

DRAFT (chemicals w/i document)— 7/22/98

FOOD SAFETY WHITE PAPER**BACKGROUND**

Over the years, the Federal government has performed a vital role in safeguarding the food supply from microbial and chemical contamination. Beginning with the passage of the federal "Food Law" in 19XX, FDA, and later other agencies such as USDA and EPA, have implemented regulatory programs directed at the production and distribution of foods so that they do not contain unsafe levels of the microbes responsible for food poisoning or pesticides, food additives, and other chemical contaminants. As a result of this comprehensive food safety program, the United States has the safest and most affordable food supply in the world.

One reason for this success is the willingness of the federal agencies to demand that the food industry meet increasingly higher standards as science reveals new threats to the safety of our diet. Moreover, USDA, FDA and EPA have historically helped to lead the way in introducing new technologies that have enabled, and will continue to allow, this country to maintain its preeminent position in feeding its citizens safe, affordable and wholesome food.

Despite this, 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 50-100 deaths.

The Clinton administration acted immediately to identify the weak points in the food safety system that had allowed these tragedies to occur, significantly increasing the 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. 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.

At the same time, the Clinton Administration and Congress moved to strengthen and streamline the regulatory programs that address chemicals in the food supply and the nation's drinking water. The Food Quality Protection Act (FQPA), unanimously passed in 1996 by both the Senate and House of Representatives, established a new, health-based standard for pesticide

residues in the diet and instituted strong new protections for infants and children. FQPA requires the reassessment of all existing pesticide residues in/on food over the next ten years, and is likely to result in many changes in pesticide use patterns and significant risk reductions over the decade. In 1996, the Safe Drinking Water Act was also reauthorized and strengthened to increase the safety of the nation's drinking water. [Finally, the Food and Drug Administration Modernization Act, passed in 1997, improved the regulation of food ? . . .] These new statutory authorities improve and make more efficient the longstanding programs to address contaminants in the food and water we consume.

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 earlier to outbreaks of foodborne illness, 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.

Similarly, the Vice President recently directed USDA and EPA to coordinate implementation of FQPA following four basic principles: use of sound science in decisions, transparency of the process and decisions, consultation with all interested stakeholders, and an appropriate transition for agriculture where regulatory action is necessary. Consultation with all interested stakeholders is to be accomplished through a number of mechanisms, including an advisory group co-chaired by USDA and EPA.

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. Working in this manner, federal agencies are realizing enhanced coordination and efficiency across the food and water safety systems. This unprecedented cooperation has also helped improve the federal government's ability to meet consumers' demands for a safer food supply. 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 source of the problem is rarely identified. Moreover, most people with diarrheal illness do not see a health care provider or have a stool specimen tested. 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.

Through NFSI, FoodNet has expanded to seven state sites that (along with CDC, FDA, and USDA labs) geographically and demographically represent the U.S. population; an eighth site will open in 1998. PulseNet, another development of the NFSI, is based on DNA fingerprinting of pathogens. PulseNet enables FDA, USDA, and over 20 state labs to quickly and accurately determine bacterial subtypes and transmit the data to a CDC computer that can match the pathogen implicated in one outbreak to outbreaks in other locales, enabling rapid tracebacks to common food vectors and removal of implicated food from the market. With continued funding, federal and state agencies will expand and upgrade FoodNet and PulseNet to ensure rapid, reliable access by agencies and states to information on foodborne disease and traceback of implicated foods.

Achievements:

FoodNet identified *Campylobacter* as the most common cause of foodborne disease, and *Listeria* as causing the highest hospitalization rate and almost half all deaths.

In view of epidemiological data on 1997 outbreaks, Guatemala agreed to not export raspberries to the United States in 1998. As a result, no illnesses have been attributed to *Cyclospora* and berry consumption in the United States in 1998 (compared to about 1,000 illnesses by this time last year). Canada is importing Guatemalan berries and is experiencing clusters of cyclosporiasis (with evidence linking raspberries to the outbreaks). Through NFSI, FDA, CDC, and USDA are providing technical assistance to Guatemala.

PulseNet made possible the quick identification (and quick resolution through tracebacks) of several multi-state outbreaks: alfalfa sprouts from Michigan; mesclun lettuce mix from STATE; cheese curds from Wisconsin; ground beef outbreaks from New York, Georgia, Virginia, Colorado (among others); and toasted oat cereal from Minnesota.

The National Antibiotic Resistance Monitoring System (NARMS), a joint effort of FDA, CDC, USDA/ARS and USDA/APHIS, identified and quickly stopped an outbreak of multiple-drug-resistant *Salmonella* Typhimurium DT104 in a Vermont dairy farm family. NARMS subsequently concluded that DT104 was more widespread than previously thought, prompting a nationwide warning to state health departments.

Frozen ground beef patties were associated with illnesses on several occasions in 1997 and 1998. USDA in response increased the number of samples tested and is identifying more contaminated

product which is being removed from commerce.

- USDA, FDA, and EPA cooperate on analytical methods for the surveillance of pesticide residues, and the agencies, with the food industry, have developed a standard pesticide residue tracking system.

Proposed surveillance system advances:

To be developed.

Science-based Inspections and Prevention

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.

Prevention strategies are also being applied to the management of chemicals in the food supply. In 1993, the Clinton Administration announced that reducing the use and risk of pesticides was a high priority. As a part of that policy, the Administration established a goal that 75% of all U.S. cropland would adopt Integrated Pest Management (IPM) before the year 2000. FQPA also requires research and education programs to support IPM, and directs federal agencies to use IPM techniques when controlling pests and to promote IPM through procurement and regulatory policies and other activities.

Achievements:

HACCP is becoming standard practice in the meat, poultry, and seafood industries: Almost 7,000 federal and state inspectors and seafood industry officials will have been trained in HACCP, and all seafood processors will have been inspected to verify proper use of HACCP, by year's end; over 1,000 federal and state regulatory and over 2,000 meat and poultry inspectors will have been trained in HACCP, and 312 meat and poultry plants will have implemented HACCP, by year's end. In addition, by the year 2000, USDA will have implemented HACCP in over 6,000 meat

and poultry plants.

Mandatory warning labels on packaged juices not treated to reduce or eliminate harmful pathogens will be required beginning in the Fall 1998 apple cider season in order to alert consumers, particularly to vulnerable groups such as children, to possible public health risks. FDA has proposed mandatory use of HACCP in all juice manufacturing to prevent contamination.

- EPA and USDA are working together to achieve the goal of 75% of U.S. cropland using IPM practices. As part of this effort, EPA initiated the Pesticide Environmental Stewardship Program (PESP) to partner with user groups to reduce the risk of pesticide use, often through reliance on biological pesticides and IPM strategies. USDA, in cooperation with EPA, is conducting research and education programs to support the adoption of IPM [may be more on USDA's IPM program].
- FDA, USDA and EPA cooperate to deter illegal uses of pesticides. When FDA and USDA find illegal pesticide residues in/on food, they refer the information to EPA for follow up and enforcement. When EPA or the states find pesticide products being used illegally, they notify USDA if poultry or meat are involved and FDA for all other foods so that the public is protected from consumption of adulterated food.
- EPA and FDA have an MOU under which FDA conducts toxicological Good Laboratory Practice inspections for both agencies. Compliance with GLPs is important to insure the quality of data submitted for registration of pesticides used on food crops and for antimicrobials used to disinfect surfaces with which food may come in contact.

Proposed inspection system advances:

In a move to further develop a seamless inspection system, USDA is developing legislation that will integrate state meat and poultry inspection systems with the federal system and ensure that all plants meet the same standards.

FDA and USDA will develop a Memorandum of Understanding through which inspection resources are coordinated to ensure the broadest possible coverage of product and to minimize duplication.

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 develops the

methods and technologies that enable detection and control of contaminants. Research-generated data 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 multi-agency collaboration in research and risk assessment.

Better coordination of basic and applied research was one of the first goals identified in the NFSI's first year. USDA and HHS undertook a self-assessment of their microbial food safety research programs, and this project was expanded by the Office of Science and Technology Policy, which established a formal interagency working group including all agencies with food and water safety research components. This group's report is expected by mid-Summer 1998 and will be used to help plan NFSI budgets for FY 2000.

While there is a need to improve our understanding of food- and waterborne pathogens, there is also a need to improve our understanding of the potential health effects of pesticides in the diet. As a result of the National Academy of Sciences 1993 report, "Pesticides in the Diets of Infants and Children" and the enactment of the Food Quality Protection Act in 1996, EPA's pesticides research program focuses on: the development of methods to evaluate the human health effects of cumulative exposures to pesticides with similar modes of action from various sources; methods to assess aggregate exposure of multiple pesticides from various sources; methods and measurements to characterize age-related differences and activity patterns in children and other susceptible subpopulations and high exposure groups; and methods to evaluate the effects of pre- and perinatal exposure to pesticides. Data from this research will improve EPA's ability to meet the mandate of FQPA to setting a single, health-based standard for all pesticides in all foods and that provides for special protections for infants and children. This unique research program fills a critical gap and, thus, helps to ensure that the food supply is safe from all potential sources of contamination, chemical as well as microbial.

Achievements:

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, several USDA agencies, EPA, DOD, and NMFS have begun to advance microbial risk assessment science and to set priorities on research needs.

The use of new food safety products has been authorized during the NFSI's first year: including a spray for use on baby chicks to help prevent *Salmonella* contamination of poultry; chlorine dioxide disinfectant for poultry chiller water; and irradiation for red meats.

Significant advances in pathogen detection methods include: critically needed new or improved detection methods for *Cyclospora*, *Campylobacter*, *Vibrio parahaemolyticus*, and *E. coli* O157:H7 for produce and other products; a new intensive effort to develop detection methods for

drinking water pathogens.

Significant risk assessment advances include: Publication of the first quantitative microbial risk assessment (on *Salmonella* Enteritidis in eggs); this assessment is likely to be a model for all future microbial risk assessments; new efforts to develop risk assessment methods for pathogens in drinking water, including dose-response studies for Norwalk viruses and *Cryptosporidium*.

- EPA and USDA have worked together to focus AMS' Pesticide Data Program on monitoring for pesticides on food that are an important component of kids diets. USDA, EPA and HHS have cooperated on improvement of dietary information obtained in the latest NHANES study, especially for foods eaten by children; this information will improve our risk assessments.
- EPA began a targeted research program to: 1) develop new/revised human health effects test methods to improve our understanding of the effects of pesticides on infants and children and other susceptible subpopulations and high-exposure groups, and 2) develop new methods to evaluate health effects of cumulative exposures, including multiple acute exposures to pesticides and other toxic substances and mixtures of chemicals with similar modes of action.

Proposed research and risk assessment advances:

On July 4th, the President called for the creation of a national institute for food safety research to strategically plan and coordinate such research across all federal agencies, including research conducted in partnership with private sector and academic institutions. The Secretaries of USDA and HHS are to report back to the President by October 4 with a plan for the institute.

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.

Achievements:

USDA, CDC, FDA, EPA, and DOD 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 in food-related illness incidence reduction.

New standard outbreak procedures (SOPs)—developed by FORCG—are being used by federal, state, and local agencies to guide rapid information sharing, evaluation and use of epidemiological data, and traceback activities. In addition, FDA and USDA have developed traceback SOPs to use when fresh produce is implicated in an outbreak. (Fresh produce tracebacks are particularly difficult because these highly perishable foods are consumed or discarded so quickly that samples are often not available, nor do they move through the marketplace as discrete, trackable units as do prepared foods.) FDA has developed a training course on the SOPs which will be available to state food safety officials.

USDA has developed a new recall policy, in coordination with CDC and FDA, to more effectively communicate product recalls and to collaborate on product traceback.

- Early last October, USDA notified EPA of Georgia peanuts that were contaminated with residues of arsenic. The origin of the arsenic residues were believed to be from illegal use of an arsenic-containing herbicide, monosodium methanearsonic acid (MSMA). The State of Georgia responded by prosecuting the growers who were suspected of misusing MSMA. Luckily, this misuse was caught before the contaminated peanuts entered the market. Further, EPA and USDA cooperated with the State and took steps to determine if other peanuts or peanut butter contained levels of arsenic. USDA only found very low levels of arsenic in a limited number of samples. EPA determined that the levels found did not present any health concerns. EPA, USDA, and the State planned outreach efforts to deter peanut growers from any further illegal use of MSMA.
- [insert dioxin in chickens incident?]

Proposed outbreak response advances:

To be developed.

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. Education, therefore, is widely recognized as an integral part of a successful, coordinated food safety program. Truly effective 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, the federal food safety agencies through NFSI 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 campaign has begun to pay off in greater knowledge about safe food-handling practices among consumers. The partnership has also begun to bring the power of its collaborative outreach to partners and workers in the retail and food-service industries.

Achievements:

The education partnership developed the national "Fight BAC!" campaign to promote consumer use of safe food practices. More than 100 national, state, and local organizations support the "FIGHT BAC!" campaign and disseminate educational materials. These "BAC Fighters" maximize the campaign's national outreach and provide important links into thousands of communities nationwide.

Another public/private partnership, the Food Safety Training and Education Alliance for Retail, Food Service, Vending, Institutions, and Regulators, is working to meet the retail food service industry's needs for food safety materials (particularly multilingual materials) and training.

Proposed education system advances:

September is National Food Safety month. September food safety education activities include training programs for church kitchen food handlers; translation of educational materials into Hmong, Cambodian, and Laotian; seminars to educate senior citizens about their special vulnerabilities for foodborne illness and how they can prevent it; and Spanish-language training of Spanish daycare workers in safe food handling practices.

- EPA, with assistance from USDA, FDA and its advisory group, the Pesticide Program Dialogue Committee, is developing a new "right-to-know" consumer brochure for grocery store display. The brochure will inform the public about the use of pesticides on foods while emphasizing the importance of a balanced diet and by providing tips for reducing exposure. EPA will seek advice on the brochure from consumer information groups, magazine editors and other media experts, nutritionists, food producers and food retail industry representatives, and public health education organizations during the development process. EPA will also use focus groups and other research to help the Agency determine what information about chemicals in their foods is most useful to consumers and how best to communicate that information.

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, EPA, 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.

Achievements:

Grassroots meetings were held around the country with the U.S. produce industry, states, consumers, and academia to get input for the guidance document in its draft, proposal, and final draft stages.

FDA and the fresh sprout industry have formed a working group to find possible solutions to the problem of microbiological contamination of sprouts. This working group, which has members from industry, academia, and government, has written Voluntary Sprout Grower Guidelines which have been delivered to 85 firms.

- Substantial efforts have been undertaken to educate producer countries about changes in pesticide tolerances due to FQPA to avoid trade issues, to minimize the risk to U.S. consumers, and to reduce enforcement burdens for FDA.

Proposed produce safety-assurance advances:

Good agricultural/good manufacturing practices guidance for the fresh produce industry will be finalized. Promotion of and outreach about the guidance will be targeted to the domestic produce industry; technical assistance will be provided to countries exporting fresh fruits and vegetables to the United States.

Strategic Planning for the Future

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; leveraging of inspection resources; 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 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 recently submitted a joint food safety initiative 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, and get additional resources to enhance inspection activities. 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 food- and waterborne 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.

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Proposed surveillance system advances:

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Achievements:

HACCP is becoming standard practice in the meat, poultry, and seafood industries: Almost 7,000 federal and state inspectors and seafood industry officials will have been trained in HACCP, and all seafood processors will have been inspected to verify proper use of HACCP, by year's end; over 1,000 federal and state regulatory and over 2,000 meat and poultry inspectors will have been trained in HACCP, and 312 meat and poultry plants will have implemented HACCP, by year's end. In addition, by the year 2000, USDA will have implemented HACCP in over 6,000 meat

and poultry plants.

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Proposed inspection system advances:

In a move to further develop a seamless inspection system, USDA is developing legislation that will integrate state meat and poultry inspection systems with the federal system and ensure that all plants meet the same standards.

FDA and USDA will develop a Memorandum of Understanding through which inspection resources are coordinated to ensure the broadest possible coverage of product and to minimize duplication.

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 develops the

methods and technologies that enable detection and control of contaminants. Research-generated data 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 multi-agency collaboration in research and risk assessment.

Better coordination of basic and applied research was one of the first goals identified in the NFSI's first year. USDA and HHS undertook a self-assessment of their microbial food safety research programs, and this project was expanded by the Office of Science and Technology Policy, which established a formal interagency working group including all agencies with food and water safety research components. This group's report is expected by mid-Summer 1998 and will be used to help plan NFSI budgets for FY 2000.

While there is a need to improve our understanding of food- and waterborne pathogens, there is also a need to improve our understanding of the potential health effects of pesticides in the diet. As a result of the National Academy of Sciences 1993 report, "Pesticides in the Diets of Infants and Children" and the enactment of the Food Quality Protection Act in 1996, EPA's pesticides research program focuses on: the development of methods to evaluate the human health effects of cumulative exposures to pesticides with similar modes of action from various sources; methods to assess aggregate exposure of multiple pesticides from various sources; methods and measurements to characterize age-related differences and activity patterns in children and other susceptible subpopulations and high exposure groups; and methods to evaluate the effects of pre- and perinatal exposure to pesticides. Data from this research will improve EPA's ability to meet the mandate of FQPA to setting a single, health-based standard for all pesticides in all foods and that provides for special protections for infants and children. This unique research program fills a critical gap and, thus, helps to ensure that the food supply is safe from all potential sources of contamination, chemical as well as microbial.

Achievements:

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, several USDA agencies, EPA, DOD, and NMFS have begun to advance microbial risk assessment science and to set priorities on research needs.

The use of new food safety products has been authorized during the NFSI's first year: including a spray for use on baby chicks to help prevent *Salmonella* contamination of poultry; chlorine dioxide disinfectant for poultry chiller water; and irradiation for red meats.

Significant advances in pathogen detection methods include: critically needed new or improved detection methods for *Cyclospora*, *Campylobacter*, *Vibrio parahaemolyticus*, and *E. coli* O157:H7 for produce and other products; a new intensive effort to develop detection methods for

drinking water pathogens.

Significant risk assessment advances include: Publication of the first quantitative microbial risk assessment (on *Salmonella* Enteritidis in eggs); this assessment is likely to be a model for all future microbial risk assessments; new efforts to develop risk assessment methods for pathogens in drinking water, including dose-response studies for Norwalk viruses and *Cryptosporidium*.

- EPA and USDA have worked together to focus AMS' Pesticide Data Program on monitoring for pesticides on food that are an important component of kids diets. USDA, EPA and HHS have cooperated on improvement of dietary information obtained in the latest NHANES study, especially for foods eaten by children; this information will improve our risk assessments.
- EPA began a targeted research program to: 1) develop new/revised human health effects test methods to improve our understanding of the effects of pesticides on infants and children and other susceptible subpopulations and high-exposure groups, and 2) develop new methods to evaluate health effects of cumulative exposures, including multiple acute exposures to pesticides and other toxic substances and mixtures of chemicals with similar modes of action.

Proposed research and risk assessment advances:

On July 4th, the President called for the creation of a national institute for food safety research to strategically plan and coordinate such research across all federal agencies, including research conducted in partnership with private sector and academic institutions. The Secretaries of USDA and HHS are to report back to the President by October 4 with a plan for the institute.

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.

Achievements:

USDA, CDC, FDA, EPA, and DOD 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 in food-related illness incidence reduction.

New standard outbreak procedures (SOPs)—developed by FORCG—are being used by federal, state, and local agencies to guide rapid information sharing, evaluation and use of epidemiological data, and traceback activities. In addition, FDA and USDA have developed traceback SOPs to use when fresh produce is implicated in an outbreak. (Fresh produce tracebacks are particularly difficult because these highly perishable foods are consumed or discarded so quickly that samples are often not available, nor do they move through the marketplace as discrete, trackable units as do prepared foods.) FDA has developed a training course on the SOPs which will be available to state food safety officials.

USDA has developed a new recall policy, in coordination with CDC and FDA, to more effectively communicate product recalls and to collaborate on product traceback.

- Early last October, USDA notified EPA of Georgia peanuts that were contaminated with residues of arsenic. The origin of the arsenic residues were believed to be from illegal use of an arsenic-containing herbicide, monosodium methanearsonic acid (MSMA). The State of Georgia responded by prosecuting the growers who were suspected of misusing MSMA. Luckily, this misuse was caught before the contaminated peanuts entered the market. Further, EPA and USDA cooperated with the State and took steps to determine if other peanuts or peanut butter contained levels of arsenic. USDA only found very low levels of arsenic in a limited number of samples. EPA determined that the levels found did not present any health concerns. EPA, USDA, and the State planned outreach efforts to deter peanut growers from any further illegal use of MSMA.

- [insert dioxin in chickens incident?]

Proposed outbreak response advances:

To be developed.

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. Education, therefore, is widely recognized as an integral part of a successful, coordinated food safety program. Truly effective 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, the federal food safety agencies through NFSI 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 campaign has begun to pay off in greater knowledge about safe food-handling practices among consumers. The partnership has also begun to bring the power of its collaborative outreach to partners and workers in the retail and food-service industries.

Achievements:

The education partnership developed the national "Fight BAC!" campaign to promote consumer use of safe food practices. More than 100 national, state, and local organizations support the "FIGHT BAC!" campaign and disseminate educational materials. These "BAC Fighters" maximize the campaign's national outreach and provide important links into thousands of communities nationwide.

Another public/private partnership, the Food Safety Training and Education Alliance for Retail, Food Service, Vending, Institutions, and Regulators, is working to meet the retail food service industry's needs for food safety materials (particularly multilingual materials) and training.

Proposed education system advances:

September is National Food Safety month. September food safety education activities include training programs for church kitchen food handlers; translation of educational materials into Hmong, Cambodian, and Laotian; seminars to educate senior citizens about their special vulnerabilities for foodborne illness and how they can prevent it; and Spanish-language training of Spanish daycare workers in safe food handling practices.

- EPA, with assistance from USDA, FDA and its advisory group, the Pesticide Program Dialogue Committee, is developing a new "right-to-know" consumer brochure for grocery store display. The brochure will inform the public about the use of pesticides on foods while emphasizing the importance of a balanced diet and by providing tips for reducing exposure. EPA will seek advice on the brochure from consumer information groups, magazine editors and other media experts, nutritionists, food producers and food retail industry representatives, and public health education organizations during the development process. EPA will also use focus groups and other research to help the Agency determine what information about chemicals in their foods is most useful to consumers and how best to communicate that information.

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

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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, EPA, 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.

Achievements:

Grassroots meetings were held around the country with the U.S. produce industry, states, consumers, and academia to get input for the guidance document in its draft, proposal, and final draft stages.

FDA and the fresh sprout industry have formed a working group to find possible solutions to the problem of microbiological contamination of sprouts. This working group, which has members from industry, academia, and government, has written Voluntary Sprout Grower Guidelines which have been delivered to 85 firms.

- Substantial efforts have been undertaken to educate producer countries about changes in pesticide tolerances due to FQPA to avoid trade issues, to minimize the risk to U.S. consumers, and to reduce enforcement burdens for FDA.

Proposed produce safety-assurance advances:

Good agricultural/good manufacturing practices guidance for the fresh produce industry will be finalized. Promotion of and outreach about the guidance will be targeted to the domestic produce industry; technical assistance will be provided to countries exporting fresh fruits and vegetables to the United States.

Strategic Planning for the Future.

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; leveraging of inspection resources; 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 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 recently submitted a joint food safety initiative 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, and get additional resources to enhance inspection activities. 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 food- and waterborne 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.

DRAFT (chemicals w/ document)— 7/22/98

FOOD SAFETY WHITE PAPER

BACKGROUND

Over the years, the Federal government has performed a vital role in safeguarding the food supply from microbial and chemical contamination. Beginning with the passage of the federal "Food Law" in 19XX, FDA, and later other agencies such as USDA and EPA, have implemented regulatory programs directed at the production and distribution of foods so that they do not contain unsafe levels of the microbes responsible for food poisoning or pesticides, food additives, and other chemical contaminants. As a result of this comprehensive food safety program, the United States has the safest and most affordable food supply in the world.

One reason for this success is the willingness of the federal agencies to demand that the food industry meet increasingly higher standards as science reveals new threats to the safety of our diet. Moreover, USDA, FDA and EPA have historically helped to lead the way in introducing new technologies that have enabled, and will continue to allow, this country to maintain its preeminent position in feeding its citizens safe, affordable and wholesome food.

Despite this, 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 50-100 deaths.

The Clinton administration acted immediately to identify the weak points in the food safety system that had allowed these tragedies to occur, significantly increasing the 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. 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.

At the same time, the Clinton Administration and Congress moved to strengthen and streamline the regulatory programs that address chemicals in the food supply and the nation's drinking water. The Food Quality Protection Act (FQPA), unanimously passed in 1996 by both the Senate and House of Representatives, established a new, health-based standard for pesticide

residues in the diet and instituted strong new protections for infants and children. FQPA requires the reassessment of all existing pesticide residues in/on food over the next ten years, and is likely to result in many changes in pesticide use patterns and significant risk reductions over the decade. In 1996, the Safe Drinking Water Act was also reauthorized and strengthened to increase the safety of the nation's drinking water. [Finally, the Food and Drug Administration Modernization Act, passed in 1997, improved the regulation of food ? . . .] These new statutory authorities improve and make more efficient the longstanding programs to address contaminants in the food and water we consume.

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 earlier to outbreaks of foodborne illness, 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.

Similarly, the Vice President recently directed USDA and EPA to coordinate implementation of FQPA following four basic principles: use of sound science in decisions, transparency of the process and decisions, consultation with all interested stakeholders, and an appropriate transition for agriculture where regulatory action is necessary. Consultation with all interested stakeholders is to be accomplished through a number of mechanisms, including an advisory group co-chaired by USDA and EPA.

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. Working in this manner, federal agencies are realizing enhanced coordination and efficiency across the food and water safety systems. This unprecedented cooperation has also helped improve the federal government's ability to meet consumers' demands for a safer food supply. 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 source of the problem is rarely identified. Moreover, most people with diarrheal illness do not see a health care provider or have a stool specimen tested. 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.

Through NFSI, FoodNet has expanded to seven state sites that (along with CDC, FDA, and USDA labs) geographically and demographically represent the U.S. population; an eighth site will open in 1998. PulseNet, another development of the NFSI, is based on DNA fingerprinting of pathogens. PulseNet enables FDA, USDA, and over 20 state labs to quickly and accurately determine bacterial subtypes and transmit the data to a CDC computer that can match the pathogen implicated in one outbreak to outbreaks in other locales, enabling rapid tracebacks to common food vectors and removal of implicated food from the market. With continued funding, federal and state agencies will expand and upgrade FoodNet and PulseNet to ensure rapid, reliable access by agencies and states to information on foodborne disease and traceback of implicated foods.

Achievements:

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FDA and USDA will develop a Memorandum of Understanding through which inspection resources are coordinated to ensure the broadest possible coverage of product and to minimize duplication.

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methods and technologies that enable detection and control of contaminants. Research-generated data 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 multi-agency collaboration in research and risk assessment.

Better coordination of basic and applied research was one of the first goals identified in the NFSI's first year. USDA and HHS undertook a self-assessment of their microbial food safety research programs, and this project was expanded by the Office of Science and Technology Policy, which established a formal interagency working group including all agencies with food and water safety research components. This group's report is expected by mid-Summer 1998 and will be used to help plan NFSI budgets for FY 2000.

While there is a need to improve our understanding of food- and waterborne pathogens, there is also a need to improve our understanding of the potential health effects of pesticides in the diet. As a result of the National Academy of Sciences 1993 report, "Pesticides in the Diets of Infants and Children" and the enactment of the Food Quality Protection Act in 1996, EPA's pesticides research program focuses on: the development of methods to evaluate the human health effects of cumulative exposures to pesticides with similar modes of action from various sources; methods to assess aggregate exposure of multiple pesticides from various sources; methods and measurements to characterize age-related differences and activity patterns in children and other susceptible subpopulations and high exposure groups; and methods to evaluate the effects of pre- and perinatal exposure to pesticides. Data from this research will improve EPA's ability to meet the mandate of FQPA to setting a single, health-based standard for all pesticides in all foods and that provides for special protections for infants and children. This unique research program fills a critical gap and, thus, helps to ensure that the food supply is safe from all potential sources of contamination, chemical as well as microbial.

Achievements:

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, several USDA agencies, EPA, DOD, and NMFS have begun to advance microbial risk assessment science and to set priorities on research needs.

The use of new food safety products has been authorized during the NFSI's first year: including a spray for use on baby chicks to help prevent *Salmonella* contamination of poultry; chlorine dioxide disinfectant for poultry chiller water; and irradiation for red meats.

Significant advances in pathogen detection methods include: critically needed new or improved detection methods for *Cyclospora*, *Campylobacter*, *Vibrio parahaemolyticus*, and *E. coli* O157:H7 for produce and other products; a new intensive effort to develop detection methods for

drinking water pathogens.

Significant risk assessment advances include: Publication of the first quantitative microbial risk assessment (on *Salmonella* Enteritidis in eggs); this assessment is likely to be a model for all future microbial risk assessments; new efforts to develop risk assessment methods for pathogens in drinking water, including dose-response studies for Norwalk viruses and *Cryptosporidium*.

- EPA and USDA have worked together to focus AMS' Pesticide Data Program on monitoring for pesticides on food that are an important component of kids diets. USDA, EPA and HHS have cooperated on improvement of dietary information obtained in the latest NHANES study, especially for foods eaten by children; this information will improve our risk assessments.
- EPA began a targeted research program to: 1) develop new/revised human health effects test methods to improve our understanding of the effects of pesticides on infants and children and other susceptible subpopulations and high-exposure groups, and 2) develop new methods to evaluate health effects of cumulative exposures, including multiple acute exposures to pesticides and other toxic substances and mixtures of chemicals with similar modes of action.

Proposed research and risk assessment advances:

On July 4th, the President called for the creation of a national institute for food safety research to strategically plan and coordinate such research across all federal agencies, including research conducted in partnership with private sector and academic institutions. The Secretaries of USDA and HHS are to report back to the President by October 4 with a plan for the institute.

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.

Achievements:

USDA, CDC, FDA, EPA, and DOD 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 in food-related illness incidence reduction.

New standard outbreak procedures (SOPs)—developed by FORCG—are being used by federal, state, and local agencies to guide rapid information sharing, evaluation and use of epidemiological data, and traceback activities. In addition, FDA and USDA have developed traceback SOPs to use when fresh produce is implicated in an outbreak. (Fresh produce tracebacks are particularly difficult because these highly perishable foods are consumed or discarded so quickly that samples are often not available, nor do they move through the marketplace as discrete, trackable units as do prepared foods.) FDA has developed a training course on the SOPs which will be available to state food safety officials.

USDA has developed a new recall policy, in coordination with CDC and FDA, to more effectively communicate product recalls and to collaborate on product traceback.

- Early last October, USDA notified EPA of Georgia peanuts that were contaminated with residues of arsenic. The origin of the arsenic residues were believed to be from illegal use of an arsenic-containing herbicide, monosodium methanearsonic acid (MSMA). The State of Georgia responded by prosecuting the growers who were suspected of misusing MSMA. Luckily, this misuse was caught before the contaminated peanuts entered the market. Further, EPA and USDA cooperated with the State and took steps to determine if other peanuts or peanut butter contained levels of arsenic. USDA only found very low levels of arsenic in a limited number of samples. EPA determined that the levels found did not present any health concerns. EPA, USDA, and the State planned outreach efforts to deter peanut growers from any further illegal use of MSMA.
- [insert dioxin in chickens incident?]

Proposed outbreak response advances:

To be developed.

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. Education, therefore, is widely recognized as an integral part of a successful, coordinated food safety program. Truly effective 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, the federal food safety agencies through NFSI 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 campaign has begun to pay off in greater knowledge about safe food-handling practices among consumers. The partnership has also begun to bring the power of its collaborative outreach to partners and workers in the retail and food-service industries.

Achievements:

The education partnership developed the national "Fight BAC!" campaign to promote consumer use of safe food practices. More than 100 national, state, and local organizations support the "FIGHT BAC!" campaign and disseminate educational materials. These "BAC Fighters" maximize the campaign's national outreach and provide important links into thousands of communities nationwide.

Another public/private partnership, the Food Safety Training and Education Alliance for Retail, Food Service, Vending, Institutions, and Regulators, is working to meet the retail food service industry's needs for food safety materials (particularly multilingual materials) and training.

Proposed education system advances:

September is National Food Safety month. September food safety education activities include training programs for church kitchen food handlers; translation of educational materials into Hmong, Cambodian, and Laotian; seminars to educate senior citizens about their special vulnerabilities for foodborne illness and how they can prevent it; and Spanish-language training of Spanish daycare workers in safe food handling practices.

- EPA, with assistance from USDA, FDA and its advisory group, the Pesticide Program Dialogue Committee, is developing a new "right-to-know" consumer brochure for grocery store display. The brochure will inform the public about the use of pesticides on foods while emphasizing the importance of a balanced diet and by providing tips for reducing exposure. EPA will seek advice on the brochure from consumer information groups, magazine editors and other media experts, nutritionists, food producers and food retail industry representatives, and public health education organizations during the development process. EPA will also use focus groups and other research to help the Agency determine what information about chemicals in their foods is most useful to consumers and how best to communicate that information.

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, EPA, 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.

Achievements:

Grassroots meetings were held around the country with the U.S. produce industry, states, consumers, and academia to get input for the guidance document in its draft, proposal, and final draft stages.

FDA and the fresh sprout industry have formed a working group to find possible solutions to the problem of microbiological contamination of sprouts. This working group, which has members from industry, academia, and government, has written Voluntary Sprout Grower Guidelines which have been delivered to 85 firms.

- Substantial efforts have been undertaken to educate producer countries about changes in pesticide tolerances due to FQPA to avoid trade issues, to minimize the risk to U.S. consumers, and to reduce enforcement burdens for FDA.

Proposed produce safety-assurance advances:

Good agricultural/good manufacturing practices guidance for the fresh produce industry will be finalized. Promotion of and outreach about the guidance will be targeted to the domestic produce industry; technical assistance will be provided to countries exporting fresh fruits and vegetables to the United States.

Strategic Planning for the Future

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; leveraging of inspection resources; 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 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 recently submitted a joint food safety initiative 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, and get additional resources to enhance inspection activities. 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 food- and waterborne 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.