NLWJC - Kagan

DPC - Box 007 - Folder 011

Consumer Safety - Food Safety Initiative [1]

cws pro-food safety

Elena, Here is an event idea for next week Mary

POTENTIAL PRESIDENTIAL FOOD SAFETY ANNOUNCEMENT

This could be an event for Thursday, September 24; Friday, September 25; or the radio address on Saturday, September 26. The President could: (1) announce the results of a new study showing that incidence of salmonella has been reduced by almost 50 percent in chicken and almost 40 percent in pork since the President implemented HACCP; (2) announce some food safety grants; and (3) call on Congress to fully fund his food safety initiative, as this study shows we are on the right track toward improving food safety.

Here is some language on how the event might look:

The President announced that his new, prevention-oriented meat and poultry inspection system has nearly cut in half the proportion of broiler chickens contaminated with salmonella -- and greatly reduced the frequency of salmonella in pork. These data, while preliminary, indicate that the Administration's science-based inspection system, introduced in 1996, is already having a significant impact on the safety of food American families eat.

Salmonella is a potentially deadly bacteria that sickens an estimated 800,000 to 4 million Americans each year, costing the nation an estimated $726 million to $3.6 billion each year in lost productivity and medical costs. It is estimated to cause up to 4000 death per year.[1]

Initial testing in large plants indicates that salmonella, found on 20 percent of broiler chickens before implementation of the new Hazard Analysis and Critical Control Points inspection system (HACCP), was found on only 10.4 percent of chickens during testing earlier this year. And salmonella was found in only 5.5 percent of swine from plants that had implemented HACCP; 8.7 percent had tested positive previously. Today's results stem from testing conducted over a six-month period earlier this year, after implementation of HACCP in large plants.

Reflecting the Administration's comprehensive, farm-to-table approach to food safety, the President also announced several new grants in food safety research and education. The new research grants fund efforts to prevent or reduce illness caused by foodborne pathogens. And the food safety education grants specifically target higher-risk communities and under-served populations, emphasizing information for consumers and food preparers about safe food handling practices.

Today's announcements demonstrate that the Administration's food safety strategy is already producing real public health benefits for American families. Still, President Clinton stressed the need to do even more to protect public health and improve food safety. Specifically, he urged Congress to fully fund his National Food Safety Initiative.

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[1] USDA, Economic Research Service, 1993 data

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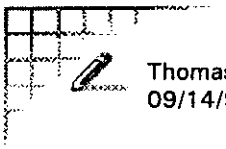


Thomas L. Freedman
09/14/98 01:14:04 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP, Michelle Crisci/WHO/EOP

cc: Mary L. Smith/OPD/EOP, Laura Emmett/WHO/EOP
Subject: Good News on Salmonella

1. USDA has results back on the initial implementation of our science-based HACCP system for reducing pathogens.

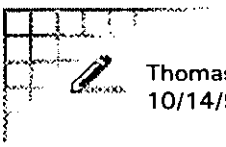
2. While the data is preliminary, it is very, very good. Swine went from salmonella infection rates of 8.7% as a baseline to 5.5%; poultry is even better going from a baseline of 20% to 10.4%.

3. The data show that 88% of large plants are participating.

4. The President could announce this with Secretary Glickman, note that the data is just from the first 6 months, but it shows we must stay the course in implementing our food safety plans. We need Congress to provide the resources that are pending in Congress and we need to go ahead to apply HACCP to the small plants -- which is the stage we are at now.

5. They hope to have the study ready by the end of the week. Interested?

ccw pre - food safety



Thomas L. Freedman
10/14/98 03:09:42 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP, Mary L. Smith/OPD/EOP

cc: Laura Emmett/WHO/EOP
Subject: Today's NYT on Food

The NYT today ran this story applauding our success in using HACCP to reduce salmonella.

EATING WELL

Success for New U.S. Standards on Meat and Poultry

By MARIAN BURROS

The federal government's new system for reducing contamination in meat and poultry appears to be having positive results. Two weeks ago, the Agriculture Department announced that the system has almost cut in half the number of broiler chickens contaminated with salmonella in the plants where it is in use. It has also greatly reduced the amount of salmonella-infected pork.

The system, called Hazard Analysis and Critical Control Points, and also known as Haacp (pronounced HASS-ip), became mandatory in January at the largest meat and poultry processing plants (like Perdue's and Tyson's). By the year 2000, the standards will include smaller plants as well. Under Haacp, plants must identify critical points in the production process where contamination is likely to occur and implement plans to prevent the contamination.

The system, with its routine testing for various bacteria, marks the first time the federal government has set microbial standards and required industry and government testing on such a large scale.

It is a definite step up from the old sniff-and-poke method.

There are many ways for producers to reduce the levels of contamination to meet the system's standards. Scientific study has increased in the wake of highly publicized outbreaks of food-borne illness as well as huge and costly recalls of tainted food, especially ground beef.

Critics charge that the meat and poultry industries resisted change. It was easier -- and cheaper -- to tell consumers it was their fault if they got sick from eating tainted beef or chicken because they had mishandled it. The industry realized that sales of its products were affected by these incidents. More or less.

Some of the ideas for safer food are so simple you wonder why no one ever thought of them before. More humane handling of cattle, for example, reduces stress and thereby reduces shedding of deadly E. coli 0157:H7. When the cattle are stressed, the E. coli are released from their intestinal tract and are excreted in their manure.

And just last month, scientists at Cornell University discovered that if cattle were switched from a diet of grain to a diet of hay or fresh grass for five days before slaughter, E. coli 0157:H7 is virtually eliminated.

No one is suggesting that any of the new technologies will completely eliminate the hazards associated with eating raw or minimally processed foods. And in fact, recalls of contaminated food do not appear to have fallen. Late last month, about two million pounds of meat and poultry headed for institutional use were recalled because of salmonella contamination at a Georgia processing plant.

But the new ideas can reduce the level of risk. Some of them, like inoculating animals with "good" bacteria to crowd out the dangerous bacteria, have already won federal approval; others are still in the development stage.

Some of New York City's best-known chickens are already participating in a new technology called competitive exclusion. One-quarter of Bell & Evans chickens are being sprayed with Preempt, a mixture of friendly bacteria that prevent harmful bacteria like salmonella from ever taking hold. The spray, produced by MS Bioscience Inc. in Madison, Wis., has been approved by the Food and Drug Administration. The president of Bell & Evans, Scott Sechler, says that eventually, all the company's chickens will be treated with Preempt.

The president of MS Bioscience, Dr. John DeLoach, says the chickens are sprayed in the hatchery and within two days they have a lifetime protection against salmonella.

But the spray is only part of the MS Bioscience regimen: there must also be clean litter for the chickens, and neither antibiotics nor growth promoters can be used. DeLoach admits he is not sure what part is responsible for the success.

Sechler said: "We are very happy with the results so far. For the most part we found completely negative tests with a very small amount of positives. The percentages amazed us."

Possible future treatments include the work of Dr. Michael Doyle, who is the director of the Center for Food Safety and Quality Enhancement at the University of Georgia. Doyle is experimenting with another form of competitive exclusion, giving young calves an oral dose of friendly E. coli bacteria to prevent the growth of E. coli 0157:H7. But sufficient tests for FDA approval are at least two years away, Doyle said.

Scientists have been working on the egg front as well. Pasteurized Eggs LP of Laconia, N.H., has patented a technique for pasteurizing eggs in

their shells. The eggs would carry an Agriculture Department shield that certifies them as pasteurized and 99.999 percent salmonella free. The company says that the pasteurized eggs will retain their characteristic taste, appearance and cooking characteristics. Welcome back sunny side up and real Caesar salad.

Shady Brook Farms has been using trisodium phosphate, an anti-bacterial rinse, on its turkey carcasses for several years, and according to the company it virtually eliminates such disease causing bacteria as E. coli 0157:H7, salmonella and listeria.

But elimination of all bacteria from food is neither feasible nor desirable. There is such a thing as "too pristine," James Jay, a microbiologist at the University of Nevada at Las Vegas, said. Getting rid of all bacteria on a carcass leaves the meat with no protection if it is recontaminated, he added.

No matter what improvements are made to reduce the levels of harmful bacteria in the food supply, everyone still needs to be careful at home and follow the recommendations for safe handling.

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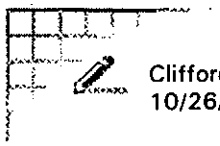

Clifford J. Gabriel
10/26/98 03:38:33 PM

Record Type: Record

To: See the distribution list at the bottom of this message

cc:
Subject: CAST Foodborne Pathogen News Release

Here's a copy of the embargoed CAST press release. Cliff
---------- Forwarded by Clifford J. Gabriel/OSTP/EOP on 10/26/98 03:37 PM ----------

"Kayleen A. Niyo" <kniyo @ cast-science.org>
10/26/98 03:35:49 PM

Please respond to kniyo@cast-science.org

Record Type: Record

To: Clifford J. Gabriel/OSTP/EOP

cc:
Subject: CAST Foodborne Pathogen News Release

Cliff,

Below is the news release. Thanks for your help on this important topic.

News Release

For Information, Contact:
Dr. Peggy M. Foegeding, North Carolina State University, Raleigh, North Carolina,
(919) 782-5419; e-mail: foegedin@bellsouth.net
Dr. Tanya Roberts, USDA-ERS, Washington, D.C., (202) 694-5464, e-mail: tanyar@econ.ag.gov
Dr. Richard E. Stuckey, Executive Vice President of CAST, 4420 West Lincoln Way,
Ames, Iowa, (515) 292-2125; e-mail: rstuckey@cast-science.org

For Release On: October 29, 1998

Scientists Update Foodborne Pathogen Recommendations

New Report Discusses Food Safety

Scientists offer 18 recommendations as a platform to focus and stimulate efforts toward food safety improvements. The Council for Agricultural Science and Technology (CAST), an international consortium of 36 scientific and professional societies, released a report Foodborne Pathogens: Review of Recommendations in which a CAST task force of 18 scientists updated the 15 recommendations contained in the 1994 CAST report Foodborne Pathogens: Risks and Consequences. The task force members represent a variety of organizations and backgrounds including consumers, producers, the food processing industry, governmental agencies, academicians, private consultants, epidemiologists, microbiologists, economists, and attorneys.

Information Is Critical Food Safety Problem

Information continues to be the critical food safety problem. Pathogens cannot be seen with the naked eye, so the public cannot readily detect the safety of meals, foods, or ingredients purchased anywhere along the food continuum. The ability to link human illness with foodborne pathogens also is difficult. Thus, the majority of foodborne illness cases are unreported. The complexity of food safety from farm to table requires many types of scientific expertise to design sensible public and private interventions.

The original report Foodborne Pathogens: Risks and Consequences published by the Council for Agricultural Science and Technology (CAST) in 1994 was well-received and widely quoted. With encouragement of producer organizations, governmental employees, scientists, and public interest groups, the CAST Board of Directors authorized an update of the recommendations from the original report.

What Do the Experts Recommend?

The CAST task force members strove to provide recommendations that are specific and practical with the goal that efforts involved in moving toward implementation of these
recommendations would ensure real improvements in the safety of foods. Briefly stated, the 18 recommendations are as follows.

more

Goal Setting

1. Base food-safety policy on risk assessment and include risk management and risk communication strategies.
2. Base food safety regulations on risk assessment and risk management.
3. Set federal food safety goals and priorities.

Research Needs

4. Expand food-safety information database by more complete reporting of the incidence of foodborne disease by pathogen, by food, and by contributory factors.
5. Conduct continued, rigorous epidemiologic studies to assist in establishing the cause of illness and effect of foodborne occurrence of a particular pathogen or toxin.
6. Improve and regularly update foodborne disease estimates.
7. Support research on mechanisms of chronic illnesses associated with

foodborne pathogens.
8. Use dose-response modeling in the risk assessment process.
9. Conduct research to identify likely domestic and imported food and pathogen/toxin associations.
10. Encourage and support vigorous fundamental and applied research efforts related to foodborne pathogens.
11. Develop rapid, accurate detection methods for foodborne pathogens and toxins.

Production Control
12. Require producers, aquaculturalists, and seafood harvesters to adopt effective preharvest intervention strategies in the interest of enhancing public health.
13. Apply foodborne pathogen control practices from food source to consumption.
14. Harmonize international food safety standards.

Education
15. Educate the general public and food handlers relative to safe food preparation and handling.
16. Identify high-risk populations and provide food safety education.
17. Provide risk information relative to food choices to persons with enhanced disease susceptibility.
18. Use and evaluate food labeling to communicate safe food preparation and storage practices to food preparers.

A detailed discussion of each of the above recommendations is contained in the full report. The report is available in print and on the CAST World Wide Web site at http://www.cast-science.org.

Editor: A free copy of Foodborne Pathogens: Review of Recommendations is available to journalists on request.

Foodborne Pathogens: Review of Recommendations, 45 pages, is available for $15.00 from CAST. CAST identifies food and fiber, environmental, and other agricultural issues and interprets related scientific research information for legislators, regulators, and the media for use in public policy decision making. CAST is a nonprofit organization of 36 scientific societies and many individual, student, company, nonprofit, and associate society members. The CAST World Wide Web site is http://www.cast-science.org.

Kay

Kayleen A. Niyo, Ph.D.
Managing Scientific Editor
kniyo@cast-science.org

Council for Agricultural Science and Technology
4420 West Lincoln Way, Ames, IA 50014-3447, USA
Phone: (515) 292-2125 Ext. 31, Fax: (515) 292-4512
WWW: http://www.cast-science.org

Cons Pro - Food safety

CDC to release dramatically lower foodborne disease illness estimates

Armed with the latest FoodNet data, the Centers for Disease Control and Prevention is poised to release new foodborne illness estimates that will be dramatically lower than what have been publicly cited for years. The new numbers may place government officials in the difficult position of defending spending increases for food safety programs in light of a significantly lower illness rate.

In the next several months, CDC plans to release new estimates on foodborne deaths and illnesses that afflict Americans each year, sources say. CDC has been revaluating its data and plans to report significant reductions, said a source, who added that health officials are preparing for a backlash once the new numbers are released.

The food industry has repeatedly questioned the government's widely quoted 9,000 deaths per year estimate from tainted food, as the number was used to rally support for the president's Food Safety Initiative. With CDC's expanded surveillance and monitoring network, that estimate is expected to drop significantly to about to 2,000-3,000 deaths from foodborne illness.

CDC's data will present new estimates for all foodborne diseases. For example, public health officials have maintained that as many as 250 deaths were attributed each year to *E. coli* O157:H7 poisonings. The new estimate is closer to 100 deaths, said a CDC official. In the same vein, up to 1,000 deaths each year were linked to *Salmonella* infections. Now, CDC is finding closer to 500 people die each year from *Salmonella* infections. Some 2 million to 4 million people each year were estimated to suffer from salmonellosis, but the new estimate may be closer to 1.6 million, said the source.

FoodNet data are showing a "remarkable decline" in disease rates so far this year. Some of the decline may be linked to USDA's HACCP program, which went into effect in January. USDA is anxious for CDC to release this information, said the source. After six consecutive months, public health officials are seeing a dramatic reduction in certain foodborne illnesses.

—Joan Murphy

1

Chem Food Processing News

690-6960

Cuts pro-food safety

Tim - I don't think there's enough here to propose a conference - keep thinking. A couple of questions: (1) Is the CDC analysis mentioned here the same as the report we talked about last week? And on another subject entirely, could you put together a list of the people who would be appropriate to invite to a deputies meeting on country-of-origin labeling? Thanks. Elena

White House Conference on Food Safety

A White House Conference on Food Safety could be held on a number of subjects, ranging from consumer education, partnerships with state and local government, international food safety issues, or research and technology. The recommendation is to hold a conference on new food safety technology and research.

Such a conference would be well-received by consumer groups, industry, producers, and academia and would receive strong bi-partisan support in Congress. In fact, one of the leading consumer groups recently requested that USDA host a conference on research and technology. USDA held a similar conference several years ago, which was widely attended.

The Administration's food safety initiative includes substantial increases for food safety research and technology. In addition, the Administration's new regulatory systems also depend on new technologies and research i.e. microbiological testing, interventions to reduce or remove pathogens. As a result, the conference could be viewed as building on Administration initiatives, including in preparation for the FY 2000 budget proposal.

The private sector and academia are also investing substantial resources in new research and technologies. A couple of examples include: a laboratory that has done extensive work for the Department of Energy and for the military is working on converting Gulf War technology that identifies nerve gas to the identification of pathogens; and a number of researchers are working on vaccines against E. Coli O157:H7 in animals.

While a number of options are possible, the conference could include a series of scientific panels that would present the latest research on new technologies. One panel could discuss efforts focused toward on-farm and pre-slaughter research. This could include research on vaccines as well as research to identify where and/or why pathogens appear on farm. There is on-going research in Federal agencies as well as various academic instititions e.g. Washington, Colorado, and Georgia, on this issue for various animal species.

Need research

Another panel could focus on research aimed at improving the ability to rapidly detect pathogens as well as on intervention technologies that are under development in research labs. This could also include work on sensor technology to be used on retail packages. It also might be possible to bring NASA research and technology into the food safety arena. In addition to these panels on research, there could be a panel on new food safety technologies and technological developments that are in use in slaughter and processing operations.

Glean

A final panel could be on future trends and challenges of the future, such as continued globabization of the food supply, population demographics, new products, packaging, and production technologies, and the effect those trends may have on our food safety research and technologies. This would complement the long-term strategic planning underway by the Federal food safety agencies.

The conference could be used as a forum for a speech, or the President or Vice President could host a general discussion on these issues, and then panels could be convenee throughout the day. There could also be displays and demonstrations of research and technological developments.

Possible Announcements for Conference

The conference itself would be likely to generate media interest. However, several additional announcements could be considered.

First, the President could issue a directive or an executive order on food safety research and technology. This would include several components:

> --**Interagency Food Safety Research Council**--As part of the President's Food Safety Initiative, the Administration has recently formed an interagency food safety research group. There are xx agencies represented on this group, which is charged with developing a comprehensive food safety research agenda. The Executive Order would institutionalize this working group.
>
> –The Executive Order could require the council to hold annual or biannual national public meetings/conference to discuss advances in research and technology.
>
> --The Executive Order could also direct the council to award annual or biannual Presidential Awards for Advances in Food Safety Research and Technology.

Second, the Centers for Disease Control is in the process of completing its analysis of the latest data on the extent of foodborne illness. Depending on the timing of the conference, this could possibly be released at the conference.

Third, depending on the timing of the conference, the Administration could announce implementation of PulseNet, which CDC will implement in the next 6-8 weeks. Pulsenet will electronically link CDC, USDA, and FDA labs with state public health labs in several states (with more states to be added by years end). The labs are all equipped with DNA fingerprinting technology, with the CDC laboratory serving as a hub and database for PulseNet. It works like this--a laboratory isolates E. coli O157:H7 from food--fingerprints it and enters the information into PulseNet. The laboratory then receives information on any similar fingerprints submitted on human pathogens by CDC or the States. In this way, PulseNet can identify a potential outbreak or a potential food source of an outbreak. This approach resembles the FBI national network and database for fingerprinting individuals throughout the United States and centrally generating a "rap" sheet where there is a match.

Cons pro-food safety

NEW PRODUCT CLEARED FOR USE IN PROTECTING U.S. POULTRY AGAINST SALMONELLA

WASHINGTON, Feb. XX, 1998--A new product from U.S. Department of Agriculture researchers that reduces potential salmonella contamination in poultry has been cleared for use in the United States, Secretary of Agriculture Dan Glickman announced today.

The U.S. Food and Drug Administration approved the product, called PREEMPT, which prevents *Salmonella* bacteria from taking hold in the intestines of one-day-old chickens. Milk Specialties Co. of Dundee, Ill., will market the product under a licensing agreement with the Agricultural Research Service, USDA's chief research agency.

Glickman said it is the first time FDA has approved a mixture of bacterial microbes as an animal drug. It has long been known that mature chickens at least three weeks old have a natural resistance to salmonella colonization in the intestines. Scientists have also known that feeding baby chicks the bacteria from mature chickens protected the chicks from salmonella. But scientists didn't know exactly which of the intestinal bacteria were most effective.

"The ARS researchers developed and patented a system that was never before used in poultry research to select a blend of 29 bacterial strains from older birds' intestines and put them together in a mixture," said Glickman.

The mixture can be sprayed in a mist over newly hatched chicks to give them the same level of salmonella resistance that develops in an older bird.

In field tests in the United States, PREEMPT reduced the number of salmonella in chicks' intestines between 85 and 100 percent. The FDA approval was based on five tests by ARS and Milk Specialties. The tests were conducted in U.S. commercial chicken houses and involved 250,000 chickens.

The work was done under a five-year cooperative research and development agreement between scientists at ARS' Food Animal Protection Research Laboratory in College Station, Texas, and Milk Specialties. ARS scientists Donald E. Corrier, David J. Nisbet and James A.

Byrd and Texas A&M researcher Billy Hargis conducted the field tests.

ARS patented the bacterial mix, originally called CF-3, and the method for producing it in 1994. The technology was licensed to Milk Specialties in 1994. The company is currently marketing the product in Japan. A similar product, developed by the same research group, is being tested in pigs.

About 400,000 cases of salmonella poisoning are reported to the Centers for Disease Control and Prevention each year. The usual exposure is from raw or undercooked meat, poultry, milk and eggs. The human health care bill for salmonellosis averages $4 billion annually.

Salmonella is passed on to humans via undercooked poultry. Even though contamination can occur at any point during marketing and transportation from farm to table, PREEMPT will help poultry producers send cleaner birds to market.

#

NOTE TO EDITORS: Contact for details Larry Stanker, Food Animal Protection Research Laboratory, Agricultural Research Service, USDA, College Station, Texas 77845. Telephone: (409) 260-9484.

PRESERVATION PHOTOCOPY

03-20-98;12:04PM;USDA FSIS OA

cons pro-food safety

DRAFT

USDA

Report to Congress

Food Net: An Active Surveillance System for Bacterial Foodborne Diseases in the United States

Food Safety and Inspection Service
United States Department of Agriculture
Washington, DC

April, 1998

DRAFT

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Preface

The U.S. Department of Agriculture has been directed by Congress to provide an annual report on the incidence of foodborne illness in the United States. This report is to be submitted to the House and Senate Committees on Appropriations.

This report includes a description of the Foodborne Diseases Active Surveillance Network (FoodNet) and foodborne illness data for calendar year 1997.

Questions about this report or about FSIS may be directed to the Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, D.C. 20250.

Overview of FoodNet

The Food Safety and Inspection Service (FSIS) of the U. S. Department of Agriculture (USDA) administers a comprehensive system of inspection laws to ensure that meat, poultry, and egg products moving in interstate and foreign commerce for use as human food are safe, wholesome, and accurately labeled.

Over the past decade, foodborne illnesses caused by bacterial contamination have heightened concern about the safety of food. The Centers for Disease Control and Prevention (CDC) has identified bacterial pathogens as the most common cause of foodborne illnesses because they can be easily transmitted and multiply rapidly in food, thus making them difficult to control. CDC has targeted seven bacterial foodborne pathogens (*Campylobacter, E. coli O157:H7, Listeria, Salmonella, Shigella, Vibrio, and Yersinia*) as those of greatest concern to public health. Government economists have estimated that foodborne illnesses cost billions of dollars each year in lost productivity and medical care. However, an accurate picture of both the number and causes of foodborne illnesses in the United States is unknown.

In July 1995, as part of the federal government's campaign to improve the safety of the nation's food supply, FSIS began a collaborative project with CDC and the Food and Drug Administration, known originally as the Sentinel Site Study and more recently as the Foodborne Diseases Active Surveillance Network or FoodNet, to collect more precise information on the incidence of foodborne disease in the United States. This project includes direct working links with state and local health departments at seven selected sites nationwide as a means of obtaining the most complete and current foodborne illness data available. This study, which is expected to continue for several years, will provide much-needed baseline data regarding the incidence of foodborne illness in the United States which is attributable to consumption of meat, poultry, and other food products.

Background

Bacterial foodborne diseases are currently reported to local and state health departments and CDC through passive surveillance systems. As with all passive systems, cases are frequently unreported. In fact, only 1% to 5% of foodborne disease cases are believed to be reported to CDC.

In July 1994, the USDA Pathogen Reduction Task Force recommended that FSIS work with CDC on research and surveillance activities that will better characterize risks for foodborne pathogens. This recommendation echoed a National Academy of Sciences recommendation for more community-based surveillance of foodborne disease. To improve data on the incidence and causes of foodborne illness, FSIS and CDC have established seven foodborne illness sites to study the epidemiological links among outbreaks of foodborne illness and to explore what relationships may exist between outbreaks and the types of meat, poultry, and egg products consumed. The selected sites are Northern California, Oregon, the Minneapolis/St. Paul metropolitan area, the metropolitan Atlanta area, Connecticut, counties in Maryland and upstate New York.

Objectives

The major objectives of FoodNet are to:

- determine the yearly incidence of diarrheal illness due to bacterial foodborne pathogens (i.e., *Campylobacter, E. coli O157:H7, Listeria, Salmonella, Shigella, Vibrio, and Yersinia*);
- develop a network to collaboratively respond to emerging foodborne diseases;
- determine the proportion of foodborne disease cases attributed to specific commodities; and
- determine whether federal interventions are having a measurable effect on the incidence of foodborne illness attributable to consumption of meat, poultry, and other foods.

Scope and Duration of Study

FoodNet is a comprehensive effort to track major pathogens that cause foodborne illness, to examine the epidemiological links among outbreaks of foodborne illness, and to explore what relationships may exist between outbreaks and the types of food products consumed.

Active surveillance data will be collected on reported illnesses associated with the seven bacterial pathogens targeted by CDC. Collected data will be used to identify emerging

pathogens and monitor illness incidence. The results will be used to help monitor the effectiveness of new food safety programs aimed at reducing the levels of these pathogens in meat, poultry, and other foods.

For the project to be successful, data must be collected over a number of years to chart national trends and consider the effectiveness of control strategies. It is hoped that the success of FoodNet will prompt the future collection of such data in state health departments all over the country so that a truly accurate picture of the extent and causes of foodborne illness will be achieved.

Components of FoodNet

- **Active Surveillance:** The purpose of this survey is to determine in each site the actual number of laboratory-confirmed cases of illness caused by the seven targeted bacteria and, as of 1997, two targeted parasites.

  - **Bacterial:** In 1997, the total population under surveillance was 15.9 million persons. Culture-confirmed cases for the five sites total 7933. The Tables in the last section provide detailed information about these cases.

  - **Parasitic:** In 1997, data collection began in four sites for illnesses caused by the parasites *Cryptosporidium* and *Cyclospora*. A total of 464 cases were found. Beginning in January 1998, all sites will survey for these parasites.

- **Laboratory Survey:** The primary purpose of this survey is to determine whether or not laboratories within the site boundaries are performing cultures for foodborne pathogens. A baseline survey of 230 clinical labs which perform stool cultures in the sites was completed in late 1995. This survey demonstrated that all 230 labs in the five sites routinely culture for *Salmonella* and *Shigella*, 95% for *Campylobacter*, 48% for *E. coli O157*, 30% for *Yersinia*, and 19% for *Vibrio*. The survey was repeated in 1997 to determine the total number of bacterial stool cultures performed, including those that did and did not yield a pathogen, to collect specific information on *Campylobacter* isolation techniques, and to collect information regarding testing for *Cryptosporidium* and *Cyclospora*. Analysis is being conducted by CDC.

- **Physician Survey:** The primary purpose of this survey is to determine whether or not physicians who see patients for diarrheal complaints are referring them for laboratory analysis. A total of 5074 surveys were mailed to physicians in non-surgical specialties in five sites in 1996; 2939 (58%) were returned. In 1997, the survey was conducted in Maryland and New York, the two newest sites. Analysis is being conducted by CDC.

- **Population Survey:** An outside contractor, Macro International, performs this survey for FoodNet. Both adult and pediatric surveys are being used. The primary purpose of this survey is to determine population behavior in the site areas, particularly regarding what foods are consumed and how food is handled and prepared. The first full year of data collection was completed in June 1997. A total of 12,209 interviews were conducted. Preliminary analysis at CDC indicates 11% of persons interviewed had a diarrheal illness in the previous 4 weeks, which represents 1.3 diarrheal episodes per person per year. The second year of data collection began in February 1998.

- **Case-Control Studies:** The primary purpose of these studies is to determine patient behavior and food consumption just prior to becoming ill.

  - E. coli O157:H7

  The first year of the *E. coli O157:H7* study was completed in May, 1997. It has not resumed. Data is being analyzed at CDC and the Minnesota Department of Health.

  According to CDC, Preliminary analysis indicates that consumption of pink hamburgers or pink ground beef and living on or visiting a farm are risk factors for sporadic infection. Ref. CDC

  - Salmonella

  The *Salmonella* serogroup B & D study began in April 1996 in three sites and in August 1996 in two sites and ended 12 months later in all sites. It has not resumed. Data is being analyzed at CDC.

- Campylobacter

In 1997, it was decided to add a case-control study for *Campylobacter* which was found to be the most frequent cause of illness in all sites. The questionnaire was developed in 1997 and the study began in January 1998 in four sites, February 1998 in one site, and March 1998 in two sites.

Future Plans

Plan for 1998:

Counties in New York (Genesee, Livingston, Monroe, Ontario, Orleans, Wayne, and Yates) and Maryland (Ann Arundel, Baltimore, Carroll, Harford, Howard, and Baltimore City) will join FoodNet as fully participating sites. An invitation will be presented to all remaining state public health departments to join as the eighth site. Selection of this eighth site will be made in the fall of 1998, and participation will begin in 1999.

Plan for 1999:

The eighth site will begin to participate in FoodNet. Case-control studies for additional pathogens such as Listeria and Cryptosporidium will begin. Validation studies for the Physician survey and Laboratory survey will be performed to validate collected data. The Laboratory survey will be repeated. The FoodNet population under surveillance will increase to 24,979,368 with the addition of statewide surveillance in Georgia and the Albany, NY metropolitan area. The addition of the eighth site will increase the population as well.

DRAFT

Foodborne Illness Data

The following information represents findings from the second year of data collection. It is important to note, however, that the tables and charts that follow are based solely on the number of laboratory-confirmed actual cases in the sites. No analysis of the probable causes of the illnesses is presented; only the pathogen found in each patient.

Population in sites (based on 1996 Census data):

	1996	1997
California:	2,063,454	2,063,454
Connecticut:	1,626,366	2,460,127
Georgia	2,729,783	3,541,230
Minnesota	4,657,758	4,657,758
Oregon	3,203,735	3,203,735
TOTAL	**14,281,096**	**15,926,304**

The total United States population is 263,552,678.

These population totals are based on 1996 Census data. Connecticut includes the addition of Fairfield county. Georgia includes the addition of 12 counties.

Active Cases:

There were 7,933 laboratory-confirmed diarrheal cases in 1997 that were attributable to the seven targeted bacterial pathogens (i.e., *Campylobacter, E. coli O157:H7, Listeria, Salmonella, Shigella, Vibrio, and Yersinia*). This represents an increase of 611 cases (8%) over the 7,322 final case figure for 1996. However, the population figure also increased by 1,645,208 (11%). A comparison of cases per 100,000 population for 1996 and 1997 shows that the prevalence of cases decreased from 51.3% to 49.7%. (Table 3)

Most frequently isolated pathogen:

For the second year, *Campylobacter* is the most frequently isolated bacterium from persons with diarrhea (45.8%); *Salmonella* is second (26.9%); *Shigella* is third (14.7%); *E. coli O157:H7* is fourth (4.1%); *Yersinia* is fifth (1.6%); *Listeria* is sixth (.8%); *Vibrio* is last (.6%).

Table 1: Percent Pathogen by Site
From January 1, 1997 to December 31, 1997

Site		Pathogen							
		Campylo-bacter	*E. coli* O157	*Listeria*	*Salmon-ella*	*Shigella*	*Vibrio*	*Yersinia*	Total
California	Cases	1,001	19	13	380	291	30	33	1,767
	Percent	56.6%	1.1%	0.7%	21.5%	16.5%	1.7%	1.9%	100%
Connecticut	Cases	477	34	7	430	77	4	12	1,041
	Percent	45.8%	3.3%	0.7%	41.3%	7.4%	0.4%	1.2%	100%
Georgia	Cases	469	8	20	457	549	1	44	1,548
	Percent	30.3%	0.5%	1.3%	29.5%	35.5%	0.1%	2.8%	100%
Minnesota	Cases	1,179	202	18	636	138	2	31	2,206
	Percent	53.4%	9.2%	0.8%	28.8%	6.3%	0.1%	1.4%	100%
Oregon	Cases	719	80	11	356	178	12	15	1,371
	Percent	52.4%	5.8%	0.8%	26.0%	13.0%	0.9%	1.1%	100%
Total	Cases	3,845	343	69	2,259	1,233	49	135	7,933
	Percent	48.5%	4.3%	0.9%	28.5%	15.5%	0.6%	1.7%	100%

This table shows the number of actual cases of illness caused by each pathogen in each site. Note ~~the~~ *Campylobacter* is the most frequently found pathogen.

that

Table 2: Percent Site by Pathogen
From January 1, 1997 to December 31, 1997

Pathogen		CA	CT	GA	MN	OR	Total
Campylobacter	Cases	1,001	477	469	1,179	719	3,845
	Percent	26.0%	12.4%	12.2%	30.7%	18.7%	100.0%
E. coli O157	Cases	19	34	8	202	80	343
	Percent	5.5%	9.9%	2.3%	58.9%	23.3%	100.0%
Listeria	Cases	13	7	20	18	11	69
	Percent	18.8%	10.1%	29.0%	26.1%	15.9%	100.0%
Salmonella	Cases	380	430	457	636	356	2,259
	Percent	16.8%	19.0%	20.2%	28.2%	15.8%	100.0%
Shigella	Cases	291	77	549	138	178	1,233
	Percent	23.6%	6.2%	44.5%	11.2%	14.4%	100.0%
Vibrio	Cases	30	4	1	2	12	49
	Percent	61.2%	8.2%	2.0%	4.1%	24.5%	100.0%
Yersinia	Cases	33	12	44	31	15	135
	Percent	24.4%	8.9%	32.6%	23.0%	11.1%	100.0%
Total	Cases	1,767	1,041	1,548	2,206	1,371	7,933
	Percent	22.3%	13.1%	19.5%	27.8%	17.3%	100.0%

Table 3: Cases per 100,000 by Pathogen for All Sites

	1996*		1997	
Pathogen	**Rate per 100,000**	**Total**	**Rate per 100,000**	**Total**
Campylobacter	23.5	3,359	24.1	3,845
E. coli O157	2.7	388	2.2	343
Listeria	0.4	64	0.4	69
Salmonella	14.5	2,069	14.2	2,259
Shigella	8.9	1,272	7.7	1,233
Vibrio	0.1	21	0.3	49
Yersinia	1.0	149	0.8	135
Total	51.3	7,322	49.7	7,933

*Figures represent final 1996 data.

Table 4: Pathogen by Month—All Sites
From January 1, 1997 to December 31, 1997

	Month												
Pathogen	**JAN**	**FEB**	**MAR**	**APR**	**MAY**	**JUN**	**JUL**	**AUG**	**SEP**	**OCT**	**NOV**	**DEC**	**Total**
Campylobacter	255	210	249	271	335	497	470	407	364	358	234	195	3,845
E. coli O157	11	11	15	8	18	41	93	45	49	24	15	13	343
Listeria	3	4	3	5	5	6	11	8	9	7	3	5	69
Salmonella	179	135	146	216	172	207	245	267	255	183	129	125	2,259
Shigella	80	78	74	103	88	109	113	171	134	101	90	92	1,233
Vibrio	0	0	2	1	1	4	10	18	7	3	2	1	49
Yersinia	17	11	9	11	15	7	8	9	11	6	8	23	135
Total	545	449	498	615	634	871	950	925	829	682	481	454	7,933

This table shows the number of actual cases for all sites for each month in 1997.
Note that July has the greatest number of cases.

Table 5: Age Distribution by Pathogen for All Sites From January 1, 1997 to December 31, 1997

Pathogen		UNK	0-<1	1-<10	10-<20	20-<30	30-<40	40-<50	50-<60	60+	Total
Campylobacter	Cases	8	120	613	300	672	798	558	358	418	3845
	Percent	0.2%	3.1%	15.9%	7.8%	17.5%	20.8%	14.5%	9.3%	10.9%	100.0%
E. coli 0157	Cases	0	10	156	55	30	18	12	24	38	343
	Percent	0.0%	2.9%	45.5%	16.0%	8.7%	5.2%	3.5%	7.0%	11.1%	100.0%
Listeria	Cases	0	4	2	1	2	9	5	7	39	69
	Percent	0.0%	5.8%	2.9%	1.4%	2.9%	13.0%	7.2%	10.1%	56.5%	100.0%
Salmonella	Cases	5	277	537	217	297	315	241	139	231	2259
	Percent	0.2%	12.3%	23.8%	9.6%	13.1%	13.9%	10.7%	6.2%	10.2%	100.0%
Shigella	Cases	4	27	578	74	155	208	100	54	33	1233
	Percent	0.3%	2.2%	46.9%	6.0%	12.6%	16.9%	8.1%	4.4%	2.7%	100.0%
Vibrio	Cases	0	0	0	0	15	18	4	4	8	49
	Percent	0.0%	0.0%	0.0%	0.0%	30.6%	36.7%	8.2%	8.2%	16.3%	100.0%
Yersinia	Cases	0	56	28	7	7	12	10	5	10	135
	Percent	0.0%	41.5%	20.7%	5.2%	5.2%	8.9%	7.4%	3.7%	7.4%	100.0%
Total	Cases	17	494	1914	654	1178	1378	930	591	777	7933
	Percent	0.2%	6.2%	24.1%	8.2%	14.8%	17.4%	11.7%	7.4%	9.8%	100.0%

This table shows the number of cases by age group. The greatest number of cases involves children between the ages of 1 and 10 years.

Table 6: Sex Distribution by Pathogen for All Sites
From January 1, 1997 to December 31, 1997

Pathogen		Male	Female	Total
Campylobacter	Cases	2112	1723	3835
	Percent	55.1%	44.9%	100.0%
E. coli 0157	Cases	163	180	343
	Percent	47.5%	52.5%	100.0%
Listeria	Cases	38	31	69
	Percent	55.1%	44.9%	100.0%
Salmonella	Cases	1138	1117	2255
	Percent	50.5%	49.5%	100.0%
Shigella	Cases	637	593	1230
	Percent	51.8%	48.2%	100.0%
Vibrio	Cases	31	18	49
	Percent	63.3%	36.7%	100.0%
Yersinia	Cases	61	73	134
	Percent	45.5%	54.5%	100.0%
Total	Cases	4180	3735	7915
	Percent	53%	47%	100%

This table shows the number of cases by sex. There are 18 cases where sex is unknown.

Table 7: *Salmonella* Typhimurium and Enteritidis Serotypes by Site
From January 1, 1997 to December 31, 1997

	Site					
Serotype	**CA**	**CT**	**GA**	**MN**	**OR**	**Total**
Typhimurium	86	116	152	179	113	646
Enteritidis	32	142	23	122	38	357

There were 2,259 cases attributable to *Salmonella*. The most frequently occurring Serotypes were Typhimurium and Enteritidis.

Table 8: Patient Outcome by Pathogen for All Sites
From January 1, 1997 to December 31, 1997

Pathogen		Alive	Unknown	Dead	Total
Campylobacter	Cases	2972	871	2	3845
	Percent	77.3%	22.7%	0.1%	100.0%
E. coli 0157	Cases	329	4	10	343
	Percent	95.9%	1.2%	2.9%	100.0%
Listeria	Cases	50	5	14	69
	Percent	72.5%	7.2%	20.3%	100.0%
Salmonella	Cases	1843	405	11	2259
	Percent	81.6%	17.9%	0.5%	100.0%
Shigella	Cases	970	262	1	1233
	Percent	78.7%	21.2%	0.1%	100.0%
Vibrio	Cases	25	24	0	49
	Percent	51.0%	17.0%	0.0%	100.0%
Yersinia	Cases	112	23	0	135
	Percent	83.0%	17.0%	0.0%	100.0%
Total	Cases	6301	1594	38	7933
	Percent	79.4%	20.1%	0.5%	100%

This table shows the number of known deaths of patients who tested positive for one of the seven targeted pathogens. Note that these deaths may or may not have been caused by the pathogen, but may be attributable to an underlying illness such as AIDS. Further case control study is warranted.

Cons Pro - food safety

POSSIBLE FOOD SAFETY EVENTS

Research and Technology

Issue a directive to Secretaries of USDA and HHS working with OSTP to establish Presidential awards for advances in food safety research and technology. The directive could also include a national food safety research and technology conference, for which there is great interest among all constituencies.

Or Issue an Executive Order on food safety research and technology: components include:

--Interagency Research Council chaired by OSTP (only Federal members or Could this become a Presidential Commission and have non-Federal members?) Regular meetings, annual report to POTUS and Congress

--Annual national public meetings/conference to discuss advances in research and technology

--Annual or Biannual Presidential Awards for Advances in Food Safety Research and Technology--Basic and Applied Awards, top three in each category? Open competition to government, private labs, and companies.

The directive may be better since the details of the awards need to be sorted out.

Host a meeting on food safety research and technology: invite research labs, companies to demonstrate their products, demonstrate DNA fingerprinting foodnet system. This would need sufficient lead time to truly be successful. It would be better to incorporate a meeting into the conference, or the conference could be a forum for a speech.

Tour a FoodNet sentinel site that has DNA fingerprinting--High Tech early warning system to detect and limit foodborne illness outbreaks. The Secretary viewed this technology in Seattle. It is great. CBS news is interested.

Outbreak Response

Issue an Executive Order formalizing FORCG--the Foodborne Outbreak Response Coordinating Group. The purpose of FORCG is to improve the coordination and outbreak response to foodborne illness by all federal, state, and local agencies involved. HHS and USDA, and EPA, have been developing an MOU on FORCG. We could either formally sign the MOU or the MOU could be changed into an Executive Order. I am attaching a DRAFT MOU for your review.

Food Safety Education

Do a Fight Bac Event with school children, highlight the importance of safe food handling

Get restaurants, fast food companies, and major retailers to agree to promote Fight Bac consumer education message and host an event announcing their participation.

Is there a restaurant/retail manager/employee education effort we could undertake? I.e. develop training/education materials?

Miscellaneous

Tour a meat or poultry plant that is implementing the new food safety system

Is there a food code event we could arrange? Challenge states to adopt the food code?

Tax credits for new technology?

SBA coordinate regional meetings with small business re education, technical and financial assistance?

THE WHITE HOUSE
WASHINGTON

EK-

You had asked about the status of E. Coli research mentioned in a Cabinet Report.

Attached is a brief summary of the research indicating that results on a vaccine are quite preliminary.

We will continue to look in this area.

Tom

Cum pro - Prod safety

O157:H7 Vaccines

There are at least 3 groups working on vaccines against *Escherichia coli* O157:H7 in humans or animals. The real need is to develop an effective therapeutic agent against this disease in humans. This new publication by NIH researchers on an O157 vaccine is extremely premature. Unknown is who should be vaccinated and whether the vaccine is broad based enough. The NIH vaccine may be effective only against *E. coli* O157:H7 and not related *E. coli* bacteria which also cause human disease. The real target of an O157 vaccine should probably be U.S. cattle since these animals are the reservoir of the O157 bacterium. However, vaccine trials in cattle to date have not proved effective against this infection.

A brief description of the pertinent research groups working on O157 vaccines in the U.S. are summarized below.

1) John Robbins, National Institutes of Health

Vaccine Trial - In a recent clinical trial, the vaccine against *E. coli* O157 caused adult volunteers to produce enough antibody to kill the bacteria in laboratory cultures, without serious side-effects in the volunteers (a few of the vaccinees had a mild skin reaction at the injection site). The power of the vaccinees' serum to kill the bacteria persisted throughout the clinical trial, which lasted for 6 months. The results of this clinical trial are reported in an article in the February issue of the *Journal of Infectious Diseases*. The NIH scientists propose that this vaccine-induced bactericidal activity is a measure of immunity. More clinical trials are necessary. It is unclear whether this vaccine will confer immunity to other disease-causing *E. coli* or only to *E. coli* O157:H7. In this case, the vaccine may not be broad enough in its scope for an effective vaccine for cattle/children.

Cattle - The NIH vaccine is now being tested in cattle in cooperation with the Calgene Corporation. Preliminary results show that the cattle elicit an antibody response, but whether the antibodies will clear O157 from the cattle gut has yet to be determined. Once this data is evaluated, a determination will be made as to whether the vaccine is sufficiently immunogenic to continue research. If continued research is warranted, USDA (APHIS) will become involved since challenge studies of cattle with O157 will require USDA protocol approval. The purpose of these studies would be to determine if infection in cattle could be prevented by the vaccine when cattle are purposely given *E. coli* O157:H7.

Proposed Trial in Children - A clinical trial in children is being proposed and is in the initial planning phase. No details are currently available.

2) Alison O'Brien-Uniformed Services University of the Health Sciences
With ARS and University of North Carolina

Dr. O'Brien's research group is working to develop a broad spectrum vaccine that will hopefully be effective against all enterohemorrhagic *E. coli*. This group includes *E. coli* O157:H7. This

work is very preliminary. The group is currently trying to combine different shiga toxins with the attachment factor of O157:H7 to produce an effective immunizing antigen. If successful, this work will result in a broad spectrum vaccine that will be effective against O157:H7 and other serotypes compared to the NIH vaccine which may be specific to only O157:H7.

This group received a USDA grant "Intimin: candidate for an *E. coli* O157:H7 anti-transmission vaccine." Intimin is required for enterohemorraghic *E. coli* (EHEC) O157:H7 infection and disease in neonatal calves and piglets. Objectives of this grant are to determine if antibodies against intimin passively protect neonatal pigs and cattle from O157:H7 infection and disease and to determine if intimin plays a role in colonization of older cattle. A piglet model will be used first for proof of concept, then a calf model to confirm applicability to calves.

3) Agricultural Research Service

ARS experience with the immune response and vaccine against *E coli* O157:H7 in cattle has not been encouraging because:

-- Oral infection with O157:H7 in cattle caused an anti-O157 LPS serum immune response. The immune response did not correlate with reduced fecal shedding or with protection against re-infection.

-- a preliminary live-oral O157:H7 vaccine was tried in cattle. The vaccine strain does not express Shiga toxin, which is believed to be a critical virulence factor. However, the vaccine did not prevent subsequent infection or shedding despite a significant immune response (serum antibody) against O157 LPS.

ARS developed a vaccine which inhibits the effects of the Shiga-like toxin important in edema of pigs. A similar toxoid based vaccine for humans would produce broader protection than the NIH human vaccine because of similarities of the Shiga-like toxin produced by several bacterial species. The toxoid vaccine was shown to protect pigs and was effective in vivo. The NIH vaccine in humans has not yet been demonstrated to protect against disease.

Cms pro-food safety

EK-
USDA says there is not much here that isn't being done. We've asked for more on the topic indicated.
TOM

MEMORANDUM

TO: **ELENA KAGAN**

FROM: **TOM FREEDMAN, MARY L. SMITH**

RE: **REP. STABENOW FOOD SAFETY BILL**

DATE: **FEBRUARY 3, 1998**

SUMMARY

USDA says that Rep. Stabenow introduced this bill as a placeholder -- she was politically unable to introduce the enforcement bill which was introduced in the Senate. USDA supports Rep. Stabenow's bill, but does not put a priority on it. We've attached the section-by-section analysis of the bill. We've asked USDA to look into the Rapid Response Team idea (Sec. 4 of the bill) to see if we could do this without legislation.

HOW STABENOW'S BILL DIFFERS FROM ADMINISTRATION PROPOSALS

Rep. Stabenow's bill addresses primarily education, research, and consumer protection. Her bill is not directed toward enforcement. Furthermore, her bill does not provide for giving FDA authority to prevent the importation of produce from countries without safety precautions equivalent to our own -- which our legislation provides for. (The Administration's legislation was introduced by Rep. Anna Eshoo (D-CA)).

USDA's main enforcement bill, which provides for civil penalties and mandatory recall, has been introduced by Sen. Harkin (D-IA), along with Sens. Daschle (D-SD), Leahy (D-VT), and Sen. Johnson (D-SD).

Section by Section Analysis: Debbie Stabenow's Food Safety Bill

Summary

The Safe Food Action Plan, by Congresswoman Debbie Stabenow, seeks to improve food safety through research, consumer education, federal rapid response to food safety emergencies, and technology transfer programs. The bill uses existing funds and formulas to re-prioritize federal spending toward increased food safety for the nation.

Section 1: Short title, Table of Contents

Defines the short title as the "Safe Food Action Plan Act" and lists the table of contents.

Section 2: Findings

Recognizes the pressing need for increased federal attention to food safety. Cites the great number of people sickened with illnesses from food they have consumed as the reason for developing a pro-active federal food safety strategy.

Section 3: Food Safety Research, Education and Extension Priority

Directs the Secretary of Agriculture to establish food safety as a priority for the USDA. The Secretary is encouraged to integrate the efforts of USDA with other agencies that handle food safety. Communication with other agencies is stressed as the key to improving the combined federal approach to solving food safety problems. The Secretary is also directed to promote research, extension, and education programs with a multi-disciplinary approach.

Section 4: Food Safety Rapid Response Team

Directs the Secretary of Agriculture to develop a Food Safety Rapid Response Team within the USDA for food safety emergencies. The Secretary will appoint a rapid response coordinating officer to manage the team and to integrate its efforts with other federal, state, and local agencies, as well as with land grants, universities, and other research institutions. The Rapid Response team must prepare an action plan, detailing how it will operate and how the team can be integrated with other agencies that handle food safety. The rapid response action plan must be submitted to Congress for review 12 months after enactment of the Safe Food Action Plan.

Section 5: Emphasis on Food Safety Research in Fund for Rural America

The Fund for Rural America, which provides financial assistance through USDA for many rural projects, is directed to include "increasing food safety from farm-to-consumer" as one of its program priorities.

Section 6: Nation Food Safety Research, Education, and Extension Program

This Section establishes the "National Food Safety Research, Education, and Extension Program." The program will support research that will reduce the threat of various pathogens to human health, survey and collect data to learn more about pathogens and prepare for future outbreaks, conduct risk assessment analysis to predict the most dangerous gaps in current knowledge, and improve ways to disseminate information about food safety. The USDA is directed to coordinate its efforts at the federal level with all the relevant agencies, as well as with state governments, the private sector, universities and land grant institutions. Grants for such purposes will be awarded on a competitive basis. The Secretary is permitted to consult with the National Academy of Sciences about the National Food Safety Research, Education and Extension Program.

Section 7: Development and Commercialization of Food Safety Technology

The CRADA program, (cooperative agreement for research and development) is expanded to include the development of technology food safety as a program priority.

United States Department of Agriculture

1999 National Food Safety Initiative

BACKGROUNDER

Cons pro- food safety

February 1998

On January 25, 1997, the President announced the National Food Safety Initiative. The initiative includes components for reducing the incidence of foodborne illness from farm-to-table. Key components include expansion of the Federal food safety surveillance system, improved coordination between Federal, State, and local health authorities, improved risk assessment capabilities, increased inspection, expanded research, consumer education, and strategic planning. Utilizing the funds provided by Congress in 1998, an increase of $42.8 million, the U.S. Department of Agriculture (USDA) and Department of Health and Human Services (HHS) have initiated changes to ensure the safety of a wider variety of food products from a broader range of hazards. In addition, USDA and HHS have identified measures that need to be taken to ensure the safety of fresh fruits and vegetables consistent with the President's directive on this issue. USDA, HHS, and other interested parties will seek input on measures that can be taken to improve food safety during production, transportation, storage, distribution, and in the home.

1999 Budget Request:

For 1999, the Administration is proposing an increase of $100.6 million for the National Food Safety Initiative. Of this amount, $45.6 million is allocated to USDA and $55 million to HHS. The 1999 National Food Safety Initiative builds on the successes of the 1998 initiative as well as fills the gaps that have been identified in the past year. In 1999, the focus of the initiative is on enhancing the safety of imported and domestic fruits and vegetables, targeting food safety education, implementing Hazard Analysis and Critical Control Point (HACCP) systems in appropriate sectors of the food supply, and developing scientific information and tools to control a greater range of food safety hazards. Funding is requested for the following activities:

Enhance surveillance and investigation to improve outbreak response (+$7.0 million):

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

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

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

HHS (+$0.2 million): HHS will ensure quick and accurate detection and coordination of foodborne illness outbreaks and evaluation of responses. The agencies will improve information and data sharing among the agencies at Federal, State, and local levels.

Improve the capability to estimate risks associated with foodborne hazards (+$11.1 million):

HHS (+$7.2 million): FDA will initiate a program of research in quantitative risk assessment (particularly for microbial hazards) that is targeted to address the limitations in risk assessment methodologies and available data related to 1) dose-response relations for the general population and high risk groups (e.g. neonates, elderly, immune-compromised), 2) the impact of production, processing, distribution, marketing, and preparation practices, and 3) the quantification of factors contributing to incidence and prevalence of pathogenic microorganisms in raw ingredients and finished products. FDA will continue to build the activities of the interagency Risk Assessment Consortium at JIFSAN that provides a forum for coordination of federal microbial risk assessment research and as clearinghouse for risk assessment information and expertise.

USDA (+$3.9 million): The Agricultural Research Service (ARS), Cooperative State Research, Education and Extension Service (CSREES), ERS, FSIS, and the Office of the Chief Economist (OCE) will conduct quantitative risk assessments to identify food safety hazards and controls, make faster and more accurate regulatory decisions, target more effectively program resources, and facilitate the development and evaluation of surveillance plans and risk reduction strategies.

Expand inspection and compliance efforts, implement new preventive measures with a new emphasis on produce and imports, and facilitate the implementation of HACCP (+$35.4 million):

HHS (+$27.6 million): FDA will protect American consumers by seeking legislation that would prevent the import of unsafe food products from countries with food safety systems that are not on a par with the U.S. system or that refuse to allow entry of U.S. inspectors into facilities producing products offered for import. FDA will verify implementation of seafood HACCP and implement HACCP for juices. FDA will provide technical assistance and educational outreach to promote the adoption of voluntary GAP/GMP guidance in the domestic fresh produce industry.

USDA (+$7.8 million): The Food Safety and Inspection Service (FSIS) will provide special onetime assistance to State meat and poultry inspection programs to facilitate implementation of HACCP.

Continue to build the national food safety education campaign (+$13.6 million):

USDA (+$9.5 million) and HHS (+$4.1 million) for the following activities:

Consumer and Food Handler Education-USDA (+$4.7 million) and HHS (+4.1 million): Building on the national campaign launched by the public-private Partnership for Food Safety Education in 1997, FSIS, CSREES and FDA will target specific programs to change unsafe behaviors used by home food handlers, cooks and food handlers in retail settings and in congregate

feeding sites. CDC, FSIS and FDA will begin development of materials to assist in educating school children about how to prevent foodborne illness. FDA will target vulnerable groups (e.g., those affected by Vibrio in raw oysters and pregnant women and Listeria) with specific food safety messages. FDA will develop multilingual training programs for food service and retail workers and provide technical assistance to domestic and foreign fresh produce industries to promote adoption of good agricultural and manufacturing guidance. FSIS will target vulnerable groups (e.g., senior citizens and people with compromised immune systems) and will launch a campaign to promote thorough cooking of meat and poultry products.

School Food Service Provider Education-USDA (+$2.0 million): The Food and Nutrition Service (FNS) will develop and operate training workshops to educate local school food service professionals about the latest safe food handling practices specific to their needs and the updated Food Code.

Producer Education-USDA (+$2.8 million): FSIS and CSREES will work with industry and academia to educate food animal producers and fruit and vegetable producers on food safety assurance practices, risk management, and risk communication.

Accelerate food safety research efforts (+$33.3 million):

USDA (+$24.1 million) for the following activities:

Basic Research (+$1.3 million): Research will be conducted to enhance the understanding of pathogen growth and control;

Applied Research (+$13.8 million): Alternative food production, processing, and handling systems that eliminate or reduce pathogen contamination will be designed and evaluated. Conditions under which food products become contaminated during food handling, distribution, and storage will be identified; and,

Methods Development (+$2.7 million): Rapid tests will be developed that identify a broader range of pathogens on food products, specifically fruits and vegetables, throughout the food production, manufacturing and distribution system;

Baseline Studies (+$6.3 million): A microbiological baseline for pathogens on fruits and vegetables will be developed utilizing existing program infrastructure.

HHS (+$9.2 million):

FDA will intensify research to prevent and respond to new food safety hazards, such as *E. coli* O157:H7, *Campylobacter*, *Cyclospora*, and *Salmonella Typhimurium* DT 104. FDA will focus research in the four areas identified in interagency research planning as critical to reducing microbial risk in produce: improved detection methods, resistance to traditional preservation techniques, antibiotic resistance, and development of prevention/intervention strategies.

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

EXECUTIVE SUMMARY

A Consolidated, Multi-Agency Plan for Improving Food Safety

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

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

The impetus to focus increased Federal attention on food safety came from a number of sources. The most important of these sources is the rapidly increasing number and complexity of food safety issues (such as newly recognized pathogens and their sudden appearance on foods, such as fresh produce, where they had not been seen before). These trends, along with the increasing number of foodborne disease outbreaks, and increasing public concern, converged last year into an inescapable reality: without significant new resources, food safety agencies will not be able to

meet the challenges of the 21st century. Estimates cited in the report released by the Vice President in May 1997 are that every year from 6.5 million to 33 million Americans become ill and as many as 9,000 die as a result of foodborne pathogens. These illnesses and deaths are far too many. Our challenge is to continue to build the best food safety system possible and to reduce the burden of avoidable human suffering and economic loss to the greatest extent possible.

The FY 1998 Food Safety Initiative

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

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

- Build enhanced "early warning" and surveillance systems to help detect and respond to foodborne illness outbreaks, and to provide the data needed to prevent future outbreaks.

- Achieve better coordination of interagency responses to foodborne disease outbreaks including electronic communication and data exchange among Federal, State, and local health authorities.

- Develop and implement inspection strategies that provide greater assurance of the safety of foods, including implementation of Hazard Analysis Critical Control Point (HACCP) and other food safety control systems, and enhanced inspection coverage of food processors and imported foods.

- Improve risk assessment methods for foodborne pathogens and develop data bases needed to help food safety agencies to better characterize the nature and size of risk to humans and make decisions on how to best allocate resources to control the hazards.

- Expand food safety education and training particularly for consumers and retail food service workers to acquaint them with safe food processing, storage, and handling techniques.

- Conduct research to develop more effective methods for detecting, controlling, and preventing foodborne hazards.

- Continue long-range strategic planning for improving the food safety system.

The FY 1999 Food Safety Initiative

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

Surveillance

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

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

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

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

Coordination

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

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

Inspections and Compliance

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

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

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

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

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

Risk Assessment

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

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

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

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

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

Education

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

product-specific and audience-specific messages to address risks relevant to groups throughout the food chain.

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

Improve retailer and food service worker education: USDA will provide education to local school food service professionals based on the Food Code (a 1999 revision is planned). FDA and USDA will continue training for State sanitarians on new retail and restaurant food processing techniques. Development of multilingual training programs (begun in FY 1998) will be expanded.

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

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

Research

Food safety practices and programs must be science-based to effectively detect and identify pathogens, minimize their presence, assess risk, and respond to outbreaks. Basic research is needed to understand the ecology and etiology of foodborne pathogens, their genetic content, how they multiply, how they are transmitted, and under what conditions they grow. Applied research is then needed to develop the practices and technologies that will enable pathogen detection and control. To better coordinate food safety research, the FY 1999 food safety initiative includes development of an interagency process for reviewing ongoing research and identifying other research needs of FDA, Agricultural Research Service (ARS), CSREES, CDC, and EPA on the highest priority issues.

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

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

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

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

Develop microbiological baselines for pathogens on fruits and vegetables: Utilizing existing program infrastructure, USDA will conduct a scientifically-sound microbiological survey program for foodborne pathogens on domestic and imported fruits and vegetables. Program costs will be minimized by using the existing infrastructure of the Pesticide Data Program for statistically reliable sampling, participating laboratories, and data reporting capabilities.

PRESIDENT'S FOOD SAFETY INITIATVE
1999 BUDGET PROPOSAL
(Dollars in Thousands)

		1998		1999	
	1997	Appro.	Change from 1997	Request	Change from 1998
A. SURVEILLANCE					
DEPARTMENT OF AGRICULTURE:					
Food Safety and Inspection Service	$1,000	$1,500	$500	$1,500	$0
Economic Research Service	32	32	0	285	253
Subtotal, USDA	1,032	1,532	500	1,785	253
DEPARTMENT OF HEALTH AND HUMAN SERVICES:					
Food and Drug Administration	678	3,838	3,160	6,038	2,200
Centers for Disease Control	4,500	14,500	10,000	19,000	4,500
Subtotal, HHS	5,178	18,338	13,160	25,038	6,700
Subtotal, Surveillance	6,210	19,870	13,660	26,823	6,953
B. COORDINATION					
DEPARTMENT OF HEALTH AND HUMAN SERVICES:					
Food and Drug Administration	6,598	7,148	550	7,348	200
C. INSPECTIONS					
DEPARTMENT OF AGRICULTURE:					
Food Safety and Inspection Service	0	565	565	8,412	7,847
DEPARTMENT OF HEALTH AND HUMAN SERVICES:					
Food and Drug Administration	67,376	75,246	7,870	102,846	27,600
Subtotal, Inspections	67,376	75,811	8,435	111,258	35,447
D. RISK ASSESSMENT					
DEPARTMENT OF AGRICULTURE:					
Agricultural Research Service	5,461	4,498	(963)	4,818	320
Cooperative State Research, Education, and Extension Service	145	150	5	1,962	1,812
Food Safety and Inspection Service	0	0	0	1,000	1,000
Economic Research Service	33	33	0	686	653
Office of the Chief Economist	62	60	(2)	158	98
Subtotal, USDA	5,701	4,741	(960)	8,624	3,883
DEPARTMENT OF HEALTH AND HUMAN SERVICES:					
Food and Drug Administration	2,382	6,332	3,950	13,532	7,200
Subtotal, Risk Assessment	8,083	11,073	2,990	22,156	11,083

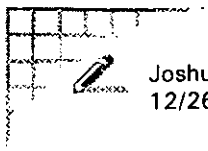
PRESIDENT'S FOOD SAFETY INITIATVE
1999 BUDGET PROPOSAL
(Dollars in Thousands)

		1998		1999	
	1997	Appro.	Change from 1997	Request	Change from 1998
E. EDUCATION					
DEPARTMENT OF AGRICULTURE:					
Cooperative State Research, Education, and Extension Service	2,365	2,365	0	7,365	5,000
Food Safety and Inspection Service	0	0	0	2,500	2,500
Food and Consumer Service	0	0	0	2,000	2,000
Office of the Chief Economist	27	38	11	38	0
Economic Research Service	420	420	0	420	0
Subtotal, USDA	2,812	2,823	11	12,323	9,500
DEPARTMENT OF HEALTH AND HUMAN SERVICES:					
Food and Drug Administration	4,415	6,485	2,070	10,085	3,600
Centers for Disease Control	0	0	0	500	500
Subtotal, HHS	4,415	6,485	2,070	10,585	4,100
Subtotal, Education	7,227	9,308	2,081	22,908	13,600
F. RESEARCH					
DEPARTMENT OF AGRICULTURE:					
Agricultural Research Service	44,186	50,351	6,165	64,001	13,650
Cooperative State Research, Education, and Extension Service	3,724	6,250	2,526	10,438	4,188
Agricultural Marketing Service	0	0	0	6,257	6,257
Subtotal, USDA	47,910	56,601	8,691	80,696	24,095
DEPARTMENT OF HEALTH AND HUMAN SERVICES:					
Food and Drug Administration	19,127	25,527	6,400	34,727	9,200
Subtotal, Research	67,037	82,128	15,091	115,423	33,295
TOTAL, INITIATIVE	162,531	205,338	42,807	305,916	100,578

PRESIDENT'S FOOD SAFETY INITIATVE
1999 BUDGET PROPOSAL
(Dollars in Thousands)

		1998		1999	
	1997	Appro.	Change from 1997	Request	Change from 1998
AGENCY TOTALS:					
DEPARTMENT OF AGRICULTURE:					
Agricultural Research Service	49,647	54,849	5,202	68,819	13,970
Cooperative State Research, Education, and Extension Service	6,234	8,765	2,531	19,765	11,000
Agricultural Marketing Service	0	0	0	6,257	6,257
Food Safety and Inspection Service	1,000	2,065	1,065	13,412	11,347
Economic Research Service	485	485	0	1,391	906
Office of the Chief Economist	89	98	9	196	98
Food and Consumer Service	0	0	0	2,000	2,000
Subtotal, USDA Initiative	57,455	66,262	8,807	111,840	45,578
DEPARTMENT OF HEALTH AND HUMAN SERVICES:					
Food and Drug Administration	100,576	124,576	24,000	174,576	50,000
Centers for Disease Control	4,500	14,500	10,000	19,500	5,000
Subtotal, HHS	105,076	139,076	34,000	194,076	55,000
TOTAL, INITIATIVE	162,531	205,338	42,807	305,916	100,578

Cons pro - food safety



Joshua Gotbaum
12/26/97 12:17:14 AM

Record Type: Non-Record

To: Elena Kagan/OPD/EOP

cc: Jim R. Esquea/OMB/EOP, Richard J. Turman/OMB/EOP, Barry T. Clendenin/OMB/EOP
Subject: FDA & CDC Funding for Food Safety Activities

As I mentioned when we met Wednesday, OMB passed back funding we believed sufficient to fulfill the President's statement. However, the budget office at HHS allocated the funds 80% to domestic initiatives. We have informed them that this is inconsistent with the President's announcement. We hope this will resolve the issue and will report back if it doesn't. Please let us know if you hear otherwise.

And thanks for the heads up.

---------- Forwarded by Joshua Gotbaum/OMB/EOP on 12/26/97 12:11 AM ----------

Jim R. Esquea
12/23/97 06:36:19 PM

Record Type: Record

To: Joshua Gotbaum/OMB/EOP@EOP, Barry T. Clendenin/OMB/EOP@EOP

cc: Richard J. Turman/OMB/EOP@EOP, Thomas Reilly/OMB/EOP@EOP, Wm G. White/OMB/EOP@EOP, Jill M. Pizzuto/OMB/EOP@EOP
Subject: FDA & CDC Funding for Food Safety Activities

You asked that we provide you with an assessment of the OSTP staff complaint that FDA and CDC have not been provided enough funding to meet the Administration's stated goals in the President's Food Safety Initiative.

FDA's Food Safety Import Funding Level

The passback for FDA included $24 million in FDA's base to continue food safety initiative activities begun in FY 1998 and an additional $25 million to fund food import inspection activities and some expanded domestic food safety activities, for a total food safety initiative level of $49 million.

When we passed back the $25 million for FDA (we also passed back $5 million for CDC food safety), we advised HHS that this was all the additional funding they would be getting to cover additional FDA food safety initiative activities and the President's food safety commitments. We did not passback a split for domestic and international food safety and left it to HHS' judgment, assuming that HHS would allocate the funds to meet the President's most recent import inspection commitment.

In previous discussions with FDA, we determined that FDA could reasonably obligate in FY

1999 at least $15 million to develop a comprehensive international import inspection program and hire over 60 international import inspectors (FDA currently has roughly four FTEs doing international inspection). With such an increase, FDA will be able to evaluate/investigate the food safety systems of 50 to 55 countries phased in over two years.

HHS Advised FDA to Spend Less on Imports

Instead of adequately funding the food import inspection initiative to meet the President's commitment to "dramatically expanding" FDA's food import inspections, HHS apparently advised FDA that of the $25 million we passed back, $20 million was for domestic food safety and $5 million for the President's Food Import inspection initiative.

We spoke to Bill Beldon today at ASMB and advised him that the HHS split for domestic and food import was not sufficient to meet the President's commitment for food import inspections and that FDA would need at least $15 million, although we were not precluding HHS from allocating more than $15 million to import inspections of the total $25 million passed back for food safety. Bill acknowledged our concern and said he would communicate this concern to the rest of ASMB and FDA.

It is our considered judgment that the additional $25 million (+20% over the FY 1998 enacted level for FDA food safety activities) that was passed back to FDA will be enough to meet the Administration's commitments on food safety in FY 1999, but the funds need to be allocated according to Administration priorities i.e., the majority of the $25 million should go to import inspection.

Funding for FDA Food Safety Activities in the FY99 Budget
(BA -- $ in Millions)

	FY97 Enacted	FY98 Budget	FY98 Enacted	FY99 HHS Req.	FY99 OMB Rec.	FY99 HHS Appeal
Food Safety, Total Activities	100.7	124.7	124.7	213	149.7	188.8
Initiative Funding *(Non-adds)*		(24)	(24)	(112)	(49)	(88)

Analysis of OSTP Concern Re: CDC Food Safety Funding

In the attached e-mail OSTP staff states that "$5 million would not enable CDC to put in place the early warning system the President promised last January." We assume OSTP is referring to the "Food Safety: From Farm to Table" initiative announced to support the FY 1998 Budget. If this is the case, the statement is not accurate.

The Food Safety initiative announced by the President last January (and subsequently summarized in a May 1997 report prepared by EPA, HHS and USDA) outlined specific policies and resource levels for **FY 1998.** While the interagency report identified some "long-term" activities, it did not identify specific resource levels for FY 1999 or other outyears. Specifically, the initiative proposed an additional $10 million for CDC in FY 1998 (a 222% increase) over FY 1997 to expand from five to eight the number of "Foodnet" active surveillance sentinel sites that conduct

epidemiological research on foodborne pathogens, as well as expand the use of molecular "finger-printing" technology to identify the source of infectious agents.

Congress enacted the resources proposed in the FY 1998 Food Safety initiative for CDC. The OMB recommended level for FY 1999 is a $5 million (+34%) increase over the level proposed by the President in FY 1998 for CDC, but lower than the $21 million (+145%) increase requested by HHS for FY 1999. The OMB recommendation would allow CDC to build upon the activities that CDC will conduct in FY 1998, although not to the level that HHS would like. HHS is appealing for an additional $5 million over the OMB recommendation in FY 1999.

Funding for CDC Food Safety Activities in the FY99 Budget
(BA -- $ in Millions)

	FY97 Enacted	FY98 Budget	FY98 Enacted	FY99 HHS Req.	FY99 OMB Rec.	FY99 HHS Appeal
CDC Surveillance	4.5	14.5	14.5	35.5	19.5	24.5

Jim R. Esquea
12/29/97 07:11:50 PM

Record Type: Record

To: Elena Kagan/OPD/EOP

cc: See the distribution list at the bottom of this message
Subject: FDA & CDC Funding for Food Safety Activities

Josh Gotbaum asked that I forward the attached E-mail to you re: FDA & CDC food safety funding.

As noted in the attachment, HHS was provided an additional $25 million over the FY 1998 enacted level of $24 million for FDA food safety activities. HHS was advised that the additional $25 million was to be used to meet the President's food safety commitments.

HHS instructed FDA to use $5 million of the $25 million for import inspection and the balance for domestic food safety activities. We spoke to HHS staff and advised them that $5 million was not sufficient for import inspection and that a greater portion of the $25 million was to be dedicated to international import inspection. We will keep you updated if there are further developments.....

---------- Forwarded by Jim R. Esquea/OMB/EOP on 12/29/97 06:17 PM ----------

Jim R. Esquea
12/23/97 06:36:19 PM

Record Type: Record

To: Joshua Gotbaum/OMB/EOP@EOP, Barry T. Clendenin/OMB/EOP@EOP

cc: Richard J. Turman/OMB/EOP@EOP, Thomas Reilly/OMB/EOP@EOP, Wm G. White/OMB/EOP@EOP, Jill M. Pizzuto/OMB/EOP@EOP
Subject: FDA & CDC Funding for Food Safety Activities

You asked that we provide you with an assessment of the OSTP staff complaint that FDA and CDC have not been provided enough funding to meet the Administration's stated goals in the President's Food Safety Initiative.

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When we passed back the $25 million for FDA (we also passed back $5 million for CDC food safety), we advised HHS that this was all the additional funding they would be getting to cover additional FDA food safety initiative activities and the President's food safety commitments. We did not passback a split for domestic and international food safety and left it to HHS' judgment, assuming that HHS would allocate the funds to meet the President's most recent import inspection commitment.

Cons Pro - Food safety

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

Ek -
FYI. USDA disagrees with the decision by OMB to say user fees will pay for food safety. Raines made the decision. Evidently they have done this ~~in the past~~ last year as well.
Tom

January 6, 1998

Honorable Franklin D. Raines
Director
Office of Management and Budget
Room 252 Old Executive Office Building
Washington. D.C. 20503

Dear Frank:

My staff advises me that OMB has decided to change the presentation of the meat and poultry inspection user fee proposal in the budget. They tell me that our "current law" appropriations request will anticipate enactment of the user fees, and therefore will request only $150 million rather than the full $620 million which would be required to operate the program under current law.

I am writing to urge you to reconsider this decision. I realize that there are budgetary reasons for this sort of presentation, but it really creates some problems from a policy perspective. It will allow some in Congress to accuse the Administration of having under funded the meat and poultry inspection program and raise questions about the seriousness of our overall commitment to food safety. It also sets the stage for a crisis later in the year if the Congress does not enact user fee legislation, and we have to find a way to fund the appropriations requirements of the program or shut it down.

We intend to work hard to secure enactment of the user fee legislation. I do not think our cause is helped, however, by a budget presentation which raises questions about our commitment to food safety.

Sincerely,

DAN GLICKMAN
Secretary

Cms pro - food safety

11-21 Food Safety Mtg - USDA/FDA

Outline is basis for report
not exhaustive report - some detail but flexible
good for consumer, but doesn't scare ind.

Science based
Food genome project - corn/rice etc.
bred plants that will be resistant to pests
provide higher yields/
resistant to pests ⇒ no pesticides
feed animals " " - disease ??

+50 on farms

cattle
sheep
swine
poultry

Expanded retail site program
Doubles # of cities

FDA Research re how to identify pathogens -
especially as regards seafood

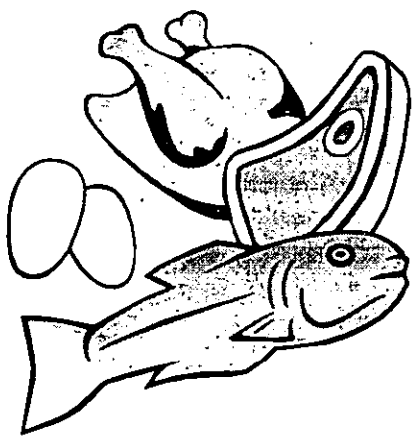
Petroleum - not much -
a bit in USDA

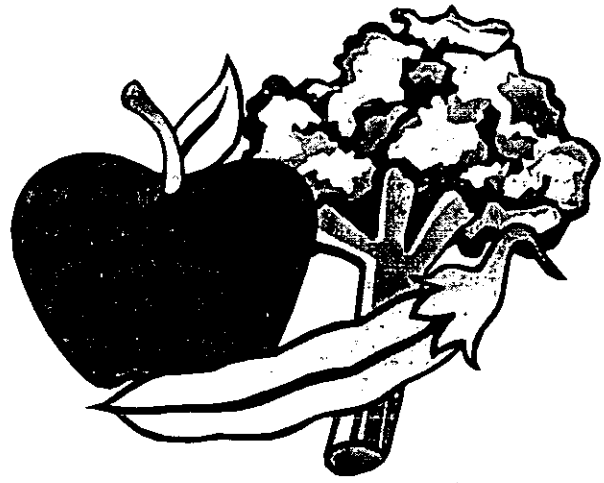
Education ⇒ producers/consumers

Cons pro - food safety

PRESIDENT'S FOOD SAFETY INITIATIVE

USDA - HHS





October 27, 1997

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

EXECUTIVE SUMMARY

A Consolidated, Multi-Agency Plan for Improving Food Safety

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

The Administration, through a Presidential Directive issued on October 2, 1997, is taking additional actions to improve the safety of domestic and imported fresh fruits and vegetables. The President has proposed additional funds to enable the Food and Drug Administration (FDA) to expand dramatically its coverage of imported foods and will send to the Congress legislation that would enable FDA to halt imports of fruits, vegetables, or other foods from any foreign country whose food safety systems are not on par with those of the United States. In addition, the President has directed the Secretaries of the Department of Health and Human Services (HHS) and the U.S. Department of Agriculture (USDA) to work together with the agricultural community to develop guidance on good manufacturing practices and good agricultural practices for fruits and vegetables as well as to accelerate food safety research, education, and outreach to prevent importation of unsafe products. FDA, working with USDA, will undertake development of these guidelines, and public outreach to the broad agricultural community.

The impetus to focus significant Federal attention on food safety came from a number of sources. The most important of these sources is the rapidly increasing number and complexity of food safety issues (such as newly recognized pathogens and their sudden appearance on foods, such as fresh produce, where they had not been seen before). These trends, along with increasing foodborne disease outbreaks, and increasing public concern, converged last year into an inescapable reality: without

significant new resources, food safety agencies will not be able to meet the challenges of the 21st century. Estimates cited in the report released by the Vice President in May 1997 are that every year from 6.5 million to 33 million Americans become ill and as many as 9,000 die as a result of foodborne pathogens. These illnesses and deaths are far too many. Our challenge is to continue to build the best food safety system possible and to reduce the burden of avoidable human suffering and economic loss to the greatest extent possible.

The FY 1998 Food Safety Initiative

The FY 1998 budget was designed to support the President's National Food Safety Initiative through a request for an additional $43 million for USDA, FDA, and the Centers for Disease Control and Prevention (CDC) food safety proposals. This initiative, the first installment of a major governmentwide effort to enhance the safety of the Nation's food supply, has won wide support among industry and consumer groups and the general public. Based on the latest action for the 1998 appropriations bill, Congress would fund all but $2 million for education activities of this initiative.

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

- Build enhanced "early warning" and surveillance systems to help detect and respond to foodborne illness outbreaks, and to provide the data needed to prevent future outbreaks.

- Achieve better coordination of interagency responses to foodborne disease outbreaks including electronic communication and data exchange among Federal, State, and local health authorities.

- Develop and implement inspection strategies that provide greater assurance of the safety of foods, including Hazard Analysis Critical Control Point (HACCP) and other food safety control systems, and enhanced inspection coverage of food processors and imported foods.

- Improve risk assessment methods for foodborne pathogens and develop data bases needed to help food safety agencies to better characterize the nature and size of risk to humans and make decisions on how to best allocate resources to control the hazards.

- Expand food safety education and training particularly for consumers and retail food service workers to acquaint them with safe food processing, storage, and handling techniques.

- Conduct research to develop more effective methods for detecting, controlling, and preventing foodborne hazards.

The FY 1999 Food Safety Initiative

The FY 1999 Food Safety Initiative further reflects the coordination between the Federal food safety agencies and builds on the key components identified in the FY 1998 initiative: surveillance; coordination; inspections and compliance; education; research and risk assessment. A new focus is being placed on enhancing the safety of domestic produce and imported fruits and vegetables, improving the food handling practices of school food service providers, and develop information and tools necessary to cover a broader range of food safety hazards.

Surveillance

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

Enhance surveillance and investigative systems: CDC, FDA and USDA will direct additional resources to FoodNet sites and other State and local health departments to expand the range of pathogens under surveillance, to begin implementing and evaluating control strategies, and to facilitate intrastate, interstate, and State-Federal information sharing.

Epidemiologic and technical studies of emerging and drug-resistant pathogens and other contaminants: FDA will work with CDC and USDA to monitor and reduce the incidence of foodborne disease associated with emerging and drug-resistant pathogens. CDC will provide critical training and technical assistance to State and local health agencies to conduct investigations for evidence of pathogens and contaminants in food and to support development of better diagnostic assays for toxins in clinical specimens.

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

Coordination

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

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

Establish a Federal-State-local employee exchange: FDA, USDA and CDC will cooperate with other Federal agencies to establish a program to improve outbreak coordination through exchange of employees among Federal, State, and local food safety programs.

Inspections and Compliance

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

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

Increase capabilities of automated systems for inspection reporting: USDA and FDA will work together to improve the capabilities of automated systems for compiling inspection data on imports, retail foods, and milk and to standardize inspection reports and reporting of results, and for rapid sharing of inspection results, including information about imported products, among Federal, State, and local food safety agencies.

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

Develop country profiles: USDA, working with FDA, will develop country profiles assessing the in-country safety parameters and likelihood of meeting U.S. entry requirements for fresh produce.

Expand HACCP and HACCP training: FDA, working with USDA, and through industry partnerships, will expand HACCP in appropriate sectors of the food industry, such as implementing HACCP in the juice industry. USDA will expand HACCP training for meat and poultry products, emphasizing processes exempt from continuous inspection.

Develop assistance and outreach to State and local programs: FDA will work with USDA to expand efforts to achieve adoption of the Food Code by all 50 States. USDA will provide an annual fund of $150 for each school-lunch self-preparation facility to support a minimum of two independent health and safety inspections per year.

Risk Assessment

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. Risk assessment also focuses data collection and scientific research in the most critical areas. Working together, the Federal agencies with food safety and risk assessment responsibilities will build on and expand efforts already underway through the National Food Safety Initiative announced in May 1997. Intensive work is needed to develop better risk assessment methods and models to make it possible to carry out quantitative risk assessments for microbial agents.

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

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

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

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

Education

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

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

Improve retailer and food service worker education: USDA will provide education to local school food service professionals based on the Food Code (a 1999 revision is planned). FDA and USDA will continue training for State sanitarians on new retail and restaurant food processing techniques. Development of multilingual training programs (begun in FY 1998) will be expanded.

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

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

Research

Food safety practices and programs must be science-based to effectively detect and identify pathogens, minimize their presence, assess risk, and respond to outbreaks. Basic research is needed to understand the ecology and etiology of foodborne pathogens, their genetic content, how they multiply, how they are transmitted, and under what conditions they grow. Applied research is then needed to develop the practices and technologies that will enable pathogen detection and control. To better coordinate food safety research, the FY 1999 food safety initiative includes development of an interagency process for reviewing ongoing research and identifying other research needs of FDA, Agricultural Research Service (ARS), CSREES, CDC, and EPA on the highest priority issues.

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

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

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

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

PRESIDENT'S FOOD SAFETY INITIATVE
1999 BUDGET PROPOSAL
(Dollars in Millions)

	1997	1998 Budget	1998 Change from 1997	1999 Request	1999 Change from 1998
A. SURVEILLANCE					
DEPARTMENT OF AGRICULTURE:					
Food Safety and Inspection Service	$1.0	$1.5	$0.5	$1.5	0.0
Economic Research Service	0.0	0.0	0.0	0.5	$0.5
Subtotal, USDA	1.0	1.5	0.5	2.0	0.5
DEPARTMENT OF HEALTH AND HUMAN SERVICES:					
Food and Drug Administration	6.7	9.9	3.2	15.3	5.4
Centers for Disease Control	4.5	14.5	10.0	32.8	18.3
Subtotal, HHS	11.2	24.4	13.2	48.1	23.7
Subtotal, Surveillance	12.2	25.9	13.7	50.1	24.2
B. COORDINATION					
DEPARTMENT OF HEALTH AND HUMAN SERVICES:					
Food and Drug Administration	0.7	1.3	0.6	2.3	1.0
C. INSPECTIONS					
DEPARTMENT OF AGRICULTURE:					
Food Safety and Inspection Service	0.0	0.6	0.6	11.0	10.4
Foreign Agricultural Service	0.0	0.0	0.0	3.0	3.0
Food and Consumer Service	0.0	0.0	0.0	10.5	10.5
Subtotal, USDA	0.0	0.6	0.6	24.5	23.9
DEPARTMENT OF HEALTH AND HUMAN SERVICES:					
Food and Drug Administration	67.4	75.3	7.9	108.4	33.1
Subtotal, Inspections	67.4	75.9	8.5	132.9	57.0
D. RISK ASSESSMENT					
DEPARTMENT OF AGRICULTURE:					
Agricultural Research Service	5.5	5.9	0.4	6.4	0.5
Cooperative State Research, Education, and Extension Service	0.7	1.2	0.5	1.2	0.0
Food Safety and Inspection Service	0.0	0.0	0.0	1.0	1.0
Economic Research Service	0.0	0.0	0.0	1.0	1.0
Office of the Chief Economist	0.1	0.1	0.0	0.1	0.0
Subtotal, USDA	6.3	7.2	0.9	9.7	2.5
DEPARTMENT OF HEALTH AND HUMAN SERVICES:					
Food and Drug Administration	2.4	6.3	3.9	24.4	18.1
Subtotal, Risk Assessment	8.7	13.5	4.8	34.1	20.6

PRESIDENT'S FOOD SAFETY INITIATVE
1999 BUDGET PROPOSAL
(Dollars in Millions)

		1998		1999	
	1997	Budget	Change from 1997	Request	Change from 1998
E. EDUCATION					
DEPARTMENT OF AGRICULTURE:					
Cooperative State Research, Education, and Extension Service	2.4	4.4	2.0	7.4	3.0
Food Safety and Inspection Service	0.0	0.0	0.0	2.5	2.5
Food and Consumer Service	0.0	0.0	0.0	2.0	2.0
Economic Research Service	0.4	0.4	0.0	0.4	0.0
Subtotal, USDA	2.8	4.8	2.0	12.3	7.5
DEPARTMENT OF HEALTH AND HUMAN SERVICES:					
Food and Drug Administration	4.4	6.4	2.0	16.9	10.5
Centers for Disease Control	0.0	0.0	0.0	2.7	2.7
Subtotal, HHS	4.4	6.4	2.0	19.6	13.2
Subtotal, Education	7.2	11.2	4.0	31.9	20.7
F. RESEARCH					
DEPARTMENT OF AGRICULTURE:					
Agricultural Research Service	44.2	47.9	3.7	62.4	14.5
Cooperative State Research, Education, and Extension Service	2.6	6.2	3.6	12.2	6.0
Agricultural Marketing Service	0.0	0.0	0.0	6.3	6.3
Subtotal, USDA	46.8	54.1	7.3	80.9	26.8
DEPARTMENT OF HEALTH AND HUMAN SERVICES:					
Food and Drug Administration	19.1	25.5	6.4	45.7	20.2
Subtotal, Research	65.9	79.6	13.7	126.6	47.0
TOTAL, INITIATIVE	162.1	207.4	45.3	377.9	170.5

PRESIDENT'S FOOD SAFETY INITIATVE
1999 BUDGET PROPOSAL
(Dollars in Millions)

		1998		1999	
	1997	Budget	Change from 1997	Request	Change from 1998
AGENCY TOTALS:					
DEPARTMENT OF AGRICULTURE:					
Agricultural Research Service	$49.7	$53.8	$4.1	$68.8	$15.0
Cooperative State Research, Education, and Extension Service	5.7	11.8	6.1	20.8	9.0
Agricultural Marketing Service	0.0	0.0	0.0	6.3	6.3
Food Safety and Inspection Service	1.0	2.1	1.1	16.0	13.9
Economic Research Service	0.4	0.4	0.0	1.9	1.5
Office of the Chief Economist	0.1	0.1	0.0	0.1	0.0
Food and Consumer Service	0.0	0.0	0.0	12.5	12.5
Foreign Agricultural Service	0.0	0.0	0.0	3.0	3.0
Subtotal, USDA	56.9	68.2	11.3	129.4	61.2
DEPARTMENT OF HEALTH AND HUMAN SERVICES:					
Food and Drug Administration	100.7	124.7	24.0	213.0	88.3
Centers for Disease Control	4.5	14.5	10.0	35.5	21.0
Subtotal, HHS	105.2	139.2	34.0	248.5	109.3
TOTAL, INITIATIVE	162.1	207.4	45.3	377.9	170.5

SURVEILLANCE

OVERVIEW

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 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. In addition, the data collected from surveillance activities need to be analyzed to determine the economic consequences of policies and programs which reduce foodborne disease incidence and their associated medical costs and productivity losses.

GOAL

Gain greater understanding of foodborne illness outbreaks by enhancing the capacity of States to monitor foodborne disease and to investigate and control outbreaks.

STRATEGY

In cooperation with State and local health departments, the Federal Government has established an early-warning system for foodborne diseases. Foodborne infections can be identified, investigated, and tracked through enhanced State and local capacity, including building laboratory capacity, performing molecular subtyping, and the activities of FoodNet.

OBJECTIVES

- Increase laboratory testing capability, including subtyping methods for pathogens.

- Enhance basic foodborne disease surveillance and control activities, including standard molecular subtyping methodologies for bacterial foodborne pathogens and make them available in 22 States.

- Expand the scope of activities of the active surveillance network (FoodNet) to include bacterial and parasitic foodborne pathogens.

- Collaborate with the World Health Organization, other international health organizations, and major exporting countries to enhance foodborne disease surveillance activities in other countries.

- Identify pesticides and toxicants of highest concern for foodborne illness using National Health and Nutrition Examination Survey (NHANES) data.

- Expand antimicrobial resistance monitoring of animal and animal food isolates to assess the impact of various interventions and control efforts. The identification and containment of resistance as a result of these monitoring programs will help ensure the continued effectiveness of both human and veterinary drugs, and aid in increasing the availability and distribution of effective drugs.

- Enhance microbiologic monitoring and surveillance activities related to pathogen reduction under HACCP.

- Expand analysis in the area of foodborne pathogens in food animal populations.

- Refine existing economic estimates of the costs of foodborne illness based on better estimates of the extent of foodborne disease in the U.S. and develop new estimates of foodborne illness costs for additional pathogens as well as acute and chronic diseases.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
FY 1999 BUDGET REQUEST

SURVEILLANCE -- $18.3 million

One of CDC's major areas of expertise is surveillance of human health. However, the current public health system in the United States has limited means to identify, track, and characterize the causes of foodborne illness. A more effective early warning system is needed to detect and stop outbreaks quickly before they affect large numbers of people. In addition, improved information on the occurrence and epidemiologic features of priority pathogens, *E. coli O157:H7*, *Cyclospora*, Hepatitis A virus, *Salmonella*, and *Shigella*, may provide important information to reduce the risk of contamination and subsequent foodborne illness.

Active Surveillance Network (FoodNet):

- Reduce the incidence of foodborne illness by enhancing local, State, and Federal ability to conduct epidemiologic and laboratory surveillance and response, research, prevention and control activities, and training.

  Performance Measure: Expand the scope of activities of the active surveillance network (FoodNet) to include bacterial and parasitic foodborne pathogens.

Basic Foodborne Disease Surveillance and Control Activities, Including Standard Molecular Subtyping Methodologies:

- Increase national and international surveillance and response for foodborne illness by improving epidemiology and laboratory capacities.

  Performance Measure: Enhance the basic foodborne disease surveillance and control activities, including standard molecular subtyping methodologies for bacterial foodborne pathogens, in 22 States.

  Performance Measure: Collaborate with international health organizations and major exporting countries to improve foodborne disease surveillance and control activities.

  Performance Measure: Identify pesticides and toxicants of highest concern for foodborne illness using NHANES data.

National Data Bank and Subtyping Network:

- Further develop the computer network and database system which captures fingerprints of pathogens in a national database, linking CDC, FDA, FSIS, and States that have the capacity.

  Performance Measure: Expand the National Data Bank and Subtyping Network (DNA Fingerprinting) by increasing the number of State and Federal laboratories in the network from 10 to 20, and by adding *Salmonella typhimurium* to the database.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
FY 1999 BUDGET REQUEST

SURVEILLANCE -- $5.4 million

The Food Safety Initiative stresses the imperative of food safety "from farm to table." FDA will participate in food safety surveillance at the farm level and at points of distribution before food comes to the table. Improved surveillance is a key component of the "early warning" system for foodborne disease because surveillance activities provide the basis for establishing better techniques and strategies to detect and track the magnitude of foodborne disease outbreaks, sharing information and providing exposure assessment data for risk management decision makers, and monitoring the success of prevention, control, and education programs.

For FY 1999, FDA requests a total of $5.4 million. FDA will engage in a number of activities to achieve its goal of expanding a national "early-warning" system to help detect and respond to outbreaks of foodborne illness earlier and provide data needed to help prevent future outbreaks. FDA will increase a number of its efforts related to establishing an effective "early warning" system. These include working with other Federal and State agencies to enhance the monitoring and surveillance of foodborne disease, to upgrade the national surveillance system for foodborne infections in humans, to enhance microbiologic monitoring and surveillance activities related to pathogen reduction under HACCP, and to develop better techniques for characterizing foodborne pathogen isolates.

FY 1999 Activities:

- Surveillance Systems. Support sentinel sites to allow appropriate geographic diversity of the network, and cover a greater proportion of the U.S. population and a greater spectrum of new and re-emerging pathogens, including parasites and viruses that can be transmitted through foods.

- Surveillance Studies. Enhance microbiologic monitoring and surveillance activities related to pathogen reduction under HACCP.

- Antibiotic Resistance in Foodborne Pathogens. An expansion in this area, namely in the systematic collection, analysis, and interpretation of antimicrobial susceptibility surveillance data, will enable FDA to ensure accurate and valid information that can be used to further minimize the transmission of resistant pathogens through the food chain. The early identification of emerging resistance will allow FDA to focus education efforts in the human and veterinary communities. Continued and expanded monitoring will allow assessment of the impact of various interventions and control efforts. The identification and containment of resistance

as a result of these monitoring programs will help ensure the continued effectiveness of both human and veterinary drugs, and aid in increasing the availability and distribution of effective drugs.

- Foodborne Pathogens in Food Animal Populations. Timely and improved information about the type and extent of infections in food-producing animals, animal carriage of human pathogens, and increased knowledge concerning related factors, will provide a foundation for regulatory decisions, and education campaigns. Ultimately, recommendations derived from study findings will allow improved animal husbandry practices and safer foods.

DEPARTMENT OF AGRICULTURE
ECONOMIC RESEARCH SERVICE
FY 1999 BUDGET REQUEST

SURVEILLANCE -- $0.5 million

Foodborne illnesses cause an estimated $6 billion - $35 billion annually in medical costs and productivity losses for the seven pathogens analyzed to date. Existing research on the costs associated with foodborne illness and the benefits of improving food safety are subject to some uncertainty. Estimates of medical costs and productivity losses from foodborne illness are available only for diseases caused by 7 microbial pathogens; while evidence suggests that as many as 40 bacteria, parasites, or viruses in food may cause illness or death. In addition, current estimates of the costs of foodborne disease are based on imprecise estimates of disease incidence and severity. For many foodborne diseases we can only express the number of cases and the number of deaths as a range of possible values.

Through collaboration with CDC and FSIS, ERS will develop new estimates of the national incidence of foodborne disease, evaluate the distribution of illness among sub-populations, and study mortality and rates for specific illnesses. We will use this new data to refine estimates of the costs of illness from specific foodborne diseases, to narrow the confidence intervals for specific cost-of-illness measures, and to include new foodborne pathogens in the cost estimates. Better estimates of the benefits of safer food will enable USDA to make better cost/benefit assessments of programs and policies which increase their safety. Also, this information will allow for tracking success over time in achieving the goal of a safer food supply.

FY 1999 Activities:

- Develop better estimates of the extent of foodborne disease in the U.S.
- Refine existing economic estimates of the costs of foodborne illness.
- Develop new estimates of foodborne illness costs for additional pathogens, acute and chronic diseases, and public health outcomes.
- Evaluate the economic consequences for consumers of policies and programs which reduce foodborne disease incidence and their associated medical costs and productivity losses.

COORDINATION

OVERVIEW

PROBLEM

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. Joint efforts are often hindered by a lack of communication or a misunderstanding of each agency's role in a particular situation.

GOAL

Enhance the level of public health protection by improving coordination among State and Federal agencies responsible for responding to foodborne disease outbreaks.

STRATEGY

Working together, agencies with risk management responsibility will build upon and expand efforts already underway under the President's Food Safety Initiative. Federal agencies and State representatives have formed an intergovernmental group, the Foodborne Outbreak Response Coordinating Group (FORCG), to evaluate and make recommendations for improving response to interstate outbreaks of foodborne illness. This group has begun its review of the response to foodborne illness outbreaks. A contract has been awarded to the National Association of State Departments of Agriculture to catalog Federal and State statutes covering food to assist in reviewing existing food safety infrastructure at the Federal, State, and local level. This cooperative effort will be continued and expanded in an effort to provide rapid, efficient response to foodborne outbreaks and minimize their spread.

OBJECTIVE

- Federal agencies will work to expand assistance to States and local governments in developing the infrastructure necessary to ensure proper detection, evaluation, and coordination in response to foodborne outbreaks.

- Federal agencies will cooperate in establishing a program to improve outbreak coordination through the exchange of employees among Federal, State, and local food safety programs and within State and local programs.

- The agencies will plan and hold a series of meetings with stakeholders on specific issues identified in the food safety initiative (e.g., risk assessment and research priorities, educational programs and approaches). Obtain input on the effectiveness of the food safety initiative, stakeholders views on food safety program needs and priorities. Analyze the results of stakeholder meetings to develop GPRA performance measures and to help establish future directions for the Food Safety Program.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
FY 1999 BUDGET REQUEST

COORDINATION -- $1.0 million

Improved coordination among Federal and State agencies is essential to the efforts to more effectively manage and respond to interstate foodborne illness outbreaks. With its $1.0 million request, FDA will increase its efforts to work with other Federal agencies to develop and implement systems and procedures that will ensure more coordinated and rapid responses to foodborne illness outbreaks in order to achieve its goals of enhancing the level of public health protection by improving coordination among State and Federal agencies responsible for responding to foodborne disease outbreaks.

Reducing the response time to illness outbreaks could significantly reduce the adverse health and economic impacts of food related health emergencies. Other important advantages of enhanced coordination include an increased ability to leverage resources and experience of other agencies and to eliminate duplication of effort.

FY 1999 Activities:

- Work with other Federal agencies to expand assistance to States and local governments in developing the infrastructure necessary to ensure proper detection, evaluation, communication, and coordination in response to foodborne outbreaks.

- Cooperate with other Federal agencies in establishing a program to improve outbreak coordination through the exchange of employees among Federal, State, and local food safety programs, and within State and local programs.

- Plan and hold a series of meetings, in cooperation with CDC and USDA, with stakeholders on specific issues identified in the food safety initiative (e.g., risk assessment and research priorities, educational programs and approaches, as well as compliance monitoring and other regulatory activities) to obtain input on the effectiveness of the food safety initiative, stakeholder views on food safety regulatory, research, and educational needs as well as determine food safety priorities.

INSPECTIONS AND COMPLIANCE

OVERVIEW

PROBLEM

Monitoring the food supply to ensure its safety must occur at several levels to be effective: Federal assessment of agricultural and production practices in foreign countries, Federal oversight of imported and domestic products in the U.S., and local oversight of food processing and manufacturing facilities, retail food, food service, and institutional establishments such as school lunch programs. During the past several years, and in conjunction with changing lifestyles, consumers are demanding more variety and convenience in the food supply. They want a wider variety of fresh fruits and vegetables available year-round and more convenient and easily prepared. The number of entries of all FDA-regulated imported food products has doubled in the past 5 years while the number of entries examined has dropped by 50 percent. Likewise, the number of FDA inspections of domestic food plants has fallen precipitously from 21,000 in the 1980's to 5,000 in 1997. Approximately 93,000 schools are the responsibility of 23,000 school food authorities providing lunches to about 26 million children every day; 70,000 of these lunches are prepared by the schools. Currently, school food service operations are the responsibility of local agencies and many schools receive little or no oversight on food safety. Because children are at a relatively greater risk of contracting foodborne illness, school food service providers need to take additional precautions to ensure the safety of the food they prepare.

GOALS

Develop and implement more efficient and effective procedures for monitoring the safety of the Nation's food supply at all levels.

STRATEGY

Working together, FDA, USDA, CDC, and EPA will build upon and expand efforts already underway under the President's Food Safety Initiative and implement the President's directive on domestic and imported produce and imported foods. These include: expanded efforts to ensure that food products offered for entry to the U.S. from foreign countries meet our safety standards; development of Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs) for fresh produce; continued emphasis on seafood HACCP to assure inspection of the seafood industry by the end of FY 1999, expanded HACCP in other appropriate segments of the food industry and the adoption of the Food Code; expanded HACCP training for State meat and poultry

inspectors and local public health officials; extended laboratory certification process; and development of additional partnerships between agencies at the Federal, State, and local level.

OBJECTIVES

- Agencies will work together to increase capabilities in the area of automated systems (e.g., an inspection database and Federal/State communication system on imports, and for cooperative programs including retail foods and milk) for standardization of inspection reports and results reporting, for rapid sharing of inspection results, and for information about imported products among major food safety organizations, including USDA, FDA, CDC, the States and local health departments;

- Agencies will increase monitoring of the safety of fresh fruits and vegetables;

- FDA, working with USDA, will develop and issue GAP's and GMP's guidance to minimize microbial hazards in fresh produce;

- FDA will develop proposed legislation to amend the Food, Drug, and Cosmetic Act to assure that imported products are produced under systems that provide the same level of protection as the U.S. system for production of domestic products;

- USDA will document known relative measures or practices affecting the safety of U.S. food imports or targeted problem regions. Working cooperatively with FDA, USDA will establish country profiles assessing the in-country safety parameters and likelihood of meeting U.S. entry requirements for fresh produce;

- Based on the country profiles, FDA will evaluate growing, harvesting, handling, transportation and production facilities of foreign countries;

- USDA will provide an annual fund of $150 for each self-preparation facility providing school lunches to support a minimum of two independent health and safety inspections each school year;

- FDA, working with USDA and through partnerships, will expand HACCP in appropriate segments of the food industry. This will include efforts to more promptly verify implementation of the seafood HACCP regulation, and to implement HACCP systems in appropriate non-seafood segments of the industry, such as the juice industry;

- USDA will expand training for the meat and poultry industry, including information on: HACCP; safe handling techniques and storage temperatures during transportation; and microbial hazards. Emphasis will be on processes that are exempt from continuous inspection by Federal or State "equal-to" programs and are inspected by State or local agencies (e.g., curing, smoking, grinding, fabrication, stuffing, cooking/cooling, and packaging);

- FDA will work with USDA and expand efforts to achieve adoption of the Food Code by all 50 States; and

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
FY 1999 BUDGET REQUEST

INSPECTIONS AND COMPLIANCE -- $33.1 million

This request will provide an additional $33.1 million to enhance FDA's coverage of the food supply and meet the agency's goal of developing and implementing more efficient and effective procedures for monitoring the Nation's food supply. Inspection coverage for both domestic and imported food products has declined significantly over the past decade. Domestic establishment inspections have declined from approximately 21,000 annually in the early 1980s to around 5,000 in recent years. At the current inspection level, FDA visits a food establishment on an average of once every 10 years. The number of inspections conducted by States under contract to FDA also declined from 12,000 in 1985 to approximately 5,000 today.

In addition, the globalization of the food supply has resulted in dramatic increases in imported foods over the past decade. During the period between FY 1991 to FY 1996 the number of import food entries went from 1.1 million to 2.2 million per year —an increase of 100 percent. Without additional resources to keep pace with this increase, the level of coverage of imported foods dropped from about 7 percent in FY 1991 to 3 percent in FY 1996. The level of coverage for imported fresh fruits and vegetables, which is approximately 0.2 percent, is much lower than the overall coverage of imported products, and is expected to decline as the number of imports continues to increase without additional resources.

With the additional resources, FDA will work to further enhance its ability to more efficiently and effectively monitor the food supply. Emphasis will be on expanding implementation of HACCP and other quality control systems in the food industry, increasing the number of Federal-State inspection partnerships, and expanding efforts to certify private laboratories to conduct food-related analyses. In addition, FDA will work to significantly enhance the safety of domestic and imported fresh produce through the development of guidance in the form of GMP's and GAP's, expanded sampling and analysis of these products and developing and implementing evaluations of growing, harvesting, handling, and production facilities in foreign countries.

FY 1999 Activities:

- Expand implementation of HACCP in appropriate segments of the food industry. This will include efforts to more promptly verify the implementation of the seafood HACCP regulation; and to implement HACCP systems in an appropriate non-seafood segment of the food industry.

- Expand efforts to enhance the safety of foods by working to achieve adoption of the Food Code, by all 50 States.

- Work with other Federal agencies, including USDA, CDC, EPA, and the Occupational Safety and Health Administration (OSHA), to implement strategies to improve the safety of fresh produce.

  - Based on country profiles compiled by USDA, FDA will evaluate growing, harvesting, handling, transportation and production facilities of foreign countries.

  - USDA and FDA will work with all affected parties (I.e., producers, distributors, public health authorities, etc.) to communicate fresh fruits and vegetable GAPs.

- Undertake other efforts to enhance coverage of imported produce. This will include:

  - Reviewing and evaluating ways to increase coverage of imports through such means as increased personnel, and increased programs to ensure safe foods.

  - Collecting and analyzing approximately 1,000 samples to document inspection findings and determine the status of products offered for entry into the U.S.

- Undertake other efforts to enhance general coverage of other imported food products. This will include:

  - Expanding the Federal/State communication system with the States to inform Federal agencies of problems found with imported products in their jurisdictions.

- Expand efforts to significantly reduce the average time between inspections, especially for the highest risk food products, (e.g., through new partnerships). This will include:

  - Working more closely with other Federal agencies, industry, professional and trade associations, and academia to assure effective implementation of HACCP, particularly at the production, processing, and retail levels.

  - Working with USDA to create a data system to compile inspection data from Federal and State inspections.

- Expand and implement automated systems for Cooperative Programs to include retail food and milk products. This will permit Federal and State investigators to generate standardized inspection reports and directly enter inspection findings into a national food safety inspection database.

- Increase efforts to more effectively ensure the safety of food products during transportation by working with FSIS; and through partnerships with States, to provide the transportation industry with training and training materials on the safe transport of foods.

DEPARTMENT OF AGRICULTURE
FOREIGN AGRICULTURAL SERVICE
FY 1999 BUDGET REQUEST

INSPECTIONS AND COMPLIANCE -- $3.0 million

This request will provide $3.0 million to enhance the Foreign Agricultural Service's (FAS) ability to address trade implications associated with U.S. Government regulatory actions associated with assuring that foreign government's food safety requirements are equivalent to those of the United States. Actions taken by regulatory agencies involved in implementing the President's Food Safety Initiative can and will be seen by trading partners as non-tariff trade barriers unless steps are taken to (1) fully document areas where a foreign government's food safety measures are deficient and (2) provide technical assistance and training to facilitate compliance where appropriate.

In accordance with international trade agreement disciplines, the United States will need to clearly identify the risks and establish why a foreign government's measures do not meet the United States' level of protection. Although the decision will ultimately rest with the U.S. regulatory agency, it will be FAS foreign service officers serving in the overseas markets that will, with the appropriate regulatory agency, explain U.S. government regulatory actions to host country officials. Recognizing that this is an emerging area for FAS overseas offices to handle while continuing to maintain positive relationship with our trading partners, FAS will need to restructure reporting requirements, devote resources to staff training and in some cases add additional staff overseas as appropriate.

Similarly, the newly established FoodNet, which tracks incidences of foodborne illnesses in the United States, will likely increase the reporting of such illnesses. This could lead to the impression in foreign markets that U.S. food is not safe. Existing international protocols and guidelines outlining how, when and to whom this information should be provided must be developed.

FY 1999 Activities:

- Expand foreign training and technical assistance directed toward countries that export produce to the United States. FAS has historically engaged in projects to provide exporting countries with assistance in developing and implementing programs and procedures that address deficiencies in food safety measures. However, with imports of produce increasing, efforts must be augmented.

- Working with the Institute for Cooperation in Agriculture (IICA) and FDA, develop a strategy to reduce microbial contamination in Latin American produce destined for the United States.

- Provide countries with short-term training in the United States to facilitate understanding of current research findings and evolving regulatory practice.

- Build on the existing network of professionals in the FAS stationed around the world to document known measures and practices affecting which impact on the safety of food products exported to the United States. Cooperatively with FDA, establish country profiles and determine where current practices and measures are inconsistent with international standards and U.S. food safety requirements.

- FAS, in cooperation with FSIS, FDA, and CDC will increase international communication on emerging food borne illness outbreaks. Group would be responsible for developing international protocols notifying foreign governments of food borne illness outbreaks, recalls and food shipments which have been denied entry into a foreign market for an identified food safety concern.

  - Work with key export markets, Japan, EU, Canada, Mexico, and Korea to formalize procedures for reporting and communicating publicly foodborne illness outbreaks, recalls and other regulatory actions.

  - Work with the relevant CODEX Committees, principally the Committee on Import and Export Certification, to further develop existing international guidelines on risk communication.

DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
FY 1999 BUDGET REQUEST

INSPECTIONS AND COMPLIANCE -- $10.4 million

The Federal program is undergoing transformation from an organoleptic program with emphasis on in-plant inspection to a HACCP-based program with farm-to-table food safety emphasis. This same transformation will follow in the State programs in Fiscal Years 1999 and 2000. Federal assistance is needed to ensure that the Cooperative State Inspection programs appropriately implement provisions of the HACCP final rule in order to maintain programs that are "equal to" the Federal inspection program, as required by statute.

For FY 1999 FSIS proposes waiving the statutory matching requirement for Federal assistance to State programs to permit 100 percent Federal funding for the short-term implementation of automation and laboratory testing improvements in order to provide the necessary infrastructure for State programs to operate in a HACCP environment. In addition, the proposed waiver includes 100 percent funding for the development and delivery of training in HACCP principles and procedures for State inspection personnel. Upon completion of implementation, the State programs will resume responsibility for maintaining infrastructure improvements and training inspection personnel, with Federal assistance through 50/50 matching grants.

FY 1999 Activities:

The following initiatives will enable FSIS to improve nationwide food safety by strengthening meat and poultry HACCP implementation in State programs so that interstate shipment of State inspected product can be realistically considered:

- FSIS, in cooperation with FDA, will implement the Field Automation and Information Management (FAIM) project in the State programs to provide the necessary automation infrastructure for States to operate HACCP-based inspection programs ($7.75 million). FAIM will enable both the Federal and State programs to collect the same kind of data and information from establishments and permit Federal and State programs to share information to more effectively handle crises, such as recalls. In addition, FAIM will eliminate the need for costly design and development of new State automation systems, of which the FSIS share is estimated to be $4.6 million.

- Provide the State programs with microbial identification systems, which are used by FSIS laboratories for pathogen detection, so that States can test for pathogens as required by the HACCP final rule ($1.64 million).

- Develop and deliver training for State inspection personnel in HACCP principles and procedures and related inspection changes ($1.0 million).

DEPARTMENT OF AGRICULTURE
FOOD AND CONSUMER SERVICE
FY 1999 BUDGET REQUEST

INSPECTIONS AND COMPLIANCE -- $10.5 million

Approximately 93,000 schools in 23,000 school food authorities provide lunches to about 26 million children every day. An estimated 70,000 of these schools currently prepare their own meals. Production and manufacturing safety concerns are handled by existing law and regulation; however, preparation and service at schools is a local matter, and many schools receive little or no oversight on food safety. Working through the National School Lunch Program, FCS will provide necessary assistance to assist school food service providers. Adoption of this initiative will enhance the ability of States and local school food services to safeguard the health and safety of children participating in the school meal programs

FY 1999 Activities:

- Annually provide $150 to each self-preparation facility to support a minimum of two independent safety inspections each school year.

RISK ASSESSMENT

OVERVIEW

PROBLEM

Risk assessment characterizes the nature and size of risk to human health associated with hazards and strives to make clear the degree of uncertainty of the data and the assumptions used to develop the estimates of risk. Risk assessment drives the development of effective intervention strategies and focuses data collection and scientific research in the most critical areas. Risk assessment techniques are far less developed for foodborne and waterborne pathogens than for chemical hazards. Intensive commitment is necessary to develop critically needed methods of analyzing available data, including data collected after the implementation of pathogen reduction practices, and addressing its uncertainty. In addition, research is needed to develop improved methods and models that will make it possible to perform quantitative microbial risk assessments.

GOAL

Improve the capability to estimate risks associated with foodborne and waterborne contaminants, especially microbial pathogens, in order to make faster and more accurate regulatory decisions, more effectively target program resources, and facilitate the development and evaluation of surveillance plans and risk reduction strategies, such as pathogen reduction practices implemented from farm to the consumer.

STRATEGY

Working together, agencies with risk management responsibility will build upon and expand efforts already underway under the President's Food Safety Initiative. In an effort to coordinate research priorities, eliminate redundancies of effort, and encourage multidisciplinary research efforts, in FY 1997 these agencies took initial steps to establish the interagency Risk Assessment Consortium at the Joint Institute of Food Safety and Applied Nutrition (JIFSAN). The mission of the Consortium is, through the collective efforts of participating agencies, to advance the science of microbial risk assessment. Today, the science of risk assessment is in its infancy. JIFSAN will provide the forum and leadership for the agencies to evaluate risk assessment activities, identify data gaps and modeling deficiencies in order to determine the next best research initiatives, eliminate unnecessary duplicative activities, and ensure complementary risk assessment work that will advance risk assessment in their respective agencies.

OBJECTIVES

- Expand the interagency activities of the Risk Assessment Consortium to further focus critical research needs, identify specific research on analytical methods, and reach a 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 potential to reduce the incidence of foodborne illness.

- FDA, USDA and EPA will enhance research efforts by building upon results of short-term research projects and emerging food safety needs. Additional research will include efforts to:

  -- Conduct focused food consumption surveys that target food consumed by a variety of subpopulations (e.g., children, immuno-compromised persons).

  -- Develop effective modeling techniques for food consumption data that more accurately reflect actual food consumption by consumers, facilitating improved risk assessments and evaluation of dietary interventions of public health importance.

  -- Develop more effective modeling techniques for assessing human exposure to a variety of foodborne and waterborne contaminants, including emerging pathogens.

  -- Develop appropriate animal models for determining whether threshold or non-threshold models for infectivity are more appropriate for describing low dose infectivity rates for infectious and toxicoinfectious microorganisms.

  -- Conduct studies into the identification of biomarkers of susceptibility, chronic sequelae, microbiological toxicokinetics, and infectious dose.

- Conduct meetings and symposia in conjunction with national scientific organizations (e.g., National Academy of Sciences and FASEB) and with animal and public health professionals to assess state-of-the-art risk assessment methodologies to include techniques for assessing exposure and dose response.

- Develop more effective modeling techniques for the growth, death, and adaptation of foodborne and waterborne pathogens at all points from farm to table (e.g., food growth and production, manufacturing, distribution and preparation at retail and by the consumer).

- Evaluate science-based pathogen and residue reduction systems which are compatible with HACCP-based inspection in plants.

- Interact with diverse stakeholders in animal and public health to identify needed food safety practices from farm to table to prevent foodborne illnesses and maintain sustainable food animal production units in the HACCP era.

- Evaluate the costs and benefits of alternative pathogen control strategies using results from the risk assessment models.

- Rank pathogen control options on the basis of their cost effectiveness.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
FY 1999 BUDGET REQUEST

RISK ASSESSMENT -- $18.1 million

FDA requests an additional $18.1 million in FY 1999 with the goal of advancing the science of risk assessment and to describe the relationship between antimicrobial drug use in animals and human pathogen drug resistance. In the future, risk assessments will be essential when establishing and providing the appropriate level of public health protection. In the meantime, FDA and USDA need science-based microbial risk assessments to set priorities and target regulations to hazards, evaluate risk reduction strategies, design public health policy, and target research programs to improve food safety. Risk assessment is fundamental to identifying where and how a hazard can be introduced into the food supply and how to prevent the hazard. Moreover, it is essential to target limited resources to the greatest risks to public health. Better risk assessment modeling techniques will help to better characterize the risk to humans from the use of both subtherapeutic and therapeutic veterinary antibiotics in food-producing animals. Another objective of the initiative related to animals is to identify and fill data gaps regarding the ecology of microbial pathogens such as *Salmonella*, *Campylobacter*, and *E. coli* 0157 in animal feed.

Microbial risk assessment is in the early developmental stages where cooperative efforts (e.g., the interagency Risk Assessment Consortium at JIFSAN) between agencies with risk management responsibility would be most effective in moving development of effective microbial risk assessment techniques forward quickly. Effective risk assessments would permit the ranking of food safety concerns, thus providing the basis for establishing the optimal level of protection for the U.S. population and the most efficient use of resources.

FY 1999 activities:

- Expand the activities of the Risk Assessment Consortium (based at JIFSAN) to further focus critical research needs, identify specific research on analytical methods, and prioritize these needs based on their potential to reduce the uncertainty of risk management decisions in food safety and provide the greatest potential to reduce foodborne illness.

    - Conduct national and international meetings and symposia in conjunction with national scientific organizations to assess state-of-the-art risk assessment methodologies to include techniques for assessing exposure and dose response.

- Enhance research efforts by building upon results of short-term research projects and emerging food safety needs. Additional research will include efforts to:

  - Develop effective modeling techniques for food consumption data that more accurately reflect actual food consumption by consumers, facilitating improved risk assessments and evaluation of dietary interventions of public health importance.

  - Develop more effective modeling techniques for assessing human exposure to a variety of foodborne contaminants, including emerging pathogens.

  - Develop appropriate animal models for determining whether threshold or non-threshold models for infectivity are more appropriate for describing low dose infectivity rates for infectious and toxicoinfectious microorganisms.

  - Conduct studies into the identification of biomarkers of susceptibility, chronic sequelae, microbiological toxicokinetics, and infectious dose.

- Develop more effective modeling techniques for the growth, death, and adaptation of foodborne pathogens at all points from farm to table (e.g., food growth and production, manufacturing, distribution, and preparation at retail and by the consumer).

- Develop data and modeling techniques to better understand the causal relationship between antimicrobial drug use in animals and human pathogen drug resistance;

- Identify and better characterize potential risk to humans from pathogens in animal feed. Quantitative risk assessment models need to be developed which account for all of the factors listed below, in order to obtain realistic estimates of human health risks associated with the use and use patterns of different antimicrobial agents in animals. FDA will review the following factors:

  - the type of antimicrobial used;

  - the potential for transfer of resistance from animal bacteria to human bacteria;

  - the creation of multiple drug resistance populations;

  - the pathogenicity of animal bacteria to humans;

  - whether an antimicrobial drug results in a significant increase in frequency of antimicrobial resistant coliform bacteria in the gut of the animal;

  - increased shedding of resistant Salmonella in animals;

  - increased virulence/pathogenicity of bacteria.

DEPARTMENT OF AGRICULTURE
AGRICULTURAL RESEARCH SERVICE
FY 1999 BUDGET REQUEST

RISK ASSESSMENT -- $0.5 million

HACCP programs and the underlying risk assessments are important for all foods. They are particularly important for refrigerated and semi-preserved foods. Effective HACCP programs need to be supported by quantitative risk assessment to understand the potential for each step in the farm-to-consumer chain to enhance or reduce the risk of illness. This risk assessment will help determine which steps are critical, what degree of control the step must provide and the critical values (Critical Control Points) for that step. An expert system is required to make it possible to accomplish this risk assessment. The system will contain data banks with models for growth rates, lag times, survival, thermal inactivation and radiation inactivation for each pathogen. It will contain information on normal contamination levels in raw food ingredients, food composition parameters (pH, water activity) and processing operations, for example, to be able to calculate the temperature profile of a beef roast being cooked in an oven. The user must be able to assemble the appropriate modules of the expert system, with help from the system itself, to simulate the unit operations of the food process and to accurately make estimates of microbial behavior during the process.

Building on existing ARS resources and expertise in microbial pathogen modeling, ARS will develop the necessary model components and software architecture to form the computerized expertise system. With additional funds ARS will provide a workable expert system for food microbiologists in the industry and regulatory agencies that can be used without extensive software training. It should be sufficiently complete and precise to provide a meaningful analysis of the food process and to accurately determine appropriate critical control point parameter values. This system is necessary to make conducting risk assessments routine so they can be done quickly, frequently and easily, and contribute importantly to improving food safety.

FY 1999 Activities:

- Collect the individual model components by pathogen and type of model (growth, thermal inactivation). Put them into a consistent format with identifiable input and output parameters.

- Develop a software architecture that can find the relevant data bases and models and allow easy linkage of the individual components. The system will prompt the user with relevant questions about the food and process.

- Develop the system to be able to store and then compare the outputs for several scenarios, for example, compare the final pathogen numbers in a product made with various levels of added salt.

DEPARTMENT OF AGRICULTURE
ECONOMIC RESEARCH SERVICE
FY 1999 BUDGET REQUEST

RISK ASSESSMENT -- $0.5 million

Microbial hazards in the food supply cause an estimated 6 million - 33 million cases of illness each year, and up to 9,000 deaths. Risk assessments and benefit/cost analyses of options to control microbial pathogens in the food supply are an essential component of our efforts to improve food safety. Economists need data from other scientific disciplines to perform benefit/cost analyses of control options for improving food safety. Economic analysis of pathogen control options is needed to ensure that control strategies are prioritized on a costs-effectiveness basis. Risk/benefit assessments have been done for some food safety risks (such as *E. coli O157:H7* in hamburger), but risk/benefit assessments are needed for other food safety risks, such as microbial pathogens in fruits and vegetables.

The best way to further this multi-disciplinary exchange is to set up a formal collaboration among groups of scientists. Economists from ERS will work with scientists to bring a systems view to their analyses of options for pathogen control from farm-to-table. By incorporating the results of risk assessment in economic analyses of pathogen control options, we will further enhance understanding of the economic consequences of specific food safety policies (such as HACCP, safe handling labels, and consumer education). Better risk/benefits assessments of food safety outcomes will enable USDA to make better-informed choices among alternative program and policy options intended to increase food safety. This will help us increase the net benefits of expenditures devoted to increasing the safety of the food supply.

FY 1999 Activities:

- Apply risk assessment models (such as fault tree analysis and probabilistic-scenario analysis) to identify where pathogens gain entry into the food chain;
- Identify points along the food chain where control efforts are possible;
- Evaluate the costs and benefits of alternative pathogen control strategies using results from the risk assessment models;
- Rank pathogen control options on the basis of their cost effectiveness.

DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
FY 1999 BUDGET REQUEST

RISK ASSESSMENT -- $1.0 million

Implementation of appropriate risk mitigation strategies for reducing pathogen contamination of animals before they reach the slaughterhouse is an important facet of the farm-to-table food safety strategy. Risk assessments will provide the information necessary to identify appropriate control strategies.

Risk assessments from farm-to-table cannot be conducted without significant data linking food animal production practices to processing contamination risk factors. The multi-billion dollar food animal production industry includes more than a million small food animal production units, markets, trucking businesses, and pre-slaughter preparation suppliers. Pathogen Reduction/HACCP systems will be implemented in FY 1999 in small establishments and very small establishments in FY 2000. Integral HACCP implementation from farm-to-table is having microbial quantitative risk factor data available to conduct appropriate risk assessments. In order to identify and assess risk mitigation factors from farm through processing, further data collection and pilot projects focusing in small food animal production units need to be conducted.

FSIS is leading meat and poultry and egg processing food safety risk assessment, management and communication strategies from farm-to-table. Animal and public health experts and stakeholders must collaborate in building consensus to implement practical pathogen risk reduction techniques based on sound science and risk analysis from farm to table.

Risk assessment and cost-benefit analyses are needed to identify risk management practices that can be employed at the production level to ensure control of pathogenic contamination from farm-to-table. In FY 1997, FSIS let contracts to implement practical food animal production risk reduction practices for *Salmonella, E. coli O157:H7, Campylobacter* and *Yersinia,* and measure the pathogen reduction effect on carcasses. Data collected would be used for risk assessments and to determine further risk mitigation pilot projects from farm through processing. During FY 1999, FSIS will build upon these efforts and focus on quantitative microbial risk factor data collection from small food animal production units and the establishments they supply. FSIS will provide seed monies to collaborate with animal production experts in identifying cost effective pathogen reduction strategies to reduce foodborne illnesses.

FY 1999 Activities:

- Through contracts and cooperative agreements, conduct up to 10 pilot projects evaluating science-based pathogen reduction systems which are compatible with HACCP-based inspection in plants.

- Through contracts and cooperative agreements, conduct risk assessments and cost-benefit analyses for priority pathogens on 4 commodities (dairy beef, lamb, broilers and pork) from farm through processing.

- Provide leadership in determining practical risk management strategies applicable to small food animal production units supplying establishments implementing pathogen reduction and HACCP systems.

EDUCATION

OVERVIEW

PROBLEM

Food safety education is an integral part of a successful, coordinated food safety program. Education efforts have been ongoing for years, but have had little demonstrated effect in promoting the use of safe food handling behaviors by consumers and food service workers as indicated by the high number of foodborne illnesses and outbreaks. Moreover, healthcare professionals, veterinarians and animal producers, and workers in various segments of the food industry (such as transportation) are not as knowledgeable about microbial pathogens, foodborne illness, and how their actions may be fostering food contamination.

Producers' ability to embrace HACCP systems will be directly related to their understanding of what can be done, based on science and consumer demands, to implement food safety and quality improvements. Educational efforts of both animal and public health experts are needed to focus production systems from farm to slaughter on understanding the public health risks associated with human pathogens in food animals. State agricultural and public health agencies must have the ability to enhance commodity-specific educational programs in collaboration with universities, Federal agencies, and industries from farm to table. Those responsible for food transportation must be aware of the contamination risks of mishandling food during shipment. Health professionals need specific knowledge about causes and effects of foodborne illness for effective detection and treatment. Finally, consumers must have information on controlling pathogens when food reaches their table.

Public-Private Food Safety Education Partnership: In FY 1997, under the President's Food Safety Initiative, FDA, FSIS, CSREES and CDC laid the foundation for a nationwide food safety education campaign, in a new public-private partnership with industry, consumer groups, and State representatives through the Association of Food and Drug Officials. The basis of the campaign is four key food safety messages to be used nationwide by educators. Coordination with industry will continue to fund the campaign.

In FY 1998, food safety education initiatives will be enhanced as we continue to target segments of the wide variety of audiences from farm to table, all of whom have the ability to control foodborne pathogens. They include: consumers; animal and targeted producers; retail, food service, and institutional food preparers. Product-specific and audience-specific messages that address the risks relevant to such groups throughout the food chain will be developed based on research and evaluated for effectiveness.

GOALS

Our unified, strategic goal is to minimize the incidence of foodborne illness. To achieve this goal, individuals involved in the farm-to-table food production, distribution, retail and food service and sale of food products, as well as consumers, need to understand their role in assuring the safety of the food supply. New and innovative strategies will be developed to improve food handling practices from farm-to-table.

Through dialogue with stakeholders (e.g., Federal and State agencies, consumers, academia, and the food industry) on the current effectiveness of the Food Safety Initiative, needs, priorities, and future food safety directions will be assessed.

STRATEGY

In implementing FY 1997 and FY 1998 education activities, FDA, FSIS, CSREES, and CDC have been working closely together to coordinate food safety educational efforts and will continue to do so. This year, we established working groups and identified participants from each agency to work on each project specified in the Food Safety Initiative. In May 1997, the agencies teamed up with industry, consumer groups and states represented by AFDO, and signed a memorandum of understanding launching a public-private partnership for food safety education, and now, a nationwide consumer food safety education campaign will be launched by the Partnership. In June 1997, the four agencies jointly sponsored a national conference on food safety education.

Electronic communications are being coordinated through initiation of a unified internet address (www.foodsafety.gov). Use of new technologies, such as joint video-teleconferences held over the past few years, will continue to play an increasing role in the coordination of our efforts. Now, through a joint consumer research meeting of government officials to be held next Spring, and by evaluating gaps and needs in school-based programs together, the agencies will begin to capitalize on each other's strengths and speak with one voice more consistently and more often. This will allow us to maximize use of our resources while expanding our reach. Strategies will include:

- educating audiences along the farm-to-table continuum.
- forming additional partnerships and alliances to maximize resources and broaden the impact and scope of educational efforts.
- designing and evaluating messages and identifying appropriate educational methods to promote use of safe food handling practices, based on research.

- expanding the use of innovative outreach methods, including the use of new technologies.

OBJECTIVES

Food Producers and Distributors

- FDA and USDA will inform appropriate audiences about good agricultural and manufacturing practices (GAPs and GMPs).

- USDA will continue to enhance our coordination with the States to provide producer education. Assure State agricultural agencies have the resources in risk management and communication to work with industry and academia to educate food animal producers on food safety assurance and risk management and communication.

Retailers and Food Service Workers

- FDA and USDA will develop multilingual education programs for food service workers.

- USDA, working with FDA, will continue training for State sanitarians on new food processing techniques for meat and poultry products that are appearing in retail stores and restaurants beyond federally inspected establishments.

- USDA will provide education to local school food service professionals, serving about 26 million children every day, in the use of safe food handling practices and update technical assistance materials to concur with the Food Code.

- USDA will support education efforts by State agriculture and public health agencies with the meat, poultry, and egg production sector, the food transportation industry, distributors, and retail stores and restaurants. Special emphasis will be placed on those small and disadvantaged members of the community who are outside of the mainstream and who may not understand their roles in assuring food safety and improving public health.

School Children

- CDC will work with USDA and FDA to train school personnel to promote food safety education to youth through the Nation's schools. CDC will collaborate with USDA, FDA, and State, territorial, and local education and health agencies and other relevant organizations to develop education and training materials to help schools teach children about food safety.

Consumers and Health Professionals

- FDA, CDC, and USDA will cooperate in implementing education campaigns, using the new educational messages developed in FY 1997 and FY 1998 under the public-private partnership, with special audiences.

- FDA, working with USDA, will initiate evaluation of point-of-sale materials and messages, including warning labels, to convey food safety information, such as those voluntarily used on unpasteurized cider for use by at-risk populations.

- FDA and USDA will cooperate in evaluating the effectiveness of the messages developed within the public-private partnership in FY 1998. We will make program modifications based on research outcomes. Further research by FDA, CDC, Food Safety Inspection Service, and Cooperative State Research, Education, and Extension Service will provide information about the barriers to message comprehension and behavioral change.

- CDC will establish training programs targeted to proper identification of foodborne disease to address the needs of audiences including epidemiologists and laboratorians in State and local health departments, practicing physicians, and nurse epidemiologists.

- CDC, working with and through the World Health Organization, other international health organizations, and major food exporting nations will provide education and training to epidemiologists and public health laboratory workers for proper detection, surveillance, and outbreak investigation of foodborne disease in countries that export food to the U.S.

All Audiences and Stakeholders

- The agencies will expand participation in umbrella alliances of consumer educators, and retail educators. Alliances of educators will allow easier information exchange, thereby avoiding duplication of effort, and, with the use of distance learning mechanisms, will allow information to be disseminated rapidly.

- The agencies will explore initiation of distance learning programs for importers, producers, retailers, health professionals and students through universities, such as the Cooperative Extension system and University of Maryland/Joint Institute for Food Safety and Applied Nutrition.

- The agencies will continue implementation of plans to establish a nationwide food safety education clearinghouse. Building on the evaluation of needs and options in 1997-1998, we will formalize the further consolidation of innovative technologies and services, such as databases and other electronic mechanisms, within the Government.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
FY 1999 BUDGET REQUEST

EDUCATION -- $2.7 million

Providing food-safety education to the Nation's youth and to public health professionals is an important part of the prevention and control of foodborne illness. In addition, identifying and characterizing foodborne disease in exporting countries will strengthen food safety programs. CDC will collaborate with State, local, and territorial education and health agencies to develop education and training materials to help schools teach children about food safety. CDC will also address the educational needs of epidemiologists and laboratory directors in State health departments to strengthen the ability of public health personnel to properly identify and report foodborne disease. Lastly, CDC will work with WHO and its regional offices to provide education and training to epidemiologists and public health laboratory workers for proper detection, surveillance, and outbreak investigation of foodborne disease in countries that export food to the United States.

School-based Health Education for Disease Prevention:

- Collaborate with FDA, USDA, State, territorial, and local education and health agencies and other relevant organizations to develop education and training materials to help schools teach children about food safety.

  Performance Measure: Enhance State and local education agencies by providing foodborne disease prevention education and training materials to assist schools teach children about food safety.

Professional Education for Public Health Physicians, Nurses, Microbiologists, and Other Public Health Workers Important for Proper Identification and Reporting of Disease:

- Establish training programs targeted to proper identification of foodborne illness and reporting of disease to address the needs of audiences, including epidemiologists and laboratorians in State and local health departments, practicing physicians, and nurse epidemiologists.

  Performance Measure: Strengthen the ability of public health personnel to properly identify and report foodborne disease through networks such as the existing National Laboratory Training Network and Public Health Training Network.

- Work with and through WHO, other international health organizations, and major food exporting nations to provide education and training to epidemiologists and public health laboratory workers for proper detection, surveillance, and outbreak investigation of foodborne disease.

  Performance Measure: Enhance the number of courses to increase international epidemiology capacity targeted at foodborne diseases, including international training courses for laboratory directors to better detect foodborne pathogens.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
FY 1999 BUDGET REQUEST

EDUCATION -- $10.5 million

Data on consumer and food handler practices indicate that most foodborne illnesses occur in the home or are caused by food prepared and consumed at food service/retail establishments. Therefore, innovative food safety education programs offer an efficient and cost-effective means to reduce the potential for foodborne illness by changing unsafe food handling behaviors in the home and in retail food establishments. Using the concepts set forth in the Food Code, FDA will work with other Federal agencies and States to develop and implement a national education program to ensure greater safety in food handling practices by consumers and all segments of the retail food industry. FDA is requesting a total of $10.5 million to achieve the following goals: 1) reduce the potential for foodborne illnesses by using new and innovative education and information sharing strategies for improving food handling practices of consumers and retail food service establishments; and 2) obtain information directly from stakeholders (e.g., Federal and State agencies, consumers, academia, and the food industry) on the current effectiveness of the Food Safety Initiative as well as identifying needs, priorities, and future food safety directions.

In addition, since data systems do not exist to provide comprehensive information needed to meet the requirements of GPRA (i.e., establish realistic performance goals and measures), these meetings will provide opportunities for the Agency to obtain a broader view of the Program's impact on its various stakeholder groups. To maintain an effective regulatory program, FDA must make every effort to ensure that its research, regulatory, and education activities are focused where the greatest needs exist. Information from stakeholders will help the Agency meet this objective.

Education activities will undergo significant coordination with USDA and CDC, as in FY 1997 and FY 1998.

FY 1999 Activities:

- Continue work to identify barriers to safe food-handling which can help guide the design of more effective training programs and materials related to food safety.

- Expand the food safety initiative education campaign, through partnerships and alliances, to use new education tools especially targeted to school programs and specific at-risk audiences.

- Explore innovative methods (e.g., distance learning mechanisms) for more efficiently and inexpensively sharing food safety information with larger audiences.

- Work with USDA to improve the ability to provide education/training to the transportation industry on the safe transport of foods.

- Analyze the results of the stakeholder meetings to develop GPRA performance measures and help establish future directions for the Food Safety Education Program.

- FDA and USDA will expand communication about fresh fruits and vegetables good agricultural and manufacturing practices (GAPs and GMPs) to appropriate audiences.

- FDA and USDA, in cooperation with States and industry, will develop multilingual education programs for food service workers.

- FDA, working with USDA, will continue work to evaluate point-of-sale materials and messages, including warning labels, to convey food safety information, such as those voluntarily used on unpasteurized cider for at-risk populations.

- FDA and USDA will cooperate in evaluating the effectiveness of the messages developed within the public-private partnership in FY 1998. We will make program modifications based on research outcomes. Further research by FDA, CDC, FSIS and CSREES will provide information about the barriers to message comprehension and behavioral change.

- The agencies will expand participation in umbrella alliances with consumer educators and retail educators. Alliances of educators will allow easier information exchange, thereby avoiding duplication of effort, and, with the use of distance learning mechanisms, will allow information to be disseminated rapidly.

- FDA will expand on the FY 1998 initiatives, including educational partnership agreements with State and local agencies, to address the appropriate use of drugs in food animals that will ensure public health by minimizing the occurrence of residues in edible tissues. Prudent and judicious use of veterinary drugs will be an important factor in preserving their efficacy, preventing resistance development, and hence, retaining their availability.

- Partnerships between FDA Regional/District Offices and other Government agencies such as the USDA extension service as well as State and local Government departments, will increase FDA's educational outreach programs. These proposed initiatives will increase compliance with good husbandry practices and reduce the need for enforcement due to an increase in quality assurance through development of formal and informal industry quality assurance programs.

DEPARTMENT OF AGRICULTURE
COOPERATIVE STATE RESEARCH, EDUCATION, AND EXTENSION SERVICE
FY 1999 BUDGET REQUEST

EDUCATION -- $3.0 million

Millions of Americans are 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. Consumers must share in the responsibility for food safety along with producers and processors. Knowledge of food safety and foodborne risks must be increased, in conjunction with information on improved safe handling practices.

Substantial increased investment in broadening our current research-based educational efforts is essential if we are to decrease the incidence of foodborne illnesses in coming decades. CSREES, in cooperation with FDA, would expand education efforts to help consumers understand and adopt recommended safe food handling practices. A coordinated public education effort is required across all Federal agencies that play a role in protecting the safety of the food supply. With these additional funds, we will annually increase consumer awareness, understanding, and information regarding food safety and foodborne risks in which CSREES partners and cooperators play an active research, education, or extension role.

FY 1999 Activities to be accomplished by CSREES through coordinated efforts with FSIS, FDA, CDC, and the partnership for Food Safety Education, CSREES are:

- Develop a comprehensive public education campaign focusing on the role of the consumer in ensuring and improving the safety of the Nation's food supply. Particular emphasis will be given to education efforts targeting consumers handling food in the homes, at congregate meal sites, and at gleaning and food recovery program sites.

- Develop materials and resources for educating consumers about food safety, targeting two groups -- older Americans, and those with limited incomes and limited resources -- who are at particularly high risk for foodborne illness.

- Establish a national database and communications network to provide rapid access to information related to consumer food safety, safe food handling practices in the home, recommended time and temperature guidelines for consumer food preparation and storage, and foodborne illness outbreaks of regional, national, and international significance.

DEPARTMENT OF AGRICULTURE
FOOD AND CONSUMER SERVICE
FY 1999 BUDGET REQUEST

EDUCATION -- $2.0 million

Approximately 93,000 schools in 23,000 school food authorities provide lunches to about 26 million children every day. An estimated 70,000 of these schools currently prepare their own meals. Local school food service professionals need additional training in safe food handling practices and technical assistance materials on this subject need to be updated to concur with the updated Food Code. In order to change unsafe food handling practices by school food service providers, they must be provided with training and materials that address their specific health and safety needs. Adoption of this initiative will enhance the ability of States and local school food services to safeguard the health and safety of children participating in the school meal programs.

FY 1999 Activities:

- Develop and operate training workshops for local food service professionals engaged in preparing food for schools and revise, print and distribute an updated version of "Serving It Safe."

DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
FY 1999 BUDGET REQUEST

EDUCATION -- $2.0 million

The implementation of the Pathogen Reduction/HACCP Systems final rule is driving dramatic changes within the food animal production communities. Producers' ability to react and respond to these changes will be directly related to their understanding of what can be done, based on science and consumer demands, to implement food safety and quality improvements. Slaughter plants may demand more from their food animal suppliers in order to assure chemical, physical and microbial safety of their meat and poultry products. The rapid rate of change will involve about 1.0 million beef, 0.2 million dairy, 0.2 million pork and 0.1 million sheep producers. Within each of the various production groups there is wide diversity in production practices and public health concerns.

Public health goals of reducing foodborne illnesses will be successful only if animal and human health experts collaborate and coordinate educational programs for risk management and communication in nationwide food production, processing, distribution and retail industries. In the animal production areas, there will be millions of suppliers who will be impacted by in-plant implementation of pathogen reduction and HACCP systems.

To reduce foodborne illnesses, FSIS will support farm to table risk reduction strategies. This will necessitate collaboration of animal and human health experts from State and Federal agencies, industries, academia and other key stakeholders. FSIS must partner with FDA and other Federal agencies to:

- Assure State agricultural agencies have the resources in risk management and communication to work with industry and academia to educate food animal producers on food safety assurance, and risk management and communication. This will be necessary for their food animal producers to maintain sustainable operations in the HACCP era and assure food safety from farm to slaughter.

- Assure that State public health agencies have the resources and information to carry out education programs within their States with the distribution sector and with retail stores and restaurants on safe food handling and preparation techniques.

- Support education efforts by State agriculture and public health agencies with the production sector, the local trucking industry, distributors, and retail stores and restaurants, with emphasis on those small and disadvantaged members of the community who are outside of the mainstream and who may not understand their roles in assuring food safety and improving public health.

During FY 1997 and 1998, FSIS has initiated training for State sanitarians on new meat and poultry processing techniques that are appearing in retail stores and restaurants that previously had only been performed in establishments inspected by FSIS. Additionally, FSIS plans to provide training to State inspectors in HACCP and seeks to identify small and disadvantaged producers that are in need of educational assistance. This initiative will build upon these earlier efforts and provide a mechanism to deal with some of the gaps in the farm-to-table strategy.

Educational efforts of both animal and public health experts are needed to focus production systems from farm to slaughter on understanding the public health risks associated with human pathogens and illegal chemical residues in food animals. State agricultural and public health agencies must have the infrastructure and support to enhance commodity specific educational programs in collaboration with universities, Federal agencies and industries from farm to table. This non-regulatory approach enables FSIS to accomplish its mission in partnership with States where the appropriate authority and responsibility resides to address food safety concerns and to work with their food animal production communities to meet the challenges of the HACCP era.

FY 1999 Activities:

- Provide resources for up to 25 States agriculture initiatives in animal production food safety. The States are in the best position to work with their citizens to protect the public health and assure animal production food safety.

- Provide up to 10 contracts or cooperative agreements to support educational initiatives for producers, marketers and transporters of food animals, including poultry and eggs, focussed on good production and food safety practices based on HACCP concepts.

RESEARCH

OVERVIEW

PROBLEM

Throughout the farm-to-table continuum, effective food safety practices and programs must have critical scientific knowledge as the basis of developing the most effective means to detect and identify pathogens, to minimize their presence, and to respond to outbreaks. Basic research is needed to gain a fundamental understanding of the ecology of the foodborne pathogens. It will answer such questions as what is their genetic content, how do they multiply, how are they transmitted, under what conditions do they grow, how does food become contaminated? Building on that understanding, applied research is needed to develop the practices and technologies that will facilitate pathogen detection of pathogens and control. Sound science is needed to develop effective production methods for minimizing the presence of pathogens, food processing and packaging systems that reduce or eliminate pathogen populations or provide conditions that inhibit pathogen growth, and storage and cooking procedures that prevent contamination, control pathogen growth, and curb the presence of pathogens.

GOAL

Provide Federal, State, and local agencies (and indirectly the agriculture and food industries, the retail food industry and consumers) practical and effective science-based practices and technologies that improve the safety of food. Research is, by necessity, a continuum, with each step in the progression toward a research goal building on the results of research in the previous step. Thus, research goals, even short-term goals, are often not measurable within short (i.e., less than a year) periods of time.

STRATEGY

USDA, HHS, and EPA all have important roles in generating the science-based knowledge and technology needed to effectively address pressing food safety issues. Each agency conducts a program of work that focuses on specific problems and issues designed to strengthen the effectiveness of the national food safety system. The May 1997 Report to the President on the FY 1998 Food Safety Initiative highlighted the opportunities for research coordination and collaboration across these Federal agencies and beyond to potential research partners in State agencies, the private sector, and academia, in order to achieve the maximum return on the Federal investment in food safety research.

A part of the Food Safety Initiative, the food safety research agencies will initiate an indepth review and evaluation of all research, including fresh fruits and vegetables research, that is currently underway or planned. The first step in this process will be devising a structure and mapping all research onto that

structure so that an organized picture of agency responsibilities is created. This step will be completed in approximately 6 months and will form the basis for the next step, an indepth review and evaluation of research. From the indepth review, a report will be generated that includes information on unnecessary duplicative efforts, overlaps, jurisdictional issues, research gaps, and other information pertinent to designing a research planning process. This report will serve as the basis for identifying and putting in place an ongoing interagency process for review and coordination of food safety research in the future. The decision may be made to use a resource, such as the Office of Science and Technology Policy, to facilitate the effort to develop a coordinated governmentwide food safety agenda.

OBJECTIVES

Research objectives are organized by the five major areas outlined in the 1998 Food Safety Initiative:

- **Improve Detection Methods** - Develop effective methods and technologies to detect, identify, and quantify the presence of pathogens and to develop models and sampling techniques based on an understanding of how the pathogen is affected by conditions to predict its presence. Rapid methods to be used for detection and identification of pathogens on imported and domestic fresh fruits and vegetables will be emphasized.

  - Expand on FY 1997 and FY 1998 research efforts to develop rapid analytical methods for the detection of hazardous bacterial and viral agents, e.g., *Cyclospora* and Hepatitis A virus, that may contaminate fresh fruits and vegetables.

  - Improve analytical methodology to develop more rapid and effective test methods for detecting *Vibrio vulnificus* in foods.

  - Develop rapid, accurate, and user friendly detection methods for bacterial and parasitic pathogens as they are found in animal wastes.

  - Define specific pathogens associated with manures and their survival characteristics, to assist in developing solutions, and to help producers monitor their operations.

- **Understanding Resistance to Traditional Preservation Technologies and Antibiotic Drug Resistance** - Gain a better understanding of how and why

resistance to both traditional preservation technologies and antibiotic drugs occurs and develop new ways to apply existing pathogen prevention technologies or new technologies that are more effective and sustainable in mitigating pathogen presence.

- Continue research on the mechanisms underlying the development of antibiotic resistance in foodborne pathogens in farm and aquaculture animals with a goal of preventing its development.

- **Prevention Techniques: Pathogen Avoidance, Reduction, and Elimination** - Develop new or improved production, processing, and distribution practices and technologies that prevent contamination, and if present, reduce levels of or eliminate contamination. Particular emphasis will be on development of intervention/prevention techniques for use with fresh fruits and vegetables.

  - Continue research to develop technologies, e.g., antimicrobials, thermal and non-thermal pasteurization procedures including irradiation, to reduce levels of or eliminate pathogens from fresh fruits and vegetables.

  - Work with industry and academia to develop new techniques that provide alternatives to traditional thermal processing systems for eliminating or reducing levels of pathogens in other foods.

  - Develop systems for improved sanitation of animal production facilities and for handling both liquid and solid animal wastes to effectively control pathogens.

  - Develop a better understanding of bacteria-food-host interactions controlling virulence gene expression. Research in this area will lead to an understanding of how virulent strains differ between countries such that intervention strategies can be developed that will reduce our risk of contamination from imported foods.

  - Correlate animal production practices, including transportation, with contamination of food products to establish the basis for effective prevention.

- **Food Handling, Distribution, and Storage** - Develop a better understanding of how the conditions under which food products are transported and handled influence the possibility of their acquiring contaminants and develop methods and technology to minimize those conditions and therefore the likelihood of such contamination developing.

- Undertake research to identify factors that contribute to the spread of microorganisms during transportation of fresh produce, and develop techniques for eliminating cross-contamination and sensors to help identify products not properly handled and stored.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
FY 1999 BUDGET REQUEST

RESEARCH -- $20.2 million

FDA's FY 1999 budget request includes $20.2 million for research related to food safety. This funding would allow FDA to continue its work on development of new and improved methods for more rapidly and accurately detecting and characterizing foodborne hazards, evaluating the effectiveness of surveillance initiatives, and establishing more effective strategies to control and prevent foodborne hazards.

Additional research is needed to fill critical gaps in FDA's food science capability in prevention of foodborne illness. More rapid and accurate analytical methods are needed, especially for *Cyclospora* and other parasites, and bacterial and viral agents that are difficult to detect in foods such as fresh produce. An enhanced analytical method capability is crucial to efforts to evaluate the effectiveness of HACCP systems, and to identify and assess the health implication of some of the bacterial agents encountered in imported products. In addition, research is needed to develop science-based guidance and regulation, as well as prevention techniques for pathogen avoidance, reduction, and elimination, especially in fresh produce and seafood.

FY 1999 activities to be accomplished by FDA through coordinated efforts with other Federal agencies, especially USDA, are:

- Initiate a surveillance program covering domestic and imported fresh fruits and vegetables to identify and quantify the foodborne pathogens that occur on these products. Development of this baseline will allow FDA to better evaluate its efforts as well as target resources to the most critical areas.

- Expand on current research to develop more rapid and effective test methods for detecting *Vibrio vulnificus* in foods.

- Analyze physiological, genetic, and other factors that cause hazardous foodborne microorganisms to develop resistance to preservation technologies.

- In conjunction with other food regulatory agencies supporting the initiative to provide consumers greater protection against hazardous contamination in fresh produce FDA will:

    - Develop intervention/prevention technologies, e.g., antimicrobials, thermal and non-thermal pasteurization procedures, including irradiation, to eliminate contamination on fresh fruits and vegetables.

- Develop further intelligence about pathogens and commodities to determine those commodities to be addressed and appropriate intervention strategies for GAPs, GMPs, and HACCP.

- Continue and expand work to develop rapid analytical methods for the detection of pathogens, e.g. *Cyclospora*, that may contaminate fresh fruits and vegetables.

- Develop methods to prevent or control the growth of pathogenic organisms on fresh fruits and vegetables.

- Develop effective new decontamination methods for a variety of pathogens in non-produce products, including methods for *Vibrio vulnificus* and Norwalk virus, on marine harvested and aquaculture seafood products.

- Work with industry and academia to develop new techniques that provide alternatives to traditional thermal processing systems for eliminating pathogens.

- Work with industry to develop criteria for evaluating the efficacy and safety of the new intervention technologies.

- Identify factors that contribute to the spread of microorganisms during transportation of fresh produce, and develop techniques for eliminating cross-contamination.

- 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 which have not been stored safely.

- Conduct meetings and symposia to assess state-of-the-art science associated with methods for the detection and identification of pathogenic organisms as well as methods for controlling and preventing foodborne contamination.

- Continue and expand food safety research initiated in FY 1998 such as the development of methods to detect human pathogens in animal feeds, and mechanism of transfer from animal feeds or animal products to humans, which has human health implications.

- Investigate the relationship of animal feeds as vectors to transmit pathogens as well as research on the mechanism of pathogenic transfer of foodborne pathogens, and ecological research related to such pathogens including research on the development of antibiotic resistance.

- Continue research on the mechanisms underlying the development of antibiotic resistance in foodborne pathogens in farm and aquaculture animals with a goal of preventing its development.

DEPARTMENT OF AGRICULTURE
AGRICULTURAL MARKETING SERVICE
FY 1999 BUDGET REQUEST

RESEARCH -- $6.3 million

Although the domestic food supply is unmatched in both quantity and quality, in recent years, sporadic cases of microbiological and viral contamination and parasitic infestation accounted for 90 percent of the confirmed foodborne disease outbreaks nationwide. Microorganisms once thought under control are adapting to their environments, developing resistance to conventional food processing operations, and are re-emerging with increased pathogenicity. Questionable practices in food production, the mass preparation of prepared meals, the trend to consume a greater proportion of meals away from home, the emphasis to increase fresh fruits and vegetables in the diet, and product distribution logistics may all contribute in some way to the risk of contracting foodborne illness. This could be especially true where produce, for example, is imported from sources which may have less rigorous sanitation standards.

To respond to these concerns, a scientifically-sound microbiological surveillance program for foodborne pathogens and spoilage microflora on domestic and imported fruits and vegetables should be initiated. This program will establish a much needed baseline of microbiological data by which to assess the risks of contamination in the U.S. food supply. Survey costs will be minimized by using the existing infrastructure of the Pesticide Data Program (PDP) for statistically-reliable sampling, participating State and Federal laboratories, and data reporting capabilities.

Statistically-reliable sampling is necessary to establish a microbiological baseline for assessing risks of contamination in the U.S. food supply. Elements of this program include:

- Products: Initially focus on fresh fruits and vegetables. Later, include products other than meat, poultry, egg products, and milk. Products for initial consideration (11): tomatoes, whole head lettuce, cabbage, melons, celery, grapes, peaches, bean sprouts, broccoli, raspberries, and strawberries.

- Organisms: Organisms for initial consideration: fecal coliform/*E. coli*, *Listeria monocytogenes*, *Salmonella*, and *Shigella*. Consideration can be given also to *Cyclospora* and *Cryptosporidium*, as well as mycotoxins and other types of organisms. List of organisms will be finalized after consultations with participating organizations.

- Sample Sites: Terminal markets and chain store distribution centers for fresh fruits and vegetables. (As much information as possible will be collected at the time of sampling to identify the source of the product.)

- Agencies Involved: Agricultural Marketing Service, Agricultural Research Service, National Agricultural Statistics Service (NASS), Economic Research Service, Food and Drug Administration, Centers for Disease Control and Prevention, and participating States.

FY 1999 Activities:

- Determine the statistically-reliable incidence, number, and type of important foodborne, microorganisms in the U.S. food supply, including domestically-produced and imported products.

- Establish, for the first time, a statistically-reliable, national database of the incidence of key microorganisms in food.

- Use baseline data to establish "benchmarks" by which to evaluate the efficacy of procedures to reduce or eliminate harmful foodborne microorganisms.

- Provide the Federal Government with valuable data to use for dietary risk assessments and decisionmaking, and not be as susceptible to a crisis occurring because of lack of baseline information.

- Provide other stakeholders with valuable data to use for decisionmaking purposes, including: State agencies, consumers (through outreach programs), growers, processors, retail stores, food handlers, food transporters, medical institutions, academia, global traders, and international organizations (e.g., FAO and WHO for setting international standards).

DEPARTMENT OF AGRICULTURE
AGRICULTURAL RESEARCH SERVICE
FY 1999 BUDGET REQUEST

RESEARCH -- $14.5 million

The Research, Education, and Economics (REE) mission area and ARS Strategic Plan goal of a Safe and Secure Food and Fiber System recognizes that food safety is a continuum involving both plants and animals, and that food safety problems must be addressed and solved from farm-to-table. In addition, consumers need confidence in the safety of their food supply to prevent disruptions of normal, healthy eating patterns. ARS research addresses this continuum of need by utilizing a farm-to-table approach, that includes preharvest and postharvest research to control food contaminants of both animal- and plant-based foods.

FY 1999 activities:

- Develop production systems for livestock and poultry which will assure improved sanitation of animal production facilities. This includes the development of rapid, accurate, and user friendly detection methods for bacterial and parasitic pathogens as they are found in animal wastes in order to help producers monitor their operations; the identification of the specific pathogens and their survival characteristics and ecology to assist in developing solutions; and the development of systems for handling both liquid and solid animal wastes to effectively control pathogens.

- Provide new handling systems and decontamination technologies for pathogen reduction in fresh and minimally processed fruits and vegetables which will assure both microbiological safety and product quality in cost effective processes. This will address the need for handling systems which will reduce product bruising which otherwise could provide a nucleus for pathogen growth, and the need for biofilm disruption, soil removal, penetration of inaccessible bacterial binding sites and biocide delivery. It will also include the determination of the mode of contamination and the infective state of the pathogens on various commodities, and the definition of the dose and the condition of treatment needed for both chemical and physical agents and technologies. Physical agents include microwave radiation, pulsed white light, steam pasteurization, pulsed electrical fields, high hydrostatic pressure and ionizing radiation; establishment of the absence of residues or other factors affecting regulatory status or acceptability of decontamination treatments. Also synergistic combination of surfactant, antimicrobial agents, and adjuncts will be evaluated.

- Prevent post-processing contamination of animal-based food products through correlation with animal production practices and systems. This includes prevention of initial colonization of cattle, swine and poultry and their products with pathogens by developing information on the dynamics and ecology of foodborne zoonotic pathogen transmission in current production and processing systems.

- Prevent toxins in algae from contaminating food products. This includes identification and quantification of the toxins, and development of methods for their detection and quantification in both human and animal food sources; development of livestock and crop production systems to reduce nutrients and mineral that affect algae blooms; and identification of the life history stages and bloom dynamics of the major algae species contaminating food animal food and water supplies.

- Determine how resistance to antibiotics and antimicrobial agents develops, and develop strategies to prevent this resistance. This includes elucidation of the factors in animal and plant production systems that influence the development of resistance; determination of how pathogens 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 development of techniques for manipulating the microbial ecology of the intestinal tract of animals to prevent the development of antibiotic resistance, including competitive exclusion techniques.

- Prevent increases of pathogens in animals being transported for slaughter by acquiring and combining knowledge of animal behavior, animal physiology and immunology, and microbiology to develop information for producers to use in devising transportation for their animals and poultry.

- Develop the necessary laboratory methods to detect viruses of concern in human food products by building on the knowledge of similar animal disease viruses.

- Provide the information and technology necessary for producers and processors to remove pathogens from fruits and vegetables. Develop model systems of pathogen contamination of representatives products of the major classes of fruits and vegetables.

- Provide the knowledge base and the technology for methods that will easily, accurately and with great sensitivity detect *Cryptosporidia*, *Toxoplasma*, and *Cyclospora*.

- Develop microbial sampling technologies to more accurately estimate true pathogen burden of meat and poultry products for HACCP, and in particular compare screening methods to more traditional sampling approaches.

- Develop economical sensors to alert processors and consumers of products not stored safely by developing fundamental knowledge of the identity and concentration of products which are characteristic of microbial metabolism in foods, and formatting sensors to use this information to provide visual identification of suspected microbial growth.

- Provide the necessary strategies and technologies for producers of wheat and barley to produce toxin free crops. Delineating the fungal/plant relationships and conditions necessary to interfere with the infection process in the food crop in order to provide the basic information for both changes in production technologies and breeding of resistant wheat and barley varieties.

DEPARTMENT OF AGRICULTURE
COOPERATIVE STATE RESEARCH, EDUCATION, AND EXTENSION SERVICE
FY 1999 Budget Request

RESEARCH –$6.0 million

Recent outbreaks of *E. Coli 0157:H7*, *Cyclospora*, and hepatitis A have heightened public sensitivity about food safety. Many have begun to question the effectiveness of current Federal efforts to safeguard the Nation's food supply. Understanding the processes underlying microbial, and chemical contamination of food is critical to developing new technologies to improve food safety. The research and knowledge-base available from CSREES partners and other grantees must increase to address food safety concerns. Through the development of new technologies for producers, processors, distributors, retail and institutional food handlers, and consumers the incidence of foodborne risks and illnesses will be reduced.

Fundamental research supported through the National Research Initiative of the Cooperative State Research, Education, and Extension Service (CSREES) is critical to improving our understanding of disease-causing microorganisms, naturally occurring or environmental toxicants, and chemical residues which contaminate our food supply. This knowledge is necessary to allow us to develop technologies and methodologies to prevent these substances from entering our food supply or to eliminate them.

In addition, a Special Research Grants Program in CSREES needs to be targeted to select populations, i.e., children, elderly, immunocompromised or those suffering from chronic disease, who may be more vulnerable to foodborne illness. Knowledge of food handling and storage practices among these groups - simple issues such as how long left-overs from delivered meals are stored before eaten by the elderly - would improve the basis for education and program development. Knowledge also is necessary to allow us to develop technologies and methodologies to prevent contaminants from entering our food supply or to eliminate them from foods. Expanded efforts are needed in food safety research on the detection, prevention, elimination and control of microbial agents, naturally occurring toxicants and chemical residues found in foods if we are to decrease the incidence of foodborne illnesses in coming decades.

<u>FY 1999 Activities:</u>

- Develop improved methods and models that make it possible to perform quantitative microbial risk assessment that support effective and efficient public response to concerns about foodborne illness;

- Support rigorous epidemiological studies to develop an understanding as to causes for livestock vulnerability to microbial pathogens of concern in human health that will lead to practical and cost effective intervention measures;

- Develop a better understanding of a bacteria-food-host interactions controlling virulence gene expression. Research in this area would lead to an understanding of how virulent strains differ between countries such that intervention strategies could be developed which would reduce our risk of contamination from imported foods;

- Assess consumer food handling and use behaviors, especially of vulnerable populations;

- Support development of technologies to pinpoint locations of contaminants in food materials, thus mitigating vagaries due to sampling techniques;

- Develop new or improved methods of intervention to prevent or eliminate contamination in the food chain.