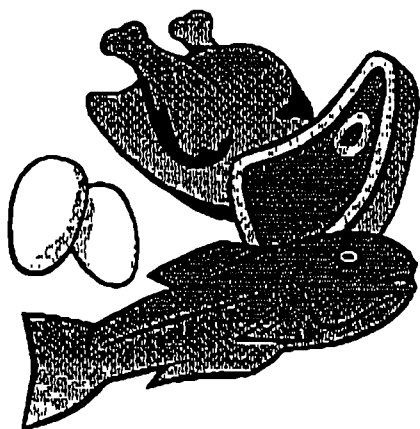


PRESIDENT'S FOOD SAFETY INITIATIVE

USDA - HHS



October 24, 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, with no new resources in FY 1998.

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).

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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 INITIATIVE
1999 BUDGET PROPOSAL
(Dollars in Millions)**

		<u>1998</u>		<u>1999</u>	
	<u>1997</u>	<u>Budget</u>	<u>Change from 1997</u>	<u>Request</u>	<u>Change from 1998</u>
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	5.6	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	24.5	18.2
Subtotal, Risk Assessment	8.7	13.5	4.8	34.2	20.7

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

	1997	1998		1999	
		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	17.0	10.6
Centers for Disease Control	0.0	0.0	0.0	2.7	2.7
Subtotal, HHS	4.4	6.4	2.0	19.7	13.3
Subtotal, Education	7.2	11.2	4.0	32.0	20.8
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	<u>162.1</u>	<u>207.4</u>	<u>45.3</u>	<u>378.1</u>	<u>170.7</u>

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

		<u>1998</u>		<u>1999</u>	
			Change from		Change from
	<u>1997</u>	<u>Budget</u>	<u>1997</u>	<u>Request</u>	<u>1998</u>
AGENCY TOTALS:					
DEPARTMENT OF AGRICULTURE:					
Agricultural Research Service	\$49.7	\$53.8	\$4.1	\$88.8	\$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	213.2	88.5
Centers for Disease Control	4.5	14.5	10.0	35.5	21.0
Subtotal, HHS	105.2	139.2	34.0	248.7	109.5
TOTAL, INITIATIVE	162.1	207.4	45.3	378.1	170.7

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 IICA, 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 toxico-infectious 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 toxico-infectious 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
ECONOMIC RESEARCH SERVICE
FY 1999 BUDGET REQUEST**

RISK ASSESSMENT -- \$1.0 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.

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.

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 and L

- 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.

USDA CAN USE FINES TO STOP WHICH OF THE FOLLOWING OFFENSES?

Circuses mistreating elephants	YES
Dealers buying or selling dogs and cats without a license	YES
Incorrect weighing and accounting for livestock by packers	YES
A dealer selling undersized potatoes	YES
A zoo's improper treatment of its animals	YES
Failing to file reports with the onion committee	YES
Exchanging food stamps for cash	YES
A handler's failure to keep appropriate records on watermelons	YES
Interstate movement of certain livestock without a health certificate	YES
Violating food safety laws and regulations	NO

BR -
This food
safety legislation
is compelling &
held up. It
would make a
good issue for
the President to
hit again.
Tom
- I gave this
to Rahm.

Food
Safety

BR -
holdup?
up is the
- we

Mar. 6. 1998 11:40AM

**TO PROTECT CONSUMERS, THE GOVERNMENT CAN
ORDER THE RECALL OF—**

Baby swings YES

Infant formula YES

Seat belts YES

Coffee makers YES

Juice extractors YES

Cribs YES

Toys YES

Automobiles YES

Gasoline YES

Insecticides YES

/ Meat NO

/ Poultry NO

No. 5b4U P. 2/3
From: USDA



United States Department of Agriculture
Food Safety and Inspection Service

FAX

To: Tom Freedman

Fax #: 454-7431

Subject:

Date:

Pages: including this cover sheet.

COMMENTS:

Draft
Now on FORCE

form

From the desk of

Thomas J. Billy
Administrator
834-E Johnnie L. Whitten Building
Washington, DC 20250

202-720-7025
or 720-8217
Fax 205-0158

DRAFT

MEMORANDUM OF UNDERSTANDING
AMONG
THE UNITED STATES DEPARTMENT OF AGRICULTURE
AND
THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
THE ENVIRONMENTAL PROTECTION AGENCY

I. INTRODUCTION

A. Parties

The parties to this agreement are the United States Department of Agriculture (USDA), the United States Department of Health and Human Services (HHS) and the Environmental Protection Agency (EPA).

B. Background

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

In his January 25, 1997 radio address, President Clinton directed three Cabinet members — the Secretary of Agriculture, the Secretary of HHS, and the Administrator of the EPA — to identify specific steps to improve the safety of the food supply. Their May, 1997, report to the President identified several problem issues and outlined a comprehensive new initiative to address those problems and improve the safety of the nation's food supply.

One issue addressed in the report to the President was the coordination among federal, state and local agencies in responding to interstate outbreaks of foodborne illnesses.

Three federal agencies are charged with responding to outbreaks of foodborne illness (for the purpose of this MOU, foodborne illness also includes waterborne illness): USDA, EPA, and the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC)

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

All states, and many local governments, with widely varying expertise and resources, share responsibility with the federal agencies for response to such outbreaks and, also, have a critical role. Identification and investigations of foodborne illness often begin at the community or state level. States share with the federal government the legal responsibility for protecting the health of their residents. The majority of foodborne outbreaks occur at the local or state level, however, many outbreaks involve federal agency jurisdiction. Illnesses cross state borders, and most foods or food ingredients are processed or produced in another state or by international trading partners. Federal involvement is also necessary when contaminated food from a common source has been distributed to grocery stores, restaurants, and homes in more than one state.

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

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

C. Recognition of Need

Although significant coordination already occurs among the federal agencies; among federal, state and local agencies; among the various state agencies; and between state and local agencies, better coordination is needed to meet new and growing threats to the nation's food supply, enhance the level of public health protection, leverage agency resources and experience, and avoid duplication of effort and move more quickly since products can be widely distributed.

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Further, a critical element of an effective, rapid response to a foodborne illness outbreak is ready communication by all the involved parties. Although there are communication systems in place, the systems need to be expanded and coordinated to achieve rapid exchange of information and data between key outbreak response personnel in each agency at the federal, state and local levels.

The report to the President recommended the establishment of an intergovernmental group, to be known as the Foodborne Outbreak Response Coordinating Group, to improve the approach to interstate outbreaks of foodborne illness and develop a national coordinated outbreak response system.

II. PURPOSE

A. This memorandum of understanding ("Memorandum") among the parties is entered into in order to form the Foodborne Outbreak Response Coordinating Group ("FORCG").

B. The purpose of the FORCG is defined by the following goal, mission and objectives:

1. It is the goal of FORCG to improve the approach to interstate outbreaks of foodborne illness by federal, state and local agencies charged with responding to such outbreaks.
2. Toward this goal, it is the mission of FORCG to provide participation by federal, state and local agencies with outbreak response duties in the development of a national comprehensive and coordinated food borne illness outbreak response system.
3. This mission will be accomplished by subscribing to the following management objectives which will, in turn, guide FORCG:
 - a. FORCG will review and evaluate outbreak response at the federal agency level (among agencies), including cooperation among federal agencies and between state and local agencies and affected industries. FORCG will identify areas where efficiency can be gained and make specific recommendations for improvement. FORCG will work with federal, state, and local governments, the food industry, health professionals, and consumer advocates to implement beneficial changes.
 - b. The development of standard operating procedures for the rapid exchange of data and information associated with foodborne illness outbreaks between involved agencies and for dissemination to the public. The procedures will cover the exchange of data and information associated with an outbreak and will complement systems established for exchange of information about day-to-day occurrences of foodborne illness.

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c.. A nationwide audit to catalogue existing state and local food safety program infrastructures.

d. The establishment of working groups to develop recommended procedures for outbreak response coordination at the state and local levels.

III. ORGANIZATION AND MEMBERSHIP

A. Under Title II, Section 204, Subpart (a) of the Unfunded Mandate Reform Act of 1995, Pub. L. 104-4, elected state officers, or their designated representatives with authority to act on their behalf, may meet with federal officers to exchange views, information, or advice relating to the management or implementation of federal programs established pursuant to public law that explicitly or inherently share intergovernmental responsibilities or administration. The parties therefore agree that all members of FORCG will be federal officials or state employees with the requisite authority.

B. FORCG will have the following members:

1. Two representatives from USDA: The Under Secretary for Food Safety and the Administrator for FSIS, or their designees.
2. Three representatives from HHS: The Assistant Secretary for Health, the Commissioner of the FDA and the Director of CDC, or their designees.
3. Two representatives from EPA: The Assistant Administrator for the Office of Prevention, Pesticides and Toxic Substances and the Assistant Administrator for Water, or their designees.
4. One representative from the Association of Food and Drug Officials.
5. One representative of National Association of City and County Health Officials.
6. One representative from the Association of State and Territorial Public Health Laboratory Directors.
7. One representative from the Council of State and Territorial Epidemiologists.
8. One representative from the National Association of State Departments of Agriculture.
9. One representative from the Association of State Water Officials.

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IV. RESPONSIBILITIES AND SCOPE OF WORK

- A. FORCG will be co-chaired by the Under Secretary for Food Safety (USDA) and the Assistant Secretary for Health (HHS). His or her designee will facilitate each meeting.**
- B. One member will be designated as the outbreak coordinator for each department or agency that has a role in an outbreak response. HHS will designate the Assistant Secretary for Health as the primary person in charge of coordination for HHS. USDA will designate the Under Secretary for Food Safety as the primary person in charge of coordination for USDA. EPA will designate the Assistant Administrator for Water as the primary person in charge of coordination for EPA when drinking water is involved and the Assistant Administrator for the Office of Prevention, Pesticides, and Toxic Substances will be the primary person when Pesticides and Toxic Substances are involved.**

V. GENERAL PROVISIONS

- A. FORCG will meet monthly.**
- B. This Memorandum may be modified with supplemental written agreements signed by the parties and can be terminated in writing, in whole or in part, by consensus of the parties.**
- C. This Memorandum will become effective on the date the final signature is affixed hereto.**
- D. This Memorandum is entered into within the limits of the statutory authority of the parties to the Memorandum.**

SIGNATURES

AGENDA—Food Safety Interagency Working Group
June 3, 1998

1. Announcements
2. Update on GAO request
3. Update on *Farm To Table* recommendations
4. Issue Paper(s)
5. Draft Strategic Plan
6. Next meeting agenda

Single Food Agency Outline

June 3, 1998

I. Potential issues in the NAS report and/or gaps in the food safety system.

Research

- ▶ redundancy, inefficiency, and adequacy of food safety research among agencies (EPA, FDA)
- ▶ sufficiency of scientific basis for and difficulty of determining aggregate and cumulative risk in setting pesticide tolerances under FQPA (EPA)
- ▶ The various research programs need to be more effectively coordinated to eliminate duplication and focus on the highest priorities.
 - Issues revolve around lack of coordination on a federal food safety research agenda by food safety agencies.
 - Lack of identification of highest priorities.
 - Poor interaction between the research agencies and the federal food safety agencies due to conflicting priorities and scarce resources. Development of new technology is hampered by competing priorities.

Education and Outreach Program

- ▶ Concerns raised in this area are the need for a consistent federal food safety message to the consumer, public health professionals and physicians; retail, food-service, and institutional food preparers, veterinarians, animal and other producers, and food transportation workers.

Consolidation and Coordination

- ▶ whether science/research should be consolidated in a single agency (EPA)
- ▶ how to best link food safety research and surveillance by CDC (EPA)
- ▶ whether and how to best link research and regulation (EPA)
- ▶ whether to combine in a single agency or separate in different agencies the standard-setting and enforcement of food safety regulation (EPA)
- ▶ need to provide a coordinated, consistent Federal response to food contamination and food-borne illnesses (EPA)
- ▶ need for coordinated communication with State and local authorities on food safety issues, especially in cases of food contamination and illness (EPA)

Statutory Authority Issues

- ▶ Differences in the principles on which FDA, FSIS, and EPA statutory authorities are based (i.e., FDA food regulation is based on considerations of risk only; EPA pesticide

regulation must balance risks and benefits; and USDA's statute requires continuous inspection)(EPA, FDA)

- ▶ Inspection manpower and statutory authority disparity between USDA and FDA for imported foods (EPA, FDA)
- ▶ Confusing and inefficient division of regulatory authorities between USDA and FDA for several issues such as egg safety, safety of foods during transportation (an issue shared with Department of Transportation), additives to meat and meat products, game meats (FDA)
- ▶ Confusing and inefficient division of regulatory authorities between EPA and FDA for drugs that also have pesticidal activity under FFDCA and FIFRA and the regulation of antimicrobial chemicals under FFDCA and FQPA

Funding

- ▶ Funding disparity between USDA and FDA (especially for inspection and research activities)

Surveillance: Improve Safety and Decrease Contamination of Food

- ▶ The surveillance of the food supply is not adequate to identify the source of infectious agents.
 - Our understanding of many pathogens and how they contaminate food is limited; for some contaminants, we do not know how much must be present in food before there is a risk of illness and for others, we do not have the ability to detect their presence in foods. For example, there has been an increase in new disease-causing microbes. Just in the last year, new forms of Salmonella and E.coli have appeared. *E.coli* O157:H7 was not discovered until 1982. Originally thought to be only in animal products, it has been found in apple juice and lettuce.
 - A national and global increase in antimicrobial resistance, making infections very difficult to treat and a lack of resources to effectively address this critical public health concern.
- ▶ Agencies have different priorities for the types of pathogens that should be included in a surveillance program, leading to different agendas.
- ▶ number of illnesses due to bacterial contamination of food (EPA)
- ▶ illnesses caused by adulterated food from use (or misuse) of pesticides (EPA)
- ▶ need for improved control of microbial contamination by pesticides (EPA)

Responses to Food-Borne Outbreaks

- ▶ There is a piecemeal approach to food safety problems at the federal level. In addition, split jurisdictions, a misunderstanding of each agency role in an outbreak and lack of communication hampers an effective and rapid response.
 - An example frequently cited is the outbreak of Hepatitis A from frozen strawberries, served in the federal school lunch program over a year ago. Agencies involved in this outbreak included AMS that purchased the frozen strawberries for the school lunch program, FNS that has jurisdiction over school

lunch, FDA that has jurisdiction over strawberries, the state of California where they were packed and the state of Michigan that received the strawberries. Cited was the lack of coordination and communication between these agencies to clearly articulate the problem and identify the solution as well as confusion over who had jurisdiction.

- States and local regulatory agencies play a critical role in food-borne outbreaks. Yet, many state and local authorities complain that there is a lack of communication and exchange of information, jurisdictional squabbling and heavy-handed approach by the federal government rather than a national integrated system.

Risk Assessment System

- ▶ Government agencies are reacting to food safety problems rather than acting to prevent them. Food safety risks are not addressed in a consistent manner across the current government-wide food safety system.

Regulatory Reform

- ▶ Despite the fact that HACCP has been implemented in more than 300 large plants, critics state that the current regulatory agenda has not changed to reflect this new science-based system of food safety controls. Rather than streamlining burdensome regulations, critics contend that FSIS is still operating under a prescriptive “command and control” setting.

Overall Mission

- ▶ Additional areas raised might focus on whether the overall mission of the food safety agency is public health and if that mission is compromised by competing interests within the Agency or Department -- such as promoting American agricultural products or approving drugs.
 - Incompatibility of USDA’s dual missions of promotion of agriculture and protection of the public’s health (FDA)

Traceback

- ▶ Issues involve the lack of authority to take regulatory action at the farm level including traceback to identify the source of contamination.

Miscellaneous

- ▶ Divided Congressional committee jurisdictions for USDA, HHS (with different committees having jurisdictions for CDC and for FDA), and EPA (FDA)

Inspections

- ▶ Inspection manpower disparity between USDA and FDA for domestic foods (EPA, FDA)
 - Firms that process food products that pose similar health risks to the public are inspected at widely different frequencies, depending on which agency and regulatory approach govern them
 - USDA has daily inspection of meat and poultry in slaughter plants and egg-product processing plants while FDA conducts periodic inspections for all other food processing plants; that entails fewer than 700 inspectors
 - Food establishments are sometimes inspected by more than one federal agency because they come under multiple jurisdictions. For example, FDA has jurisdiction over frozen cheese pizza and inspects cheese pizza processors once every 10 years on average while USDA, with responsibility over frozen pepperoni pizzas, inspects such processors daily. Critics point to an inefficient use of inspection resources.
- ▶ Inspection manpower and statutory authority disparity between USDA and FDA for imported foods (EPA, FDA)
 - Increase in imported food, particularly fruits and vegetables from countries that have less stringent standards than that of the United States and a lack of FDA resources to provide appropriate coverage.
- ▶ FDA's inability to adequately cover imported food entries into the United States (FDA)
- ▶ more efficient and cost-effective use of Federal resources by combining Federal and/or State inspections for food safety (EPA)
 - Multiple systems between federal, state and local regulatory agencies that are not fully integrated and coordinated in their approach. State and local authorities have responsibility for the regulation of retail stores and restaurants and there can be large disparities in regulatory standards and resources between the various state and local jurisdictions.
- ▶ Enforcement authorities granted to the agencies also differ. USDA has the authority to (1) require food processors to register so that they can be inspected (2) presume that the food firms are involved in interstate commerce and are thus subject to regulation, (3) prohibit the use of processing equipment that may potentially contaminate food products, (4) temporarily detain any suspect foods from entering commerce. Conversely, FDA, without such authority, is often hindered in its ability to oversee food processors.
- ▶ Agency coordination agreements designed at overcoming the fragmented food safety system by avoiding duplication and/or gaps in inspection coverage are cited as ineffective. For example, unsanitary and other unsafe conditions are said to have persisted in food processing plants because notification required by the coordination agreements does not always take place and are not referred to the responsible agency in a timely manner.
- ▶ The lack of mandatory recall and civil penalty authority impede an agency's ability to deter abuse of food safety inspection regulations.
- ▶ GAO recently criticized the FSIS inspection force for focusing too much on violations like missing labels for imported meat and poultry products that bear little relationship to food safety. Again, the issue is that inspection needs to zero in on foods likely to pose the

greatest risks.

- ▶ More efficient use of inspection resources by basing inspection frequencies on risk-- the potential hazards associated with a product, process, and processor's compliance with federal regulations--and by eliminating duplicative inspections. Instead of continuous inspections --critics state that the agencies should test the feasibility of reducing the frequency of inspections at plants where safety risks are low and reallocating inspectors to high risk foods.

II. What Agencies are currently doing to address issues.

Inspection

- ▶ Following through on the recommendations of the first NPR report, the Administration implemented the new science-based food safety system known as HACCP. This new system focuses on preventing problems rather than catching problems after they occur. Instead of relying only on sight, touch, and smell, USDA inspectors now have additional tools targeted directly at reducing harmful bacteria like *E. coli* O157:H7 and salmonella. In 1995, the FDA issued new rules to ensure the safety of seafood using the HACCP regulatory approach.
- ▶ Leveraging inspection resources and increasing inspections for higher risk foods was addressed in the 1998 and 1999 National Food Safety Initiative.
- ▶ Working groups between USDA and FDA have been formed to:
 - Evaluate the expansion of cooperative agreements so that FSIS inspectors can provide information to FDA plants producing meat and nonmeat foods. FSIS inspectors are already in the plants, and their presence could be better used to maximize use of federal resources.
 - Review possible procedures for FSIS inspectors to exchange information with FDA on the basic sanitation conditions in warehouses.
 - Work closely with state and local regulators to establish uniform retail program standards through adoption of the Food Code. Currently as mentioned above, there are large disparities in regulatory standards between state, local and federal regulators.
 - Identify and address food safety issues related to the school lunch program and other feeding programs in USDA.
 - Consider the tasks of USDA inspectors in an HACCP environment.
 - Develop Good Agricultural Practices and Good Manufacturing Practices guidance for the domestic produce industry. FDA is also seeking legislation that would decrease the risk of importing unsafe food products from countries with food safety systems for exported products that are not on par with the U.S. system.
 - In addition, the FSIS Advisory Committee on meat and Poultry Inspection, which serves as a forum for sharing ideas and policy development on regulatory issues,

includes consumer and industry representatives, as well as state and federal officials.

Surveillance

- ▶ The Administration increased funding through the national food safety initiative to target a broad range of food-borne pathogens. The strengthened capacity of FoodNet (the food-borne diseases active surveillance network) will provide rapid identification of the causes of the outbreaks.
- ▶ FSIS, FDA and CDC collaborate with local state and health departments to analyze data, recognize trends and target prevention strategies to evaluate their effectiveness.
- ▶ FSIS, FDA and CDC have developed an MOU that will allow the agencies to jointly collect more precise information on the incidence of food-borne illness in the U.S.

Responses to Food-borne Outbreaks

- ▶ To strengthen the outbreak response and coordination, USDA, HHS and EPA have formed the Food-borne Outbreak Response Coordination Group (FORCG), an inter-departmental task force that will review food-borne illness outbreak response by federal and state governments and, based on these findings will develop and implement accelerated response procedures.
 - The Foodborne Outbreak Response Coordinating Group (FORCG) is designed to improve the approach to interstate outbreaks of foodborne illness through the development of a national comprehensive and coordinated foodborne illness outbreak response system involving federal, state and local agencies charged with responding to such outbreaks.
- ▶ Each Department will have an outbreak coordinator. For HHS, the Assistant Secretary for Health will be the primary person in charge of coordination for HHS. Outbreaks that fall under the jurisdiction of USDA will be coordinated by the Under Secretary for Food Safety. EPA will designate the Assistant Administrator for the Office of Prevention, Pesticides, and Toxic Substances.

Risk Assessment

- ▶ The Risk Assessment Consortium, JIFSAN, is an interagency group that will coordinate risk assessment activity. Created as a part of the National Food Safety Initiative, USDA, FDA, CDC, EPA and NIH will collaborate on identifying risk-assessment research priorities.
- ▶ The FSIS-FDA National Advisory Committee on Microbiological Criteria for foods also

serves as an interagency resource to provide risk assessment models for the future regulations. USDA is required to include a risk assessment in order to promulgate regulations.

- ▶ USDA and FDA sponsor an Interagency Committee on Animal Production and Food Safety. This Committee focuses on risk assessment needs at the farm level and issues such as animal identification and Salmonella.

Research

- ▶ Under the FQPA, EPA is working hard to strengthen the scientific basis of its actions, including obtaining expert scientific advice, peer review, and the input of stakeholders.
- ▶ USDA has formed the Food Safety Working Group to establish a research agenda that supports the fundamental changes that FSIS is making to food safety regulations based on the HACCP system. The goal of research agenda is to reduce the incidence of food-borne associated with the consumption of meat, poultry and egg products. The Food Safety Research Group includes the Following USDA agencies: ARS; APHIS; CSREES; ERS; FSIS; ORACBA; and the Office of the Secretary.
- ▶ USDA, HHS and EPA have also formed an interagency research planning group to identify research priorities aimed at reducing microbial risk in produce.
- ▶ The Office of Science and Technology (OSTP) has convened an interagency group which includes, USDA, HHS, EPA and NIH, to coordinate federal food safety research priorities and will recommend direction of research funds for the FY 2000 budget for the federal food safety agencies.

Education

- ▶ The Partnership for Food Safety Education is a joint effort among USDA, HHS, EPA, the Department of Education and the private sector to respond to needs identified in the Food Safety Initiative. The partnership identifies key food safety messages to improve consumers, retail and food service workers' unsafe practices and handling of food.

Pesticides

- ▶ Under the Food Quality Protection Act (FQPA), the EPA is required to reassess all "tolerances" of pesticides, or maximum residue limits, by the year 2006. This will "update" pesticide residue limits in/on food in the U.S. based on the latest scientific studies and consideration of aggregate exposure to pesticides from food, drinking water and residential and lawn uses, with special emphasis on protection of children.

Microbial Contamination

- ▶ Under FQPA, EPA must revise the antimicrobial (substances used to control harmful microorganisms) registration process with the goal of achieving significantly shorter review times for all types of antimicrobial registration actions.. EPA's plan for improving the efficiency of its regulation of antimicrobial pesticides has four stages:
 1. Establish a New Antimicrobial Division (accomplished 2/97).
 2. Develop New Policies.
 3. Address the Backlog of Pending Applications
 4. Establish a Streamlined Antimicrobial Regulatory Process.

III. Current food safety coordination efforts.

Working Groups and Meetings

- ▶ FDA, EPA and USDA Principles meetings on Food Safety
- ▶ Interagency Food Safety Risk Assessment Group (I-FRAG)
- ▶ EPA/FDA workgroup to consolidate current FIFRA, TSCA and FDA Good Laboratory Practice (GLP) regulations, harmonize internationally, and verify compliance with GLP's
- ▶ Interagency Working Group on Food Safety Research (NSTC Committee on Science)
- ▶ FDA/FSIS WGs on methods development for animal-drug residues in milk and in animal tissues
- ▶ Surveillance Advisory Committee WG
- ▶ National Antimicrobial Susceptibility Monitoring Program WG (FDA, CDC, USDA)
- ▶ Interagency Residue Control WG (FDA, USDA)
- ▶ Interagency produce research WG
- ▶ National Food Safety Initiative interagency WG
- ▶ Food safety education interagency WG
- ▶ Food Safety Education IAG (FDA/USDA)
- ▶ BSE/TSE interagency coordinating group
- ▶ Interagency WG on GPRA goals
- ▶ FoodNet WG
- ▶ CDC/FDA *Clostridium botulinum* WG
- ▶ Water WG (EPA/FDA/USDA)
- ▶ Emerging Infectious Diseases WG
- ▶ Interagency WG on GAPs/GMPs (FDA/USDA/USDA)

Committees

- ▶ The EPA & USDA co-chaired Tolerance Reassessment Advisory Committee (TRAC)

- ▶ Interagency Committee on Animal Production and Food Safety
- ▶ Food Safety Initiative Steering Committee (USDA, DHHS, EPA)
- ▶ HHS Environmental Health Policy Committee
- ▶ A variety of U.S. Codex committees

Other

- ▶ The Food Safety Initiative
- ▶ Partnership for Food Safety Education
- ▶ The Risk Assessment Consortium
- ▶ National Agricultural Pesticide Impact Assessment Program (NAPIAP)
- ▶ Conference of Food Protection
- ▶ Ad hoc Executive Board Members of: AFDO, CSTE, ASTHO, ASTPHLD
- ▶ Food Service Training and Education Alliance
- ▶ Healthy People 2000 and 2010

MOUs

- ▶ Foodborne Outbreak Response Coordinating Group (FORCG)(MOU/USDA, DHHS, EPA)
- ▶ MOU with USDA and FDA on oversight and direction for the Pesticide Data Program (PDP) through an Executive Steering Committee
- ▶ MOU and quarterly meetings with FDA (to coordinate and perform certain FIFRA/GLP inspections)
- ▶ Interagency Coordinating Committee on Animal Production and Food Safety (MOU/USDA, DHHS, DOD, and EPA)
- ▶ CVM, USDA, FSIS, AMS and EPA MOU on Regulatory Activities Concerning Residues of Drugs, Pesticides and Environmental Contaminants in Foods.
- ▶ CVM/EPA MOU on pesticides/animal drug overlaps
- ▶ CVM/APHIS MOU on biologics/immune mediators/animal drug overlaps
- ▶ FDA/FSIS MOU on cooperative notification of in-plant violations
- ▶ FDA/USDA MOU on National Advisory Committee on Microbiological Criteria for Foods
- ▶ Interstate Shellfish Sanitation Conference MOU

Coordination

- ▶ EPA/FDA/USDA coordination on possible pesticide misuse cases (illegal residues on crops or food)
- ▶ OECA/OPPTS/FDA coordination on food contamination cases

IV. Organizational issues/options for a single food agency that must be addressed.

- Combine all regulation/risk assessment and enforcement/risk management functions for all foods (for man or other animals) in one agency (including chemical contaminants, pesticide, food additives pre-market approval, nutrition, education, etc.), and separate mercantile functions in a different agency
- Combine all food-related functions (public health, and mercantile) in one agency
- Separate regulation/risk assessment from enforcement/risk management
- Separate science/research from regulation and enforcement
- Separate surveillance from other public-health functions
- Maintain current division of responsibility, but eliminate divided responsibilities (i.e., put responsibility for all meat and poultry products, all eggs and egg products, etc. in one agency)
 - ▶ Pesticide regulation in a single food agency or with EPA (EPA)
 - ▶ Drinking water in a food agency or with EPA

HHS03: DEVELOP A NATIONAL, UNIFORM INSPECTION SYSTEM TO ENSURE A SAFE FOOD SUPPLY



BACKGROUND

The Centers for Disease Control and Prevention (CDC) of the U.S. Department of Health and Human Services (HHS) estimates that at least 9,000 Americans die from foodborne illness each year; another 6.5 million become sick from eating contaminated foods.¹ Because many of these cases go undiagnosed, the actual figure is probably much higher than the conservative estimate of 6.5 million. An estimate by the Food and Drug Administration (FDA) is in fact much higher, at a minimum of 24 million cases per year.²

Most cases of foodborne illness reported in the United States today can be traced to meat, poultry, eggs, milk, and shellfish.³ Shellfish alone caused 21 percent of all reported food poisonings arising from meat, fish, or poultry between 1978 and 1987.⁴ Foods can be contaminated with harmful microorganisms (such as bacteria, viruses, and fungi); parasites (such as tapeworms, roundworms, and flukes); chemicals (such as pesticides, animal drugs, flavor and color additives, or industrial chemicals); and natural poisons (such as the toxins in some

shellfish). Since 1985, the United States has witnessed significant and highly publicized outbreaks of foodborne illness caused by highly pathogenic bacteria, including cheese contaminated with *Listeria*, milk and cantaloupe contaminated with *Salmonella*, canned mushrooms contaminated with the toxin produced by *Staphylococcus*, and hamburger contaminated with *E. coli* O157:H7. In addition to these acute outbreaks, chemical contamination of foods with animal drugs and pesticide residues may contribute to unknown increases in cases of cancer and birth defects.

Some increases in reported foodborne illness may be attributable to improved detection and reporting methodologies. Others seem to be an outgrowth of modern food processing techniques and changing consumer habits.

Much of what Americans eat today is processed at centralized facilities geared to high-speed mass production, rather than in local shops and in the home. More food is transported across the country and imported from other countries.

In 1993, consumers rarely stay home and spend hours preparing food, but instead eat on the run. They buy from carry-outs, eat at fast-food chains, and cook in microwave

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ovens. Much more of our food is bought pre-prepared and pre-cooked.

Also, consumers as a group are physiologically different than they were in the early 1900s, when most of our current food safety laws were written. The "baby boomers" are dominating an aging U.S. population. Lowered immunity is a natural part of the aging process, increasing susceptibility to various infectious diseases, including foodborne illness.⁵ Due to modern medicine, today's consumers are living longer and are more likely to live with chronic illnesses, such as cancer and acquired immunodeficiency syndrome (AIDS), that also increase susceptibility to foodborne illness. Some foodborne bacteria, including *Salmonella*, have been associated with chronic diseases such as arthritis.⁶ The parasite *Toxoplasma gondii* has been shown to cause dementia in individuals with compromised immune systems; more than half of all cases of dementia occurring in AIDS patients may be of foodborne origin.⁷

The prevention and control of foodborne illness is of great economic importance. Outbreaks are expensive, not only for those who become ill, but for society at large. An April 1985 *Journal of Food Protection* article estimated that foodborne illnesses cost the United States between \$1 billion and \$10 billion annually. This figure includes direct medical costs, lost wages and productivity, and industry losses through embargoes, voluntary destruction and recall. The article stated, "Any money spent on research, surveillance and public education would be only a small fraction of the cost otherwise borne by the economy when disease occurs. . . . In most instances food supplier losses in the form of recalls, lost business, legal fees, legal settlements and wages exceeded the medical costs and lost earnings of the victims, thus the indirect cost to the economy may equal or even double the patient-related cost estimates."⁸ Several recent studies have reached similar conclusions.

The *New England Journal of Medicine* of August 1978 published a CDC study on the

impact of one foodborne disease—salmonellosis. The study showed that "Salmonellosis is much more than an inconvenience—it is responsible for complications, operations, and hospitalizations of five to six days for previously well persons in all age groups, not just infants and the elderly." The study also stated that ". . . the cost of public health programs to detect, control, and prevent salmonellosis must be measured against the unnecessary medical expenses and loss-of-productivity costs, which may be *more than a billion dollars a year*. [emphasis added]"⁹

The present food safety and inspection system has not kept up with the changing environment. It is a complex regulatory system consisting of as many as 35 different laws and involving 12 federal agencies. Of these agencies, five have primary responsibility for food safety inspections. The FDA is responsible for the safety of most foods. Within the U.S. Department of Agriculture (USDA), the Food Safety and Inspection Service (FSIS) is responsible for ensuring the safety of meat and poultry products; the Agricultural Marketing Service (AMS) for eggs and egg products; and the Federal Grain Inspection Service (FGIS) for exported grain products. The Department of Commerce's National Marine Fisheries Service (NMFS) is primarily responsible for grading seafood products, but also provides voluntary food safety inspections at the request of the seafood industries. The FDA and FSIS are responsible for about 95 percent of all food inspections mandated by law.¹⁰

However, inconsistencies among these agencies' policies, procedures, and enforcement authority weaken the system's effectiveness. The frequency with which food processing plants are inspected and the actions taken to enforce regulatory standards for safety are determined by the legislation that governs the inspecting agency and the current allocation of resources among the agencies, and not by the relative risk the products in question pose to public safety. An optimal inspection system would be based on consistent science-based standards

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to ensure safety and would have different levels of intensity of inspection, reflecting the degree of public health risk at various stages in the processing of foods. It also would have a reliable monitoring system and an accurate compliance history for each establishment in the food industry. Our present inspection system does not meet these criteria. Different regulatory approaches, jurisdictional conflicts among agencies, and a persistent inability to allocate resources efficiently across agencies have hampered the federal government's inspection efforts.¹¹ Viewed in its entirety, the existing regulatory structure is inefficient, cumbersome, and costly.

The United States needs a scientific, risk-based system. FSIS inspectors continue to use a method developed in the early 1900s, when the Federal Meat Inspection Act, the Poultry Products Inspection Act, and other food safety statutes were enacted. This method, called "organoleptic inspection," simply means using the five senses to determine product wholesomeness. Such inspections are a critical step in the elimination of dead, dying, diseased, disabled, visibly contaminated, and otherwise unwholesome meat and poultry products from the food supply. For example, in 1989, organoleptic inspections eliminated about 70 million head of poultry, 140,000 cattle, and 181,000 pigs from the food chain.

However, public health experts now realize that the most serious outbreaks of food-borne illness in this decade are due to pathogenic microorganisms that may not be detected by the five senses during inspection. These experts are also concerned with potential risks from chemical residues—again, hazards that cannot be detected by organoleptic inspection alone. Scientific inspections, including chemical and microbiological testing or other appropriate verification steps, must be developed and implemented if regulatory agencies are to be successful in reducing foodborne illness. Rapid, on-site microbiological and chemical diagnostic tests are needed to keep pace with the daily food production volume.

Process control must be a priority to prevent product contamination and ensure a safe product.

FDA's enforcement strategy, which is grounded in the Food, Drug, and Cosmetic Act, emphasizes end-product testing. Periodic inspections provide only a snapshot of what is happening in a facility at the time of inspection. There is no way to tell whether the conditions observed at the time represent a norm. Given the agency's current resources and level of sampling, this strategy simply cannot adequately cover the expanding universe of food products and manufacturers. Again, process control must be a priority to ensure a safe product.

Viable models exist for effective process control. In 1971, the National Aeronautics and Space Administration (NASA), the U.S. Army Natick Laboratories, and the Pillsbury Company developed the Hazard Analysis Critical Control Point (HACCP) approach to process control for the production of food products. The program was intended to ensure that products produced by Pillsbury for use by astronauts were wholesome and essentially pathogen-free. Pillsbury demonstrated that adequate controls in the manufacturing process could produce a high degree of assurance that the end-products would be safe.

In 1985, a National Academy of Sciences Committee on the Scientific Basis of the Nation's Meat and Poultry Inspection Program and the National Academy of Sciences Subcommittee on Microbiological Criteria of the Committee on Food Protection embraced the HACCP concept as an effective and efficient approach to manufacturing safer food products. FDA has successfully applied HACCP principles in controlling the safety of low-acid canned foods.¹²

HACCP principles are defined differently by different users, making it imperative that a clear and consistent definition be understood by the food industry. If regulatory agencies encourage HACCP implementation by food manufacturers, each manufacturer could develop its own

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specific HACCP plan for each category of products it produces. HACCP would allow the industry to take responsibility for identifying and controlling public health hazards under its control.

It is not enough, however, to simply implement a system such as HACCP. It is not a regulatory program; HACCP only assists the industry in taking responsibility for a safer product.

An optimal inspection system would link HACCP with varying levels of government inspection that reflect the degree of public health risk present at each of the various stages in the process and that ensures HACCP plans are being implemented. Such a system would include a reliable monitoring system and an accurate compliance history for each establishment in the food industry. Our present inspection system clearly does not meet these criteria; neither does HACCP alone. HACCP only addresses process control, concentrating on critical control points in the process that pose potential public health risks. It does not provide a reliable monitoring system or an accurate compliance history of food establishments.

The current U.S. food safety inspection system also is inconsistent in its intensity and frequency of inspection for foods posing similar risks. FDA inspectors responsible for inspecting the nation's food supply are also responsible for inspecting firms that produce medical devices, drug manufacturing facilities, and blood banks. Due to limited resources, these medical-support firms usually are assigned a higher priority than food processing plants producing high-risk foods (such as low-acid canned foods and infant formulas).

Although FDA attempts to assign a risk priority to foods by categorizing them as "high" or "low" risk, the assignment of inspection frequency is inconsistent and based too much on the availability of resources. Availability is often controlled by the existence of a perceived "crisis" in the drug or medical device industry or in the nation's blood supply. Such crises usually

demand that FDA concentrate its limited resources on the crisis issue and reduce its inspection of food manufacturing firms.¹³ A recent General Accounting Office (GAO) report indicated that, on average, FDA inspects food establishments only once every three to five years.¹⁴

The Federal Meat Act of 1907 and the Poultry Products Inspection Act of 1957 require the Department of Agriculture to provide continuous inspections at slaughter establishments, examining every carcass. The acts also require that inspectors visit meat and poultry processing plants on a daily basis. These laws are inflexible and do not allow FSIS to vary its frequency of inspections to concentrate its resources on risk and issues significant to the public's health, as recommended in the National Academy of Sciences report of 1985.¹⁵

The same GAO report states, "... in fiscal year 1991, FSIS devoted about 9,000 staff years to oversee about 6,100 establishments, while FDA devoted about 255 staff years to oversee an estimated 53,000 food establishments."¹⁶ (This statement referred to the inspection of domestic food establishments and did not include import inspections.) The two agencies also have different approaches for foods posing similar risks. For example, beef broth is inspected daily by FSIS, while plants manufacturing chicken broth may be inspected by FDA once every three to five years. Meat and poultry products are inspected daily by FSIS, while shellfish are normally inspected by a small number of state inspectors. These are only a few examples of inconsistencies in the present system.

As already indicated in this paper, most authorities believe that the frequency and intensity of inspection should be based on risk. Risk should be determined by a form of risk analysis that takes into account hazards associated with the food product, the process by which it is manufactured, and the compliance history of the establishment producing the product.¹⁷ This could allow federal agencies responsible for food safety inspections to use their resources more efficiently.

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The food safety inspection system also suffers from inconsistent enforcement authority. FDA lacks the necessary enforcement power to ensure a safe food supply. FDA must prove actual or potential product contamination or establish that conditions are unsanitary. Most FDA findings of adulteration or unsanitary conditions or practices are resolved through voluntary compliance. FDA does not have direct authority to detain adulterated food products; its inspectors must take control of suspect products through federal court warrants, often a lengthy process. While an inspector is obtaining the warrant, the product may end up in the marketplace, unless the state uses its authority to seize or detain the product. FDA also lacks the authority to recall adulterated products from market and access company safety and quality-control records.¹⁸

FDA lacks a mandatory registration requirement. Establishments that are not identified by the agency go uninspected. FSIS, by contrast, requires the industry to prove safety before food products can be marketed. However, while it possesses many authorities that FDA lacks, FSIS cannot seize or prevent the shipment of known infected animals to market for slaughter.

The current food safety inspection system provides little incentive for food establishments to exceed minimum requirements. There should be a system of incentives for companies to regularly exceed standards for wholesomeness. These incentives can be positive or negative. A negative incentive would be an increased inspection cost for less than desirable compliance.

Food safety research is also duplicative and driven by the varying missions of some 21 agencies. A January 1993 report by the Committee on Food, Agricultural, and Forestry Research of the Federal Coordinating Council for Science, Engineering, and Technology reports that these agencies spend approximately \$200 million on food safety research under about 50 laws that directly or indirectly authorize such research. This research may be basic or

applied, laboratory-based or social science research. It may be broadly or specifically focused and carried out in federal laboratories, through contracts, cooperative programs, or grants to academia and the private sector. The areas of research include infectious disease agents and their toxins, drug and pesticide residues, food additives, environmental and industrial contaminants, food product processing, storage and packaging, diet and nutrition, and food production. Each area may address improved methods to identify hazards, prevention and control, mechanisms of action, risk assessment and risk management methods, or consumer behavior studies.¹⁹

The United States needs coordinated efforts for food safety research, driven by a single mission and accountable to a single authority. This would eliminate the duplication of expensive research projects and provide effective communications and information sharing among researchers.

The food safety inspection system also maintains overlapping and duplicative inspections. Inspection efforts are poorly coordinated. Coordination agreements under which agencies are required to notify other responsible agencies of plant problems or deficiencies found during inspection do not always work; a recent GAO report states such notifications do not always take place, and that problems referred to a responsible agency are not always promptly investigated.²⁰ The use of interagency agreements has been hindered by a lack of resources to follow up on referrals.

ACTION

Legislation should be enacted to create a single food safety agency responsible for administering a uniform set of scientifically based food safety laws. The President and Congress should establish a single food-safety agency within FDA responsible for food safety inspections and research. Authority for enforcing all federal food inspection laws

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and regulations, and all personnel, facilities, and equipment currently used by such programs, should be transferred to the new agency. (See Table 1 for a list of food safety responsibilities that should be transferred to this new agency).

Current laws regulating federal food inspection should be reviewed immediately to identify areas in which changes in the laws are needed to base food inspections on sound science. The new agency also should begin a review of current regulations governing federal food inspection for the purpose of producing uniform regulatory requirements, taking into consideration inherent risk in products and production methods, and the unique nature of the foods and the industries that produce them.

An immediate study should be made by the new agency of current staff and resources and the policies governing their use, and the information obtained should be used to construct a new organizational structure, a management system, inspection procedures, and research program capable of meeting public health-based objectives.

This new food safety agency must serve as a reinvention model. Its primary mission must be consumer protection and food safety. It should be customer-driven, meeting consumer needs within the boundaries of sound science. Consistent prevention of foodborne illness and poor sanitation and manufacturing practices should replace crisis management. There should be in place a management system for continuous improvement, concentrating on the continuous reduction of risks of foodborne illness. This will include continuous evaluation and reduction in the numerical regulatory standards for sanitation, microorganisms, and residues that assist in reducing risks. Empowering the front-line food inspector and eliminating cumbersome layering and complicated chains-of-command will simplify decisionmaking in the field and improve regulatory effectiveness.

The new agency should be given the authority to impose user fees for appropriate

services to aid in the cost of improving inspection processes. User fees should be considered for food establishments that require additional inspections and enforcement efforts due to repeated noncompliance. Laboratory testing conducted to release detained or recalled products in cases of known or potential contamination could be subjected to a user fee, as could other testing outside of normal monitoring or surveillance sampling. User fees also should be considered for overtime, additional shifts requiring inspection oversight, inspection of imported food products, certification of exported food products, agency responses to Freedom of Information Act (FOIA) requests, and other special services as appropriate.

The single food safety agency would eliminate the need for interagency agreements coordinating inspection activities between agencies, as well as duplicative inspections in establishments with similar products under the authority of different agencies.

The food safety agency should meet the following criteria:

- (1) The new agency should provide a scientifically sound, risk-based inspection system.

The agency must have an adequate foodborne disease outbreak reporting system. This system would provide the data needed to determine risks associated with different types of food products. This would be an integral part of the foundation of a scientifically based food safety inspection system.

HACCP or an equivalent system could be another important component of a scientific risk-based inspection system, placing responsibility for safe products on the food industry. Each food processing firm would be encouraged to have a HACCP plan for each category of food products it produces. Appropriate verification testing would be an integral part of each HACCP program.

- (2) The agency would have an automated reporting system to aid in determining inspection frequencies.

An automated reporting system can assist in identifying food establishments that are

consistently out of compliance with federal regulations. This system could be adjusted to determine inspection frequency for each establishment based on the type of product manufactured, its inherent safety risks, and the compliance history of the manufacturer. High-risk food establishments with poor compliance histories could be inspected more often than those that produce low-risk foods and maintain good compliance histories. The automated system could assist in establishing user fees for establishments requiring additional oversight.

- (3) New food safety laws should provide for uniform regulatory action and give inspectors sufficient enforcement authority.

Incentives should be used to encourage companies to consistently exceed minimum requirements. The new agency should have authority over all food products, including meat, poultry, milk, eggs, fish, shellfish, fruits, vegetables, grain products, bottled water, beverages, and any other item eaten by humans. Food safety inspectors should be given enforcement authority to seize, detain, or embargo suspected contaminated or adulterated products or food ingredients; order recalls of potentially unsafe products in the marketplace; and have access to industry quality control, food safety, and shipping records. Authority also should be granted to require the registration of all food establishments.

The law also should give the agency adequate authority to prosecute criminals, to impose civil penalties, and to terminate operations when appropriate. Authority should be granted to control hazards from the farm (or production environment) to the marketplace. For meat and poultry products in particular, an adequate trace-back system from the farm to the consumer should be put into place, with full authority to take corrective action at any point in the process. Authority also should be granted to destroy imported products known to be public health hazards.

- (4) One of the new agency's missions would be to administer food safety research functions.

Food safety research should be mission-driven and have a "protected budget"—a separate and independent line item. New food safety legislation should allow for in-house research capabilities and contracts with the best available scientists. All data and results should be published and made available to the scientific community on a competitive basis.

Research should strive to improve the scientific validity, applicability, and efficiency of inspection procedures, control measures, and risk assessment methodologies. Studies examining the cost-effectiveness of various hazard control options should be conducted as part of the agency's continuous improvement process.

IMPLICATIONS

The creation of a single food safety agency will provide enforcement of uniform, scientifically based inspection laws; eliminate unnecessary regulations; and allow for more efficient use of inspection resources. It will also eliminate a complex bureaucracy that often interferes with effective health-based decisionmaking. Most important, it will make food safer.

A uniform set of food safety laws could be administered by the present food safety agencies. This option would eliminate the inconsistent treatment of food products posing similar health risks. However, it would not address the issue of overlapping and duplicative inspections without requiring additional interagency agreements and the resources necessary to keep these agreements updated and effective.

A single food safety agency would allow inspection resources to be appropriately distributed to areas of highest risk. A uniform set of food safety laws administered by the present agencies would not allow for this efficiency, for it would be impractical to move inspectors from FSIS and place them in FDA, for instance, to meet the requirements of a uniform risk-based inspection system. Moreover, multiple agencies would continue to operate under separate

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Table 1
Food Safety Responsibilities to be Transferred into the
Food Safety Agency Within the Food and Drug Administration

Agency	Responsibility	*Legislation
<u>U.S. Department of Agriculture</u>		
Food Safety and Inspection Service	Meat and Poultry Safety	Federal Meat Inspection Act, as amended (21 U.S.C. 601 et seq.) Poultry Products Inspection Act, as amended (21 U.S.C. 451 et seq.) Talmadge-Aiken Act of 1962 (7 U.S.C. 450 et seq.)
Agricultural Marketing Service	Egg/Egg Product Safety	Egg Products Inspection Act, as amended (21 U.S.C. 1031 et seq.)
<u>Department of Health and Human Services</u>		
Food and Drug Administration	Safety of All Foods, Except Meat, Poultry, and Eggs	The Federal Food Drug and Cosmetic Act (FFDCA), as amended (21 U.S.C. 301 et seq.)
	Safety of Animal Drugs and Feeds	Pesticide Monitoring Improvements Act of 1988 (21 U.S.C. 1401 et seq.) Egg Products Inspection Act, as amended (21 U.S.C. 1031 et seq.) Safe Drinking Water Act, as amended, (21 U.S.C. 349) Infant Formula Act of 1980, as amended (21 U.S.C. 350a) Federal Anti-Tampering Act (18 U.S.C. 1365) Federal Import Milk Act, as amended (21 U.S.C. 141)
Centers For Disease Control and Prevention	Investigations of Foodborne Illnesses and Foodborne Disease Outbreaks	Public Health Service Act, as amended (42 U.S.C. 201 et seq.)
<u>U.S. Department of Commerce</u>		
National Marine Fisheries Service	Voluntary Seafood Inspection Program	Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1621 et seq.) Fish and Wildlife Act of 1956 (16 U.S.C. 742a et seq.) Lacey Act, as amended (16 U.S.C. 3371 et seq.) Magnuson Fishery Conservation and Management Act, as amended (16 U.S.C. 1801 et seq.) National Ocean Pollution Research and Development and Monitoring Planning Act of 1978 (33 U.S.C. 1701 et seq.)

Note: The food safety component of the Environmental Protection Agency (EPA) that sets tolerances for pesticides in foods could also be considered as a component of the single food safety agency. If the food safety agency deems this appropriate a recommendation to Congress to legislate such a change could be submitted.

appropriations. Any savings incurred by one agency could not easily be redirected to another agency that needed them. Duplicative administrative functions and management positions would continue; many cost-cutting opportunities inherent in a single food safety agency would be missed.

FISCAL IMPACT

All funds appropriated for current food safety activities would be transferred into FDA. Savings associated with this consolidation might include those from consolidating FDA and FSIS field offices and inspection

activities, administrative activities such as personnel offices and activities, resource management, and duplicative management positions.

Additional one-time costs could arise in creating the new agency and retraining field inspectors who now may perform different food safety tasks. Specific savings or additional costs cannot be determined at this time; this report assumes that the savings and additional costs will balance, with a neutral budget impact.

The projected total budget authority for fiscal years 1995 for the FDA and the USDA (FSIS and the food safety components of AMS) is \$817 million.

STE-OK

Endnotes

1. Bennett, John V., et al., "Infectious and Parasitic Diseases," *Closing the Gap: The Burden of Unnecessary Illness*, eds. Robert W. Amler and H. Bruce Dull (New York: Oxford University Press, 1987), pp. 102-114.
2. Archer, Douglas L., and John E. Kvenberg, "Incidence and Cost of Foodborne Diarrheal Disease in the United States," *Journal of Food Protection* 48 (1985), pp. 887-894.
3. Bean, N.H., and P.M. Griffin, "Foodborne Disease Outbreaks in the U.S., 1973-1987: Pathogens, Vehicles, and Trends," *Journal of Food Protection* (September 1990), pp. 804-817.
4. National Academy of Sciences, Institute of Medicine, *Seafood Safety* (Washington, D.C.: National Academy Press, 1991).
5. Menning, Edward L., "Danger Lurks in Your Supermarket Meatcases," *Journal of the American Veterinary Medical Association* (1988), pp. 494-497.
6. Archer, Douglas L., "The Impact of Foodborne Infections," *Food Technology*, 42(7) (July 1988), pp. 53-58.
7. Weiss, Mike, Tanya Roberts, and Hal Linstrom, "Food Safety Issues: Modernizing Meat Inspection," *Agricultural Outlook* (June, 1993), p. 33.
8. Archer and Kvenberg, pp. 887-894.
9. Cohen, Mitchell L., et al., "An Assessment of Patient Related Economic Lost in An Outbreak of Salmonella," *New England Journal of Medicine* (August 1978), pp. 299-301.

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10. See U.S. General Accounting Office (GAO), *Food Safety and Quality: Uniform, Risk-Based Inspection System Needed to Ensure Safe Food Supply*, Report to the Congress, RCED-92-152 (Washington, D.C.: U.S. General Accounting Office [GAO], June 1992).
11. Ibid.
12. National Research Council, *An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients* (Washington, D.C.: National Academy Press, 1985), pp. 50-54.
13. See U.S. Department of Health and Human Services (HHS), Office of Inspector General, *FDA Food Safety Inspection*, Audit Report No. OEI-05-90-01070 (August 1991).
14. See GAO.
15. Committee on the Scientific Basis of the Nation's Meat and Poultry Inspection, *Meat and Poultry Inspection: The Basis of the Nation's Program* (Washington, D.C.: National Academy Press, 1985), p. 10.
16. See GAO.
17. Committee on the Scientific Basis of the Nation's Meat and Poultry Inspection.
18. See HHS.
19. See Federal Coordinating Council for Science, Engineering, and Technology, Committee on Food, Agriculture, and Forestry Research of the Food, *An Overview of Food Safety Research* (Washington, D.C.: U.S. Office of Science and Technology Policy, January 1993).
20. See GAO.