storage and is working with FDA and state and local authorities to improve food safety practices at the retail level. FSIS works with other government

agencies, the food industry, and others to educate consumers on safe food handling practices.

Implementation Costs

FSIS estimates the four-year implementation cost of the final rule to the meat and poultry industry at \$305 to \$357 million, or an average of \$76 to \$89 million per year. Annual recurring costs following the implementation period are estimated at \$99.6 to \$119.8 million. Estimates of yearly public health benefits from reduced foodborne illness costs, including medical care and lost work time, range from \$990 million to \$3.7 billion. The total implementation costs amount to between one- and two-tenths of a cent per pound of product.

Request for Comments

FSIS is seeking comments, due by 60 days after the date of publication of the final rule, on certain technical issues that are associated with *E. coli* testing and the verification performance criteria. In addition, FSIS is requesting comments, due 120 days after the date of publication of the final rule, on the revised HACCP implementation schedule and guidance materials that have been prepared as appendices to the final rule.

BACKGROUND

Current FSIS regulatory requirements and inspection procedures contribute to the FSIS mission of ensuring that meat and poultry products are safe, wholesome, and accurately labeled. More than 7,400 FSIS inspectors are present in 6,200 slaughter and processing plants to ensure that diseased animals and birds do not enter the food supply and that sanitation and other requirements are met. Inspectors also monitor the meat and poultry supply for violative levels of chemical residues.

Despite the successes of the current program in removing diseased animals from the food supply and enforcing sanitation and other standards, there is a critical gap in its ability to protect public health. The current system of slaughter inspection relies largely on organoleptic (sensory) methods, which were appropriate when the first major meat inspection law was passed in 1906. At that time, animal diseases were the major concern, and invisible hazards such as pathogenic microorganisms and drug residues had not yet attracted the attention of public health authorities and regulators. Since that time, changes have been made in the inspection program to reflect changes in the production of meat and poultry, address chemical residues in slaughter plants, address bacteria in processed products, and increase the efficiency of inspection. However, the current program does not adequately target and reduce pathogenic microorganisms on raw meat and poultry. And it does not integrate systematic, preventive process control into the production process to make all meat and poultry products as safe as possible. Implementation of the final rule will help to correct these gaps.

While precise data on the incidence of illness associated with microbiological contamination of meat and poultry products is limited, foodborne illness is an important public health problem in the United States. Data from the Centers for Disease Control and Prevention suggest that foodborne microbial pathogens account for up to 7 million cases of foodborne illness each year, and up to 7,000 deaths. Of these, nearly 5 million cases of illness and more than 4,000 deaths may be associated with meat and poultry products.

The seriousness of the problem was illustrated by the outbreak of foodborne illness that occurred in several western states in early 1993. The outbreak was attributed to undercooked hamburgers contaminated with *E. coli* O157:H7 that were served at a chain of fast-food restaurants. This particular outbreak led to hundreds of cases of illness and four deaths.

This conclusion is consistent with many external studies conducted during the past decade. The National Academy of Sciences, the General Accounting Office, the National Advisory Committee on

Microbiological Criteria for Foods, and many others have called for change in the current inspection system to better address microbial pathogens and make the system more prevention-oriented.

THE RULEMAKING PROCESS

To address these concerns, FSIS, on February 3, 1995, published a proposal on Pathogen Reduction and HACCP that would mandate HACCP, set targets for pathogen reduction, require daily microbial testing to determine compliance with the targets, and require three near-term initiatives--standard operating procedures for sanitation, antimicrobial treatments, and carcass cooling standards. FSIS conducted a thorough and interactive rulemaking process on the proposal by soliciting extensive public comment and encouraging dialogue between FSIS and interested parties on the many policy and technical issues involved in the proposal.

During the comment period, which was extended twice, FSIS held seven information briefings, three scientific and technical conferences, a two-day public hearing, six issue-focused public meetings, a Federal-State conference, and a Food Safety Forum chaired by Secretary of Agriculture Dan Glickman. In addition, FSIS received approximately 7,500 written comments on the proposal.

FSIS carefully evaluated the written comments and input received through the various public events and addressed the many issues raised in formulating a final rule.

THE FINAL RULE

Hazard Analysis and Critical Control Points (HACCP)

FSIS is requiring that all federally inspected meat and poultry plants adopt HACCP systems to ensure that they have in place science-based process controls to prevent and reduce the significant food safety hazards that may arise in their particular processes and products. The HACCP approach is a system of process control that is widely recognized by scientific authorities and international organizations and is used extensively in the food industry to produce products in compliance with health and safety requirements. HACCP also provides a framework for better targeting FSIS inspection on the most significant food safety hazards and controls and more efficiently using inspection resources.

Implementation of HACCP will clarify the responsibility of industry and FSIS to produce safe meat and poultry products. FSIS's role is to set appropriate food safety standards and maintain vigorous inspection oversight to ensure that those standards are met.

Plants will be required to develop HACCP plans based on the seven principles articulated by the National Advisory Committee on Microbiological Criteria for Foods:

1. hazard analysis,
2. critical control point identification,
3. establishment of critical limits,
4. monitoring procedures,
5. corrective actions,
6. recordkeeping, and
7. verification procedures.

Plants will identify and evaluate the food safety hazards that could affect the safety of their products and institute controls necessary to prevent those hazards from occurring or to keep them within

acceptable limits. HACCP systems will be required to cover those critical control points that affect product safety, as opposed to those related to economic adulteration and quality. Each meat or poultry product produced must be covered by a HACCP plan. Plants will be required to validate their own HACCP plans--that is, ensure that they do what they were designed to do. FSIS will not approve HACCP plans in advance but will review them for conformance with the final HACCP regulations.

Verification--making sure the plan is adequate and working on a day-to-day basis--will be the responsibility of both industry and FSIS. Industry will monitor and verify the performance of the controls in their HACCP plans and maintain records of this monitoring and verification. FSIS will evaluate the HACCP plan's adequacy and successful operation as part of the inspection process. HACCP plans found by FSIS to be inadequate will have to be corrected, or the plant will face appropriate regulatory action.

FSIS currently carries out carcass-by-carcass inspection in slaughter plants to remove diseased animals from the food supply. Carcass-by-carcass inspection will continue in these plants. However, in light of improvements in process control that are expected under HACCP, FSIS of illness and four deaths. USDA's review of the outbreak concluded that the current food safety system does not adequately address the risk of microbial contamination.

This conclusion is consistent with many external studies conducted during the past decade. The National Academy of Sciences, the General Accounting Office, the National Advisory Committee on Microbiological Criteria for Foods, and many others have called for change in the current inspection system to better address microbial pathogens and make the system more to examine current tasks related to carcass-by-carcass inspection and determine what changes should be made to improve inspection effectiveness and make the use of inspection resources more productive.

FSIS is committed to implementing HACCP as rapidly as possible, taking into account the logistical effort required for such a fundamental change in industry practices and FSIS inspection strategy. FSIS has revised its proposed implementation schedule so that it is based on plant size rather than product category. Large plants with 500 or more employees will be required to have a HACCP system in place 18 months after publication of the final rule. The revised implementation schedule will ensure that 75 percent of slaughter production and 45 percent of processed products will be produced under a HACCP system within 18 months. As a result, most of the Nation's meat and poultry supply will come under HACCP-based process control one year earlier than originally proposed. Smaller plants, with 500 or fewer but 10 or more employees, must have a HACCP system in place 30 months after publication of the final rule. Very small establishments--those having fewer than 10 employees or annual sales of less than \$2.5 million--have until 42 months after publication of the final rule to have their HACCP systems in place.

ASSISTANCE FOR SMALL PLANTS

HACCP is a useful tool for improving food safety in plants of all sizes. FSIS recognizes, however, that many small plants may lack familiarity with HACCP. Thus, FSIS plans an array of assistance activities that will facilitate implementation of HACCP in small plants.

FSIS is developing 13 generic HACCP models for the major process categories, which will be available in final form before plants must begin work on their HACCP plans. The generic models will serve only as illustrations rather than as prescriptive blueprints for a specific HACCP plan.

FSIS will also conduct small-plant demonstration projects during the two-year period following issuance of the final rule at a number of sites around the country to show how HACCP systems can work in even the smallest plants under actual operating conditions.

FSIS is also making available guidance materials, as appendices to the final regulations, that will assist small, as well as large, plants in conducting their hazard analyses and developing HACCP plans. They include a *Guidebook for the Preparation of HACCP Plans* and a *Hazards and Preventive Measures Guide*. Additional guidance materials addressing other parts of the final regulations also are available.

HACCP IMPLEMENTATION CONFERENCE

FSIS plans to convene a three-day HACCP implementation conference to be held in Washington, D.C., about 60 days after publication of the final rule and intends to hold regional HACCP implementation conferences at several sites around the country. The purpose of the conference is to continue the dialogue among a diverse array of interested parties on a variety of issues related to HACCP implementation such as training and enforcement issues.

PATHOGEN REDUCTION AND MICROBIAL TESTING

The HACCP requirement will ensure that all meat and poultry plants implement science-based process controls to prevent and reduce the significant food safety hazards that are reasonably likely to occur in their particular processes and products. But HACCP-based process control must be combined with objective means of verifying that meat and poultry plants are achieving acceptable levels of food safety performance. While FSIS has in place microbiological performance standards for ready-to-eat and other processed products, microbiological performance criteria or standards for raw products, with the exception of *E. coli* O157:H7 in ground beef, do not exist.

FSIS believes it is essential to the reduction of nationwide exposure to foodborne pathogens that slaughter establishments control their operations to prevent fecal contamination and that all plants producing raw meat and poultry products institute process controls to reduce the prevalence of *Salmonella*. These regulations provide both an objective means to verify process control in slaughter plants with respect to fecal contamination and pathogen reduction performance standards for raw products that will reduce the nationwide exposure to *Salmonella*, the most common cause of foodborne illness among enteric pathogens.

GENERIC *E. COLI* TESTING FOR PROCESS CONTROL

FSIS is requiring meat and poultry slaughter plants to test carcasses for generic *E. coli* as an indicator of the adequacy of the plant's process control for fecal contamination. Plants will be required to conduct *E. coli* testing 6 months after publication of the final rule. FSIS is seeking further comment on certain technical issues such as testing frequency and sampling procedures and will be holding a conference on these issues approximately 45 days after publication of the final rule. FSIS will make any appropriate technical amendments to the *E. coli* testing protocols at least 30 days before the effective date of the rule. FSIS inspectors will not use *E. coli* testing results as an indication of process control until 6 months after the effective date for the testing requirement. A second conference is tentatively planned for approximately 9 months following publication of this rule to provide an opportunity for members of industry and others to discuss with FSIS new information based on the three months of testing that will have occurred that might justify further adjustments to the protocol.

FSIS is adopting *E. coli* verification performance criteria for each species that reflect the frequency and levels of contamination of the microorganism on such carcasses produced nationwide as

determined by FSIS baseline surveys. FSIS is using the term criteria because they are guidelines, not regulatory standards. FSIS will not use the test results by themselves to take any regulatory action but will consider them in conjunction with other information to evaluate whether a problem exists that requires regulatory action.

The required frequency of *E. coli* testing is based on production volume. Slaughter plants will be able to adopt alternative testing frequencies when they implement HACCP if the alternative is equally or more effective in verifying process control for fecal contamination. FSIS intends to update the *E. coli* criteria periodically, based on future surveys and data generated by the testing, to ensure that the criteria adequately reflect an appropriate and adequate level of performance with respect to prevention and removal of fecal contamination.

The requirement for *E. coli* testing in slaughter plants will become effective 6 months after publication of the final rule. *E. coli* test results will provide process control data that will help plants find and correct process control problems at this most fundamental phase of production. The results will also support more objective assessments by inspectors of whether plants are meeting current statutory requirements for sanitation and the prevention of adulteration. They will also play an integral role in the successful implementation of HACCP in slaughter plants.

PERFORMANCE STANDARDS FOR *SALMONELLA* AND FSIS TESTING

FSIS is adopting pathogen reduction performance standards for *Salmonella* to verify that plant HACCP systems are effective in reducing contamination with this pathogenic microorganism. FSIS believes that the production of raw meat and poultry with *Salmonella* prevalence below the current national level is readily achievable with available technology and production methods. *Salmonella* was selected as the target pathogen because it is the leading cause of foodborne illness among enteric pathogens, it is present at varying frequencies on all types of raw meat and poultry products, and it can easily be tested for in a variety of products. Furthermore, improvements in process control that result in reductions in *Salmonella* are expected to result in reductions of other pathogens found in the intestines of animals.

The microbiological performance standards FSIS is adopting are part of a fundamental shift in FSIS regulatory philosophy and strategy. FSIS is shifting from an extensive reliance on command and control regulations, which generally prescribe *how* desired objectives are to be achieved, to much greater reliance on performance standards, which generally express the objective but do not specify the means for achieving it. FSIS believes that its food safety and consumer protection goals can, in most cases, be achieved most effectively by establishing clear objectives in terms of performance standards, providing industry flexibility to devise the optimal means of achieving the objective, and then verifying through inspection and other forms of oversight that firms are meeting the established standard.

The pathogen reduction performance standards for *Salmonella* and the *E. coli* verification performance criteria complement one another. While *E. coli* testing is a good indicator of fecal contamination, it is not directly correlated with *Salmonella* contamination, which is affected by other factors as well, including the condition of incoming animals. The *Salmonella* standards will force plants not currently meeting the standards to take steps to reduce pathogens that can cause foodborne illness.

Plants will be required to achieve a prevalence of *Salmonella* contamination that is below the baseline prevalence for each raw product as reflected in the FSIS baseline surveys. These are regulatory standards that FSIS will require the plant to meet consistently over time as a condition to maintaining inspection.

FSIS, rather than the plant, will test for *Salmonella* to ensure compliance with the standards. FSIS

will conduct initial testing prior to actual enforcement of the performance standards to determine whether each plant is meeting the standard. These results will assist plants in preparing for implementation of HACCP and the pathogen reduction performance standards. FSIS will continue its testing program once the standards become effective to ensure compliance. The frequency and intensity of testing will be based on past plant performance and other factors.

The *Salmonella* enforcement strategy embodies an objective, uniform systems approach that will be administered and applied in a fair, equitable, and common-sense manner. The Agency will continually monitor and adjust its enforcement program and activities to reflect these principles while ensuring food safety.

Implementation will coincide with the implementation schedule for HACCP. Slaughter plants and plants producing raw ground product or fresh pork sausage will be required to meet the standards at the same time the plant is required to implement HACCP.

Approximately 15 months after the publication of this final rule, FSIS will convene a public conference to review available data and discuss whether they warrant refining the *Salmonella* performance standards.

The *Salmonella* standards being established are a first step in what FSIS expects to be a broader reliance in the future on pathogen-specific performance standards for raw products. FSIS plans to repeat its baseline surveys and collect substantial data through other means and, on that basis, adjust the *Salmonella* targets and possibly set targets for additional pathogens, as appropriate.

Sanitation Standard Operating Procedures

Insanitary conditions during the production of meat and poultry products increase the likelihood that pathogenic bacteria will contaminate the finished product. Poor sanitation is the most frequently observed problem in meat and poultry plants. FSIS is requiring that all meat and poultry plants adopt, maintain, and follow written Standard Operating Procedures (SOPs) for sanitation. The written sanitation SOPs must describe the specific activities plant management has determined are necessary to maintain good sanitation and prevent direct product contamination. The SOP must specify the persons responsible for carrying out these activities. Daily records must be kept showing when procedures are accomplished and when corrective actions are taken.

Sanitation SOPs will clarify that sanitation is industry's responsibility. They will make it easier for FSIS inspectors to perform their proper role of verifying that plant management is carrying out its sanitation responsibilities and will allow FSIS to focus on the prevention and correction of direct product contamination risks.

Requirements for Foreign Establishments and State Programs

Foreign countries exporting to the United States must establish inspection system requirements that are "equivalent" to U.S. requirements. Thus, all foreign meat and poultry plants that export to the United States must operate HACCP-type process control systems that are "equivalent to" HACCP and adopt equivalent performance standards.

State inspection programs must operate programs "equal to" the Federal program and will also be required to comply with the new requirements.

FOOD SAFETY FROM FARM TO TABLE

The new regulatory measures address hazards within slaughter and processing plants. FSIS

recognizes, however, that these measures must be part of a comprehensive food safety strategy that addresses hazards at other points in the farm-to-table chain. To that end, FSIS is broadening the scope of its food safety activities beyond slaughter and processing plants, with particular new emphasis on hazards that arise during transportation, distribution, and retail sale.

To improve food safety at the animal production and intermediate stages before the slaughter plant, FSIS is working with industry, academia, and other government agencies to develop and foster measures that can be taken on the farm and through distribution and marketing of animals to reduce food safety hazards associated with animals presented for slaughter. FSIS does not intend to mandate production practices at this stage but instead believes that the voluntary application of food safety assurance programs based on HACCP principles can be useful in establishing risk reduction practices on the farm and during intermediate marketing stages. The Agency believes that continued public concern about foodborne pathogens and the adoption of HACCP and performance standards will increase incentives for producers to adopt food safety practices at the animal production level.

Food safety during transportation, storage and retail sale are also important links in the food safety chain. In these areas, FSIS, the Food and Drug Administration (FDA), and State and local governments share authority for oversight of food products. FSIS and FDA are working together to develop standards governing the safety of foods during transportation and storage, with particular emphasis on the importance of temperature control in minimizing the growth of pathogenic microorganisms. In the retail area, FSIS and FDA are working with state officials to ensure the adoption of uniform, science-based standards and to foster the adoption of HACCP-type preventive approaches. State and local authorities have primary responsibility for food safety oversight of retail stores and restaurants, but FSIS and FDA, working through the Conference for Food Protection, can provide expertise and leadership to support local authorities and foster the development of sound food safety standards and practices nationwide.

Even as progress is made in reducing contamination during these stages, it will remain critical that retail food handlers and consumers follow safe food handling practices. Proper storage, preparation, and cooking of meat and poultry products are essential to achieving the goal of reducing the risk of foodborne illness to the maximum extent possible. FSIS intends to augment its food handler education efforts by expanding its collaboration with industry, other government agencies, consumer and public interest groups, educators and the media to foster the effective delivery of food safety education and information.

CHANGE WITHIN FSIS

To achieve its food safety goals and carry out the new food safety strategy, FSIS must also change itself. FSIS has conducted a top-to-bottom review of its regulatory roles, resource allocation and organizational structure and is making fundamental internal changes required to successfully carry out its HACCP-based, farm-to-table food safety strategy.

First, the Agency is reforming its existing regulations to be consistent with HACCP principles and greater reliance on performance standards and to remove unnecessary regulatory obstacles to innovation. On December 29, 1995, FSIS published an advance notice of proposed rulemaking and additional rulemaking proposals describing the Agency's strategy for regulatory and inspectional reform and initiating the rulemaking process required to achieve necessary changes. It also published, on May 2, 1996, two additional regulatory reform documents--a proposal to eliminate the prior approval system for facility blueprints, equipment, and most partial quality control plans and a proposal to add a performance standard alternative to the current command-and-control requirements governing cooked meat and poultry products. FSIS will ensure that current regulations are revised as necessary before the implementation dates to ensure consistency with the new rules.

Second, FSIS is planning a reorganization to prepare the Agency to implement a modernized system

of inspection. FSIS must realign its structure with a HACCP-based, farm-to-table strategy.

Third, FSIS will soon begin a public process to develop and evaluate new approaches to inspection that would ensure that FSIS is making the best possible use of its resources to improve food safety while still meeting all the consumer protection objectives of the current system. FSIS anticipates a major redeployment of its inspection resources to successfully implement HACCP and better target food safety hazards during transportation, storage, and retail sale.

To address these concerns, FSIS, on February 3, 1995, published a proposal on Pathogen Reduction and HACCP that would mandate HACCP, set targets for pathogen reduction, require daily microbial testing to determine compliance with the targets, and require three near-term initiatives--standard operating procedures for sanitation, antimicrobial treatments, and carcass cooling standards. FSIS conducted a thorough and interactive rulemaking process on the proposal by soliciting extensive public comment and encouraging dialogue between FSIS and interested parties on the many policy and technical issues involved in the proposal.

During the comment period, which was extended twice, FSIS held seven information briefings, three scientific and technical conferences, a two-day public hearing, six issue-focused public meetings, a Federal-State conference, and a Food Safety Forum chaired by Secretary of Agriculture Dan Glickman. In addition, FSIS received approximately 7,500 written comments on the proposal.

FSIS carefully evaluated the written comments and input received through the various public events and addressed the many issues raised in formulating a final rule.

FSIS is requiring meat and poultry slaughter plants to test carcasses for generic *E. coli* as an indicator of the adequacy of the plant's process control for fecal contamination. Plants will be required to conduct *E. coli* testing 6 months after publication of the final rule. FSIS is seeking further comment on certain technical issues such as testing frequency and sampling procedures and will be holding a conference on these issues approximately 45 days after publication of the final rule. FSIS will make any appropriate technical amendments to the *E. coli* testing protocols at least 30 days before the effective date of the rule. FSIS inspectors will not use *E. coli* testing results as an indication of process control until 6 months after the effective date for the testing requirement. A second conference is tentatively planned for approximately 9 months following publication of this rule to provide an opportunity for members of industry and others to discuss with FSIS new information based on the three months of testing that will have occurred that might justify further adjustments to the protocol.

E. coli was chosen as a more appropriate microorganism to use as a verification of process control than the originally proposed *Salmonella* based on numerous comments and the results of the scientific and technical conference on the Role of Microbiological Testing in Verifying Food Safety conducted by FSIS during the comment period. Generic *E. coli* is present in all animal feces and thus is more effective than *Salmonella* as an indicator of fecal contamination, the primary avenue of contamination for pathogenic microorganisms.

To obtain paper or diskette copies of the final rule contact:

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U.S. Department of Commerce
5285 Port Royal Road
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- *Media/Congressional Inquiries:* (202) 720-3897
- *Constituent Inquiries:* (202) 720-7943
- *Consumer Inquiries:* Call the USDA's Meat and Poultry Hotline at 1-800-535-4555; in the Washington, D.C. area, call (202) 720-3333.

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SAFE DRINKING WATER
ACT 1996

PHOTOCOPY
PRESERVATION

THE SAFE DRINKING WATER ACT AMENDMENTS OF 1996

Strengthening Protection for America's Drinking Water

President Clinton signed the Safe Drinking Water Act Amendments of 1996 on August 6, 1996. The passage of these Amendments will bring substantial changes to the national drinking water program for water utilities, States, and EPA, as well as greater protection and information to the 240 million Americans served by public water systems.

These changes will correct today's problems and help EPA, States, and water systems prepare for future drinking water safety challenges and assure the sustainable availability of safe drinking water. The Amendments increase State flexibility, provide for more efficient investments by water systems, give better information to consumers, and strengthen EPA's scientific work, including the use of risk and cost-benefit considerations in setting drinking water standards.

Four themes characterize the areas of greatest change. Together, they comprise a balanced, integrated framework of reform, and represent a major national commitment to:

- 1. new and stronger approaches to prevent contamination of drinking water;**
- 2. better information for consumers, including the "right to know";**
- 3. regulatory improvements, including better science, prioritization of effort, and risk assessment; and**
- 4. new funding for States and communities through a Drinking Water State Revolving Fund.**

+Note: The bracketed references in the text below are, first, to the relevant Section of the Amendments (P.L. 104-182), and, after the "slash" (/), to the relevant provision(s) of the Safe Drinking Water Act as newly amended.

NEW AND STRONGER PREVENTION APPROACHES

The 1996 Safe Drinking Water Act (SDWA) Amendments establish a strong new emphasis on preventing contamination problems through source water protection and enhanced water system management. That emphasis transforms the previous law, with its largely after-the-fact, regulatory focus, into a truly environmental statute that can better provide for the sustainable use of water by our nation's public water systems and their customers. The States will be central: creating and focusing prevention programs, and helping water systems improve operations and avoid contamination problems.

- **Source Water Protection:** Within 18 months after EPA publishes guidance, States must submit a program for delineating source water areas of public water systems, and for assessing the susceptibility of such source waters to contamination. States may use set asides from the State Revolving Fund (SRF) to pay for source water assessments. Assessment programs may also use data from other, related watershed-type survey activities, which will encourage the efficient use of funds and coordination among the varied programs to gather and analyze water resource-oriented data. Results of completed source water assessments must be made available to the public. These results are a statutory prerequisite for State tailored monitoring programs, because they can provide a good science basis for such tailoring. [132/1453; 1452(k)(1)(C) {SRF}]

The source water assessment results will also provide the information necessary for water systems to seek help from States in protecting source water, or initiating local government efforts. States may use set asides to protect source water (1) if they choose to adopt source water "petition" programs, under which they may use non-SDWA federal funds, under current eligibilities, to voluntarily reduce existing contamination, (2) to develop or continue other types of source water protection programs, which can focus on preventing contamination, or (3) for loans for certain source water protection activities. EPA must write guidance on State source water partnership programs, including a description of available technical and financial aid. [133/1454; 1452(g)(2)(B), 1452(k)(1)(A) {SRF}]

- **Capacity Development:** The 1996 Amendments create a program to build nationally on the demonstrated success of several States in strengthening the managerial, technical and financial capacity of water systems to reliably deliver safe drinking water. EPA is required, within 6 months, to review existing State programs and publish guidance that States may use to meet the new requirements of this provision. State programs must have two main components: (1) legal authority to ensure that **new** water systems have sufficient technical, managerial, and financial capacity to meet drinking water standards; and (2) a strategy to identify and assist **existing** water systems needing improvements in managerial, technical, or financial capacity or aid to comply with standards. States must also identify water systems in significant noncompliance status within 1 year, and report to EPA on the success of capacity development efforts in assisting such systems.

States may use an SRF set aside to fund their capacity development and implementation efforts. States that do not meet the provision's requirements are subject to withholding of their SRF allotment (20% for the new system authority, and 10% in year 2001, 15% in 2002, and 20% thereafter for the capacity strategies; but no more than 20% total). For each new regulation, EPA must analyze the likely effect of the regulation on the viability of public water systems. [119/1420; 1452(a)(1)(G)(I), (g)(2)(C), (k)(1)(B) {SRF}]

States can pursue several objectives here. One may be to better enable States to set priorities for technical and compliance assistance efforts to systems, focusing on those systems identified in the strategy as most in need of assistance. Another may be to help systems review their own characteristics, strengths, and shortcomings in light of their plans and expectations for the

future, working with the State or through their own use of the State's capacity analysis. States and systems may also want to use capacity development strategies as a means to engage in integrated resource planning to resolve conflicts over drinking water quality/management issues, or to draw in technical assistance from and coordinate with federal agencies to help in such State conflict resolution efforts.

- **Operator Certification:** Ensuring the knowledge and skills of public water system operators is widely considered one of the most important, cost-effective means to strengthen drinking water safety. To that end, the Amendments require all States to carry out a program of operator certification. Each State must either: (a) implement a program that meets the guidelines established by EPA, or (b) enforce an existing State program, provided it is substantially equivalent to or meets the overall public health objectives of EPA's guidelines. States are allowed to use a set aside from the SRF to carry out their operator certification program. EPA is required to withhold 20% of SRF funds from States that do not meet the requirements of the operator certification provision. For systems serving 3,300 persons or fewer, EPA is required to provide reimbursement (through States) for the cost of training and certification for operators required by this provision to undergo training. [123/1419; 1452(a)(1)(G)(ii), (g)(2)(D) {SRF}]

This program does not require that every water system operator be certified. That is not always necessary for proper system operation, nor is it a flexible or efficient approach. Rather, the objective of the program should be to ensure every water system has (directly, under contract, or in conjunction with other systems,) an operator to perform certain key compliance functions, and who is trained and certified to the right level that each State determines is appropriate to the functions, facilities and operations of that system.

BETTER CONSUMER INFORMATION/"RIGHT-TO-KNOW"

In addition to the much-discussed new requirement for systems to prepare consumer confidence reports, the Amendments frequently specify that the public be provided with or given access to other data collected, analyses done or implementation strategies developed under new SDWA programs. These consumer information provisions herald a new era of public involvement in safe drinking water, founded on the idea that the understanding and support of the public will be vital to address and prevent the growing threats to drinking water quality in the years ahead.

- **Consumer Confidence Reports:** Within two years, EPA must issue regulations requiring all community water systems to prepare and mail to each customer at least annually a report with information about the system's source water and the level of contaminants in the drinking water purveyed. Each Governor may allow systems serving between 500 and 10,000 people to publish the report in a newspaper rather than mail it. Systems serving less than 500 people, whose Governor has not required mailing, may elect to give effective public notice that the report is available, rather than mail or publish it. [114(a)/1414(c)(4)]

As required by this provision, EPA will consult closely with the drinking water community, risk communication experts, environmental and public interest groups, and interested parties in developing these regulations. This consultation will help ensure that the reports meet the aim of usefully informing the public, as well as the broader aim of encouraging an informed and engaged public to work with water suppliers and drinking water programs at all levels of government in the effort to secure safe drinking water.

- **Some other provisions for improved consumer information:** Persons served by a public water system must be given notice of any violation of a national drinking water standard "that has the potential to have serious adverse effects on human health as a result of short-term exposure" within 24 hours after the violation by at least one effective means, and written notice of any other violation of a national standard or monitoring requirement within one year. States must "make readily available to the public" an annual report to the Administrator on violations of

national primary drinking water regulations by public water systems within the State. [114(a)/1414(c)(1) - (3)]

Each State's triennial report to the Governor on the effectiveness of and progress under the capacity development strategy must also be available to the public. [119/1420(c)(3)] EPA must make the information from the occurrence database "available to the public in readily accessible form." [126/1445(g)(5)] The public must be provided with notice and an opportunity to comment on the annual priority list of projects eligible for State Revolving Fund (SRF) assistance that States will publish as a part of their SRF intended use plans. [130/1452(b)(3) (B)] States "shall make the results of the source water assessments ... available to the public." [132(a)/1453(a)(7)] And under the Administrative Procedures Act and several specific provisions of the SDWA Amendments, EPA must publish and make all regulations, and most guidance and information documents, available for public notice and comment.

REGULATORY IMPROVEMENTS

A decade of experience under the 1986 SDWA revealed several areas where responsible, science-based flexibilities and a better prioritization of effort could improve protection of public health compared to the one-size-fits-all approach of the 1986 statute.

- ***New risk-based contaminant selection:*** The requirement that EPA regulate an additional 25 contaminants every 3 years is eliminated. Instead, EPA has the flexibility to decide whether or not to regulate a contaminant after completing a required review of at least 5 contaminants every 5 years. EPA must use three criteria to determine whether or not to regulate a contaminant: that the contaminant adversely affects human health; it is known or substantially likely to occur in public water systems with a frequency and at levels of public health concern; and regulation of the contaminant presents a meaningful opportunity for health risk reduction. [102/1412(b)(1)]

This provision departs dramatically from the approach of the previous law. The "25 every three years" mandate allowed little risk prioritization by EPA or anyone else, and the mandate to regulate 83 specified contaminants allowed essentially none. The new provision makes risk prioritization dominant in selecting contaminants to regulate. EPA will work in partnership with the States, water systems, environmental and public health groups, the scientific community and the public to identify and closely scrutinize unregulated contaminants that are most prevalent in drinking water, present the most serious threat to health and can be most productively and effectively controlled. It is flexible enough to be neither over- nor under-inclusive. Sizeable contaminant clusters (similar to the disinfection byproducts/microbial cluster, 13 contaminants proposed) can be reviewed, other contaminants added for analysis -- with only those that meet the three criteria receiving a determination to regulate.

- ***Occurrence information: unregulated contaminants, national database, information collection:*** The collection, organization and ready availability of contaminant occurrence data takes on unprecedented importance under the new law's risk-based regulatory framework. Accordingly, the statute includes several responsive provisions. EPA must issue regulations establishing criteria for monitoring of unregulated contaminants, and, within 3 years after enactment, and every 5 years thereafter, must issue a list of no more than 30 such contaminants for which monitoring is required. Significant changes from previous law include a provision that the States may (and if they decline, EPA shall) develop a plan for monitoring by a representative sample of systems serving fewer than 10,000 people (to ensure an understanding of contaminant occurrence in different size systems), and a provision requiring that persons served by the system must be notified of the availability of monitoring results. [125(c)/1445(a) (2)]

For the first time, a national occurrence database covering regulated and unregulated

contaminants will be established, primarily using compliance monitoring detection data and information from the unregulated contaminant monitoring program. The principal use of the database will be for EPA to make occurrence determinations on whether or not to regulate a certain contaminant, but it may also be useful for such purposes as State tailoring of system monitoring and source water protection. The occurrence database will also improve public understanding and participation in drinking water protection because the data must "be available to the public in readily accessible form." [126/1445(g)]

In addition, without first issuing a regulation, EPA may now require systems to submit information for individual system compliance purposes as well as to establish new regulations. In the latter case, EPA must pay for any requirements to install treatment equipment or process changes, to test treatment technology, or to analyze or process monitoring samples. [125(a)/1445(a)(1)] A key benefit of this for the regulatory process will be the ability to gather data that systems have already collected but were not required to. This will advance risk assessment by enabling EPA, with the smallest impact on systems, to decide whether to undertake, and if needed, how to focus further inquiry.

- **Cost-benefit analysis and research for new standards:** For all future drinking water standards, EPA is to conduct a thorough cost-benefit analysis and provide comprehensive, informative, and understandable information to the public. EPA is also required to use the "best available, peer-reviewed science and supporting studies" in carrying out actions within the standard setting section "to the degree that an Agency action is based on science." [103/1412(b)(3)]

To ensure that adequate scientific information is developed to support these new requirements, \$10 million annually is to be set aside from the SRF for top priority health effects research. [130/1452(n)] Several programs of research and funding are separately authorized for disinfection byproducts/microbial pathogens (\$87.5 million over 7 years) [137/1458(c)]; waterborne disease occurrence (\$15 million over 5 years) [137/1458(d)]; subpopulations at greater risk [137/1458(a)]; and biological mechanisms by which contaminants affect human health [137/1458(b)]; as well as in support of drinking water program activities generally (\$186.2 million over 7 years) [201].

Standard setting has new flexibility compared to the previous law. After first defining a maximum contaminant level (MCL) or treatment technique standard based on affordable technology, as previously, EPA must determine whether the costs of that standard would be justified by the benefits. If not, then EPA may adjust an MCL to a level that "maximizes health risk reduction benefits at a cost that is justified by the benefits." The authority to adjust the MCL cannot be used if the costs to large systems are justified by the benefits, and other systems are likely to receive variances. The rationale is that affordability problems for smaller systems should not change a national standard if those systems would receive a variance from that national standard anyway, based on affordability grounds. Flexibility to "minimize the overall risk of adverse health effects" is also authorized where certain means of controlling one contaminant may increase the risk from another contaminant ("risk-risk" balancing situations). [104/1412(b)(4) - (6)]

The cost-benefit provision was included mainly to address the concern that the health protection benefits of certain future standards might not be "worth" their costs, even if large systems could afford to meet such standards through their economies of scale. The new standard-setting retains the previous law's approach to defining an affordable technology standard, but subjects that standard in every case to the "justified" test. EPA can proceed with a standard based on the affordable technology approach, or may adjust an affordable technology-based MCL to a level that is "justified". In the latter case, the new law's further requirement that the MCL must also maximize health benefits ensures that health protection remains the paramount consideration in standard setting.

- ***Small system technologies, variances, and exemptions:*** A fundamental problem with the previous law was that, in setting standards based on technology that large systems could afford, it did not recognize the often-different economics of small systems. The new law contains multiple remedies. First, as part of a new drinking water standard, EPA is to identify technologies that comply with the standard and are specifically affordable for each of three groups of smaller systems. [105/1412(b)(4)(E)] Second, where such technologies do not exist for a certain group of smaller systems or quality of source water, a "variance" technology must be identified that need not meet the standard but must provide the maximum protection affordable for such groups of smaller systems and source waters. [111/1412(b)(15)] Within 2 years, EPA must identify affordable compliance and, where appropriate, variance technologies for existing regulations, and issue regulations for small system variances.

States with primacy will make decisions on affordability variances for specific systems serving up to 3,300 persons, while EPA must also approve variances for systems between 3,300 and 10,000. The variance decision must include consideration of whether the system could comply with the standard through water treatment, alternative water supplies, or restructuring or consolidation. EPA is also required to publish information States can use to make affordability determinations. Consumers may petition EPA to object to a variance proposed by a State, and EPA must respond to petitions within 60 days. If EPA objects to a variance, it cannot be granted until the State makes the requested changes or responds in writing to each objection. [116/1415(e)]

The statute also authorizes "source water" variances from a standard on condition that the systems install affordable compliance technology. This gives the certainty of a variance to any size system able to install treatment, but whose unavoidably poor source water quality may prevent it from meeting the standard even with treatment. [115/1415(a)(1)(A)]

These new provisions create a logical and workable hierarchy of options for small systems. Most small systems whose source water quality does not meet a national standard will be able to comply if they are allowed to use treatment specifically affordable for systems of their size. For those systems which cannot afford such treatment, the State (with EPA review if applicable) will assess whether other changes -- e.g., source water, restructuring, or connection to another system -- could enable them to meet the standard. Only if such changes are not practicable can a system be authorized to provide drinking water that does not fully meet a national standard. And that authorization will only be for the most protective technology the system can afford, which will give much more protection than was actually provided under the all-or-nothing regime of the previous law.

Moreover, a system serving 3,300 persons or fewer may receive exemptions from a standard for up to nine years (three years are now allowed) if it serves an economically disadvantaged community, is reasonably likely to get financial assistance to comply during the exemption term, and cannot comply by an alternative water source or by management or restructuring changes. Exemptions are meant to enable a system to avoid a continuing violation of a standard if it cannot now comply but will in the near future. [117(a)/1416]

- ***Compliance time frames:*** The Amendments extend to 3 years the previous, unworkably short 18-month deadline for systems to comply with new regulations, unless EPA determines an earlier date is "practicable." EPA or States (for individual systems) may give an additional 2 years if necessary for capital improvements. [108/1412(b)(10)]
- ***Monitoring reforms:*** States may grant "interim monitoring relief" to systems under 10,000 (exempting them from additional quarterly monitoring) if monitoring done at the time of "greatest vulnerability to the contaminant" fails to detect it, and the State finds that further monitoring is unlikely to detect it. This relief may not cover any microbiological contaminants

(or their indicators), disinfectants, or disinfection or corrosion byproducts. [125(b)/1418(a)]

States with an approved program for source water assessments may implement tailored, alternative monitoring requirements for any contaminant for which interim relief may be granted (except unregulated microbiological contaminants or indicators). This provision strikes a balance encompassing two key aims of the new law: more flexibility for States to craft a drinking water program that responds to local conditions and needs, and the assurance that both regulation and deregulation under that program will be solidly founded on good science. The new law also explicitly protects "existing authorities" available to States to alter monitoring requirements through waivers or other EPA initiatives, such as the chemical monitoring reform process now underway. [125(b)/1418(b)-(d)]

- **Enforcement:** The Amendments streamline processes for administrative compliance orders and penalties up to \$5000, raise the administrative and emergency penalty caps, make enforceable many SDWA provisions and requirements imposed under them by EPA or primacy States, and give up to a 2 year enforcement moratorium for violations being remedied by a specific plan to consolidate with another system. States must also adopt administrative penalty authority for primacy. These measures will facilitate more effective enforcement, encouraging compliance while keeping safeguards for systems. [113/1414]
- **Radon, Arsenic, DBP/Cryptosporidium, Sulfate:**

Arsenic: EPA is required to conduct additional research on arsenic, particularly the health effects at low levels of exposure, after consultation with NAS and others. EPA must propose a regulation not later than January 1, 2000, and issue a final regulation 12 months later. The objective is to provide for a better understanding of arsenic's characteristics in drinking water that may create chronic health effects, within a time frame to regulate that is limited but longer than permitted under the previous law. As the conference report suggests, EPA has already initiated a research partnership on this issue with the American Water Works Association Research Foundation, and intends to continue in that direction under the statutory timetable. [109(a)/1412(b)(12)(A)]

Radon: EPA is to arrange for a risk assessment by NAS, issue a cost-benefit analysis within 30 months, and issue a proposed regulation within 36 months. If the resulting MCL for radon is "more stringent than necessary to reduce the contribution to radon in indoor air from drinking water to a concentration that is equivalent to the national average concentration of radon in outdoor air," then EPA must establish an alternative MCL at a level that would reduce such contribution to the level equivalent to outdoor air radon. Water systems may comply with the alternative level if their State develops and implements a program for multi-media radon risk reduction that achieves risk reduction benefits equal to or greater than those that would be achieved under the MCL promulgated using the cost-benefit analysis. In States without an approved multi-media mitigation program, systems may submit a local program to EPA under the same criteria, conditions and approval process applicable to States. [109(b)/1412(b)(13)]

This multi-media approach is consistent with the basic philosophy of the new statute, to enable cost-effective risk reduction to be used for each contaminant. Compared to the contribution from drinking water, indoor air is generally the dominant form of exposure to radon, and the new law permits States and systems to reduce risk through that avenue of exposure where it would be more cost-effective than through drinking water.

DBPs/Cryptosporidium: The negotiated schedule for disinfection byproducts/ *Cryptosporidium* is established in the law, and the Explanatory Statement of the Conference Committee addresses both the process of and the substance adopted by the regulatory negotiation for DBPs/*Cryptosporidium*. The new law allows EPA to use the risk-risk authority but precludes use of the new 1412(b)(6) cost-benefit provision to regulate DBPs, and deems the

"considerations used in the development of the [DBP] proposal" as consistent with the risk-risk authority for the purposes of the Stage I and Stage II DBP rules. [102(a)/1412(b)(2)(C); 104(a)/1412(b)(6)(C); 104(b)]

Sulfate: EPA must conduct, jointly with the Centers for Disease Control and Prevention, a dose-response study for sulfate within 30 months. Sulfate will thereafter be considered in the first round of the new contaminant selection process. If EPA determines to regulate sulfate, such regulation shall include the flexible compliance options similar to those proposed by EPA in November, 1994. This approach serves the purpose for sulfate that the new contaminant selection process does for the drinking water program as a whole: to allow for the better prioritization of the nation's resources to the severity of the risks. [109(a)/1412(b)(12)(B)]

A DRINKING WATER STATE REVOLVING FUND FOR STATES AND COMMUNITIES

The creation of a Drinking Water State Revolving Fund (SRF), to assist communities in installing and upgrading safe drinking water treatment facilities, is among the new statute's most dramatic departures from the past, and among the most important changes in the nation's drinking water program since passage of the original SDWA in 1974. President Clinton proposed this SRF in 1993 to advance the same kind of national commitment to safe drinking water as America has made to wastewater treatment and clean water.

- ***Drinking Water State Revolving Fund:*** The SRF is authorized at \$599 million for Fiscal Year 1994, and \$1 billion annually thereafter through Fiscal Year 2003. The full span of this authorization is meaningful because the law permits appropriation in future years of any funds authorized but not appropriated in prior years. Funds are allotted to all primacy States (Wyoming is grandfathered) through Fiscal Year 1997 based on the current formula for Public Water System Supervision grants, and thereafter based on the results of the most recent SRF needs survey. EPA must publish the first needs survey within 180 days. A minimum allotment of 1% will be available for all States, and the required State match is 20 percent. One and one-half percent of the SRF can be used for grants to Indian Tribes and Alaska Native villages. Community water systems and non-profit non-community water systems are eligible, but federal systems are not. Projects, including associated land "integral to a project," are eligible if they "will facilitate compliance with" applicable national drinking water regulations or will "significantly further the health protection objectives" of SDWA. States will annually prepare intended use plans identifying eligible projects and their priority, based on seriousness of health risk, compliance needs (including filtration), and system economic need calculated on a per-household basis. States may provide loan subsidies and loan forgiveness to disadvantaged communities for up to 30% of the annual SRF capitalization grant. [130/1452(a) - (b), (d)]

Before Fiscal Year 2002, State Governors may shift up to 33% of the SDWA capitalization grant into the Clean Water SRF, or up to an equivalent dollar amount from the Clean Water SRF into the Safe Drinking Water SRF. [302]

- ***SRF Grants to States for Prevention Programs and Projects:*** One of the most notable features of new law is the authorization to States to use SRF funds for the new prevention programs. Up to 10% of their capitalization grants may be used for source water protection, capacity development, and operator certification programs, as well as for the State's overall drinking water program (for which annual grants of \$100 million are separately authorized elsewhere in the law [124/1443(a)(7)]). Up to another 15% (no more than 10% for any one purpose) can be used for prevention projects in water systems, including source water protection loans, technical and financial aid for capacity development, source water assessments, and wellhead protection. [130/1452(g)(2), (k)]

These authorizations reflect not only Congress' intention to provide funding for new mandates,

but also the high priority and importance placed on these prevention activities -- some of which are discretionary for States and systems. The success of these activities will determine whether the new law's potential as a preventive, environmental statute is realized, and how far we as a nation can advance under it towards the sustainable use of water. Appropriately, extremely wide discretion is assured to States in both the design and implementation of these activities, and in the allocation of SRF grant funds to them. This will enable States to further State priorities, and to coordinate with other State and local activities that may help meet the objectives of the new prevention programs.

The authorization of funds for these programs and activities also reflects the broader balance struck on funding priorities in the new law. The SDWA needs surveys will define needs requiring substantial levels of SRF funding if the new loan program is to be effective in helping to address those needs on a sustainable, long-term basis (that is, if the SRF is to revolve at a level responsive to the needs). Because prevention programs are cost-effective means to avoid the need for treatment, they also are vital to prevent capital compliance needs from growing unmanageably. The structure of the new SRF can meet both objectives -- and assure safe drinking water for decades to come -- if we make a sustained commitment to sufficient funding to achieve the promise of this critical program.



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Revised September 25, 1996

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Safe H₂O r
Act 90

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[DOCID: f:pub1182.104][[Page 110 STAT. 1613]]

Public Law

104-182104th Congress

An Act To

reauthorize and amend title XIV of the Public Health Service Act (commonly known as the "Safe Drinking Water Act"), and for other purposes.

<<NOTE: Aug. 6, 1996 - [S. 1316]>> Be it enacted by the Senate and House of Representatives of the United States of America in Congress

<<NOTE: Safe Drinking Water Act Amendments of 1996. Inter-governmental relations. Environmental protection.>> assembled, SECTION 1. SHORT TITLE;

TABLE OF CONTENTS. (a) <<NOTE: 42 USC 201 note.>> Short

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infestation of Lake Champlain. TITLE IV--ADDITIONAL ASSISTANCE FOR

WATER INFRASTRUCTURE AND WATERSHEDS Sec. 401. National program.

TITLE V--CLERICAL AMENDMENTS Sec. 501. Clerical amendments. SEC. 2. REFERENCES; EFFECTIVE DATE; DISCLAIMER. (a) References to Safe Drinking Water

Act.--Except as otherwise expressly provided, whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to that section or other provision of title XIV of the Public Health Service Act (commonly known as the "Safe Drinking Water Act") (42 U.S.C. 300f et seq.). (b) <<NOTE:

42 USC 300f note.>> Effective Date.--Except as otherwise specified in this Act or in the amendments made by this Act, this Act and the amendments made by this Act shall take effect on the date of enactment of this Act. (c)

<<NOTE: 42 USC 300f note.>> Disclaimer.--Except for the provisions of section 302 (relating to transfers of funds), nothing in this Act or in any amendments made by this Act to title XIV of the Public Health Service Act (commonly known as the "Safe Drinking Water Act") or any other law shall be construed by the Administrator of the Environmental Protection Agency or the courts as affecting, modifying, expanding, changing, or altering--

(1) the provisions of the Federal Water Pollution Control Act;

(2) the duties and responsibilities of the Administrator under that Act; or

(3) the regulation or control of point or nonpoint sources of pollution discharged into waters covered by that Act. The Administrator shall identify in the agency's annual budget all funding and full-time

equivalents administering such title XIV separately from funding and staffing for the Federal Water Pollution Control Act. SEC. 3. <<NOTE: 42 USC 300f note.>> FINDINGS. The Congress finds that--

(1) safe drinking water is essential to the protection of public health; (2) because the requirements of the Safe Drinking Water Act (42 U.S.C. 300f et seq.) now exceed the financial and technical capacity of some public water systems, especially many small public water systems, the Federal Government needs to provide assistance to communities to help the communities meet Federal drinking water requirements; [[Page 110 STAT. 1615]] (3) the Federal Government commits to maintaining and

improving its partnership with the States in the administration and implementation of the Safe Drinking Water Act; (4) States play a central role in the implementation of safe drinking water programs, and States need increased financial resources and appropriate flexibility to ensure the prompt and effective development and implementation of drinking water programs; (5) the existing process for the assessment and selection of additional drinking water contaminants needs to be revised and improved to ensure that there is a sound scientific basis for setting priorities in establishing drinking water regulations;

(6) procedures for assessing the health effects of contaminants establishing drinking water standards should be revised to provide greater opportunity for public education and participation;

(7) in considering the appropriate level of regulation for contaminants in drinking water, risk assessment, based on sound and objective science, and benefit-cost analysis are important analytical tools for improving the efficiency and effectiveness of drinking water regulations to protect human health; (8) more effective protection of public health requires--

(A) a Federal commitment to set priorities that will allow scarce Federal, State, and local resources to be targeted toward the drinking water problems of greatest public health concern; (B) maximizing the value of the different and complementary strengths and responsibilities of the Federal and State governments in those States that have primary enforcement responsibility for the Safe Drinking Water Act; and

(C) prevention of drinking water contamination through well-trained system operators, water systems with adequate managerial, technical, and financial capacity, and enhanced protection of source waters of public water systems;

(9) compliance with the requirements of the Safe Drinking Water Act continues to be a concern at public water systems experiencing technical and financial limitations, and Federal, State, and local governments need more resources and more effective authority to attain the objectives of the Safe Drinking Water Act; and (10) consumers served by public water systems should be provided with information on the source of the water they are drinking and its quality and safety, as well as prompt notification of any violation of drinking water regulations.

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Office of Pesticide Programs

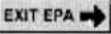
The Food Quality Protection Act (FQPA) of 1996

NEW! EPA is seeking comments on draft science policy guidance documents relating to FQPA implementation.

- [Introduction](#)
- [Amendments to FFDCA](#)
- [Amendments to FIFRA](#)
- [EPA's Implementation of FQPA](#)
- [Science Issues Raised by FQPA](#)
- [Federal Advisory Committees](#)

Introduction

In 1996, Congress unanimously passed landmark pesticide food safety legislation supported by the Administration and a broad coalition of environmental, public health, agricultural and industry groups. President Clinton promptly signed the bill on August 3, 1996, and the Food Quality Protection Act of 1996 became law (P.L. 104-170, formerly known as H.R. 1627).

EPA regulates pesticides under two major federal statutes. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA registers pesticides for use in the United States and prescribes labeling and other regulatory requirements to prevent unreasonable adverse effects on health or the environment. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), EPA establishes tolerances (maximum legally permissible levels) for pesticide residues in food. Tolerances are enforced by the Department of Health and Human Services/Food and Drug Administration (HHS/FDA) for most foods, and by the U.S. Department of Agriculture/Food Safety and Inspection Service (USDA/FSIS) for meat, poultry, and some egg products. 

For over two decades, there have been efforts to update and resolve inconsistencies in the two major pesticide statutes, but consensus on necessary reforms remained elusive. The 1996 law represents a major breakthrough, amending both major pesticide laws to establish a more consistent, protective regulatory scheme, grounded in sound science. It mandates a single, health-based standard for all pesticides in all foods; provides special protections for infants and children; expedites approval of safer pesticides; creates incentives for the development and maintenance of effective crop protection tools for American farmers; and requires periodic re-evaluation of pesticide registrations and tolerances to ensure that the scientific data supporting pesticide registrations will remain up to date in the future.

This site contains information about the law, EPA's implementation of the law, and opportunities for public involvement.

- [Overview of Federal Laws Directing OPP Activities](#)
- [Highlights of the FQPA](#)
- [Full Text of FQPA \(Public Law 104-170, Aug. 3, 1996\)](#) (PDF format, size 257350)
- [New Directions in Public Health Protection Speech](#) by Lynn R. Goldman, M.D., Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances to the American Crop Protection Association (Sept. 10, 1996)
- [Progress Review/Scientist to Scientist Meeting on Food Quality Protection Issues](#), January 11-12, 1999

- [Agenda](#)
-

FQPA Amendments to FFDCA

FQPA changed the way EPA sets residue limits (tolerances) for pesticides on foods under FFDCA.

- [FQPA Amendment Issues](#)
 - [Children & Consumers](#)
 - [Health](#)
 - [Reregistration Eligibility Decisions \(REDs\)](#)
 - [Tolerances/Residue Levels](#)
- [Readers Guide to FQPA amendments to FFDCA](#)
- [Full Text of Original Law](#) 

FQPA Amendments to FIFRA

FQPA changed the way EPA reviews and approves pesticides.

- [FQPA Amendment Issues](#)
 - [Emergency Exemptions](#)
 - [Pesticide Registration/Reregistration](#)
 - [Pesticide Review](#)
 - [Training](#)
 - [Readers Guide to FQPA amendments to FIFRA](#)
 - [Full Text of Original Law](#) 
-

EPA's Implementation of FQPA

As a result of the sweeping changes FQPA required of EPA's pesticide program, the law also raised some challenging implementation issues and deadlines.

- [PR Notice 97-1 Agency Actions under the Requirements of the Food Quality Protection Act \(Pesticide Regulation Notice\)](#)
 - [1996 Food Quality Protection Act Implementation Plan \(3/97\) \(PDF format, 284K\)](#)
 - [Regulatory Decision Process Chart](#) as referenced on page 27 of the FQPA Implementation Plan (10K. In Adobe Acrobat's [Portable Document Format](#). Must be printed on legal-sized paper.)
 - [FQPA Implementation Activities](#)
 - [March 1997 Update](#)
 - [June 1997 Update](#)
-

Federal Advisory Committees

OPP sees stakeholder consultation and public involvement as a critical step in making the federal pesticide programs work. A number of Federal Advisory Committees help EPA engage public stakeholders. These committees include:

- Tolerance Reassessment Advisory Committee (TRAC) provides advice on organophosphate tolerance reassessment.
- Pesticide Program Dialogue Committee (PPDC) allows stakeholders to provide feedback on various topics, such as FQPA implementation.
- Food Safety Advisory Committee (FSAC) provides a forum for stakeholders to discuss pesticide regulation, policies, and implementation.
- Endocrine Disruptors Screening & Testing Advisory Committee (EDSTAC) advises EPA on the screening and testing of endocrine disruptors, as required by the FQPA.

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*www.epa.gov/oppfead1/fqpa/
updated February 8, 1999*

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FoodNet

CDC/USDA/FDA Foodborne Diseases
Active Surveillance Network
CDC's Emerging Infections Program
1997 Surveillance Report

Prologue | Executive Summary | Background | Results | Additional Studies
Conclusion | Future Activities | Publications | FoodNet Working Group
Summary Tables and Graphs

Prologue

The *1997 Final FoodNet Surveillance Report* consists of two parts: Part I is the Narrative Report, and Part II is the summary tables and graphs. The Narrative Report is based on the report "1997 Surveillance Results", written for the Department of Health and Human Services in April 1998. The new document has two revisions from the earlier one. First, this report uses the 1997 postcensus population estimates which became available in August 1998. Second, the new report includes additional cases that were reported after publication of the initial report but before the closeout of the surveillance data. Therefore, tables 1A and 1B have been updated and incidence rates recalculated.

Further information concerning FoodNet can be obtained by contacting the Foodborne and Diarrheal Diseases Branch at telephone number 404.639.2206 or via the internet at <http://www.cdc.gov/ncidod/dbmd/foodnet/foodnet.htm>

Executive summary

Foodborne infections are an important public health challenge. The Centers for Disease Control and Prevention (CDC) is actively involved in preventing foodborne disease. CDC's principal role in the interagency national Food Safety Initiative launched this year has been to enhance surveillance for and investigation of infections that are foodborne. These efforts will provide crucial data to identify control points, focus future prevention strategies and decision making within food safety regulatory agencies, measure changes in the burden of disease, and improve the national early warning system for food safety emergencies.

One major project is the collaborative Foodborne Diseases Active Surveillance Network (FoodNet), which CDC conducts with states and other federal agencies. FoodNet is measuring the burden and sources of specific diseases that are usually foodborne in the United States through active surveillance and additional studies. FoodNet will track and interpret trends in these diseases over time and will conduct studies of causes of emerging foodborne diseases. Ongoing FoodNet surveillance will be used to document the effectiveness of new food safety control measures, such as the USDA Pathogen Reduction and Hazard Analysis and Critical Control Points (HACCP) Rule, in decreasing the number of cases of major foodborne diseases in the United States each year. FoodNet and other efforts at CDC augment, but do not replace, longstanding activities at CDC and in states to identify, control, and prevent foodborne disease hazards. FoodNet is a sentinel network that can respond rapidly to new and emerging foodborne pathogens. Enhanced surveillance and investigation are integral to developing and evaluating new prevention and control strategies that can improve the

safety of our food and the public's health.

The following are key findings of CDC FoodNet surveillance activities during 1997:

C The overall burden of diarrheal disease is great. FoodNet estimates that 360 million cases of diarrheal illness occur per year, resulting in approximately 28 million medical consultations. Further studies will define the causes and impact of these illnesses and what proportion of them may be related to food.

C In 1997, FoodNet tracked infections caused by seven bacterial pathogens and began to track two parasitic pathogens. Among the agents under surveillance, *Campylobacter* was the most frequently diagnosed, even though outbreaks caused by this pathogen are rare. A study of *Campylobacter* infections that began in 1998 will identify control points and direct future prevention strategies. Based on these surveillance findings, the USDA Agricultural Research Service is augmenting research into possible prevention strategies for *Campylobacter*.

C FoodNet showed that *Escherichia coli* O157:H7 infections were more common in northern states and that undercooked ground beef was the principal food source of *E. coli* O157:H7 infections. In contrast with the findings of previous investigations, hamburgers eaten at fast-food restaurants were not associated with infection, suggesting that recent changes in the meat industry may have reduced *E. coli* O157:H7 infections associated with consumption of hamburgers at fast-food restaurants. Expanded efforts to reduce contamination of meat and to promote thorough cooking of hamburgers can further reduce the number of these infections. A second study is planned to explore other potential control points.

C Hospitalization associated with foodborne diseases is an important public health problem. In FoodNet sites, *Listeria* infections had the highest hospitalization rate and caused nearly half of the reported deaths. Because of this, FoodNet will conduct additional studies of *Listeria* infections to identify food sources and potential control points.

C In the summer of 1997, an outbreak of *Vibrio parahaemolyticus* infections in the western United States was identified by FoodNet and state surveillance and was associated with consumption of raw oysters. As a result, public health officials closed oyster beds in Washington State and warned the public about the risk associated with those shellfish, thus preventing further human illness. In the future, surveillance of seafood-associated infections can be used to document the effect of FDA's seafood safety programs.

Background

FoodNet is the principal foodborne disease component of CDC's Emerging Infections Program (EIP). FoodNet is a collaborative project among CDC, the U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA), and the seven EIP sites. As of January 1, 1998, the total population of these sites is 20.3 million, or 7.5% of the U.S. population.

Objectives

The objectives of FoodNet are to determine the frequency and severity of foodborne diseases; determine the proportion of common foodborne diseases that results from eating specific foods; and describe the epidemiology of new and emerging bacterial, parasitic, and viral foodborne pathogens. To address these objectives, FoodNet uses active surveillance and conducts related epidemiological studies. By monitoring the

burden of foodborne diseases over time, FoodNet will document the effectiveness of new food safety initiatives, such as the USDA Pathogen Reduction and Hazard Analysis and Critical Control Points (HACCP) Rule, in decreasing the number of cases of foodborne diseases in the United States each year.

Methods

In 1997, FoodNet conducted population-based active surveillance for confirmed cases of *Campylobacter*, *Escherichia coli* O157, *Listeria*, *Salmonella*, *Shigella*, *Vibrio*, and *Yersinia* infections in Minnesota, Oregon, and selected counties in California, Connecticut, and Georgia (total population: 16.1 million). Active surveillance data from Maryland and New York will be included in 1998. To identify cases, FoodNet personnel contact each of the nearly 300 clinical laboratories within the catchment areas, either weekly or monthly, depending on the size of the clinical laboratory.

Results

Cases reported

In 1997, a total of 8576 confirmed cases of infections caused by the pathogens under surveillance were identified in the five sites. Of these, 8059 were bacterial; 3974 *Campylobacter* infections, 2205 *Salmonella* infections, 1273 *Shigella* infections, 340 *E. coli* O157 infections, 139 *Yersinia* infections, 77 *Listeria* infections, and 51 *Vibrio* infections (Table 1A). The most commonly identified *Salmonella* serotypes were Typhimurium (646 cases), Enteritidis (361), Heidelberg (141), Newport (77), and Montevideo (67). In addition, 517 cases of parasitic disease were reported from four sites; 468 cases of *Cryptosporidium* and 49 of *Cyclospora* (Table 1B).

Table 1A. Infections caused by specific bacterial pathogens, reported by FoodNet sites, 1997

Pathogen	CA	CT	GA	MN	OR	Total
<i>Campylobacter</i>	1036	527	499	1175	737	3974
<i>E. coli</i> O157	19	34	8	199	80	340
<i>Listeria</i>	14	12	20	18	13	77
<i>Salmonella</i>	370	417	470	619	329	2205
<i>Shigella</i>	293	78	586	138	177	1273
<i>Vibrio</i>	31	4	2	2	12	51
<i>Yersinia</i>	35	15	43	31	15	139
Total	1798	1088	1628	2182	1363	8059

Table 1B. Infections caused by specific parasitic pathogens, reported by FoodNet sites, 1997

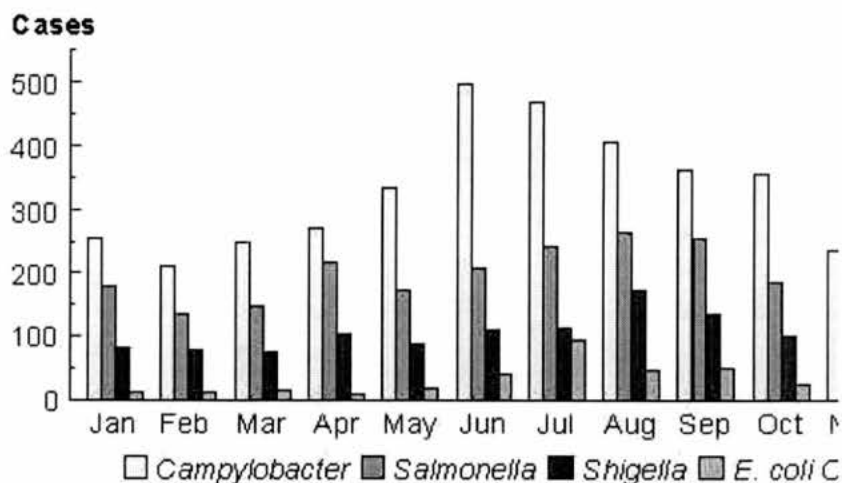
Pathogen	CA	CT	GA	MN	OR*	Total
<i>Cryptosporidium</i>	157	42	-	243	26	468
<i>Cyclospora</i>	16	29	-	3	1	49
Total	173	71	-	246	27	517

*Oregon began surveillance for
parasitic disease on July 1,
1997

Seasonality

Isolation rates for several pathogens showed wide seasonal variation; 66% of *Vibrio*, 52% of *E. coli* O157, 35% of *Campylobacter*, and 32% of *Salmonella* were isolated during June through August (Figure 1).

Figure 1. Cases of foodborne disease caused by specific pathogens, by month, FoodNet Sites, 1997



1997 Rates

To compare the number of cases among sites with different populations, annual incidence rates were calculated. Incidence is the number of reported culture-confirmed cases divided by the 1997 postcensus estimates of the population. Overall incidence rates were higher for infections with *Campylobacter* (24.7/100,000 population), *Salmonella* (13.7/100,000), and *Shigella* (7.9/100,000). Lower overall incidence rates were reported for *E. coli* O157 infection (2.1/100,000), *Yersinia* (0.9/100,000), *Listeria* (0.5/100,000), and *Vibrio* (0.3/100,000).

1996 Rates

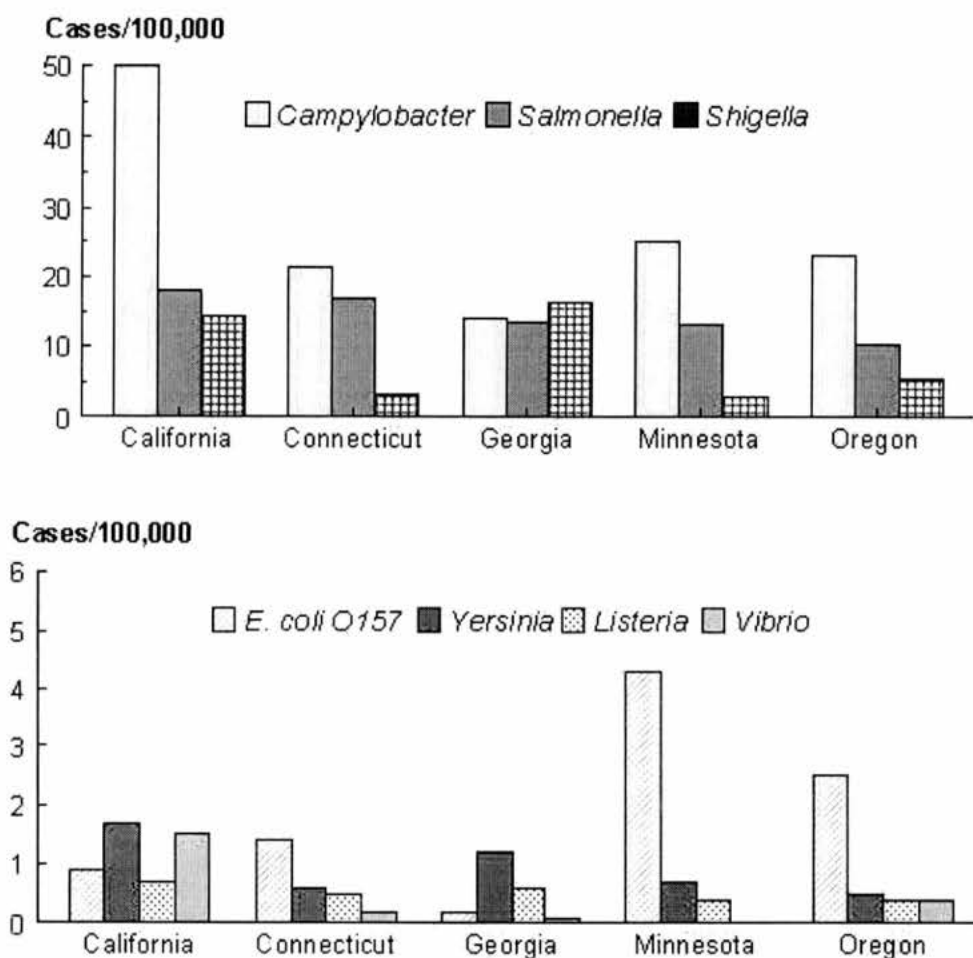
Incidence rates in 1996, calculated using the 1996 postcensus population, were similar to those in 1997. Overall incidence rates in 1996 were higher for infections with, *Salmonella* (14.5/100,000), *E. coli* O157 (2.7/100,000) and *Shigella* (8.9/100,000), and lower for infections with *Campylobacter* (23.5/100,000 population), *Yersinia* (1.0/100,000), *Listeria* (0.5/100,000), and *Vibrio* (0.1/100,000). It is too soon to determine whether differences between 1996 and 1997 rates reflect year-to-year variation or longer-term trends. The increase in *Vibrio* infections in 1997 was a result of an outbreak of *V. parahaemolyticus* infections associated with oysters from the Northwest

coast.

Rates by site

Incidence rates for many of these pathogens varied substantially among the sites (Figure 2). The incidence rates for *Campylobacter* infection varied from 14/100,000 in Georgia to 49/100,000 in California, and for *Shigella* varied from 3/100,000 in Minnesota to 16/100,000 in Georgia. Although incidence rates for *Salmonella* infection were similar among the sites, the rates for *Salmonella* serotype Enteritidis infection varied dramatically, from 0.6/100,000 in Georgia to 5.8/100,000 in Connecticut. Incidence rates for *E. coli* O157 infection varied from 0.2/100,000 in Georgia to 4/100,000 in Minnesota, and for *Yersinia* infection varied from 0.5/100,000 in Oregon to 1.7/100,000 in California. Reasons for these regional differences in incidence rates are being investigated; for example, some laboratories do not test specimens routinely for all pathogens.

Figure 2. Cases of foodborne disease caused by specific pathogens per 100,000 population, FoodNet sites, 1997

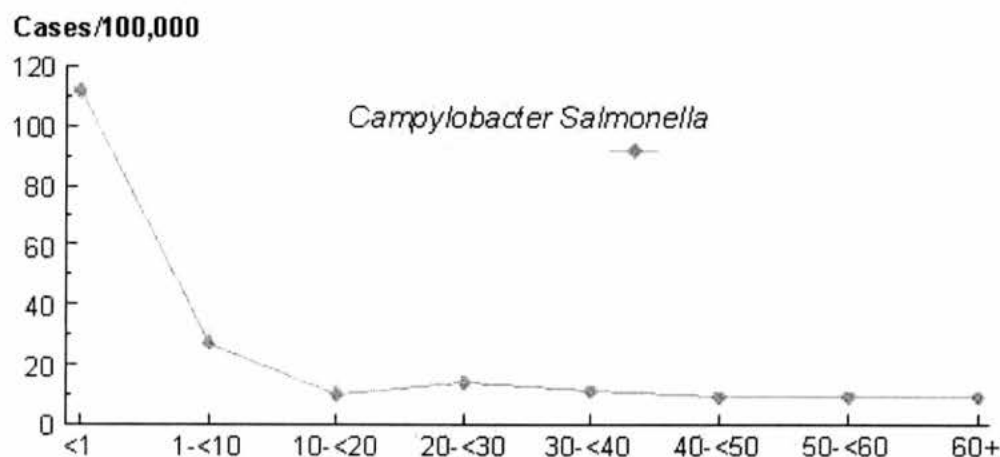


Rates by age

Annual incidence rates of foodborne illness varied by age, especially for *Campylobacter* and *Salmonella* infections (Figure 3). For children <1 year of age, the rate of *Salmonella*

infection was 111/100,000, and the rate of *Campylobacter* infection was 56/100,000, rates substantially higher than for other age groups.

Figure 3. Incidence of *Campylobacter* and *Salmonella* infections by age group, FoodNet Sites, 1997



Rates by sex

There were significant differences in sex-specific incidence rates (Table 2). Overall, males were more likely than females to be infected with one of these pathogens. In particular, rates of *Vibrio* infection were 100% higher among males than females, and rates of *Campylobacter* infection were 27% higher among males than females.

Table 2. Sex-specific incidence rates per 100,000 population, by pathogen, FoodNet Sites, 1997

Isolate	Male	Female	Overall
<i>Campylobacter</i>	27.6	21.7	24.7
<i>E. coli</i> O157	2.0	2.2	2.1
<i>Listeria</i>	0.5	0.4	0.5
<i>Salmonella</i>	14.0	13.3	13.7
<i>Shigella</i>	8.3	7.5	7.9
<i>Vibrio</i>	0.4	0.2	0.3
<i>Yersinia</i>	0.8	0.9	0.9
Total	53.6	46.2	50.1

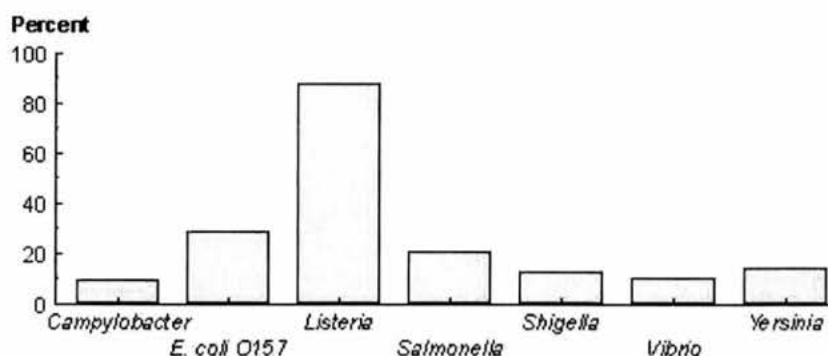
Rates by age and sex

Compared with females, the incidence rate of *Campylobacter* infection was higher for males in all age groups except infants (<1 year of age); rates for infants were similar for males and females. In contrast, rates of *Salmonella* infection were higher for male infants and children aged 1-10 years compared with females.

Hospitalizations

Overall, 15% of infected persons were hospitalized; there were significant differences in hospitalization rates by pathogen (Figure 4). The rate of hospitalization was highest for persons infected with *Listeria* (88%) followed by those infected with *E. coli* O157 (29%), *Salmonella* (21%), *Yersinia* (15%), *Shigella* (13%), *Campylobacter* (10%), and *Vibrio* (10%).

Figure 4. Percentage of persons hospitalized with infections caused by specific pathogens, FoodNet Sites, 1997



Deaths

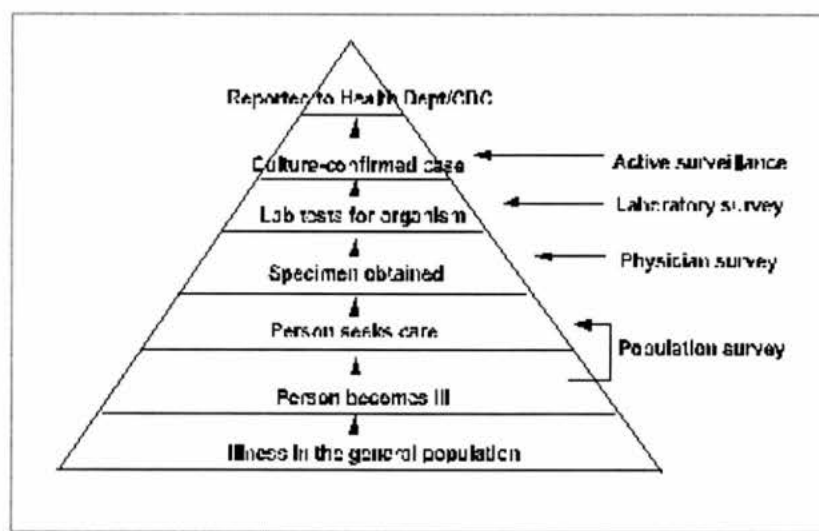
Thirty-three persons died; of those, 15 were infected with *Listeria*, 12 with *Salmonella*, four with *E. coli* O157, one with *Shigella*, and one with *Campylobacter*. The pathogen with the highest case-fatality rate was *Listeria*; 20% of persons infected with *Listeria* died.

Additional Studies

Burden of illness

Cases reported through active surveillance represent a fraction of the number of cases in the community. To better estimate the number of cases of foodborne disease in the community, we conducted surveys of laboratories, physicians, and the general population in the FoodNet sites (Figure 5).

Figure 5. Burden of illness pyramid



Laboratory survey

All microbiology laboratories in the FoodNet sites routinely test all stools submitted for culture for *Campylobacter*, *Salmonella*, and *Shigella*; however, only 50% routinely test for *E. coli* O157, 30% for *Yersinia*, and 19% for *Vibrio*.

Physician survey

Physicians who practice in the FoodNet sites reported that they were more likely to request stool specimens for culture from patients with any of the following features: bloody diarrhea, AIDS, duration of illness greater than 3 days, history of travel to a developing country, and fever.

Population Survey

Of the 10,000 residents of the FoodNet sites we surveyed, 11% reported a diarrheal illness during the previous month or 1.4 episodes of diarrhea per person per year. Of those who were ill, only 8% sought medical care. Of those seeking medical care, 20% reported submitting a stool specimen for culture.

Causes of foodborne disease

As a part of FoodNet, case-control studies are conducted to determine the proportion of foodborne diseases that are caused by specific foods or food preparation practices. By determining this proportion, specific prevention efforts can be developed and their effectiveness documented.

E. coli O157:H7 case-control study

A case-control study of *E. coli* O157:H7 infections conducted at FoodNet sites included interviews with 200 patients or their parents and 380 healthy controls. Undercooked ground beef was determined to be the principal food source of these infections. Based on these findings, efforts to reduce contamination of ground beef and to promote thorough cooking could reduce the incidence of this infection. A follow-up case-control study will further define other potential control measures for the prevention of *E. coli* O157:H7 infections.

Salmonella case-control study

Salmonella of many different serotypes are the second most commonly diagnosed

bacterial cause of diarrheal illness. Two serotypes, Enteritidis and Typhimurium, account for half of all cases of salmonellosis. FoodNet case-control studies of these two types are nearing completion and will help define the sources and points of control for these infections.

***Campylobacter* case-control study**

Campylobacter is the most commonly diagnosed bacterial cause of diarrheal illness. FoodNet case-control studies to determine the sources and risk factors for this infection began in 1998.

Conclusion

Through active surveillance and additional studies, FoodNet is providing better estimates of the burden of foodborne illness and is tracking trends in these diseases over time. In 1997, surveillance of the seven pathogens studied showed that 50 cases of these infections were diagnosed per 100,000 population, representing a total of 130,000 culture-confirmed cases in the entire U.S. population. Additional FoodNet surveys showed that these cases represent a fraction of the burden of foodborne illness. Based on these surveys, at least 60 more of these infections may have occurred for each one that was diagnosed, suggesting that approximately 8 million cases of these bacterial infections occurred in 1997 in the United States.

In addition, FoodNet is a sentinel network that can rapidly respond to new and emerging bacterial, parasitic, and viral foodborne pathogens. Many diarrheal illnesses are not diagnosed because their causative organisms are not detected by routine laboratory tests. Determining the infectious causes and the food source or other sources of these infections is critical to developing methods to prevent them in the future. Beginning in 1998, studies of mild and severe diarrheal illnesses will help define the full spectrum of microbes that cause diarrheal illness in the United States.

Future activities

Continue active laboratory-based surveillance for *Campylobacter*, *Salmonella*, *Shigella*, *Escherichia coli* O157:H7, *Listeria*, *Yersinia*, and *Vibrio* infections and active surveillance for hemolytic uremic syndrome (HUS).

Expand the population under active surveillance with the inclusion of additional counties in Connecticut, Georgia, New York, and Maryland. In 1998, the population within the catchment areas will include 20.3 million persons or 7.5% of the U.S. population. An eighth site will be identified in 1998 for further expansion of FoodNet in 1999.

Conduct a prospective case-control study of sporadic *Campylobacter* infections in the seven EIP sites.

Conduct a prospective case-control study of sporadic *Shigella* infections in the California site.

Begin prospective case-control studies of *Cryptosporidium* and *Listeria* infections.

Conduct a follow-up prospective case-control study of *E. coli* O157:H7 infections, which will include pulsed-field gel electrophoresis subtyping of isolates.

Begin rapid reporting of foodborne outbreaks in FoodNet sites.

Conduct a study of patients hospitalized with acute severe gastroenteritis of unknown

etiology in New York, Oregon, and Connecticut.

Publications

Angulo FJ, Voetsch AC, Vugia D, et al. Determining the burden of human illness from foodborne diseases: CDC's Emerging Infectious Disease Program Foodborne Diseases Active Surveillance Network (FoodNet). *Microbial Foodborne Pathogens, Vet Clin North Am.* 1998; 14:165-72.

Angulo FJ, Voetsch AC, Swerdlow DL, et al. Determining the burden of foodborne illness: FoodNet 1996-97 [Abstract]. In: Program and abstracts of the International Conference on Emerging Infectious Diseases, Atlanta, March 8-11, 1998. Washington, D.C: American Society for Microbiology, 1998: p 84.

CDC. The Foodborne Diseases Active Surveillance Network, 1996. *MMWR.* 1997; 46: 258-61.

Bender J, Mead P, Voetsch D, et al. Hemolytic uremic syndrome (HUS) cases identified in the 1996 FoodNet *Escherichia coli* O157:H7 surveillance. [Abstract] In: Program and abstracts of the International Conference on Emerging Infectious Diseases, Atlanta, March 8-11, 1998. Washington, D.C: American Society for Microbiology, 1998: p 116.

Deneen V, Wicklund JH, Marcus R, et al. The impact of physician knowledge of laboratory practices on surveillance for *E. coli* O157:H7. [Abstract] In: Program and abstracts of the International Conference on Emerging Infectious Diseases, Atlanta, March 8-11, 1998. Washington, D.C: American Society for Microbiology, 1998: p 117.

FoodNet Working Group. Foodborne Diseases Active Surveillance Network (FoodNet). *Emerging Infectious Diseases* 1997; 3: 581-3.

Hennessy T, Deneen V, Marcus R, et al. The FoodNet Physician Survey: implications for foodborne disease surveillance. [Abstract] In: Program and abstracts of the International Conference on Emerging Infectious Diseases, Atlanta, March 8-11, 1998. Washington, D.C: American Society for Microbiology, 1998: p 49.

Herikstad H, Vugia D, Hadler J, et al. Population-based estimates of the burden of diarrheal illness: FoodNet 1996-97. [Abstract] In: Program and abstracts of the International Conference on Emerging Infectious Diseases, Atlanta, March 8-11, 1998. Washington, D.C: American Society for Microbiology, 1998: p 49.

Kassenborg H, Hedberg C, Evans M, et al. Case-control study of sporadic *Escherichia coli* O157:H7 infections in 5 FoodNet sites (CA, CT, GA, MN, OR). [Abstract] In: Program and abstracts of the International Conference on Emerging Infectious Diseases, Atlanta, March 8-11, 1998. Washington, D.C: American Society for Microbiology, 1998: p 50.

Ladd-Wilson S, Yang S, Deneen V, et al. High risk food consumption, handling and preparation practices in the FoodNet Sites: 1996-97. In: Program and abstracts of the International Conference on Emerging Infectious Diseases, Atlanta, March 8-11, 1998. Washington, D.C: American Society for Microbiology, 1998: p 83.

Marcus R, Fiorentino T, Evans M, et al. FoodNet active surveillance for *Salmonella* Enteritidis 1996. [Abstract] In: Program and abstracts of the International Conference on

Emerging Infectious Diseases, Atlanta, March 8-11, 1998. Washington, D.C: American Society for Microbiology, 1998: p 117.

Ray S, Voetsch D, Segler S, et al. FoodNet active surveillance for *Yersinia Enterocolitica* infection, 1996. [Abstract] In: Program and abstracts of the International Conference on Emerging Infectious Diseases, Atlanta, March 8-11, 1998. Washington, D.C: American Society for Microbiology, 1998: p 82.

Reilly K, Shallow S, Angulo FJ, et al. Laboratory-based active surveillance for *Campylobacter* infections: CDC's Emerging Infections Program sites, 1996. [Abstract] In: Program and abstracts of the International Conference on Emerging Infectious Diseases, Atlanta, March 8-11, 1998. Washington, D.C: American Society for Microbiology, 1998: p 83.

Villar R, Bardsley M, Reddy S, et al. Chart review of deaths with enteric pathogens occurring in the FoodNet sites, 1996. [Abstract] In: Program and abstracts of the International Conference on Emerging Infectious Diseases, Atlanta, March 8-11, 1998. Washington, D.C: American Society for Microbiology, 1998: p 84.

Vugia DJ, Shallow S, Farley M, et al. *Salmonella* bacteremia incidence and characteristics, FoodNet 96. [Abstract] In: Program and abstracts of the International Conference on Emerging Infectious Diseases, Atlanta, March 8-11, 1998. Washington, D.C: American Society for Microbiology, 1998: p 83.

FoodNet Working Group

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Mary Ann Davis	Bernadette Albanese	
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Michael Samuel	Jackie Hunter	
	Amy Carnahan	
	Melissa Kent	

Summary Tables and Graphs

Tables (linked tables will open in new window)

[Percent site by pathogen](#)
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[Cases per 100,000 by pathogen for all sites](#)
[Cases per 100,000 by month by pathogen for all sites](#)
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[Salmonella serotypes by site](#)
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[Age distribution for invasive specimens for all sites](#)
[Sex distribution for invasive specimens for all sites](#)

Graphs

Campylobacter
Cryptosporidium
Cyclospora
Escherichia coli O157
Listeria
Salmonella
Salmonella Enteritidis
Salmonella Typhimurium
Salmonella Heidelberg
Salmonella Newport
Salmonella Montevideo
Salmonella Agona
Shigella

<i>Shigella sonnei</i>
<i>Shigella flexneri</i>
<i>Shigella dysenteriae</i>
<i>Vibrio</i>
<i>Yersinia</i>

Age-specific rates per 100,000 distribution by pathogen

Campylobacter

[All sites](#) | [By site](#)

Cryptosporidium

[All sites](#) | [By site](#)

Cyclospora

[All sites](#) | [By site](#)

Escherichia coli O157:H7

[All sites](#) | [By site](#)

Listeria

[All sites](#) | [By site](#)

Salmonella

[All sites](#) | [By site](#)

Shigella

[All sites](#) | [By site](#)

Vibrio

[All sites](#) | [By site](#)

Yersinia

[All sites](#) | [By site](#)

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the Catchment

Volume 1, Fall 1998

A First Catch

Since its inception in December 1995, FoodNet, the Foodborne Diseases Active Surveillance Network, has made large strides in investigating and describing the burden of foodborne disease in the United States. Requests from persons in state health departments, regulatory agencies, and other locations have led us to start up an informal reporting outlet. Thus, *The Catchment* — a means to update you on FoodNet activities, accomplishments, and plans for future directions.

Pardon us if we take the "catchy" theme too far, but we'd like to fish for future catches together with you. While the staff at FDDB will coordinate newsletter production, your input on content will help determine the newsletter's direction. How about a per-issue focus on projects under way at individual FoodNet sites? Or do you have a question about a particular program component which we could highlight here?

Not to mention format; do you like the rustle of news on paper, or maybe you prefer to catch up on the web? Just let us know. You can drop a note to Sam Yang at say9@cdc.gov.

FoodNet: What We Are, Where We Are, and What We're Doing In 1998

What we are

FoodNet is the foodborne diseases component of the CDC Emerging Infections Program (EIP), a world-spanning effort to combat the ongoing threat of emerging infectious diseases. FoodNet is a collaborative project among CDC, participating EIP sites, the U.S. Department of Agriculture (USDA), and the U.S. Food and Drug Administration (FDA). The objectives of FoodNet are to 1) describe the epidemiology of infectious foodborne diseases of national importance, 2) determine more precisely the frequency and severity of foodborne diseases in the United States, and 3) determine the proportion of some infections caused by eating specific foods. Data on a variety of bacterial and parasitic pathogens are currently being collected and analyzed. These pathogens include *Campylobacter*, *Cryptosporidium*, *Cyclospora*, *Escherichia coli* O157, *Listeria*, *Salmonella*, *Shigella*, *Yersinia*, and *Vibrio*. Program results are being used to help develop and refine foodborne disease prevention and control strategies.

Where we are

The project began with five active surveillance sites: the entire states of Minnesota and Oregon, and selected counties in California, Georgia, and Connecticut. The total population of these catchment areas in 1996 was 14.3 million people, or 5% of the American population. In 1997, an additional county was added in Connecticut (Fairfield), and selected counties were introduced in two more states: Maryland (around Baltimore) and New York (around Rochester). This year, Connecticut will conduct surveillance statewide. Currently, 20.3 million persons are covered, which is nearly 8% of the American population, and there are plans to grow again; Georgia plans to go statewide this year.

Why emphasize statewide surveillance? This method allows us to improve estimates of the national burden of foodborne disease. Statewide surveillance also enhances our ability to detect outbreaks of foodborne illness.

What we're doing

Active surveillance of laboratory-confirmed cases of foodborne illness is FoodNet's core activity. However, FoodNet is designed to monitor foodborne illness at all levels, from the general population through health care providers and laboratories. FoodNet also conducts investigations that target specific infections to learn more about the sources of those infections through detailed epidemiologic studies. In 1998, these additional activities include:

- A *Campylobacter* case-control study: Currently ongoing in all seven sites, this study will help to identify risk factors for *Campylobacter* infection.
- A second population survey: Because the majority of persons with a foodborne illness never see a doctor, little is known about the true extent of foodborne disease. To help give an estimate, during 1996-1997, a population survey was conducted in five FoodNet sites (Minnesota, Oregon, and selected counties in California, Connecticut, and Georgia). About 9,000 persons were surveyed randomly via telephone. Information was gathered on the extent of diarrheal illness in the community and the extent of exposure to specific foods. A similar survey is being readministered this year in all seven sites, including Maryland and New York.

Foodborne Diseases Active Surveillance Network (FoodNet) Population 20.3 million



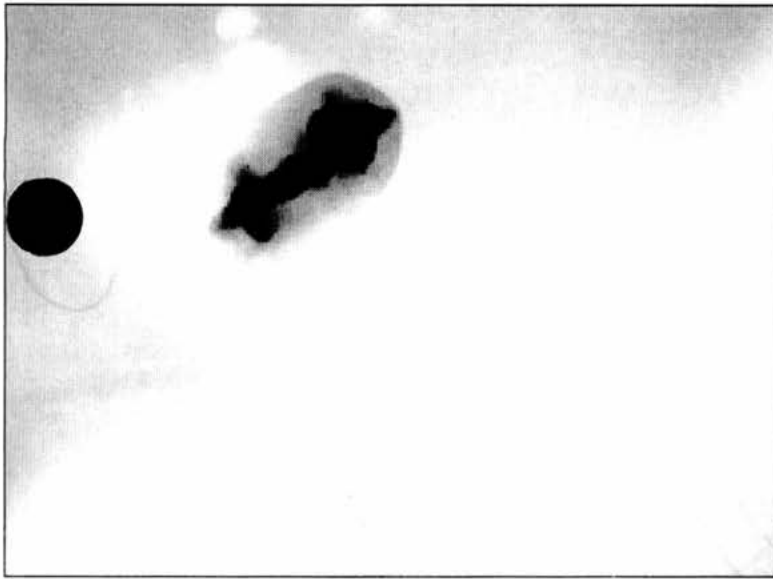
Seven Emerging Infections Program (EIP) Sites



A Glimpse of What We Did In 1996 and 1997

To give you an idea of what we did in 1996 and 1997, we've put together an overview of FoodNet abstracts presented at the International Conference on Emerging Infectious Diseases, held in Atlanta, Georgia, March 8-11, 1998. This overview provides abstract titles, authors, and some interesting findings.

Title	Authors	Some Findings
Active surveillance for hemolytic uremic syndrome at selected sites, United States, 1997	Mead P, Bender J, Dembek Z, Gilbert L, Shallow S, Shiferaw B, Griffin P	Preliminary results suggest that most U.S. cases of diarrhea-associated hemolytic uremic syndrome are caused by infection with <i>E. coli</i> O157:H7. Active surveillance networks based on data from specialty health care providers can provide timely and detailed surveillance data and may be valuable in monitoring other serious sequelae of foodborne disease.
Case-control study of sporadic <i>Escherichia coli</i> O157:H7 infections in 5 FoodNet sites (CA, CT, GA, MN, OR)	Kassenborg H, Hedberg C, Evans M, Chin G, Fiorentino T, Vugia D, Bardsley M, Slutsker L, Griffin P	Consumption of pink hamburgers is a risk factor for infection. Differences in exposure to <i>E. coli</i> O157:H7 on farms and through locally processed ground beef may contribute to the regional variability in the annual incidence of <i>E. coli</i> O157:H7.
Deaths from enteric bacterial pathogens: a chart review of deaths occurring in the active surveillance network population (FoodNet) during 1996	Villar R, Bardsley M, Reddy S, Fiorentino T, Wicklund J, McGivern T, Vugia D, Swerdlow D, and FoodNet	Deaths from foodborne bacterial pathogens occurred primarily among adults with serious underlying disease. Focusing food safety programs on high-risk groups may prevent fatal infections from foodborne pathogens.
Determining the burden and causes of foodborne illness: Foodborne Diseases Active Surveillance Network (FoodNet), 1996-1997	Angulo F, Voetsch D, Swerdlow D, Griffin P, Vugia D, Marcus R, Farley M, Blake P, Hedberg C, Cieslak P, Dietz V, Pinner R, Tauxe R, and FoodNet	Using data collected from active surveillance for culture-confirmed cases of foodborne disease; surveys of the population, physicians, and laboratories; and case-control studies, FoodNet provides a network for monitoring the burden of foodborne diseases, identifying the source of specific foodborne disease, and responding to new and emerging foodborne diseases of national importance.
FoodNet active surveillance for <i>Salmonella</i> Enteritidis (SE): 1996	Marcus R, Fiorentino T, Evans M, Swerdlow D, Werner B, Shiferaw B, Hadler J, and FoodNet	More than 15 years after SE began to increase in the northeastern U.S., rates continue to vary markedly by region.
FoodNet active surveillance for <i>Yersinia enterocolitica</i> (YE) infection: 1996	Ray S, Voetsch D, Segler S, Koehler J, Vugia D, Fiorentino T, Townes J, Farley M, and FoodNet	YE infection shows considerable geographic and racial variation. In FoodNet sites, it is most common among black, Hispanic, and Asian children less than 1 year old.
The FoodNet physician survey: implications for foodborne disease surveillance	Hennessy T, Deneen V, Marcus R, Reddy S, Vugia D, Townes J, Bardsley M, Swerdlow D, and FoodNet	This study marked the first U.S. population-based study of physician diagnostic practices for diarrhea. Physicians ordered no stool culture for over half of patients seeking care for diarrhea. Variability in culture ordering practices suggests a need for clinical diagnostic guidelines.
Hemolytic uremic syndrome (HUS) cases identified in the 1996 FoodNet <i>Escherichia coli</i> O157:H7 surveillance	Bender J, Mead P, Voetsch D, Vugia D, Fiorentino T, Koehler J, Shiferaw B, Griffin P, and FoodNet	There are regional differences in both the <i>E. coli</i> O157:H7 and HUS incidence among the FoodNet sites. Differences may be explained by regional variability of <i>E. coli</i> O157:H7 and completeness of reporting.
High-risk food consumption, handling, and preparation practices of adults in the FoodNet sites, 1996-1997	Ladd-Wilson S, Yang S, Deneen V, Koehler J, Marcus R, Vugia D, Voetsch D, Angulo F, and FoodNet	Although risky food handling and consumption practices were apparent in all groups studied, health officials should consider focusing food safety educational campaigns on 18-25-year-olds, men, Hispanics, and higher socioeconomic groups. State-specific food preferences warrant home-grown messages.
The impact of physician knowledge of laboratory practices on detection of <i>Escherichia coli</i> O157:H7	Deneen J, Wicklund J, Marcus R, Shallow S, Segler S, Townes J, Reddy S, Hennessy T, and FoodNet	Physicians often assume incorrectly that their laboratories culture all stool specimens for <i>E. coli</i> O157:H7, and so do not order this test for persons with bloody diarrhea. To increase awareness and improve detection of <i>E. coli</i> O157:H7, laboratories should identify which organisms were tested when reporting negative stool culture results.
Laboratory-based active surveillance for <i>Campylobacter</i> infections, FoodNet, 1996	Reilly, K, Shallow S, Angulo F, Cassidy M, Wicklund J, Fiorentino T, Bardsley M, Vugia D, and FoodNet	<i>Campylobacter</i> is the most frequently diagnosed foodborne pathogen nationwide. <i>Campylobacter</i> infection results in substantial health care costs and lost productivity.
Population-based estimate of burden of diarrheal illness: FoodNet 1996-1997	Herikstad H, Vugia D, Hadler J, Blake P, Deneen V, Townes J, Yang S, Angulo F, and FoodNet	An estimated 340,000,000 episodes of acute diarrheal illness occur in the United States annually, and 1 in 12 persons with this illness seek medical care. Diarrheal illness is a major burden for the population and health care system.
<i>Salmonella</i> bacteremia incidences and characteristics, FoodNet 1996	Vugia D, Shallow S, Farley M, Marcus R, Shiferaw B, Angulo F, and FoodNet	<i>Salmonella</i> bacteremia is a notable cause of morbidity and mortality in the general population. Rates of hospitalization and death are higher in bacteremic cases, but possible contributors are yet to be identified.



Focus: *Escherichia coli* O157:H7 and Diarrhea-Associated Hemolytic Uremic Syndrome (D+HUS) In FoodNet Sites

The Catchment asked **Dr. Paul Mead**, a medical epidemiologist from the Foodborne and Diarrheal Diseases Branch, a few questions about the ongoing diarrhea-associated (D+) HUS surveillance project.

Catchment: *Just what is HUS?*

Dr. Mead: Hemolytic uremic syndrome, or HUS, is a life-threatening illness characterized by hemolytic anemia, thrombocytopenia, and acute renal failure. In the United States, about 90% of HUS cases are associated with diarrhea (D+HUS) and are caused by infection with Shiga toxin-producing *Escherichia coli*. *E. coli* O157:H7 has been isolated most frequently, but we know that other strains can cause HUS.

D+HUS develops most commonly in children, specifically in about 10% of children infected with *E. coli* O157:H7. Overall, 3%-5% of patients with D+HUS die in the acute phase of illness, and 10% - 30% experience long-term complications.

Catchment: *When and why did FoodNet establish surveillance for D+HUS?*

Dr. Mead: We began active surveillance for HUS in 1997 in five locations with a total population of 14.3 million people: Minnesota, Oregon, and selected counties in California, Connecticut, and Georgia. The system is based on a network of pediatric nephrologists, so much of the data gathered focus on HUS in children. To be reported, a patient should have hemolytic anemia, thrombocytopenia and acute renal injury, but no specific lab criteria must be met.

We began surveillance for several reasons. First, to determine the incidence and better define the clinical features of D+HUS. Second, by examining stools from patients with HUS, we hope to get a sense of what proportion of HUS cases are caused by *E. coli* O157, and what proportion are caused by serotypes other than O157. Finally, we hope the system will create a springboard from which to launch future studies of the pathogenesis and treatment of D+HUS.

Catchment: *So how is surveillance going?*

Dr. Mead: During the first 12 months of surveillance, 32 cases of D+HUS were reported, and 25 of these were in persons living within the catchment area. Patients were very young—median age 3 years—and most cases occurred in the summertime. Seven (23%) of 30 patients reported having diarrhea without blood. The median interval between diarrhea onset and HUS diagnosis was 5 days. At the time of HUS diagnosis, patients had a median serum creatinine level of 3.1 mg/dl (range 0.5-14.1 mg/dl), a median hemoglobin of 18%, and a median platelet count of 38 k/ml. Patients were hospitalized for a median of 12 days, 87% received transfusions, and 44% underwent dialysis. Complications included seizures (9%), bacteremia (6%), and death (3%). *E. coli* O157:H7 was isolated from 69% of stool specimens obtained within 14 days of diarrhea onset from patients who had not received antibiotics. At this time, due to lack of testing, no other serotypes have been identified.

Catchment: *Among the data collected, what stands out most?*

Dr. Mead: Several things stand out. First, nearly 25% of patients reported having diarrhea without blood. Second, over 50% of patients with D+HUS had not been treated with antimicrobial agents. Finally, *E. coli* O157:H7 accounted for at least 69% of D+HUS cases among children in the FoodNet catchment area. We'll be very interested to see what our continuing data collection adds to this picture.

Catchment: *Are there any changes planned for the near future?*

Dr. Mead: One of our goals from the start has been to determine which non-O157 strains are causing HUS. With recently received funding, we are working with participating reference laboratories to improve their ability to isolate non-O157 Shiga toxin-producing *E. coli* from stool specimens. In addition, we have transferred to each site the technology for detecting antibodies to *E. coli* O157 in patients' serum. Together, these tools should greatly improve our ability to define the role of non-O157 strains as a cause of HUS. A second major, long-term goal has been to determine the incidence of HUS among adults. Sites are now searching 1997 hospital discharge databases using ICD-9 codes to determine the completeness of reporting for pediatric cases. From this we should also be able to identify which providers or types of providers are diagnosing cases in adults. These providers could then be added to the network.

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Many Thanks To Drew Voetsch

On behalf of the entire FoodNet Team, *The Catchment* would like to thank Drew Voetsch for his dedicated work as FoodNet's coordinator and to wish him luck as he takes a new job position in Australia. After graduating in the fall of 1995 with an MPH from Emory University's Rollins School of Public Health in Atlanta, Drew was hired by CDC to help design, initiate, and maintain FoodNet. Drew held a tremendous load of responsibilities as FoodNet's coordinator, some of which included organizing FoodNet's budget, initiating electronic surveillance, managing and analyzing surveillance data, and coordinating other FoodNet surveys. Starting this fall, Drew will be launching an active surveillance program for foodborne diseases similar to FoodNet in Australia. Drew, best of luck in your new endeavor!

The Catchment also welcomes Dr. Tom Van Gilder to the FoodNet Team. Before joining FoodNet, Tom worked at CDC in the Epidemiology Program Office in the State Branch, where he supervised Epidemic Intelligence Service Officers and Preventive Medicine Residents stationed in various state health departments.

Tom is now the Director of Science for FoodNet projects. Welcome, Tom!



Note to readers:

We'd like to spotlight other studies in future "**Catchment**" issues. Have a study you'd like to know more about? *Please contact us!*

Resources

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The Catchment

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REPORT TO THE POTUS JOINT
INSTITUTE PHOTOGRAPHY RESEARCH

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Department of Health and Human Services
U. S. Department of Agriculture
October 1, 1998

Joint Institute for Food Safety Research Report to the President

Executive Summary

I. Introduction

II. Background

III. Structure of the Institute

IV. Organizing Principles

V. Goals/Outcomes of the Institute

VI. Implementation Schedule

Appendices

A. President Clinton's Memorandum for the Secretary of Health and Human Services and the Secretary of Agriculture, July 3, 1998

B. Executive Summary, President Clinton's National Food Safety Initiative, May 1997

C. Executive Order: President's Council on Food Safety, August 25, 1998

D. Federal Agencies with Research and Risk Assessment Responsibilities

E. Glossary of Acronyms

EXECUTIVE SUMMARY

On July 3, 1998, President Clinton directed the Department of Health and Human Services (DHHS) and the Department of Agriculture (USDA) to report back within 90 days with a plan to create a Joint Institute for Food Safety Research ("the Institute"). The Institute is to (1) coordinate planning and priority setting for food safety research among the two Departments, other government agencies, and the private sector and (2) foster effective translation of research results into practice along the farm-to-table continuum. Enhanced and more efficient national investment in food safety research will do much to

lower incidence of foodborne illness in the United States.

DHHS and USDA will have joint leadership of the Institute and will use existing resources to support it. This acknowledgment of the critical need to expand and coordinate food safety research also emphasizes the companion needs to expand and strengthen public-private partnerships and to augment collaboration among state, local, and other Federal agencies, thereby providing effectively the scientific information required to help achieve public health goals.

This document articulates the concept of the Institute, describes goals and the administrative principles underlying its organization, presents a proposed structure for the Institute, and a draft time line for its implementation. Appendices A through E provide, respectively, the Presidential Directive for the Institute, the Executive Summary from the May 1997 Food Safety Initiative Report to the President, the Executive Order creating the President's Council on Food Safety, a listing of the 12 Federal Agencies involved in food safety, and a glossary of acronyms. These materials will help define the history of Executive Branch Directives on food safety and the interagency consultative efforts that have contributed to the establishment of the Institute. Enhanced and more efficient food safety research will do much to meet the needs of Federal food safety regulatory agencies.

The ultimate goal of the Institute is to coordinate food safety research, such that the incidence of foodborne illness is reduced to the greatest extent feasible.

I. INTRODUCTION

On July 3, 1998, President Clinton directed the Secretary of Health and Human Services and the Secretary of Agriculture to report back to him within 90 days on the creation of a Joint Institute for Food Safety Research ("Institute"). The Institute will:

"(1) develop a strategic plan for conducting food safety research activities consistent with [the President's National] Food Safety Initiative; and

(2) efficiently coordinate all Federal food safety research, including with the private sector and academia."

As the President's memorandum directed, the Secretary of Health and Human Services and the Secretary of Agriculture will jointly lead the Institute, which will cooperate and consult with all interested parties, including other Federal agencies and offices -- such as the Environmental Protection Agency, the National Partnership for Reinventing Government, and the Office of Science and Technology Policy -- as well as State and local agencies focusing on research and public health, and consumers, producers, industry, and academia. The Institute will make efforts to build on ongoing private sector research, through the use of public-private partnerships and other appropriate mechanisms.

This document articulates the concept of the Institute and provides a proposed structure, operating principles, goals and outcomes, and an implementation schedule for the Institute.

The ultimate goal of the Institute's research agenda is to reduce the incidence of adverse human health effects associated with the consumption of food. The objective of creating the Institute -- and all other Administration food safety activities -- is to reduce the incidence of foodborne illness to the greatest extent feasible. Scientific information about

prevention of foodborne illness and detection of organisms that may cause it is critical to further reduce the incidence of foodborne illness.

This report will serve as a starting point for development of the Institute. The report will be published in the Federal Register for comment during October/November of 1998 with a public meeting in November/December of 1998. A detailed draft proposal, based on the public comments received, will be developed by January of 1999. The final proposal will be submitted to the National Science and Technology Council of the Office of Science and Technology Policy (NSTC/OSTP) in March 1999 for final review. A final report, which will serve as the detailed blueprint for the Institute, will be announced in the Federal Register in April of 1999.

II. BACKGROUND

The National Food Safety Initiative

In his January 25, 1997, radio address, President Clinton announced he would request \$43.2 million in his 1998 budget to fund a nationwide early-warning system for foodborne illness, increase seafood safety inspections, and expand food safety research, training, and education. The President directed three Cabinet members -- the Secretary of Health and Human Services, the Secretary of Agriculture, and the Administrator of the Environmental Protection Agency (EPA) -- to identify specific actions to improve the safety of the food supply. He further directed them to consult with stakeholders (consumers, producers, industry, States, universities, and the public) and to report back to him in 90 days. The President emphasized the need to explore opportunities for public-private partnerships to improve food safety, particularly in the areas of surveillance, inspections, research, risk assessment, education, and coordination among local, State, and Federal health authorities. Through a series of interagency and stakeholder meetings and consultations, the May 1997 Report to the President entitled "Food Safety from Farm to Table: A National Food Safety Initiative" was developed and issued. (See Appendix B.)

Although the American food supply is among the safest in the world, the Administration called for the National Food Safety Initiative (FSI) because every year millions of Americans continue to experience illness caused by the food they eat. The FSI recognized that research provides new information and technologies essential to successful implementation of five key activities: standard setting and rulemaking, inspection and compliance, education, surveillance, and risk assessment. For his Fiscal Year 1999 budget, President Clinton requested an increase of \$101 million in support of food safety activities. This request is currently under consideration by Congress. To ensure that current research investments are adequately supporting the five key activities identified by the FSI, Federal research agencies are working on a coordinated, interagency research plan. Federal agencies that conduct food safety research have recently completed a major step in the development of this plan by creating a Federal inventory of food safety research projects, active or planned, for Fiscal Year 1998, including the scientific and fiscal resources that support the research. DHHS and USDA, in collaboration with NSTC/OSTP, will use this information to identify additional priority food safety research areas that are not currently addressed in the FSI and will develop future food safety initiatives and their budgetary requirements for consideration by the Office of Management and Budget.

The FSI identified five broad areas in which significant knowledge gaps require a concerted interagency research effort:

- Improving detection methods;

- Understanding microbial resistance to traditional preservation technologies;
- Understanding antibiotic drug resistance;
- Developing prevention techniques for pathogen avoidance, reduction, and elimination; and
- Understanding the contribution of food handling, distribution, and storage to pathogen contamination of food and developing preventions.

The FSI also identified the research goal to develop methods and scientific data that would enhance the ability of Federal agencies to conduct microbial risk assessments. Two additional research areas, critical for addressing this goal, are:

- Developing and validating microbial exposure models, based on probabilistic methodology; and
- Developing and validating dose-response assessment models for use in risk assessment.

When the FSI was developed in 1997, these immediate needs were given priority within the research and risk assessment agenda because microbial contamination of foods by pathogens has increasingly been linked to increasing incidence of foodborne illness and to high rates of morbidity and mortality. As these research and risk assessment activities progress and improvements in preventative measures are developed, the Institute will provide leadership for identification of other research and risk assessment priorities, which will receive increased attention from Federal food safety research agencies in future years.

III. STRUCTURE OF INSTITUTE

The Institute will report to The President's Council on Food Safety (see Appendix C), which is chaired by the Secretaries of Agriculture and Health and Human Services and the Assistant to the President for Science and Technology/Director of the Office of Science and Technology Policy. The Institute will be led by an Executive Director, who will be a highly recognized food safety scientist, jointly recruited, appointed, and supported by the USDA and DHHS. The Executive Director will supervise a small, permanent Institute staff of no more than 10 employees, and existing staff resources of USDA and DHHS will support the Institute and its operations.(1)

The Executive Director will report to an Executive Research Committee, and the Executive Research Committee will report to the President's Council on Food Safety. The Executive Research Committee will comprise three senior research officials appointed by one of the three co- chairs of the President's Council on Food Safety. The Executive Director will facilitate the work of the Federal budget and policy committee, which will be chaired by the Executive Research Committee.

The Federal policy and budget committee will be comprised of Federal food safety policy officials and agency heads, representing both research agencies and regulatory agencies, and its membership will represent agencies of the USDA, DHHS, the Environmental Protection Agency, the National Science Foundation, and other relevant Federal agencies. This Federal policy and budget committee will serve as a mechanism by which the Government's chief scientific and public health experts can interact with the Executive Director and the Executive Research Committee to ensure the goals of the Institute are achieved. This committee also will be the vehicle for consultation and coordination across all Federal food safety agencies, including activities such as budget development for submission to OMB.

The Executive Director will be advised by the Joint Institute for Food Safety Research

Advisory Committee, which will have 16 stakeholder members (6 members appointed by the Secretary of Agriculture, 6 members appointed by the Secretary of Health and Human Services, and 4 members appointed by OSTP/NSTC). Members of this committee may be chosen from existing advisory committees to the USDA, DHHS, and OSTP/NSTC. USDA, DHHS, and OSTP/NSTC will jointly support the Advisory Committee.

The work of the Institute will be accomplished through temporary interagency task forces that form and close as specific issues are resolved and through a small, permanent Institute staff, which will provide technical, administrative, clerical and computer support. The Institute will focus initially on microbial pathogens, in keeping with the President's National Food Safety Initiative. In future years, based on the direction of the President's Food Safety Council, advice of the Joint Institute for Food Safety Research Advisory Committee, and on other public input, the Institute may expand its scope progressively to include other known or potential contributors to foodborne illness and/or food safety, such as chemical contaminants, natural toxins, pesticide residues, animal drug residues, food additives, and nutrition. All of these topics already are foci for important food safety research activities that warrant coordination by the Institute. With this scope, the Institute would develop broad-based strategic planning with input from stakeholders and coordinate the resources administered by the numerous Federal agencies that participate in food safety research. (See Appendix D.)

IV. ORGANIZING PRINCIPLES

The DHHS and USDA have developed the following principles as the foundation for establishing and operating the Institute.

A. Optimize Current Investment and Infrastructure

The Institute's mission includes optimizing the effectiveness of current food safety research investments and infrastructure to maximize funds going to conduct research, rather than for construction or maintenance of additional research facilities. For this reason, the President's directive is not intended to result in construction of new research or administrative facilities. The Institute will focus on coordinated planning for research programs and budgets and on enhanced communications among existing organizational entities working within existing facilities. The Institute will be supported by a small staff and will draw on current resources within the responsible food safety agencies. The Institute will assist in fulfilling the Administration's farm-to-table strategy by relying on access to existing Federal research laboratories throughout the country.

B. Provide Centralized Communication with Stakeholders

Effective communication between the Federal food safety research providers and the users of the knowledge gained is critical to establishing priority-based research programs that are responsive to national needs. More than a dozen Federal agencies actively contribute to food safety research efforts. Food safety researchers have numerous critical constituencies: (1) regulatory agencies that rely on scientific information for the protection of public health; (2) industry and producers, including retailers, who design and implement effective food safety programs; and (3) consumers. While each agency makes a critical contribution, providing their unique expertise, perspective, and infrastructure, this array of activities can be daunting to stakeholders. Effective interchange -- not only among Federal laboratories and the managers of Federally supported extramural research programs, but also their counterparts in industry and academia -- is critical to developing cost-effective programs that maximize the benefits to public health. Therefore, the Institute will serve as a centralized focal point

for communication between stakeholders and the appropriate members of the Federal research community by facilitating public input into priorities through public meetings and advice from the Joint Institute for Food Safety Research Advisory Committee.

C. Use Current Intramural and Extramural Research Programs in Innovative Ways

Leveraging Federal research dollars for maximum public health benefit is critical to effective implementation of the FSI farm-to-table strategy. To better leverage current and future funds, the Institute will foster development of joint program announcements involving multiple Federal research programs and multi-center trials to demonstrate the cost-effectiveness of prevention strategies and technologies. Particular emphasis will be placed on "on-farm" research for the development of new technologies and tools to prevent microbial contamination of raw foods.

D. Mobilize Resources to Minimize the Impact of Current and Emerging Food Safety Problems

Food safety concerns are usually complex, involving the interaction of factors associated with agricultural productivity, public health, food processing and distribution practices, market economies and international trade, and consumer preferences and perceptions. The research needed to solve food safety problems is equally complex, requiring contributions from both basic and applied researchers in physical and biological sciences, equally important advances in economic and behavioral research, and innovations in food technology and engineering. The impact of new food safety problems related to threats to public health and the economic well-being of industry, is often dependent on how rapidly research resources can be mobilized. In the absence of a centralized coordinating mechanism to provide leadership, such as the Institute, the timely mobilization of resources among diverse groups of scientific disciplines has historically been a barrier to effective problem identification and resolution. This barrier is of particular concern to food safety regulatory agencies. The Institute, through advanced communications and coordination systems, will realize increased efficiencies in bringing to bear research resources when they are needed to minimize the impact of current and emerging food safety problems.

E. Increase Accountability for Federal Research Priorities and Implementation of Strategies to the Public

One of the Administration's highest priorities has been to make Federal agencies more responsive to the needs of the nation through transparent decision-making. To effectively encompass the nation's food safety research needs, the Administration to date has focused on joint research planning and prioritization, with the participation of numerous Federal agencies. Establishment of the Institute will build on this planning process, thereby increasing the transparency of Federal food safety research efforts, to better assure the public that Federal investments are strategic and not redundant.

V. GOALS/OUTCOMES OF THE INSTITUTE

A. Coordination in Research Planning, Budget Development, and Prioritization

The ultimate goal of the Institute's research agenda is to reduce the incidence of adverse human health effects associated with the consumption of food. Research planning, budget development, and prioritization will be a consultative process among food safety research and regulatory agencies, with a primary purpose being to fulfill the informational needs of food safety regulatory agencies. As stated above, DHHS and

USDA will cooperate to lead this effort, in consultation with the National Science and Technology Council of the Office of Science and Technology Policy (NSTC/OSTP) and other interested parties, including other Federal agencies and offices. The goals of this effort are: (1) to maximize the public health benefit to the American people for resources devoted to basic and applied research, by assuring that the information acquired is applicable to the development of effective food safety guidance, policy, and regulation; (2) to maximize the return-on-investment to producers, processors, and the public for resources devoted to research by developing cost-effective prevention technologies; (3) to effectively communicate and operate together with Federal, state, and local public health, agriculture and research agencies and Government partners; and (4) to develop partnerships among the Federal, State, and local Governments and industry or academia to identify and solve, scientifically, food safety issues. The Institute will not only develop coordinated budgets for submission to OMB, but also it will coordinate and monitor Agency activities to further these goals and to provide periodic assessments of research accomplishments.

B. Scientific Support of Food Safety Regulation

The Nation's collective food safety research capabilities must be responsive to the risk-based public health priorities of the food safety regulatory agencies. Science and technology are required to develop effective food safety guidance, policy, and regulation. The Institute will identify research needs to: (1) achieve public health goals; (2) support guidance, pathogen reduction regulation, and hazard analysis and critical control points (HACCP) systems approaches to regulation (*e.g.*, meat, poultry, seafood, fresh juice), and compliance strategies; and (3) shift research orientation to a risk-based approach. Through the Federal policy and budget committee, which advises the Institute Director, food safety regulatory agencies will play an integral role in the Institute's operation and its development of research strategies to foster public health goals.

C. Communication/Links with Other Food Safety Agencies

Through participation in the Institute, all Federal food safety research agencies will coordinate, complement, and bolster research efforts on related and multifaceted food safety issues. The Institute will coordinate the use of existing mechanisms, such as interagency agreements, contracts, and the development of scientific conferences, and the development of new mechanisms, such as jointly funded program announcements and other innovative approaches to further the achievement of the Institute's goals.

D. Communication/Links with Industry and Academic Partners

The Institute will encourage the development of public-private partnerships with industry and academia to efficiently develop and transfer new information and technologies. Technology transfer mechanisms for cooperation between Federal agencies and industry exist through the Cooperative Research and Development Agreement (CRADA) process. This mechanism protects the intellectual property rights of the parties involved and is designed to avoid conflicts of interest, which are of particular concern within regulatory agencies. The Institute will foster and build on existing technology transfer mechanisms.

Several food safety research consortia, which include Federal, state, academic, and industry partners, already exist and are supported in part through competitively awarded Federal extramural research grants. These institutes can optimize and combine resources to perform stronger and more cost-effective research programs in food safety than can a single entity. The USDA and DHHS research agencies will continue to use grants, contracts, and cooperative agreements in partnership with academia.

VI. IMPLEMENTATION SCHEDULE

October/November 1998 Announce report in Federal Register for comment and notice of public meeting

November/December 1998 Host public meeting

January 1999 Analyze comments and develop a more detailed proposal for the Institute

March 1999 Submit proposal to National Science and Technology Council for review

April 1999 Announce final report in the Federal Register

May 1999 Recruit Executive Director for the Institute and Joint Institute for Food Safety Research Advisory Committee Members are appointed by Secretary of Health and Human Services and Secretary of Agriculture and Office of Science and Technology Policy

A. PRESIDENT CLINTON'S MEMORANDUM FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES AND THE SECRETARY OF AGRICULTURE, JULY 3, 1998

APPENDIX B - FOOD SAFETY FROM FARM TO TABLE: A NATIONAL FOOD SAFETY INITIATIVE REPORT TO THE PRESIDENT MAY 1997 EXECUTIVE SUMMARY

APPENDIX C - EXECUTIVE ORDER: PRESIDENT'S COUNCIL ON FOOD SAFETY, AUGUST 25, 1998

APPENDIX D

Federal Food Safety Agencies

Twelve Federal agencies have food safety responsibilities:

1. Agricultural Marketing Service, (AMS), U.S. Department of Agriculture (USDA)
2. Animal and Plant Health Inspection Service, (APHIS), USDA
3. Agricultural Research Service (ARS), USDA
4. Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS)
5. Cooperative State Research, Education, and Extension Service (CSREES), USDA
6. Economic Research Service, (ERS), USDA
7. Environmental Protection Agency, (EPA)
8. Food and Drug Administration, (FDA), DHHS
9. Food Safety and Inspection Service, (FSIS), USDA
10. Grain Inspection, Packers and Stockyards Administration, (GIPSA), USDA
11. National Institutes of Health, (NIH), DHHS
12. National Marine Fisheries Service (NMFS), Department of Commerce

APPENDIX E

Glossary of Acronyms

AMS Agricultural Marketing Service
APHIS Animal and Plant Health Inspection Service
ARS Agricultural Research Service
CDC Centers for Disease Control and Prevention
CRADA Cooperative Research and Development Agreement
CSREES Cooperative State Research, Education, and Extension Service
DHHS Department of Health and Human Services
EPA Environmental Protection Agency
ERS Economic Research Service
FDA Food and Drug Administration
FSI National Food Safety Initiative
FSIS Food Safety and Inspection Service
GIPSA Grain Inspection, Packers and Stockyards Administration
HACCP Hazard Analysis Critical Control Points
JIFSR Joint Institute for Food Safety Research
NIH National Institutes of Health
NMFS National Marine Fisheries Service
NPR National Performance Review
NSTC/OSTP National Science and Technology Council/Office of Science and Technology
OMB Office of Management and Budget
USDA U.S. Department of Agriculture

This is a mirror of the Joint Institute for Food Safety Research Report to the President, October 1, 1998 from CSREES.

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FULSNET 1998

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May 22, 1998

VICE PRESIDENT GORE LAUNCHES COMPUTER NETWORK TO FIGHT FOOD-BORNE ILLNESS

Message Creation Date was at 22-MAY-1998 13:26:00

THE WHITE HOUSE

Office of the Vice President

For Immediate Release:

Contact:

Friday, May 22, 1998

(202) 456-7035

VICE PRESIDENT GORE LAUNCHES COMPUTER NETWORK
TO FIGHT FOOD-BORNE ILLNESS

New Food Safety System Five Times Faster At Locating Serious and Wide-Spread Food Contamination Problems

Washington, D.C. -- Addressing a problem that affects 33 million Americans each year, Vice President Gore announced today a new national computer network that will be five times faster at identifying and combating food-borne illness.

PulseNet -- a national computer network that identifies outbreaks of food-borne illness -- will enable public health laboratories across the country to use the Internet to provide alerts when outbreaks of food-borne disease occur.

"President Clinton and I are committed to finding ways to ensure that the food Americans put on their tables is safe," said the Vice President, who was joined at a White House ceremony by Health and Human Services Secretary Donna Shalala and Agriculture Secretary Dan Glickman. "With this efficient new computer network, we can more effectively trace widespread foodborne disease outbreaks and warn millions of Americans to stay away from contaminated food products."

In as little as 48 hours, PulseNet can identify rogue E.coli strains in foods by identifying the distinctive DNA fingerprints of pathogens found in both food sources and the patients suffering from gastric illness. In 1993, it took three weeks to track an rogue E.coli contamination in hamburger meat produced by single source.

PulseNet will link food safety investigators at the Centers for Disease Control, the Food and Drug Administration, the Agriculture Department, four key area laboratories and state health departments to link directly with the PulseNet database.

As of today, epidemiologists in the following states will be on PulseNet -- Massachusetts, Minnesota, Texas, Washington California, Colorado, Florida, Georgia, Iowa, New Hampshire, New York, Ohio, Oregon, Utah, Virginia and

Wisconsin. The CDC plans to have all states on the network by 1999.

This important Administration initiative will reduce the number of Americans who suffer from episodes of food-borne illness and prevent over 9,000 deaths a year. This initiative is part of the Vice President's effort to reinvent government through partnerships at state and federal agencies and make smart use of the latest technology.

The Vice President also announced the formation of FORCG (pronounced Force G), a partnership of federal and state agencies to better respond to food-borne illness outbreaks.

This is a mirror of the White House press release, May 22, 1998, from the White House Briefing Room.

HHS Press Release and CDC Fact Sheet on PulseNet

Additional information on the Food Safety Initiative

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HHS NEWS

U.S. Department of Health and Human Services

FOR IMMEDIATE RELEASE Friday, May 22, 1998
Contact: CDC, Media Relations Division
(404) 639-3286

National Computer Network in Place to Combat Foodborne Illness

Detects and Traces E. Coli Strains Up to Five Times Faster

HHS Secretary Donna E. Shalala today announced completion of PulseNet, a national computer network of public health laboratories that will help rapidly identify and stop episodes of foodborne illness. The new system enables epidemiologists to move up to five times faster than previously feasible in identifying serious and wide-spread food contamination problems.

Speaking at a White House event with Vice President Al Gore, Secretary Shalala said the new national PulseNet system is the latest feature of the Clinton administration's initiative to improve food safety and detect foodborne disease. She said the next step should be increased resources for food safety efforts, and legislation to help ensure the safety of imported foods.

"America's food supply is unmatched in quality and quantity, but we face new challenges as our food distribution systems change and as new pathogens emerge and familiar ones grow resistant to treatment," Shalala said. "PulseNet will help us keep ahead of these challenges. We also need action by Congress to increase food safety resources at CDC and the Food and Drug Administration, and to pass legislation that will give FDA authority to ensure the safety of imported foods."

PulseNet is based on a molecular technology called pulsed-field gel electrophoresis (PFGE), standardized by HHS' Centers for Disease Control and Prevention, to identify distinctive "fingerprint" patterns of *E. coli* O157:H7. Under the networked computer system officially launched today, public health laboratories throughout the country can use this technology and share information via the Internet to determine when foodborne disease outbreaks are occurring. In this way, epidemiologists are able to rapidly assess whether a widespread food incident is underway, and can more quickly trace the source of the problem.

"Foods reaching American tables today are produced, processed and distributed very differently from even a decade ago. Food from a single source may be rapidly distributed to communities across the nation, making it more difficult to detect a disease outbreak caused by a contaminated food product," Secretary Shalala said. "PulseNet combines the latest in microbiology and computer technology to quickly detect whether illness occurring in many different locations, during the same timeframe, are linked to a common food source."

The PFGE technology underlying PulseNet was first used by CDC in a foodborne illness outbreak in 1993, but lack of computer networking prevented the rapid response that is possible today. Computer networking began with public health labs in four states in 1995, and has recently been expanded to 12 additional states.

Today's announcement marks the ability of the four key area laboratories, as well as U.S. Department of Agriculture and Food And Drug Administration labs, to link directly with the CDC computer server and gain direct access to the CDC database, allowing rapid direct exchange of information.

"With these computer links, the PulseNet system is in place, and its full technical potential is available to help protect Americans from foodborne illness," Secretary Shalala said.

The PulseNet computer network grew out of the experience of public health experts when investigating a large outbreak of foodborne illness caused by a deadly strain of bacteria, *E. coli* O157:H7, in 1993. Today, what takes as little as 48 hours with PulseNet took weeks in 1993 as investigators searched for the common food source of the outbreak--ultimately determined to be hamburger patties served at a large chain of regional fast food restaurants.

In the 1993 outbreak, CDC scientists performed the relatively new technique of DNA "fingerprinting" and determined the strain of *E. coli* O157:H7 found in patients matched the strain found in hamburger patties - the source of the outbreak. The prompt recall of the suspected ground beef patties prevented an estimated 800 additional illnesses in 1993; however, more than 700 persons became ill and 4 children died in the outbreak. The process of matching the bacterial strains in multiple communities was slowed because public health labs in multiple states could not quickly share information about their samples of *E. coli*. Now, with PulseNet, labs can instantly determine if a sample of the *E. coli* strain causing illness in their communities is also causing illness in communities next door or across the country.

"PulseNet can help public health experts recognize that foodborne illness occurring at the same time but in widely dispersed locations are from the same strain, and may be from a common exposure," said acting CDC Director Claire Broome, M.D. "By matching bacteria subtype patterns, we can detect nationwide outbreaks quickly and better direct public health actions."

Because bacteria replicate themselves by dividing in two, the next generation and many after have the same or nearly the same genetic makeup as the parent bacterium. The similarity of genetic materials over generations makes this an excellent tool to identify outbreaks from a common source, including food. Today PulseNet participants perform DNA fingerprinting on *E. coli* O157:H7 isolates. In the near future, another bacterium that is an important cause of foodborne illness, *Salmonella* serotype Typhimurium, will be added to PulseNet. Over time, CDC will set up additional databases of DNA fingerprints for other bacteria that can cause illness through food.

Federal food safety agencies worked with the Association of State and Territorial Public Health Laboratory Directors in creating PulseNet. In 1995, CDC began to set up PulseNet with state public health laboratories in Massachusetts, Minnesota, Texas and Washington, which are designated area laboratories and provide PulseNet services to states in their region. In addition, USDA and FDA have come on-line.

Additional laboratories are joining CDC's PulseNet. In addition to the four area laboratories directly linked to CDC, other labs connected to PulseNet include those from California, Colorado, Florida, Georgia, Iowa, New Hampshire, New York, Ohio, Oregon, Utah, Virginia and Wisconsin.

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This is a mirror of the page at <http://www.cdc.gov/od/oc/media/pressrel/r980522.htm>

White House Press Release on PulseNet

PulseNet, The National Molecular Subtyping Network for Foodborne Disease Surveillance

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