

NLWJC - Kagan

DPC - Box 008 - Folder 003

**Consumer Protection - Food Safety
Initiative 2000**

Elena,

Attached is a relatively cogent description of the initiative (tabbed) and the breakdown of dollars.

I have been describing the idea this way: this year we worked hard to better coordinate federal agencies and improve the technology and resources they have. Next year's initiative builds on that by also working to integrate federal, state, and local public health agencies in a science-based system. For instance, FDA will partner and enter into contracts with local agencies to inspect along federal guidelines. The most prominent result would be a better inspection system. FDA's inspection program is viewed widely as deficient, with most plants only being inspected once every seven to ten years. HHS estimates that a combination of the improved federal and local inspections and our risk-based approach will reduce the inspection cycle so that high risk operations will be inspected once a year. FDA will also increase the number of international inspections from 100 to 250 and will conduct evaluations of foreign food production systems.

Bill Schultz is writing up a one pager for tomorrow to help DPC and Neal Lane and others argue for this and I will forward that as well.

Hope you are feeling better.

Tom

President's Food Safety Initiative

Joint Budget Submission

FY 2000

Department Of Health And Human Services

and

Department Of Agriculture



PRESIDENT'S FOOD SAFETY INITIATIVE

FY 2000 Budget Request

Executive Summary

Introduction

This document represents a joint effort among CDC, FDA, and USDA to coordinate agency budget requests for the President's Food Safety Initiative. The document is structured as follows: A) An Executive Summary that provides an overview of the importance of this initiative, highlights major accomplishments to date, including establishment of the President's Council on Food Safety, and summarizes the fiscal year 2000 budget requests for each agency. It also highlights the three integrated components essential for a strong and effective food safety system: 1) sustained progress toward a seamless, science-based food safety system; 2) enhanced public health surveillance, and increased speed and efficiency in responding to outbreaks of foodborne illness; and 3) greater emphasis on the control of foodborne hazards in the pre-harvest phase of the farm-to-table continuum; B) An integrated budget table showing dollars for fiscal years 1998, 1999, and 2000, by agency, and by food safety category (surveillance, coordination, inspections, education, research, and risk assessment); and C) Narrative descriptions of activities planned with the requested funding for fiscal year 2000, including specific budget tables for each.

Overview

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

The 1998 and 1999 budgets included additional funding to address the need for critical new investment in the food safety system as identified in the May 1997 report. The 1998 budget initiative brought much-needed new resources to enhance surveillance of foodborne disease and outbreaks and better coordinate our response to outbreaks, improve inspections and compliance, target important new research and risk assessment to critical scientific gaps, and expand education and training especially of those who handle food at critical points from the retail setting to the home.

Also, in 1998 the President's Council on Food Safety and the Joint Institute for Food Safety Research were created through two Executive Orders to develop strategic plans for coordinating food safety activities. The Secretaries of HHS and USDA play a major role in both of these organizations.

The 1999 initiative builds on gains made in these areas, and places increased emphasis on ensuring the safety of domestic and imported fresh produce and imported foods; targets retail food safety education; transforms traditional meat and poultry inspection systems to science-based HACCP systems; and develops scientific information and tools to control a greater range of food safety hazards. These activities have laid the foundation for building a strong, scientific base for a farm-to-table food safety system that protects public health by monitoring and addressing a broad range of food safety hazards.

For the 2000 budget, the agencies are requesting an increase of \$86.2 million of the fiscal year 1999 President's Budget for the Food Safety Initiative. These funds will be used to build on the foundation established in 1998 and 1999 and will target resources to: (1) further develop a nationally integrated food safety system by expanding and strengthening the partnership between Federal, state, and local agencies; (2) continue enhancing surveillance for foodborne diseases and increasing the speed and efficiency of responses to outbreaks of foodborne illness; and, (3) put greater emphasis on the control of foodborne hazards in the pre-harvest phase of the farm-to-table continuum. Only through continued investment can the Administration realize the President's goal of establishing a seamless, science-based food safety system.

President's Council on Food Safety

Through the ongoing process of working together under the President's Food Safety Initiative, the agencies (FDA, CDC of HHS, USDA, and EPA) have identified new opportunities to improve food safety, avoid duplication, and leverage agency resources. This process will be greatly enhanced by the President's Council on Food Safety (the Council) and the Joint Institute for Food Safety Research (JIFSR). By creating the Council and JIFSR, the President has re-emphasized the importance of establishing a seamless, science-based food safety system. This represents an efficient and effective way to ensure the implementation of a farm-to-table food safety strategy that reduces the level of foodborne illness in the most effective way possible. The definition of an effective system is embodied in the principles and goals of the Food Safety Initiative and the mission statement of the Council:

“One that is based on an integrated system of government regulatory oversight; operated in collaboration with the industry and public; based on the best knowledge of risk and its mitigation that current science can provide; that keeps the numbers of injuries and illnesses from food as low as feasible.”

This vision also reflects the findings from the National Academy of Sciences (NAS) report “Ensuring Safe Food from Production to Consumption,” that an effective food safety system is an interdependent system composed of Government agencies at all levels, as well as other stakeholders. NAS found that the successful integrated operation of a food safety system requires officials at all levels of Government to work together in support of common goals of a science-based system.

Throughout 1999, the Council will work to meet the President's goal of developing a comprehensive food safety strategy and coordinating food safety budgets that will result in further improvements

in the safety of the food supply and ensure the most effective use of Federal resources. The strategic plan will take into consideration the findings and recommendations of the NAS report and input from the public. Upon completion of its evaluation of the current food safety system, the Council will make additional recommendations on how to advance the efforts identified in the President's Food Safety Initiative.

Accomplishments to Date

In the first two years of the President's Food Safety Initiative, HHS and USDA have focused on building a strong, scientific foundation for a farm-to-table food safety system. The coordinated activities have greatly enhanced the capacities of the states and Federal government to monitor the incidence of specific foodborne diseases; rapidly respond to outbreaks of foodborne illness and prevent future outbreaks; identify foodborne hazards that pose the highest public health risks and direct resources to minimize those risks; and develop safe food practices education programs aimed at improving food safety for Americans.

Significant gains have already accrued with direct benefits to the public health:

More rapid identification of foodborne illness and containment of outbreaks

- PulseNet (DNA fingerprinting) and FoodNet (monitoring of foodborne illness) together strengthen the ability of the nation's public health officials to rapidly detect and limit the health consequences of foodborne illness and make it possible to estimate more accurately the true magnitude of foodborne illness in the United States.
- This technology has already been used in several instances to reduce outbreaks. PulseNet data were used several times to detect and limit the size of foodborne illness outbreaks, e.g. for alfalfa sprouts, mesclun lettuce mix, ground beef, cheese curds, and *Salmonella* Agona in cereal. While we cannot quantify the number of illnesses prevented, by identifying and stopping pathogens much earlier than we otherwise would have, we have definitely reduced the number of potential illnesses in these particular cases.
- FoodNet sites were able to identify *Campylobacter* as the most common cause of foodborne disease, although it has rarely caused outbreaks of illness since the 1980s. These findings led to new interagency efforts in research and surveillance to better understand how this pathogen enters the food chain and how to control it. Within FoodNet, there are now special studies to determine which foods and behaviors are associated with *Campylobacter*, *E. coli* O157:H7, and some *Salmonella*.
- PulseNet, data allowed for the rapid identification and subsequent traceback from two independent *E. coli* O157:H7 outbreaks to a common source of alfalfa sprouts in Michigan. In another incident *E. coli* O157:H7 contaminated mesclun lettuce mix implicated in illnesses in two different states was identified as having the same pathogenic fingerprint and quickly traced back to the common packer. Because of

the PulseNet data FDA was able to more rapidly identify, respond, and effectively limit the extent of illness.

- In Wisconsin, epidemiological and PulseNet data were used to confirm that approximately 50 cases of *E. coli* O157:H7 were attributed to cheese curds manufactured by a specific facility. Initial follow-up inspections by the state did not reveal the source of contamination. However, because DNA fingerprints of isolates from the curd matched DNA fingerprints of isolates from ill individuals, the state, with FDA, pursued the investigation at the firm and found inadequate separation of raw and pasteurized milk products. FDA is currently conducting research on cheese fermentation at the National Center for Food Safety and Technology to determine the survivability of pathogens, including *E. coli* O157:H7 in cheese.
- PulseNet and epidemiological data were used to correlate *E. coli* O157:H7 outbreaks from ground beef to particular processors. USDA then did further sampling and was able to identify other processors and their products. The processors voluntarily recalled their products from the market, preventing illnesses.
- PulseNet data combined with epidemiological data were able to differentiate several discrete outbreaks among multiple clusters of *E. coli* O157:H7 that occurred in June, 1998, in the Northeast United States. The majority of the clusters were associated with ground beef consumption, however, many of the clusters have an unknown vehicle and are still being investigated.
- In the recent *Salmonella* Agona outbreak associated with toasted oat cereal, FoodNet detected an increase in the number of *Salmonella* Agona cases across the United States. PulseNet determined that the majority of the *Salmonella* Agona isolates were indistinguishable and through epidemiological investigation were associated with a common vehicle. Without the FoodNet and PulseNet data, linking of the outbreaks across the U.S. and identification of the source of the pathogen would have taken far longer and been complicated by the other, non-associated *S. Agona* outbreaks at the time. With FoodNet and PulseNet, public health officials were able to quickly focus on the outbreaks associated with the cereal and its removal from the market, preventing additional illnesses.
- FDA, CDC, USDA/ARS and USDA/APHIS collaborated in response to an outbreak of salmonellosis among residents of a Vermont dairy farm. This illness was caused by *Salmonella* Typhimurium DT104, a multi-resistant pathogen, on the farm and in the surrounding area. The National Antibiotic Resistance Monitoring System (NARMS) facilitated the recognition that *Salmonella* Typhimurium DT104 was widespread in the U.S. which prompted CDC to warn state health departments of its presence and provide preventive steps to minimize its spread. Expansion of NARMS under the NFSI and better coordination between the agencies provided this resource.

- Collection of better, more reliable surveillance data on the occurrence and source of major foodborne disease through FoodNet, PulseNet, and the National Antimicrobial Resistance Monitoring System (NARMS), providing a baseline for measurement of public health benefits of food safety activities and improved early warning of outbreaks.
- FoodNet has provided, in addition to better more reliable data about foodborne illness in the population in general, specific information about the prevalence of certain pathogens that is being used to put preventive measures in place, e.g., for *Campylobacter*.
- A new tool for modeling the behavior of *Salmonella* in raw and cooked poultry products.
- Systematic surveillance for antibiotic resistance in foodborne pathogens to identify new resistant strains and comparison of resistance in strains isolated from ill humans with those isolated from animals and foods.
- Prevention of *Salmonella* contamination in food products from poultry with the development and commercialization of a competitive exclusion culture (CEC) to control *Salmonella* on commercial broiler farms. Advances were also made in methods to reduce *Salmonella* levels in the air with electrostatic ionization during times when birds are highly susceptible to the spread of the pathogen, such as, shortly after hatch and during an induced molt.
- A new rapid method for the detection of *E. coli* 0157:H7 which is sensitive to low numbers of bacteria, inexpensive, and user-friendly. Also, advances in irradiation technology that offers opportunities to significantly reduce pathogens in certain food commodities, which increase shelf life and maintain freshness -- all major consumer demands.
- New techniques for the rapid detection of *Campylobacter*.

Better Coordination Among Food Safety Agencies/Benefit of Faster Response to Foodborne Outbreaks

- Definition of core capacities for all state health departments for the surveillance and investigation of foodborne diseases, and efforts to assure those capacities are in place, to facilitate rapid and uniform response to outbreaks.
- Development and utilization of uniform procedures for more rapid containment of foodborne illness outbreaks. The establishment of FORCG to review and suggest improvements in actions of federal and state representatives in response to outbreaks.
- Coordination of an interagency food safety research plan for fresh produce and work on an interagency food safety research inventory and plan for all food safety research among the federal agencies developed under auspices of the Office of Science and Technology Policy.

- Foundation for a consistent, uniform approach to developing microbial risk assessment techniques in the U.S. and internationally by the Risk Assessment Consortium.
- Within the framework of the initiative, additional funds helped establish the successful working relationships for implementing FoodNet, PulseNet, NARMS, FORCG, the Risk Assessment Consortium, the Joint Institute for Food Safety Research, and the Partnership for Food Safety Education.
- Creation of the President's Council on Food Safety and the Joint Institute for Food Safety Research.

Seamless Food Safety System

- A meeting of representatives of federal food safety agencies with state and local departments of health and agriculture 50 states, Puerto Rico and the District of Columbia to develop recommendations and implementation plans for a national, integrated food safety system encompassing all levels of government.
- The partnerships established under the President's Food Safety Initiative have contributed to the ability of Federal food safety agencies to leverage resources, avoid duplication, and provide the basis for an integrated and seamless food safety system. Further improvements will be made in 1999 with funds provided for the distribution of computers and technical assistance to State meat and poultry inspection programs.

Preventive Controls/Allows for Better Targeting of Resources

- Implementation of science-based preventative systems for foods associated with foodborne illness, including Hazard Analysis and Critical Control Point (HACCP) systems for seafood, meat, and poultry, voluntary Good Agricultural/Good Manufacturing Practices guidance for fresh fruits and vegetables, warning labels on fresh packaged juices, and proposed HACCP for juices.
- Enhanced State public health and regulatory laboratory capabilities, State and local epidemiologic capabilities, State inspector HACCP training, and automated systems in the 25 State meat and poultry inspection programs to ensure uniform Federal and State implementation of HACCP regulations.
- Development of rapid detection methods and technology for the control of foodborne hazards, including methods for *E. Coli* 0157:H7, a competitive exclusion spray to prevent *Salmonella* in chicks, and antimicrobial treatments for poultry.
- Completion of the first farm-to-table quantitative risk assessment for a pathogen -- *Salmonella* -- in eggs.

- A measurable decline in the prevalence of *Salmonella* contamination in pork and broiler chickens as a result of implementation of HACCP in large meat and poultry establishments.
- Research to develop fundamental knowledge of pathogens, expand available predictive microbiology models to account for additional microbiological attributes, develop food handling and preservation technologies for reducing or eliminating foodborne contamination from the farm to the table.
- Research that indicates decreased *E. coli* numbers in cattle hay. Additional studies will be conducted to determine whether feeding hay to cattle prior to slaughter will significantly reduce post harvest contamination by pathogenic *E. coli*.
- An instrument to assure levels of chlorine in disinfection water are proper.
- Better tools for understanding the basis for microbial attachment and detachment to animal carcasses.
- Research that has found naturally occurring food additives that block the attachment of *E. coli* to bovine meat tissue.
- Increased ability to detect emerging pathogen and identify relationships between animal and human isolates.
- Approval of irradiation for certain commodities, such as red meat.
- Research begun to validate the effectiveness of various interventions techniques, such as washing, antimicrobial rinses, and non-thermal processes, on pathogens in juices.

Outreach to Consumers

- These activities have already resulted in measurable, positive changes in consumer behavior with regard to food safety issues.
- Improved consumer and food service worker awareness of safe food preparation practices through the Partnership for Food Safety Education and the Food Service Training and Education Alliance, respectively.
- Increased information for producers on safe food production practices and how to reduce the risks of pathogenic organisms during production.
- Workshops that will teach farmers the principles of safe food production and how to reduce the risks of pathogenic organisms on the fruits, vegetables, meat, and poultry.

- Development of the national "Fight BAC!" campaign to promote consumer use of safe food practices.
- Life-size "BAC" character and puppets to deliver messages to adults and school age children.
- 30-second television public service announcements, New web site (www.fightbac.org) where consumers, health professionals, educators, and the media can learn the latest news about preventing foodborne illness, and information kits for supermarket consumer affairs professionals (e.g., Wegman's) and community action groups.
- More than 100 national, state and local organizations from the public health, government, consumer and industry sectors have agreed to support the "FIGHT BAC!" campaign and disseminate educational materials. These "BAC Fighters" will maximize the campaign's national outreach and provide important links into thousands of communities nationwide.

Outreach to Industry

- A national food safety database containing educational materials and resources for use by a variety of audiences and the Food Animal Residue Avoidance Databank (FARAD). FARAD is a central and unique source of residue avoidance information for producers, veterinarians, and regulatory agencies working with food animal products.
- Created an industry/National Center for Food Safety and Technology task force on sprout safety and research plans to validate the effectiveness of interventions such as antimicrobial rinses.
- Publication of the Annual Report "FDA/USDA/CDC National Antimicrobial Susceptibility Monitoring Program- Veterinary Isolates, April 1, 1998," has provided the animal production industry with national salmonella susceptibility data from food animals. The publication of this report has initiated activities between producers, the AVMA, veterinarians and the pharmaceutical industry. Producers are increasingly aware of the food safety issues associated with antimicrobial resistance and as a result are developing studies to identify prudent and judicious antimicrobial use practices, interventions and mitigations for extant resistance in organisms of concern, and determine other husbandry practices that reduce the need for antimicrobials in food animal production. An effective response on the part of industry will ensure that drugs necessary for the treatment of food animals will remain effective longer and that foodborne pathogens will be less likely to be resistant to antimicrobials.

These accomplishment, taken as a whole, point to significant gains for public health from just this initial investment. The fiscal year 2000 request, builds upon 1998 and 1999 and seeks to establish the next segments needed for improving the overall safety of the food supply.

Progressing Toward A Seamless, Science-Based Food Safety System

Only through stronger partnerships among Federal, State and local food safety agencies can the goal of reducing foodborne illness to the fullest extent possible be realized. First, as identified in the farm-to-table strategy, steps must be taken at each point of the farm-to-table continuum where hazards can occur to improve the safety of foods. Because the States are involved in all facets of food production, Federal agencies must work closely with the various State agencies that have the authority, and the responsibility, for food safety. Second, partnerships enable food safety agencies to use scarce resources more efficiently and to avoid duplication. Third, food safety officials are becoming increasingly more aware that one level of the farm-to-table chain affects another. For example, the requirements being set within meat and poultry plants under the HACCP rule have repercussions at the animal production level, where producers must be prepared to supply animals that meet HACCP system requirements for incoming raw materials. Fourth, distinctions between the segments of the farm-to-table chain are becoming indistinguishable. For example, many retail food operations, such as supermarkets, are now engaged in food preparation like smoking fish or roasting chickens, but are not subject to Federal inspection. For these reasons, it is clear that Federal agencies must work more closely with all involved State agencies.

From the outset of the President's Food Safety Initiative, the Administration has recognized the need for strengthening partnerships between Federal agencies and State and local public health agencies. In the first two years of the Food Safety Initiative, additional funds were provided to improve coordination between all agencies involved in the food safety system. Within the framework of the initiative, additional funds helped establish the successful working relationships for implementing FoodNet, PulseNet, NARMS, FORCG, the Risk Assessment Consortium, and the Partnership for Food Safety Education. In addition, Food Safety Initiative funds have enabled food safety agencies to provide training and materials to State and local agencies for expanding and improving their ongoing inspection and compliance capabilities, food safety education efforts, and foodborne illness surveillance capabilities.

Great progress has also been made by cooperative Federal agencies in implementing HACCP systems for seafood, meat, and poultry and a comprehensive initiative for ensuring the safety of fruits and vegetables. Other efforts include the coordination of activities for ensuring the safety of food during transportation and at the retail level. These are complex issues involving numerous Federal, State, and local officials. The partnerships established and strengthened under the President's Food Safety Initiative have contributed to the ability of Federal food safety agencies to leverage resources, avoid duplication, and provide the basis for an integrated and seamless food safety system. Further improvements will be made in 1999 with funds provided for the distribution of computers and technical assistance to State meat and poultry inspection programs. Additional partnerships will be formed with the states to increase the number of high risk, non-meat and poultry, food inspections and to enhance the capabilities of states to improve food safety at the retail level.

In September, 1998, representatives of food safety agencies from of all 50 states, Puerto Rico, and the District of Columbia met with HHS and USDA in Kansas City to discuss how federal, state, and local food safety activities could be better integrated to provide a more effective and efficient food safety system. The State representatives strongly support the concept of a nationally integrated food safety system building on the current Federal-State partnerships. The 2000 budget proposal includes

funds for HHS, with USDA, to accelerate their planning with the states, including opportunities for public input, so as to be fully prepared to begin implementing such a system. To further foster progress toward a seamless, science-based food safety system, the 2000 budget includes funds to enable USDA and HHS to develop stronger ties with State food safety agencies.

USDA is currently providing the training and equipment necessary to State personnel in the 25 State meat and poultry inspection programs to assure that State programs implement meat and poultry HACCP requirements that are 'at least equal to' the Federal program of continuous inspection. Providing the 25 State meat and poultry inspection programs access to Federal computer networks will facilitate the coordination of inspection coverage between the two programs and ensure a consistent approach to inspection and an efficient allocation of resources. In addition, legislation will be proposed to authorize the Secretary of Agriculture to enter into Federal-State cooperative agreements that provide for State meat and poultry inspection programs to enforce Federal meat and poultry inspection laws and regulations with their State as part of a seamless national inspection program. Products shipped under such new Federal-State cooperative agreements would be permitted to enter interstate commerce.

Another major aspect of the 2000 budget proposal is to significantly increase HHS efforts to coordinate its Federal inspection responsibilities with State and local agencies. Through grants, contracts, and other mechanisms, FDA will utilize State-conducted inspections to increase the frequency of coverage for domestic firms. With the additional resources, HHS estimates that a combination of Federal and State inspectors will be able to reduce the existing inspection cycle from once seven years for any particular establishment to a risk-based approach that enables highest risk operations to be inspected once a year.

Encouraging the use of preventive control measures, such as HACCP and the Food Code, by the retail food industry will be the third major focus of cooperative federal-state activity. HHS and USDA, have worked, through the Conference for Food Protection (a forum for all stakeholders to have input into the code development process), with the states to promote use of safe practices in retail food operations and adoption of Food Code provisions, including HACCP. The Food Code is a model that provides scientifically sound technical and legal basis for regulating the retail segment of the food industry. It is the Federal government's best advice on a comprehensive system of regulation to ensure food in restaurants, retail food stores and institutional establishments is safe. The target audience of the Food Code is the 75 State and territorial agencies and over 3,000 local agencies directly regulating over one million retail operations. In 2000, the agencies will continue to work with and provide training, assistance, and resources to improve the safety of food products at retail.

HHS, with the assistance of USDA, will also work cooperatively with foreign governments to evaluate foreign food production and inspection systems. Under the initiative, HHS and USDA will increase the number of international arrangements for assuring food safety to facilitate the mutual understanding of the risks associated with foreign products, exclusive of meat and poultry, and the control measures necessary to reduce those risks. FDA will also follow-up on foodborne illness

outbreaks associated with imported products and work toward equivalence determinations for other countries.

Enhancing Surveillance and Increasing the Speed and Efficiency of Responses to Foodborne Illness Outbreaks

Foodborne surveillance data are critical for both USDA and HHS to define the burden of specific foodborne diseases on the public health, to detect outbreaks rapidly so they can be brought under control, and to monitor the success of long-term control measures. The 2000 budget proposal will continue to enhance surveillance, harnessing new biotechnologies and electronic communications to protect the public health. Surveillance data on foodborne diseases will continue to improve, by promoting better surveillance in all states, and by more detailed investigations through FoodNet. Collaborative epidemiologic investigations conducted in FoodNet sites will expand to include outbreaks of unknown cause, and will continue to define the principal sources, and likely control points for the major foodborne infections. PulseNet, the molecular sub-typing network, will be expanded to more pathogens providing rapid detection of outbreaks. Guidelines for its efficient use will be developed and made available. CDC is establishing the critical core capacities needed in all states to conduct surveillance of foodborne illness; the 2000 budget proposal will enhance these capacities nationwide. Foodborne outbreak reports will be made electronically. The results will then be made available quickly by tracking the trends on sources of outbreaks, the effectiveness of existing prevention measures, and the need for any new preventive controls.

As foodborne illness surveillance data becomes more timely and accurate, more outbreaks will be identified that require a rapid response, including emergency epidemiologic and traceback investigations to identify the food source. These epidemiologic investigations are critical to identify and control the source of the outbreaks rapidly, and also can provide invaluable information to prevent future outbreaks. New tools can greatly enhance these investigations. For example, PulseNet can quickly link apparently disparate outbreaks so that common sources can be identified, investigated, and controlled. We have successful examples of this in 1998 with the result that outbreaks were shortened. Most initial investigations are conducted by teams of epidemiologists, microbiologists, and sanitarians employed by local and state health departments. When needed, CDC provides additional epidemiologic and diagnostic assistance and coordination, and FDA and USDA provide technical assistance, traceback support, and implementation of emergency national control measures. Public health departments and food safety agencies at the federal, state, and local levels must have the capacity to respond rapidly and in a manner that provides consistent, high quality epidemiologic investigations to guide decision making about disease control. CDC is defining, with state partners, the critical capacities needed in all states to respond to outbreaks of foodborne illness. HHS is developing training materials to improve the quality of efforts by the various team members in epidemiologic investigations. FORCG is in the processing of refining, with States, the uniform procedures developed for all agencies to follow in coordinating outbreak investigations.

Continued enhancements to surveillance are needed because new foodborne diseases continue to be identified for which control measures remain unclear. Activities supported by the 2000 budget will

continue to focus on achieving full utilization of State health laboratories, Federal food laboratories, and epidemiology departments to improve the accessibility and rapid analysis of surveillance systems now in place, and to expand the scope of these systems to be more comprehensive in the array of pathogens tracked. It will be critical to identify new and emerging foodborne contaminants, measure the risk they pose to the public, determine possible points of control, evaluate the effectiveness of prevention and control efforts, and target needed research and education efforts.

Global comparison of national surveillance data for *Salmonella* will mark the beginning of an international 'preparedness' strategy, providing early warning about potential outbreaks related to food in international trade. In another area of increasing public health concern, access to international databases linking veterinary and human databases will provide a basis for comparison that can guide strategies prolong the usefulness of antibiotics.

HHS and USDA will work with state health departments and other partners to further address the need for detailed information on the human illness impact of pathogens at varying doses. This dose-response information is critical to conduct quantitative risk assessments. Better information about the proportion of persons who become ill after eating food contaminated with different concentrations of pathogens can be obtained in several ways. Volunteer feeding trials are being conducted, as are animal model studies. Extremely useful information can also be generated in the occasional outbreak setting where the implicated food can be collected and analyzed meaningfully. Under these activities, food specimens would be collected as quickly as possible from patients with foodborne illness. These specimens would be sent immediately to appropriate laboratories for quantitative analysis to establish the concentration of the pathogen in the food.

Greater Emphasis on the Control of Foodborne Hazards in the Pre-Harvest Phase of the Farm-to-Table Continuum

In order to ensure effective control of microbiological contamination, the President's Food Safety Initiative addresses foodborne hazards throughout the farm-to-table continuum. A majority of Federal and state resources are allocated to the inspection of commercial food processors and handlers and improvement of food handling practices by consumers. In addition, a significant amount of research is aimed at developing analytical methods and prevention control programs for use in post-harvest operations.

Continued outbreaks of foodborne illness due to a variety of pathogens of fecal origin in various foods, including ground beef and other meats, poultry, eggs, and fresh fruits and vegetables, have sustained a high level of awareness among the public about the issue of food safety. Changes, such as the implementation of HACCP systems and the "Guide to Minimize Microbial Food Safety Hazards," have enhanced the awareness of the potential role of production practices in contamination of various food products. Producers of food animals, fruits, and vegetables must be much more involved in learning about opportunities to reduce the chance of contamination by pathogens of fecal origin, whether from domestic or wild animal species or human beings. This emphasis has brought more attention to management practices that will reduce the prevalence of pathogens, e.g.,

Salmonella, *E. coli*, and *Campylobacter*, as well as provide resources for educating producers on the implementation of such practices.

In 1999, the agencies will begin to address some of the producer needs under the President's Food Safety Initiative. Agencies will evaluate risk-based pathogen reduction strategies for producers and provide that information to them for use in running their operations. For 2000, a greater emphasis needs to be placed on the control of foodborne hazards in the pre-harvest phase of the overall food safety strategy. To achieve this, the 2000 budget will target additional research and risk-assessment activities to the development of effective, reliable, and cost-effective methods for controlling or eliminating pathogens in or on food products prior to harvest.

An interagency research planning process was initiated under the auspices of the Office of Science and Technology Policy. HHS and USDA accelerated research plan for fresh fruits and vegetables was developed and implemented, as were individual agency plans. All these research efforts will be coordinated by the new President's Council on Food Safety, established by Executive Order 13100 in July 1998.

Research projects supported by the 2000 budget will contribute to the development of effective methods of handling and treating poultry, swine, and cattle manure during production that prevent transmission of pathogens to agricultural lands and to crops used for human food. Control of animal production practices will also help prevent possible distribution of pathogens to crops or other animals from surface runoff and irrigation waters. For some foodborne illnesses, the causative agent is never identified. This may be due to the lack of a detection method for the pathogen or for the pathogen in the specific food. Improved detection methodologies will be developed to enable producers to monitor their production processes for contamination.

Antibiotic resistance is an important factor that must be controlled in both animal health and the use of animals and their products as foods. Research is needed to develop the knowledge to prevent the development of this antibiotic drug resistance. The development of resistant human pathogenic bacteria is closely associated with the use of antimicrobial agents in human medicine, but it is also likely that food producing animals are sources or vectors of resistant bacteria that may be transmitted directly or indirectly to humans. Effective strategies must be devised to prevent both the emergence and the maintenance in food producing animals of pathogenic and non-pathogenic antibiotic resistant bacteria.

The interagency Risk Assessment Consortium was formed to provide a central forum for developing and using microbial risk assessment techniques, a first step toward providing uniform, standardized techniques and approaches to applying risk assessment to food safety issues. Risk assessment modeling supported by the 2000 budget for pre-harvest activities will evaluate the effects of various on-farm production practices, processing systems, and transportation systems on the contamination of food. The proposed research will result in improved information to base decisions on production practices that will result in fewer pathogens in food animals being presented for slaughter.

In support of the President's directive to ensure the safety of fruits and vegetables, a survey will be conducted of fruit and vegetable growers and packinghouse handling practices with regard to food safety. A primary use of these data would be to establish a baseline of agricultural practices related to microbial food safety and to provide a benchmark to measure future industry changes. Survey data reported by producers would inform domestic and international data users on U.S. grower food safety practices. The survey information would also be used to target specific industry educational outreach programs to increase fruit and vegetable industry awareness on microbial food safety.

Conclusion

Expected outcomes from the President's Food Safety Initiative for 2000 include a strengthened food safety foundation specifically in surveillance, inspections, research and risk assessment, education, and coordination of response to foodborne illness outbreaks. Progress will be made toward realizing the President's goal of establishing a seamless, science-based food safety system that involves all levels of government. Baselines for foodborne illness outbreaks will be established which will enable public health agencies to monitor the impact of prevention control interventions and more rapidly identify trends in emerging pathogens. Additional steps will be taken to make food inspection techniques consistent across the country, so that inspection results will be "interchangeable" among federal, state and local agencies. Risk assessment will be used to direct research, surveillance and other efforts. Research will facilitate the adoption of new methodologies for rapid identification of foodborne hazards and greater control of those hazards from farm-to-table. Educational programs will improve safe food practices and will provide necessary information to producers for responding to increased challenges for ensuring the safety of products during production.

**PRESIDENT'S FOOD SAFETY INITIATIVE
FY 2000 PROPOSAL**

	1997 Approp.	1998 Approp.	1999 Budget	2000 Proposal	Proposed Increase
ACTIVITY	Dollars in Thousands				
<u>SURVEILLANCE:</u>					
USDA:					
Food Safety and Inspection Service	\$1,000	\$1,500	\$1,500	\$1,500	\$0
Economic Research Service	<u>32</u>	<u>32</u>	<u>285</u>	<u>285</u>	<u>0</u>
Subtotal, USDA	1,032	1,532	1,785	1,785	0
HHS:					
Food and Drug Administration	737	3,897	6,097	15,097	9,000
Centers for Disease Control and Prevention	<u>4,500</u>	<u>14,500</u>	<u>19,000</u>	<u>37,000</u>	<u>18,000</u>
Subtotal, HHS	<u>5,237</u>	<u>18,397</u>	<u>25,097</u>	<u>52,097</u>	<u>27,000</u>
Subtotal, Surveillance	6,269	19,929	26,882	53,882	27,000
<u>COORDINATION:</u>					
USDA:					
Food Safety and Inspection Service	0	0	0	1,450	1,450
HHS:					
Food and Drug Administration	<u>7,173</u>	<u>7,723</u>	<u>7,923</u>	<u>7,923</u>	<u>0</u>
Subtotal, Coordination	7,173	7,723	7,923	9,373	1,450
<u>INSPECTIONS:</u>					
USDA:					
Food Safety and Inspection Service	0	565	8,412	8,778	366
Foreign Agricultural Service	<u>0</u>	<u>0</u>	<u>0</u>	<u>1,000</u>	<u>1,000</u>
Subtotal, USDA	0	565	8,412	9,778	1,366
HHS:					
Food and Drug Administration	<u>73,244</u>	<u>81,114</u>	<u>108,714</u>	<u>134,314</u>	<u>25,600</u>
Subtotal, Inspections	73,244	81,679	117,126	144,092	26,966

	1997 Approp.	1998 Approp.	1999 Budget	2000 Proposal	Proposed Increase
ACTIVITY (Cont.)	Dollars in Thousands				
<u>RISK ASSESSMENT:</u>					
USDA:					
Agricultural Research Service Cooperative State Research, Education, and Extension Service	5,461	4,498	4,818	7,218	2,400
Food Safety and Inspection Service	145	150	1,962	1,962	0
Economic Research Service	0	0	1,000	2,000	1,000
National Agricultural Statistics Service	33	33	686	686	0
Office of the Chief Economist	0	0	0	2,500	2,500
	<u>62</u>	<u>60</u>	<u>158</u>	<u>158</u>	<u>0</u>
Subtotal, USDA	5,701	4,741	8,624	14,524	5,900
HHS:					
Food and Drug Administration	<u>2,589</u>	<u>6,539</u>	<u>13,739</u>	<u>16,439</u>	<u>2,700</u>
Subtotal, Risk Assessment	8,290	11,280	22,363	30,963	8,600
<u>EDUCATION:</u>					
USDA:					
Cooperative State Research, Education, and Extension Service	2,365	2,365	7,365	8,287	922
Food Safety and Inspection Service	0	0	2,500	2,720	220
Food And Nutrition Service	0	0	2,000	2,000	0
Office of the Chief Economist	27	38	38	38	0
Economic Research Service	<u>420</u>	<u>420</u>	<u>420</u>	<u>420</u>	<u>0</u>
Subtotal, USDA	2,812	2,823	12,323	13,465	1,142
HHS:					
Food and Drug Administration Centers for Disease Control	4,800	6,870	10,470	15,170	4,700
	<u>0</u>	<u>0</u>	<u>500</u>	<u>500</u>	<u>0</u>
Subtotal, HHS	4,800	6,870	<u>10,970</u>	15,670	4,700
Subtotal, Education	7,612	9,693	23,293	29,135	5,842
<u>RESEARCH:</u>					
USDA:					
Agricultural Research Service	44,186	50,351	64,001	71,701	7,700
Cooperative State Research, Education, and Extension Service	3,724	6,250	10,438	12,151	1,713
Agricultural Marketing Service	<u>0</u>	<u>0</u>	<u>6,257</u>	<u>6,257</u>	<u>0</u>
Subtotal, USDA	47,910	56,601	80,696	90,109	9,413
HHS:					
Food and Drug Administration	<u>20,793</u>	<u>27,193</u>	<u>36,393</u>	<u>43,293</u>	<u>6,900</u>
Subtotal, Research	<u>68,703</u>	<u>83,794</u>	117,089	<u>133,402</u>	<u>16,313</u>
TOTAL, INITIATIVE	<u>171,291</u>	<u>214,098</u>	<u>314,676</u>	<u>400,847</u>	<u>86,171</u>

**PRESIDENT'S FOOD SAFETY INITIATIVE
FY 2000 PROPOSAL**

	1997 Approp.	1998 Approp.	1999 Budget	1999 Enacted	2000 Proposal	Increase Over 1999 Budget
TOTAL INITIATIVE	Dollars in Thousands					
USDA:						
Agricultural Research Service	\$49,647	\$54,849	\$68,819	\$67,219	\$78,919	\$10,100
Cooperative State Research, Education, and Extension Service	6,234	8,765	19,765	24,765 a/	22,400	2,635
Agricultural Marketing Service	0	0	6,257	2,831	6,257	0
Food Safety and Inspection Service	1,000	2,065	13,412	18,352	16,448	3,036
Economic Research Service	485	485	1,391	938	1,391	0
Office of the Chief Economist	89	98	196	196	196	0
Foreign Agricultural Service	0	0	0	0	1,000	1,000
National Agricultural Statistics Service	0	0	0	0	2,500	2,500
Food and Consumer Service	0	0	2,000	2,000	2,000	0
Subtotal, USDA	57,455	66,262	111,840	116,481	131,111	19,271
HHS:						
Food and Drug Administration	109,335	133,335	183,335	158,335	232,335	48,900
Centers for Disease Control	4,500	14,500	19,500	19,500	37,500	18,000
Subtotal, HHS	113,835	147,835	202,835	177,835	269,735	66,900
TOTAL, INITIATIVE	<u>171,290</u>	<u>214,097</u>	<u>314,675</u>	<u>294,316 b/</u>	<u>400,846</u>	<u>86,171</u>

a/ The Conference Report accompanying the Omnibus Appropriations Act for 1999 directs USDA to consult with the Food and Drug Administration regarding food safety research objectives of the agency and recommends that \$5.0 million of the funds provided to USDA for the food safety component of the National Research Initiative be used to meet those needs.

b/ The Conference Report accompanying the Omnibus Appropriations Act for 1999 (the Act) identifies the funding increases for activities identified under the President's Food Safety Initiative. The agencies are currently evaluating the Act to determine the final allocation of funds to support the various activities of the Initiative.

FY 2000 Activities

Surveillance - FY 2000 Budget Request

FoodNet, PulseNet, and other improvements in national epidemiologic capacity funded by FSI funds in FY 1998 and 1999 are beginning to provide better, more reliable information about foodborne illnesses and outbreaks. Federal and state public health officials are now using this data to trace the causative agent of outbreaks back to the source. In FY 2000, these surveillance mechanisms will have established a baseline that will be used by the food safety agencies to identify outbreaks, evaluate the effect of interventions to reduce the number of illnesses, and to identify illnesses caused by emerging pathogens.

Increased reliability of FoodNet data will result in an increased number of foodborne outbreaks being identified. This will trigger an increase in the number of epidemiologic outbreak and traceback investigations that must be conducted to determine the source of the contamination and facilitate its removal from the marketplace. The capacity of state health departments to identify outbreaks and determine the pathogen involved will be expanded and enhanced to accommodate the increase. FY 2000 activities will continue to focus on achieving full capacity for state health laboratories, accessibility of surveillance systems now in place, and expanding the scope of the systems to be more comprehensive in the array of pathogens tracked. Information generated by these activities will be used to identify new and emerging foodborne contaminants, characterize consumer risk, determine possible points of control, evaluate the effectiveness of prevention and control efforts, and target needed research and education efforts.

An increased number of state health departments will be added to the pathogen DNA-fingerprint network, PulseNet, and data on *Salmonella* Typhimurium will be added to the database (the current database contains *E. coli* O157:H7 data), greatly extending its usefulness in epidemiologic and traceback investigations. Global surveillance for Salmonellosis will mark the beginning of a 'preparedness' strategy, providing early warning to U.S. food safety officials about the existence of potential safety concerns in countries importing products into the U.S. Likewise access to international databases linking veterinary and human databases will provide forewarning of the emergence and spread of antibiotic resistance.

Coordination Strategy

CDC, USDA, and FDA participate in working groups along with state representatives, such as the FORCG and the FoodNet working group, to provide guidance and direction on surveillance activities to meet each agency's needs. These working groups coordinate planning and prioritization of work to meet the needs of each agency, identifying gaps that must be filled, resources that must be developed, and complementary work to meet these needs.

FY 2000 Activities

Communicating outbreak data to federal and state public health authorities

- CDC will implement electronic reporting of foodborne outbreaks with rapid analysis to identify unusual patterns and to disseminate this information to USDA, FDA, and others for use in food safety policy decision-making and coordinating responses to outbreaks

- FDA, working with the states, CDC, and USDA will initiate development of electronic communication and data-sharing systems for use in federal-state monitoring and traceback investigations

Tracing foodborne illness to its source

- FDA, working with the states, will provide training and resources to states to strengthen outbreak response and traceback capabilities

International foodborne illness

- CDC in collaboration with the World Health Organization and other international partners, will begin global surveillance for Salmonellosis. This information will provide another type of early warning for U.S. food safety authorities to initiate appropriate oversight measures for imported foods.

Better, more reliable foodborne illness data about an increased number of pathogens:

- CDC, with support from FDA and USDA, will expand the scope of FoodNet to improve the qualitative and quantitative database for foodborne disease, i.e., to more fully reflect the cross-section of the U.S. population and to enhance the accuracy of data generated. CDC will also expand surveillance in FoodNet to include foodborne outbreaks and outbreak investigations.
- CDC will expand PulseNet to 30 state health departments with capacity for *E. coli* O157:H7 and *Salmonella* Typhimurium subtyping and begin addition of *Salmonella* Enteritidis. PulseNet data will be fully integrated into routine surveillance.
- CDC will expand the capacity of state and local health departments to test for Norwalk-like caliciviruses and initiate a surveillance network to monitor circulation of Norwalk-like virus strains in the U.S.
- CDC will evaluate the effectiveness of an algorithm for preventing illness among persons who potentially have been exposed to food service workers infected with hepatitis A.

Antibiotic resistance

- FDA, working with CDC, will expand and increase the overall capacity of NARMS and its geographic scope to assure a higher probability of detecting emerging resistant pathogens capable of animal to human transmission and to minimize the occurrence of foodborne outbreaks including those from outside the U.S. By increasing the number of bacterial isolates from human and animal origin in the NARMS database from 2,000 and 3,000 to 4,000 and 7,000, respectively, we will be able to increase our probability of identifying potential outbreaks.
- CDC will collaborate with USDA in working with the international community to assess feasibility of international antimicrobial resistance databases. This collaboration will facilitate international response to resistance emergence and spread of antibiotic resistance throughout the world.

Summary Budget – Surveillance

	1998 <u>Approp.</u>	1999 <u>Budget</u>	2000 Proposal	Proposed Increase
SURVEILLANCE	Dollars in Thousands			
USDA:				
Food Safety and Inspection Service	\$1,500	\$1,500	\$1,500	\$0
Economic Research Service	<u>32</u>	<u>285</u>	<u>285</u>	<u>0</u>
Subtotal, USDA	1,532	1,785	1,785	0
HHS:				
Food and Drug Administration	3,897	6,097	15,097	9,000
Centers for Disease Control and Prevention	<u>14,500</u>	<u>19,000</u>	<u>37,000</u>	<u>18,000</u>
Subtotal, HHS	<u>18,397</u>	<u>25,097</u>	<u>52,097</u>	<u>27,000</u>
TOTAL, Surveillance	<u>19,929</u>	<u>26,882</u>	<u>53,882</u>	<u>27,000</u>

Coordination - FY 2000 Budget Request

A national, rapid, effective response to foodborne illness outbreaks requires a coordinated effort that crosses agency lines, while recognizing the unique statutory responsibilities of each federal, state, and local agency involved. This requires agreement about the roles and responsibilities of federal, state, and local public health officials and the most expeditious manner of operating within those parameters in responding to outbreaks, collecting epidemiologic data, and quickly initiating traceback investigations.

FORCG has made significant strides toward a cohesive national outbreak response system, with the development of standard, uniform procedures, for use of federal, state, and local officials in responding to outbreaks, that reduce the time between identification of an outbreak and initiation of measures to contain the outbreaks and limit the number of illnesses. Work that will continue to refine the uniform procedures and build a nationally responsive system for rapid outbreak response is an integral part of a nationally integrated food safety system.

Coordination Strategy

FORCG is the primary point of coordination between federal agencies and state representatives. In responding to outbreaks, individual agencies in FORCG have identified gaps in resources or expertise that, if filled, would greatly strengthen their contribution to coordination, rapid response and containment of the outbreak. This budget request includes funding to meet these needs.

FY 2000 Activities

- CDC will meet with international health organizations to discuss the importance, as the national and international distribution of foodstuffs increases, of why the domestic food supply needs to remain safe.
- USDA will increase the number of District Epidemiology Officers in FSIS by 10, for a total of 18, to provide coverage for an increase in the number of product recalls. Product recalls have increased from 40 in 1996 to 50 in 1997.

Summary Budget – Coordination

	1998 Approp.	1999 Budget	2000 Proposal	Proposed Increase
COORDINATION	Dollars in Thousands			
USDA: Food Safety and Inspection Service	\$0	\$0	\$1,450	\$1,450
HHS: Food and Drug Administration	<u>7,723</u>	<u>7,923</u>	<u>7,923</u>	<u>0</u>
TOTAL, Coordination	<u>7,723</u>	<u>7,923</u>	<u>9,373</u>	<u>1,450</u>

Preventive Controls [Improved Inspections and Compliance] - FY 2000 Budget Request

A center point of inspection activities for FDA and USDA will be assistance to states to enhance their inspection capacity and to conduct inspections to augment federal inspections, particularly to verify implementation of HACCP regulations. Training, technical assistance, and grants to the states will be used. Increase coverage and frequency of coverage of domestic firms, with the highest risk firms (those firms producing, processing, or distributing high risk products) to be inspected once per year and lower risk firms less frequently, is a primary goal of FDA. Both agencies will also continue to work to eliminate barriers to cross-utilization of inspection resources. Use of preventive control measures, such as HACCP and the Food Code, by the retail food service industry will be a major focus of cooperative federal-state activity. FDA and USDA will work with states, providing resources and training to promote adoption of the Food Code by retail food service establishments.

Emphasis on development and use of food production preventive control measures will continue with evaluations of foreign food production systems, increasing the number of state and international arrangements for assuring food safety, and working with USDA and industry to develop additional measures. Evaluations of foreign food production systems will be conducted to follow-up on foodborne illness outbreaks associated with imported products, and to assure that food products imported into the U.S. meet the level of safety as foods produced in the United States. These evaluations will also be used to verify agreements between trading partners, such as Mutual Recognition Agreements (MRAs).

Coordination Strategy

FDA and USDA will continue to work closely together in providing state and local food safety officials and industry with the training necessary to effectively use preventive controls systems, such as HACCP, and to perform inspections of HACCP systems. The agencies also have in place several working groups considering how the agencies might more effectively use their inspection resources, as well as ensure compliance in transportation and food service operations.

FY 2000 Activities

State Inspections

- FDA will expand support, training, and guidance to our state counterparts (using partnerships, contracts, and other mechanisms), state inspection of FDA-regulated high risk establishments, following FDA guidelines and procedures.
- USDA will expand special assistance to states to implement Field Automation Information Management to provide FSIS off-shelf inspection automation infrastructure to provide the automated infrastructure for FSIS off-shelf inspection that will accommodate HACCP requirements, laboratory equipment for pathogen detection required by the HACCP final rules, and HACCP training for state inspectors.
- USDA will conduct pathogen testing on 56,000 samples of state-inspected meat and poultry products in FSIS laboratories to determine the compliance of some 2,000 state inspected establishments with pathogen reduction performance standards, and will contract for comprehensive reviews and audits of 20 state laboratories to facilitate state implementation

of HACCP and to permit state-inspected meat and poultry products to enter interstate commerce.

- FDA will hire individuals with expertise in epidemiology to assist in epidemiologic and environmental assessments of foodborne outbreaks.

Retail Foods

- FDA will work with States, providing training, training funds, and equipment to aid the retail food service industry in implementing HACCP, implementing use of food safety provisions in the Food Code, and in adoption of the Food Code.
- FDA and USDA will work with states to promote adoption of the Food Code by an increased number of states.

Imports

- USDA will facilitate the collection of data on agricultural practices in the U.S., report on good agricultural production and manufacturing practices within the food sector, and support FDA field staff visits to foreign countries, primarily in Latin American, South America, and Asia, associated with the GAP/GMPs.

Preventive Control Systems

- FDA and USDA will continue to provide HACCP training/assistance and inspection training to states, as appropriate, for seafood, meat, and poultry HACCP and FDA will implement HACCP for fruit and vegetable juices.
- FDA and USDA will increase the number of MRAs, equivalency, and other international agreements. FDA will increase the number of inspections of foreign food processors from 100 to 250 and will conduct evaluations of foreign food production systems to support its arrangements.
- USDA, with FDA and in cooperation with the Risk Assessment Consortium, will conduct international risk assessment workshops and other training activities for foreign governments to facilitate understanding of the risks associated with microbial contamination on food, particularly produce, and the control measures needed to reduce incidence of foodborne illness. These workshops and training sessions will be initiated by USDA with FDA, or done in cooperation with other organizations such as the International Institute for Cooperation in Agriculture, the Food and Agriculture Organization, and/or the World Health Organization as appropriate.

Summary Budget -- Preventive Controls Inspections and Compliance

	1998 Approp.	1999 Budget	2000 Proposal	Proposed Increase
INSPECTIONS	Dollars in Thousands			
USDA:				
Food Safety and Inspection Service	\$565	\$8,412	\$8,778	\$366
Foreign Agricultural Service	<u> 0</u>	<u> 0</u>	<u>1,000</u>	<u>1,000</u>
Subtotal, USDA	565	8,412	9,778	1,366
HHS:				
Food and Drug Administration	<u>81,114</u>	<u>108,714</u>	<u>134,314</u>	<u>25,600</u>
TOTAL, Inspections	<u>81,679</u>	<u>117,126</u>	<u>144,092</u>	<u>26,966</u>

Education - FY 2000 Budget Request

Education is at the heart of translating science (including regulatory science), and scientific advances, into readily accessible, comprehensible information for use by industry, producers, health professionals, consumers, food service operations and others to change unsafe food practices and to respond appropriately when a foodborne illness occurs. To improve case identification and disease surveillance, educational materials will be produced for clinical and food microbiologists and for public health professionals based on research conducted in FY 1998 and 1999. Retail food service operations (including fast food restaurants, vending operations, institutional feeding operations such as schools, hospitals, and nursing homes) have been reported to be the source of a substantial number of foodborne illnesses. Federal agencies will cooperate with states and industry to provide training and educational materials geared toward use of safe food practices by food service workers and implementation of the food safety provisions of the Food Code.

To minimize the occurrence of animal drug residues in edible animal tissues, education programs will be targeted to veterinarians and food animal producers on proper drug use. Educational programs will be developed to train school personnel and health professionals on methods to prevent foodborne illness.

Further evaluation of the effectiveness of the national consumer education campaign, "Fight BAC!", in changing consumer food practices will be conducted with the refinement of messages and campaign methods.

The Partnership for Food Safety Education is a powerful model for the development of other alliances to leverage available resources in implementing the education and training programs a national food safety system will demand for success. By joining the expertise of federal, state, and local authorities with industry, academia, and consumer groups, partnerships allow expanded scope of education efforts beyond what any one entity can accomplish alone and, thus, will be the mainstay of education and training efforts for a national food safety program. Training and education programs for food service workers will also be developed and implemented through a recently formed public/private partnership and will be research and science-based.

Coordination Strategy

Coordination of education programs and setting priorities for future activities occurs through such public/private partnerships as the Partnership for Food Safety Education, the Food Service Training and Education Alliance, the Seafood HACCP Alliance, as well as interagency working groups and states.

FY 2000 Activities

Retail Food Service

- FDA, USDA, and CDC will work with other Federal agencies, states, and local agencies to implement a national education and training program to ensure greater safety in retail food preparation practices, including use of HACCP principles in retail establishments, based on the results of the pilot program initiated in FY 1999.

- FDA and USDA will, through contracts and partnerships with states, industry, and others, conduct education activities promoting use of safe food preparation, storage, and distribution practices by retail food service workers and by the food transportation industry.
- FDA will evaluate food service HACCP pilots initiated in FY 1999, expand and refine this pilot program based on the evaluations, and conduct a pilot program using the recently developed Recommended National Retail Food Regulatory Program standards. These standards were developed in conjunction with the Conference of Food Protection which includes membership from all states, and the District of Columbia, as well as representation from industry and consumer groups.
- FDA will expand behavioral research, to identify barriers for safe food preparation practices by the retail food service industry, that can help guide the design of more effective training programs and materials. USDA will develop educational programs to provide Meat and Poultry HACCP education and training to small retailers.
- FDA and USDA will continue to form and support partnerships and alliances, such as the Partnership for Food Safety Education and the Food Service Training and Education Alliance.

Animal Drug Use

- FDA will develop and expand educational partnership agreements with state and local agencies to address appropriate use of drugs in food animals and disseminate materials developed in FY 1998 and 1999 on minimizing the occurrence of drug residues in edible animal tissues.
- FDA will work with veterinary practitioners, producer groups, and veterinary medical schools to increase awareness of food safety issues related to the use of animal drugs and feeds through exhibit programs, satellite teleconferences, town hall meetings, and industry workshops.
- FDA will work cooperatively with veterinarians, producers, and other stakeholders to encourage development of recommendations on prudent use of antimicrobials and support educational strategies to encourage implementation.

Consumers

- USDA and FDA will increase efforts to integrate research and education through technology transfer (see Research) and the development of educational programs that focus on the adoption of recommended food safety practices consistent with the current knowledge base.
- USDA, FDA, and CDC will expand educational programs for consumers that focus on the role of the consumer in ensuring and improving the safety of the nation's food supply through the Partnership for Food Safety Education and other mechanisms. Efforts to reach vulnerable segments of the population with targeted education will be expanded.

Producers

- USDA, working with FDA, will increase efforts to provide domestic fruit and vegetable growers education and outreach on how to minimize contamination of their crops and use FDA's GAP/GMP guidance for the microbial risk from fresh fruits and vegetables.
- USDA and FDA will develop educational programs for veterinarians on how to function as auditors or certifiers of best management practices for livestock production units for pathogen reduction in animals.
- USDA and FDA will develop educational programs and provide them to producers on the management systems needed to reduce or eliminate specific pathogens that can cause human illness through contamination of food products.

Health Professionals

- CDC, working with FDA, will develop appropriate education and training materials based on analysis of the FY 1999 survey results of training needs for food safety professionals at state and local environmental health agencies and begin plans for delivery of needed training.
- CDC, working with FDA and USDA, will develop and deliver standardized distance-based training on food microbiology to laboratorians in states and territorial public health laboratories to assist in identification of foodborne pathogens associated with diarrheal illness through the National Laboratory Training Network in collaboration with the Association of Public Health Laboratories.
- CDC will provide distance-based training programs in foodborne disease prevention targeted to public health nurses nationwide through the Public Health Training Network.

School Children

- CDC, FDA, and USDA will broaden the dissemination of school-based food safety education programs and include teacher enhancement programs. Much of this will be done in cooperation with the Partnership on Food Safety Education.

Summary Budget -- Education

	1998 Approp.	1999 Budget	2000 Proposal	Proposed Increase
EDUCATION	Dollars in Thousands			
USDA:				
Cooperative State Research, Education, and Extension Service	\$2,365	\$7,365	\$8,287	\$922
Food Safety and Inspection Service	0	2,500	2,720	220
Food And Nutrition Service	0	2,000	2,000	0
Office of the Chief Economist	38	38	38	0
Economic Research Service	<u>420</u>	<u>420</u>	<u>420</u>	<u>0</u>
Subtotal, USDA	2,823	12,323	13,465	1,142
HHS:				
Food and Drug Administration	6,870	10,470	15,170	4,700
Centers for Disease Control	<u>0</u>	<u>500</u>	<u>500</u>	<u>0</u>
Subtotal, HHS	6,870	<u>10,970</u>	15,670	4,700
TOTAL, Education	<u>9,693</u>	<u>23,293</u>	<u>29,135</u>	<u>5,842</u>

Research - FY 2000 Budget Request

Building on the progress made in research currently underway, research in FY 2000 will focus on filling gaps in data required to support development of additional preventive control mechanisms and on the development of more, rapid detection methods. Translation of science from theory to practice will be another focus. Working with the private sector, including academia, the agencies will develop, validate, and evaluate the safety of simple techniques for consumers, retail food service establishments, and small businesses to use in enhancing food safety. Producers of food animals and fresh fruits and vegetables are increasingly aware of the role production practices play in the safety of foods and that they must be more involved in reducing the opportunity for contamination by pathogens of fecal origin, whether from domestic or wild animal species or human beings. Effective methods of handling and treating poultry, swine, and cattle manure during production will prevent transmission of pathogens to agricultural lands and to crops used for human food, and will help prevent possible distribution of pathogens to crops or other animals from surface runoff and irrigation waters.

For some foodborne illnesses, the causative agent is never identified. This may be due to the lack of a detection method for the pathogen or for the pathogen in the specific food matrix. Research will be conducted to determine the proportion of outbreaks for which the etiologic agent remains unknown and create a research base to begin identifying the agents. Development of detection methods and preventive methods for foodborne pathogens will continue. The budget request will support research to develop and assess new technologies to prevent antibiotic resistance in pathogens and to develop methods to detect resistant pathogens in milk, meat, eggs, animal feeds, feces, and the environment.

The fundamental work in areas identified as critical to improving food safety will be expanded to develop more accurate, rapid detection methods for pathogens, particularly pathogens that no methods exist for, more effective intervention strategies to control microbial contamination, determine factors underlying microbial resistance to traditional preservation techniques and modify techniques accordingly, and understand and minimize the occurrence of antibiotic resistance in pathogens. Research associated with fresh produce will continue on its accelerated schedule as described in the interagency multi-year research plan.

Coordination Strategy

All food safety research will be coordinated through the Joint Institute on Food Safety Research which, it is anticipated, will become operational October 1, 1999. USDA, FDA, and CDC will continue to work with other food safety agencies, under the auspices of the Joint Institute on Food Safety Research, to develop and implement an overall interagency research plan that will be responsive to the public health needs of the regulatory agencies and improve the efficiency and effectiveness of foodborne outbreak response.

FY 2000 Activities

Improved Detection Methods

- USDA and FDA will collaborate to: expand method development and prevention technology research; refine methods already developed to make them more user-friendly, adaptable to field-use situations, and better able to identify specific pathogens rather than just fecal

contamination, as well as develop better sampling techniques to enhance detection of pathogens that occur sporadically at low levels on food.

- CDC, FDA, and USDA will further improve diagnostic methods for *Cyclospora*, *Cryptosporidium*, or *Campylobacter* and develop methods for other newly identified human foodborne pathogens and for Norwalk-like caliciviruses to support surveillance and targeted case-control studies.
- CDC will determine the proportion of foodborne outbreaks for which the causative agent is unknown, and create a research base to begin identifying the agents.
- USDA, working with FDA, will establish culture collections of resistant and non-resistant bacterial and fungal pathogens to facilitate identification and traceback of the pathogens to their source (e.g., environment, manure, water, animal feed).
- FDA will expand its ongoing research on the development of methods for detecting foodborne pathogens in animal feeds.
- CDC will define reservoirs or external life cycles of foodborne pathogens, including the reservoir of *Cyclospora*, as a basis for devising strategies for preventing pathogen contamination at the production level.

Technology Transfer

- FDA will collaborate with other agencies and the private sector, at the National Center for Food Safety and Technology (NCFST) and the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) and with academia, to translate preventive technologies and techniques developed into appropriate versions for use by small industry and consumers.
- FDA, CDC, and USDA will expand mechanisms to transfer technologies to states, small and large industry, foreign governments, consumers, and others.

Antibiotic Resistance

- USDA and FDA will determine the concentration, length of use, and other selective factors or conditions favoring the acquisition and dissemination of resistance genes among pathogens and non-pathogens in food producing animals. Basic information will be developed using chemostat model systems, on the time and dose dependency of various antibiotics that favor the emergence of resistant organisms in the gastrointestinal tract of food animal species. The dynamics of development and persistence of antimicrobial (e.g., antibiotic) resistance in the food animal production environment will be confirmed and used to develop detection methods and preventive strategies.
- USDA and FDA will develop technologies and controls, including competitive exclusion, that will prolong the usefulness of antibiotics for both human and animal use, and prevent food products of animal origin from being carriers of resistant organisms.

- USDA and FDA will determine how antibiotic resistance in bacteria may be transferred among different bacterial populations.
- CDC will define reservoirs or external life cycles of pathogens, including the impact of low doses of antibiotics on the spread of Shiga toxin *E. coli* O157:H7 in cattle, as a basis for devising strategies for preventing pathogen contamination (including antimicrobial resistant pathogens in food animals) at the production level.
- USDA and FDA will determine the effectiveness of best management practices interventions in the production setting related to control of antibiotic usage in food animals. This knowledge will also be used to develop educational programs for producers (see Education).
- USDA will establish culture collections of resistant and non-resistant bacterial and fungal pathogens. These resources will be used to develop molecular characterization methods to facilitate the identification of the resistant bacterial pathogens detected in food products, and the tracing of these organisms to their source (e.g., environment, manure, water, animal feed).

Pathogen Control, Reduction, and Elimination

- USDA will design effective control programs for zoonotic bacteria and parasites. This pre-harvest research will develop practical and economical pathogen reduction processes for manure from food producing animals. Different processes are needed and will be developed for each major type of animal production facility, and the processes will be suitable to farm size and manure production levels and have well-defined process parameters.
- USDA will determine how bacteria and fungi normally present on plants influence the growth and survivability of human pathogens that may be present. Data will be developed on the characteristics of fruits and vegetables, such as the presence of inhibitors of normal surface flora on fresh fruits and vegetables, associated with high quality products that resist growth of pathogens.
- USDA, through grants, will facilitate epidemiologic studies to determine risk factors in the production of livestock or fresh fruits and vegetables that are related to the presence of specific organisms in the digestive tract of animals and the subsequent shedding of these organisms in the feces. Further work will focus on the production management practices that are determined to be most effective; field testing will be done and transfer of new methodologies facilitated through demonstration or extension efforts.
- FDA and USDA will expand research to develop technologies to control pathogens on fruits and vegetables, including proper handling procedures, rinses, and other procedures to reduce pathogen population on fresh-cut produce.

Food Handling, Distribution, and Storage

- USDA will investigate the ecology of foodborne pathogens during handling, distribution, and storage, particularly of fresh fruits and vegetables, to determine sources of contamination and factors that increase the risk of disease transmission.

- USDA will extend product contamination studies to the distribution and storage phase of the food supply, evaluate the management practices that are determined to be most effective in initial experiments by monitoring field experiments, and facilitate the transfer of new methodologies through demonstration or extension efforts.

Other

- CDC will evaluate the economic impact of foodborne illness by conducting studies to document the economic burden of foodborne illness.

Summary Budget -- Research

	1998 Approp.	1999 Budget	2000 Proposal	Proposed Increase
RESEARCH	Dollars in Thousands			
USDA:				
Agricultural Research Service	\$50,351	\$64,001	\$71,701	\$7,700
Cooperative State Research, Education, and Extension Service	6,250	10,438	12,151	1,713
Agricultural Marketing Service	<u>0</u>	<u>6,257</u>	<u>6,257</u>	<u>0</u>
Subtotal, USDA	56,601	80,696	90,109	9,413
HHS:				
Food and Drug Administration	<u>27,193</u>	<u>36,393</u>	<u>43,293</u>	<u>6,900</u>
TOTAL, Research	<u>83,794</u>	<u>117,089</u>	<u>133,402</u>	<u>16,313</u>

Risk Assessment - FY 2000 Budget Request

Agencies will be conducting microbial risk assessments as a routine matter in making food safety policy decisions and prioritizing public health risks. In the pre-harvest production area, data will be generated on which to base predictive models for the risk of transmission of zoonotic pathogens through farm management systems to the presentation of the animals for slaughter and the transmission of zoonotic parasites through farm management systems, animal manure, and water run off. Work will be expanded in the collection of data about the number of microorganisms present in food associated with an outbreak and characteristics of individuals who ate the food, but did not become ill, in an effort to determine dose-response relationships for specific pathogens.

A study of production techniques used by fresh fruit and vegetable producers will produce some of the type of data needed for development of intervention technologies, as well as risk assessments to determine the need for more specific Good Agricultural/Good Manufacturing Practices guidance. Fundamental research to develop risk assessment techniques will expand as the growing use of strategies based on risk assessments alerts food safety officials to additional hazards in the food supply.

Coordination Strategy

The identification of critical information needs in risk assessment and setting methodological priorities will be coordinated through the interagency Risk Assessment Consortium formed in FY 1998.

FY 2000 Activities

Risk Assessment Consortium

- FDA, CDC, USDA and other participants, will continue to build and expand the cooperative base of the Risk Assessment Consortium to identify critical needs for development of microbial risk assessment techniques applicable to a wide range of foods and to meet the requirements of agencies participating in the consortium. The Consortium will evaluate how risk assessment can be used in priority setting, particularly for emerging pathogens.
- FDA, USDA, CDC and other participants will expand the risk assessment clearinghouse to better establish government, industry, academic partnerships.

Risk Assessments

- FDA will conduct risk assessments of priority microbiological safety concerns as a matter of routine.
- FDA will determine, based on technology transfer and research, how to most effectively integrate risk assessment into development of HACCP programs, as appropriate, for various commodities.
- FDA will increase the number of risk assessments performed for antimicrobial products as part of the pre-approval food safety evaluation from 2 to 3 per year.

Modeling

- FDA, USDA, CDC and other agencies at the Consortium will develop models suitable for answering complex questions related to food safety issues, such as evaluating the relative effectiveness of risk management options or regulatory policies.
- USDA will develop a system that will contain data banks with models for the growth rates, lag times, survival, thermal inactivation, and radiation inactivation, as appropriate for additional pathogens. For post-harvest operations, it will contain information on normal contamination levels in raw food ingredients and food composition parameters (pH, water activity and processing). For pre-harvest operations it will contain data describing risk of various food animal production and transportation practices and interventions. These data banks will be made available to other agencies.
- FDA will evaluate the effectiveness of integrating individual food production, processing, and consumption models to develop process pathway models for various foods.
- USDA and FDA will initiate studies and gather data on the incidence and number of pathogens on food producing animals at various critical stages in production and management systems. With this data the research will develop predictive models for the risk of transmission of zoonotic pathogens through farm management systems to the presentation of the animals for slaughter, and ultimately, to consumers. In addition to production practices, microbiological and animal behavioral data on various systems used for transporting swine will be generated and evaluated in relation to the subsequent contamination of the animals at slaughter. The research will also develop predictive models for the risk of transmission of zoonotic parasites through farm management systems, animal manure, and water run off.
- FDA will initiate mechanisms to transfer technologies and models developed for risk assessment to states, industry, foreign governments, and other users.

Dose-Response Assessments

- USDA will enter into cooperative agreements with 5 States to collect food specimens during investigations of foodborne disease epidemics. FDA will expand work to collect data about the level of contamination in foods associated with outbreaks and characteristics of people who ate the food but didn't become ill. Information at the local level is necessary to accurately determine the exposure to pathogens in suspect foods. USDA specimens will be analyzed to identify and enumerate pathogens. FSIS will use this information to support selection of appropriate dose-response model forms that will be used to assist the agency in determining acceptable pathogen levels on/in regulated meat, poultry, and egg products.

Exposure Assessment

- FDA will continue to extramurally fund research that expands the scope of exposure assessment and dose-response and other types of research that feed into the development of risk assessment techniques and models.

- FDA will make available to the food safety community, through technology transfer mechanisms, user-friendly software developed for predictive microbiology and risk assessment as a result of work conducted at the Consortium.

Fruit and Vegetable Survey

- USDA will use as a base of data to establish a baseline of agricultural practices for fresh produce a FY 1999 pilot study to be conducted in California and New York, which will provide information for the final design of materials and plans. These two pilot States were chosen based on distinct differences in crops grown, growing conditions, and agricultural practices.
- USDA will conduct a statistical survey of approximately 10,000 fruit and vegetable growers, as well as fruit and vegetable packing houses, to establish a baseline for good agricultural practices as they relate to microbial food safety issues. It would be conducted in major fruit and vegetable States which account for nearly 85 percent of the nation's acreage. The survey would consist of core questions covering water, manure management, facility sanitation, worker sanitation and hygiene, and transportation practices. The survey would also include questions related to specific practices and the related cost data to allow the calculation of associated cost/benefit analyses.
- USDA will provide the statistical survey data to FDA for use in providing guidance to industry to reduce the microbial risk from fresh fruits and vegetables.

Summary Budget -- Risk Assessment

	1998 Appro.	1999 Budget	2000 Proposal	Proposed Increase
RISK ASSESSMENT	Dollars in Thousands			
USDA:				
Agricultural Research Service	\$4,498	\$4,818	\$7,218	\$2,400
Cooperative State Research, Education, and Extension Service	150	1,962	1,962	0
Food Safety and Inspection Service	0	1,000	2,000	1,000
Economic Research Service	33	686	686	0
National Agricultural Statistics Service	0	0	2,500	2,500
Office of the Chief Economist	<u>60</u>	<u>158</u>	<u>158</u>	<u>0</u>
Subtotal, USDA	4,741	8,624	14,524	5,900
HHS:				
Food and Drug Administration	<u>6,539</u>	<u>13,739</u>	<u>16,439</u>	<u>2,700</u>
TOTAL, Risk Assessment	<u>11,280</u>	<u>22,363</u>	<u>30,963</u>	<u>8,600</u>

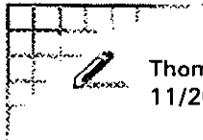
FY 2000 Food Safety Initiative Activities – FDA

CATEGORY	EXPANDED ACTIVITIES	NEW ACTIVITIES
<p>Surveillance/ Coordination</p> <p>\$9.0 million</p>	<p>1) PulseNet to 40 state health departments for full integration of data into routine surveillance.</p> <p>2) FoodNet to improve the qualitative and quantitative database for foodborne disease.</p> <p>3) Assist state/local governments in developing an infrastructure to ensure proper detection, evaluation, and coordination in response to foodborne illness outbreaks.</p> <p>4) NARMS capacity in systematic collection, analysis and interpretation of antimicrobial susceptibility data.</p> <p>5) Geographical scope and capacity of NARMS to take preventive steps to minimize foodborne outbreaks involving resistant pathogens originating inside or outside the U.S.</p> <p>6) Collaborative efforts with the World Health Organization to integrate veterinary diagnostic laboratories into current human international databases.</p>	<p>1) Electronic communication and data-sharing systems for use in federal-state monitoring and traceback investigations of outbreaks identified through FoodNet.</p> <p>2) With states: develop standard systems and procedures to provide uniformity in communications and actions of Federal, state and local agencies in response to foodborne outbreaks.</p> <p>3) Animal feed process inspections and increased compliance with BSE regulations.</p> <p>4) Increased sampling of feeds for mycotoxins, pesticides, chemicals and pathogens.</p> <p>5) Identifying emerging diseases associated with transmission through feed and working on resistance issues associated with bioengineered plants, animals, microbes and microbial-derived products.</p>

CATEGORY	EXPANDED ACTIVITIES	NEW ACTIVITIES
Research \$6.9 million	<ol style="list-style-type: none"> 1) Method development and prevention technology research with USDA. 2) Make detection methods more user-friendly and adaptable to field-use situations. 3) Continue research projects begun in FY 1998 to: improve analytical methods to detect Salmonella contamination of animal food; study the transmission of resistance factors through the live animal to slaughter; and evaluate the impact of pathogen reduction approaches. 	<ol style="list-style-type: none"> 1) With CDC/USDA: improve diagnostic methods for Cyclospora, Cryptosporidium, or Campylobacter species that are pathogenic for humans. 2) With USDA/ARS and FSIS: establish culture collections of resistant and non-resistant bacterial and fungal pathogens to facilitate identification and traceback of the pathogens. 3) With other agencies/the private sector/academia: translate preventive technologies and techniques developed into appropriate versions for use by small and large industry, foreign governments and consumers. 4) Study various aspects of the development of resistance. 5) Novel approaches to in vivo control of animal pathogens which preclude the development of resistant human pathogens. 6) Resistance dynamics of pathogens associated with the animal production environment. 7) Assess the potential health risks to animals and humans. 8) Risks from animal-derived foods. 9) Investigate viruses associated with food animal products as emerging foodborne pathogens.

CATEGORY	EXPANDED ACTIVITIES	NEW ACTIVITIES
<p>Risk Assessment</p> <p>\$2.7 million</p>	<ol style="list-style-type: none"> 1) Cooperative base of the Risk Assessment Consortium to identify critical needs for development of microbial risk assessment techniques applicable to a wide range of foods. 2) Number of risk assessments performed for antimicrobial products from 2 to 3 per year. 3) Data collected on contamination levels in foods associated with outbreaks and characteristics of people did not become ill after eating the same foods. 4) Exposure assessment and dose-response. 5) Models for microbiological hazards to determine safe off-label use levels as mandated in the Animal Medicinal Drug Use Clarification Act, and import tolerances as mandated in the Animal Drug Availability Act. 6) Follow-up activities resulting from an intensified surveillance program. 7) Risk assessments for anti-microbial products for pre-approval food safety evaluation. 	<ol style="list-style-type: none"> 1) Make available to the food safety community user-friendly software developed for predictive microbiology and risk assessment. 2) Evaluate the effectiveness of integrating individual food production, processing, and consumption models to develop process pathway models for various foods. 3) With USDA/CDC/other Consortium members: develop models suitable for answering complex questions related to food safety issues, such as, evaluating the relative effectiveness of risk management options or regulatory policies. 4) Determine how to most effectively integrate risk assessment into development of HACCP programs.
<p>Inspections/ Compliance</p> <p>\$25.6 million</p>	<ol style="list-style-type: none"> 1) Provide training, training funds and equipment to states to aid the retail food service industry in implementing HACCP, and in adopting the Food Code, including food handling provisions. 2) Coverage of imported food products by increasing the number of Mutual Recognition Agreements and other international agreements, and conducting evaluations of foreign food production systems to support its arrangements. 	<ol style="list-style-type: none"> 1) Begin development of a national, integrated federal/state/local food safety system 2) Develop mechanisms for gaining consistency between federal, state, and local food safety statutes. 3) Establish mechanisms for developing consistent federal/state/local inspections through training & other arrangements.

CATEGORY	EXPANDED ACTIVITIES	NEW ACTIVITIES
Education \$4.7 million	<ol style="list-style-type: none"> 1) Identify barriers for safe food preparation practices by the retail food service industry. 2) Support partnerships and alliances with other food safety organizations. 3) Increase food safety awareness through outreach activities with stakeholders. 4) Educational partnership agreements with state and local agencies to address appropriate uses of drugs in food animals. 5) Partnerships with states and local governments to disseminate information. 	<ol style="list-style-type: none"> 1) With USDA/CDC/states/local governments: implement a national education program for safety in retail food preparation policies. 2) Through contracts and partnerships, conduct education activities promoting use of safe food preparation, storage and distribution practices by the retail food service workers and the food transportation industry. 3) Work with veterinarians, producers and other stakeholders to develop recommendations on prudent use of antimicrobials and support educational strategies to encourage implementation.



Thomas L. Freedman
11/20/98 05:56:43 PM

Record Type: Record

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

cc:

Subject: Food Safety and OMB issues



112009CR.W Here are the agencies' cross cut and how they want to pitch its utility -- there are a couple of other OMB budget issues that may bump up to your level:

1. Food Safety. We've conceptualized it as a policy to create a seamless national system which the agencies are enthusiastic about. However, USDA says that if they get user fees for their budget again, the Secretary will not want to do a food safety initiative this year. (OMB is saying there will be some user fees in the passback.) The other proposed actions are: moves to encourage full adoption of the model Food Code for restaurants; developing performance standards for food service workers; and legislation that will give USDA the authority to issue mandatory recalls and impose civil penalties for unsafe meat and poultry.

2. Equal Pay. We asked for \$30 million. OMB sources say they want to keep focusing on reducing the backlog of cases. When pressed in a meeting with Sylvia, EEOC said if they had to choose they'd rather have the backlog reduced. I don't think \$30 million is enough to force them to choose, and that equal pay is popular enough that the Hill would add it to the on-going backlog reduction effort. I am making that argument but, if you agree, contacting folks on your level would be helpful.

3. Imported Food Reg. at FDA. I discussed with Elena the idea of doing our legislation on imported food standards as an agency regulation -- FDA thought they could get 75% done without a bill. Schultz at FDA now feels that Senator Collins is sympathetic to this as a bill, doesn't want to alienate Collins, and would rather try and get it as a bill. Should we push him?

FDA'S YEAR 2000 FOOD SAFETY GOALS
(If funds are appropriated)

INSPECTIONS

- o Establish a nationally integrated food safety system with Federal, state, and local authorities.
 - For the first time in decades, FDA will ensure that every high risk food manufacturer in the United States is inspected at least once a year.
 - For other food firms, inspections will be twice as often as today (from once every 8 years to once every 4 years).
 - For the first time ever, state and Federal inspection results will be shared, via an electronic connection, that will reduce overlapping efforts and greatly enhance the ability of those authorities to improve public health
- o FDA will have an enhanced international food safety program, which will include evaluations of other countries' food safety systems and provision of technical assistance to foreign countries who import to this country (thereby continuing the shift to ensuring that foods are safely produced before they arrive at our shores).

RESEARCH

- o FDA will be able to ensure the applicability and effectiveness of the new preventive control techniques used to ensure the safety of seafood, juices, eggs, fresh produce and other foods.
- o New detection tests will be developed for such dangerous contaminants as Salmonella in eggs and Cyclospora in fresh produce, and test methods for E. coli O157:H7 in foods in which it cannot now be detected.

OUTBREAK RESPONSE

- o With its increased surveillance, CDC expects an increase of 40% of foodborne illness from E. coli O157:H7 and salmonella, and 10% for all foodborne illness. Funding is needed so that FDA will have the laboratory and staff capability to respond rapidly to those outbreaks when they occur--to track down their source and prevent further danger.

- o CDC's new PulseNet contaminant tracing system will be connected to FDA's laboratories, thus enabling FDA to use this state-of-the-art disease detection system to control foodborne illness at the source.

RETAIL

- o CDC estimates that one-third of foodborne illness comes from retail establishments. A majority of states will adopt FDA's model food code that raises the standards for safer handling of food in restaurants, nursing homes, hospitals, and grocery stores. If funding is available, FDA can provide the necessary training and education to state and local inspectors (as well as industry) to implement those new standards.

EDUCATION

- o Targeted resources are needed so that the most vulnerable (e.g., elderly, very young, and pregnant women) will be taught how they should and can avoid contaminated food. The result will be that their behavior will begin to change so that the most severe illnesses and deaths can be prevented.

RISK ASSESSMENT

- o New information will become available about how much of a contaminant must be in a food to make people sick (such as Listeria) and how certain contaminants (such as Salmonella) can best be controlled.