FDA

COMMONLY CITED ISSUES

- Inspection manpower disparity between USDA and FDA for domestic foods;
- Inspection manpower and statutory authority disparity between USDA and FDA for imported foods
- Differences in the principles on which FDA, FSIS, and EPA statutory authorities are based (i.e., FDA food regulation is based on considerations of risk only; EPA pesticide regulation must balance risks and benefits; and USDA's statute requires continuous inspection)
- Funding disparity between USDA and FDA (especially for inspection and research activities)
- Divided Congressional committee jurisdictions for USDA, HHS (with different committees having jurisdictions for CDC and for FDA), and EPA
- Incompatibility of USDA's dual missions of promotion of agriculture and protection of the public's health
- Redundancy and inefficiency in food safety research among agencies
- Confusing and inefficient division of regulatory authorities between USDA and FDA for several issues such as egg safety, safety of foods during transportation (an issue shared with Department of Transportation), additives to meat and meat products, game meats
- FDA's inability to adequately cover imported food entries into the United States
- Confusing and inefficient division of regulatory authorities between EPA and FDA for drugs that also have pesticidal activity under FFDCA and FIFRA and the regulation of antimicrobial chemicals under FFDCA and FQPA

EXISTING (SELECTED) INTERAGENCY COORDINATION MECHANISMS

- Foodborne Outbreak Response Coordinating Group (MOU/USDA, DHHS, EPA)
- Interagency Coordinating Committee on Animal Production and Food Safety (MOU/USDA, DHHS, DOD, and EPA)
- Interagency Working Group on Food Safety Research (NSTC Committee on Science)
- Food Safety Initiative Steering Committee (USDA, DHHS, EPA)
- CVM, USDA, FSIS, AMS and EPA MOU on Regulatory Activities Concerning Residues of Drugs, Pesticides and Environmental Contaminants in Foods.
- FDA, USDA, DOD and EPA MOU for Interagency Coordination Committee on Animal Production and Food Safety (DRAFT)
- FDA/FSIS WGs on methods development for animal-drug residues in milk and in animal tissues
- CVM/EPA MOU on pesticides/animal drug overlaps
- CVM/APHIS MOU on biologics/immune mediators/animal drug overlaps
- Surveillance Advisory Committee WG
- National Antimicrobial Susceptibility Monitoring Program WG (FDA, CDC, USDA)
- Interagency Residue Control WG (FDA, USDA)
- FDA/FSIS MOU on cooperative notification of in-plant violations
- FDA/USDA MOU on National Advisory Committee on Microbiological Criteria for Foods

- Interagency produce research WG
- Interstate Shellfish Sanitation Conference MOU
- Conference of Food Protection
- Ad hoc Executive Board Members of: AFDO, CSTE, ASTHO, ASTPHLD
- Risk Assessment Consortium
- National Food Safety Initiative interagency WG
- Food safety education interagency WG
- Food Safety Education Partnership
- Food Safety Education IAG (FDA/USDA)
- Food Service Training and Education Alliance
- BSE/TSE interagency coordinating group
- HHS Environmental Health Policy Committee
- Interagency WG on GPRA goals
- Healthy People 2000 and 2010
- FoodNet WG
- CDC/FDA *Clostridium botulinum* WG
- Water WG (EPA/FDA/USDA)
- Emerging Infectious Diseases WG
- Interagency WG on GAPs/GMPs (FDA/USDA/USTR)
- A variety of U.S. Codex committees

ORGANIZATIONAL MODELS (other than current model)

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

USDA 1 5-27-98

Joint paper submitted to NAS in Dec.

SUBJECT: Issues sent to the NAS for Study on the Food-Safety System

The following list of issues has been synthesized from suggestions by USDA, FDA, CDC, and EPA. These issues, separated into public-policy and science-focused categories, have been suggested for inclusion in the charge to the NAS study committee.

Public-Policy Issues

-- the degree to which food-safety risks (e.g., specific pathogens, chemicals,) are appropriately addressed across the current government-wide food-safety regulatory system;

-- the degree to which each agency's food-safety program mission is protection of the public's health;

-- the degree to which each agency's mission is compromised by competing missions within its own organization or from within the department of which it is a part;

-- the degree to which each agency's decisions are science-based;

-- the degree to which each agency's regional operations are effective and efficient;

-- the degree to which current food-safety programs (federal, state, and local regulatory agencies) are fully integrated and coordinated in their approach;

-- the degree to which each agency's organization includes, as appropriate, critical public-health and safety programs as integral parts of each agency's public health functions (e.g., inspection, compliance, enforcement, surveillance, outbreak investigation, education, research);

-- the degree to which resources are available and are effectively used to carry out each agency's mission, and are successfully leveraged with mission partners;

-- the degree to which the costs of organizational change (lost productivity, disruption of current initiatives, etc.) as compared to the public-health benefits (e.g., increased system efficiency and effectiveness) effected by the change;

-- the degree to which current legislation impedes or is in conflict with the use of current science in carrying out the public-health mission of the agencies.

Science-Focused Issues

-- the degree to which each agency's food-safety programs include critical science functions, such as risk assessment, microbiology, chemistry, food science, food engineering, toxicology, nutrition, etc.:

-- the adequacy of the science-based programs that support the animal-health protection mission of eac agency; the adequacy of the science-based program that support the human-food-safety mission of each agency; and the degree to which those programs are effectively integrated.

BACKGROUND

The current federal food safety system consists of as many as 35 different laws administered by 12 agencies. Two agencies account for most federal food safety spending. FDA is responsible for the safety of most foods. Within USDA, FSIS is responsible for the safety of meat, poultry and egg products. During the past 20 years, organizations --most recently, the Vice President's National Performance Review Team--have issued reports detailing problems with the federal food safety system and have issued recommendations. While many of these recommendations have been acted on, in particular the implementation of a science-based system of food safety controls, known as HACCP, critics continue to point to a food safety system hampered by inconsistent and inflexible oversight and enforcement authorities, inefficient resource use, and ineffective coordination.

Principal Criticisms of the Inspection Programs:

---Firms that process food products that pose similar health risks to the public are inspected at widely different frequencies, depending on which agency and regulatory approach govern them.

--USDA has daily inspection of meat and poultry in slaughter plants and egg - product processing plants while FDA conducts periodically, inspections for all other food processing plants; that entails fewer than 700 inspectors.

--Food establishments are sometimes inspected by more than one federal agency because they come under multiple jurisdictions. For example, FDA has jurisdiction over frozen cheese pizza and inspects cheese pizza processors once every 10 years on average while USDA, with responsibility over frozen pepperoni pizza, inspects such processors daily. Critics point to an inefficient use of inspection resources.

--Enforcement authorities granted to the agencies also differ. USDA has the authority to (1) require food processors to register so that they can be inspected (2) presume that the food firms are involved in interstate commerce and are thus subject to regulation, (3) prohibit the use of processing equipment that may potentially contaminate food products, (4) temporarily detain any suspect foods from entering commerce. Conversely, FDA, without such authority, is often hindered in its ability to oversee food processors.

--Agency coordination agreements designed at overcoming the fragmented food safety system by avoiding duplication and /or gaps in inspection coverage are cited as ineffective. For example, unsanitary and other unsafe conditions are said to have persisted in food processing plants because notification required by the coordination agreements, does not always take place and are not referred to the responsible agency in a timely manner.

--Increase in imported food, particularly fruits and vegetables from countries that have less stringent standards than that of the United States and a lack of FDA resources to provide appropriate coverage.

--Multiple systems between federal, state and local regulatory agencies that are not fully integrated and coordinated in their approach. State and local authorities have responsibility for the regulation of retail stores and restaurants and there can be large disparities in regulatory standards and resources between the various state and local jurisdictions.

--The lack of mandatory recall and civil penalty authority impede an agency's ability to deter abuse of food safety regulations.

--GAO recently criticized the FSIS inspection force for focusing too much on violations like missing shipping labels for imported meat and poultry products that bear little relationship to food safety. Again the issue is that inspection needs to zero in on foods likely to pose the greatest risks.

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

Principal Criticism of the Surveillance Program

There is general agreement among experts that today's hazards are mostly invisible and they stem from shifts in agriculture, trade patterns, technology and dietary habits. At the same time, critics state that the surveillance of the food supply is not adequate to identify the source of infectious agents and that inspection methods are just beginning to catch up with the new hazards. The following factors have contributed to this perception:

--Our understanding of many pathogens and how they contaminate food is limited; for some contaminates, we do not know how much must be present in food before there is a risk of illness and for others, we do not have the ability to detect their presence in foods. For example, there has been an increase in new disease-causing microbes. Just in the last year, new forms of Salmonella and *E. coli* have appeared. *E. coli* O157:H7 was not discovered until 1982. Originally thought to be only in animal products, it has been found in apple juice and lettuce.

--A national and global increase in antimicrobial resistance, making infections very difficult to treat and a lack of resources to effectively address this critical public health concern.

--Agencies have different priorities for the types of pathogens that should be included in a surveillance program, leading to different agendas.

Principal Criticism on Responses to Food-borne Outbreaks

Although significant coordination already occurs, critics of the current system cite, the federal food safety agencies piecemeal approach to food safety problems. In addition, split jurisdictions, a misunderstanding of each agency role in an outbreak and lack of communication hampers an effective and rapid response.

--An example frequently cited is the outbreak of Hepatitis A from frozen strawberries, served in the federal school lunch program over a year ago. Agencies involved in this outbreak included AMS that purchased the frozen strawberries for the school lunch program, FNS that has jurisdiction over school lunch, FDA that has jurisdiction over strawberries, the state of California where they were packed and the state of Michigan that received the strawberries. Cited was the lack of coordination and communication between these agencies to clearly articulate the problem and identify the solution as well as confusion over who had jurisdiction.

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

Criticism of Current Risk Assessment Program

The Centers for Disease Control and Prevention estimate that 9,000 people die each year from food-borne illnesses, but that figure doesn't take into account under reporting. Similarly, the number of Americans who become ill each year from food-borne illnesses is anywhere from 6.5 million to 81 million. Recalls of food have increased nearly fivefold since 1988.

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

Criticism of the Scope and Focus of Research

New food-borne pathogens have developed over the past ten years. Many of these organisms cannot be detected readily due to a lack of suitable methods or their sporadic occurrence in foods. The various research programs need to be more effectively coordinated to eliminate duplication and focus on the highest priorities.

--Issues revolve around lack of coordination on a federal food safety research agenda by the food safety agencies.

--Lack of identification of highest priorities

--Poor interaction between the research agencies and the federal food safety agencies due to conflicting priorities and scarce resources. Development of new technology is hampered by competing priorities.

Criticism of the Education and Outreach Program

Despite intense educational efforts targeted at food preparers and handlers at each stage of the food chain, food-borne illness remains prevalent throughout the United States.

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

Regulatory Reform

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

Overall Mission

--Additional areas raised might focus on whether the overall mission of the food safety agency is public health and if that mission is compromised by competing interests within the Agency or Department-- such as promoting American agricultural products or approving drugs.

Traceback

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

Addressing the Criticism

The fiscal year (FY) 1998 and 1999 National Food Safety Initiative presents a coordinated proposal of actions to enhance the safety of the Nation's food supply and responds to perceived gaps in the federal food safety system. Listed below are several interagency activities that highlight a more clearly defined coordinated policy among the federal food safety agencies.

The over-arching mechanism for coordination is the "Principles Group", a sub-cabinet level USDA, HHS, EPA and NIH Steering Committee that oversees all of the activities under the National Food Safety Initiative. There is also an interagency working group that monitors implementation of the National Food Safety Initiative.

Inspection

--Following through on the recommendations of the first NPR report, the Administration implemented the new science-based food safety system known as HACCP. This new system focuses on preventing problems rather than catching problems after they occur. Instead of relying only on sight, touch, and smell, USDA inspectors now have additional tools targeted directly at reducing harmful bacteria like *E. coli* O157:H7 and salmonella. In 1995, the FDA issued new rules to ensure the safety of seafood using the HACCP regulatory approach.

--Leveraging inspection resources and increasing inspections for higher risk foods was addressed in the 1998 and 1999 National Food Safety Initiative.
Working groups between USDA and FDA have been formed to:

- **Evaluate the expansion of cooperative agreements so that FSIS inspectors can provide information to FDA plants producing meat and nonmeat foods. FSIS inspectors are already in these plants, and their presence could be better used to maximize use of federal resources.**

- **Review possible procedures for FSIS inspectors to exchange information with FDA on basic sanitation conditions in warehouses.**

- **Work closely with state and local regulators to establish uniform retail program standards through adoption of the Food Code. Currently as mentioned above, there are large disparities in regulatory standards between state, local and federal regulators.**

- **Identify and address food safety issues related to the school lunch program and other feeding programs in USDA.**

- **Consider the tasks of USDA inspectors in an HACCP environment.**

- **Develop Good Agricultural Practices and Good Manufacturing Practices guidance for the domestic produce industry. FDA is also seeking legislation that would decrease the risk of importing unsafe food products from countries with food safety systems for exported products that are not on par with the U.S. system.**

In addition, the FSIS Advisory Committee on Meat and Poultry Inspection, which serves as a forum for sharing ideas and policy development on regulatory issues, includes consumer and industry representatives, as well as state and federal officials.

Surveillance

- **The Administration increased funding through the national food safety initiative to target a broad range of food-borne pathogens. The strengthened capacity of FoodNet (the food-borne diseases active surveillance network) will provide rapid identification of the causes of outbreaks.**

- **FSIS, FDA and CDC collaborate with state and local health departments to analyze data, recognize trends and target prevention strategies to evaluate their effectiveness.**

- **FSIS, FDA, and CDC have developed an MOU that will allow the agencies to jointly collect more precise information on the incidence of food-borne illness in the U.S.**

Responses to Food-borne Outbreaks

- **To strengthen the outbreak response and coordination, USDA, HHS and EPA have formed the Food-borne Outbreak Response Coordination Group, an inter-departmental task force that will review food-borne illness outbreak response by federal and state governments and, based on these findings will develop and implement accelerated response procedures.**

- **Each Department will have an outbreak coordinator. For HHS, the Assistant Secretary for Health will be the primary person in charge of coordination for HHS. Outbreaks that fall under the jurisdiction of USDA will be coordinated by the Under Secretary for Food Safety. EPA will designate the Assistant Administrator for Water and the Assistant Administrator for the Office of Prevention, Pesticides, and Toxic Substances.**

Risk Assessment

- **The Risk Assessment Consortium, JIFSAN, is an interagency group that will**

coordinate risk assessment activity. Created as a part of the National Food Safety Initiative, USDA, FDA, CDC, EPA and NIH will collaborate on identifying risk-assessment research priorities.

- The FSIS-FDA National Advisory Committee on Microbiological Criteria for foods also serves as an interagency resource to provide risk assessment models for future regulations. USDA is required to include a risk assessment in order to promulgate regulations.

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

Research

- USDA has formed the Food Safety Research Working Group to establish a research agenda that supports the fundamental changes that FSIS is making to food safety regulations based on the HACCP system. The goal of the research agenda is to reduce the incidence of food-borne illness associated with the consumption of meat, poultry and egg products. The Food Safety Research Group includes the Following USDA agencies: ARS; APHIS; CSREES; ERS; FSIS; ORACBA; and the Office of the Secretary.

- USDA, HHS and EPA have also formed an interagency research planning group to identify research priorities aimed at reducing microbial risk in produce.

- The Office of Science and Technology (OSTP) has convened an interagency group which includes, USDA, HHS, EPA and NIH, to coordinate federal food safety research priorities and will recommend direction of research funds for the FY 2000 budget for the federal food safety agencies.

Education

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

Single Food Agency
EPA Responses to Questions Posed by NPR

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

The NAS report may identify the following issues, some of which affect the Environmental Protection Agency (EPA) or are EPA's responsibility, and others of which require interagency coordination and/or legislative change. The potential issues include:

- adequacy of food safety research;
- whether science/research should be consolidated in a single agency;
- how to best link food safety research and surveillance by CDC;
- whether and how to best link research and regulation;
- inconsistent statutory standards for food regulation in FIFRA, FFDCA, FQPA and FSIS's authorizing legislation;
- number of illnesses due to bacterial contamination of food;
- illnesses caused by adulterated food from use (or misuse) of pesticides;
- need for improved control of microbial contamination by pesticides;
- sufficiency of scientific basis for and difficulty of determining aggregate and cumulative risk in setting pesticide tolerances under FQPA;
- whether to combine in a single agency or separate in different agencies the standard-setting and enforcement of food safety regulation;
- Federal resources needed for food safety inspections and enforcement of both domestically-grown and imported foods;
- more efficient and cost-effective use of Federal resources by combining Federal and/or State inspections for food safety;
- need to provide a coordinated, consistent Federal response to food contamination and food-borne illnesses;
- need for coordinated communication with State and local authorities on food safety issues, especially in cases of food contamination and illness.

2. What EPA is doing to address pesticide-related issues.

EPA participates in a number of interagency committees and efforts to coordinate food safety research, regulation, enforcement and emergency response (see response to question # 3). EPA has primary responsibility for a few of the issues listed above, and EPA's efforts to address these issues follows.

Adulterated Foods Due to Pesticides

A major responsibility of the Environmental Protection Agency's Office of Pesticide Programs (OPP) is ensuring that food that may come in contact with pesticides is safe. EPA regulates pesticides in the United States under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA). FIFRA grants EPA authority to register (license) pesticide products distributed and sold in the United States after a review of data is completed that shows that the pesticide can perform its function

without causing unreasonable adverse effects to human health or the environment when used according to approved label directions. Under FFDCA, EPA is responsible for setting maximum residue limits, called "tolerances," of pesticides used in food production to ensure that a reasonable certainty of no harm will occur from the residues left on food.

The tolerance setting process has recently been given increased emphasis by the Food Quality Protection Act (FQPA). In 1996, FQPA amended both FIFRA and FFDCA strengthening the way EPA sets tolerances to ensure a higher level of protection to the American people from potentially toxic levels of pesticide residues in/on food, and reflecting a national commitment to greater protection of infants/children. FQPA established a single, health based standard to be used when assessing the risks of pesticide residues in food and feed. The new safety standard considers the aggregate exposure of pesticides using dietary residues and other non-occupational sources of exposures, such as drinking water, residential or other uses. In addition, when setting tolerances under the new standard, EPA must now focus explicitly on exposures and risks to infants and children. It must consider the cumulative effects from pesticides that share a common mechanism of action and those that may be potential endocrine disruptors.

FQPA requires EPA to reassess all tolerances by 2006; this will "update" pesticide residue limits in/on food in the U.S. based on the latest scientific studies and consideration of aggregate exposure to pesticides from food, drinking water and residential and lawn uses, with special emphasis on protection of children. This reassessment will provide greater protection of the food supply for the American people.

Tolerance setting requires some input from other Agencies (e.g., food consumption data), and the Food and Drug Administration is responsible for enforcement of tolerances for most foods while the United States Department of Agriculture enforces tolerances for meat, poultry and some egg products.

Improved control of microbial contamination by pesticides

Antimicrobial pesticides are substances used to control harmful microorganisms including bacteria, viruses, and fungi, on objects and surfaces. Types of antimicrobial products have traditionally included disinfectants, sanitizers, sterilizers, and antiseptics and germicides. Prior to FQPA, to obtain registrations for antimicrobial products, manufacturers were required to meet the general standards of FIFRA and to submit to EPA detailed information concerning their products including effectiveness data to document their claims against specific microorganisms. FIFRA contained no specific provisions for regulating antimicrobial products. EPA shared regulatory responsibilities with FDA for some products, and gave no particular review priority to antimicrobial products over other types of products.

Under FQPA, EPA must revise the antimicrobial registration process with the goal of achieving significantly shorter review times for all types of antimicrobial registration actions. Amendments to FIFRA also reduce dual regulation and establish more specific regulatory requirements tailored to antimicrobials.

EPA has developed a program to achieve the goals set out in the new law. EPA's plan for improving the efficiency of its regulation of antimicrobial pesticides has four stages:

1. Establish a New Antimicrobial Division (accomplished 2/97).

2. Develop New Policies. EPA is moving to resolve several urgent issues affecting the regulation of antimicrobial products, particularly as they involve the jurisdiction of the FDA and EPA. The Agency has:
   - established policies for evaluating the risks of non-food use pesticides whose use may involve significant exposure to children;
   - clarified the types of pesticide products assigned to the Antimicrobial Division;
   - clarified jurisdiction over the establishment of tolerances for food contact sanitizers;
   - established procedures and published policies for revising antimicrobial pesticide product labeling as envisioned by the new law.

3. Address the Backlog of Pending Applications. EPA has reduced the backlog from 388 actions in September 1997 to 57 actions in 1998 (an 85% reduction), and progress continues to be made on the backlog.

4. Establish a Streamlined Antimicrobial Regulatory Process. To streamline its activities, EPA has:
   - established dedicated review teams for expedited actions;
   - defined a simplified notification process for certain label changes;
   - provided quick turnaround review of requests for minor formulation changes; and
   - continues to work with stakeholders to develop clear rules and guidelines.

To successfully implement its new antimicrobials program, EPA is working with other government officials, the regulated industry, agricultural and other user groups, food processors, academia, environmental and public interest groups, the international community and the media to reach all interested parties. EPA is consulting with other government agencies including FDA and USDA on a range of issues relevant to improve food safety. The Agency is also working to keep the regulated community and other stakeholders informed of progress on antimicrobial implementation activities.

Scientific Basis for Setting Pesticide Tolerances

In order to keep up with developing science, EPA conducts research and develops new safety tests. On important scientific questions, EPA is advised by the FIFRA Scientific Advisory Panel and sometimes by other independent science boards including the National Academy of Science. Standing committees are used to provide advice to EPA. Recent examples of this include:

- The Endocrine Disruptors Screening and Testing Advisory Committee (EDSTAC) established to give advice and counsel on developing a strategy to screen and test

endocrine disrupting chemicals and pesticides. This committee is comprised of representatives from industry, state and federal government, public health, environmental, labor, small business, and academia. This strategy will be aimed at reducing or mitigating risk to human health and the environment. The final report on a proposed strategy is due by July 1998.

- The FIFRA Scientific Advisory Panel has met four times between September, 1997 and May, 1998 to consider key scientific issues raised by the new FQPA, including how best to protect children, how to determine aggregate exposure, and how to establish a procedure for determining common mechanisms of toxicity.

- EPA is also seeking the advice of the International Life Sciences Institute (ILSI) on options for cumulative assessment methods.

In sum, under FQPA, EPA is working hard to strengthen the scientific basis of its actions, including obtaining expert scientific advice, peer review, and the input of stakeholders.

Coordinated Federal response to food contamination emergencies

The Foodborne Outbreak Response Coordinating Group (FORCG) is designed to improve the approach to interstate outbreaks of foodborne illness through the development of a national comprehensive and coordinated foodborne illness outbreak response system involving federal, state and local agencies charged with responding to such outbreaks. FORCG members include EPA, USDA, FDA and CDC at the federal level, and public health, agriculture and epidemiologist representatives at the state level. A key element of FORCG's mission is to develop standard operating procedures for the rapid exchange of information on foodborne illness outbreaks between involved state, local and federal agencies and for dissemination to the public. For example, FORCG was "activated" for a recent outbreak of illness associated with contaminated frozen burritos (which involved hundreds of children who became ill from eating burritos in school lunches). The group was called together to respond to this emergency and there was a rapid and comprehensive exchange of information between federal and state partners.

3. Current food safety coordination efforts by EPA.

The U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA) are routinely informed when EPA makes tolerance decisions. Further, EPA sends proposed rules to USDA and FDA for review where appropriate. EPA, USDA and FDA work closely together using both memorandums of understanding and working committees to deal with a variety of issues that affect the agencies, including improvements in the nation's food safety system. These include:

- FDA, EPA and USDA Principles meetings on Food Safety
- Foodborne Outbreak Response Coordinating Group (FORCG)
- The EPA & USDA co-chaired Tolerance Reassessment Advisory Committee (TRAC)
- The Food Safety Initiative

- Interagency Committee on Animal Production and Food Safety
- Partnership for Food Safety Education
- Interagency Food Safety Risk Assessment Group (I-FRAG)
- The Risk Assessment Consortium
- MOU with USDA and FDA on oversight and direction for the Pesticide Data Program (PDP) through an Executive Steering Committee
- MOU and quarterly meetings with FDA (to coordinate and perform certain FIFRA/GLP inspections)
- EPA/FDA/USDA coordination on possible pesticide misuse cases (illegal residues on crops or food)
- OECA/OPPTS/FDA coordination on food contamination cases
- EPA/FDA workgroup to consolidate current FIFRA, TSCA and FDA Good Laboratory Practice (GLP) regulations, harmonize internationally, and verify compliance with GLP's
- National Agricultural Pesticide Impact Assessment Program (NAPIAP)

EPA also actively solicits advice and comments on pesticide regulation and implementation, including FQPA implementation, from key stakeholders and the public. EPA works with other government officials, the regulated industry, agricultural and other use groups, food processors, academia, environmental and public interest groups, and the international community to reach all interested parties. Specific committees providing advice to EPA include:

- The Food Safety Advisory Committee (FSAC)
- The Endocrine Disruptors Screening and Testing Advisory Committee (EDSTAC)
- The Pesticide Program Dialogue Committee (PPDC)
- The Pesticide Issues Discussion Group
- The FIFRA Scientific Advisory Panel (SAP)
- EPA's Science Advisory Board (SAB)
- State FIFRA Issues Research and Evaluation Group (SFIREG)
- The Consumer Labeling Initiative (CLI)

4. Draft response to recommendations of the May report.

It is EPA's understanding that FDA and USDA will respond to this question.

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

Although there are a number of organizational options that indirectly impact the pesticide-safety of the food supply, in the short time available, our response is limited to those that directly affect EPA.

Pesticide regulation in a single food agency or with EPA

EPA has concerns about the utility and feasibility of including all or part the Agency's Office of Pesticide Programs (OPP) in a single food agency, and it is not readily apparent how such a move would increase the safety of the food supply in the United States from exposure to

pesticides. If only the parts of OPP directly concerned with food were to be moved to a new food safety agency, one concern is that OPP is responsible for many other, related areas in addition to food safety, and the relevant legislation (FIFRA) does not deal exclusively with food safety. While food safety is a key element of our pesticide regulatory system, FIFRA also includes critical environmental protection responsibilities not directly associated with food safety such as protection of communities, water, air, fish, birds, and ecosystems. In addition, OPP's responsibilities include protection of workers exposed to pesticides and registration of many non-food pesticides including those used in and around homes, in industry, in hospitals, in forestry, etc.

Further, there would be problems even in setting food tolerances. The Food Quality Protection Act (FQPA) requires that before the EPA sets a pesticide tolerance on food, EPA must look at the aggregate risk from both dietary and non-dietary sources. Much coordination must take place in order to ensure that the appropriate tolerance is set since the use of the pesticide product might have other non-food uses. When assessing the risks of a chemical, such sources as worker exposure, non-target species, drinking water, ecological systems, residential, and lawn care, etc., need to be considered. Many pesticide products are used not only on food crops but also have residential or lawn uses, and exposure to all of these uses must be considered together. If the portion of the program that addresses risks from non-food uses would remain with EPA, a complicated, time-consuming interagency process to share databases, review the science and identify risk mitigation strategies would be necessary, and could hinder timely establishment and reassessment of tolerances. It might be difficult for a strictly food safety agency to focus on and bring the coordination required by FQPA to bear in setting tolerances. In sum, the coordination of these risk assessment and risk management efforts would present a major problem if the pesticide program were divided.

Pesticide exposure is not solely a food safety issue; there are other goals that are addressed by pesticide regulation under FIFRA. If the new food safety agency would incorporate the entire Office of Pesticide Programs, it is likely to impede progress on these other goals by de-emphasizing non-food programs. This might include not only the registration of non-food pesticides but also addressing non-food safety aspects such as environmental issues and worker protection. In many cases, risks posed from non-food use are potentially of more concern than from food use. If the pesticide program were taken from EPA and placed in a food safety agency, the environmental and worker aspects of pesticide regulation would need to compete against the food safety mission. Environmental concerns about pesticide use is one reason why pesticide responsibilities were placed in EPA in 1970.

Very few antimicrobial pesticides that control microbial contamination have solely food uses; most have both food and non-food uses or non-food uses only. If antimicrobial pesticides with food uses are removed from EPA and placed in a single food safety agency, there is concern that the products with non-food uses will not be given appropriate attention. These non-food uses, for example, include applications in hospitals for control of disease. Consequently, their regulation is of extreme importance to the public.

Further, bringing all of OPP to a new agency would isolate it from needed support from

and coordination with other EPA programs such as the Office of Water, Office of Research and Development, and others.

In conclusion, real benefits from moving the pesticide program from EPA to another entity are not readily apparent. With the recently passed Food Quality Protection Act, and the increased interagency cooperation on food safety that has resulted, EPA is confident that our current pesticide regulatory system is protective of the public.

Drinking water in a food agency or with EPA

EPA's drinking water program under the Safe Drinking Water Act (SDWA) protects public drinking water supplies by establishing Maximum Contaminant Levels (MCLs) for microbiological, radiological, and chemical contaminants found in drinking water, by regulating public drinking water suppliers in the U.S. through the Public Drinking Water Supply Supervision Program, and by supporting prevention programs such as drinking water source protection.

It is impractical and imprudent to move the drinking water program (located in the Office of Ground Water and Drinking Water) to a new food agency, as the drinking water program regulates an entirely different industry. Also, the drinking water program only regulates the drinking water treatment and supply industry, not specific sources of contamination. (The one exception to this is the underground injection control program, which regulates waste pumped into the ground.) In addition, the scope of the Office of Ground Water and Drinking Water (OGWDW) goes beyond ingestion of drinking water to cover drinking water in all steps of the supply process: from protection of the source water, to drinking water treatment and delivery, to consumer information.

OGWDW is integrally linked to other parts of EPA's Office of Water in every step of the drinking water protection and supply process, and a move to a new agency would rip apart those vital links. For example, contamination of drinking water sources is prevented through a closely-linked network of Clean Water Act (CWA) and SDWA programs, including the new Clean Water Action Plan. Drinking water is a designated use under the CWA, requiring that programs under both SDWA and CWA coordinate closely in protection efforts. In addition, EPA is integrating the public information programs for CWA and SDWA programs so that consumers can easily find information about their water for drinking, swimming, and fishing uses.

With the new requirements of the Food Quality Protection Act and the 1996 amendments to the SDWA, EPA's Office of Water and the Office of Prevention, Pesticides and Toxic Substances are strengthening their cooperation. The two offices are working together to set priorities and share resources, information, and assessments.

USDA 5-27-98

DRAFT

Food Safety Initiative Activities

Category / Activity / Sub Activity	1. A New Early-Warning System for Foodborne Disease Surveillance	Lead/Contact	Start Date	End Date	FY 1998 USDA Funding (millions)	Status/Notes
1. A New Early-Warning System for Foodborne Disease Surveillance					**$1.5**	**Two sites will become operational in 1998 in FoodNet, with three more underway. Epidemiologists and other scientific personnel have been added to several of the sites. State sites are also being networked into the developing database on DNA fingerprinting of pathogenic microbials. Results of Vermont Salmonella outbreak investigations are being studied and other monitoring of microorganisms' antimicrobial resistance, including sampling results of large meat plants under FSIS/HACCP.**
Description:	In cooperation with State and local health departments, the Federal Government is proposing to improve a system for promptly and accurately detecting and reporting foodborne illnesses and outbreaks so public health agencies can rapidly institute appropriately and correctly focused measures to control the spread of foodborne disease. This system will also collect critical data to recognize trends and target prevention strategies, including systems based on HACCP principles, and to evaluate the effectiveness and efficiency of prevention strategies already in place.					
1.a Conduct surveillance of Human Pathogens in Food-Animal Populations and Enhance Oversight of Animal Foodstuffs, Feeds and manures for the Effect of Drugs and Other Therapies						
	1.a.1 USDA, CDC, FDA and EPA will convene a working group to discuss how to conduct surveillance of human pathogens in food animals and their manures, and should target one pathogen on which to begin surveillance in FY99.	Tollefson & Falci (FDA); Buntain (FSIS); Wachsmuth (FSIS)	10/1/97	9/30/98		USDA formed a task force on manure management. A manure document is being prepared.

Category / Activity / Sub Activity	1. A New Early-Warning System for Foodborne Disease Surveillance	Lead/Contact	Start Date	End Date	FY 1998 USDA Funding (millions)	Status/Notes
	1.a.2 FDA should increase the monitoring of animal-feed processing to determine the nature sand extent of pathogen contamination and the effect of control strategies on pathogen reduction in animals.	Tollefson (FDA; Wachsmuth (FSIS)	10/1/97	9/30/00		work is ongoing.
	1.b Create a National Electronic Network for Fingerprint Comparison					
	1.b.1 CDC will provide resources and technical assistance to state health departments for DNA fingerprinting of E.coli O157;H7 and S.typhimurium, and begin to establish a centralized national electronic database of DNA fingerprint patterns.	CDC; Wachsmuth (FSIS)	1/25/97	9/30/97		(1) Process was initiated in January 1996. FDA/CFSAN site will be connected to CDC net to share isolate results by early 1998. The FSIS fingerprinting network site in Athens, GA became operational in February. (2) CDC has contracted the set-up of sites in the states of Washington, Minnesota, Texas and Massachusetts. Debugging of the program is underway. (3) Plans are underway to expand the CDC Net to five additional sites.
	1.b.2 The national electronic database of DNA fingerprint patterns of E.coli O157:H7 will continue to be expanded.	CDC; Wachsmuth (FSIS)	10/1/97	9/30/98		See Activity Above.
	1.b.3 In collaboration with participating state health department laboratories, FDA and FSIS CDC will develop standardized methods for DNA fingerprinting of Salmonella serotypes Typhimurium and Enteritidis and will transfer the techniques to health depts.	CDC; Wachsmuth (FSIS)	10/1/97	9/30/98		Group met in Seattle, WA, 3/30-4/3/98, on standardizing methods and exploring extension of fingerprinting for S. Typhimurium and evaluating faster turnaround on fingerprinting for O157:H7 and S. Enteriditis. Selected a method for S. Typhimurium subtype Newport.
	1.b.4 CDC, ASTPHLD, and CSTE will develop guidelines for maximizing the utility of DNA fingerprinting at state health departments in foodborne disease surveillance and outbreak investigations.	CDC; Wachsmuth (FSIS)	10/1/97	9/30/98		FSIS is monitoring progress in merging/meshing its database with theirs over Pulsenet.

Category / Activity / Sub Activity	1. A New Early-Warning System for Foodborne Disease Surveillance	Lead/Contact	Start Date	End Date	FY 1998 USDA Funding (millions)	Status/Notes
1.b.5 CDC, FDA, and FSIS will set up centralized national electronic databases of DNA fingerprint patterns of S. Typhimurium and Enteritidis.		Falci (FDA); Wachsmuth (FSIS)	10/1/97	9/30/98		See Activity 1.b.1 under Create a National Electronic Network for Fingerprint Comparison.
1.b.6 CDC should continue to develop standardized DNA fingerprinting methods for other foodborne disease-causing bacteria as appropriate and should transfer the methods to health depts. and federal labs.		CDC; Wachsmuth (FSIS)	10/1/97	9/30/00		In process --will occur as result of the CDC Net expansion.
1.b.7 CDC should begin implementing automated foodborne disease outbreak dimension algorithms based on the DNA fingerprint patterns submitted by state health department laboratories.		CDC; Wachsmuth (FSIS)	10/1/97	9/30/00		
1.c Enhance and Expand Foodborne Disease Active Surveillance						
1.c.1 Two new active surveillance sites in New York and Maryland, will begin FoodNet activities		Falci (FDA); Wachsmuth (FSIS)	1/25/97	1/15/98	**($1.5)**	October 1, 1997 started the FoodNet sites in Rochester, NY and Baltimore, Maryland. Exchange of data at these sites is operational. The two new sites funded, in part, by a transfer from USDA/FSIS will expand the portion of the U.S. population under surveillance.
1.c.2 CDC, FDA, FSIS and the Council of State and Territorial Epidemiologists (CSTE) will add at least one site to FoodNet.		Falci (FDA); Wachsmuth (FSIS)	10/1/97	9/30/98		Site selection has not been made, but is expected by fall of 1998, with participation in 1999.
1.c.3 CDC will enhance personnel resources at all sites to improve surveillance, analysis of data, and timely and appropriate release of information.		CDC; Wachsmuth (FSIS)	10/1/97	9/30/98		3 to 4 part-time epidemiology interviewers have been hired by the states that have FoodNet Sites.
1.c.4 CDC and the FoodNet sites will develop and conduct case-control studies of Salmonella,		Falci (FDA); Wachsmuth (FSIS)	10/1/97	9/30/98		(1)Salmonella, and E.coli O157:H7 case control studies are completed and will be discussed and

Category / Activity / Sub Activity	1. A New Early-Warning System for Foodborne Disease Surveillance	Lead/Contact	Start Date	End Date	FY 1998 USDA Funding (millions)	Status/Notes
	E.coli O157:H7, and Campylobacter and Cryptosporidium infections to guide control efforts.					reported on at the March 8, 1998 Infectious Disease Conference in Atlanta, GA. E. coli study completed, discussed, and reported. (2) Campylobacter case control study has begun and is expected to be completed during 1999. (3) A letter has been sent to CDC requesting better surveillance of reported Cryptosporidium cases at the FoodNet sites.
1.d Enhance Early Detection of Foodborne Disease Nationwide						
	1.d. 1 Council for State and territorial Epidemiologists (CSTE) and CDC, in conjunction with FDA and FSIS, will develop a protocol for evaluating epidemiological outbreak data.	Falci (FDA); Wachsmuth (FSIS)	1/25/97	9/30/97		A protocol has been drafted and was discussed at the June 1997 CSTE Meeting. FSIS and CSTE met on a USDA/FDA protocol on March 4. Discussions continue on the draft and changes are still being incorporated.
	1.d. 2 CSTE and CDC, in conjunction with FDA and FSIS, will develop criteria for local and state health officials to provide information on outbreaks to federal authorities for review and necessary action.	Falci (FDA); Wachsmuth (FSIS)	1/25/97	5/1/98		Criteria have been drafted and were discussed at the June 1997 CSTE meeting. The draft criteria is being discussed and updated.
	1.d. 3 FoodNet sites will gather epidemiologic data on cases of HUS.	CDC; Wachsmuth (FSIS)	1/25/97	9/30/97		Active Surveillance for HUS was implemented in 5 FoodNet sites. Efforts are underway to expand this effort to the newly added New York and Maryland FoodNet Sites. Pediatric nephrologist were contacted monthly. 23 HUS cases have been reported at the 5 sites. A full report was presented at the March 8, 1998, Infectious Disease Conference.
	1.d. 4 CSTE and CDC in conjunction with FDA and FSIS, will conduct an inventory of state and local health departments to conduct surveillance, investigation, control and prevention of foodborne illness.	Greenblat (?); Falci (FDA); Wachsmuth (FSIS)	10/1/97	9/30/98		Preliminary draft has been started. The drafts will be further discussed at CSTE meeting in June.

Category / Activity / Sub Activity	1. A New Early-Warning System for Foodborne Disease Surveillance	Lead/Contact	Start Date	End Date	FY 1998 USDA Funding (millions)	Status/Notes
	1.d. 5 CDC will help states remedy identified deficiencies.	CDC; Wachsmuth (FSIS)	10/1/97	9/30/98		
	1.d. 6 CDC and CSTE will develop an electronic module for collecting and transmitting data to USDA and FDA on outbreaks and response to multi-state outbreaks of foodborne illness.	Ostroff (CDC); Falci (FDA); Burkhead (CSTE); Wachsmuth (FSIS)	10/1/97	9/30/98		Discussions have been held at CDC. Draft paper and funds for the system have not been put in place.
	1.d. 7 CDC will begin a case-control study of hepatitis-A to determine the proportion of cases due to contamination of food so that optimal control strategies could be determined.	CDC; Wachsmuth (FSIS)				Will not be done.
	1.d. 8 Epidemic assistance, in the form of EIS Officers, for outbreaks of foodborne diseases will be expanded when states request direct CDC participation in investigations.	CDC; Wachsmuth (FSIS)	10/1/97	9/30/98		In process.
	1.d. 9 CDC and, where appropriate, FDA and FSIS, will collaborate with state health departments to improve diagnostics, outbreak detection, and electronic communications.	CDC; Majkowski (FSIS)	10/1/97	9/30/98		In process.
	1.d.10 Vibrio surveillance will be strengthened by CDC, FDA and states by increasing personnel, epidemiologic and laboratory resources devoted to the Gulf Coast Vibrio surveillance program.	Falci (FDA)	10/1/97	9/30/98		(1) Retail market survey for the quantitative occurrence of vibrio vulnificus started. (2) Samples of molluscan shellfish are being analyzed in state laboratories. Vibrio paraheamolyticus in molluscan shellfish is being planned for 1999.
	1.d.11 Surveillance and investigative systems should continue to improve the ability of state and local health departments to promptly and accurately identify foods that are the source of foodborne illness.	Falci (FDA); Wachsmuth (FSIS)	10/1/97	9/30/00		In process.

Category / Activity / Sub Activity	1. A New Early-Warning System for Foodborne Disease Surveillance	Lead/Contact	Start Date	End Date	FY 1998 USDA Funding (millions)	Status/Notes
1.e Increase National Surveillance for Antimicrobial Resistance of Foodborne Pathogens						
1.e.1 CDC, FDA and FSIS will conduct surveillance of antimicrobially resistant Salmonella and E.coli O157:H7 isolates		Tollefson (FDA); Wachsmuth (FSIS)	1/25/97	9/30/00		Process began January 1996 and is ongoing.
1.e.2 CDC, FDA, and FSIS will initiate surveillance of antimicrobial resistance in isolates of Campylobacter from humans and animals, including poultry.		Tollefson (FDA); Wachsmuth (FSIS)	10/1/97	9/30/00		Campylobacter testing from human isolates began January 1997; Campylobacter testing from poultry isolates began January 1998.
1.e.3 FDA and CDC will conduct surveillance and epidemiologic studies to monitor and reduce the incidence of foodborne disease associated with emerging and drug resistant pathogens.		Tollefson (FDA); Wachsmuth (FSIS)	10/1/97	9/30/98		An outbreak investigation of Salmonella Typhimurium DT104 problem on a Vermont dairy farm has been initiated in collaboration with USDA/ARS, USDA/APHIS, and the Vermont State Health Department. Samples were collected January 7 -9, 1998 as a followup to the original Vermont investigation. These will be susceptibility tested to determine the status of DT104 colonization and shedding in cattle and other animal species on the farm.
1.e.4 CDC, FDA, and FSIS should continue monitoring, comparing and testing the antimicrobial resistance of E.coli O157:H7, Salmonella, and Campylobacter strains in humans and animals.		Tollefson (FDA); Wachsmuth (FSIS)	10/1/97	9/30/00		(1) System is on-going; a preliminary report of the 1997 results will be available in March 1998. A large scientific symposium on the National Antimicrobial Resistance Monitoring Program and related epidemiology research is planned for August 31 - September 3 in Athens, GA. (2) USDA has arranged to have all Salmonella isolates collected as part of the implementation of HACCP for meat and poultry in the large USDA-inspected slaughter plants sent to ARS for susceptibility testing and inclusion in the National Antimicrobial Resistance Monitoring Program. This will greatly increase the number of

Category / Activity / Sub Activity	1. A New Early-Warning System for Foodborne Disease Surveillance	Lead/Contact	Start Date	End Date	FY 1998 USDA Funding (millions)	Status/Notes
						non-clinical isolates and aid in the interpretation of the data. (3) In July 1998, USDA has plans to begin targeted Campylobacter testing for poultry in the large USDA-inspected slaughter plants sent to ARS for susceptibility testing and inclusion in the National Antimicrobial Resistance Monitoring Program. This will greatly increase the number of non-clinical isolates and aid in the interpretation of the data.
	1.e.5 FDA and CDC should conduct physician and veterinary drug prescribing surveys, including patients and animal producers, to asses the effect of antimicrobial drug use on resistance patterns and prevalence to guide regulatory policy and education.	Tollefson (FDA)	10/1/97	9/30/00		CDC is in the process of conducting pediatric prescribing practices. FDA has purchased a database of antimicrobial use in beef cattle, dairy cattle, and swine, and will receive and analyze these data in 1998. FDA is also in the planning stages for veterinary prescribing practices and producer antimicrobial use surveys with USDA/APHIS for feedlot cattle; the actual survey will take place in late 1999. This survey ill combine antimicrobial use information with on-farm sampling to determine the resistance pattern among the enteric pathogens.
	1.e.6 FDA should assist the WHO in the development of a veterinary database within the WHONET system.	Tollefson (FDA; Wachsmuth (FSIS)	10/1/97	9/30/00		FDA participated in a meeting at WHO/FAO in Berlin, October 13-17, 1997, on the medical impact of use of antimicrobials in food animals that included a workshop on mechanisms for international monitoring. A report of this meeting including recommendations has been completed. During 1998 and 1999, FDA will continue to investigate and support WHO efforts to develop an international veterinary monitoring program on antimicrobial resistance.
	1.f Modernize Public Health Laboratories					
	1.f.1 CDC will collaborate with Food Net sites to determine serotypes of E.coli other than	CDC; Wachsmuth (FSIS)	1/25/97	9/30/97		Protocol (including forms) for collecting and testing stool and serum have been developed. The protocol

Category / Activity / Sub Activity	1. A New Early-Warning System for Foodborne Disease Surveillance	Lead/Contact	Start Date	End Date	FY 1998 USDA Funding (millions)	Status/Notes
	O157:H7 that cause HUS in children.					will be finalized following the completion of E.coli O157:H7 HUS.
	1.f.2 The Association of State and Territorial Public Health Laboratory Directors (ASTPHLD) and CDC will improve diagnotic assays and provide additional resources to improve the capacity of state laboratories to detect foodborne pathogens.	ASTPHLD; Wachsmuth (FSIS)	10/1/97	9/30/98		Discussions were held in Atlanta on 12/15/97.
	1.f.3 CDC will provide sufficient funds to states to support the production of serotyping reagents for Salmonella, which are critical for outbreak identification.	CDC; Wachsmuth (FSIS)	10/1/97	9/30/98		USDA will be monitoring progress to harmonize methodology and technology for human and animal serotypes.
	1.f.4 CDC will develop DNA amplification-based tests for foodborne pathenogenic bacteria that are difficult to detect by culture.	CDC; Wachsmuth (FSIS)	10/1/97	9/30/98		
	1.f.5 CDC will provide resources and technical assistance to states to improve their capacity in diagnosing those pathogens which are difficult to detect by culture.	Falci (FDA; Wachsmuth (FSIS)	1/25/97	9/30/98		SEE FIRST ITEM (1.b.1) UNDER CREATE A NATIONAL ELECTRONIC NETWORK FOR FINGERPRINT COMPARISON.

Category / Activity / Sub Activity	Lead/Contact	Start Date	End Date	FY 1998 USDA Funding (millions)	Status/Notes
2. Interstate Outbreak Containment and Response Coordination					
2. Interstate Outbreak Containment and Response Coordination				**$0.0**	**Foodborne Outbreak Response Coordination Group (FORCG) has been established. An MOU was made to establish FORCG.**
Description: Improve coordination among Federal, State, and local agencies through enhanced communication systems coordination and a new management system that will improve the exchange of critical information and clarify or consolidate the Federal agencies' role in foodborne illness outbreak containment.					
2.a Enhance State and Local Infrastructure for Foodborne Outbreak Detection, Evaluation, and Response Coordination					
2.a.1 FORCG, with assistance from AFDO, ASTHLD, CSTE, and NASDA will begin a nationwide audit to catalogue the existing state and local food safety program infrastructure.	Oliver (FDA) and Mondschien, Joan (FSIS)	1/27/97	9/30/97		FDA contract with NASDA signed. NASDA will catalog all federal and state food statutes in the country.
2.a.2 FORCG, in consultation with the appropriate outside organizations, will establish working groups with appropriate federal, state, and local officials to develop recommended procedures for outbreak-response coordination at the state and local level.	Oliver (FDA) and Mondschein (FSIS)	8/7/97	9/30/97		Ongoing
2.a.3 CDC, EPA, FDA, and FSIS will assist states and local governments in developing the infrastructure necessary to ensure proper detection, evaluation, and coordinated response to foodborne outbreaks. FORCG to be discussed at National Meetings (AFDO).	Oliver (FDA) and Mondschein (FSIS)	10/1/97	9/30/98		Preliminary discussions held as part of the 7/28/97 FORCG meeting. In process of writing SOPS.
2.b Improve Outbreak Containment Through Better Federal-State-Local Coordination of the Evaluation of and Response to Foodborne Illness					

Category / Activity / Sub Activity	2. Interstate Outbreak Containment and Response Coordination	Lead/Contact	Start Date	End Date	FY 1998 USDA Funding (millions)	Status/Notes
	2.b.1 CDC, EPA, FDA, and FSIS will establish, through a formal MOU, an intergovernmental group, the Foodborne Outbreak Response Coordinating Group (FORCG), to improve the approach to interstate outbreaks of foodborne illness.	Oliver (FDA) and Mondschein (FSIS)	1/25/97	7/28/97		End of March, the group developed and cleared an MOU to establish FORCG. Development of the MOU is underway. An informal FORCG group has been established. Representatives: CDC-Ostroff, Broome; USDA-Wachsmuth, Mondschein; FDA -Pendergast, Oliver, Morrison; EPA-Schaub; AFDO-Richardson; CSTE-Osterholm; ASTPHLD-(Bradford);NASDA-(USDA to supply contact). First meeting held on 7/28/97. A meeting was held March 31,1998.
	2.b.2 FORCG will review and evaluate outbreak response. Based on these reviews, FORCG will assess the infrastructure for outbreak response, make recommendations, and work with impacted groups to implement beneficial changes.	Oliver (FDA) and Mondschein (FSIS)	1/27/97	9/30/97		(1) FORCG Subcommittee has been established. Members: FDA-Carson, Ralston; USDA-Majkowski; EPA-Schaub, McKinnon; AFDO-Richardson; CDC-Shapiro. (2) FORCG Subgroup review of the Hepatitis A Outbreak has been completed on 11/25/97. It was determined that overall the outbreak response went very well. Several areas of improvement were identified. Three documents are under development by FDA, USDA, and CDC. These documents will be consolidated into one final product.
	2.b.3 Establish as a formal institutional position, with appropriate backup designees, an outbreak coordinator for each department or agency.	O'Hara (HHS), Woteki (USDA), Goldman (EPA)	1/27/97	9/30/97		Formal Institutional Position: HHS-Assistant Secretary for Health; USDA-Under Secretary for Food Safety; EPA-Assistant Administrator for Water with backup designees positions of Deputy Secretary for Health, Administrator, FSIS, and Assistant Administrator for pestides.
	2.b.4 Develop standard procedures for the rapid exchange of data and information associated with foodborne illness outbreaks between involved agencies and for dissemination to the public.	Oliver (FDA); Mondschein (FSIS)	1/27/97	9/30/97		In process.

Category / Activity / Sub Activity	Lead/Contact	Start Date	End Date	FY 1998 USDA Funding (millions)	Status/Notes
3. Risk Assessment					
3. Risk Assessment				**$4.7**	**The Risk Assessment Consortium was established in November 1997 as part of the Joint Institute for Food Safety and Applied Nutrition (JIFSAN), which is a collaborative activity of FDA's Center for Food Safety and Applied Nutrition (CFSAN) and Center For Veterinary Medicine (CVM). The Consortium has had several meetings, with two teams (Microbial Risk Assessment Team [MRAT] and the Advisory Group) formed within CFSAN. Efforts are underway to identify data gaps and modeling deficiencies to help set research priorities and, at the same time, eliminate duplicate activities among consortium agencies. An example in application is recently completed (April 1998) risk assessments of shell eggs and egg products and related ANPR drafts being reviewed prior to incorporation into inspection and compliance functions.**
Description: Improve the capability to estimate risks associated with foodborne and waterborne contaminants, especially microbial pathogens, in order to make faster and more accurate regulatory decisions, more effectively target program resources, and facilitate the development and evaluation of surveillance plans and risk reduction strategies, such as pathogen reduction practices implemented from the farm to the consumer.					
3.a Establish a Risk Assessment Consortium					
3.a.1 Establish as part of the Joint Institute for Food Safety and Applied Nutrition, a risk assessment consortium. An interagency policy group will be established.	Long (FDA); Etzel (FSIS); Ahl (ORACBA)	1/27/97	9/30/98		(1) Risk Assessment Consortium Established. The first meeting of the Risk Assessment consortium was held 11/12-14/97. Two additional meetings were held 1/23/98 and 2/25/98. Two teams with CFSAN , the Microbial Risk Assessment Team (MRAT) and the

Category / Activity / Sub Activity	Lead/Contact	Start Date	End Date	FY 1998 USDA Funding (millions)	Status/Notes
Category 3. Risk Assessment					
					Advisory Group have been formed. MRAT has meet, assignments have been made and work is underway. The Advisory Group composed of CFSAN Senior managers will contribute to a number of related activities, such as guiding the development of the "white paper", determining needs for outside expertise, developing Risk Assessment Training, and mentoring the members of MRAT. (2) Policy group was established.
3.a.2 The Consortium will begin the process of establishing a clearinghouse that will collect and catalogue available methodology.	Long (FDA); Etzel (FSIS); Ahl (ORACBA)	1/17/97	9/30/97		Existing clearinghouses are being studies/evaluated to help determine budgeting and potential applications and formats. The "Bad Bug Book" will be posted on the clearinghouse section of the food safety webpage (FoodSafety.gov).
3.a.3 The Consortium will work with its member agencies to catalogue their microbial risk assessment research advances and identify data sets that would provide the scientific data needed to develop new models.	Long (FDA); Etzel (FSIS); Ahl (ORACBA)	1/25/97	9/30/97		An example of recent cooperation is a risk assessment on shell eggs; the ANPR has been drafted and is in clearance (See subactivity 5.a.4).
3.a.4 A strategic plan will be developed for research into dose-response calculations, chronic sequelae, biomarkers, and adapting surveillance data.	Long (FDA); Etzel (FSIS); Ahl (ORACBA)	10/1/97	9/30/98		
3.a.5 A series of public meetings will be held to develop a strategy to address long-term research needs for the analysis of farm-to-table scenarios, including potential pathogen introduction at each level, food consumption data, and computer modeling.	Long (FDA); Etzel (FSIS); Ahl (ORACBA)	10/1/97	9/30/98		A public meeting to discuss dose-response issues is tentatively planned for March 1998. The Dose-Response Workgroup met on Dec. 1, 1997 to identify the key dose-response issues. The Dose-response workgroup met again in January to begin preparations for the public meeting.
3.a.6 Begin a comprehensive review of existing data and federal information collection programs to determine the extent to which they may fill	Long (FDA); Etzel (FSIS); Ahl (ORACBA)	10/1/97	9/30/00		

Category / Activity / Sub Activity	Lead/Contact	Start Date	End Date	FY 1998 USDA Funding (millions)	Status/Notes
3. Risk Assessment					
existing data gaps, and suggest additional data needs to better support risk assessments.					
3.a.7 The Consortium will continue to collectively identify critical research needs, propose effective research on analytical approaches and methods, and reach consensus on the priority of these needs.	Long (FDA); Etzel (FSIS); Ahl (ORACBA)	10/1/97	9/30/00		Identification of research needs is ongoing. A draft of the RFAs and RFPs is expected to be distributed to the Consortium members during mid-January 1998 with two tentative meetings to discuss RFAs and RFPs scheduled for 1/23/98 and 2/25/98. RFPs are scheduled to be finalized and issued by mid-July 1998.
3.b Develop and Validate Exposure Assessment Models Based on Probabilistic Methodology				**($4.6)**	
3.b.1 Working with FDA, EPA, and USDA, the consortium will identify priority research programs in two areas needing augmentation: exposure assessment methods and techniques for acquisition and analysis of experimental data for model development.	Long (FDA); Etzel (FSIS); Ahl (ORACBA)	10/1/97	9/30/98		
3.b.2 Future initiatives would be fluid to adjust to results of short-term research, emerging food safety needs, and changes in the direction of research programs within individual agencies.	Long (FDA); Etzel (FSIS); Ahl (ORACBA)	10/1/97	9/30/00		
3.c Develop and Validate Dose-Response-Assessment Models for Use in Risk Assessment				**($0.1)**	
3.c.1 Working with FDA, EPA, and USDA, the consortium will identify priority research programs in dose-response-assessment methods and models that need to be augmented.	Long (FDA); Etzel (FSIS); Ahl (ORACBA)	10/1/97	9/30/98		

Category / Activity / Sub Activity	3. Risk Assessment	Lead/Contact	Start Date	End Date	FY 1998 USDA Funding (millions)	Status/Notes
3.c.2 Risk assessment research priorities for development and validation of dose-response-assessment models will be collectively established by the interagency consortium.		Long (FDA); Etzel (FSIS); Ahl (ORACBA)	10/1/97	9/30/00		

Category / Activity / Sub Activity	Lead/Contact	Start Date	End Date	FY 1998 USDA Funding (millions)	Status/Notes
4. Research				**$56.6**	**USDA research on detection methods for Cyclospora has been underway since July 1997, but culturing problems with the Cyclospora have slowed the progress as alternative culture methods are explored. There has been more success with E. coli O157:H7 and Salmonella, with work on non-O157:H7 E. coli continuing. Less, but significant, progress has been made for detecting Cryptosporidia. Research on pathogens in farm and aquaculture animals and feeds has been coordinated and duplication eliminated. Basic and applied methods (steam pasteurization, competitive exclusion, irradiation, etc.) research has been conducted by USDA for meat, poultry, egg, seafood, and produce.**
Description: Provide Federal, State, and local agencies (and indirectly the agriculture and food industries, the retail food industry and consumer) practical and effective science-based practices and technologies that improve the safety of food. Research is also needed to support HACCP implementation to verify that critical control points in HACCP are working, especially where there are data gaps hampering HACCP application and risk assessment.					
4.a Improved Detection Methods				**($12.4)**	
4.a.1 EPA, CDC, ARS, CSREES, and FDA, in conjunction with states and academia, will conduct research to develop detection methods and control measures for Cyclospora.	Cebula (FDA); Robens (USDA); Wachsmuth (FSIS)	1/25/97	9/30/97		(1) ARS continues to work with FDA and CDC, and the University of Arizona to develop detection methods, however problems in obtaining reliable cultures of Cyclospora have greatly slowed the work. (2) A protocol has been developed for Concentration and Preparation of Oocysts from Produce for the PCR and microscopy. A public meeting to review the science was held on 7/23/97. NACMCF/Fresh Produce Working Group meetings held 8/12-14/97.

Category 4. Research Activity Sub Activity	Lead/Contact	Start Date	End Date	FY 1998 USDA Funding (millions)	Status/Notes
					Tissue culture assays were conducted using monolayers of cultured intestinal epithelial cells. Culturing using conventional monolayer technology yielded limited success. A new cell culture system, the rotary cell culture system (bioreactor) was chosen to propagate C.cayetanensis. Preliminary data indicates that both monolayer and bioreactor tissue culture systems can be used for oocyst viability studies. Data also suggest that C.cayetanensis may be culturable in the bioreactor. Preliminary feeding studies for the development of an animal model for the mechanisms utilized by these parasites have been completed. Antibodies to be used in detection methods have been raised in rabbits to both whole and homogenized oocysts.
4.a.2 ARS, FDA, and EPA will enhance ongoing research test methods for Campylobacter, Salmonella, Toxoplasma, E.coli O157:H7 & other Shiga-like toxin-producing E. coli, Cryptosporidium, hepatitis A & Norwalk viruses, mycotoxins, marine toxins.	Cebula (FDA); Robens (USDA); Wachsmuth (FSIS)	10/1/97	9/30/98		(1) ARS has worked closely with the FSIS to develop methods for Campylobacter culture and identification in the regulatory environment. Antibodies have been identified which appear to be specific to C. jejuni and E. Coli, and confirmation is ongoing. (2) ARS has developed a rapid test for detecting E.coli O157:H7 for use by producers and industry. Serologic tests to detect animals which have experienced infection but which may not be actively shedding E.coli or Salmonella have been developed. (3) ARS has developed a single procedure Multiplex PCR assay for detection of E.coli O157:H7 and Salmonella. Development of methods for detecting non-O157:H7 E.coli is ongoing. (4) ARS is augmenting their ongoing Cryptosporidia methodology research to include molecular probes. This research has already developed PCR and immunohistochemical methods to detect Cryptosporidia. (5) ARS has improved methods to sample and identify Campylobacter. The methods will be evaluated during May and June and applied in poultry studies in July.

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4.a.3 FDA will expand its ongoing research on the development of methods for detecting foodborne pathogens in animal feeds.	Alderson; Wachsmuth (FSIS)	10/1/97	9/30/98		Conducted interagency coordination of effort and identified specific areas for targeted investigation. Development of resources for intramural programs is underway.
4.a.4 FDA, ARS, CSREES, and EPA should undertake research to develop test methods for Vibrio vulnificus in foods.	Cebula (FDA); Wachsmuth (FSIS)	10/1/97	9/30/00		
4.b Understanding Resistance to Traditional Preservation Technologies				**($0.1)**	
4.b.1 ARS/CSREES and FDA should undertake research into physiological, genetic, and other factors that cause foodborne disease causing microorganisms to develop resistance to preservation techniques.	Cebula (FDA); Wachsmuth (FSIS)	10/1/97	9/30/00		
4.c Understanding Antibiotic Drug Resistance				**($1.0)**	
4.c.1 FDA and ARS will conduct research to identify and characterize the factors that lead to the development of multiple drug (antibiotic) resistance in foodborne pathogens in farm and aquaculture animals.	Alderson; Wachsmuth (FSIS)	10/1/97	9/30/98		Conducted interagency coordination to ensure non-duplication of effort and identify specific areas for targeted investigation. In the process of developing resources for intramural programs.
4.c.2 ARS and FDA will investigate techniques for manipulating the microbial ecology of the intestinal tract of agricultural and aquaculture animals to prevent the development of antibiotic resistance or select for nonresistance.	Alderson; Wachsmuth (FSIS)	10/1/97	9/30/98		
4.d Prevention Techniques: Pathogen Avoidance, Reduction, and Elimination				**($33.5)**	

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4.d.1 Expand research into the microbial ecology of foodborne pathogens and how initial colonization in plants and animals can be prevented.	Alderson and Cebula (FDA); Robens (USDA); Wachsmuth (FSIS)	10/1/97	9/30/98		(1) CVM continues to advise companies on the approval of foodborne competitive exclusion products. (2) ARS is developing infection models of O157:H7 in neonatal and weaned calves. (3) ARS is initiating an epidemiological study of Salmonella and Campylobacter to help describe how broilers contract these pathogens. (4) Studies into the on-farm ecology of E.coli O157:H7 and Salmonella in beef cattle are ongoing. These are focused on quantifying transmission from animal to animal and from reservoirs of infection. (5) ARS is developing techniques to augment natural immunity to help prevent initial infection with intestinal pathogens in newly hatched poultry and in weaning pigs.
4.d.2 Expand research on new methods to reduce or eliminate pathogenic microorganisms and mycotoxins from agricultural and aquacultural animals before slaughter or harvest, including the use of probiotics.	Cebula (FDA); Robens (USDA); Wachsmuth (FSIS)	10/1/97	9/30/98		(1) Initial ARS studies are underway to ascertain the host response genes responsible for genetic resistance to Salmonella in calves. (2) ARS is developing vaccines to prevent pathogens in food producing animals, and has demonstrated 2 factors, intamin and Shiga toxin, are necessary for colonizing E.coli in weaned calves. (3) Studies to describe the mechanisms of how pathogens attach to poultry carcasses and selected fruits and vegetables are being initiated in order to provide the knowledge for preventing biofilm formation. (4) ARS has demonstrated that viable Cryptosporidia can be transmitted into oysters, clams and other aquaculture animals. The source of the infection has not been proven, but is theorized to be C. parvum from cattle or deer feces.
4.d.3 Develop new methods to reduce or eliminate pathogenic microorganisms and mycotoxins from plants before harvest.	Cebula (FDA); Robens (USDA); Wachsmuth (FSIS)	10/1/97	9/30/98		(1) ARS is developing the use of non-aflatoxin producing Aspergillus flavus strain to competitively exclude the toxin producing fungi and thus proven

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					aflatoxin in cottonseed. (2) Genetic markers of resistance to Aspergillus colonization and aflatoxin formation in corn have been identified.
4.d.4 Develop new disinfection methods and systems for improved sanitation of production processing and marketing equipment and facilities.	Cebula (FDA); Robens (USDA); Wachsmuth (FSIS)	10/1/97	9/30/98		ARS research is identifying factors to prevent the formation of biofilms (bacterial films that are difficult to remove from surfaces) in poultry processing facilities; developing spray scalding to reduce cross contamination in poultry processing plants; and developing new methods to prevent spillage of fecal matter during initial processing and evisceration.
4.d.5 Expand research on new methods of decontamination of meat, poultry, seafood, fresh produce, and eggs.	Cebula (FDA); Robens (USDA); Wachsmuth (FSIS)	10/1/97	9/30/98		(1) ARS demonstrated that a hot water and quick chill (thermoflux) significantly reduced Salmonella incidence in meat from specific areas of pork. (2) ARS is developing steam pasteurization for poultry to kill pathogens on poultry skin. (3) ARS has demonstrated that Irradiation will kill cyclospora on certain fruits and vegetables.
4.d.6 Initiate research to develop new technologies for eliminating animal feeds as a source of foodborne pathogens.	Alderson; Wachsmuth (FSIS)	10/1/97	9/30/98		Conducted interagency coordination to ensure non-duplication of effort and identify specific areas for targeted investigation. Development of resources for intramural programs is underway.
4.d.7 ARS, CSREES, and FDA should undertake research to develop new decontamination methods for contaminants such as Vibrio and Norwalk virus on or in marine-harvested and aquaculture-reared seafood and for Cyclospora and hepatitis A on produce.	Cebula (FDA); Wachsmuth (FSIS)	10/1/97	9/30/00		
4.d.8 ARS, CSREES, and FDA should work with industry and academia to develop new techniques that provide alternatives to traditional thermal processing from eliminating pathogens.	Cebula (FDA); Robens (USDA); Wachsmuth (FSIS)	10/1/97	9/30/00		ARS has worked closely with industry to develop bacterial cultures to competitively inhibit Salmonella in broiler chicks, and substances to enhance the immune response in chicks and neonatal swine. ARS received FDA approval for competitive

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					exclusion product (PREEMPT) to reduce Salmonella population on chicks. May be effective against other pathogens.
4.d.9 FDA, FSIS, and EPA should work with industry and academia to develop criteria for evaluating the efficiency and safety of new intervention technologies.	Cebula (FDA); Robens (USDA); Wachsmuth (FSIS)	10/1/97	9/30/00		In conjunction with a pork slaughter plant ARS will develop approaches to determine where in the process Critical Control Points should be located.
4.e Food Handling, Distribution, and Storage				**($9.6)**	
4.e.1 ARS, CSREES, and FDA should undertake research to identify factors that contribute to the spread of microorganisms during transportation of live animals and fresh produce and develop techniques for eliminating cross-contamination.	Cebula and Alderson (FDA); Robens (USDA); Wachsmuth (FSIS)	10/1/97	9/30/00		(1) ARS has carried out preliminary studies with broilers demonstrating that Salmonella and Campylobacter are increased during transportation to slaughter and that consumption of litter during fasting is a contributing factor. Similar transportation studies with swine are being planned. (2) ARS has demonstrated that fecal shedding of E.coli O157:H7 is increased in cattle that are alternatively fasted and fed. (3) The Salmonella serotypes in trailers used for hauling swine were found to be identical to those found in preslaughter holding pens, confirming common belief that animals are carrying Salmonella into the slaughter plant.
4.e.2 FDA, ARS, and CSREES should work with industry and academia to develop and assess the effectiveness of in-or on-package sensors of storage conditions to alert consumers of products not stored safely.	Cebula (FDA); Wachsmuth (FSIS)	10/1/97	9/30/00		
4.f Charge an Interagency Committee Convened by the Office of Science and Technology Policy (OSTP) to Coordinate Federal Research Priorities and Planning					

Category 4. Research Activity Sub Activity	Lead/Contact	Start Date	End Date	FY 1998 USDA Funding (millions)	Status/Notes
4.f.1 Review food safety responsibilities and research programs of the various agencies with a view to recommending direction of research funds and programs.	Cebula (FDA); Robens (USDA); Wachsmuth (FSIS); Kennedy (USDA)	1/25/97	9/30/97		Interagency review of research related to the Produce Initiative began in September 1997. A research plan for FY 99 will be available in early 1998 for fruits and vegetable related research.

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5. Improving Inspections and Compliance					
5. Improving Inspections and Compliance				**$0.6**	**Risk assessments of shell eggs and egg products are nearing completion and related ANPR drafts are being reviewed. HACCP training has been conducted, with FSIS completing inspector training for large plants inspection staff in January. Evaluation of cross-utilization of FSIS inspectors for non-meat production areas is underway and an MOU is being developed to document the procedures. FSIS held several public meetings on the impact of HACCP on inspection and the application of HACCP to other components of the farm-to-table continuum. Federal-State-local meetings of public health officials have been held, training has been planned, and other cooperative ventures--including legislative review of interstate shipment of State-inspected meat and poultry--have been conducted or are underway in developing an integrated regulatory approach to food safety. A review of foreign food safety programs and requirements is nearing completion. Meetings have been held, and guidance shared, with industry--including transportation--to foster increased HACCP-based compliance.**
Description: Develop and implement more efficient and effective procedures for monitoring the safety of the Nation's food supply at all levels, and promote the adoption of HACCP in the food industry at all governmental levels.					

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5. Improving Inspections and Compliance					
5.a Enhance Development of HACCP Procedures					
5.a. 1 Based on the best science available, FDA will propose appropriate regulatory and non-regulatory options, including HACCP, for the manufacture of fruit and vegetable juice products.	Tolen (FDA)	5/1/97	9/30/97		Juice HACCP Proposal drafted and being reviewed by HHS and it is anticipated the regulation will be issued in March 1998. Juice Warning Labels proposed drafted and being reviewed by General Counsel. Proposal is expected to issue in March 1998.
5.a. 2 Based on the best science available, FSIS will propose appropriate regulatory and non-regulatory options, including HACCP, for egg products.	Wachsmuth (FSIS); Ahl (ORACBA-USDA)	5/1/97	9/30/98		FSIS conducting risk assessment that is expected to be completed in early 1998. FSIS will issue an ANPR (sent to OGC 1/28/98) to solicit public comment.
5.a. 3 FDA and USDA will immediately identify preventive measures to address public health problems, such as those recently associated with fruits and vegetables, e.g., hepatitis A virus associated with frozen strawberries.		5/1/97	9/30/97		FDA, at the request of AMS (Processed Products Branch), is reviewing the PPB's instructions and procedures for employee hygiene, product sampling, product grading, equipment sanitation, and field grading facilities. FDA has visited 5 PPB field offices and observed PPB procedures of grading and production sample collection. (2) Good Agricultural Practices and Good Manufacturing Practices Broadscope Guidance has been drafted. Final Guidance is scheduled to publish in March 1998. (3) Six domestic and one international grassroots meetings have been held on Broadscope Guidance.
5.a. 4 FSIS and FDA will jointly publish an ANPR in which they will evaluate the public health, food technology, and regulatory issues involved in reducing the risk of human illness from Salmonella Enteritidis in shell eggs.	Troxell (FDA); Stolfa (FSIS)	5/1/97	9/30/98		(1) Salmonella in egg products guidance has been developed. Risk assessment has been completed. Responses to OMB comments are being prepared. Responses will be completed and package resubmitted to OMB by the end of March. (2) Draft labeling proposal is under review within CFSAN. Target date for clearing CFSAN is the end of March. (3) Shell eggs refrigeration at retail proposal is

Category / Activity / Sub Activity	5. Improving Inspections and Compliance	Lead/Contact	Start Date	End Date	FY 1998 USDA Funding (millions)	Status/Notes
						expected to go to OMB by the end of March. FSIS is currently completing a risk assessment on shell eggs; the ANPR has been drafted and is in clearance.
	5.a. 5 FDA will evaluate whether and how to propose to require the use of HACCP in other appropriate food commodities and animal feeds.		5/1/97	9/30/97		On hold until the regulatory effectiveness of the seafood HACCP regulation is reviewed and after proposing HACCP for fresh fruits and vegetable juices.
	5.a. 6 FDA will provide additional training in seafood HACCP and FSIS will complete HACCP Training of inspectors in large meat and poultry plants.	Mina (FSIS)	5/1/97	9/30/98		Completed development of a training course for regulators that could be provided to many training sites simultaneously by satellite, with facilitation at each site. The course was offered and attended by about 800 Federal and State Inspectors and other personnel located in many sites nationwide in March 1997. The course was subsequently held in Boston, New York, Annapolis, Seattle, and Detroit for regional exposure. An additional 103 Federal and State regulators were trained during the first quarter of FY 1998. (2) FSIS completed training of inspectors for 1st HACCP implementation phase. Large plants completed in January 1998. (3) Seafood Alliance, in cooperation with FDA, Provided Seafood HACCP training to an additional 1352 students bringing the total to 6861.
	5.a. 7 FSIS and FDA will evaluate expanding existing cooperative agreements so that plants producing meat and nonmeat foods are inspected by FSIS inspectors trained in FDA inspection standards.	Mayl (FDA) and Derfler (FSIS)	1/15/98	9/30/98		Joint meeting held 2/19/98 to discuss MOU development. Agreed to form smaller working groups to begin process. Next meeting to be held in March.
	5.a. 8 FSIS will conduct a series of public meetings to discuss the design and testing of new inspection concepts consistent with HACCP	Derfler (FSIS)	5/1/97	9/30/98		The first public meeting was held on June 24, 1997 in Washington, DC. Another meeting is planned for late 1998.

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	Principles to achieve food safety and other consumer protection objectives.					
	5.a. 9 FSIS will conduct a series of public meetings to discuss how HACCP requirements will be implemented in slaughter plants and how the roles and responsibilities of inspection personnel will change with that implementation.	Derfler (FSIS)	1/20/97	1/30/98		Meeting held December 16, 1997 in Washington, DC. Additional meetings held January 14 (Des Moines, IA), January 16 (Denver, CO) and January 21 (Memphis, TN).
	5.a.10 FDA and USDA will cooperate in evaluating the feasibility of HACCP for commodities such as fresh fruits and vegetables.	Kelly (USDA)		9/30/98		Redirected to Guidance by president's Directive (Produce and Imported Food Safety Initiative).
	5.a.11 FDA will implement seafood HACCP by hiring approximately 80 investigators to conduct inspections to ensure the proper implementation of seafood HACCP.			9/30/98		A vacancy announcement for 19 microbiologist and 61 CSO/CSIs for seafood HACCP should issue by the end of February 1998.
	5.a.12 A performance-based organization (PBO) will be created as the organizational structure for the voluntary fee-for-service seafood program currently located at NMFS.	Spiller, P.	5/1/97	9/30/98		PBO legislation has been drafted. Commerce has given its approval for the PBO. Draft legislation is being reviewed by HHS and OMB. Discussions continue between the Department of Commerce and FDAÆs Budget Office to resolve pending budget issues.
	5.a.13 FDA should further the use of HACCP principles, as appropriate, for other foods, including animal feeds, and use risk assessment techniques where possible.	Tolen (FDA)	10/1/97	9/30/00		
	5.b Enhance the Safety of Foods in Retail Food Establishments Particularly at State and Local Levels					
	5.b.1 FDA and FSIS will hold a series of meetings with state and local regulators in five	Guzewich (FDA) and Stafko (FSIS)	1/25/97	9/30/98		(1) Six grassroots meetings have been held. (2) Draft Model State Retail Food Program Standards

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5. Improving Inspections and Compliance					
regions to establish retail program standards in accordance with the 1997 model state code (the Food Code) to enhance national uniformity.					are being developed and will be presented at the Conference For Food Protection on 4/2/98.
5.b.2 FSIS and FDA will provide HACCP training to state and local inspectors that will augment the training program for federal inspection personnel, more fully covering the farm-to-table process.	Tolen (FDA) and Mina (FSIS)	10/1/97	9/30/98	**($0.6)**	Plan being developed for training State and local public health officials inspecting retail establishments in HACCP principles.
5.b.3 The Food Code should be adopted by all 50 States.	Guzewich (FDA) and Stafko (FSIS)	10/1/97	9/30/98		USDA and FDA are developing a strategy to encourage State adoption of the Code. Currently, eight states have adopted the Code.
5.c Enhance Federal-State Inspection Partnerships					
5.c.1 FSIS will hold two public meetings on the issue of interstate distribution of state-inspected meat and poultry products.	Stafko (FSIS)	1/25/97	9/30/98		Two meetings have been held. June 16-17, 1997, in Sioux Falls, SD and July 22, 1997, in Washington, DC. Concept paper reviewed by the USDA Meat and Poultry Advisory Committee and new legislation is being drafted.
5.c.2 FDA will develop additional federal-state partnerships to improve coordination between the federal food safety agencies and state regulators for the training of state inspectors in food safety standards applicable at all levels.	Tolen (FDA)	1/25/97	9/30/98		A model Federal-State partnership agreement for Seafood HACCP-based inspection has been developed. The Model is being used by the FDA District Offices as a basis for negotiations with States for partnerships.
5.c.3 FDA will expand the number of federal-sate partnerships to include more extensive HACCP training of state inspectors, the seafood industry, and the retail food industry.	Tolen (FDA)	10/1/97	9/30/98		
5.c.4 FSIS will initiate HACCP training for state inspectors with respect to meat and poultry	Smith (FSIS)	10/1/97	9/30/98		FSIS will conduct train-the-trainer session for State employees.

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5. Improving Inspections and Compliance					
products.					
5.c.5 FDA and FSIS should work more closely with industry, professional and trade associations, and academia to ensure effective implementation of HACCP principles, particularly at the production, processing, and retail levels.	Tolen (FDA) and Smith (FSIS)	10/1/97	9/30/00		The First Edition of the "Fish and Fishery Products and Hazards Control Guide" published in September 1996. An addendum to the First Edition is being developed, among other things, it will respond to comments received on the first edition.
5.c.6 FDA should create a data system to compile inspection data from federal and state inspections, as well as provide the states with equipment and technology for the rapid sharing of inspection results.	Tolen (FDA)	10/1/97	9/30/00		A low cost, low tech data system ("Cardiff") by which both Federal and State inspection programs could transmit the results of inspections into a common national database has been identified. Acquisition of the equipment and software has been initiated.
5.d Enhance Coverage of Imported Foods with Specific Attention to Foods Regulated by FDA					
5.d.1 FDA will work to increase the number of mutual recognition agreements (MRAs) with trading partners.	Tolen (FDA)	10/1/97	9/30/98		Draft guidance containing the criteria FDA intends to use to decide whether another country's regulatory system for food safety is equivalent to the US System published on June 4, 1997. CFSAN is currently analyzing the information received from countries about their regulatory systems in preparation for making equivalence determinations.
5.d.2 FDA will initiate a federal-state communication system through which states can inform federal agencies of problems found with imported products in their jurisdictions.		10/1/97	9/30/98		
5.d.3 FDA will initiate a system for certifying and accrediting private laboratories, including use of a quality-assurance procedure, that will be authorized to test samples of food products for contaminants.	Tolen (FDA)	10/1/97	9/30/00		

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	5.d.4 When FDA and FSIS become aware of possible public health problems associated with a regulated food product, the agencies will provide technical assistance to the foreign country importing the product.	Tolen (FDA); Wachsmuth and Prucha (FSIS)	10/1/97	9/30/00		FSIS requires foreign inspection programs to submit detailed descriptions of corrective actions they will take or have taken to address public health problems associated with meat or poultry products processed for export to the United States. Appropriate technical advice is provided when requested.
	5.d.5 FSIS should continue to verify foreign government-inspection progress for conformance with the new HACCP and Pathogen Reduction Requirements.	Wachsmuth and Prucha (FSIS)	9/30/97	9/30/00		FSIS has contacted all 37 countries eligible to export meat or poultry to the U.S. to determine whether they have implemented requirements equal to those contained in the PR/HACCP rule regarding SSOP's and E. coli. Most have implemented both requirements, but discussions continue on the equivalency of alternative approaches used in some countries. Eligible countries are also being asked about the number of large plants in their programs that would be affected by the mandatory U.S. implementation in January.
	5.d.6 The laboratory-certification process should be extended to include assessing the utility of existing accrediting bodies with FDA providing performance standards and oversight to the process.	Tolen (FDA)	10/1/97	9/30/00		
	5.d.7 FDA should expand the Federal-state communication system states use to inform the federal agencies of problems found with imported products in their jurisdictions.	Tolen (FDA); Majkowski (FSIS)	10/1/97	9/30/00		
	5.d.8 FDA should evaluate the feasibility of combining the communication system with the Federal-state inspection data system, making the data and information more widely accessible.	Tolen (FDA); Majkowski (FSIS)	10/1/97	9/30/00		
	5.d.9 FDA should review and evaluate ways to	Tolen (FDA)	10/1/97	9/30/00		

increase coverage of imports through such means as increased personnel, increased partnerships, or innovative information-sharing with the states.

5.e Enhance Safety of Foods During Transportation

5.e.1 FDA and FSIS will evaluate the comments and information received n response to the ANPR as a basis for determining what, if any, regulatory approach to take, including development of guidelines.	Troxell (FDA) and Stafko (FSIS)	10/1/97	9/30/98		Agencies have been meeting with industry which is developing voluntary guidelines for consideration.
5.e.2 FDA and FSIS, through partnerships with states, should provide training and training materials to the transportation industry on safe food transportation.	Tolen (FDA) and Stafko (FSIS)	10/1/97	9/30/00		Joint meeting held in January. Industry has put together guidance and declined partnership offer.

5.f Good Agricultural Practices and Good Manufacturing Practices

5.f.1 Reissuance of the Prepared Cut Vegetable Salad Manufacturers Survey. The Survey is intended to establish baseline data on the industry to assist in preparation of GMP guidance documents.	Gardine (FDA	10/2/97	9/30/98		Survey reissued on 1/12/98.
5.f.2 HHS and USDA, in partnership with the agricultural community, will issue within 1 year guidance on good agricultural practices and good manufacturing practices for fruits and vegetables.	Gardine (FDA) and Kelly (FSIS)	10/2/97	10/2/98		(1) A Public Meeting on GAPs was held 11/17/97. Grassroots Meetings in 6 regions were held 12/1-12/12--Over 400 individuals in attendance. Over 100 individuals in attendance at the International Meeting held 12/8/97--32 foreign governments were represented, as well as trade and consumer organizations and Congressional Staff. (2) Draft GAP document prepared for minimally processed produce

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						as science based non-biding guidance to industry to reduce, to the extent possible, microbiological risks in fresh and minimally processed produce. Over 30 written comments on the draft have been received. Comment review is planned to begin January 12th. (3) A Task Group, consisting of representatives of involved federal agencies (including FDA, USDA, EPA, OSHA) and various State Departments of Agriculture or Health, has been established to evaluate comments received from the Grassroots and International Meetings and to revise the draft GAP document. Publication of the revised draft guidance is planned for late March 1998 with a 45 day comment period.
5.f.3 Status report and complete schedule for the GAPs and GMPs, assistance to foreign countries, prevention of the importation of unsafe produce.		Gardine (FDA) and Kelly (USDA)	10/2/97	1/2/98		Status report is under review.
5.f.4 Accelerate food safety research needed for GAPs, GMPs, assisting foreign countries and preventing importation of unsafe food products.		Cebula (FDA) and Robens (USDA)	10/2/97	9/30/99		

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6. Education					
6. Education				**$2.8**	**Food Safety Education Partnership established by MOU in May 1997 and includes industry, consumer groups, FDA, CDC, USDA, and the Dept. of Education. Food Safety Campaign launched on 10/24/97. Community action and supermarket kits ordered for distribution to begin in March. Food Safety Information Kits (Education Packets) sent by FDA to thousands of Food Safety Educators. FDA/CFSAN has met with the Educational Foundation to plan 1998 National Food Safety Month. Expansion of National Food safety Month is underway in cooperation with the Education Foundation of the National Restaurant Association to plan 1998 activities and the Department of Education for America Goes Back to School. The Research Plan submitted on October 31, 1997. The 1997 survey to identify trends in the quality of food handling practices, safe food selection, and food safety knowledge and concern results will be available in April 1998. Various technologies have been applied in sharing information, including videoconferences and the Internet with E-mail. For example: (1) a single, agency-neutral address "FoodSafety.gov" was established with an e-mail address of foodsafety.gov and (2) launched EdNet on 10/27/97.**
Description: Develop new and innovative strategies to improve farm-to-table food-handling practices by assessing the current effectiveness of the Food Safety Initiative and identifying needs, priorities, and future food safety directions through a dialogue with stakeholders (e.g., Federal and State agencies, consumers, academia, and the food industry).					

Category 6. Education Activity Sub Activity	Lead/Contact	Start Date	End Date	FY 1998 USDA Funding (millions)	Status/Notes
6.a Improve Consumer, Retail, and Food Service Education				**($2.5)**	
6.a.1 Establish a Consumer Food Safety Education Partnership.	Durham (FDA) and Conley (FSIS)	1/25/97	9/30/98		Food Safety Education Partnership Established. A memorandum of understanding was signed in May 1997, formalizing a food safety education partnership that includes industry, consumer groups, FDA, CDC, USDA, and the Dept. of Education.
6.a.2 Launch a nationwide food safety education campaign for the general public.	Durham (FDA) and Conley (FSIS)	5/12/97	5/31/98		Food Safety Campaign launched on 10/24/97. Hold videoconference for State/local and Extension Health Educators. Community action and supermarket kits ordered for distribution to begin in March.
6.a.3 Promote September as National Food Safety Month.	Durham (FDA) and Conley (FSIS)	5/12/97	9/30/98		Food Safety Information Kits (Education Packets) sent by FDA to thousands of Food Safety Educators. FDA/CFSAN has met with the Educational Foundation to plan 1998 National Food Safety Month. Expansion National Food safety Month is underway in cooperation with the Education Foundation of the National Restaurant Association to plan 1998 activities and the Department of Education for America Goes Back to School.
6.a.4 Form alliances with industry, consumer, trade, state and local food protection agencies, and academic organizations to share food safety education materials and to conduct joint food safety activities.	Durham (FDA) and Conley (FSIS)	1/25/97	9/30/97		(1) The Food Safety Education Conference was held on June 12-13, 1997. Over 500 persons attended including Hillary Clinton. 88% of the attendees rated the conference as very good. (2) Retail Food Service Education Alliance Formed. Meeting held in July and October 1997. Subcommittees have been formed to implement he actions. (3) The Consumer Education Alliance-EdNet (ednet@foodsafety.gov) launched on October 27, 1997.

Category 6. Education / Activity / Sub Activity	Lead/Contact	Start Date	End Date	FY 1998 USDA Funding (millions)	Status/Notes
6.a.5 FDA, CDC, FSIS and CSREES will promote and incorporate food safety education into school programs.	Durham (FDA) and Conley (FSIS)	1/25/97	9/30/98		Food safety standards developed and being reviewed by States for inclusion in Family Consumer Science curriculum. Final release by States expected in May. Study is underway to help determine in which subjects and at what grades food safety education would be best received.
6.a.6 FDA, FSIS and CSREES will form an alliance, joining expertise of federal, state, and local agencies, industry, and professional and trade associations to promote and implement the 1997 food Code and develop multilingual communication techniques.	Durham (FDA) and Conley (FSIS)	1/25/97	9/30/97		Completed a Spanish Translation of the brochure "If you eat raw oysters you should know..." The National Hispanic Healthy Nation Symposium was held September 10-13, in California. FDA serves on the Committee and food safety was included as part of the forum.
6.a.7 Convene the National Food Safety Education Council, an Independent scientific review board to periodically review safety education messages.	Durham (FDA) and Conley (FSIS)	1/25/97	9/30/97		Several internal planing meetings were held with FSIS. Multiple options are being explored including a possible subcommittee to the Micro Advisory Committee or as group of government communicators and scientists from several federal agencies.
6.b Conduct Research to identify Barriers to Safe Food Handling, Upon Which Educational Programs Will Be Centered					
6.b.1 HHS and USDA will develop national safe-food-handling guidelines like the Dietary Guidelines and review them periodically.	Durham (FDA) and Conley (FSIS)	1/25/97	9/30/97		Broad guidelines have been developed by the Partnership for Food Safety Education and will be assessed and refined in FY 98 and FY99. More detailed guidance for each of the four major guidelines is planned for FY99.
6.b.2 Conduct additional research necessary to determine the best way to communicate key safety food principles in order to achieve behavior change.	Durham (FDA) and Conley (FSIS)	10/1/97	9/30/98		The Research Plan submitted on October 31, 1997. The 1997 survey to identify trends in the quality of food handling practices, safe food selection, and food safety knowledge and concern results will be available in April 1998.

Category 6. Education / Activity / Sub Activity	Lead/Contact	Start Date	End Date	FY 1998 USDA Funding (millions)	Status/Notes
6.b.3 Conduct research necessary to develop a visual communication tool that conveys food safety principles, as the food guide pyramid does for nutrition principles.	Durham (FDA) and Conley (FSIS)	10/1/97	9/30/00		A visual communication tool has been developed by the Partnership for Food Safety. This tool will be assessed and refined in FY99.
6.b.4 Through partnerships and alliances, implement an education campaign to use the new education tools especially targeted to school programs and specific at-risk audiences.	Durham (FDA) and Conley (FSIS)	10/1/97	9/30/00		
6.c Expand Existing Information Systems					
6.c.1 Expand existing information systems while laying the groundwork for a National Clearinghouse for Food Safety Education.	Durham (FDA) and Conley (FSIS)	1/25/97	9/30/97		National Clearinghouse for Food Safety Education is being developed. A FoodSafe Listserve is established. A single, agency-neutral address "FoodSafety.gov" established with an e-mail address of foodsafety.gov.
6.c.2 Explore innovative methods for sharing food safety information including consolidation of government Internet sites to reach larger audiences and provide easier aces to information through a single site.	Durham (FDA) and Conley (FSIS)	1/25/97	9/30/97		(1) A single, agency-neutral address "FoodSafety.gov" established with an e-mail address of foodsafety.gov. (2) Launched EdNet on 10/27/97.
6.c.3 Establish a National Clearinghouse for Food Safety Education.	Durham (FDA) and Conley (FSIS)	10/1/97	9/30/98		First steps of researching and cataloguing existing activities and developing options is underway.
6.c.4 Consider use of food labels and other point-of-sale materials to convey food safety information.	Durham (FDA) and Conley (FSIS)	10/1/97	9/30/98		Point of sale materials are being used in the Partnership for Food Safety Education Campaign. The food safety research activities will assess the effectiveness of point of sale and labeling materials.
6.c.5 Develop and initiate a targeted multilingual program to change food workers' unsafe food	Durham (FDA) and Conley (FSIS)	10/1/97	9/30/98		First steps of cataloging existing activities and identifying options are underway.

Category 6. Education / Activity / Sub Activity	Lead/Contact	Start Date	End Date	FY 1998 USDA Funding (millions)	Status/Notes
preparation behaviors.					
6.c.6 Evaluate education program and continue to support those programs initiated in FY97 and FY98.	Durham (FDA) and Conley (FSIS)	10/1/97	9/30/00		
6.d Improve Veterinarian and Producer Education				**($0.3)**	
6.d.1 Use existing mechanisms to strengthen and implement programs to educate producers, veterinarians, and state and local regulators about proper drug use and incorporation of HACCP principles into industry QA program to reduce foodborne pathogens.	CVM	10/1/97	9/30/00		
6.d.2 Encourage evaluation and improvement of veterinary and producer education at veterinary and agricultural colleges to address foodborne pathogens in animals and their manures.	CVM	10/1/97	9/30/00		
6.d.3 Develop and disseminate guidelines and educational materials through existing networks to food producers and the veterinary medical community.	CVM	10/1/97	9/30/00		
6.e Improve Health-Professional Education					
6.e.1 In cooperation with FDA, FSIS and CSREES, CDC should train public health professionals on foodborne disease and clinical microbiology and foodborne illnesses with non-traditional symptoms by using multimedia, distance-learning techniques and NLTN.	Durham (FDA) and Conley (FSIS)	10/1/97	9/30/00		

Category 6. Education Activity Sub Activity	Lead/Contact	Start Date	End Date	FY 1998 USDA Funding (millions)	Status/Notes
6.f Improve Industry Education in the Transportation Area					
6.f.1 Form an alliance among government agencies and the private sector to develop educational materials and train food transportation vehicle owners and operators and food processing establishments on hazards associated with the transportation of food.	Durham (FDA) and Conley (FSIS)	10/1/97	9/30/00		

Category / Activity / Sub Activity	Lead/Contact	Start Date	End Date	FY 1998 USDA Funding (millions)	Status/Notes
7. Strategic Planning					
7. Strategic Planning				**$0.0**	**White House Meeting held on June 11, 1997. White Paper will be ready for agencies' review by end of March.**
Description: Develop an inclusive, public process to identify priorities, outline strategies for change, and ways to measure progress, which will be incorporated into a strategic plan for improving the food-safety system.					
7.a Initiate a Longer-Term Strategic Planning Process to Develop a Strategic Plan for Improving the Food-Safety System					
7.a.1 Initiate a longer-term strategic planning process giving interested parties an opportunity to comment on the possible approaches for structuring dialogue before implementation.	Hulabak (FDA); Mondschein (FSIS)	10/1/97	9/30/98		White House Meeting held on June 11, 1997. White Paper will be ready for agencies' review by end of March.
7.b Prepare a 3 to 5 Year Strategic Plan					
7.b.1 Prepare a 3 to 5 year Strategic Plan and incorporate the relevant parts of the plan into the GPRA strategic plan commensurate with the budget.	Hulabak (FDA); Mondschein (FSIS)	10/1/97	9/30/98		
7.c Measure Progress to Evaluate the Effectiveness of the Plan in Reducing the Annual Incidence of Foodborne Illness					
7.c.1 Review progress of Strategic Plans implementation to determine the plan's effect on the annual incidence of foodborne illness.	Hulabak (FDA); Mondschein (FSIS)	10/1/98	9/30/99		

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FSI - NPR - IWG
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DRAFT

National Academy of Sciences study of the effectiveness of the current food-safety system

In October 1997, Congress mandated a study by the National Academy of Sciences (NAS) on the effectiveness of the current food-safety system. This study has, in effect, become part of the strategic planning component of the federal food safety initiative.

According to the NAS's study plan, the study will focus on 1) determining the scientific basis of an effective food safety system; 2) assessing the effectiveness of the current food safety system; 3) identifying scientific needs and gaps within the current system; and 4) providing recommendations on scientific and organizational changes needed to ensure an effective science-based food safety system.

The committee that will carry out this study had its first meeting March 23-25, with subsequent meetings planned for April and May. The study report is scheduled to be delivered to Congress by August 15, 1998. The NAS's public statement about this committee and the committee list is attached.

The federal food safety agencies that are part of the NAS committee's analysis should consider planning a public meeting or other mechanisms to discuss the study's conclusions and recommendations after the study is submitted to Congress. A meeting could be constructed as a panel discussion among federal agency representatives, state and local government representatives, industry and consumer representatives, and representatives from the Congressional committees that mandated the study with opportunity for public comment. Alternatively, the committees recommendation could be published in the Federal Register for comment.

Office of Science and Technology Policy's interagency food-safety research budget review for FY 1999 Budget

Following the recommendation of the May 1997 food-safety report to the President, an interagency committee was established to coordinate federal food safety research and planning. The Office of Science and Technology Policy's (OSTP) National Science and Technology Council (NSTC) has established the NSTC Interagency Working Group (IWG) on Food Safety Research.

The IWG will conduct an in-depth review of all federal research related to microbiological aspects of food safety, as well as research related to natural toxins, and tissue residues of veterinary drugs. The review, which began in February 1998, will have several steps: 1) describing all existing research efforts; 2) identification of data needs and priorities; and 3) comparison of current research portfolio with identified needs. The third step will include identification of unnecessary duplication, jurisdictional issues, research gaps, and other information pertinent to designing a more coordinated research and education plan. Based on this review, the IWG will make recommendations for future coordinated research.

As part of the review of the research portfolio, the IWG should consider convening a national meeting of stakeholders to solicit their views and recommendation on the adequacy of the federal investment and the appropriateness of priorities and funding mechanisms.

The goal of this exercise is to produce a report that can inform budget planning for FY 2000. Therefore, the IWG plans to complete its work by May 29, 1998 (and proposes annual updates for five years). In addition to using the report to inform FY 2000 budget planning, the food safety agencies could highlight the report, its findings and recommendations, and their responses to it through a White House Conference on Food Safety Research and Technology.

Planning for the FY 2000 Food Safety Initiative Budget Proposal

The FY 2000 budget proposal needs to identify significant new programs for attention and resource commitment to improving the safety of the food supply. The process of developing these new themes should engage the public in identifying priorities for FY 2000's focus.

Data from Food Net will be invaluable in identifying new pathogens problems/new emphases as will engaging public health, medical, and scientific experts, and industry and consumer groups to assist in framing the major food safety issues.

Issue analysis for strategic plan development

In the May 1997 Report to the President, the food safety agencies committed to undertake a longer-term strategic planning effort to consider "how best to address important challenges and make the best use of the agencies' limited resources. The report suggested development of a 3-to 5-year strategic long-range agenda to help "set priorities, improve coordination and efficiency, identify gaps in the current system, enhance and strengthen prevention and intervention strategies, and identify measures to show progress." Although the NAS will be considering some of these matters, given the broad scope of that committee's charge (and the August deadline), many important issues will remain in need of focused analysis by federal agencies.

We suggest that the federal food safety agencies consider two options for analysis to support the development of a food-safety strategic plan: 1) an analysis focused on present-day strategic questions, and 2) an analysis focused on anticipating issues that are 5-10 years in the future.

An analysis focused on present-day issues could be constructed to develop approaches to further optimize food-safety assurance for one or more sectors of the food supply. Such an activity could consist of a series of public meetings with stakeholders (consumer organizations, state and local governments, food industry) to develop, for example, agreement about optimal approaches for the introduction of HACCP concepts into additional sectors of the food production system, or agreement about optimal approaches for health-protective management of animal manures. More than one such issue could be tackled in a series of stakeholder dialogues.

A predictive analysis focused on anticipating future food-safety challenges could be constructed, for example, to develop scenarios to describe the likely characteristics of the food system 5-10 years in the future and the actions that would be required of federal, state and local food-safety agencies to respond to changes in the system. Factors that could be considered in such an analysis include likely new production and processing technologies, new products and packaging, consumer interests, population demographics, and trends towards increasing concentration in domestic food industries and globalization of the food supply. An analysis of this sort could be undertaken by an independent contractor or by the USDA's Economic Research Service.

Because the May 1997 report committed to giving interested parties opportunities to comment on possible approaches for structuring the strategic planning process before its implementation, it would be advisable to vet ideas with major stakeholders and develop initial support for the general approach.

Single Food Agency Outline
June 3, 1998

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

Research

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

Education and Outreach Program

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

Consolidation and Coordination

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

Statutory Authority Issues

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

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

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

Funding

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

Surveillance: Improve Safety and Decrease Contamination of Food

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

Responses to Food-Borne Outbreaks

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

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

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

Risk Assessment System

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

Regulatory Reform

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

Overall Mission

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

Traceback

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

Miscellaneous

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

Inspections

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

greatest risks.

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

II. What Agencies are currently doing to address issues.

Inspection

- Following through on the recommendations of the first NPR report, the Administration implemented the new science-based food safety system known as HACCP. This new system focuses on preventing problems rather than catching problems after they occur. Instead of relying only on sight, touch, and smell, USDA inspectors now have additional tools targeted directly at reducing harmful bacteria like *E. coli* O157:H7 and salmonella. In 1995, the FDA issued new rules to ensure the safety of seafood using the HACCP regulatory approach.

- Leveraging inspection resources and increasing inspections for higher risk foods was addressed in the 1998 and 1999 National Food Safety Initiative.

- Working groups between USDA and FDA have been formed to:
  - Evaluate the expansion of cooperative agreements so that FSIS inspectors can provide information to FDA plants producing meat and nonmeat foods. FSIS inspectors are already in the plants, and their presence could be better used to maximize use of federal resources.
  - Review possible procedures for FSIS inspectors to exchange information with FDA on the basic sanitation conditions in warehouses.
  - Work closely with state and local regulators to establish uniform retail program standards through adoption of the Food Code. Currently as mentioned above, there are large disparities in regulatory standards between state, local and federal regulators.
  - Identify and address food safety issues related to the school lunch program and other feeding programs in USDA.
  - Consider the tasks of USDA inspectors in an HACCP environment.
  - Develop Good Agricultural Practices and Good Manufacturing Practices guidance for the domestic produce industry. FDA is also seeking legislation that would decrease the risk of importing unsafe food products from countries with food safety systems for exported products that are not on par with the U.S. system.
  - In addition, the FSIS Advisory Committee on meat and Poultry Inspection, which serves as a forum for sharing ideas and policy development on regulatory issues,

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

Surveillance

- The Administration increased funding through the national food safety initiative to target a broad range of food-borne pathogens. The strengthened capacity of FoodNet (the food-borne diseases active surveillance network) will provide rapid identification of the causes of the outbreaks.

- FSIS, FDA and CDC collaborate with local state and health departments to analyze data, recognize trends and target prevention strategies to evaluate their effectiveness.

- FSIS, FDA and CDC have developed an MOU that will allow the agencies to jointly collect more precise information on the incidence of food-borne illness in the U.S.

Responses to Food-borne Outbreaks

- To strengthen the outbreak response and coordination, USDA, HHS and EPA have formed the Food-borne Outbreak Response Coordination Group (FORCG), an inter-departmental task force that will review food-borne illness outbreak response by federal and state governments and, based on these findings will develop and implement accelerated response procedures.
  - The Foodborne Outbreak Response Coordinating Group (FORCG) is designed to improve the approach to interstate outbreaks of foodborne illness through the development of a national comprehensive and coordinated foodborne illness outbreak response system involving federal, state and local agencies charged with responding to such outbreaks.

- Each Department will have an outbreak coordinator. For HHS, the Assistant Secretary for Health will be the primary person in charge of coordination for HHS. Outbreaks that fall under the jurisdiction of USDA will be coordinated by the Under Secretary for Food Safety. EPA will designate the Assistant Administrator for the Office of Prevention, Pesticides, and Toxic Substances.

Risk Assessment

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

- The FSIS-FDA National Advisory Committee on Microbiological Criteria for foods also

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

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

Research

- Under the FQPA, EPA is working hard to strengthen the scientific basis of its actions, including obtaining expert scientific advice, peer review, and the input of stakeholders.

- USDA has formed the Food Safety Working Group to establish a research agenda that supports the fundamental changes that FSIS is making to food safety regulations based on the HACCP system. The goal of research agenda is to reduce the incidence of food-borne associated with the consumption of meat, poultry and egg products. The Food Safety Research Group includes the Following USDA agencies: ARS; APHIS; CSREES; ERS; FSIS; ORACBA; and the Office of the Secretary.

- USDA, HHS and EPA have also formed an interagency research planning group to identify research priorities aimed at reducing microbial risk in produce.

- The Office of Science and Technology (OSTP) has convened an interagency group which includes, USDA, HHS, EPA and NIH, to coordinate federal food safety research priorities and will recommend direction of research funds for the FY 2000 budget for the federal food safety agencies.

Education

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

Pesticides

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

Microbial Contamination

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

III. Current food safety coordination efforts.

Working Groups and Meetings

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

Committees

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

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

Other

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

MOUs

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

Coordination

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

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

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

6-3-98

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

BACKGROUND

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

Most cases of foodborne illness reported in the United States today can be traced to meat, poultry, eggs, milk, and shellfish.[3] Shellfish alone caused 21 percent of all reported food poisonings arising from meat, fish, or poultry between 1978 and 1987.[4] Foods can be contaminated with harmful microorganisms (such as bacteria, viruses, and fungi); parasites (such as tapeworms, roundworms, and flukes); chemicals (such as pesticides, animal drugs, flavor and color additives, or industrial chemicals); and natural poisons (such as the toxins in some shellfish). Since 1985, the United States has witnessed significant and highly publicized outbreaks of foodborne illness caused by highly pathogenic bacteria, including cheese contaminated with Listeria, milk and cantaloupe contaminated with Salmonella, canned mushrooms contaminated with the toxin produced by Staphylococcus, and hamburger contaminated with E. coli O157:H7. In addition to these acute outbreaks, chemical contamination of foods with animal drugs and pesticide residues may contribute to unknown increases in cases of cancer and birth defects.

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

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

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

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

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

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

The *New England Journal of Medicine* of August 1978 published a CDC study on the impact of one foodborne disease—salmonellosis. The study showed that "Salmonellosis is much more than an inconvenience—it is responsible for complications, operations, and hospitalizations of five to six days for previously well persons in all age groups, not just infants and the elderly." The study also stated that ". . . the cost of public health programs to detect, control, and prevent salmonellosis must be measured against the unnecessary medical expenses and loss-of-productivity costs, which may be *more than a billion dollars a year.* [emphasis added]"[9]

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

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

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

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

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

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

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

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

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

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

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

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

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

Although FDA attempts to assign a risk priority to foods by categorizing them as "high" or "low" risk, the assignment of inspection frequency is inconsistent and based too much on the availability of resources. Availability is often controlled by the existence of a perceived "crisis" in the drug or medical device industry or in the nation's blood supply. Such crises usually demand that FDA concentrate its limited resources on the crisis issue and reduce its inspection of food manufacturing firms.[13] A recent General Accounting Office (GAO) report indicated that, on average, FDA inspects food establishments only once every three to five years.[14]

The Federal Meat Act of 1907 and the Poultry Products Inspection Act of 1957 require the Department of Agriculture to provide continuous inspections at slaughter establishments, examining every carcass. The acts also require that inspectors visit meat and poultry processing plants on a daily basis. These laws are inflexible and do not allow FSIS to vary its frequency of inspections to concentrate its resources on risk and issues significant to the public's health, as recommended in the National Academy of Sciences report of 1985.[15]

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

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

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

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

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

Food safety research is also duplicative and driven by the varying missions of some 21 agencies. A January 1993 report by the Committee on Food, Agricultural, and Forestry Research of the Federal Coordinating Council for Science, Engineering, and Technology reports that these agencies spend approximately $200 million on food safety research under about 50 laws that directly or indirectly authorize such research. This research may be basic or applied, laboratory-based or social science research. It may be broadly or specifically focused and carried out in federal laboratories, through contracts, cooperative programs, or grants to academia and the private sector. The areas of research include infectious disease agents and their toxins, drug and pesticide residues, food additives, environmental and industrial contaminants, food product processing, storage and packaging, diet and nutrition, and food production. Each area may address improved methods to identify hazards, prevention and control, mechanisms of action, risk assessment and risk management methods, or consumer behavior studies.[19]

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

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

ACTION

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

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

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

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

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

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

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

The food safety agency should meet the following criteria:

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

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

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

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

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

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

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

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

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

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

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

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

IMPLICATIONS

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

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

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

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

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

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

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

FISCAL IMPACT

All funds appropriated for current food safety activities would be transferred into FDA. Savings associated with this consolidation might include those from consolidating FDA and FSIS field offices and inspection activities, administrative activities such as personnel offices and activities, resource management, and duplicative management positions.

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

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

Endnotes

1. Bennett, John V., et al., "Infectious and Parasitic Diseases," *Closing the Gap: The Burden of Unnecessary Illness*, eds. Robert W. Amler and H. Bruce Dull (New York: Oxford University Press, 1987), pp. 102-114.
2. Archer, Douglas L., and John E. Kvenberg, "Incidence and Cost of Foodborne Diarrheal Disease in the United States," *Journal of Food Protection* 48 (1985), pp. 887-894.
3. Bean, N.H., and P.M. Griffin, "Foodborne Disease Outbreaks in the U.S., 1973-1987: Pathogens, Vehicles, and Trends," *Journal of Food Protection* (September 1990), pp. 804-817.
4. National Academy of Sciences, Institute of Medicine, *Seafood Safety* (Washington, D.C.: National Academy Press, 1991).
5. Menning, Edward L., "Danger Lurks in Your Supermarket Meatcases," *Journal of the American Veterinary Medical Association* (1988), pp. 494-497.
6. Archer, Douglas L., "The Impact of Foodborne Infections," *Food Technology*, 42:(7) (July 1988), pp. 53-58.
7. Weiss, Mike, Tanya Roberts, and Hal Linstrom, "Food Safety Issues: Modernizing Meat Inspection," *Agricultural Outlook* (June, 1993), p. 33.
8. Archer and Kvenberg, pp. 887-894.
9. Cohen, Mitchell L., et al., "An Assessment of Patient Related Economic Lost in An Outbreak of Salmonella," *New England Journal of Medicine* (August 1978), pp. 299-301.
10. See U.S. General Accounting Office (GAO), *Food Safety and Quality: Uniform, Risk-Based Inspection System Needed to Ensure Safe Food Supply*, Report to the Congress, RCED-92-152 (Washington, D.C.: U.S. General Accounting Office [GAO], June 1992).
11. Ibid.
12. National Research Council, *An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients* (Washington, D.C.: National Academy Press, 1985), pp. 50-54.
13. See U.S. Department of Health and Human Services (HHS), Office of Inspector General, *FDA Food Safety Inspection*, Audit Report No. OEI-05-90-01070 (August 1991).
14. See GAO.
15. Committee on the Scientific Basis of the Nation's Meat and Poultry Inspection, *Meat and Poultry Inspection: The Basis of the Nation's Program* (Washington, D.C.: National Academy Press, 1985), p. 10.
16. See GAO.
17. Committee on the Scientific Basis of the Nation's Meat and Poultry Inspection.
18. See HHS.
19. See Federal Coordinating Council for Science, Engineering, and Technology, Committee on Food, Agriculture, and Forestry Research of the Food, *An Overview of Food Safety Research* (Washington, D.C.: U.S. Office of Science and Technology Policy, January 1993).
20. See GAO.

AGENDA—Food Safety Interagency Working Group
June 3, 1998

1. Announcements

2. Update on GAO request

3. Update on *Farm To Table* recommendations

4. Issue Paper(s)

5. Draft Strategic Plan

6. Next meeting agenda

Food Safety Strategic Planning Group

Draft Vision

Consumers can be confident that food is safe, healthy, and affordable. We work within a seamless food safety system that uses farm-to-table preventive strategies and integrates research, surveillance, inspections, and enforcement. We are vigilant in our response to new and emergent threats and consider the needs of vulnerable populations. We use science and risk-based approaches along with public/private partnerships. Food is safe because everyone understands and accepts their responsibilities.

U.S. Department of Agriculture

Department of Health and Human Services
Food and Drug Administration

July 14, 1998

REPORT TO THE DOMESTIC POLICY COUNCIL

Subject: Status of Foodborne Illness for 1998

On behalf of our agencies and the Centers for Disease Control and Prevention (CDC), this memorandum is intended to provide you with a brief report on the foodborne illness outbreaks identified thus far in 1998.

It has been less than two years since the President directed the Departments of Agriculture and Health and Human Services and the Environmental Protection Agency to develop an initiative to reduce the millions of illnesses and thousands of deaths caused by food contaminated with bacteria, viruses, and parasites. With initial funding by Congress, we have already made major progress in efforts to better understand the causes of, and methods to prevent, these illnesses; to increase consumer and industry understanding of such preventive techniques; to implement a state-of-the-art inspection system for meat, poultry, and seafood, and to improve our ability to identify and track major outbreaks of foodborne illness.

Combining the most modern techniques of DNA "fingerprinting" with proven methods of epidemiologic investigation, we have improved our ability to detect – and combat – foodborne illness more rapidly than ever before. For example, with additional resources from the National Food Safety Initiative, the CDC and the Department of Agriculture are identifying more cases of illness due to meat contaminated with deadly *E. coli* O157:H7 and removing contaminated product from the market before more cases can occur. CDC and the Food and Drug Administration rapidly investigated an outbreak of *Salmonella* infections transmitted by popular children's cereal, thus preventing additional cases.

Of course, this progress, while substantial, is only the beginning, and foodborne disease illnesses and outbreaks continue to occur at a pace that is of serious concern. Already, one outbreak affected persons in 23 states and another outbreak affected an estimated 6500 persons. As the attached table demonstrates, almost every state has investigated a foodborne outbreak. Those states where relatively few outbreaks have been investigated

are usually those with fewer resources for such investigations. Similarly, the number of outbreaks for which the pathogen is unknown attests to the need for further improvements in tools for investigations. The sources of the outbreaks range from neighborhood picnics to restaurants to major food manufacturers.

Investigation of outbreaks gives us important insights into how foodborne illnesses occur, can be tracked, and can be contained – and how the National Food Safety Initiative can target the problem. For example, the new PulseNet system created by CDC is improving identification of these outbreaks, so state and Federal disease detectives are taking action faster than ever before. These life-saving advances to investigative capabilities now need to be repeated for other pathogens. The new state-of the art HACCP-based inspection system will reduce many of the problems in manufacturing facilities by helping food producers prevent contamination from occurring. And education of food processors, retailers, and consumers is helping them to adopt the latest methods of preventing food contamination.

However, outbreaks represent only the tip of the iceberg of foodborne illnesses. For every outbreak that is recognized and investigated, hundreds more persons develop foodborne illness that is not linked to an outbreak. While we continue to believe that the American food supply is the safest in the world, this listing of current outbreaks demonstrates that we as a nation have a tremendous opportunity to make the food supply safer. Indeed, if we can secure the necessary funding to implement the initiative, the partnerships that has been developed among the state and local governments, the Federal agencies responsible for food safety, and the food industry can save thousands of lives each year and eliminate billions of dollars in wasted costs to society. We believe that the National Food Safety Initiative will make an extremely important contribution in reducing death and illness caused by food pathogens in this country.

Michael A. Friedman
Acting Commissioner of Food and Drugs

Catherine E. Woteki
Under Secretary for Food Safety

BACKGROUND

The most devastating outbreak of foodborne illness yet to affect the United States struck in January 1993, only weeks after the Clinton administration entered office. This outbreak, linked to undercooked fast-food hamburgers contaminated with *E. coli* O157:H7 bacteria, ultimately caused the deaths of four children, and sickened 732 more. The same year, *Cryptosporidium* in Milwaukee's drinking water made 400,.000 people sick and contributed to the deaths of about 100 people.

The Clinton administration acted immediately to identify the weak points in the food safety system that had allowed this tragedy to occur, significantly increasing emphasis on prevention and on the application of science to the food safety system for meat and poultry. Food- and waterborne illness outbreaks continued to occur, however, and we recognized that we face new challenges as we enter the 21st century. New pathogens are emerging. Familiar ones are growing resistant to treatment. Americans eat in restaurants more. Effective change to meet these challenges has required comprehensive review of the adequacy of the current system and focused attention on those hazards judged to be the most immediate threats to the public's health. This review has resulted in the first significant reevaluation of microbial food safety hazards and their solutions for over 40 years; it has resulted in significant expansion of a number of food safety programs, increasing consumer protections for our food supply. Additionally, Congress and the Clinton administration acted in 1996 to reauthorize and strengthen the Safe Drinking Water Act to increase the safety of the nation's drinking water.

ACCOMPLISHMENTS

Building on previous administration efforts, President Clinton in January 1997 announced a comprehensive new food safety initiative, and called for development of a plan to detect and respond to outbreaks of foodborne illness earlier, and to give us the data we need to prevent future outbreaks. The federal food safety agencies, working in partnership with their colleagues in the states, in the food industries, in academia, and with consumers, developed the National Food Safety Initiative (NFSI) to focus on the goal of reducing foodborne illness caused by microbial contamination of food. This goal was to be reached through systematic improvements in six key components of the food safety system: foodborne outbreak response coordination, surveillance, inspections, research, risk assessment, and education. The plan for the NFSI was presented to the President in May 1997. In October 1997, the President announced the addition to the NFSI of a special focus on ensuring the safety of domestic and imported fresh produce.

The practical effect of the NFSI's implementation is that the food and water safety agencies have developed new ways of working together. These new relationships -- both formal and informal -- have already resulted in greater efficiencies of service and response, reduced redundancies, and more creative problem solving. The NFSI has facilitated the federal food safety agencies working as a "virtual agency." Working in this manner, federal agencies are realizing enhanced coordination and efficiency across the food and water safety systems. The following discussion illustrates this progress.

Accurate and Active Surveillance

Before the development of FoodNet, an active surveillance system for food- and waterborne illnesses supported by CDC, FDA, and USDA through the NFSI, surveillance for these illnesses had always been passive (i.e., information was not sought, but merely received when reported). Food- and waterborne illnesses are vastly under recognized because, although most diarrheal illnesses are caused by food (or water), the suspect food is rarely identified. Moreover, most people with diarrheal illness do not see a health care provider or have a stool specimen cultured. Thus, passive surveillance provides an underestimate of food- and waterborne illness. FoodNet surveys are helping us develop better estimates of the number of these undiagnosed illnesses. For example, CDC calculates that, for every case of *Salmonella* reported, 62 more cases occur in people who do not see a health care provider or have a stool cultured.

The NFSI has made possible the expansion of FoodNet to seven sites that geographically and demographically represent the U.S. population. This system, in which CDC, USDA, FDA, and the state sites collaborate, is beginning to make accurate information available about foodborne disease incidence. PulseNet, another development of the NFSI, is based on DNA fingerprinting of pathogens. The development of this new information resource enables FDA, USDA, and over 20 state laboratories to quickly determine bacterial subtypes with a high degree of accuracy and transmit that information digitally to a central computer at CDC that can match the pathogen implicated in one outbreak to previously unconnected outbreaks in other locales. Quick, accurate links among outbreaks make possible rapid tracebacks to common food vectors and removal of implicated food from the market. With continued funding, federal and state agencies plan expansion and upgrading of the FoodNet and PulseNet systems, and further procedural integration to ensure rapid, reliable access by agencies and states to information on foodborne disease and traceback of implicated foods.

Additional achievements:

- FoodNet conducted active surveillance on seven bacterial pathogens and began data collection on two parasitic pathogens in seven sites; the eighth FoodNet site will open in 1998. FoodNet's 1997 data were published in the medical literature.

- Four new EIS officers (disease detectives) added to Field Services to enhance state-based surveillance and outbreak response.

- EPA and CDC are working closely to conduct waterborne outbreak surveillance for drinking waters and to estimate national drinking water infectious disease risks; they will report their findings to Congress.

- Although *Campylobacter* has rarely caused outbreaks of illness since the 1980s, FoodNet sites were able to identify it as the most common cause of foodborne disease. 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.*

- FoodNet 1997 data shows *Listeria* infections had the highest hospitalization rate and caused more deaths than any other single pathogen tracked and almost half of all deaths. As a result, CDC will conduct additional studies of *Listeria* infections to identify food sources and potential control points where preventive measures may be applied.

- Working closely with CDC and using epidemiological data in FY 97, FDA was able to disallow the importation of berries from Guatemala in FY 98. The Rapid Assessment Team, composed of epidemiological experts from states and representatives of CDC and FDA, reviewed the epidemiological data and assisted in determining that Guatemalan raspberries were implicated in the U.S. cyclosporiosis outbreaks. As a result of the U.S. not allowing importation of Guatemalan berries, no illnesses have been attributed to *Cyclospora* and consumption of berries in the U.S. thus far in FY 98, as compared to approx. 1,000 illnesses at the same time last year. Canada, on the other hand, is importing Guatemalan berries and is experiencing clusters of cyclosporiosis, although they do have traceback data clearly implicating the berries in the outbreaks. During this period, FDA and CDC have provided technical assistance to Guatemala.

- 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, presenting additional illnesses.

- FDA, CDC, USDA/ARS and USDA/APHIS recently 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.

- NARMS recently attracted global interest when it was selected as a model by a World Health Organization task force charged to make specific recommendations on antimicrobial resistance monitoring of zoonotic organisms.

Advances anticipated with continued funding:

- Based on FoodNet data, FDA and USDA will initiate additional targeted surveys to determine pathogen sources.

- Completion of PulseNet network so state and federal laboratories across the country have access to the data and the capability to rapidly link foodborne outbreaks with the food source of the contamination.

- Increased capacity of the National Antimicrobial Resistance Monitoring System (NARMS) to detect emerging resistance trends in pathogens associated with food animals

- Establish 5 additional veterinary sentinel sites corresponding to human FoodNet sites for collection of animal microbial resistance data for NARMS

Science-based Inspections and Preventive Controls

Making the federal inspection system for seafood more efficient and modernizing meat and poultry inspection programs were early goals of the Clinton administration, providing the first major overhaul of the meat and poultry systems in 90 years. Implementation of science-based, hazard-prevention systems (Hazard Analysis and Critical Control Points (HACCP) systems), widely recognized by scientists and other food safety experts as the most effective and efficient mechanisms to ensure the identification and control of hazards, accomplishes both goals. Working collaboratively, USDA, FDA, and the meat, poultry, and seafood industries are well on the way to putting these systems in place. Data are being collected from early experiences with HACCP that will be used to help evaluate these systems' effectiveness and help agencies and industries fine-tune preventive designs. This new focus on efficient, risk-based, preventive controls has led to redoubling of efforts to leverage inspection resources to make maximum use of federal and state field forces. New partnerships among federal agencies and new federal-state partnerships are being developed to coordinate inspection coverage and vertically integrate personnel to provide major gains in efficiency.

Additional achievements:

- In implementing the seafood HACCP regulations, all processors will be inspected by the end of 1998 to verify proper use of HACCP; a significant portion have already been visited and technical assistance provided to correct deficiencies, as needed.

- 6,861 industry officials and federal and state inspectors trained in seafood HACCP through Seafood Alliance; 1,137 federal and state regulators trained and 2,100 inspectors trained in meat and poultry HACCP

- Mandatory warning labels on packaged juices not treated to reduce or eliminate harmful pathogens will be required beginning in the Fall apple cider season in order to alert consumers of the public health risk, particularly to vulnerable groups, such as children.

- USDA has implemented *Salmonella* testing in over 300 of the largest meat and poultry plants to reduce the risk of salmonellosis from consumption of these products.

- Publication of a Notice of Proposed Rulemaking for mandatory use of HACCP in the manufacture of all fruit and vegetable juices.

- Publication of an Advanced Notice of Proposed Rulemaking seeking information and

comment on various alternative approaches to improving egg safety from the farm to the consumer.

- Draft guidance "Managing Food Safety: A HACCP Principles Guide for Operators of Food Service, Retail Food Stores, and Other Establishments at the Retail Level" developed by FDA and states to improve uniformity of HACCP application at retail throughout the nation. This guidance will be pilot tested during FY 99 with the goal of reporting on the best way to implement HACCP at the retail level at the Conference for Food Protection (organization of state public health officials, consumers, and industry) in the Spring of 2000.

- In 1995, at FDA's request, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) was asked to investigate and characterize the association between cases of foodborne illness and fresh produce. The committee complete this task on March 5, 1998 and submitted a paper entitled "Microbiological Safety Evaluations and Recommendations on Fresh Produce" to FDA. Among the recommendations within this document were the development of Good Agricultural and Good Manufacturing Practices for the industry, proactive and practical education programs, need for additional data for risk assessments, research to fill knowledge gaps, and better systems for identifying and tracing outbreak investigations. This paper has been submitted for publication in a peer-reviewed journal.

Advances anticipated with continued funding:

- Develop a vertically integrated food safety inspection system for USDA, FDA, and state inspectors to provide more effective and efficient coverage of the food industry, maximize national food safety resources, and improve the consistency and uniformity of inspections across all levels of government. Several planning meetings with various state partners have been held or are planned for this fiscal year.

- "FDA's Recommended National Retail Food Regulatory Program Standards" developed by FDA with other federal, state, and local regulatory officials, industry, trade associations, academia, and consumers will be pilot tested during FY 99 by state and local regulatory officials.

- Adoption of the Food Code by states: A conference of program directors from State Agriculture and Public Health agencies will be held in September and a joint FDA/USDA meeting of all State Agriculture and Health Commissioners will be held in November to promote adoption of the Food Code by states and improve follow up to outbreaks at the federal and state levels. To date only 10 states have adopted the Food Code and 23 states have begun a process leading towards adoption.

- Development of a Memorandum of Understanding between FDA and USDA under which inspection resources may be shared and USDA inspectors may conduct inspections of firms producing FDA-regulated products for FDA.

- By 2000, USDA will have implemented the science-based HACCP inspection system in over 6,000 federally inspected meat and poultry plants.

Priority-based and Coordinated Research and Risk Assessment

Food and water safety practices and programs must be science-based to effectively prioritize risks and develop effective techniques to detect and identify food contaminants, minimize their presence, and respond to illnesses and outbreaks. Basic research is needed to understand the ecology and etiology of foodborne pathogens, their genetic content, how they multiply, how they are transmitted, and under what conditions they grow and survive. Applied research is then needed to develop the methods and technologies that will enable detection and control of contaminants. Data generated through basic and applied research are used in risk assessments to characterize the nature and magnitude of risks associated with food- and waterborne hazards, assist in accurate targeting of resources to control those hazards, and evaluate the effectiveness of control measures. Risk assessments are also used to focus data collection and scientific research on the most critical areas. The NFSI has resulted in an unprecedented degree of collaboration in research and risk assessment associated with microbial contamination of foods among federal agencies.

The need to better coordinate basic and applied research was one of the first goals identified in the first year of the initiative. USDA and HHS undertook a self-assessment of their microbial food safety research programs; this project was built upon and expanded by the Office of Science and Technology Policy with the establishment of a formal interagency working group that includes all agencies with food and water safety research components. This working group's report is expected to be issued during Summer 1998 and will be used to help plan NFSI budgets for FY 2000.

On July 4th, the President called for the creation of a national institute for food safety research to strategically plan and coordinate food safety research across all federal agencies, including research that they conduct in partnership with the private sector and through academic institutions. As the President directed, the Secretaries of Health and Human Services and Agriculture to report back by October 4, 1998, with a plan for creating an institute that will develop a strategic approach for conducting food safety research activities consistent with the NFSI.

Initial funding of the NFSI enabled establishment of the interagency Risk Assessment Consortium at the Joint Institute of Food Safety and Applied Nutrition at the University of Maryland, through which FDA, CDC, a number of USDA agencies, EPA, DoD, and NMFS have begun work to cooperatively advance the science of microbial risk assessment. Consortium members plan further work to focus critical risk-research needs and reach consensus on the priorities of those needs based on their potential to reduce decision-making uncertainty.

Additional achievements:

- EPA began an intensive research program to develop analytical methods for detection and

enumeration of pathogens in drinking and ambient waters and to carry out dose-response studies for Norwalk viruses and *Cryptosporidium*.

- In conjunction with the Risk Assessment Consortium, EPA is developing a new pathogen risk assessment paradigm for water.

- New or improved methods developed for detection of *Cyclospora, Campylobacter, Vibrio parahaemolyticus*, and *E. coli* O157:H7 for produce and other products. Methods were previously not available and desperately needed.

- Coordinated interagency research plan, with input by industry, academia, and consumers, to identify specific research needs for fresh produce to insure maximum use of research resources.

- Development and approval of a commercial spray for use on baby chicks that will prevent *Salmonella* on poultry products, a major source of salmonellosis in the United States.

- Elucidation of some microbial characteristics that lead to evolution of new, particularly resistant, pathogens. This work is being used to develop preventive techniques and help predict where the next food safety threats are likely to occur.

- Approval of the use of irradiation for red meats and chlorine dioxide for use in poultry chiller water as additional disinfection tools.

- USDA/FDA published the first ever quantitative microbial risk assessment, on *Salmonella* Enteritidis in eggs and egg products; this risk assessment will likely be a model for future microbial risk assessments generated to prioritize public health risks and allocate resources to elimination of those risks.

- An international workshop on transmissible spongiform encephalopathies (TSEs) was sponsored by JIFSAN and drew over 300 attendees. The purpose of the workshop was to define the state of current knowledge and identify practical guiding principles for evaluating the risks posed by TSEs. A framework document for risk assessment was initiated, the JIFSAN TSE website will serve as a clearinghouse for TSE information, and followup meetings are planned. This proactive approach was initiated to continue to keep TSEs out of the U.S. food supply.

- USDA established a contract with the Harvard School of Public Health's Center for Risk Analysis to conduct a risk analysis of TSEs in the United States and to review current U.S. efforts to prevent entry of BSE into the country.

- Clearinghouse of risk assessment research, data, and methodology established at the Risk Assessment Consortium.

- Co-funding a scientist to work with the World Health Organization on development of

international risk assessment guidelines that are critical to harmonization of food safety standards.

- Results from research on antimicrobial drugs used in animals to increase productivity by maintaining animal health have been used to establish an acceptable daily intake for tetracyclines in animal-derived food that does not alter the human intestinal microflora. The normal endogenous intestinal microflora forms a protective barrier against invading bacterial pathogens.

- Initial development begun for a risk assessment framework to rank the relative public health risk associated with the use of various antimicrobial agents in food producing animals.

Advances anticipated with continued funding:

- Additional new, rapid detection methods for pathogens and other food contaminants.

- Disinfection and processing interventions to eliminate or reduce levels of microbial and chemical contaminants on products that cannot be cooked, such as fresh fruits and vegetables.

Rapid and Coordinated Foodborne Outbreak Response

As our surveillance systems improve, we get an ever clearer picture of the illness outbreaks in the nation. Because of enhanced surveillance, including PulseNet and FoodNet, that the NFSI has made possible, many more cases of foodborne illness are being detected and reported. As a result, we are beginning to document what we have always suspected: that our estimates of disease incidence have been significant underestimates. In addition, new bacterial DNA fingerprinting techniques are helping us to recognize that many cases of foodborne illness that would likely have been thought to be random are actually part of outbreaks (two or more cases associated with a common food). With the improved and more timely information that these advances provide, agencies can identify the contaminated food or water more quickly and get it off the market or stop its use before it makes more people sick. In addition, USDA, CDC, FDA, EPA, and DoD have formed a new intergovernmental group (the Foodborne Outbreak Response Coordinating Group, or FORCG) to improve federal, state, and local responses to outbreaks of food- and waterborne illnesses. Vice President Gore participated in the signing of the Memorandum of Understanding formalizing FORCG in May 1998. Working with all stakeholders, FORCG is working to further focus coordination, use resources more efficiently, and measure progress toward our common goal of reducing the incidence of food-related illness. Additional achievements:

- Standard, uniform procedures, developed by federal agencies and states and reviewed by approximately 100 workshop participants at the annual meeting of the Association of Food and Drug Officials, to guide rapid sharing of information, evaluation and use of epidemiological data, and conducting traceback activities, are being followed by federal,

state, and local agencies.

- A Rapid Assessment Team, composed of state epidemiologists from the Council of State and Territorial Epidemiologists and representatives of FDA and CDC, has been formed to assist in the review of epidemiological data associated with outbreaks and in determining the implicated food.

- FDA has developed comprehensive traceback standard operating procedures for use when fresh fruits and vegetables are implicated in an outbreak. NFSI provided funding to present a traceback course for FDA and, with FY 1999 funding, future courses are planned for states at their request. In most instances, fruits and vegetables are not shipped in discrete units as are commercially prepared products. Since fruits and vegetables are highly perishable, food samples are typically unavailable.

Advances anticipated with continued funding:

- Develop a vertically integrated outbreak response system among federal, state, and local agencies that has standard operating procedures for rapid exchange of information and epidemiologic data.

Targeted and Effective Education

Foodborne illness remains prevalent throughout the United States, in part because food preparers and handlers at each point of the food chain are not fully informed of risks and related safe-handling practices. Understanding and practicing proper safe food-handling techniques, such as thoroughly washing hands and cooking food to proper temperatures, can significantly reduce foodborne illness. Food safety education, therefore, is widely recognized as an integral part of a successful, coordinated food safety program. Truly effective food safety education must deliver product-specific and audience-specific messages about food hazards and how to avoid them to groups throughout the food chain. Recognizing these facts, and as a function of the NFSI, the federal food safety agencies have successfully undertaken a heretofore unprecedented public-private partnership with industry, consumer groups, and state representatives to get food safety messages to consumers and others. Early survey data show that this education campaign has begun to pay off in greater knowledge about safe food-handling practices among consumers. The education partnership has also begun to bring the power of its collaborative outreach to partners and workers in the retail and food-service industries.

Additional achievements:

- Development of the national "Fight BAC!" campaign to promote consumer use of safe food practices.

    - Sponsored by the public/private Partnership for Food Safety Education, officially launched in May, 1997 at a White House signing ceremony presided over by Vice President Gore.

- Lifesize "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.

- Extensive consumer research conducted on which to base consumer food safety messages, including focus groups to determine the most effective juice labeling, a consumer advisory at retail firms to inform consumers of potential hazards, and current food safety advisories.

- Food Safety Training and Education Alliance for Retail, Food Service, Vending, Institutions, and Regulators — a public/private partnership formed specifically to meet retail food service needs for materials, particularly multilingual materials, and training.

- Making safe food practices part of the culture — materials have been develop for inclusion of food safety in the curricula for school children to inculcate life-long use.

Advances anticipated with continued funding:

- National Food Safety month of September. Food safety education planning guides will be distributed for use by local health departments and community food safety educators in planning educational programs for consumers during September. Among the many local and regional activities that are planned are:

  - Training food handlers in church kitchens on safe food handling practices and providing them with food safety "tool kits";

  - Translation of food safety educational materials into languages spoken in local communities such as Hmong, Cambodian, and Laotian;

  - Conducting "train the trainer" seminars to educate senior citizens about their risk for foodborne illness and how they can prevent it; and

  - Training Spanish daycare workers in safe food handling practices in their own language.

- Agencies and the American School Food Service Association will distribute posters describing the importance of handwashing prior to eating for display in school cafeterias.

Enhanced Safety for Domestic and Imported Fruits and Vegetables

The rich variety of foods, especially fruits and vegetables, that is available to us year round is made possible because of the globalization of trade in fresh produce that has occurred in recent years. We are becoming increasingly aware, however, that with this abundance comes added responsibility to ensure that imported fruits and vegetables meet the same standards as domestic produce. As a first step, proposed good agricultural practices/good manufacturing practices guidelines for fresh fruits and vegetables have been developed through the NFSI by FDA in collaboration with USDA, states, and the food industries to provide practical and flexible guidance for building safety assurance into food production from the farm to the table. Furthermore, FDA and USDA are combining their resources and expertise to develop an assessment of food production systems used in countries exporting food to the United States, and to provide technical assistance and outreach to trade partners to ensure their use of sound food-production practices. USDA and EPA are working together to ensure that fresh produce and fruits are grown from waters that are safe and fertilized with treated manures and biosolids, thereby preventing exposure of edible material to pathogens. In addition, the administration is seeking passage of legislation that would give the FDA greater authority over imported foods, to ensure that imports of fruits, vegetables, and other food products meet U.S. food safety requirements or otherwise achieve the same level of protection as is required for U.S. products. This legislation would give FDA authority that is comparable to the authority that USDA already has to prevent the importation of unsafe meat and poultry.

Additional achievements:

- Grassroots meetings around the country with the U.S. produce industry, states, consumers, and academia providing input into the guidance document at the draft and proposal stages and in preparing the final guidance.

- Site visits to various types of fresh fruit and vegetable producers around the country.

- FDA charged the NACMCF Fresh Produce Subcommittee with considering the increasing number of outbreaks associated with fresh sprouts. As part of this activity, the Fresh Produce Subcommittee and invited experts are touring sprout growing and seed operations in California.

- As the result of an October, 1996 meeting between FDA and sprout industry, a working group was established to find possible solutions to the problem of microbiological contamination of sprouts. The working group, consisting of industry, academia, and government, prepared and distributed the Voluntary Sprout Grower Guidelines in August 1997 to 85 firms.

Advances anticipated with continued funding:

- Finalization of the fresh produce guidance.

- Education and outreach targeted to the domestic produce industry and technical assistance to countries exporting fresh fruits and vegetables to the United States to promote use of the guidance.

- FDA, in cooperation with states, will conduct a survey of production practices by the fresh sprout industry.

Strategic Planning for the Future

In the first two years of the NFSI, the agencies have taken giant strides forward in building an infrastructure for a strengthened national food safety system. The building blocks of the infrastructure are in place: FoodNet and PulseNet; FORCG; expanding reliance on preventive controls (e.g., HACCP, GAP/GMP guidance, retail food service guidance and standards); coordinated food safety research; the interagency Risk Assessment Consortium; sharing of inspection responsibilities; and innovative public/private education partnerships. How best to capitalize on the progress made?

In the May 1997 plan for the NFSI presented to the President, the food safety agencies made a commitment to develop a longer-term strategic planning process, with the participation of all concerned parties, to consider how to best address important challenges and make the best use of the agencies' limited resources. The charge is to develop a strategic long-range agenda that can be used to help set priorities, improve coordination and efficiency, identify gaps in the current system, enhance and strengthen prevention and intervention strategies, and identify measures to show progress. The agencies have already identified a major gap—risks posed by chemical contamination of foods—that must be considered in strategic planning for the NFSI.

In July, 1998, the food safety agencies took the first steps to set the groundwork for this process by participating in interagency strategic planning sessions. The result was a statement encompassing the agencies' vision of the goal of the U.S. food safety system and the roles of all who have a hand in food safety from producer to consumer:

> "Consumers can be confident that food is safe, healthy, and affordable. We work within a seamless food safety system that uses farm-to-table preventive strategies and integrated research, surveillance, inspection, and enforcement. We are vigilant to new and emergent threats and consider the needs of vulnerable populations. We use science- and risk-based approaches along with public/private partnerships. Food is safe because everyone understands and accepts their responsibilities."

The next steps in the strategic planning process are to seek public participation in the process, beginning with a validation of the vision statement, and to develop a public process for strategic planning. The interagency strategic planning process will encompass the OSTP coordinated

research plan and the Congressionally mandated National Academy of Science's report on the adequacy of the current food safety system.

Conclusion: The Case for Needed Resources

A major benefit of the NFSI has been the gains made in improved coordination and collaboration to ensure the safety of the U.S. food supply among federal agencies, their partners in state governments, and with the food industry. In addition to the numerous agreements and other collaborative mechanisms that agencies have long worked within, the NFSI has encouraged or made possible numerous additional increases in efficiency, a number of which have been described above. Beginning in the FY1997 budget year, federal food safety agencies began working together to develop coordinated budget submissions; they will submit a joint food safety budget for FY 1999. The proposals presented in these submissions have been examined to eliminate unnecessary duplication; the agencies have striven to propose food safety programs that capitalize on existing agency strengths and avoid programmatic and administrative redundancies. These coordinated food safety budget submissions were the first of their sort ever submitted by agencies to the Office of Management and Budget.

The FY1997 and FY1998 joint budget submissions made it clear that the U.S. federal and state food safety systems are in dire need of additional resources. The gains shown by federal and state agencies after less than one full year of increased funding make it clear that those dollars have been well spent. But a one-year funding increase will not build a system capable of resolving today's public health issues and tomorrow's challenges. USDA has a tremendous responsibility to make certain that all meat and poultry produced for domestic consumption and for export are safe. USDA must continue to be fully funded to meet this responsibility. FDA has responsibility for virtually all of the remainder of the food supply. But if FDA is to have a meaningful safety-ensuring presence, FDA needs more resources. Additionally, if FDA is to work with foreign countries that export food to the United States to ensure that those foods are produced under the same level of protection provided in the United States, FDA needs more resources. If FoodNet is to provide a truly accurate picture of the burden of foodborne disease in the entire country, then CDC and the states need more resources. Federal agencies, states, and the private sector have made good progress, but much more needs to be done—and can be done, with continued funding—to prevent the many food-related illnesses that still occur. The NFSI provides a record of accomplishment and the foundation necessary for continued growth.