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

cc: Laura Emmett/WHO/EOP
Subject: Draft council reponse to NAS report

EXSUM.220 NASRevised.doc Attached are the draft executive summary and full response to the NAS report. On the crucial question of single food agency the executive summary reads: "The Council supports the goal of **NAS recommendation IIIa**. Here, the NAS calls for a new statute that establishes a unified framework for food safety programs with a single official with control over all federal food safety resources. The report acknowledges that there may be many organizational approaches to achieving the goal of a "single voice" for federal food safety activities. As recommended by the NAS, the Council will conduct an assessment of structural models that would strengthen the federal food safety system through better coordination, planning, and resource allocation."

You should meet with Neal Lane this week to agree on strategy for next steps. Also, I am sending you a draft plan for moving responsibilities around and where the relevant players would stand on it.

Council on Food Safety
Assessment of the NAS Report
Ensuring Safe Food from Production to Consumption

Americans have one of the world's safest food supplies. This is largely a result of sustained education and research efforts along the farm to table continuum as well as surveillance and regulatory programs. The federal food safety system is comprised of 12 agencies, is authorized by a diverse set of statutes, and is supported by numerous key partnerships with state, local, and tribal governments. Together these agencies have created a system that has given U.S. consumers confidence in the safety of their food purchases.

As good as the nation's food safety system is, it must improved. Illnesses and deaths due to contaminated food continue to cause considerable human suffering and economic loss. That is why, at the very beginning of his first term, President Clinton set a course to strengthen the nation's food safety system. Under the President's leadership, surveillance and research have dramatically increased, programs are better coordinated, and regulations are more science-based. But this is only the beginning. The Council on Food Safety, with the help of the public, will continue to identify problems and promote solutions.

The Council welcomes the input provided by the National Academy of Sciences in its August 1998 report *Ensuring Safe Food From Production to Consumption.* This report lays out a clear rationale for a national food safety plan, one that is based on science and risk.

· The Council supports **NAS recommendation I**, which states that the food safety system should be based on science. In this assessment of the NAS report, the Council provides numerous examples of where this is already the case and examples of areas that need to be strengthened.

· The Council supports **NAS recommendation IIa**, which calls for federal statutes to be based on scientifically supportable assessments of risk to public health. In this regard, the Council will conduct a thorough review of existing statutes and determine what can be accomplished with existing regulatory flexibility and what improvements will require statutory changes.

· The Council supports **NAS recommendation IIb**, which calls for the production of a comprehensive national food safety plan. In fact, the development of such a plan is already well underway and one of the primary functions of the Council as specified in Executive Order 13100. A key component of the plan will be a comparative risk assessment of the nation's food supply.

· The Council supports the goal of **NAS recommendation IIIa**. Here, the NAS calls

for a new statute that establishes a unified framework for food safety programs with a single official with control over all federal food safety resources. The report acknowledges that there may be many organizational approaches to achieving the goal of a "single voice" for federal food safety activities. As recommended by the NAS, the Council will conduct an assessment of structural models that would strengthen the federal food safety system through better coordination, planning, and resource allocation.

The Council supports **NAS recommendation IIIb**. This recommendation argues that agencies should have the legal partnering tools needed to unify their efforts with state and local governments. Fortunately, federal food safety agencies already have many of the tools identified by the NAS and have used them to establish extensive partnerships with state, tribal, and local governments. However, some tools are missing and much more needs to be done to better coordinate the federal government's interactions with other levels of government. As part of the Council's strategic plan, the National Integrated Food Safety System project will identify barriers to effective partnering and recommend ways to overcome them.

Ensuring Safe Food from Production to Consumption

At the request of Congress, the National Academy of Sciences (NAS) conducted a study of the current food safety system to: (1) determine the scientific basis of an effective food safety system; (2) assess the effectiveness of the current system; (3) identify scientific and organizational needs and gaps at the federal level; and (4) provide recommendations on scientific and organizational changes needed to ensure an effective food safety system. To conduct this study, the NAS established a committee and obtained input from federal agencies and other stakeholders of the federal food safety system. The NAS issued its report on August 20, 1998.

On August 25, 1998, through Executive Order 13100, the President established the Council and charged it to develop a comprehensive strategic plan for federal food safety activities and to make recommendations to the President on how to implement the plan. Also on August 25, 1998, the President issued a directive tasking the Council to provide him with an assessment of the NAS report in 180 days. Specifically, the President directed:

"...the Council to review and respond to this report as one of its first orders of business. After providing opportunity for public comment, including public meetings, the Council shall report back to me within 180 days with its views on the NAS=ðs recommendations. In developing its report, the Council should take into account the comprehensive strategic federal food safety plan that it will be developing.Ü

In response to the PresidentÕ s directive, the Council established a task force consisting of representatives from the following departments and agencies: OSTP, HHS, USDA, EPA, OMB, and DOC. The task force benefited from valuable input obtained at four public meetings (Arlington, VA; Sacramento, CA; Chicago, IL; and Dallas, TX) and from public comment dockets maintained by EPA, FSIS, and FDA.

In general, the Council finds the NAS report a constructive contribution to its efforts to improve the effectiveness of the federal food safety system through strengthening science and risk assessment, strategic planning, and better federal integration with state and local governments. In particular, the NAS places appropriate weight throughout its report on applying science to the management of government food safety efforts. The Council believes that science based food safety surveillance and inspection are very important elements of the nation's food safety system.

The NAS report also recommends that the nation's food safety system should be based on risk. The Council agrees with the report's thesis that a food safety system that includes regulation, research and development, education, inspection and enforcement, and surveillance should be based on science and should use various risk analyses including quantitative and qualitative risk assessments and risk management principles to achieve such a system.

The Council recognizes that a food safety system comprised of 12 agencies with differing missions and statutory authority may increase thc potential for uneven adoption and inconsistent application of regulatory philosophies based on science. However, the Council believes that through implementation of its strategic plan (including its assessment of existing statutes and structure) the potential for uneven adoption and inconsistent application among federal agencies will be reduced. The Council is committed to identifying further improvements that would result in a seamless science-based food safety system.

Recommendation I

Base the food safety system on science.

The NAS report notes that the United States has enjoyed notable successes in improving food safety and that with increasing knowledge, many rational, science-based regulatory philosophies have been adopted. The report suggests, however, that adoption of these regulatory philosophies has been uneven and difficult to ensure given the fragmentation of food safety activities, and the differing missions of the various agencies responsible for specific components of food safety. The greatest strides in ensuring food safety from production to consumption, the NAS argued, can be made through a scientific, risk-based system that ensures surveillance, regulatory, research, educational resources are allocated to maximize effectiveness.

Council Assessment

The Council strongly endorses this recommendation. Many federal food safety programs are already, or are being modified to be science-based. The Council recognizes that scientifically robust programs will result in better identification of public health needs, determination of the most effective means of reducing public health risk including the most cost-effective opportunities for improvement, and priority setting.

The scientific information generated through surveillance, research, and risk assessment efforts will result in improved food safety only if there is a commensurate strong effort to translate that scientific information into practical, usable information at the working level, e.g., through guidance or education. This means there must be education for all those involved in producing, manufacturing, transporting, and preparing food as well as for those persons involved in government food safety regulatory activities.

The Council's goal is to ensure that science and risk based decision-making are central to the Administration's on-going efforts and its strategic plan. Fortunately, considerable improvements have been made over the past several years. The strong scientific underpinnings of the President's Food Safety Initiative, enactment of the Food Quality Protection Act (FQPA), restructuring of food safety agencies within USDA, and many individual agency activities, such as implementation of HACCP programs for meat, poultry, and seafood, have strengthened the overall science base of the food safety system.

The Council believes that the necessary elements of a science-based program—surveillance, outbreak response, risk assessment, research, inspection, and education of stakeholders—are largely in place, and that improvements planned for the next 5-10 years will enhance food safety. Specifically, the Council will consider in its strategic plan the following elements of a science-based food safety system:

Surveillance. Food safety agencies will continue to develop more effective ways to achieve surveillance goals and to monitor the safety of the food supply. Although FoodNet (foodborne outbreak monitoring system), PulseNet (foodborne pathogen DNA fingerprinting system), and the National Antibiotic Resistance Monitoring System (NARMS) provide information never before available in the United States on foodborne illnesses and the occurrence of antibiotic resistant pathogens, enhanced quantitative data on the entire range of infectious and non-infectious foodborne hazards will require additional efforts.

Risk assessment. Risk assessment is a valuable tool for setting priorities, allocation of resources, and regulatory decision-making. The development of a comparative risk assessment for hazards in the food supply will be an important aspect of both strategic planning and budgeting. As currently done for chemical hazards such as pesticide residues, the federal government needs to create and use a national microbial risk assessment capability as a means of identifying hazards and quantifying risk and assist in creating similar capacities internationally. EPA will use risk assessment to determine acceptable levels of pesticides residues. Under FQPA, this approach has been strengthened to further protect all consumers, and especially children, from the risks of pesticides in their

diet.

Through the Joint Institute for Food Safety Research, a research infrastructure has been established to improve and coordinate food safety research activities across the federal government. The Institute will continue a critical review of the federally supported food safety research that was begun through the National Science and Technology Council. Future goals in the area of research include: coordination of research planning, budget development, and prioritization; scientific support of food safety guidance, policy, and regulation; enhanced communication and links among federal agencies; and enhanced communication and links with industry and academic partners through use of public-private partnerships and technology transfer mechanisms.

Education. Food safety agencies will expand science-based education and training programs for producers, processors, distributors, food service workers, and consumers as well as those involved in regulatory activities. It is essential to include in these programs new scientific information on foodborne hazards and their control and effective food safety management strategies.

Inspection/Preventive Controls. USDA and FDA will further improve and evaluate the effectiveness of inspections of domestically and internationally produced food and will continue to develop and implement science-based preventive controls such as HACCP systems and the Good Agricultural Practices. Where necessary, regulatory requirements will be established, such as additional performance standards for pathogen reduction that can be developed as more monitoring and surveillance data become available.

Registrations and Tolerance Setting. EPA will use risk analysisCôincluding quantitative and qualitative risk assessment and risk management principlesCôto determine acceptable levels of pesticides residues. Under FQPA, this approach has been strengthened to further protect all consumer, and especially children, from the risks of pesticides in their diet. ÑConsistency of Science-Based Standards. USDA, FDA, and EPA will work toward clear food safety standards nationally and internationally. The Conference for Food Production brings together all 50 states for purposes of regulating retail establishments, and the Food Code is gaining wider adoption among the states. Internationally, the Codex Alimentarius Commission (CAC) is the primary mechanism through which these activities will take place. U.S. food safety agencies should also become more active in providing technical assistance to developing countries.

Private Sector Incentives. The federal and state regulatory agencies will work with the private sector to develop new technologies to further food safety and to encourage commercial scale-up applicable in large and small companies, and industry adoption. A research effort with industry, consumer, academic, and government participation could develop new technologies and evaluate them.

Evaluation. Evaluating the effectiveness of science based regulatory programs continues to be critical. For example, Salmonella data from the first year of HACCP implementation in poultry facilities show a trend toward fewer contaminated products. Also, by providing important information on trends in the incidence of infections with foodborne pathogens, FoodNet assists in the evaluation of the effect of preventive controls. The effect of preventive controls implemented by the dairy industry on the reduction in the number of cases of listeriosis was readily apparent in a CDC-conducted case-control study that was a forerunner of FoodNet.

Scientific Challenges

The Council faces a number of challenges in improving the scientific basis of the food safety system. A general

challenge is that while food safety agencies must be guided primarily by science, the agencies must also consider other factors such as technical limitations, statutory mandates, policy considerations, budget constraints, practicality, and consumer assurances and societal preferences. Science must be advanced within the context of these competing interests. The following are a few examples of actions that would strengthen the scientific underpinnings of federal food safety efforts:

Emerging new pathogens, changing food habits, a global food supply, and a changing population require new data that are difficult to predict and obtain in a timely way. An example is the impact of E. coli O157:H7, which was unknown as a foodborne pathogen 20 years ago, but has been responsible for major outbreaks of foodborne illness in recent years.

Gaps exist in our knowledge of microbial pathogens and in our ability to measure their impact on human health. For example, there are gaps in knowledge about the pathogens associated with fresh fruits and vegetables and the routes of contamination.

Assessment of cumulative risk from multiple sources presents a major scientific challenge. Implementation of the new FQPA standards for pesticide residues requires EPA to assess aggregate risk from food, water, and residential exposure as well as cumulative risk from multiple pesticides.

Gaps exist in our knowledge of monitoring and detection of food contaminants. For example, our current knowledge is insufficient to detect and monitor the presence of non-indigenous pathogens or unapproved pesticides on food.

Gaps exist in our knowledge of effective interventions, prevention, and alternatives that minimize contamination of food. For example, the existing level of knowledge is insufficient to develop on-farm preventive controls and systems of testing. With the advent of FQPA, more research is also needed to develop safer pesticide alternatives or crop production techniques in order to ease the transition from older pest control techniques to newer, safer ones.
Insufficient data exist on the entire range of infectious and non-infectious foodborne hazards. Even with the improvements made through FoodNet and PulseNet, enhancement of quantitative data on the entire range of infectious and non-infectious foodborne hazards will strengthen monitoring and surveillance programs for prevention, early identification, and prediction of emerging food safety problems.

Recommendation IIa

Congress should change federal statutes so that inspection, enforcement, and research efforts can be based on scientifically supportable assessments of risks to public health.

The report identifies a need for a "national food law that is clear, rational, and comprehensive, as well as scientifically based on risk" as a major component of a model food safety system. The report concludes it is necessary to revise the current statutes on food safety to create a comprehensive national food law under which:

Inspection, enforcement, and research efforts can be based on a scientifically supportable assessment of risks to public health. This means eliminating the continuous inspection system for meat and poultry and replacing it with a science-based approach that is capable of detecting hazards of concern.

There is a single set of flexible science-based regulations for all foods that allows resources to be assigned based on risk, that permits coordination of federal and state resources, and that makes it possible to address all risks from farm to table.

All imported foods come only from countries with food safety standards equivalent to U.S. standards.

The NAS report states that the lawsCðparticularly what the report characterizes as the requirement that there be continuous inspection of meat and poultry production through sight, smell, and touch (Aðorganoleptic@ð) inspectionCðcreate inefficiencies, do not allow resource use to reflect the risks involved, and inhibit the use of scientific decision-making in activities related to food safety, including the monitoring of imported food.

Council Assessment

The report's recommendation that federal statutes provide agencies with authority to make decisions based on scientific assessments of risks to the public health is sound. Decisions based on public health risk assessments allow agencies to make effective use of science to set food safety priorities, allocate resources to higher risk areas, and instill consumer confidence that high-risk hazards are being addressed.

Since the federal food safety regulatory agencies operate under very different legislative authorities, the Council will conduct a full assessment of these statutes and evaluate the degree of regulatory flexibility that already exists. Therefore, the Council recommends that a legislative review be undertaken as part of the strategic planning process. The purpose of the review would be to: 1) examine the similarities and differences in federal food safety statutes; 2) identify the "best" statutory approaches for reducing foodborne illness; and 3) assess both gaps and statutory barriers to implementation of the plan. The need for statutory changes could then be determined, and, if necessary, legislative principles developed which would form the basis for discussions with stakeholders and Congress. For example, given the recent overhaul of pesticide legislation, the Council believes that further statutory changes may not be needed for pesticides at this time.

In some cases, the NAS report overstates the problem with existing statutory requirements. For example, the report concludes that the statutes require the current method of organoleptic inspection of all carcasses. Even though the current law requires continuous inspection, it does not specify how this inspection mandate is to be carried out. The statutes do require appropriate examination of animals prior to slaughter and examination post-slaughter at all official slaughter and processing facilities. This continuous inspection requirement for animals is important to ensure use of the best sanitary dressing processes, prevention of fecal contamination (which harbors the pathogens that cause disease), reduction in the incidence of disease-causing pathogens, and prevention of meat from diseased animals from entering the food supply. Inspection of all animals and carcasses also serves to protect the public from diseases and other hazards to human health. Europe's experience with Bovine Spongiform Encepha lopathy (BSE) should serve as a reminder that wholesale elimination of inspection of all animals and carcasses is not the most prudent course of action.

USDA has the flexibility to create, and in fact has begun to develop and test, a more risk based inspection system by adopting regulations requiring that HACCP be implemented in all slaughter and processing plants. USDA is also studying how best to effect further inspection improvements in the future.

The food safety agencies have achieved and can continue to accomplish significant science-based improvements in their food safety programs under current authorities. However, new authorities that would improve the federal food safety system have been proposed by the President and are waiting action by Congress or have been

identified and are in need of Executive branch clearance before a formal legislative proposal can be advanced for congressional consideration. Further analysis of the statutes may result in additional proposed statutory modifications.

Current Legislative Challenges

Congress should pass:

the Food Safety Enforcement Enhancement Act, forwarded by the Clinton Administration and introduced during the last Congress that increases the enforcement capabilities of USDA; and
legislation that gives FDA increased authority to effectively assure the safety of food imports.

The Administration should also explore areas where regulatory jurisdiction is split between agencies or where resources could be more effectively shared between agencies. Examples include:

- developing a legislative proposal to improve the current system for the regulation of eggs and egg products;
- modifying statutes to permit FSIS inspectors not only to report their findings to FDA but actually to perform inspections and enforcement for that agency to increase interagency efficiencies; and
- developing a legislative proposal giving FSIS explicit authority to enter into cooperative agreements for food safety risk assessment.

Recommendation IIb

Congress and the Administration should require development of a comprehensive national food safety plan. Funds appropriated for food safety programs (including research and education programs) should be allocated in accordance with science-based assessments of risk and potential benefit.

This recommendation contains two parts. The first part recommends that Congress and the Administration require preparation of a comprehensive, national food safety plan. The NAS report lists several essential features of such a plan, including a unified food safety mission; integrated federal, state and local activities; adequate support for research and surveillance; and increased efforts to ensure the safety of imported foods. The second part of the recommendation stresses that resources should be allocated on the basis of science-based assessments of risk and potential benefits.

Council Assessment

The Council agrees that a comprehensive national food safety strategic plan should be developed and the development of such a plan is underway. In fact, the President's Food Safety Initiative was an initial step toward a national food safety plan. The 1997 Farm to Table report was a means of leveraging federal food safety resources through coordinated planning and cooperative work to meet common needs such as development of surveillance data, response to outbreaks, research into preventive interventions, development of risk assessment techniques particularly for microbial risk assessments, and consumer education. This initial plan also took some steps toward extending food safety planning to the state and local level.

Strategic Planning

Picking up where Farm to Table report left off, the Council will continue and expand the strategic planning process. One of the Council's primary purposes is to develop a comprehensive strategic plan for federal food safety activities that contains specific recommendations on needed changes, including goals with measurable outcomes. The plan's principal goal is to enhance the safety of the nation's food supply and protect public health through a seamless science- and risk-based food safety system. The plan will set priorities, improve coordination and efficiency, identify gaps in the current system and mechanisms to fill those gaps, continue to enhance and strengthen prevention strategies, and develop performance measures to show progress.

Preparation of the food safety strategic plan will be a public process, and will consider both short- and long-term issues including new and emerging threats and the special needs of vulnerable populations such as children and the elderly. Once the plan is sufficiently complete, the Council will advise agencies of priorities for investing in food safety and ensure that federal agencies annually submit coordinated food safety budgets to OMB to sustain and strengthen existing capacities. In short, the President's Council on Food Safety will develop a national food safety plan and make budget recommendations to accomplish what the NAS report recommends.

The Council has defined the scope of future federal level food safety strategic planning and a process for interagency planning and public participation. An interagency task force anticipates having a draft plan ready for public review and discussion in January 2000. Even while developing this plan, the task force intends to continue its consultations with stakeholders. The following is the draft vision statement for the Council's strategic plan:

"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 subpopulations. We use science- and risk-based approaches along with public/private partnerships. Food is safe because everyone understands and accepts their responsibilities."

The President's Council on Food Safety held four public meetings in the Fall of 1998 in Arlington, VA; Sacramento, CA; Chicago, IL; and Dallas, TX to solicit comments on this draft vision for food safety and to identify a strategic planning process, goals and critical steps as well as potential barriers to achieving that vision.

The Council's strategic planning task force is analyzing the transcripts of the 1998 public meetings and the input received through the notice and comment process to determine the major themes, issues, and subject areas. The task force will also consider the conclusions and recommendations of the NAS report, input from the federal, state, and local government National Integrated Food Safety System project, and input from the agencies involved. The task force will then develop a proposed set of strategic goals and objectives and present a draft plan to the President's Council on Food Safety. Following Council review, the draft plan will be provided to the public for formal review and comment. After public comment, the task force will prepare a final plan with specific recommendations on needed changes and steps to achieve a seamless food safety system including resource needs, roles, and barriers to implementation, and submit this final plan to the Council for approval.

The planning process will build upon common ground and provide the forum to tackle some of the difficult public health, resource, and management questions facing the federal food safety agencies and our state, tribal and local government partners. The plan will identify areas for enhanced coordination and efficiencies, determine whether legislative changes would be beneficial, and clarify federal, state, and local government roles and responsibilities

in the national food safety system (see discussion under recommendation IIIb).

Allocation of Resources

The NAS report recommendation goes a step further than a national plan by urging that resources be allocated according to science-based assessments of risk and potential benefits. As stipulated in Executive Order 13100, the Council will develop annual budget recommendations consistent with the strategic plan. The Council will develop guidance for food safety agencies to consider during the preparation of their individual budgets. The Council has created a budget task force that will:

work with the strategic planning task force and review the draft and final strategic plans and Council budget guidance on priority areas for investment to identify budget data and other information that will be necessary to plan and coordinate agency budget submissions to OMB;
design a uniform format for presenting food safety initiative budget components in the OMB budget process for use in both individual agencies and the unified budget submissions;
develop necessary guidance to facilitate submission of a unified food safety initiative budget and any other food safety issues deemed appropriate by the Council;
establish a timetable for developing coordinated food safety budget requests and for submitting information to the Council that accommodates the various agencies' budget planning processes; and
consider the issue of whether to amend OMB Circular No. A-11 (OMB guidance to agencies on budget structure and reporting elements) to include food safety as a budget cross-cut.

Comparative Risk Assessment

An important part to both risk-based planning and resource allocation will be the development of a comprehensive comparative risk assessment of the food supply. The Council has requested the Interagency Food Safety Risk Assessment Consortium, which consists of EPA, FDA, CDC, and USDA, to consider how to develop a comparative risk analysis for food safety strategic planning.

The Council believes that various steps may need to be taken to evaluate risks including: a ranking of foodborne pathogen risks based on CDC surveillance and economic data; consideration of a broader range of food safety hazards including not only microbial risks, but also pesticides and chemicals; and finally selection of highly ranked hazards, an evaluation of control measures, and an evaluation of net benefits. The Council must avoid applying risk assessment that is too strict, rigorous, or inflexible. Instead, the assessment must be used to prioritize the known greatest risks at the current time, with the understanding that scientific risk estimates can, and will likely, change frequently over time.

Challenges in Planning

The Council faces the following challenges in developing a comprehensive food safety strategic plan and allocating resources based on risk:

Developing and successfully implementing a national plan will require strong cooperation, coordination, and communication, since each federal, state, and local agency has unique mandates, authorities, history, culture, and operating procedures.
The diversity of stakeholders in food safety is enormous. It will be difficult, but imperative, that all stakeholders are represented in the Council's planning process.

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Recommendation IIIa

To implement a science-based system, Congress should establish by statute a unified and central framework for managing federal food safety programs, one that is headed by a single official and which has the responsibility and control of resources for all federal food safety activities, including outbreak management, standard-setting, inspection, monitoring, surveillance, risk assessment, enforcement, research, and education.

The NAS report finds that the current regulatory structure for food safety in the United States is not well equipped to meet current challenges. Specifically, it points out that the system is facing tremendous pressures with regard to:

- emerging pathogens and ability to detect them;
- maintaining adequate inspection and monitoring of the increasing volume of imported foods, especially fruits and vegetables;
- maintaining adequate inspection of commercial food services and the increasing number of larger food processing plants; and
- the growing number of people at high risk for foodborne illnesses.

The report cites the strengths of the current food safety system, including the advent of FoodNet and PulseNet, HACCP implementation, and the Partnership for Food Safety Education. It also identifies deficiencies, which it attributes partly to "the fragmented nature of the system." The report attributes the fragmentation largely to a lack of adequate integration among the various federal agencies involved in the implementation of the primary statutes that regulate food safety, and observes that this lack of adequate integration occurs also with state and local activities. The report notes that 12 primary federal agencies are involved in key food safety functions and references more than 50 memoranda of agreement between various agencies related to food safety.

The NAS report attributes the lack of adequate integration among federal, state and local food safety authorities in part to the absence of "focused leadership" that has the responsibility, the authority and the resources to address key food safety problems. The report presents several examples of possible organizational structures to create a single federal voice for food safety. These include:

- a Food Safety Council with representatives from the agencies with a central chair appointed by the President, reporting to Congress and having control of resources;
- designating one current agency as the lead agency and having the head of that agency be the responsible individual;
- a single agency reporting to one current cabinet-level secretary; and
- an independent single agency at cabinet level.

Although the report indicates many of the NAS committee's members believe that a single, unified agency headed by a single administrator is the most viable structure for implementing the "single voice" concept, the report recognizes that there may be many other models that would be workable.

Council Assessment

The Council agrees with the goal of the NAS recommendation--that there should be a fully integrated food safety system in the U.S. The food safety agencies are committed to this goal, and the Council is confident that its comprehensive strategic plan will be a major step toward creating a seamless system. The Council will conduct, through a public process, a thorough assessment of structural and organizational options before recommending major legislative or administrative actions on reorganization. The Council will identify and analyze existing models in government for achieving mutual and truly national food safety goals. Some of these models might address structure, and some might address facilitating mechanisms.

The Council's strategic plan will bring agreement on the vision, goals, and actions needed to enhance the safety of the nation's food supply and protect public health by reducing the annual incidence of acute and chronic foodborne illness. It will also clarify the roles and responsibilities of each food safety agency as well as those of our state, tribal, and local government partners.

While the Council recognizes that certain models of reorganization may improve coordination and allow for a better allocation of resources, any reorganization of food safety activities must recognize the non-food-safety-related responsibilities of each agency and how these relate to the food safety responsibilities. Reorganization must not be done at the expense of these responsibilities and activities. The Council is concerned that, if not done carefully, separating food safety from non-food safety activities in each agency could act to weaken consumer protection overall.

The Council recognizes that expertise and knowledge, particularly expertise in state-of -the-art science and technology, provides a resource to food safety activities. For example, analytical methods for detection and quantification on economic adulterants in foods may be adapted to detection of chemical contaminants that threaten public health. Expertise in non-food safety regulatory science and legal procedures are critical when warnings are required on food labels to assure safety. In addition, reorganizations must avoid interfering with the public health framework established to identify and respond to infectious and non-infectious public health threats whether they are foodborne or not. Thus, in its strategic planning the Council will be cognizant of the interplay between the food safety and non-food safety activities of each agency and how they strengthen each other.

The Council believes that there are programs that can benefit from immediate reorganization. For example, during the last two years, FDA and NOAA have been developing a proposal to transfer the NOAA Seafood Inspection Program to FDA as a Performance Based Organization (PBO) in order to operate the voluntary Seafood Inspection Program on a more business-like basis. The PBO would be formed under the umbrella of FDA and would include all seafood inspection activities now carried out by NOAA. The fiscal year 2000 budget proposes to transfer the existing Seafood Inspection Program from NOAA to FDA. This action will fully consolidate federal seafood inspection activities within one agency thereby increasing the efficiency and effectiveness of seafood oversight. It will also enhance the overall safety and wholesomeness of seafood products. Funds are provided to cover the costs of transition, including training and education activities.

Factors to Consider in Organizational Restructuring

The Council assessment of structural and organizational options must take into consideration the following factors:

- Many food safety issues can only be dealt with through collaboration and partnerships between agencies. For example, BSE is an animal health issue and a human health issue. Foodborne disease problems are also waterborne disease problems. Salmonella enteritidis in shell eggs is not only a food safety issue but also an animal health and a marketing issue.
- Research and education programs for food safety do not operate as separate activities within the agencies, but rather draw significant strength from one another. For example, any attempt at placing "pure" food safety research and education in one agency could actually jeopardize the ability to deliver improved food safety to consumers. While some projects are entirely focused on food safety, the food safety research portfolio includes many other projects in such areas as animal health and animal genetics. Similarly, scientific expertise and endeavors should always inform regulatory activities. Each regulatory agency must have a cadre of trained and involved scientists to facilitate communications and cooperation with the research/education agencies. Thus, any restructuring must ensure continued coordination and communication between food safety programs and non-food safety functions that strengthen these programs.
- The Council should build upon existing successful partnerships. For example, CSREES FSIS, FDA, CDC and other private and governmental organizations now participate in the Partnership for Food Safety Education. This group serves to coordinate food safety educational programs among private and governmental agencies, and is a key element of the Food Safety Initiative. Yet this and other partnerships would not be possible without relying on the many effective working relationships developed among the participants over the years, including joint projects on residue control and nutrition labeling. Any reorganization needs to recognize the importance of existing partnerships.
- Food safety standards at the federal, state, local, and international levels need to be consistent. Mechanisms such as the Codex Alimentarius for international standards and the Conference for Food Protection for federal and state standards are in place to reduce inconsistency, but better integration at all levels is needed and viewed as a long-range project.

Recommendation IIIb

Congress should provide the agency responsible for food safety at the federal level with the tools necessary to integrate and unify the efforts of authorities at the state and local levels to enhance food safety.

The NAS report recommends that federal, state, and local governments function as an integrated enterprise, along with their partners in the private sector. The report identified five statutory tools required to integrate federal, state, and local food safety activities into an effective national system:

- authority to mandate adherence to minimal federal standards for products or processes;
- continued authority to deputize state and local officials to serve as enforcers of federal law;
- funding to support, in whole or in part, activities of state and local officials that are judged necessary or appropriate to enhance the safety of food;
- authority given to the Federal official responsible for food safety to direct action by other agencies with assessment and monitoring capabilities; and
- authority to convene working groups, create partnerships, and direct other forms and means of collaboration to achieve integrated protection of the food supply.

This recommendation acknowledges the "equally critical roles" of state and local government entities with those of the federal government in ensuring food safety, and suggests changes in federal authorizing and appropriating

legislation may be necessary to achieve better integration of federal, state, and local activities.

Council Assessment

The Council agrees that the roles of state, tribal, and local governments in the food safety system are critical and supports steps taken toward the development of a more fully integrated national food safety system. While more needs to be done to optimize and develop new partnerships, the federal food safety agencies have already established extensive interactions with state and local regulatory agencies. In fact, a critical factor for the Council to consider is the manner in which existing federal/state or local activities are integrated and coordinated. The Council believes that its strategic planning process provides a fresh opportunity for their non-federal partners to participate as primary and equal partners in the development of the future food safety system.

Some overlap occurs between federal and state and local food safety efforts. Neither federal food safety agencies nor state and local agencies have sufficient resources to carry out a comprehensive food safety program, but all these agencies have expertise and resources that, when combined in an integrated program, would significantly enhance the impact of food safety programs.

The Council also agrees that the five statutory tools identified by the NAS are critical to ensuring good coordination between the federal government and state and local agencies. Fortunately, the federal food safety regulatory agencies (FDA, FSIS, and EPA) already have many of the statutory tools recommended by NAS.

The Council recognizes and agrees with the report's conclusion that the lack of integration among federal, state, and local authorities often complicate the administration of regulatory programs. We need to utilize available mechanisms to leverage resources and expertise from government, industry, academia, and consumers to expand the nation's food safety capabilities beyond what any one group can accomplish. Increased awareness and knowledge of food safety in each segment of the food safety community reduces the need for extensive regulation of industry and decreases the incidence of contamination at every point in the food safety system in order to protect public health.

National Integrated Food Safety System (NIFSS) Project

HHS, USDA, and EPA are working with state and local officials in a National Integrated Food Safety System (NIFSS) project to identify the appropriate roles and to develop mutually supporting common goals for all levels of government in the U.S. food safety system. This work is considered integral to the Council's strategic plan and coordinated budget recommendations and will be the basis for improved integration with state, tribal and local governments.

Under the leadership of the FDA, the current project is proceeding under existing federal, state, and local laws although all levels of government recognize that changes in some of the federal and state laws will be necessary to achieve an integrated system. The project began with a meeting of state and local officials from public health and agriculture agencies and state laboratories representing all 50 states, Puerto Rico, and the District of Columbia, CDC and USDA in Kansas City in September 1998. In December 1998, six work groups and an 18 member Coordinating Committee composed of federal, state and local officials met in Baltimore, Maryland to begin to develop plans for implementing recommendations and overcoming the obstacles identified at the Kansas City meeting. The next meeting is planned for late winter or early spring, 1999. The group estimates that a fully integrated federal/state/local food safety system will take approximately 10 years to build. The Association of Food and Drug Officials,

which is an organization of state and local public health officials and regulators, endorses the concept of a NIFSS.

Challenges to Developing a National Integrated Food Safety System

Even though there is some uniformity between federal and state standards (e.g., standards associated with the intrastate shipment of meat or poultry), the Council recognizes the following challenges to building an integrated food safety system:

- Integrated federal, state, and local food safety systems will help build a more consistent, uniform level of safety assurance across the nation. To accomplish this, however, clear, national standards are needed, together with uniform food safety messages and enhanced training, capability, and technical assistance to meet all levels of regulatory, industry, academic, and consumer need.
- Consumers are concerned that the economic interests of industry within states may be a source of conflict if those states have an expanded food safety role that includes activities thought to be primarily a federal responsibility (e.g., firm inspections).
- Industry is concerned that food safety regulation will be inconsistent among the states if systems are integrated without adequate preparation of the state agencies to step into the expanded food safety role.
- In order for integration to work, it is crucial that state and local governments have access to high quality scientists and health care professionals. The strategic plan will explore incentives for education and training of epidemiologists, laboratory workers, public health nurses, and environmental sanitarians.

Examples of Recent Changes that Strengthen the Federal Food Safety System Scientific Base

USDA 1994 reorganization (separated public health from marketing functions)
HACCP implementation (12/97 seafood and 1/98 meat and poultry)
FQPA enactment and implementation
FoodNet/PulseNet established
FDA Fresh Produce Guidelines released
Joint Institute for Food Safety Research created
Research funding increased
Food Safety Research Database initiated
Annual Food Safety Research Conference held
Interagency Risk Assessment Consortium established
Risk Assessment Clearinghouse established

Recent Steps Taken to Create a Unified
Federal Food Safety System

1997 President's Food Safety Initiative implemented
JIFSAN/Interagency Risk Assessment Consortium created
President's Fresh Produce plan implemented
FORC-G established
President's Council on Food Safety established
Restructuring of seafood inspection proposed
Partnership for Food Safety Education created

Examples of Federal/State/Local Cooperation
Milk Sanitation Program - Pasteurized Milk Ordinance
Retail Food Safety Program - Food Code
National, Integrated Food Safety System Project
Interstate Shellfish Sanitation Program
States conduct 5,000 inspections of FDA-regulated plants
FDA maintains more than 100 state partnerships
Conference for Food Protection
FoodNet/Emerging Infections Program
PulseNet
Epidemiology and Laboratory Cooperative Agreements
Appropriate delegation of pesticide responsibility to states
Partial funding of states for implementation of some pesticide programs and for most compliance programs
State FIFRA Issues Research and Evaluation Group
State and local government involvement in FORC-G
State conducts inspections in 250 FSIS regulated plants
FSIS oversees and supports 26 state "equal to" meat and poultry inspection programs
FSIS supports animal production food safety outreach projects involving 11 states
FSIS supports animal production food safety workshops
HACCP based enhancement of state labs, computer capabilities, and state training
Partnership for Food Safety Education "Fight BAC!" campaign

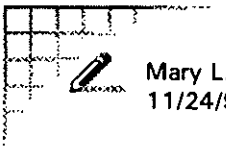
Recent Advances in Applying Scientific Assessments
Of Public Health Risks to Food Safety

HACCP implemented
FQPA tolerance reassessment based on aggregate exposure, cumulative risk, and vulnerable subpopulations.
Single, risk-based pesticide standard for food established
Tolerance setting focusing on the riskiest pesticides
Priority registration given to "safer" pesticides
Risk Assessment Consortium established
FoodNet/PulseNet established
Good Agricultural Practices guidance for fresh produce established
Unpasteurized juice warning labels required

Progress in Strategic Planning

President's 1997 Farm to Table Food Safety Initiative
President's Fresh Produce and Imported Food Safety Initiative
Establishment of the Joint Institute for Food Safety Research
Establishment of the President's Council
Input from the National Academy of Sciences, Council of Agricultural Science and Technology, and other organizations
National Integrated Food Safety System project meetings
Input from multiple public meetings

Cins pro- food safety - council



Mary L. Smith
11/24/98 09:23:54 PM

Record Type: Record

To: Elena Kagan/OPD/EOP, Bruce N. Reed/OPD/EOP, Thomas L. Freedman/OPD/EOP

cc:

Subject: Charter and Action Memos for Food Safety Council

I will send you a copy of the charter for the Food Safety Council and four decision memoranda that will be discussed at the first Council meeting, which is tentatively set for December 16. The action memos are on the following: (1) Assessment of the NAS report; (2) Process for developing a strategic plan; (3) Process for developing coordinated food safety budgets and a unified food safety initiative budget; and (4) Scope of the food safety strategic plan.

The agencies are seeking comments by November 30. If you have any comments before November 30, let me know. Thanks, Mary

United States Department of Agriculture
Food Safety and Inspection Service
Washington, D.C. 20250

SUBJECT: President's Council on Food Safety Clearance Documents

TO: See Distribution List

FROM: Joan Mondshein
Confidential Assistant to the Administrator
Food Safety and Inspection Service

20 NOV 1998

Charles Danner
Director, Planning Staff
Food Safety and Inspection Service

Attached for your final review are the most recent charter and decision memoranda (4) drafts which, when finalized, will be discussed by the President's Council on Food Safety at its first meeting in early December.

The final charter will provide general direction to the Council. Comments received on the earlier draft of this document have been incorporated in the attached version.

The decision memoranda define important food safety issues that were addressed in the President's Executive Order establishing the Council. Discussion of the issues contained in the papers and approval of the charter will form the major portion of the agenda for the first meeting.

Please review the attached documents and forward your comments to Charles Danner by COB Monday, November 30, 1998. You may telephone, fax or email your comments to:

Phone: 202-720-4745
Fax: 202-690-1742
Email: charles.danner@usda.gov

Attachments

Distribution:

Eric Olsen, USDA OSEC
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Jean Logan, NPR

(Draft 11/2)

PRESIDENT'S COUNCIL ON FOOD SAFETY
CHARTER

Article I: Purpose.

On August 25, 1998, the President, by Executive Order, No. 13100, established the President's Council on Food Safety ("Council") to improve the safety of the food supply through science-based regulation and well-coordinated inspection, enforcement, research, and education programs. The purpose of the Council is to develop and update periodically a comprehensive strategic plan for Federal food safety activities, to make recommendations to the President on how to implement the comprehensive strategy and enhance coordination among Federal agencies, State, local and tribal governments, and the private sector, to advise Federal agencies in setting priority areas for investment in food safety, to oversee research efforts of the Joint Institute for Food Safety Research, and to evaluate and make recommendations to the President on the proposals contained in the National Academy of Sciences report on food safety.

This Charter provides the basis for collaboration among the members of the Council in carrying out the responsibilities of the Council as set forth in the Executive Order.

Article II: Membership

Council membership shall comprise:

1. Secretary of Agriculture,
2. Secretary of Commerce,
3. Secretary of Health and Human Services,
4. Administrator of the Environmental Protection Agency,
5. Director of the Office of Management and Budget,
6. Assistant to the President for Science and Technology/Director of the Office of Science and Technology Policy,
7. Assistant to the President for Domestic Policy, and
8. Director of the National Partnership for Reinventing Government.

Each member may designate a senior Federal employee, subject to the approval of the co-chairs, to serve as an alternate representative to perform the duties of the Council member.

Article III: Co-Chairs

The Secretaries of Agriculture and of Health and Human Services and the Assistant to the

President for Science and Technology/Director of the Office of Science and Technology Policy, or their designated alternates, shall serve as co-chairs of the Council.

The co-chairs shall provide leadership and direction to the Council, and coordinate the formation and schedule of standing committees. Each meeting will be led by one co-chair and this responsibility shall rotate quarterly among the co-chairs.

Article IV: Staff Support Services

Staff support services for the activities of the Council will be provided by the Co-Chairs through a Secretariat, which will consist of a senior Federal employee from each of the following: the Department of Agriculture, Department of Health and Human Services, and the Office of Science and Technology. Other members may provide additional staff support services, as necessary. The Secretariat will facilitate planning, coordination, and communication among Council members.

Article V: Meetings

The Council shall meet on a quarterly basis at a time and location chosen by the co-chairs. Additional meetings may be held at the call of the co-chairs or at the request of a majority of the members.

A majority of the Council membership shall constitute a quorum for the transaction of business. All decisions made by the Council at the meetings shall be by general agreement.

The Secretariat will prepare a summary report of each meeting of the Council for distribution to the membership and make each report available for public inspection and copying and on the Council Internet web site.

The Council may prepare a report for submission to the President on October 1 of each year. The report will contain, at a minimum, a description of the Council's activities and accomplishments during the preceding fiscal year and a description of the planned activities for the coming year, and a review of strategic planning objectives and progress made toward accomplishing those objectives.

Article VI: Duties and Responsibilities

The specific responsibilities of the Council are to:

1. Develop and update periodically a comprehensive strategic Federal food safety plan ("plan") to reduce the annual incidence of acute and chronic foodborne illness by further enhancing the safety of the nation's food supply. The plan will address public health, resource, and management questions facing Federal food safety agencies and will focus on the full range of food safety issues, including the needs of regulatory agencies, and the actions necessary to ensure the safety of the food Americans use and consume. The planning process will consider both

short-term and long- term issues including new and emerging threats to the nation's food supply and the special needs of vulnerable populations such as children and the elderly. In developing this plan, the Council will take into consideration the findings and recommendations of the National Academy of Sciences report "Ensuring Safe Food from Production to Consumption" and the review of Federal food safety research by the interagency working group under the auspices of the National Science and Technology Group.

The final plan will help set priorities, improve coordination and efficiency, identify gaps in the current system and ways to fill those gaps, enhance and strengthen prevention and intervention strategies, and identify reliable measures to indicate progress.

The Council will conduct public meetings to engage consumers, producers, industry, food service providers, retailers, health professionals, State and local governments, Tribes, academia, and the public in the strategic planning process.

2. Advise Federal agencies of priority areas for investment in food safety and ensure that the member agencies develop annual coordinated food safety budgets for submission to the Office of Management and Budget (OMB) to sustain and strengthen priority activities on food safety, eliminate duplication, and ensure the most effective use of resources for achieving the goals of the plan.

3. Oversee the Joint Institute for Food Safety Research (JIFSR). The Council will evaluate the reports from JIFSR on food safety research activities and give direction to JIFSR on research needed to establish the most effective possible food safety system.

4. Evaluate and report to the President on the National Academy of Sciences (NAS) report, "Ensuring Safe Food from Production to Consumption". After providing opportunity for public comment, including public meetings, the Council will, by February 21, 1999, report to the President on the Council's response to and recommendations concerning the NAS report and appropriate additional actions to improve food safety.

Article VII: Committees

The co-chairs, after consultation with Council members, may establish committees of Council members, their alternates, or other Federal employees, as they deem necessary, to facilitate and carry out effectively the responsibilities of the Council. Such committees shall report to the Council.

The following committees shall be established by the co-chairs:

1. Strategic Planning Committee

The Committee shall develop a comprehensive strategic Federal food safety plan ("plan") that will review public health, resource and management issues facing Federal food safety agencies and will focus on the full range of issues and the actions necessary to ensure the safety of the

food Americans use and consume. The Committee will conduct public meetings to engage consumers, producers, industry, food service providers, retailers, health professionals, State and local governments, Tribes, academia, and the public in the strategic planning process. The plan will include a comprehensive strategy for the enhancement of coordination among Federal agencies, State, local and tribal governments, and the private sector on food safety issues.

The Committee will provide the plan to the Council that will help set priorities, improve coordination and efficiency, identify gaps in the current system including legal authorities, and ways to fill those gaps, and enhance and strengthen prevention and intervention techniques.

2. Budget Committee

The Committee will examine all Federal food safety related budgets to identify priority areas for investment in food safety and ensure that resources are used effectively and to eliminate duplication.

3. JIFSR Executive Research Committee

The Committee will evaluate the reports from the JIFSR on its efforts to coordinate food safety research and make recommendations to the Council regarding research needed to establish the most effective possible food safety system.

4. NAS Report Review Committee

The Committee shall prepare a response to the NAS report, after providing for public comment, and shall submit the report to the Council by January 21, 1999.

Article VIII: Web Site

The Council shall establish an Internet web site. The Department of Agriculture shall be the system owner of the web site and shall be responsible for maintaining it. The Council website will provide links to websites of federal agencies having food safety responsibilities.

Article IX: Effective Date

This Charter shall become effective on the latest date affixed below and may be modified with supplemental agreements signed by the members of the Council.

Secretary of Agriculture

Secretary of Commerce

Secretary of Health
and Human Services

Administrator of Environmental
Protection Agency

Director of Office
of Management and Budget

Assistant to the President for Science
and Technology/Director of the
Office of Science and Technology
Policy

Assistant to the President
for Domestic Policy

Director of the National Partnership
for Reinventing Government

November 16, 1998

MEMORANDUM FOR THE PRESIDENT'S COUNCIL ON FOOD SAFETY

FROM: INTERAGENCY FOOD SAFETY WORKING GROUP

SUBJECT: Assessment of NAS Report "Ensuring Safe Food from Production to Consumption"

ACTION: Approval of plan to provide the President with an assessment of the NAS Report "Ensuring Safe Food from Production to Consumption."

BACKGROUND: In the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 1998, funds were provided to the Agricultural Research Service to support the NAS to "1) determine the scientific basis of an effective food safety system, 2) assess the effectiveness of the current food safety system in the United States, 3) identify scientific needs and gaps within the current system, and 4) provide recommendations on the scientific and organizational changes in federal food safety activity needed to ensure an effective science-based food safety system."

The NAS established their study committee under the auspices of both the Institute of Medicine and the National Research Council and held three meetings (from March through June 1998) obtaining input from Federal agencies and other stakeholders of the Federal food safety system. The NAS issued their report on August 20, 1998. Attached is a summary of its findings and recommendations.

Congress viewed this study as part one of a possible two-part process. Should the NAS recommend that a single Federal food safety agency is required to achieve adequate performance and levels of public health protection, Congress planned to appropriate additional funds to support a second NAS study, which would focus on how such an agency should function. The NAS Committee did not explicitly recommend the establishment of a single Federal food safety agency, and funds for part two were not appropriated for fiscal year 1999.

On August 25, 1998, the President issued a directive tasking the Council on Food Safety to provide him with an assessment of the NAS report in 180 days (by February 21, 1999). Specifically, the President directed:

> "...the Council to review and respond to this report as one of its first orders of business. After providing opportunity for public comment, including public

meetings, the Council shall report back to me within 180 days with its views on the NAS's recommendations. In developing its report, the council should take into account the comprehensive strategic Federal food safety plan that it will be developing."

Four public meeting have been scheduled to solicit stakeholder input (October 2, in Arlington, VA; October 20, in Sacramento, CA; November 10, in Chicago, IL; and December 8 in Dallas, TX).

RECOMMENDATION: The Interagency Food Safety Working Group recommends that the Council establish a task force consisting of one representative from each of the following agencies: OSTP, HHS, USDA, EPA, and DOC. This 5 person task force will systematically assess the NAS report by providing 1) an analysis of the report's findings, including whether we agree or disagree with the findings and why; 2) an assessment of the strengths and weaknesses of each recommendation as they relate to the findings that are determined to have merit; and 3) recommendations on whether to incorporate particular elements of the NAS report into the Council's comprehensive strategic plan. If appropriate, the task force should identify barriers (e.g., legal) to implementation and recommend ways to overcome them. Each task force representative will be responsible for coordinating input from within his or her own agency. The task force will be chaired by OSTP and provide a draft report to the Council by February 5, 1999. Once the report is submitted to the President by February 21, 1999, the Council will seek additional public input on its assessment of the NAS report's recommendations.

MEMORANDUM FOR THE PRESIDENT'S COUNCIL ON FOOD SAFETY

FROM; INTERAGENCY FOOD SAFETY WORKING GROUP

SUBJECT: Process for developing a Food Safety Strategic Plan for all Federal food safety agencies

ACTION: Approval of a process for preparing a food safety strategic plan

BACKGROUND: On January 25, 1997, the President announced a new food safety initiative. He directed the Secretaries of Agriculture and Health and Human Services and the Administrator of the Environmental Protection Agency to identify specific steps to improve food safety. Those agencies held public meetings with consumers, producers, industry, states, universities, and the public, and reported back to the President. The Report, issued in May 1997, was entitled *Food Safety from Farm to Table, A National Food-Safety Initiative*. In that report, the Federal agencies involved in food safety recommended a longer-term strategic planning effort to consider how to best address important challenges and make the best use of the agencies' limited resources. The agencies made a commitment to involve all public and private stakeholders in the process.

The President's Council on Food Safety will be responsible for development of a 5-year Federal food safety strategic plan. A coordinated food safety strategic planning effort is needed to build on common ground and to tackle some of the difficult public health, resource, and management questions facing Federal food safety agencies. The strategic plan will focus on not just microbial contamination but the full range of issues that are discussed in the scope of food safety decision paper. It will also identify actions necessary to ensure the safety of the food Americans consume. The charge is to develop a comprehensive strategic long-range plan that addresses the steps necessary to achieve a seamless food safety system including key public health, resource, and management issues regarding food safety. The plan will be used to help set priorities, improve coordination and efficiency, identify gaps in the current system and mechanisms to fill those gaps, continue to enhance and strengthen prevention and intervention strategies, and develop performance measures to show progress. Each agency will incorporate the relevant parts of the strategic plan into its Government Performance and Results Act (GPRA) strategic plan, commensurate with its budget.

The food safety agencies have already taken the first steps in developing the food safety strategic plan, by participating in interagency strategic planning sessions and developing a draft vision statement for the U.S. food safety system and the roles of all those involved in food safety. The vision statement establishes the essential characteristics of an effective food safety system:

> 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-based and risk-based approaches along with public/private partnerships. Food is safe because everyone understands and accepts their responsibilities.

During early 1997, the federal food safety agencies engaged a wide range of stakeholders in discussions about food safety issues through a series of public meetings and through written comments to public dockets. At four additional meetings, held between October and December 1998, the food safety agencies engaged consumers, producers, industry, food service providers, retailers, health professionals, State and local governments, Tribes, academia, and the public in the strategic planning process. Participants commented on the draft vision statement as well as the strategic planning process. They were also asked to discuss goals and critical steps and to identify potential barriers to achieving those goals.

Additionally, at the request of Congress, the National Academy of Sciences (NAS) conducted a study of the current food safety system to: (1) determine the scientific basis of an effective food safety system; (2) assess the effectiveness of the current system; (3) identify scientific and organizational needs and gaps at the federal level; and (4) provide recommendations. The NAS released its findings, conclusions, and recommendations in an August 20th report, *Ensuring Safe Food from Production to Consumption*. The report stated that "changes in statutes or organization should be based on a rational, well-developed national food safety plan formulated by current federal agencies charged with food safety efforts and with representation from the many stakeholders involved in ensuring safe food."

RECOMMENDATION: The Interagency Food Safety Working Group recommends that the President's Food Safety Council convene a task force to develop a comprehensive food safety strategic plan based on the recommendations and comment received from its various constituencies. The task force will consist of representatives from each of the following agencies: HHS (CFSAN, CVM, NIH, CDC), USDA (FSIS, ARS, CSREES, ORACBA), and EPA.

The task force will first conduct a content analysis of the transcripts and dockets of the 1998 meetings and the input received through the notice and comment process to determine the major themes, issues, and subject areas that emerged during the public outreach phase. This will identify what stakeholders want in a food safety strategic plan. The task force will also consider the conclusions and recommendations of:

The National Academy of Sciences' report on *Ensuring Safe Food from Production to Consumption*,

The review of Federal food safety research and the research plan currently being developed by an interagency working group under the auspices of the National Science and Technology Council,

Input from the 50-State meeting on state/local issues and recommendations, and

Input from the agencies involved.

The task force will then develop a proposed set of strategic goals and objectives and present a draft strategic plan to the President's Food Safety Council. Following Council review, the draft food safety strategic plan will then be presented to the public for review.

After a suitable period of further public comment, the task force will prepare a final draft of the strategic plan with specific recommendations on needed changes and steps to achieve a seamless food safety system including resource needs, roles, and barriers to implementation, and submit it to the Council for approval.

Discussion Paper: Coordinated Food Safety Budget Process

For Consideration by the President's Council on Food Safety

Action Required: Approval of a process to develop coordinated food safety budgets and a unified food safety initiative budget submission.

Background

Executive Order 13100 established the President's Council on Food Safety, to "advise agencies of priority areas for investment in food safety and ensure that Federal agencies annually develop coordinated food safety budgets for submission to the Office of Management and Budget (OMB) that sustain and strengthen existing capacities, eliminates duplication, and ensure the most effective use of resources for improving food safety." The President further directed the Council to "ensure that the Federal agencies annually develop a unified budget for submission to OMB for the President's Food Safety Initiative and such other Food Safety issues as the Council determines appropriate."

Timetable for the Federal Budget Process

The Federal agency budget process begins no later than the spring of each year, at least 9 months before the budget is transmitted to Congress. In the spring and summer, the process focuses on the review of program performance, as well as ways to ensure efficient Government resources and successful implementation of programs and policies. Beginning in early fall, Executive branch departments and agencies submit initial materials to OMB in accordance with a schedule developed by OMB. Initial due dates for submitting material may differ between agencies, but final OMB action on budget decisionmaking is the same. OMB reviews agency budget requests, based on Presidential priorities, program performance, and budget constraints. A complete set of budget proposals is presented to the President by early December for approval. After this process is complete, agencies revise their budget requests to bring them into accord with the President's decisions. Under current law, the budget must be submitted to Congress no later than the first Monday in February.

The Federal Budget Process

The budget process is governed by OMB Circular No. A-11, "Preparation and Submission of Budget Estimates," which provides detailed instructions and guidance on the preparation and submission of agency budget requests and related materials, including the development of strategic plans and annual performance plans. Policy guidance is given to agencies for the upcoming budget year and out-years to provide initial guidelines for preparation of agency budget requests. OMB works with agencies to identify major issues for the upcoming budget; undertakes the analysis

necessary to provide the context for decisionmaking; identifies major options; and develops and implements plans for analysis of future issues.
During the OMB review process, major issues and options are prepared for consideration by the President, organized around major Administration themes and cross-cutting issues. The A-11 requires data for cross-cutting issues in addition to agency budget submissions to analyze individual agency budgets, make Government-wide resource allocation decisions, and prepare unified budget presentations. Contributing agencies submit detailed budget schedules and narrative information that describes agency functions and provides budget justifications. The narrative justifications include evidence of cooperative development of complementary requests among the major agencies involved. OMB utilizes the information to make crosscutting comparisons between agencies and to make Government-wide resource allocation decisions.

One example of a cross-cutting activity is for research and development. Agencies are required to report cross-cutting data for the specific areas of research identified by the National Science and Technology Council (NSTC). Prior to the beginning of the budget process, NSTC identifies a set of research and development areas that are important national efforts requiring coordinated investments across several agencies. These priorities, and other guidance, are provided to participating agencies to consider during the development of agency budgets. The agencies utilize this information to justify proposed changes in research and development activities addressed by NSTC. The A-11 also identifies other cross-cutting areas such as drug control programs and violent crime control programs.

Current Interagency Budget Planning Process

Currently, a formal process for coordinating the budget for food safety functions has not be established as it has been for other cross-cutting functions. In the absence of specific guidance, the Department of Heath and Human Services (HHS), and the Department of Agriculture (USDA) have coordinated a multi-agency effort to present a unified budget for the President's Food Safety Initiative. This process began with and is based on the May 1997 report to the President, entitled, *Food Safety from Farm-to-Table: A National Food Safety Initiative*. The report recognized microbial foodborne illness as an emerging public health hazard that requires aggressive government action. The report recognizes that only through joint planning can Federal resources be maximized and the greatest improvements in food safety be achieved. The farm-to-table strategy developed in the May 1997 report identifies critical gaps in the food safety system for controlling or eliminating foodborne pathogens from the food supply and proposes a strategy for closing those gaps.

The involved agencies have worked collaboratively to present a unified food safety initiative budget to OMB and the Congress for 1998 and 1999. However, the process for coordination and joint planning has not been initiated until the completion of individual agency budget decisionmaking. The result is inclusion of food safety initiative budget requests in individual agency budget submissions to OMB and preparation of a unified budget submission "after the fact".

The Council's Role in Food Safety Budget Planning

A primary responsibility of the Council is the development of a comprehensive Federal food safety strategic plan with the goal of a "seamless," science-based food safety system (e.g., a system that is an integrated Federal, State, and local system). The plan will contain specific recommendations on needed changes, including measurable outcome goals, steps necessary to achieve the goal, and key food safety public health, resource, and management issues. In developing the strategic plan, the Council will consult with all interested parties and will consider both short-term and long-term issues including new and emerging threats, and the special needs of vulnerable populations such as children and the elderly.

The strategic plan will provide a solid basis for coordinated food safety budget planning and resource requests. The Council will also ensure that the agencies submit a unified food safety initiative budget that includes other food safety issues, as determined appropriate by the Council.

Preparation of a Coordinated Food Safety Budget Planning Process

Developing a coordinated budget process for food safety activities includes a number of key factors. The first key factor is the development of guidance by the Council for food safety agencies to consider during the preparation of their budgets. In order for this guidance to be most useful, the Council should make it available to the agencies by late February to coincide with the beginning of the budget planning process of the involved agencies. A second major factor is the collection of budget data necessary for coordinating food safety budgets and recommending government-wide resource allocations. A third factor is establishing a process for agencies to submit relevant budget information to the Council and OMB for use in evaluating agency budget submissions.

Recommendation: Form a task force composed of representatives from the budget and program planning staffs of HHS, USDA, and EPA to work with the Council to develop a coordinated budget process for food safety activities similar to other cross-cutting issues. The team will work throughout the budget process to assure coordination of activities and resource requests. The task force should conduct the following functions:

- Review the strategic plan and Council budget guidance to identify budget data and other information that will be necessary to plan and evaluate agency budget submissions;
- Design a uniform format for presenting food safety initiative budget components for use in both agency and the unified budget submissions;
- Develop necessary guidance to facilitate submission of a unified food safety initiative budget and any other agencies deemed appropriate by the Council;
- Develop a timetable for submitting information to the Council that accommodates the various agencies budget processes.

DRAFT - 11/20/98

MEMORANDUM TO PRESIDENT'S COUNCIL ON FOOD SAFETY

FROM: Interagency Food Safety Working Group

SUBJECT: Scope of the Council's Comprehensive Strategic Food Safety Plan

ACTION: Decision on the scope -- what's in and what's out – of the Council's initial actions and comprehensive strategic Federal food safety plan.

BACKGROUND: On January 25, 1997, the **President issued a directive** to the Secretaries of USDA and HAS and the Administrator of EPA to work with stakeholders and the public to identify ways to further improve the safety of the food supply, and to report back to him in 90 days. The Federal food safety agencies (HAS, USDA and EPA) initially focused on the goal of reducing illnesses caused by microbial contamination of food and water. The plan for meeting this goal was presented to the President in May, 1997 in "Food Safety From Farm to Table: A National Food Safety Initiative"(FBI).

To implement the plan, USDA and HAS submitted **joint budget requests** for pathogen research, surveillance, risk assessment, inspection and education for F, F, and F. Microbial contamination of water and biomedical research are included within the scope of the FBI, and NH and EPA participated in the Initiative; however, support for NH and EPA programs have not been included in the joint budget submissions.

The May, 1997 report made a commitment to prepare a comprehensive 5-year **strategic plan**, with the participation of all concerned parties. The President's Council on Food Safety was established in August, 1998 under E.G. 13100 and is now responsible for development of this strategic food safety plan. The first steps to lay the groundwork for development of the strategic plan have already been taken by drafting a vision statement for the U.S. food safety system along with a series of questions designed to elicit the public's view on the vision, goals and critical steps as well as potential barriers to achieving that vision. In developing the vision, the agencies assumed that the scope of the strategic plan would be broadened beyond the FBI to include chemical hazards in the food supply.

Independently, the **National Academy of Sciences** (AS) was charged by Congress with: 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; and 4) providing recommendations on the scientific and organizational changes needed to ensure an effective system. The AS released its findings and recommendations in August, 1998 in "Ensuring Safe Food from Production to Consumption". In the report, AS broadly defined food safety as "not only the avoidance of foodborne pathogens, chemical toxicants, and physical hazards, but also issues such as nutrition, food quality, labeling, and education". While the scope of the study included all these components, the report focused primarily on microbial, chemical and physical hazards from "substances that can cause adverse consequences" in domestically-produced and imported foods, including additives, agricultural chemicals and animal drug residues.

For the Council's purposes in **defining "food safety"** and determining the scope of the strategic plan, this paper identifies two categories of activities: "core food safety activities" and "collateral" or related activities. "Core food safety activities" includes programs or activities that enhance the safety of the nation's food supply and protect public health by reducing the annual incidence of acute and chronic foodborne illness. "Collateral activities" are related to and have implications for food safety but are undertaken to serve another primary purpose or mission, such as insuring fishable, swimmable waters. Specific food safety research or regulatory actions may need to be coordinated with these collateral activities, and vice versa, but they will not be included in the initial strategic plan. Collateral activities will be identified as appropriate for coordination or integration, and could be brought in the future within the scope of the strategic plan and the Council's work.

This framework is designed to allow the Council to focus on the important, "core" activities that directly impact food safety. Once developed, the strategic plan should assist the agencies to address the important food safety challenges by identifying priorities and making the best use of limited resources. This paper does not, therefore, determine priorities within the initial scope for Federal attention and resources, but rather leaves those decisions to the strategic planning process. Further, activities within the scope may not all be addressed in the same depth or at the same time depending on our assessment of the public health risks and potential benefits of action.

RECOMMENDATION: It is recommended that the Council and the strategic plan focus first on "core food safety activities" defined as microbial hazards, physical hazards, and chemical substances. Other "collateral activities" that are less directly related to the safety of the food supply will be considered for collaborative efforts or enhanced coordination on a specific, targeted basis as needed. Included in this second category are: miscellaneous food constituents, the nutrition programs, and waterborne hazards. *[Note: USDA and FDA recommended water be in the core.]*

Table 1: Recommended Scope of Food Safety Strategic Plan

	Core	Collateral
Microbial Hazards	X	
Chemical Substances	X	
Misc. Food Constituents		X
Nutrition Programs		X
Physical Hazards	X	
Waterborne Hazards		X

The remainder of this paper defines the categories above and examines the pros and cons for inclusion of each category within the scope of the Council's comprehensive food safety strategic plan. Table 2 (attached) provides information on "core" and "collateral activities" at the food

safety agencies.

OPTIONS: Building federal capacity to prevent, reduce and respond to microbial hazards in the food supply will continue to be a priority issue addressed by the Council and in the strategic plan. This includes not only known and emerging problems due to human pathogens in imported and domestic food (from farm to table) and antibiotic resistance in pathogens, but also some naturally-occurring toxicants (e.g., mycotoxins). Federal programs for microbial research, monitoring, surveillance, regulation and prevention (including irradiation of food), voluntary and mandatory certification and inspection, and enforcement as well as labeling and education (e.g., Fight BAC) that encourage proper food handling to avoid microbial contamination will be part within the scope of the plan.

This paper examines options for expanding the scope of the strategic plan beyond pathogens. Several categories of work have been identified which, separately or in combination, would broaden the scope and make the plan more comprehensive:

Option 1: Chemical Substances
Option 2: Miscellaneous Food Constituents
Option 3: Nutrition Programs
Option 4: Physical Hazards
Option 5: Waterborne Hazards

Option 1: Chemical Substances *[Note: This section is still under discussion, and may be revised.]* Food itself is a complex collection of "naturally-occurring" and added (inadvertently or for a specific purpose) chemicals with nutritive and other properties. "Added chemicals", including synthetic chemicals and metals, are sometimes inadvertently introduced into foods (e.g., industrial contaminants) and/or are present at unauthorized levels, while others are intentionally added and present in food, in most cases, at or below legal and "safe" levels.

The category includes a diverse set of substances: environmental contaminants (e.g., methyl mercury in fish, lead in baby food); industrial contamination (e.g., dioxin in chicken feed, polybrominated biphenyls in animal feed); pesticides (both residues in/on food and antimicrobials used to control pathogens); sanitizers; components of packaging materials (e.g., fungicide treated fruit and vegetable wraps); animal drugs (including residues in meat and/or milk); byproducts of manufacturing and process-induced components of foods (e.g., nitrosamines and pyrolysis products). Among the chemical substances of concern are naturally-occurring and added substances in dietary supplements (particularly herbals and botanicals, such as ephedrine alkaloids in ma huang and *Digitalis lanata* in a plantain-containing supplement). Similarly, nutrients present in either low or high levels may pose health risks to vulnerable populations in products specifically designed to meet their needs (e.g., infant formula, medical foods, and foods for special dietary purposes). Another area of concern included in the category are genetically modified plants and products used in food or animal production. This category also includes food and feed additives (e.g., coloring agents, preservatives, food packaging waxes), flavors, enzymes, and vitamins and minerals (including high levels of substances such as Selenium and Vitamin D). Because of broad public concern about the risks posed by chemicals, they have

historically been the subject of Federal attention and regulation.

Under this option, all FDA, USDA, EPA and CDC chemical-related food safety responsibilities, including those aimed at ensuring "safe" and lawful levels of chemicals in food, would be considered in the strategic plan. The plan would address chemical/pesticide research (including research on preventive controls and intervention strategies), monitoring/surveillance (food and human diseases), regulation and related voluntary programs, inspection, enforcement, education and outreach.

There are several reasons to include chemical substances as "core food safety activities" in the comprehensive strategic plan.

- Food safety involves protecting consumers from a wide range of potential hazards including the risks posed by chemicals.
- Significant Federal programs/resources at HAS, EPA and USDA are devoted to protecting the public's health from chemical hazards in food; since the mission of these programs is to ensure safe food, they should be part of the food safety strategic plan.
- Some resource efficiencies in surveillance and enforcement efforts could likely be achieved by integrating work on pathogens and chemicals.
- There is broad public concern about the safety of pesticide residues, food additives, and other chemical hazards in food.
- The plan will be perceived by the public as deficient if chemical substances are left out.
- The AS report specifically cited the need to include chemical hazards in any discussion of food safety and called for development of a comprehensive strategic plan for food safety; there would be a significant gap if chemical hazards were not considered in developing the plan.
- Some chemical substances present new and important challenges for the food safety system (e.g., endocrine disruption, protections for vulnerable populations) that should be considered in the strategic plan.
- There is a direct link between certain chemicals and our ability to control microbial contamination. For example, antimicrobials, pesticides and food additives play a role in controlling microbial contamination of food.
- There is growing interest in dietary supplements; some supplements, including herbal products, may pose a risk of adverse health effects because they contain a toxic constituent. The Dietary Supplements Health and Education Act exempted dietary supplements from Federal premarket approval of their safety, so effective post-market approaches are needed.
- There is public concern about the safety of products from genetically modified plants and animals.
- Including chemicals broadens the spectrum of programs included in the Initiative and the stakeholders, and should bring additional opportunities for improvements to the food safety system.

On the other hand, there are some reasons to exclude chemical substances from the "core".

- Some may argue that the urgency of the problem with pathogens warrants a focus on

microbial contamination alone.

- There are legal, scientific, regulatory and organizational distinctions that make chemical issues different from microbes; it may be an awkward blend and create challenges in terms of balancing competing priorities.
- The potential risks associated with this diverse group of substances varies widely in scope and severity. Some believe that including all chemical hazards may broaden the scope of the strategic plan beyond what is manageable.
- Some chemicals may not be priorities, and thus may not need to be included initially. For example, there are classes of pesticides (e.g., plant growth regulators with no toxic mode of action) that are addressed differently from those with a toxic mode of action. Similarly, risks posed by regulated food/feed additives are generally well characterized and addressed in terms of science and regulation.
- Pesticide residues are being extensively addressed due to the recent legislation, and these activities can be supported through other mechanisms.

Recommendation: All chemical substances in food should be included within the scope of the Council's efforts and its strategic plan, and potentially the annual coordinated budgets. This does not mean, however, that because these substances are in the same category for purposes of this paper that they pose public health risks of the same magnitude, or that they will all be a priority in the strategic plan or for budget initiatives; their inclusion does provide opportunities for better coordination, integration, and resource efficiencies. Further, continued progress on goals and objectives for microbial hazards can be ensured by adding chemical hazard activities slowly on a priority basis to the budget, so that they can be absorbed into the overall FBI work in an orderly fashion (exact timing for budget inclusion to be determined by the Budget Task Force).

Option 2: Miscellaneous Food Constituents There are a number of miscellaneous constituents such as artificial sweeteners, fat substitutes, and other "naturally occurring" substances that serve various functions when added to food. These constituents are not typically considered "chemical hazards", but as components of food products are a candidate for inclusion within the scope.

Reasons to include these miscellaneous food constituents within the "core activities" of the strategic plan are provided below.

- Food processors are examining "new" sources of ingredients (e.g., gums and fibers) for more conventional functional properties and adding them to food; the use of these ingredients raises safety questions.
- Food processors are utilizing macronutrient substitutes (e.g., non-nutritive sweeteners and fat substitutes); since quantities of these substitutes in the diet may be larger than traditional food additives, there are questions about the effect of their use on the quality of the American diet.

Reasons to exclude these miscellaneous constituents from the "core activities" are the following.

- Some may argue that the urgency of the problems with pathogens and chemicals warrants a focus on those hazards; inclusion of these miscellaneous constituents would broaden the scope beyond what may be practical.

- These areas are not likely to be priorities in the plan, and may not need to be addressed at this time.
- Although there are concerns about the effect of these constituents in the American diet, the primary purpose of programs dealing with them is not to reduce foodborne illnesses.

Recommendation: Include this category in the" collateral activities", but do not consider it in developing the strategic plan (and budget) at this time. Although related to food safety, Federal programs dealing with these constituents are not focused on reducing the incidence of acute or chronic foodborne illness due to these products in the food supply. The issue can always be revisited if significant food safety issues arise.

Option 3: Nutrition Programs There are several HAS and USDA programs as well as public-private partnerships designed to define and educate the American people on the benefits of a healthy, nutritious diet. USDA and FDA have developed the food pyramid, which recommends daily quantities of fruits, vegetables, meat and grains. Both agencies also have labeling programs designed to inform the public on the caloric and nutritional content of food. These programs are important in encouraging the consumption of a healthy, nutritious diet which can help to reduce the incidence of both acute and chronic disease.

Some feel that these nutrition programs are aligned with food safety and should be part of the "core activities" for the following reasons.

- The Federal government cannot ensure a healthy and affordable food supply, as outlined in the vision, without consideration of the nutrition programs.
- This would provide an opportunity to develop public health messages about both the nutritional benefits and the infectious/toxicologic hazards associated with various foods.
- Nutrition information could send a positive, constructive message to the American people, making food safety about more than just food contamination and poisoning. Food safety could also be about eating a wholesome, balanced diet to reduce the risk of disease, particularly chronic diseases (e.g., some cancers), and malnutrition.

On the other hand, the nutrition programs might not be considered "core activities" for several reasons.

- Some would argue that the urgency of the problems with pathogens and chemicals warrants a focus on these hazards; consideration of the nutrition programs would broaden the scope beyond what is practical and include areas that do not need attention or funding.
- Inclusion of the nutrition programs could dilute FBI efforts on infectious and toxicologic hazards to the point of ineffectiveness.
- The intent of these programs is to promote healthy eating habits by the American people and reduce the incidence of chronic disease; their primary purpose is not to enhance the safety of the food supply.

Recommendation: Federal programs to define and promote a healthy diet should be considered "collateral activities". They can support and help to implement the vision of a safe, healthy and affordable food supply, but are not designed to ensure food safety.

Option 4: Physical Hazards This includes a diverse set of "foreign" physical hazards in food that can cause serious harm if consumed, including stones, bones, metal chips or parts, and glass. Included also in this category are insect and rodent infestations (e.g., insects in flour, rat droppings). For purposes of this paper, tampering is included here although it is recognized that tampering may include the addition of biological and microbiological agents, as well as chemical or other agents, to foods to intentionally harm the consumer. This category was included in AS' definition of food safety concerns, but received little attention in the report.

Incidents of contamination of food with physical hazards can have significant adverse consequences. Reasons for inclusion in the "core food safety activities" include the following.

- Some physical hazards can result in significant harm to individuals.
- The public perceives contamination with physical hazards as part of the food safety issue.
- USDA and FDA legislation covers control and prevention of physical hazards, and USDA has substantial resources devoted to inspecting for physical hazards.
- These hazards are relatively easy to detect and may be easy to mitigate with limited Federal attention and/or resources.

Reasons to not include physical hazards in the "core activities" are as follows.

- Some may argue that the urgency of the problem with pathogens and chemicals warrants a focus on them.
- Food processors and handlers have numerous safeguards in place to protect against physical hazards and tampering in order to avoid liability and other costs as well as the harmful publicity associated with incidents of easily-detected physical materials in food.
- Partly for the reason cited above and because these hazards generally do not pose a wide-spread threat to public health, some food safety agencies have paid less attention to these hazards. Expanding the scope to include them seems unnecessary and would divert Federal resources from more significant public health problems.
- The food safety system for controlling these hazards is perceived by some to not be broken, with the exception of dealing with tampering and bioterrorism, and thus does not warrant increased attention at this time.

Recommendation: Physical hazards should be included in the "core food safety activities", and addressed in the strategic plan.

Option 5: Waterborne Hazards Water is an essential component of food production, processing and preparation; food production and processing are also a significant source of contamination to the nation's waters. Public water suppliers provide a majority of the drinking water used for washing and final preparation of food, including for use in reconstituted food products available in restaurants and the home. Waterborne hazards include: pathogens in irrigation and other waters used on farms and ranches and that can contaminate food -- sometimes as a result of poor farming practices, in particular mismanagement of animal wastes; pathogens and chemicals in surface or groundwater from point and non-point sources that can contaminate food; microbes and chemicals in public and private water supplies used for food processing and preparation; as well as chemicals and especially pathogens in drinking water

consumed by the public (*Cryptosporidium* in Milwaukee; *E Coli* in Alpine, Wyoming).

There are several reasons to include waterborne hazards as "core" activities in the strategic plan.

- Drinking water is part of the diet and an important component of many final food products (6 of the top 10 foods consumed by Americans are mixed with water before consumption *Is this correct?*).
- Water is used in most food production and manufacturing processes and drinking water is used in food preparation and consumption; use of potable water is a fundamental requirement of all regulations and guidance (GMPs, GAP/GMP guidance for produce, HACCP regulations, and recommended codes -- e.g., Pasteurized Grade A milk code, Food Code).
- Some programs to reduce pathogen contamination of water are already included in the President's Food Safety Initiative, and EPA's research on pathogens to support its water program is in the OSTP research Inventory -- i.e., microbial contamination of water is already in the FBI.
- Inclusion within the scope would provide attention to the important role of irrigation and processing water in food safety.
- There may be public health benefits that can be achieved by inclusion of EPA's water programs within the "core"' scope, since:
  - There is a need to coordinate across the government on research on emerging pathogens in order to ensure efficiency and non-duplication of Federal research (e.g., the agencies share mutual objectives in the areas of risk assessment, health effects, dose response, and analytical methods for pathogens whether in food or water);
  - Irrigation water and animal manures can be a pathway for contamination of food by pathogens; several acute disease outbreaks have occurred from this route (e.g., *Cryptosporidium* in apple juice), and there is a need for coordination of surveillance and inspections; and
  - Several commonly waterborne pathogens are sometimes transmitted by the foodborne route.
- EPA develops fish advisories for locally-caught fish, while FDA develops action levels for commercial seafood; inconsistencies in the action levels/fish advisories might be addressed through these joint efforts.
- Water, whether for consumption by humans or animals, is considered "food" under the Federal Food, Drug, and Cosmetic Act.

However, there are also significant reasons why waterborne hazards should not be included in the "core" activities.

- The purpose of EPA's water programs is to insure fishable, swimmable surface waters and safe tap water for drinking, and not to enhance food safety by reducing acute or chronic illnesses.
- Inclusion of these programs in the food safety initiative could divert EPA from its primary responsibilities under SDWA and CWA, including meeting statutory and judicial deadlines, and may expand the scope beyond what is manageable.

- Tap water that is safe for drinking is also safe for food production, processing and consumption.
- EPA does not regulate water in food production, processing, preparation and consumption, and it has not been a primary concern for EPA.
- The issues related to animal manures and irrigation water would not only bring into the strategic plan a large range of EPA activities but also a suite of programs managed by USDA and the Department. of Interior.
- We already coordinate on regulatory issues via the President's Clean Water Action Plan and via the Animal Feeding Operation Strategy; duplicative coordination is inefficient.
- It will be extremely difficult, if not impossible, to separate EPA's regulation/enforcement water program budget for food safety from the budget for the entire water program.

Recommendation: Water safety should be considered a "collateral activity" which is related to food safety but whose primary mission is not to reduce foodborne illnesses. Collaboration to avoid duplication of research efforts and ensure adequate EPA input into development of FDA and USDA guidelines (e.g., Good Agricultural Practices, Good Manufacturing Practices and the Food Code) is critical but can be accomplished without water being a part of the initial strategic plan.

TABLE 2
FEDERAL ACTIVITIES RELATING TO FOOD SAFETY

Federal Agency	Other Agencies Involved	Activity	Type of Activity	Issues Addressed	Core or Collateral Activity
U.S. Department of Agriculture					
Food Safety & Inspection Service	FDA EPA CDC	Sets standards for meat, poultry and egg shells shipped interstate; inspects domestic and imported meat and poultry and enforces standards; recalls adulterated products.	Regulation, Inspection, & Enforcement	Pathogens Chemical residues Physical hazards Food quality	Core
Agricultural Marketing Service	EPA	Pesticide data program to monitor and collect pesticide residue information for EPA risk assessment; microbial data program surveillance and monitoring; manages voluntary quality certification program.	Regulatory Support, Monitoring, & Risk Assessment	Pesticides Pathogens Food quality	Core
Agricultural Research Service	EPA FDA	Research (basic) on elimination, mitigation and detection of hazards	Research, & Regulatory Support	Pathogens Chemicals	Core
Cooperative State Research, Education & Extension Service	EPA FDA	Research (applied), outreach, and education on elimination, mitigation, and detection of hazards.	Research, & Regulatory Support	Pathogens Chemicals	Core
Animal & Plant Health Inspection Service	EPA FDA	Regulation of biotechnology and irradiation, methods.	Regulation, Inspection, & Enforcement	Biotechnology Irradiation	Core
Economic Research Service	EPA FDA	Data Interpretation.	Regulatory Support, Guidance, & Risk Assessment	Pesticide uses Chemicals	Core
National Agricultural Statistical Service	EPA FDA	Data collection and monitoring	Regulatory Support, & Risk Assessment		Core

Federal Agency	Other Agencies Involved	Activity	Type of Activity	Issues Addressed	Core or Collateral Activity
Grain Inspection, Packers & Stockyards Administration		Inspect for toxins (e.g., aflatoxin)	Inspection	Toxins	
Office of Risk Assessment & Cost Benefit Analysis	EPA FDA	Data interpretation, guidance, and risk assessment	Regulatory Support, & Guidance		Core
Office of Pest Management Policy	EPA FDA	Data collection, interpretation, guidance, and risk assessment	Regulatory Support, & Guidance	Pesticides	Core
Food & Drug Administration					
Center for Food Safety & Applied Nutrition	USDA EPA CDC		Regulation, Inspection, Enforcement	Pathogens Chemicals Nutrition	Core
Center for Veterinary Drugs	USDA CDC			Animal Drugs	Core
Centers for Disease Control & Prevention					
Centers for Disease Control & Prevention	USDA FDA EPA	Investigates outbreaks of foodborne illness; monitors and collects information on food- and waterborne illnesses; conducts nationwide surveillance for food- and waterborne diseases; designs and implements surveillance systems; performs research on diagnostic and subtyping methods; and training and education.	Surveillance, Monitoring, Research, Training, & Education	Food- and waterborne pathogens FoodNet and PulseNet Infectious disease outbreaks Chemical hazards	Core
U.S. Environmental Protection Agency					

Federal Agency	Other Agencies Involved	Activity	Type of Activity	Issues Addressed	Core or Collateral Activity
Office of Prevention, Pesticides & Toxic Substances	USDA FDA CDC	Regulation of pesticide uses, residues in/on food and antimicrobials for control of pathogens. Supports investigations of certain chemical contamination incidents and regulates chemicals.	Regulation, & Risk Assessment	Pesticides Chemicals	Core
Office of Water	USDA CDC FDA	Regulates drinking water quality and biosolids; establishes discharge standards for facilities. Provides criteria for ambient water contamination, watershed controls, and other pathogen elimination/protection authorities.	Regulation, Guidance, Research & Risk Assessment	Pathogens in water Chemicals in water Animal wastes Other agricultural wastes	Collateral
Office of Research & Development	OSTP USDA FDA	Responsible for research on pesticide testing methods, chemical monitoring methods development, and risk assessment issues; provides technical and scientific advice on risk assessment, and testing and monitoring methods.	Research, Guidance, & Risk Assessment	Chemicals Pesticides Pathogens?	Core (pesticides)
Office of Enforcement & Compliance Assurance	FDA USDA	Ensures that pesticides used on crops/food are registered, are not adulterated, and are used correctly. Ensures that data used to support pesticides registration is not fraudulent. Referrals for possible illegal residues. Collects pesticide production information.	Inspections, Enforcement, Referrals, Regulation, & Risk Assessment Support	Product inspections Use inspections Lab Inspections Pesticide misuse Recalls	Core (pesticides)
Department of Commerce					
National Marine Fisheries Service	FDA	Voluntary inspection program for seafood quality.	Inspection		

Cons pro - food safety - council

United States Department of Agriculture

Food Safety and Inspection Service

Washington, D.C. 20250

11 DEC 1998

To: Bruce Reed
Assistant to the President for Domestic Policy
2nd Floor West Wing
The White House
Washington, DC 20502

From: Charles Danner Kenneth Elam for Charles Danner
Acting Associate Deputy Administrator, USDA/FSIS/OM

Subject: Materials for the December 16, 1998, Meeting of the President's Council on Food Safety

The enclosed materials are provided for your review, prior to the December 16, 1998, meeting. An agenda for the meeting is included.

In addition to the agenda, there is a background paper and papers that address the Charter of the President's Council on Food Safety, an assessment of the NAS report, the process for developing a Food Safety Strategic Plan for all Federal food safety agencies, and the process for coordinated Federal food safety budgets.

If you have any questions regarding the enclosed materials, call me at 202.720.4425

Enclosures

President's Council on Food Safety

Old Executive Office Building, Room 324
December 16, 1998
10:00 a.m. — 11:00 a.m.

10:00 **Introductions and Opening Remarks**
Dan Glickman
Secretary, United States Department of Agriculture

Donna Shalala
Secretary, United States Department of Health and Human Services

Neal Lane
Assistant to the President for Science and Technology and
Director of the Office of Science and Technology Policy

10:05 **Elements of the Executive Order**
Bruce Reed, Assistant to the President for Domestic Policy

10:10 **Discussion and Approval of Charter**
Catherine E. Woteki, Under Secretary for Food Safety, USDA

10:15 **Discussion and Approval of Council's Scope**
Lynn R. Goldman, Assistant Administrator for Prevention, Pesticides and Toxic Substances, EPA

10:30 **FY2000 Budget and Future Crosscut**
Jacob Lew, Director of the Office of Management and Budget

10:40 **Comprehensive Plan**
James A. O'Hara, Deputy Assistant Secretary for Health, HHS

10:45 **NAS Report Assessment**
Cliff Gabriel, Office of Science and Technology Policy

10:50 **Joint Institute for Food Safety Research**
Eileen Kennedy, Deputy Under Secretary for Research, Education and Economics, USDA
William Raub, Deputy Assistant Secretary for Science Policy, HHS

10:55 **Closing Remarks**
Dan Glickman
Secretary, United States Department of Agriculture

Donna Shalala
Secretary, Health and Human Services

Neal Lane
Assistant to the President for Science and Technology and
Director of the Office of Science and Technology Policy

BACKGROUND

On January 25, 1997, the President announced his food safety initiative. He directed the Secretaries of Agriculture and Health and Human Services and the Administrator of the Environmental Protection Agency to identify ways to further improve the safety of the food supply. Those agencies held public meetings with consumers, producers, industry, states, universities, and the public, and reported back to the President. The Report, issued in May 1997, was entitled *Food Safety from Farm to Table, A National Food-Safety Initiative*. To implement the report, USDA and HHS submitted joint budget requests for pathogen research, surveillance, risk assessment, inspection, and education for FY98, FY99 and FY 2000.

The report made a commitment to prepare a comprehensive 5-year strategic plan, with the participation of all concerned parties. The President's Council on Food Safety was established in August 1998 under E.O. 13100 to: 1) develop a comprehensive strategic Federal food safety plan; 2) advise agencies of priority areas for investment in food safety and ensure that Federal agencies annually develop coordinated food safety budgets for submission to the Office of Management and Budget (OMB); and 3) ensure that the Joint Institute for Food Safety Research (JIFSR) establishes mechanisms to guide Federal research efforts toward the highest priority food safety needs.

A coordinated food safety strategic planning effort is needed to build on common ground and to tackle some of the difficult public health, resource, and management questions facing Federal food safety agencies. The strategic plan will focus on not just microbial contamination but the full range of issues that are discussed in the scope of the food safety decision paper. It will also identify actions necessary to ensure the safety of the food Americans consume. The charge is to develop a comprehensive strategic long-range plan that addresses the steps necessary to achieve a seamless food safety system including key public health, resource, and management issues regarding food safety. The plan will be used to set priorities, improve coordination and efficiency, identify gaps in the current system and mechanisms to fill those gaps, continue to enhance and strengthen prevention and intervention strategies, and develop performance measures to show progress. Each agency will incorporate the relevant parts of the strategic plan into its Government Performance and Results Act (GPRA) strategic plan, commensurate with its budget.

In developing the strategic plan, the Council will consult with all interested parties and will consider both short-term and long-term issues including new and emerging threats, and the special needs of vulnerable populations such as children and the elderly.

Additionally, at the request of Congress, the National Academy of Sciences (NAS) conducted a study of the current food safety system to: 1) determine the scientific basis of an effective food safety system; 2) assess the effectiveness of the current system; 3) identify scientific and organizational needs and gaps; and 4) provide recommendations on scientific and organizational changes needed to ensure an effective food safety system. The NAS released its findings, conclusions, and recommendations in an August 20, 1998 report, *Ensuring Safe Food from Production to Consumption.*

The following papers address the Charter of the President's Council on Food Safety and the process for preparing an assessment of the NAS report, for developing a Food Safety Strategic Plan for all Federal food safety agencies, and for coordinated food safety Federal budgets.

(Final 12/11)

PRESIDENT'S COUNCIL ON FOOD SAFETY
CHARTER

Article I: Purpose.

On August 25, 1998, the President, by Executive Order 13100, established the President's Council on Food Safety ("Council") to improve the safety of the food supply through science-based regulation and well-coordinated inspection, enforcement, research, and education programs. The purpose of the Council is to protect the health of the American people by preventing foodborne illness through improving the safety of the food supply by means of science-based regulation and well-coordinated surveillance and investigation, inspection, enforcement, research, and educational programs. The Council is to: develop and update periodically a comprehensive strategic plan for Federal food safety activities; make recommendations to the President on how to implement the comprehensive strategy and enhance coordination among Federal agencies, State, local and tribal governments, and the private sector; advise Federal agencies in setting priority areas for investment in food safety and developing a coordinated food safety budget for the Administration; and to oversee research efforts of the Joint Institute for Food Safety Research. The President also directed the Council to evaluate and report back to him on the proposals contained in the National Academy of Sciences (NAS) report on food safety.

This Charter provides the basis for collaboration among the members of the Council in carrying out its responsibilities as set forth in the Executive Order.

Article II: Membership

The following individuals shall be members of the Council:

1. Secretary of Agriculture,
2. Secretary of Commerce,
3. Secretary of Health and Human Services,
4. Administrator of the Environmental Protection Agency,
5. Director of the Office of Management and Budget,
6. Assistant to the President for Science and Technology/Director of the Office of Science and Technology Policy,
7. Assistant to the President for Domestic Policy, and
8. Director of the National Partnership for Reinventing Government.

Each member may designate a senior Federal employee to serve as an alternate representative to perform the duties of the Council member.

Article III: Co-Chairs

The Secretaries of Agriculture and of Health and Human Services and the Assistant to the President for Science and Technology/Director of the Office of Science and Technology Policy, or their designated alternates, shall serve as co-chairs of the Council.

The co-chairs shall provide leadership and direction to the Council, and coordinate the formation and schedule of standing committees. Each meeting will be led by one co-chair, and this responsibility shall rotate quarterly among the co-chairs.

Article IV: Staff Support Services

Staff support services for the activities of the Council will be provided by the Co-Chairs through a Secretariat, which will consist of a senior Federal employee from the Department of Agriculture and one from the Department of Health and Human Services. Other members may provide additional staff support services, as necessary. The Secretariat will facilitate planning, coordination, and communication among Council members.

Article V: Meetings

The Council shall meet on a quarterly basis at a time and location chosen by the co-chairs. Additional meetings may be held at the call of the co-chairs or at the request of a majority of the members.

A majority of the Council membership shall constitute a quorum for the transaction of business. All decisions made by the Council at the meetings shall be by consensus defined as substantial agreement as determined by the chair.

The Secretariat will prepare updates of the Council's activities and make the information available for public inspection and copying and on the Council Internet web site.

The Council will prepare a report for submission to the President on October 1 of each year. The report will contain, at a minimum, a description of the Council's activities and accomplishments during the preceding fiscal year, a description of the planned activities for the coming year, a review of strategic planning objectives, and progress made toward accomplishing those objectives.

Article VI: Duties and Responsibilities

The specific responsibilities of the Council are to:

1. Develop and update periodically a comprehensive strategic Federal food safety plan ("plan") to reduce the incidence of foodborne illness and its chronic sequelae by further

enhancing the safety of the nation's food supply and monitoring the impact of these enhancements. The plan will address public health, resource, and management questions facing Federal food safety agencies and will focus on the full range of food safety issues, including the needs of regulatory agencies and the actions necessary to ensure the safety of the food Americans consume. The planning process will consider both short-term and long-term issues including new and emerging threats to the nation's food supply and the special needs of vulnerable populations such as children and the elderly. In developing this plan, the Council will take into consideration the findings and recommendations of the NAS report "Ensuring Safe Food from Production to Consumption" and the review of Federal food safety research by the interagency working group under the auspices of the National Science and Technology Council.

The strategic plan will help set priorities, improve coordination and efficiency, identify gaps in the current system and ways to fill those gaps, enhance and strengthen prevention and intervention strategies, and identify reliable measures to indicate progress.

The Council will conduct public meetings to engage consumers, producers, industry, food service providers, retailers, health professionals, State and local governments, Tribes, academia, and the public in the strategic planning process.

2. Consistent with the strategic plan, advise Federal agencies of priority areas for investment in food safety and work with member agencies in developing annual food safety budgets for submission to the Office of Management and Budget (OMB) to sustain and strengthen priority activities on food safety, eliminate duplication, and ensure the most effective use of resources for achieving the goals of the plan.

3. Oversee the Joint Institute for Food Safety Research (JIFSR). The Council will evaluate the reports from JIFSR on food safety research activities and give direction to JIFSR on research needed to establish the most effective possible food safety system.

4. Evaluate and report to the President on the NAS report, "Ensuring Safe Food from Production to Consumption". After providing opportunity for public comment, including public meetings, the Council will, by February 21, 1999, report to the President on the Council's response to and recommendations concerning the NAS report and appropriate additional actions to improve food safety.

Article VII: Committees

The co-chairs, after consultation with Council members, shall establish committees of Council members, their alternates, or other Federal employees, as they deem necessary, to facilitate and carry out effectively the responsibilities of the Council. Such committees shall report to the Council.

The following committee shall be established by the co-chairs:

JIFSR Executive Research Committee

This committee will evaluate the reports from the JIFSR on its efforts to coordinate food safety research and make recommendations to the Council regarding research needed to establish the most effective possible food safety system.

Article VIII: Web Site

The Council shall establish an Internet web site. The Department of Agriculture shall be the system owner of the web site and shall be responsible for maintaining it. The Council website will provide links to websites of all federal agencies having food safety responsibilities.

Article IX: Effective Date

This Charter shall become effective on the latest date affixed below and may be modified with supplemental agreements signed by all the members of the Council.

Secretary of Agriculture	Secretary of Commerce
Secretary of Health and Human Services	Administrator of Environmental Protection Agency
Director of Office of Management and Budget	Assistant to the President for Science and Technology/Director of the Office of Science and Technology Policy

Assistant to the President
for Domestic Policy

Director of the National Partnership
for Reinventing Government

Discussion Paper: Assessment of NAS Report "Ensuring Safe Food from Production to Consumption"

Action Required: Approval of plan to provide the President with an assessment of the NAS Report "Ensuring Safe Food from Production to Consumption."

BACKGROUND: In response to the Congressionally mandated Food Safety study, the National Academy of Sciences (NAS) established a study committee and obtained input from Federal agencies and other stakeholders of the Federal food safety system. The NAS issued its report on August 20, 1998. Congress viewed this study as part one of a possible two-part process. Had the NAS recommended that a single Federal food safety agency be required to achieve adequate performance and levels of public health protection, Congress planned to appropriate additional funds to support a second NAS study, which would focus on how such an agency should function. The NAS Committee did not explicitly recommend the establishment of a single Federal food safety agency, and funds for part two were not appropriated for fiscal year 1999. On August 25, 1998, the President issued a directive tasking the Council on Food Safety to provide him with an assessment of the NAS report in 180 days (by February 21, 1999). Specifically, the President directed:

> "...the Council to review and respond to this report as one of its first orders of business. After providing opportunity for public comment, including public meetings, the Council shall report back to me within 180 days with its views on the NAS's recommendations. In developing its report, the council should take into account the comprehensive strategic Federal food safety plan that it will be developing."

Four public meetings have been held to solicit stakeholder input on the NAS report (October 2, in Arlington, VA; October 20, in Sacramento, CA; November 10, in Chicago, IL; and December 8 in Dallas, TX).

RECOMMENDATION: The Interagency Food Safety Working Group recommends that the Council establish a task force consisting of one representative from each of the following agencies: OSTP, HHS, USDA, EPA, OMB, and DOC. This 6 person task force will systematically assess the NAS report by providing a) agency/department specific analysis of the strengths and weaknesses of the report's findings and recommendations, including whether the agency/department agrees or disagrees and why; b) an assessment of the cross-agency/department issues identified by the report; and c) recommendations on whether to incorporate particular elements of the NAS report into the Council's comprehensive strategic plan. If appropriate, the task force should identify barriers to implementation. Each task force representative will be responsible for coordinating input from within his or her own agency. The task force will be chaired by OSTP and will provide a draft report to the Council by February 5, 1999. Once the report is submitted to the President by February 21, 1999, the Council may seek additional public input on its assessment of the NAS report's recommendations.

DISCUSSION PAPER: Process for developing a Food Safety Strategic Plan for all Federal food safety agencies

ACTION REQUIRED: Approval of a process for preparing a food safety strategic plan

The President's Council on Food Safety will be responsible for development of a 5-year Federal food safety strategic plan. The charge is to develop a comprehensive strategic long-range plan that addresses the steps necessary to achieve a seamless food safety system including key public health, resource, and management issues regarding food safety and to ensure the safety of food. The plan will be used to set priorities, improve coordination and efficiency, identify gaps in the current system and mechanisms to fill those gaps, continue to enhance and strengthen prevention and intervention strategies, and develop performance measures to show progress. Each agency will incorporate the relevant parts of the strategic plan into its Government Performance and Results Act (GPRA) strategic plan, commensurate with its budget. The scope of the strategic plan (e.g., microbial vs. chemical contamination) is to be determined by the Council.

The food safety agencies have already taken the first steps to develop the food safety strategic plan, by participating in interagency strategic planning sessions and developing a draft vision statement for the U.S. food safety system and the roles of all those involved in food safety.

In addition, during 1997 and 1998, the federal food safety agencies engaged a wide range of stakeholders in discussions about food safety issues through a series of public meetings and through written comments to public dockets.

RECOMMENDATION: Convene a committee to develop a comprehensive food safety strategic plan based on the recommendations received from the various constituencies. The committee will consist of representatives from each of the following agencies: HHS, USDA, EPA, CDC, and NPR.

The committee will follow the following process:

- First conduct a content analysis of the transcripts and dockets of the 1998 meetings and public comments to determine the major themes, issues, and subject areas that emerged during the public outreach phase.

- Consider the conclusions and recommendations of the National Academy of Sciences' report on *Ensuring Safe Food from Production to Consumption*, the review of Federal food safety research and the research plan currently being developed by an interagency working group under the auspices of the National Science and Technology Council, input from the 50-State meeting on state/local issues and recommendations, and input from the agencies involved.

- Develop a proposed set of strategic goals and objectives and present a draft strategic plan to the President's Council.

- Following Council review and approval, present the draft food safety strategic plan to the public for comment in January 2000.

- Review the public comments and submit a final draft of the strategic plan to the Council in July 2000 for approval.

Discussion Paper: Coordinated Food Safety Budget Planning Process

For Consideration by the President's Council on Food Safety

Action Required: Approval of a process to develop coordinated food safety budgets and a unified food safety initiative budget submission the strategic plan.

Current Interagency Budget Planning Process

In response to the May 1997 report to the President, the Department of Heath and Human Services (HHS) and the Department of Agriculture (USDA) have coordinated a multi-agency effort to present a unified budget for the President's Food Safety Initiative. The report recognizes that only through joint planning can Federal resources be maximized and the greatest improvements in food safety be achieved.

The involved agencies also worked collaboratively to present a unified food safety initiative budget to OMB and the Congress for 1998, 1999, and 2000. However, the process for coordination and joint planning has not been initiated until the completion of individual agency budget decisionmaking. The result is inclusion of food safety initiative budget requests in individual agency budget submissions to OMB and preparation of a unified budget submission "after the fact." In fact, this year's unified budget was submitted to OMB only a few days prior to OMB passback.

Preparation of a Coordinated Food Safety Budget Planning Process

The strategic plan will provide a solid basis for coordinated food safety budget planning and resource requests. The Council will also ensure that the agencies submit a unified food safety initiative budget that includes other food safety issues, as

determined appropriate by the Council. In order for the coordinated budget planning process for food safety to be successful, these actions must be completed. First, the Council should develop guidance for food safety agencies to consider during the preparation of their individual agency budgets. In order for this guidance to be most useful, the guidance should be made available to the agencies by late February to coincide with the beginning of the budget planning process of the involved agencies (e.g., HHS process begins in March).

Second, agencies must collect the budget data necessary for coordinating food safety budgets from the earliest point in budget planning. Third, establish a process for agencies to submit relevant budget information to OMB.

Recommendation: Form a task force composed of representatives from the budget and program staffs of HHS, USDA, and EPA, in consultation with OMB, to work with the Council to develop a coordinated budget planning process for food safety activities similar to other cross-cutting issues. The agency representatives of this task force will also work throughout the budget planning process, beginning at the earliest point (i.e., HHS calendar) to assure coordination of activities and resource requests. The task force, in consultation with OMB, should conduct the following activities:

- Review the strategic plan and Council budget guidance on priority areas for investment to identify budget data and other information that will be necessary to plan and coordinate agency budget submissions;

- Design a uniform format for presenting food safety initiative budget components in the OMB budget process for use in both individual agency (to the extent possible considering individual agency procedures and the need for activities to remain transparent) and the unified budget submissions;

- Develop necessary guidance to facilitate submission of a unified food safety initiative and any other food safety issues deemed appropriate by the Council;

Cons pro- food safety council

Thomas L. Freedman
12/07/98 11:38:02 AM

Record Type: Record

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

cc: Mary L. Smith/OPD/EOP, Laura Emmett/WHO/EOP
Subject: Food Safety Council

This is the draft agenda for the meeting of the food safety council on 12/16. The main issue will be the budget discussion, hence the meeting is planned to be closed. We have held a relatively small MOU that FSIS and FDA can agree to which we can tell interested press later was one of the tangible work-products of the meeting. The MOU allows better sharing of inspection personnel between the two agencies -- but we need much more. Bruce, has been given 5 minutes to talk, I thought you might want to affirm the importance of the council, use the MOU as an example of the direction you hope we move in, and talk about how the different agencies share common goals. Do you want to speak? I've previously sent you the draft documents under discussion but will send again if you wish.

AGENDA
President's Council on Food Safety
USDA Whitten Building, Rm ?
December 16, 1998
10:00 am - 11:00 am

Introductions and Opening Remarks -- Glickman, Shalala, Lane (5 min)

Elements of the Executive Order -- Reed (5 min)

Discussion and Approval of Charter -- Woteki (5 min)

Discussion and Approval of Council's scope -- Goldman (15 min)

FY2000 Budget and future crosscut -- Lew/Gotbaum (10 min)

Comprehensive Plan -- O'Hara (5 min)

NAS Report Assessment -- Gabriel (5 min)

Joint Institute for Food Safety Research -- Kennedy and Raub (5 min)

Closing -- Glickman, Shalala, Lane (5 min)

cons pro - food safety council

President's Council on Food Safety
Food Safety Strategic Plan

October 2, 1998
Arlington, Virginia

8:30 **Registration**

9:30 **Welcome**

Dr. Neal Lane
Assistant to the President for Science and Technology, Director of the Office of Science and Technology Policy

Importance of Food Safety, Accomplishments and Successes

Donna Shalala
Secretary of Health and Human Services

Richard Rominger
Deputy Secretary of Agriculture

Introduction of Panel Members—Dr. Neal Lane

Dr. Catherine E. Woteki, Under Secretary for Food Safety, USDA
James A. O'Hara, Deputy Assistant Secretary for Health, HHS
Dr. Lynn R. Goldman, Assistant Administrator for Prevention, Pesticides and Toxic Substances, EPA
Thomas J. Billy, Administrator, Food Safety and Inspection Service, USDA
Joseph Levitt, Director, Center for Food Safety and Applied Nutrition, FDA, HHS
Dr. Morris Potter, Assistant Director for Foodborne Diseases, CDC, HHS

Agency Visions

A Safe & Affordable Food Supply—**Dr. Lynn R. Goldman**
Assuring Food Safety Requires Everyone to Play a Role—**James A. O'Hara**
Protecting the Food Supply Must Be Grounded in Sound Science—**Dr. Catherine E. Woteki**

10:10 **BREAK**

10:25 **Discussion of the Vision/Strategic Plan**

10:25 1. Does the vision statement accurately depict an achievable food safety system vision? What modifications, if any, would you make?

10:45 2. What are the barriers to pursuing this vision? What gaps currently exist in the foodsafety system that impede achievement of this vision?

3. To make the vision a reality, what changes are needed for: a) government agencies at the Federal, State, and local level; b) industry; c) public health professionals; d) consumers; and e) others?

11:45 **LUNCH**

12:30 **Discussion of Vision**

12:30 4. What should be the short-term goals and critical steps to realize this vision? What should be the long-term goals and steps?

1:15 5. What is the best way to involve the public in development of a long-term food safety strategic plan? What additional steps besides public meetings would be beneficial?

1:30 6. What are your comments on the conclusions and recommendations of the National Academy of Sciences' report, "Ensuring Safe Food From Production to Consumption"?

2:30 **Public Comment**

4:15 **Closing Remarks**

Vision Statement:

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.

Questions:

1. Does the vision statement accurately depict an achievable food safety system vision? What modifications, if any, would you make?

2. What are the barriers to pursuing this vision? What gaps currently exist in the food safety system that impede achievement of this vision?

3. To Make the vision a reality, what changes are needed for: a)government agencies at the Federal, State, and local level; b) industry; c) public health professionals; d) consumers; and e) others?

4. What should be the short-term goals and critical steps to realize this vision? What should be the long-term goals and steps?

5. What is the best way to involve the public in development of a long-term food safety strategic plan? What additional steps besides public meetings would be beneficial?

6. What are your comments on the conclusions and recommendations of the National Academy of Sciences' report, "Ensuring Safe Food From Production to Consumption"?

Comment Requests

Request to comment	Name	Call-in Date	Organization	Phone Number	Fax Number
Yes					
Bob	Garfield	8/28/98	American Frozen Food Institute	703-821-0770	703-821-1350
Susan	McNight	8/28/98	Quality Flow Inc.	847-291-7674	847-291-7679
Patrick	Boyle	9/2/98	AMI	703-841-2400	703-527-0938
Jill	Hollingsworth	9/2/98	Food Marketing Institute	202-429-8238	202-429-8272
Theresa	Stretch	9/3/98	C-FAR	217-244-4232	217-244-8594
Barbara	Stowe	9/8/98	Borden Human Sciences	202-675-4511	202-675-4512
Tim	Hammonds	9/11/98	Food Marketing Institute	202-452-8444	202-429-8282
Joseph	Corby	9/14/98	Association of Food and Drug Officials (AFDO)	518-457-5382	518-485-8986
Tom	Devine	9/14/98	GAP	202-408-0034	202-408-9855
Jesse	Privett	9/14/98	USDA/FSIS	806-839-3195	806-839-2148
Caroline	Smith Dewall	9/14/98	CSPI	202-332-9110	202-265-4954

Request to comment	*Name*	*Call-in Date*	*Organization*	*Phone Number*	*Fax Number*
Randy	Wurtele	9/17/98	National Joint Council of Food Inspector Locals	503-728-3814	503-728-4782
Felicia	Nestor	9/21/98	GAP	202-408-0034ex.132	202-408-9855
Rosetta	Newsome	9/21/98	Institute of Food Technologists	312-782-8424	312-782-8348
Randy	Warhaw	9/21/98	Cornell University	315-787-2279	315-787-2284
Lisa	Boral	9/23/98	ELASTIC	610-436-4801	610-436-1198
Nancy	Donley	9/23/98	S. T. O. P.	718-246-2739	718-624-4267
Heather	Klinkhamer	9/23/98	S. T. O. P.	718-246-2739	718-624-4267
Beth	Resnick	9/27/98	NACCHO	202-783-5550	202-783-1583
Lester	Friedlander	9/28/98	Veterinarian	717-746-3072	717-746-7731
Kelly	Johnson	9/28/98	National Food Processors Association	202-637-8060	202-637-8476

Tom Montgomery 10/1 United Egg Association 2/842-2345

october 2

Last Name	*First Name*	*Organization Name*	*Phone Number*	*Fax Number*
Allison	Richard	Food Safety Council	301-530-7052	
Alonso-Zaldwar	Ricardo	Los Angeles Times, Washington Bureau	202-861-9295	
Anderson	Donald	DWA	919-541-5804	
Anderson	Steve	American Frozen Food Institute	703-821-0770	703-821-1350
Balwin's	Diana	Maryland Department of Agriculture	410-841-5769	410-841-2765
Best	Wanda	USDA/CSREES	202-401-3357	202-401-5179
Boral	Lisa	ELASTIC	610-436-4801	610-436-1198
Boyle	Patrick	AMI	703-841-2400	703-527-0938
Carroll	Kathy	American Dietetic Association	312-899-4860	312-899-7458
Cates	Sheri	DWA	919-541-5804	
Clap	Steve	Food Reg. Weekly	703-295-8637	
Corby	Joseph	Association of Food and Drug Officials (AFDO)	518-457-5382	518-485-8986
Datoc	Marylynn	FDA	301-827-0413	301-827-0482
Datoc	Marylynn	FDA	301-827-0413	301-827-0482
Devine	Tom	GAP	202-408-0034	202-408-9855
Dieteman	Kathryn	Shandwick Public Affairs	202-383-9700	202-383-0079
Dimatteo	Catherine	Organic Trade Association	413-774-7511	413-774-6432
Donley	Nancy	S. T. O. P.	718-246-2739	718-624-4267
Earl	Robert	International Food Informational Council	202-296-6540	202-296-6547
Finelli	Mary	Humane Society	301-258-3056	301-258-3081
Fong	George	Florida Department of Agriculture	850-488-9670	850-922-9110
Friedlander	Lester	Veterinarian	717-746-3072	717-746-7731

Last Name	*First Name*	*Organization Name*	*Phone Number*	*Fax Number*
Garfield	Bob	American Frozen Food Institute	703-821-0770	703-821-1350
George	Bernat	IICA	202-458-6955	
Gould	Chris	Safe Food Coalition	202-822-8060	202-822-9088
Grove	Tina	Taf-Environ	703-516-2394	703-516-2390
Grover	Steven	National Resturant Association	202-331-5986	202-973-3671
Hahn	Robert	Public Voice for Food & Health Policy	202-347-6200	202-347-6261
Hammonds	Tim	Food Marketing Institute	202-452-8444	202-429-8282
Hodges	Jim	AMI	703-841-2400	703-527-0938
Hollingsworth	Jill	Food Marketing Institute	202-429-8238	202-429-8272
Holmes	Marty	North American Meat processors	703-443-9181	202-758-8001
Huffman	Dale	Auburn University	334-821-3648	334-502-6171
Iescheid	Keith	Embassy of Chile	202-785-1746ext.124	
Iwanicki	Stan	Agrilink Foods, Inc.	716-264-3192	716-383-1281
Jatib	Maria	Iica	202-458-3767	202-458-6335
Johnson	Kelly	National Food Processors Association	202-637-8060	202-637-8476
Jolly	Bill	New Zealand Embassy	202-328-4861	202-332-4309
Kantor		University of Maryland	0	301-314-9327
Klinkhamer	Heather	S. T. O. P.	718-246-2739	718-624-4267
Kosty	Lynn	NCBA	202-347-0228	202-638-0607
Lautiner	Beth	National Pork Processors Council	515-223-2623	515-223-2646
Lee	Rebecca	USDA/FSA/PDD	202-690-2534	202-690-1809
Leonard	Rodney	Commision on Nutrution Institute	202-776-0595	202-776-0599
Lister	Sarah	Senator Thom Harkin, Senate At. Committee	202-224-5929	202-224-9287
Locher-Bussard	Connie	C-FAR	217-244-4232	217-244-8594

Last Name	*First Name*	*Organization Name*	*Phone Number*	*Fax Number*
McElvaine	Michael	USDA	202-720-8121	
McNight	Susan	Quality Flow Inc.	847-291-7674	847-291-7679
Melnick	Amy	American Society for Microbiology	202-942-9296	202942-9335
Mennecier	Paul	Embassy of France	202-944-6358	202-944-6303
Miller	Peter	Australian Embassy	202-797-3319	202-797-3049
Montgomery	Tom	United Egg Association	202-842-2345	202-682-0775
Natrajan	Nandini	Keystone Foods	610-534-5316ext.229	610-586-1665
Nestor	Felicia	GAP	202-408-0034ex.132	202-408-9855
Newsome	Rosetta	Institute of Food Technologists	312-782-8424	312-782-8348
Ontko	David	Walt Disney World Company	407-934-6697	407-828-6015
Phillips	Terry	Johns Hopkins University	240-228-4831	240-228-5353
Pretanik	Stephen	National Broiler Council	202-262-2662	202-293-4005
Privett	Jesse	USDA/FSIS	806-839-3195	806-839-2148
Prout	Terry	SMC Corporation	202-956-5213	202-956-5235
Ralph	Andrew	Meat & Livestock Australia	212-486-2405	212-355-1470
Resnick	Beth	NACCHO	202-783-5550	202-783-1583
Rice	Kim	AMI	703-841-2400	703-527-0938
Robbins	Robyn	United Food & Commercial Workers International Un.	202-466-1505	202-466-1562
Roberts	Cindy	USDA/AG Library	301-504-6409	
Sadib	Mario	Argentina Embassy	202-238-6446	202-332-1324
Sanders	Lee	American Bakers Association	202-789-0300	
Santos	Edwardo	Embassy of Chile	202-785-1746ext.124	
Sarasin	Leslie	American Frozen Food Institute	703-821-0770	703-821-1350

Last Name	*First Name*	*Organization Name*	*Phone Number*	*Fax Number*
Schwemer	Brett	Olson, Frank & Weda	202-518-6359	202-234-1560
Sell	Kyla	Sunkist Growers	202-879-0256	202-628-8233
Serade	Kirk	National Pork Producers Council	202-347-3600	202-347-5265
Sharal	Amilia	USDA/FSIS/SDB	202-720-0107	202-205-0080
Sheehan	Mary	Minnesota Department of Health	651-215-0861	651-215-0977
Slert	Patricia	Johns Hopkins University	240-228-4831	240-228-5353
Smith Dewall	Caroline	CSPI	202-332-9110	202-265-4954
Smolenski	Mark	SRI International	703-247-8472	703-247-8569
Snowden	Jill	Egg Nutrition Center	202-833-8850	202-463-0102
Stowe	Barbara	Borden Human Sciences	202-675-4511	202-675-4512
Stretch	Theresa	C-FAR	217-244-4232	217-244-8594
Takeginchi	Clyde	Phoenix Regulatory Associates	703-406-0906	703-406-9513
Tate	Michael	Tate-Francheca Company	703-907-5592	703-907-5565
Thayer	Dennis	National Resturant Association	202-331-5986	202-973-3671
Thomas	Carol	USDA/FSIS/SDB	202-720-0107	202-205-0080
Tresenfeld	Leslie	HOLE Foods Market	301-263-9686	301-263-9685
Tucker-Foreman	Carol	Safe Food Coalition	202-822-8060	202-822-9088
Turetsky	Joan	USDA/AMS	202-720-4486	
Veallos	Juan	Iica	202-458-3767	202-458-6335
Voit	Donna	CRS Congressional Research Service	202-707-7285	202-707-7000
Walsh	Hedy	Meat & Livestock Australia	212-486-2405	212-355-1470
Ward	Elise	Community Health in Focus	301-986-5706	301-656-2683
Warhaw	Randy	Cornell University	315-787-2279	315-787-2284
Wenning	Tom	National Grocer's Association	703-437-5300	703-437-7768

Last Name	*First Name*	*Organization Name*	*Phone Number*	*Fax Number*
Willard	Tim	National Food Processors Association	202-637-8060	202-637-8476
Wilson	Geoffrey	John Hopkins Applie Physics Laboratory	240-228-4831	
Wilson	Robert	CIFT	202-835-1571-202	202-296-2736
Wozniak	Chris	EPA/OPP/BPPD	703-605-0513	703-308-7026
Wurtele	Randy	National Joint Council of Food Inspector Locals	503-728-3814	503-728-4782
Yablonski	Cindy	International Bottled Water Association	703-683-5213	703-683-4074
Yamada	Al	Fresh Produce Association of the Americas	202-296-4484	202-293-3060
Zawel	Stacey	Grocery Man. Of America	202-295-3943	202-337-4508

Federal Register
Vol. 63, No. 166
Thursday, August 25, 1998

Presidential Documents

Title 3—

The President

Executive Order 13100 of August 25, 1998

President's Council on Food Safety

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to improve the safety of the food supply through science-based regulation and well-coordinated inspection, enforcement, research, and education programs, it is hereby ordered as follows:

Section 1. *Establishment of President's Council on Food Safety.* (a) There is established the President's Council on Food Safety ("Council"). The Council shall comprise the Secretaries of Agriculture, Commerce, Health and Human Services, the Director of the Office of Management and Budget (OMB), the Administrator of the Environmental Protection Agency, the Assistant to the President for Science and Technology/Director of the Office of Science and Technology Policy, the Assistant to the President for Domestic Policy, and the Director of the National Partnership for Reinventing Government. The Council shall consult with other Federal agencies and State, local, and tribal government agencies, and consumer, producer, scientific, and industry groups, as appropriate.

(b) The Secretaries of Agriculture and of Health and Human Services and the Assistant to the President for Science and Technology/Director of the Office of Science and Technology Policy shall serve as Joint Chairs of the Council.

Sec. 2. *Purpose.* The purpose of the Council shall be to develop a comprehensive strategic plan for Federal food safety activities, taking into consideration the findings and recommendations of the National Academy of Sciences report "Ensuring Safe Food from Production to Consumption" and other input from the public on how to improve the effectiveness of the current food safety system. The Council shall make recommendations to the President on how to advance Federal efforts to implement a comprehensive science-based strategy to improve the safety of the food supply and to enhance coordination among Federal agencies, State, local, and tribal governments, and the private sector. The Council shall advise Federal agencies in setting priority areas for investment in food safety.

Sec. 3. *Specific Activities and Functions.* (a) The Council shall develop a comprehensive strategic Federal food safety plan that contains specific recommendations on needed changes, including measurable outcome goals. The principal goal of the plan should be the establishment of a seamless, science-based food safety system. The plan should address the steps necessary to achieve this goal, including the key public health, resource, and management issues regarding food safety. The planning process should consider both short-term and long-term issues including new and emerging threats and the special needs of vulnerable populations such as children and the elderly. In developing this plan, the Council shall consult with all interested parties, including State and local agencies, tribes, consumers, producers, industry, and academia.

(b) Consistent with the comprehensive strategic Federal food safety plan described in section 3(a) of this order, the Council shall advise agencies of priority areas for investment in food safety and ensure that Federal agencies annually develop coordinated food safety budgets for submission to the OMB that sustain and strengthen existing capacities, eliminate duplication, and ensure the most effective use of resources for improving food

safety. The Council shall also ensure that Federal agencies annually develop a unified budget for submission to the OMB for the President's Food Safety Initiative and such other food safety issues as the Council determines appropriate.

(c) The Council shall ensure that the Joint Institute for Food Safety Research (JIFSR), in consultation with the National Science and Technology Council, establishes mechanisms to guide Federal research efforts toward the highest priority food safety needs. The JIFSR shall report to the Council on a regular basis on its efforts: (i) to develop a strategic plan for conducting food safety research activities consistent with the President's Food Safety Initiative and such other food safety activities as the JIFSR determines appropriate; and (ii) to coordinate efficiently, within the executive branch and with the private sector and academia, all Federal food safety research.

Sec. 4. *Cooperation.* All actions taken by the Council shall, as appropriate, promote partnerships and cooperation with States, tribes, and other public and private sector efforts wherever possible to improve the safety of the food supply.

Sec. 5. *General Provisions.* This order is intended only to improve the internal management of the executive branch and is not intended to, nor does it, create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers or any person. Nothing in this order shall affect or alter the statutory responsibilities of any Federal agency charged with food safety responsibilities.

THE WHITE HOUSE,
August 25, 1998.

[FR Doc. 98-23258
Filed 8-26-98; 8:45 am]
Billing code 3195-01-P

Clinton Administration Accomplishments In Improving Food Safety

The Administration has put into place improved safety standards for meat, poultry, and seafood products, and has begun the process of developing enhanced standards for fruit and vegetable juices. The Administration also has expanded research, education, and surveillance activities throughout the food safety system.

*August 1998. President Clinton signs an Executive Order creating the President's Council on Food Safety, which will develop a comprehensive strategic plan for federal food safety activities and ensure that federal agencies annually develop coordinated food safety budgets.

*July 1998. President creates a Joint Institute of Food Safety Research which will develop a strategic plan for conducting and coordinating all federal food safety research activities, including with the private sector and academia.

*February 1998. Administration announces its proposed food safety budget, which requests an approximate $101 million increase for food safety initiatives.

*May 1997. Administration announces comprehensive new initiative to improve the safety of nation's food supply --"Food Safety from Farm to Table" -- detailing a $43 million food safety program, including measures to improve surveillance, outbreak response, education, and research.

*January 1997. President announces new Early-Warning System to gather critical scientific data to help stop foodborne disease outbreaks quickly and to improve prevention systems.

*August 1996. President signs Safe Drinking Water Act of 1996. The law requires drinking water systems to protect against dangerous contaminants like Cryptosporidium, and gives people the right to know about contaminants in their tap water.

*August 1996. President signs Food Quality Protection Act of 1996, which streamlines regulation of pesticides by FDA and EPA and puts important new public-health protections in place, especially for children.

*July 1996. President announces new regulations that modernize the nation's meat and poultry inspection system for the first time in 90 years. New standards help prevent E.coli bacteria contamination in meat.

*December 1995. Administration issues new rules to ensure seafood safety, utilizing HACCP regulatory programs to require food industries to design and implement preventive measures and increase the industries' responsibility for and control of their safety assurance actions.

*1994. CDC embarks on strategic program to detect, prevent, and control emerging infectious disease threats, some of which are foodborne, making significant progress toward this goal in each successive year.

*1993. Vice-President's National Performance Review issues report recommending government and industry move toward a system of preventive controls.

PRESIDENT CLINTON SIGNS EXECUTIVE ORDER
CREATING COUNCIL ON FOOD SAFETY
August 24, 1998

President Clinton today will sign an Executive Order to create a President's Council on food Safety, which will develop a comprehensive strategic plan for federal food safety activities and ensure that federal agencies annually develop coordinated food safety budgets. The President also will sign a directive to the Council to review the recently issued National Academy of Sciences (NAS) report, "Ensuring Safe Food from Production to Consumption," and to report back with its response to the report, including appropriate additional actions to improve food safety.

President's Council on Food Safety. The President signs an Executive Order establishing a President's Council on Food Safety (Council). The Council will have three primary functions, including: (1) developing a comprehensive strategic federal food safety plan; (2) advising agencies of priority areas for investment in food safety and ensuring that federal agencies annually develop coordinated food safety budgets; and (3) overseeing the recently established Joint Institute for Food Safety Research and ensuring that it addresses the highest priority research needs.

- **Comprehensive strategic federal food safety plan.** The Council will develop a comprehensive plan to improve the safety of the nation's food supply by establishing a seamless, science-based food safety system. The plan will address the steps necessary to achieve this improved system, focusing on key public health, resource, and management issues and including measurable outcome goals. The planning process will consider both short and long-term issues including new and emerging threats and the special needs of vulnerable populations such as children and the elderly. In developing this plan, the Council will consult with all interested parties, including state and local agencies, tribes, consumers, producers, industry, and academia.

- **Coordinated federal food safety budgets.** Consistent with the comprehensive strategic federal food safety plan, the Council will advise agencies of priority areas for investment in food safety and ensure that federal agencies annually develop coordinated food safety budgets. This coordinated food safety budget process will sustain and strengthen existing activities, eliminate duplication, and ensure the most effective use of resources for improving food safety.

- **Oversight of federal food safety research efforts.** The Council will ensure that the Joint Institute for Food Safety Research addresses the highest priority food safety research gaps. The Institute will report, on a regular basis, to the Council on its efforts to conduct and coordinate food safety research activities and will receive direction from the Council on research needed to establish the most effective possible food safety system.

Review of NAS Report. The President will direct the Council, as one of its first orders of business, to review the National Academy of Sciences (NAS) report, "Ensuring Safe Food from Production to Consumption." After providing opportunity for public comment, including public meetings, the Council will report back to the President within 180 days with its response to the NAS report. The Council's report will consider appropriate additional actions to improve food

safety, including proposals for legislative reform of the food safety system.

Public Meeting to Develop Comprehensive Strategic Plan for Federal Food Safety Activities. The Clinton Administration will publish notice of the first public meeting, to be held on October 2 in Arlington, Virginia, to begin development of the Council's comprehensive strategic plan for federal food safety activities. The meeting will engage consumers, producers, industry, food service providers, retailers, health professionals, State and local governments, Tribes, academia, and the public in the strategic planning process.

Ensuring Safe Food

From Production to Consumption

Committee to Ensure Safe Food from Production to Consumption

INSTITUTE OF MEDICINE

NATIONAL RESEARCH COUNCIL

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NOTICE: The project that is the subject of this report was approved by the Governing Board of the National Research Council, whose members are drawn from the councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. The members of the committee responsible for the report were chosen for their special competences and with regard for appropriate balance.

The National Academy of Sciences is a private, nonprofit, self-perpetuating society of distinguished scholars engaged in scientific and engineering research, dedicated to the furtherance of science and technology and to their use for the general welfare. Upon the authority of the charter granted to it by the Congress in 1863, the Academy has a mandate that requires it to advise the federal government on scientific and technical matters. Dr. Bruce Alberts is president of the National Academy of Sciences.

The National Academy of Engineering was established in 1964, under the charter of the National Academy of Sciences, as a parallel organization of outstanding engineers. It is autonomous in its administration and in the selection of its members, sharing with the National Academy of Sciences the responsibility for advising the federal government. The National Academy of Engineering also sponsors engineering programs aimed at meeting national needs, encourages education and research, and recognizes the superior achievements of engineers. Dr. William A. Wulf is president of the National Academy of Engineering.

The Institute of Medicine was established in 1970 by the National Academy of Sciences to enlist distinguished members of the appropriate professions in the examination of policy matters pertaining to the health of the public. In this, the Institute acts under both the Academy's 1863 congressional charter responsibility to be an adviser to the federal government and its own initiative in identifying issues of medical care, research, and education. Dr. Kenneth I. Shine is president of the Institute of Medicine.

The National Research Council was organized by the National Academy of Sciences in 1916 to link the broad community of science and technology with the Academy's purposes of furthering knowledge and advising the federal government. Functioning in accordance with general policies determined by the Academy, the Council has become the principal operating agency of both the National Academy of Sciences and the National Academy of Engineering in providing services to the government, the public, and the scientific and engineering communities. The Council is administered jointly by both Academies and the Institute of Medicine. Dr. Bruce Alberts and Dr. William A. Wulf are chairman and vice-chairman, respectively, of the National Research Council.

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Ensuring Safe Food

From Production to Consumption

Executive Summary

Adequate, nutritious, safe food is essential to human survival, but food can also cause or convey risks to health and even life itself. Although estimates vary widely, there is agreement that foodborne illness is a serious problem. In the United States, as many as 81 million illnesses (Archer and Kvenberg, 1985) and up to 9,000 deaths (CAST, 1994) per year have been attributed to food-related hazards. Estimates of the annual cost of medical treatment and lost productivity vary widely, from $6.6 billion to $37.1 billion from seven major foodborne pathogens (Buzby and Roberts, 1997).

The nation's agriculture and food marketing systems have evolved to provide food to a growing and increasingly sophisticated population. Complex processes built on advances in science and technology have been developed to evaluate and manage the risks associated with the changing nature of the food supply. Well-established systems control many food risks, but serious hazards to public health remain.

PURPOSE AND SCOPE OF THE STUDY

As a result of the continuing concern about the food safety system in the United States, Congress commissioned the National Academy of Sciences, through the Agricultural Research Service of the US Department of Agriculture (USDA), to undertake the study that resulted in this report. The charge to the committee was twofold. The committee was asked to (1) assess the effectiveness of the current system to ensure safe food, and (2) provide recommendations on scientific and organizational changes needed to increase the effectiveness of the food safety system. Over a 6 month period, the committee held three meetings as well as two open forums where agency representatives and relevant stakeholders discussed the food safety system. The committee reviewed many documents, including reports on how other countries are reshaping their systems.

This report summarizes the committee's review of food safety in the United States by (1) describing the current US system for food safety and the changing nature of concerns which it encounters, (2) outlining an effective food safety system, (3) identifying the ways in which the current food safety system is inadequate, and (4) providing recommendations to move toward the scientific foundation and organizational structure of a more effective food safety system.

Protecting the safety of food requires attention to a wide range of potential hazards. Food safety is not limited to concerns related to foodborne pathogens, toxicity of chemical substances, or physical hazards, but may also include issues such as nutrition, food quality, labeling, and education. While the scope of this study includes all of these components, this committee's immediate concern focuses on food-related hazards.

1. The Current US Food Safety System

The US food supply is abundant and affordable and is judged by many to present an acceptable level of risk to health. The system has evolved from one that provided consumers with minimally processed basic commodities that were predominantly for home preparation to today's system of highly processed products designed either to be ready-to-eat or to require minimal preparation in the home. As a result of many technological advances, the food system has progressed dramatically from traditional food preservation processes such as salting and curing to today's marketplace with frozen ready-to-eat meals and take-out foods. Likewise, distribution systems for foods have changed greatly.

While these developments have provided the American consumer with a wide array of food products with a high degree of safety, a more diverse food supply carries additional risks as well as benefits. The availability of new food choices such as "minimally processed" vegetable products (for example, prebagged and chopped leaf lettuce mixes) presents new risks for microbial contamination. The globalization of the food system brings food from all parts of the world into the US marketplace, and with it the potential for foodborne infection or other hazards not normally found in the United States.

The current US food safety system has many of the attributes of an effective system. The nature of food safety concerns has changed due to past successful efforts to control the use of unidentified or misrepresented food ingredients and problems with the appearance and wholesomeness of food products; microbiological and chemical hazards now present new and in some cases increasingly serious challenges which cannot be detected using traditional inspection methods. The introduction of Hazard Analysis Critical Control Point (HACCP) monitoring systems in meat, poultry, and seafood products is an example of the introduction of science-based process control methodology into food safety regulation and enforcement.

Many Americans now eat in ways that increase risk, including consuming more raw or minimally processed fruits and vegetables and eating fewer home-prepared meals. A smaller number of food processing and preparation facilities provide food to increasingly larger numbers of US consumers, enhancing the extent of harm that can arise from any one incident. Simultaneously, increasing numbers of Americans have compromised immune systems because of age, illness, or medical treatment. The development of genetically modified foods and modified macronutrients are two examples of new products or technologies that require new ways of evaluating the safety of substances added to the food supply.

The federal government has usually addressed these developments by adding new structures and processes or adjusting old ones. These incremental adjustments have created a number of inefficiencies and apparent conflicts within the system. Some have been addressed (for example, pesticides have been exempted from the Delaney clause's ban on carcinogens), but others remain. USDA is obligated by statute to maintain the system of continuous on-site factory inspection by government inspectors that has been the hallmark of meat and poultry regulation. The Food and Drug Administration (FDA), meanwhile, with a more varied industry to regulate, has relied on selective monitoring, in which far fewer inspectors periodically visit settings where food is produced, processed, or stored to verify compliance with or to uncover violations of its requirements. A result is that in some cases inspectors from these two agencies oversee food processing in the same processing facility at the same time due to the different enabling statutes. Agencies are at times precluded by statute from implementing monitoring or enforcement practices that are based in science.

The size and complexity of the US food system require significant involvement of government at all levels—federal, state, and local; of the food industry—ranging from the producer to food server; of universities; of the news media; and, most importantly, of the consumer, to address adequately the multitude of issues that arise in ensuring safe food. At the federal level, the efforts are currently fragmented, with at least 12 agencies[1] involved in the key functions of safety: monitoring, surveillance, inspection, enforcement, outbreak management, research, and education. Efforts to coordinate federal activities have intensified over the last two years with the National Food Safety Initiative. There are over 50 memoranda of agreement between various agencies related to food safety. The recent proposal to create a Joint Food Safety Research Institute between USDA and FDA is an obvious outgrowth of such efforts. Notwithstanding these relatively recent activities, however, there still exist significant barriers to full integration.

Summary Findings: The Current US System for Food Safety

- has many of the attributes of an effective system;
- is a complex, inter-related activity involving government at all levels, the food industry from farm and sea to table, universities, the media, and the consumer;
- is moving toward a more science-based approach with HACCP and with risk based assessment;
- is limited by statute in implementing practices and enforcement that are based in science;
- is fragmented by having 12 primary federal agencies involved in key functions of safety: monitoring, surveillance, inspection, enforcement, outbreak management, research, and education; and
- is facing tremendous pressures with regard to:
  - — emerging pathogens and ability to detect them;
  - — maintaining adequate inspection and monitoring of the increasing volume of imported foods, especially fruits and vegetables;
  - — maintaining adequate inspection of commercial food services and the increasing number of larger food processing plants; and
  - — the growing number of people at high risk for foodborne illnesses.

2. An Effective Food Safety System

Mission

The committee defines safe food as food that is wholesome, that does not exceed an acceptable level of risk associated with pathogenic organisms or chemical and physical hazards, and whose supply is the result of the combined activities of Congress, regulatory agencies, multiple industries, universities, private organizations, and consumers. The mission of a food safety system should be stated as an operational charge that uses and reflects that definition. After reviewing the missions presented by some of the lead federal agencies involved in the US food safety system, the committee defined an overall mission as follows:

The mission of an effective food safety system is to protect and improve the public health by ensuring that foods meet science-based safety standards through the integrated activities of the public and private-sectors.

Attributes of an Effective Food Safety System

The attributes of a model food safety system can be summarized in five major components. First, it should be science-based, with a strong emphasis on risk analysis, thus allowing the greatest priority in terms of resources and activity to be placed on the risks deemed to have the greatest potential impact (see Box ES-1). Adjusting effort to risk depends on being able to identify hazards, evaluate the dose-response characteristics of the hazards, estimate or measure exposures, and then determine the likely frequency and severity of effects on health resulting from estimated exposure. Hazards are properties of substances that can cause adverse consequences. Hazards associated with food include microbiological pathogens, naturally occurring toxins, allergens, intentional and unintentional additives, modified food components, agricultural chemicals, environmental contaminants, animal drug residues, and excessive consumption of some dietary supplements. In addition, improper methods of food handling and preparation in the home can contribute to increases in other hazards.

The limited resources available to address food safety issues direct that regulatory priorities be based on risk analysis, which includes evaluation

of prevention strategies where possible. This approach enables regulators to estimate the probability that various categories of susceptible persons (for example, the elderly, or nursing mothers) might acquire illness from eating specific foods and thereby allows regulators to place greater emphasis and direct resources on those foods or hazards with the highest risk of causing human illness. Risk analysis provides a science-based approach to address food safety issues. Comprehensive human and animal disease surveillance must be an integral part of any risk analysis in order to estimate exposure.

The second component in a model system is to have a national food law that is clear, rational, and comprehensive, as well as scientifically based on risk. Scientific understanding of risks changes, so federal food safety efforts must be carried out within a flexible framework. US regulatory agencies are moving toward science-based HACCP programs[2]. This is a major step toward a science-based system, but other steps remain critical. An ideal system would be preventive and anticipatory in nature, and thus designed with integrated national surveillance and monitoring along with education and research required to support these activities woven into the fabric of the system. A reliable and accurate system of data collection, processing, evaluation, and transfer is the foundation for scientific risk analysis. Research should have both applied and basic components and be targeted at the needs of producers, processors, consumers, and regulatory decision-makers and other scientists.

Box ES-1. What is the Meaning of Science-Based?

A science base for ensuring safe food encompasses many elements. When utilized, these elements improve the ability to identify, reduce, and manage risks; minimize occurrence of foodborne hazards; gather and utilize information; enhance knowledge; and improve overall food safety. Several examples of science-based actions that have been implemented in the US food safety system that are readily recognized as positive elements of the system include:

- implementation of low-acid canned food processing technology, which reduces the risk of botulism;
- implementation of HACCP systems and risk assessment in decision-making;
- approval of irradiation technology for use in spices, pork, beef, poultry, fruits and vegetables;
- prohibition of the use of lead-based paints on utensils that come in contact with food;
- estimation of maximum allowable exposure levels to pesticides;
- development of standards for allowable practices associated with transport of foods following transport of pesticides in the same containers;
- use of labeling as a device to warn consumers who are sensitive to potential food allergens of the content of the allergen; and
- requirements that meat and poultry products at the retail level carry consumer information related to safe food handling practices.

While the approaches above are important successful science-based tools in food production and processing, these are only examples of implementation of the scientific basis for food safety. An effective food safety system also integrates science and risk analysis at all levels of the system, including food safety research, information and technology transfer, and consumer education.

Third, a model food safety system should also have a unified mission and a single official who is responsible for food safety at the federal level and who has the authority and the resources to implement science-based policy in all federal activities related to food safety. This would allow for effective and consistent regulation and enforcement. Similar risks require similar planning, action, and response. Thus the intensity, nature, and frequency of inspection should be similar for foods posing similar risks. A central voice is critical to effective marshaling of all aspects of the food safety system to create a coordinated response to foodborne disease outbreaks. Control of resources is also critical in order to encourage movement toward science-based food safety provisions and to ensure that research and education are targeted toward efforts that will produce the greatest benefit for a given cost of improving food safety.

The fourth essential feature of an ideal federal food safety system is that it be organized to be responsive to and work in true partnership with nonfederal partners. These include state and local governments, the food industry, and consumers. The food safety system must function as an integrated enterprise. It must be agile, fluid, connected, integrated, and transparent, with well-defined accountability and responsibility for each partner in the system. It must frame approaches to risk management that recognize the importance of public perception of risks as well as assessments conducted by experts.

Finally, an effective food safety system must be supported by funding adequate to carry out its major functions and mission—to promote the public's health and safety. Moving toward science-based risk analysis as the underpinning of the system should allow reallocation of resources to areas identified as critical to an integrated, focused effort to ensure safe food.

Summary Findings: An Effective Food Safety System

- should be science-based with a strong emphasis on risk analysis and prevention thus allowing the greatest priority in terms of resources and activity to be placed on the risks deemed to have the greatest potential impact;
- is based on a national food law that is clear, rational, and scientifically based on risk;
- includes comprehensive surveillance and monitoring activities which serve as a basis for risk analysis;

- has one central voice at the federal level which is responsible for food safety and has the authority and resources to implement science-based policy in all federal activities related to food safety;
- recognizes the responsibilities and central role played by the non-federal partners (state, local, industry, consumers) in the food safety system; and
- receives adequate funding to carry out major functions required.

3. Where Current US Food Safety Activities Fall Short

Statutory revision is essential to the development and implementation of an effective and efficient science-based food safety system. Major aspects of the current system are in critical need of attention in order to move toward a more effective food safety system. Food safety in the United States lacks integrated Congressional oversight, allocation of funding based on science, and sustained political support. Statutory impediments interfere with implementation of a more effective food safety system. More than 35 primary statutes regulate food safety. Statutory revision is essential to the development and implementation of an effective and efficient science-based food safety system. The meat and poultry inspection laws mandate a form of compliance monitoring that is largely unrelated to the magnitude or the types of risks that are now posed by those foods. This diverts efforts and perhaps resources from actual risks and other hazards. Inconsistent food statutes often inhibit the use of science-based decision-making in activities related to food safety, including lack of jurisdiction to evaluate food handling practices in countries of origin for some types of imported foods.

The federal government response to food safety issues is too often crisis-driven. Management decisions, emphasis, and agency culture are driven by the primary concerns of each agency and special initiatives. One result is fragmentation, which causes a lack of coordination and consistency among agencies in mission, food safety policies, regulation, and enforcement. The fact that some agencies have dual responsibilities (regulation of the quality of food products while marketing them via promotional activities) makes their actions more vulnerable to criticism regarding possible conflicts of interest and may bias their approach to food safety.

In addition to fragmented and overlapping authorities, federal activities are not well-integrated with state and local activities. This results in overlapping responsibilities, gaps in responsibilities, and inefficiencies. Although FDA recommended minimum food handling standards in a Food Code issued in 1993, the Code has not been adopted in its entirety by most state and local authorities. Surveillance efforts currently in place (such as FoodNet) have been designed to provide data representative of national trends with regard to seven indicator foodborne pathogens yet are not designed to identify trends within smaller geographic areas or communities. Similarly, there are conflicts between US requirements and those of other nations and international bodies. These inadequacies have serious implications for both food imports and food exports.

The multi-faceted federal framework of the US food safety system lacks direction from a single leader who can speak for the government when confronting food safety issues and providing answers to the public. There is no single voice in the government to communicate with stakeholders regarding food safety issues. The lack of clear leadership at the federal level impedes the federal role in the management of food safety. Leadership is needed to set priorities, deploy resources, and integrate a consistent policy into all levels of the system.

A significant impediment to moving toward a science-based food safety system is the lack of adequate emphasis on and integration of surveillance activities that provide timely information on current and potential foodborne disease and related hazards. This timely information is critical if the food safety system is to move from a mode of reaction to prevention. FDA's lack of resources to maintain adequate inspection and monitoring of commercial food facilities and of fresh fruits and vegetables, both domestic and imported, using statute-driven methods of monitoring and enforcement, increases the threat of foodborne disease and related hazards in the food supply.

The committee found that the resource base for research and surveillance was not adequate to achieve the goals identified as necessary for an effective system. Furthermore, there is not an adequately coordinated effort on the scale required to analyze risk and respond to the challenges of the changing nature of American food hazards related to increases in consumption of imported foods and of food eaten outside the home.

With respect to consumer education, the committee found two major problems: in some instances, consumer knowledge is inadequate or erroneous; and even where knowledge is adequate, it often fails to influence behavior.

Summary Findings: Where the US Food Safety System Falls Short

- inconsistent, uneven and at times archaic food statutes that inhibit use of science-based decision-making in activities related to food safety, including imported foods;
- a lack of adequate integration among the 12 primary federal agencies that are involved in implementing the 35 primary statutes that regulate food safety;
- inadequate integration of federal programs and activities with state and local activities;
- absence of focused leadership: no single federal entity is both responsible for the government's efforts and given the authority to implement policy and designate resources toward food safety activities;
- lack of similar missions with regard to food safety of the various agencies reviewed;
- inadequate emphasis on surveillance necessary to provide timely information on current and potential foodborne hazards;
- resources currently identified for research and surveillance inadequate to support science-based system;

- limited consumer knowledge, which does not appear to have much impact on food handling behavior; and
- lack of nationwide adherence to appropriate minimum standards.

4. Conclusions and Recommendations Needed to Improve the US Food Safety System

Given the concerns outlined above, the committee came to three primary conclusions:

I. An effective and efficient food safety system must be based in science.

II. To achieve a food safety system based on science, current statutes governing food safety regulation and management must be revised.

III. To implement a science-based system, reorganization of federal food safety efforts is required.

To accomplish these objectives, the committee recommends that the following measures be taken regarding the scientific and organizational changes needed to improve the US food safety system:

Recommendation I:

Base the food safety system on science.

The United States has enjoyed notable successes in improving food safety. One example is the joint government-industry development of low-acid canned food regulations, based on contingency microbiology and food engineering principles, that has almost eliminated botulism resulting from improperly processed commercial food. Similarly, the passage of the 1958 Food Additives Amendment to the Food, Drug, and Cosmetic Act of 1938 was a "technology forcing" event that improved the evaluation of the safety of added and natural substances and reduced the risks associated with the use of food additives. In a like manner, the Delaney clause of that amendment resulted in increased attention to carcinogenic substances in the food supply. With increasing knowledge, many rational, science-based regulatory philosophies have been adopted, some of which rely on quantitative risk assessment. Adoption of such a science-based regulatory philosophy has been uneven and difficult to ensure given the fragmentation of food safety activities, and the differing missions of the various agencies responsible for specific components of food safety. This philosophy must be integrated into all aspects of the food safety system, from federal to state and local.

Recommendation IIa:

Congress should change federal statutes so that inspection, enforcement, and research efforts can be based on scientifically supportable assessments of risks to public health.

Limitations on the resources available to address food safety issues require that food safety activities operate with maximal efficiency within these limits. This does not require full-scale, cost-benefit analysis of each issue, but it does require that costs, risks, and benefits be known with some precision. Thus, where feasible, regulatory priorities should be based on risk analysis which includes evaluation of prevention strategies where possible. The greatest strides in ensuring food safety from production to consumption can be made through a science-based system that ensures that surveillance, regulatory, and research resources are allocated to maximize effectiveness. This will require identification of the greatest public health needs through surveillance and risk analysis, and evaluation of prevention strategies. The state of knowledge and technology defines what is achievable through the application of current science. Public resources can have the greatest favorable effect on public health if they are allocated in accordance with the combined analysis of risk assessment and technical feasibility. However, limiting allocation of resources to *only* those areas where high priority hazards are known can create a significant problem: other hazards with somewhat lower priority but with a much greater probability of reduction or elimination might not be addressed due to limited resources. Thus both the marginal risks and marginal benefits must also be considered in allocating resources.

Not all agencies responsible for monitoring the safety of imported food are authorized to enter into agreements with the governments of exporting countries in order to reciprocally recognize food safety standards or inspection results. Uniform or harmonized food safety standards and practices should be established, and officials allowed to undertake research, monitoring, surveillance, and inspection activities within other countries. This should permit inspection and monitoring efforts to be allocated in accordance with science-based assessments of risk and benefit. Changes in federal statute that would foster and enhance science-based strategies are shown in Box ES-2.

Box ES-2. Changes in Federal Statute that Would Foster and Enhance Science-based Strategies:

- eliminate continuous inspection system for meat and poultry and replace with a science-based approach which is capable of detecting hazards of concern;
- mandate a single set of science-based inspection regulations for all foods; and
- mandate that all imported foods come from only countries with food safety standards deemed equivalent to US standards.

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Recommendation IIb:

Congress and the administration should require development of a comprehensive national food safety plan. Funds appropriated for food safety programs (including research and education programs) should be allocated in accordance with science-based assessments of risk and potential benefit.

Changes in statutes or organization should be based on a rational, well-developed national food safety plan formulated by current federal agencies charged with food safety efforts and with representation from the many stakeholders involved in ensuring safe food. Such a plan, as shown in Box ES-3, should serve as the blueprint for strategies designed to determine priorities for funding, to determine what the needs are, and to ensure that they are incorporated into activities and outcome evaluation.

Box ES-3. The National Food Safety Plan should:

- include a unified, science-based food safety mission;
- integrate federal, state, and local food safety activities;
- allocate funding for food safety in accordance with science-based assessments of risk and potential benefit;
- provide adequate and identifiable support for the research and surveillance needed to:
  - — monitor changes in risk or potential hazards created by changes in food supply or consumption patterns, and
  - — improve the capability to predict and avoid new hazards;
- increase monitoring and surveillance efforts to improve knowledge of the incidence, seriousness, and cause-effect relationships of foodborne diseases and related hazards;
- address the additional and distinctive efforts required to ensure the safety of imported foods;
- recognize the burdens imposed on state and local authorities that have primary front-line responsibility for regulation of food service establishments; and
- include a plan to address consumers' behaviors related to safe food-handling practices.

Recommendation IIIa:

To implement a science-based system, Congress should establish, by statute, a unified and central framework for managing federal food safety programs, one that is headed by a single official and which has the responsibility and control of resources for all federal food safety activities, including outbreak management, standard-setting, inspection, monitoring, surveillance, risk assessment, enforcement, research, and education.

The committee was asked to consider organizational changes that would improve the safety of food in the United States. During the 6 months of active review of information and deliberation, the committee identified characteristics needed in an organizational structure that would provide for an improved focus for food safety in the United States. The committee found that the current fragmented regulatory structure is not well-equipped to meet the current challenges. The key recommendation in this regard is that in order for there to be successful structure, one official should be responsible for federal efforts in food safety and have control of resources allocated to food safety.

This recommendation envisions an identifiable, high-ranking, presidentially-appointed head, who would direct and coordinate federal activities and speak to the nation, giving federal food safety efforts a single voice. The structure created, and the person heading it, should have control over the resources Congress allocates to the food safety effort; the structure should also have a firm foundation in statute and thus not be temporary and easily changed by political agendas or executive directives. It is also important that the person heading the structure should be accountable to an official no lower than a cabinet secretary and, ultimately, to the President.

Many members of the committee are of the view that the most viable means of achieving these goals would be to create a single, unified agency headed by a single administrator—an agency that would incorporate the several relevant functions now dispersed, and in many instances separately organized, among three departments and a department-level agency. However, designing the precise structure and assessing the associated costs involved are not possible in the time frame given the committee, nor were they included in its charge. The committee did discuss other possible structures; while it ruled out some, it certainly did not examine all possible configurations and thus the examples provided in Box ES-4 are only illustrative of possible overall structures that could be considered.

Box ES-4. Some Examples of Possible Organizational Structures to Create a Single Federal Voice for Food Safety:

- a Food Safety Council with representatives from the agencies with a central chair appointed by the President, reporting to Congress and having control of resources,
- designating one current agency as the lead agency and having the head of that agency be the responsible individual,
- a single agency reporting to one current cabinet-level secretary, and

• an independent single agency at cabinet level.

Note: These examples are provided for illustrative purposes and many other configurations are possible. It is strongly recommended that future activities be directed toward identifying a feasible structure that meets the criteria outlined.

The committee does not believe that the type of centralized focus envisioned can be achieved through appointment of an individual with formal coordinating responsibility but without legal authority or budgetary control for food safety, a model similar to a White House-based 'czar'. Nor, in the committee's view, can this goal be achieved through a coordinating committee similar to that currently provided via the National Food Safety Initiative. In evaluating possible structures, the committee realized that past experience with other structures or reorganizations, including the creation of new agencies, such as the Environmental Protection Agency (EPA), should inform any final judgment. Further, it is quite possible that other models may now exist in government that can serve as templates for structural reform. Whether or not a single agency emerges, the ultimate structure must provide for not just delegated responsibility, but also for control of resources and authority over food safety activities in the federal government.

Recommendation IIIb:

Congress should provide the agency responsible for food safety at the federal level with the tools necessary to integrate and unify the efforts of authorities at the state and local levels to enhance food safety.

This report specifically addresses the federal role in the food safety system, but the roles of state and local government entities are equally critical. For integrated operation of a food safety system, officials at all levels of government must work together in support of common goals of a science-based system. The federal government must be able to ensure nationwide adherence to minimal standards when it is deemed appropriate. The work of the states and localities in support of the federal mission deserves improved formal recognition and appropriate financial support. Statutory tools required to integrate state and local activities regarding food safety into an effective national system are shown in Box ES-5.

Box ES-5. The Statutory Tools Required to Integrate Local and State Activities Regarding Food Safety into an Effective National System:

• authority to mandate adherence to minimal federal standards for products or processes,

• continued authority to deputize state and local officials to serve as enforcers of federal law,

• funding to support, in whole or in part, activities of state and local officials that are judged necessary or appropriate to enhance the safety of food,

• authority given to the federal official responsible for food safety to direct action by other agencies with assessment and monitoring capabilities, and

• authority to convene working groups, create partnerships, and direct other forms and means of collaboration to achieve integrated protection of the food supply.

MOVING TOWARD A MODEL SYSTEM

It is recognized that these recommendations will need significant review and discussion. The committee focused on the need for a centrally managed federal system to ensure coordination and direction in food safety programs and policy, and to serve as a single voice with authority and resources to suggest and implement legislation. It had insufficient time to review all the possible organizational structures that could accomplish this goal. A successor study could focus on this. Of critical importance, though, are the first two recommendations: the first, to base the system on science, and the second, that of rewriting the current patchwork of federal food statutes that in many cases do not serve to ensure a scientifically supportable and risk-based food safety system, and certainly prevent it from being more cost effective.

Regardless of the organizational structure chosen, a revamped federal food statute is critical to being able to reallocate resources toward risks that have or will have the greatest significance to the public's health. Implementation of these recommendations should not be looked at as a cost-cutting measure, but rather as a way to design a well-defined integrated system to ensure safe food. This system may well be able to demonstrate effectively a need for additional resources to address important and specific problems. Although the National Food Safety Initiative properly seeks to alleviate problems inherent in the present decentralized structure, experience indicates that any ad hoc administrative adjustments and commitments to coordination will not suffice to bring about the vast cultural changes and collaborative efforts needed to create an integrated system.

Changing hazards associated with food and changing degrees of acceptance of risk are factors that impact the nation's ability to protect public health and ensure safe food. Risk acceptance and foodborne hazards will continue to change and evolve with new technologies and consumer demands. Federal food safety efforts must be designed to deal with those changes. This report is not a comprehensive and all-inclusive discussion of these issues. Adoption of the recommendations in this report will not end the effort to make food safer. They should, however, contribute to ensuring the safety of our food while providing a blueprint for a truly integrated system.

NOTES

[1]The major federal agencies involved include: the Agricultural Marketing Service, the Animal and Plant Health Inspection Service, the Agricultural Research Service, the Cooperative State Research, Education and Extension Service, the Economic Research Service, the Food Safety and Inspection Service, and the Grain Inspection, Packers and Stockyards Administration of the United States Department of Agriculture; the Centers for Disease Control and Prevention, the Food and Drug Administration, and the National Institutes of Health of the Department of Health and Human Services; the National Marine Fisheries Service of the Department of Commerce; and the Environmental Protection Agency.

[2]The implementation of the science-based HACCP strategy is perhaps the most notable recent advance. In contrast to the traditional reactive food safety strategies, the HACCP system focuses on preventing hazards that could cause foodborne illness by applying science-based control processes at each step, rom raw mateial to finished product.

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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. 98–045N]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Food and Drug Administration

[Docket No. 97N–0074]

ENVIRONMENTAL PROTECTION AGENCY

[Docket No. OPP–00550A; FRL–6034–3]

Food Safety Initiative Strategic Plan

AGENCY: Food Safety and Inspection Service, USDA; Research, Education, and Economics, USDA; Centers for Disease Control and Prevention, HHS; Food and Drug Administration, HHS; Environmental Protection Agency.

ACTION: Notice of public meetings.

SUMMARY: The United States Department of Agriculture (USDA), the Department of Health and Human Services (HHS), and the Environmental Protection Agency (EPA) are announcing additional public meetings, under the auspices of the President's Council on Food Safety, to discuss and begin development of a comprehensive strategic Federal food safety plan. The purpose of the strategic plan is to reduce the annual incidence of acute and chronic foodborne and waterborne illness by further enhancing the safety of the nation's food supply. The Council is also soliciting comments on the recent National Academy of Sciences' report, "Ensuring Safe Food from Production to Consumption." The USDA, the Food and Drug Administration (FDA), and the EPA have established public dockets to receive comments about the Food Safety Initiative's strategic planning process, the strategic plan and the NAS report.

DATES: The meetings will be held on October 20, 1998, November 10, 1998 and December 8, 1998. Comments should be submitted by January 7, 1999.

ADDRESSES: The meetings will be held at:

Meeting Address	Date and Time
Radisson Hotel Sacramento 500 Leisure Lane Sacramento, CA 95815 Telephone: (916) 922–2020	Tuesday, October 20, 1998, 9:30 a.m. - 4:30 p.m. PST

Meeting Address	Date and Time
Schaumburg Marriott 50 North Martingale Rd. Schaumburg, IL 60173 Telephone: (847) 240–0100	Tuesday, November 10, 1998, 9:30 a.m. - 4:30 p.m. CST
Holiday Inn Select L.B.J. Northeast 11350 L.B.J. Freeway @ Jupiter Rd. Dallas, TX 75238 Telephone: (214) 341–5400	Tuesday, December 8, 1998, 9:30 a.m. - 4:30 p.m. CST

For instructions on the submission of written and electronic comments, refer to Unit II. of this document.

FOR FURTHER INFORMATION CONTACT: To register for the meetings, contact Ms. Traci Phebus, of USDA, at (202) 501–7136, fax: (202) 501–7642, e-mail: foodsafetymeeting@usda.gov. Participants may reserve time for public comments when they register. Space will be allocated on a first come, first served basis. Participants are encouraged to submit a disk along with their written statements in Wordperfect 5.1/6.1 or ASCII file format.

Questions regarding general arrangements and logistical matters should be addressed to Ms. Jennifer Callahan. Additionally, participants who require a sign language interpreter or other special accommodations should contact Ms. Jennifer Callahan, of USDA, no later than 10 days prior to the meeting, at (202) 501–7136, fax: (202) 501–7642, e-mail: Jennifer.Callahan@usda.gov.

Information about the National Academy of Sciences' report on "Ensuring Safe Food from Production to Consumption" can be found at the following web site: http://www.nas.edu.

For questions about the meeting or to obtain copies of the report, "Food Safety From Farm to Table: A National Food Safety Initiative," contact Ms. Karen Carson, of FDA, at (202) 205–5140, fax: (202) 205–5025, e-mail: kcarson@Bangate.fda.gov. Copies of the report also are available from the following web sites:

FDA at http://www.cfsan.fda.gov/~dms/fsreport.html

CDC at http://www.cdc.gov/ncidod/foodsafe/report.htm

EPA at http://www.epa.gov/opptsfrs/home/nfssuppt.htm

Food Safety and Inspection Service (FSIS) at http://www.fsis.usda.gov

SUPPLEMENTARY INFORMATION:

I. Background

On January 25, 1997, the President issued a directive to the Secretaries of USDA and HHS and the Administrator of EPA to work with consumers, producers, industry, States, Tribes, universities, and the public to identify ways to further improve the safety of our food supply, and to report back to him in

90 days. The Federal food safety agencies, working with their colleagues in the States, in the food industries, in academia, and with consumers, initially focused on the goal of reducing illness caused by microbial contamination of food and water. 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 meeting this goal was presented to the President in May 1997, in "Food Safety From Farm to Table: A National Food Safety Initiative." In October 1997, the President issued an additional directive to ensure the safety of domestic and imported fresh produce and other imported foods. This second directive was incorporated into the National Food Safety Initiative (NFSI).

In less than 2 years, the agencies have taken significant strides forward in building a strengthened national food safety system. Building blocks for the infrastructure are in place: increased and targeted surveillance through FoodNet and PulseNet; coordination of Federal, State and local responses to outbreaks by the Foodborne Outbreak Response Coordinating Group (FORCG); expanded reliance on preventive controls (such as the Hazard Analysis and Critical Control Points (HACCP) based inspection systems for meat, poultry and seafood, and Good Agricultural and Good Manufacturing Practices guidance for produce); coordination of Federal food safety research; cooperation on risk assessment through the interagency Risk Assessment Consortium; leveraging inspection resources; and innovative public/private education partnerships. These efforts provide a common ground for moving forward.

On July 3, 1998, the President created a Joint Institute for Food Safety Research (JIFSR) to coordinate Federal food safety research efforts. On August 25, 1998, the President issued an Executive Order establishing a President's Council on Food Safety to develop a comprehensive strategic plan for Federal food safety activities, ensure the most effective use of Federal resources through the development and submission of coordinated food safety budgets, and oversee the Joint Institute for Food Safety Research. At the same time, the President directed the Council to, after providing opportunity for public comment, report back to him within 180 days with its views on the recommendations of the NAS report.

The food safety agencies had already made a commitment to prepare a 5–year comprehensive strategic plan, with the participation of all concerned parties. The President's Council on Food Safety will now be responsible for the development of this strategic Federal food safety plan. A coordinated food safety strategic planning effort is needed to build on the common ground, and to tackle some of the difficult public health, resource, and management questions facing Federal food safety agencies. The strategic plan will focus on not just microbial contamination, but the full range of issues (e.g., chemical hazards) and actions necessary to ensure the safety of the food and water Americans use and consume. The charge is to develop a strategic long-range plan that can be used to help set priorities, improve coordination and efficiency, identify gaps in the current system and mechanisms to fill those gaps, continue to enhance and strengthen prevention and intervention strategies, and identify measures to show progress. In developing the plan, the Council will consider the conclusions and

recommendations of the NAS report on "Ensuring Safe Food from Production to Consumption" and the review of Federal food safety research currently being developed by an interagency working group under the auspices of the National Science and Technology Council.

The food safety agencies have already taken the first steps to lay the groundwork for development of the strategic plan, which the Council will now develop, by participating in interagency strategic planning sessions. The result is the following draft statement encompassing the agencies' vision for the U.S. food safety system and the roles of all those involved in food safety.

Draft Vision Statement

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 step is to engage consumers, producers, industry, food service providers, retailers, health professionals, State and local governments, Tribes, academia, and the public in the strategic planning process. The first public meeting on the strategic plan will be held on October 2, 1998, in Arlington, VA and was announced in the **Federal Register** of August 27, 1998 (63 FR 45922) (FRL–6019–9). The series of meetings announced today, in addition to the October 2nd meeting, will assist the Council with development of a long-term strategic plan that addresses the important food safety challenges and makes the best use of the agencies' limited resources. They will also assist the Council in responding to the President on the NAS recommendations. Additional public meetings may be held later in the strategic planning process and will be announced in the **Federal Register** prior to the date of each meeting.

The purpose of these meetings, along with the October 2nd meeting, is to obtain the public's view on a long-term vision for food safety in the U.S. and to identify a strategic planning process, goals, and critical steps as well as potential barriers to achieving that vision. The Council is interested in comments on the draft vision statement, suggestions for goals and how they might be achieved, and comments on how to best structure a strategic planning process that involves all interested parties. The Council is also soliciting comments on the conclusions and recommendations of the NAS report, "Ensuring Safe Food from Production to Consumption." Some questions to help frame the discussion follow.

1. Does the vision statement accurately depict an achievable food safety system vision? What modifications, if any, would you make?

2. What are the barriers to pursuing this vision? What gaps currently exist in the food safety system that impede achievement of this vision?

3. To make the vision a reality, what changes are needed for: (a) government agencies at the Federal, State, and local level; (b) industry; (c) public health professionals; (d) consumers; and (e) others?

4. What should be the short-term goals and critical steps to realize this vision? What should be the long-term goals and steps?

5. What is the best way to involve the public in development of a long-term food safety strategic plan? What additional steps besides public meetings would be beneficial?

6. What are your comments on the conclusions and recommendations of the NAS report "Ensuring Safe Food from Production to Consumption"?

II. Public Dockets and Submission of Comments

The agencies have established public dockets about the Food Safety Initiative Strategic Plan and the NAS report, "Ensuring Safe Food from Production to Consumption." Comments submitted to the dockets are to be identified with the appropriate docket number. For those comments directed to USDA, use Docket No. 98–045N, and for comments directed to FDA, use Docket No. 97N–0074. Commenters are encouraged to submit a disk along with their written comments in Wordperfect 5.1/6.1 or ASCII file format. Submit written comments (in triplicate) to either:

USDA/FSIS

USDA/FSIS Hearing Clerk, 300 12th St., SW., Rm. 102 Cotton Annex, Washington, DC 20250–3700

FDA

Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Drive, Rm. 1-23, Rockville, MD 20857

Electronic Comments

Comments may also be submitted electronically to: oppts.homepage@epa.gov. All comments and data in electronic form must be identified by the docket number "OPP–00550." Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

Transcripts

Transcripts of the public meetings may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, Rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. The transcripts of the public meetings will be available for public examination at the FDA Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday, excluding legal holidays. Transcripts of the meetings will also be available on the internet at: http://www.fda.gov/ohrms/dockets/default.htm and http://www.epa.gov/opptsfrs/home/nfssuppt.htm.

Electronic Docket

The public docket in its entirety will be available on the internet at: http://www.epa.gov/opptsfrs/home/rules.htm#docket.

List of Subjects

Environmental protection, Food safety.

Dated: Catherine E Woteki SEP 24 1998

Catherine E. Woteki,

Undersecretary for Food Safety, United States Department of Agriculture.

Dated: [signature] SEP 24 1998

James A. O'Hara,

Deputy Assistant Secretary for Health, Department of Health and Human Services.

Dated: Lynn R. Goldman SEP 24 1998

Lynn R. Goldman

Assistant Administrator for Prevention, Pesticides and Toxic Substances, Environmental Protection Agency.

[FR Doc. 98–????? Filed ?–??–98; 8:45 am]

BILLING CODE 6560–50–F

Helen M. Green
Certified to be a true copy of the original.

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. 98-045N]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Food and Drug Administration

[Docket No. 97N-0074]

ENVIRONMENTAL PROTECTION AGENCY

[Docket No. OPP-00550; FRL-6019-9]

President's National Food Safety Initiative

AGENCY: Food Safety and Inspection Service, USDA; Research, Education, and Economics, USDA; Centers for Disease Control and Prevention, HHS; Food and Drug Administration, HHS; Environmental Protection Agency.

ACTION: Notice: public meeting; establishment of public dockets.

SUMMARY: The United States Department of Agriculture (USDA), the Department of Health and Human Services (HHS), and the Environmental Protection Agency (EPA) are announcing a public meeting to discuss and begin development of a comprehensive strategic Federal food safety plan. The purpose of the strategic plan is to reduce the annual incidence of acute and chronic foodborne and waterborne illness by further enhancing the safety of the nation's food supply. USDA, the Food and Drug Administration (FDA), and EPA are also establishing public dockets to receive comments about the Food Safety Initiative's strategic planning process and the plan.

DATES: The meeting will be held on October 2, 1998, from 9:30 a.m. to 3 p.m. Comments should be submitted by [insert date 90 days after date of publication in the **Federal Register**].

ADDRESSES: The meeting will be held at: National Rural Electric Cooperative Association, 4301 Wilson Boulevard, Arlington, VA.

For instructions on the submission of written and electronic comments, refer to Unit II. of this document.

FOR FURTHER INFORMATION CONTACT: To register for the meeting, contact Ms. Traci Phebus, of USDA, at (202) 501-7136, fax: (202) 501-7642, e-mail: foodsafetymeeting@usda.gov. Participants may reserve time for public comments when they register. Space will be allocated on a first come, first served basis. Participants are encouraged to submit a disk along with their written statements in Wordperfect 5.1/6.1 or ASCII file format.

98P-1351

Questions regarding general arrangements and logistical matters should be addressed to Ms. Torrie Mattes. Additionally, participants who require a sign language interpreter or other special accommodations should contact Ms. Torrie Mattes, of USDA, no later than 10 days prior to the meeting, at (202) 501–7136, fax: (202) 501–7642, e-mail: T.Mattes@usda.gov.

For questions about the meeting or to obtain copies of the report, "Food Safety From Farm to Table: A National Food Safety Initiative," contact Ms. Karen Carson, of FDA, at (202) 205–5140, fax: (202) 205–5025, e-mail: kcarson@Bangate.fda.gov. Copies of the report also are available from the following web sites:

FDA at http://www.cfsan.fda.gov/~dms/fsreport.html

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Food Safety and Inspection Service (FSIS) at http://www.fsis.usda.gov

Information about the National Academy of Sciences' report on "Ensuring Safe Food from Production to Consumption" can be found at the following web site: http://www.nas.edu.

SUPPLEMENTARY INFORMATION:

I. Background

On January 25, 1997, the President issued a directive to the Secretaries of USDA and HHS and the Administrator of EPA to work with consumers, producers, industry, States, Tribes, universities, and the public to identify ways to further improve the safety of our food supply, and to report back to him in 90 days. The Federal food safety agencies, working with their colleagues in the States, in the food industries, in academia, and with consumers, initially focused on the goal of reducing illness caused by microbial contamination of food and water. 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 meeting this goal was presented to the President in May 1997, in "Food Safety From Farm to Table: A National Food Safety Initiative." In October 1997, the President issued an additional directive to ensure the safety of domestic and imported fresh produce and other imported foods. This second directive was incorporated into the National Food Safety Initiative (NFSI).

In less than 2 years, the agencies have taken significant strides forward in building a strengthened national food safety system. Building blocks for the infrastructure are in place: increased and targeted surveillance through FoodNet and PulseNet; coordination of Federal, State and local responses to outbreaks by the Foodborne Outbreak Response Coordinating Group (FORCG); expanded reliance on preventive controls (such as the Hazard Analysis and Critical Control Points (HACCP) based inspection systems for meat, poultry and seafood, and Good Agricultural and Good Manufacturing Practices guidance for produce);

coordination of Federal food safety research; cooperation on risk assessment through the interagency Risk Assessment Consortium; leveraging inspection resources; and innovative public/private education partnerships. These efforts provide a common ground for moving forward.

In the May 1997 report, the food safety agencies made a commitment to prepare a 5-year comprehensive strategic plan, with the participation of all concerned parties. The President recently issued an Executive Order establishing a President's Food Safety Council which will now be responsible for development of a comprehensive strategic Federal food safety plan. A coordinated food safety strategic planning effort is needed to build on the common ground, and to tackle some of the difficult public health, resource, and management questions facing Federal food safety agencies. The strategic plan will focus on not just microbial contamination, but the full range of issues and actions necessary to ensure the safety of the food and water Americans use and consume. The charge is to develop a strategic long-range plan that can be used to help set priorities, improve coordination and efficiency, identify gaps in the current system and how to fill those gaps, enhance and strengthen prevention and intervention strategies, and identify measures to show progress. In developing the plan, the agencies will consider the conclusions and recommendations of the National Academy of Sciences' report on "Ensuring Safe Food from Production to Consumption" and the review of Federal food safety research and the research plan currently being developed by an interagency working group under the auspices of the National Science and Technology Council.

The food safety agencies have already taken the first steps to lay the groundwork for development of the strategic plan, which the Council will now develop, by participating in interagency strategic planning sessions. The result is the following draft statement encompassing the agencies' vision for the U.S. food safety system and the roles of all those involved in food safety.

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 step is to engage consumers, producers, industry, food service providers, retailers, health professionals, State and local governments, Tribes, academia, and the public in the strategic planning process, beginning with a discussion of the draft vision statement and how to structure a strategic planning process that involves all interested parties and best addresses the important food safety challenges and makes the best use of the agencies' limited resources. This October 2nd meeting is the first of several public meetings to assist with development of a long-term strategic plan. Additional public meetings will be announced in the **Federal Register** prior to the date of each meeting.

The purpose of the October 2nd meeting is to obtain the public's view on a long-term vision for food safety in the U.S. and to identify a strategic planning process, goals, and critical steps as well as potential barriers to achieving that

vision. The Council is interested in comments on the draft vision statement and suggestions for goals and how they might be achieved. Some questions to help frame the discussion follow.

1. Does the vision statement accurately depict an achievable food safety system vision? What modifications, if any, would you make?

2. What are the barriers to pursuing this vision? What gaps currently exist in the food safety system that impede achievement of this vision?

3. To make the vision a reality, what changes are needed for: (a) government agencies at the Federal, State, and local level; (b) industry; (c) public health professionals; (d) consumers; and (e) others?

4. What should be the short-term goals and critical steps to realize this vision? What should be the long-term goals and steps?

5. What is the best way to involve the public in development of a long-term food safety strategic plan? What additional steps besides public meetings would be beneficial?

II. Public Dockets and Submission of Comments

The agencies are announcing the establishment of public dockets about the Food Safety Initiative Strategic Plan. Comments submitted to the dockets are to be identified with the appropriate docket number. For those comments directed to USDA, use Docket No. 98–045N, and for comments directed to FDA, use Docket No. 97N–0074. Commenters are encouraged to submit a disk along with their written comments in Wordperfect 5.1/6.1 or ASCII file format. Submit written comments (in triplicate) to:

USDA/FSIS

USDA/FSIS Hearing Clerk, 300 12th St., SW., Rm. 102 Cotton Annex, Washington, DC 20250–3700

FDA

Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Drive, Rm. 1-23, Rockville, MD 20857

Electronic Comments

Comments may also be submitted electronically to: oppts.homepage@epa.gov. All comments and data in electronic form must be identified by the docket number "OPP–00550." Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

Transcripts

Transcripts of the public meetings may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, Rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. The transcripts of the public meetings will be available for public examination at the FDA Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday, excluding legal holidays. Transcripts of the meetings will also be available on the internet at: http://www.fda.gov/ohrms/dockets/default.htm and http://www.epa.gov/opptsfrs/home/nfssuppt.htm.

Electronic Docket

The public docket in its entirety will be available on the internet at: http://www.epa.gov/opptsfrs/home/rules.htm#docket.

List of Subjects

Environmental protection, Food safety.

Dated: AUG 20 1998

Catherine E. Woteki,

Undersecretary for Food Safety, United States Department of Agriculture.

Dated: AUG 20 1998

James A. O'Hara,

Deputy Assistant Secretary for Health, Department of Health and Human Services.

D.T. 8/20

Dated: 20 August 1998

Lynn R. Goldman,

Assistant Administrator for Prevention, Pesticides and Toxic Substances, Environmental Protection Agency.

[FR Doc. 98–????? Filed ?–??–98; 8:45 am]

BILLING CODE 6560–50–F

Certified to be a true copy of the original.

Cons pro - food safety - Council

MEMORANDUM

TO: BRUCE REED, ELENA KAGAN

FROM: TOM FREEDMAN, MARY L. SMITH

RE: BACKGROUND FOR MEETING WITH NEAL LANE ON FOOD SAFETY COUNCIL

DATE: SEPTEMBER 24, 1998

This memorandum provides points for discussion for your meeting with Neal Lane on the goals, both short-term and long-term, for the President's Council on Food Safety. We have discussed this with Cliff Gabriel, Neal Lane's deputy. In addition, the following attachments are included: (1) draft charter for President's Council on Food Safety; (2) draft agenda for public meeting for the strategic planning process on October 2; (3) draft remarks of Neal Lane to open October 2 public meeting; (4) draft report on the Joint Institute on Food Safety Research; (5) a USA Today article dated September 16 which describes PulseNet, a database that permits states to compare quickly the genetic fingerprints of bacteria responsible for outbreaks; and (6) the executive order establishing President's Council on Food Safety.

I. FOCUS OF THE COUNCIL

A. What should the Council accomplish?

- The Council should establish a seamless, science-based food safety system. In doing this, the Council should have an overarching framework that incorporates the following principles:
  - the improvement of food safety
  - efficiency
  - cooperation and coordination with states and localities as well as within the federal government. We already are cooperating with states through the states through the PulseNet system, which tracks the genetic fingerprints of bacteria in outbreaks (see attached article).
  - prevention
  - measurable outcome goals
- Concurrently with developing the overarching framework in order to develop a seamless food safety system, the Council should tackle specific issues including prevention, inspections, streamlining within the federal government, and coordinating with states. For instance, there has been some discussion about consolidating responsibility for eggs in one federal food safety agency. Currently, USDA and FDA both have responsibility for different aspects of eggs.

B. Scope of Council (issues we need to focus on and have answers for October 2 meeting)
   1. Does the Council deal with more than microbial --yes
   2. Does it include pesticides -- need to discuss
   3. What is going on with research -- Neal will give update in his opening remarks.

II. Short-Term Goals

A. Respond to the NAS study-- within 180 days from August 25 --so it will be February 21

B. FY2000 budget -- unified budget for the food safety initiative for the FY2000 budget, we will do the "coordinated budgets" for the entire food safety activities starting in FY2001

C. Joint Institute for Food Safety Research -- has to report back by October 3 (the day after the October 2 meeting) (see attachment)

III. Long-Term Goals

A. Strategic plan to be prepared by the Council (see attached charter for process)

IV. Miscellaneous Issues

A. Procedures of the Council -- How often will the Council meet, etc. See attached draft charter.

B. How the Council will obtain public input. There will be three additional public meeting to obtain input for the strategic planning process
   - October 20, 1998 in Sacramento, California
   - November 10, 1998 in Schaumburg, Illinois
   - December 8, 1998 in Dallas, Texas

DRAFT (9/23)

PRESIDENT'S COUNCIL ON FOOD SAFETY
CHARTER

Article I: Purpose.

On August 25, 1998, the President, by Executive Order, No. 13,100, established the President's Council on Food Safety ("Council") to improve the safety of the food supply through science-based regulation and well-coordinated inspection, enforcement, research, and education programs. The purpose of the Council is to develop a comprehensive strategic plan for Federal food safety activities, to make recommendations to the President on how to implement the comprehensive strategy and enhance coordination among Federal agencies, State, local and tribal governments, and the private sector, to advise Federal agencies in setting priority areas for investment in food safety, to oversee research efforts of the National Institute for Food Safety Research, and to evaluate and make recommendations to the President on the proposals contained in the National Academy of Sciences (NAS) report on food safety.

This Charter provides the basis for the collaboration among the members of the Council in carrying out the responsibilities of the Council as set forth in the Executive Order.

Article II: Membership

Council membership shall comprise:

1. Secretary of Agriculture;
2. Secretary of Commerce;
3. Secretary of Health and Human Services;
4. Administrator of the Environmental Protection Agency;
5. Director of the Office of Management and Budget;
6. Assistant to the President for Science and Technology/Director of the Office of Science and Technology Policy;
7. Assistant to the President for Domestic Policy; and,
8. Director of the National Partnership for Reinventing Government.

Each member may designate a senior Federal employee, subject to the approval of the co-chairs, to serve as an alternate representative to perform the duties of the Council member.

Article III: Officers

The Secretaries of Agriculture and of Health and Human Services and the Assistant to the President for Science and Technology/Director of the Office of Science and Technology Policy, or their designated alternates, shall serve as co-chairs of the Council.

The co-chairs shall provide leadership and direction to the Council, and coordinate the formation and schedule of standing committees. Each meeting will be led by one co-chair and this responsibility shall rotate quarterly among the co-chairs.

Article IV: Meetings

The Council shall meet on a quarterly basis at a time and location chosen by the co-chairs. Additional meetings may be held at the call of the co-chairs or at the request of a majority of the members.

A majority of the Council membership shall constitute a quorum for the transaction of business. All decisions made by the Council at the meetings shall be by consensus or general agreement. If a consensus or general agreement cannot be reached, a final decision will be made by a consensus of the co-chairs.

A summary report of each meeting of the Council shall be prepared for distribution to the membership and shall be made available for public inspection and copying and on the Council Internet web site.

The Council shall prepare a report for submission to the President not later than October 1 of each year. The report will contain, at a minimum, a description of the Council's activities and accomplishments during the preceding fiscal year and a description of the planned activities for the coming year, and a review of strategic planning objectives and progress made toward accomplishing those objectives.

Article V: Duties and Responsibilities

The specific responsibilities of the Council are to:

1. Develop a comprehensive strategic Federal food safety plan ("plan") to reduce the annual incidence of acute and chronic foodborne and waterborne illness by further enhancing the safety of the nation's food supply. The plan will address the public health, resource, and management questions facing Federal food safety agencies and will focus on the full range of food safety issues and the actions necessary to ensure the safety of the food and water Americans

use and consume. The planning process will consider both short and long term issues including new and emerging threats to food safety and the special needs of vulnerable populations such as children and the elderly. In developing this plan, the Council will take into consideration the findings and recommendations of the National Academy of Sciences report "Ensuring Safe Food from Production to Consumption" and the research plan currently being developed by the interagency working group under the auspices of the National Science and Technology Group.

The final plan will help set priorities, improve coordination and efficiency, identify gaps in the current system and ways to fill those gaps, enhance and strengthen prevention and intervention strategies, and identify reliable measures to indicate progress.

The Council will conduct public meetings to engage consumers, producers, industry, food service providers, retailers, health professionals, State and local governments, Tribes, academia, and the public in the strategic planning process.

2. Advise Federal agencies of priority areas for investment in food safety and ensure that the member agencies collegially develop annual coordinated food safety budgets for submission to OMB to sustain and strengthen priority activities on food safety, eliminate duplication, and ensure the most effective use of resources for achieving the goals of the plan.

3. Oversee the National Institute for Food Safety Research (NIFSR). The Council will evaluate the reports from NIFSR on food safety research activities and give direction to NIFSR on research needed to establish the most effective possible food safety system.

4. Evaluate and report to the President on the National Academy of Sciences (NAS) report, "Ensuring Safe Food from Production to Consumption". After providing opportunity for public comment, including public meetings, the Council will, within 180 days of the Executive Order, report to the President on the Council's response to and recommendations concerning the NAS report and appropriate additional actions to improve food safety including proposals for legislative reform of the food safety laws and regulatory structures.

Article VI: Committees

The co-chairs, after consultation with Council members, may establish committees of Council members, their alternates, or other Federal employees on a permanent or an *ad hoc* basis, as they deem necessary, to facilitate and carry out effectively the responsibilities of the Council. Such committees shall report to the Council.

The following permanent committees shall be established by the co-chairs:

1. Strategic Plan Committee

The Committee shall develop a comprehensive strategic Federal food safety plan ("plan") that

will review public health, resource and management issues facing Federal food safety agencies and will focus on the full range of issues and actions necessary to ensure the safety of the food and water Americans use and consume. The Committee will conduct public meetings to engage consumers, producers, industry, food service providers, retailers, health professionals, State and local governments, Tribes, academia, and the public in the strategic planning process. The plan will include a comprehensive strategy for the enhancement of coordination among Federal agencies, State, local and tribal governments, and the private sector on food safety issues.

The Committee will, within 12 months of the effective date of this Charter, provide the plan to the Council that will help set priorities, improve coordination and efficiency, identify gaps in the current system including legal authorities, and ways to fill those gaps, and enhance and strengthen prevention and intervention techniques.

2. Budget Committee

The Committee will examine all Federal food safety related budgets to identify priority areas for investment in food safety and ensure that resources are used effectively and to eliminate duplication.

3. NIFSR Oversight Committee

The Committee will evaluate the reports from the NIFSR on its efforts to coordinate food safety research and make recommendations to the Council regarding research needed to establish the most effective possible food safety system.

4. Ad Hoc NAS Report Review Committee

The committee shall review and report to the Council on the NAS report after providing for public comment and will, by January 1, 1999, provide a report to the Council containing a proposed Council's response to the NAS report.

Article VII: Staff Support Services

Staff support services for the activities of the Council will be provided by the Co-Chairs through a Secretariat which will consist of a senior Federal employee from each of the following: the Department of Agriculture, Department of Health and Human Services, and the Office of Science and Technology. The Secretariat will facilitate planning, coordination, and communication among Council members.

Article VIII: Web Site

The Council shall establish an Internet web site and the Department of Agriculture shall maintain and will be the system owner of the web site. The Council website will provide links to websites

of federal agencies having food safety responsibilities.

Article IX: Effective Date

This Charter shall become effective on the latest date affixed below and may be modified with supplemental agreements signed by the members of the Council.

CALENDAR (DRAFT)

August 25, 1998	Announcement of Executive Order. Directive to review NAS report, and hold public meetings.
by September 30, 1998	Determine how Council will operate, staff, schedule first meeting, consider how to accomplish the following: 1. Plan for review of NAS report – due February 1999 2. Plan for strategic plan 3. Review of agency FY 2000 budget requests and President's Food Safety Initiative budget 4. Plan for FY2001 budget (can be delayed until later) 5. Approve plan for NIFSR
September 18, 1998	Principals' Meeting to consider FY2000 budget and NIFSR report.
October 1, 1998	NIFSR report sent to President.
October 1, 1998	FY 2000 Initiative Budget to OMB.
October 2, 1998	First public meeting on strategic plan, NAS report. Arlington, Virginia
October 20, 1998	Second public meeting on strategic plan, NAS report. Sacramento, California
October 1998	Publish NIFSR report in Federal Register comment.
November 10, 1998	Third public meeting on strategic plan, NAS report. Chicago, Illinois
November 12-13, 1998	Research, Education and Economics Food Safety Conference
December 8, 1998	Fourth public meeting on strategic plan, NAS report. Dallas, Texas
January 1999	Comment period closes for NIFSR Federal Register. Analyze comments and develop a more detailed "straw proposal" for Institute.
January 1999	Discussion draft of report to President on NAS report recommendations.
January 25, 1999	HACCP Implementation - Small Plants
by February 21, 1998	Report to President on response to NAS report.

March 1999	Publish straw proposal for NIFSR in Federal Register for comment.
April 1999	Third public meeting on NIFSR.
May 1999	Publish "final" report on NIFSR in Federal Register.
August 1999	President appoints Advisory Committee for NIFSR.
August 31, 1999	Council delivers strategic plan to President.
October 1, 1999	NIFSR begins operations.

AGENDA

President's Council on Food Safety
Public Meeting on Food Safety Strategic Plan
October 2, 1998
Arlington, Virginia
DRAFT for internal use only

8:30-9:30 Registration

9:30-9:40 Welcoming Remarks: Neal Lane, Assistant to the President for Science and Technology, Office of Science Technology Policy (includes Executive Order 13100 establishing the Council, introducing the Secretaries (Co-Chairs), Council tasked with strategic planning & reporting to President on NAS recommendations in 180 days. Brief discussion of the Research Institute, the Agenda, what to expect, ground rules-3 min. rule so everyone has a voice, purpose of today's meeting is to listen to your ideas.-we are here with an open mind.)

9:40-9:50 The Importance of Food Safety, Accomplishments to Date and Success Stories.

9:40-9:45 **Donna Shalala**, Secretary of Health and Human Services
9:45-9:50 **Richard Rominger**, Deputy Secretary of Agriculture,

9:50-9:55 Introduce Agency Representatives for Strategic Plan Discussion: Neal Lane

Dr. Catherine E. Woteki, Under Secretary for Food Safety, USDA
James A. O'Hara, Deputy Assistant Secretary for Health, HHS
Dr. Lynn R. Goldman, Assistant Administrator for Prevention, Pesticides and Toxic Substances, Environmental Protection Agency
Thomas J. Billy, Administrator, Food Safety and Inspection Service, USDA
Joseph Levitt, Director, Center for Food Safety and Applied Nutrition, Food and Drug Administration, HHS
Dr. Morris Potter, Assistant Director for Foodborne Diseases, Centers for Disease Control and Prevention, HHS

9:55-10:10 The Agencies' Vision: Panel briefly describes themes contained in the vision statement: 1) A Safe & Affordable Food Supply (L. Goldman), 2) Assuring Food Safety Requires Everyone to Play a Role (J. O'Hara), and 3) Protecting the Food Supply Must Be Grounded in Sound Science (C.Woteki).

9:55-10:00 Dr. Lynn R. Goldman
10:00-10:05 James A. O'Hara
10:05-10:10 Dr. Catherine E. Woteki

10:10-10:25 Break

OPTIONAL FORM 99 (7-90)
FAX TRANSMITTAL # of pages ▸ 2

To Joan	From Torre
Dept./Agency	Phone #
Fax # 690-0550	Fax #

NSN 7540-01-317-7368 5099-101 GENERAL SERVICES ADMINISTRATION

10:25 - 11:45 Facilitated Discussion of the Vision/Strategic Plan (based on questions in FR)

10:25-10:45 #1. Does the vision statement accurately depict an achievable food safety system vision? What modifications, if any, would you make?

10:45-11:45 #2. What are the barriers to pursuing this vision? What gaps currently exist in the food safety system that impede achievement of this vision?

#3. To Make the vision a reality, what changes are needed for: a)government agencies at the Federal, State, and local level; b) industry; c) public health professionals; d) consumers; and e) others?

11:45-12:30 Lunch

12:30-2:30 Facilitated Discussion of the Vision (can't)

12:30-1:15 #4. What should be the short-term goals and critical steps to realize this vision? What should be the long-term goals and steps?

1:15-1:30 #5. What is the best way to involve the public in development of a long-term food safety strategic plan? What additional steps besides public meetings would be beneficial?

1:30-2:30 #6. What are your comments on the conclusions and recommendations of the National Academy of Sciences' report, "Ensuring Safe Food From Production to Consumption"?

2:30-2:45 Break

2:45-3:45 Prepared Remarks: (max. of 5 minutes per person)

3:45-4:00 Closing: Dr. Catherine E. Woteki, James A. O'Hara, Dr. Lynn R. Goldman

àÐ?sõæ½@@,F–□Neal Lane's Opening Remarks for Food Safety Meeting
October 2, 1998
Arlington, VA

I am privileged to welcome you to this first meeting hosted by the Pesident's Council on Food Safety. I think it's most appropriate that the President's Council is starting its deliberative process by seeking public input today. This means that we will not only welcome but we will seek input from all stakeholder—consumers, public health officials, representatives from State and local governments and food producers, processors, and distributors. Transparent decision-making will be one of the underlying operational principles of the Council's work. All Americans have a stake in the safety of our food supply. And while we can rightfully take pride in the fact that Americans do have one of the safest food supplies in the world, we know we can do better.

America's food habits are changing. Consider the foods we eat today—the manner in which they are prepared and the consumers' expectations of quality and wholesomeness all are vastly different from when our food safety system was established at the turn of the century.

The composition of our population is changing also; we are graying and becoming more ethnically diverse. By the year 2010, X percent of our population will be over the age of 65 compared to X percent in the early 1900s. By the year 2010, approximately half of our school age population will be from minority groups. How should our food safety system reflect these dramatic changes?

Our food safety system must take into consideration not only the growing diversity of our citizenry, but also the growing diversity of our food sources. Since 1985, food imports have tripled. The expansion of global markets requires us to rethink our regulatory approach for imported as well as domestically produced food.

Since the beginning of his first term, President Clinton has demonstrated vision and leadership in his efforts to improve the safety of America's food supply. Faced with the tragic E. coli O157:H7 outbreak on the West Coast in 1993, the Administration quickly understood the need to improve the safety of our food supply, and acted just as quickly. Starting with the Vice President's 1993 call for more emphasis on prevention, to the issuing HACCP regulation to the creation of the Food Safety Council, this Administration has been out in front on this issue. But much remains to be done.

We are fortunate today to have with us Morley Winograd, Senior Policy Advisor for the Vice President, and Bruce Reed, the Assistant to the President for Domestic Policy. Their attendance today is a clear indication of the importance the President places on this issue.

The President signed Executive Order 13100 establishing his Council on Food Safety on August 25, 1998. The Council was given the clear purpose of "improving the safety of the food supply through science-based regulation and well-coordinated inspection, enforcement, research, and education programs." Specifically, the Council will develop a comprehensive strategic plan that integrates Federal efforts into those of State and local governments and the private sector. For the first time, a comprehensive cross agency plan will be tied to the budget process.

The Council will also oversee food safety research activities across the Federal government. This process was initiated last year through the National Science and Technology Council and further advanced by the President's directive to create a Joint Institute for Food Safety Research. The function of the Institute will be to develop an interagency food safety research plan and appropriate outreach to the private sector and universities.

Sound science must underpin all our food safety efforts. Even though most of us in this room take this basic premise for granted, it is so central to improving our food safety system that it bears repeating—again and again. From regulation to education, we need the best science possible to direct our actions. We must tighten the links between our regulatory agencies and science agencies. We must make sure consumers and producers have the very best information available to prevent the occurrence

of food borne illnesses. We must provide our researchers with the resources they need so they can generate the knowledge that will protect us from food-borne illnesses. But resources are limited, so we need to target them wisely.

In this regard, we need to make better use of risk analysis. What do we know about specific risks associated with the farm-to-table pathway? What research is needed to help us identify and better understand those risks and how to manage them? Risk analysis is a planning tool we need to refine. We must make sure we have data to support the development of sound quantitative approached to risk analysis.

The President has also asked the Council to provide him with our assessment of the Academy report "Ensuring the Safe Food from Production to Consumption." The Academy has done an excellent job in laying out many of the issues that the Council must address over the next several months. Their report, and our assessment of it, will give the Council a jumpstart to our planning process.

This is an important meeting that starts us down the road that leads us to a safer food supply. While there have been numerous public meetings in the past on any number of food safety issues, this is the first one specifically designed to solicit input on our overall approach to food safety. Where do you think we should be going? Specifically, we look forward to hearing your views on the NAS report and on our proposed vision statement.

After brief remarks from my fellow Council co-chairs, Secretary Shalala and Deputy Secretary Rominger, who is representing Secretary Glickman, senior agency officials will facilitate a discussion on the 6 questions contained in the Federal Register notice. This discussion will take us through the rest of the morning. There will be a break for lunch and the discussion will resume until 2:30 p.m. At 2:45 p.m., there will be time for many of you to give prepared statements. Since time is limited, brevity is much appreciated. Please keep your remarks to less than 5 minutes. We encourage you to provide written remarks, which will be carefully studied and factored into our planning process.

Let me reiterate; this is an open process. We have open minds. If we are to find success, we must first hear from you. Our plan must reflect the needs of the stakeholders, not just the needs of the agencies. Our Federal programs must be designed not only for compliance with existing statutes, but also for improved efficiency and coordination with other programs—so that the whole is greater than the sum of its parts. We are looking for your advice and guidance on how we can achieve the President's goal of a safer food supply. We are here to listen and learn.

It is a pleasure for me to welcome my fellow Council co-chair, Health and Human Services Secretary Donna Shalala.

9-22-98

The Honorable William Jefferson Clinton
The White House
Washington, DC 20500

Dear Mr. President:

Attached is our report, as requested in your July 3, 1998, Memorandum, regarding the creation of a National Institute for Food Safety Research. The report articulates the concept of the Institute and provides a proposed structure, operating principles, goals and outcomes, and an implementation schedule for the Institute.

The report reflects our consultation with the Domestic Policy Council, the Office of Management and Budget, the Office of Science and Technology Policy, the National Partnership for Reinventing Government, and the Environmental Protection Agency. After your review and approval of the report, our next step will be to publish this proposal for public comment and hold a public meeting in the next few months to further consult with State and local governments, consumers, producers, industry, and academia.

We are confident our proposal will further the goals of your National Food Safety Initiative as well as more efficiently coordinate the Nation's Federal food safety research among Federal agencies and academia to meet the needs of regulatory agencies and the private sector.

Sincerely,

Donna E. Shalala
Secretary of Health and Human Services

Dan Glickman
Secretary of Agriculture

Enclosure

DRAFT 2, September 22, 1998 (without DHHS comments)

National Institute for Food Safety Research

Report to the President

October 1, 1998

EXECUTIVE SUMMARY

On July 3, 1998 President Clinton directed the Department of Health and Human Services (DHHS) and the Department of Agriculture (USDA) to report back within 90 days with a plan to create a Joint Institute for Food Safety Research ("the Institute"). The Institute is to (1) coordinate planning and priority setting for food safety research among the two Departments, other government agencies, and the private sector and (2) foster effective translation of research results into practice along the farm-to-table continuum. Enhanced and more efficient national investment in food safety research will do much to lower incidence of foodborne illness in the United States.

DHHS and USDA will have joint leadership of the Institute and will use existing resources to support it. This acknowledgement of the critical need to expand and coordinate food safety research also emphasizes the companion needs to expand and strengthen public-private partnerships and to augment collaboration among state, local, and other Federal agencies, thereby providing effectively the scientific information required to help achieve public health goals.

This document articulates the concept of the Institute, describes goals and the administrative principles underlying its organization, presents a proposed structure for the Institute, and a draft timeline for its implementation. Appendices A through E provide, respectively, the Presidential Directive for the Institute, the Executive Summary from the May 1997 Food Safety Initiative Report to the President, the Executive Order creating the President's Council on Food Safety, a listing of the twelve Federal agencies involved in food safety, and a glossary of acronyms. These materials will help define the history of Executive Branch Directives on food safety and the interagency consultative efforts that have contributed to the establishment of the Institute.

The ultimate goal of the Institute is to coordinate food safety research, such that the incidence of foodborne illness is reduced to the greatest extent feasible.

I. INTRODUCTION

On July 3, 1998, President Clinton directed the Secretary of Health and Human Services and the Secretary of Agriculture to report back to him within 90 days on the creation of a Joint Institute for Food Safety Research ("Institute"). The Institute will:

> "(1) develop a strategic plan for conducting food safety research activities consistent with [the President's National] Food Safety Initiative; and
> (2) efficiently coordinate all Federal food safety research, including with the private sector and academia."

As the President's memorandum directed, the Secretary of Health and Human Services and the Secretary of Agriculture will jointly lead the Institute, which will cooperate and consult with all interested parties, including other Federal agencies and offices -- such as the Environmental Protection Agency, the National Partnership for Reinventing Government, and the Office of Science and Technology Policy -- as well as State and local agencies focusing on research and public health, and consumers, producers, industry, and academia. The Institute will make efforts to build on ongoing private sector research, through the use of public-private partnerships and other appropriate mechanisms.

This document articulates the concept of the Institute and provides a proposed structure, operating principles, goals and outcomes, and an implementation schedule for the Institute.

The ultimate goal of the Institute's research agenda is to reduce the incidence of adverse human health effects associated with the consumption of food. The objective of creating the Institute--and all other Administration food safety activities — is to reduce the incidence of foodborne illness to the greatest extent feasible. Scientific information about prevention of foodborne illness and detection of organisms that may cause it is critical to further reduce the incidence of foodborne illness.

This report will serve as a starting rather than ending point for development of the Institute. The report will be published in the Federal Register for comment during October-November of 1998 with a public meeting in November/December of 1998. A draft proposal, based on the public comments received, will be announced in the Federal Register in February/March of 1999, with a public meeting in March/April of 1999. The final proposal will be submitted to the National Science and Technology Council of the Office of Science and Technology Policy (NSTC/OSTP) in June, 1999 for final review. A final report, which will serve as the detailed blueprint for the Institute, will be announced in the Federal Register in July of 1999. The Institute will officially begin its operations on October 1, 1999.

II. BACKGROUND

A. The National Food Safety Initiative

In his January 25, 1997 radio address, President Clinton announced he would request $43.2 million in his 1998 budget to fund a nationwide early-warning system for foodborne illness, increase seafood safety inspections, and expand food safety research, training, and education. The President directed three Cabinet members--the Secretary of Health and Human Services, the Secretary of Agriculture, and the Administrator of the Environmental Protection Agency (EPA)--to identify specific actions to improve the safety of the food supply. He further directed them to consult with stakeholders (consumers, producers, industry, states, universities, and the public) and to report back to him in 90 days. The President emphasized the need to explore opportunities for public-private partnerships to improve food safety, particularly in the areas of surveillance, inspections, research, risk assessment, education, and coordination among local, state, and Federal health authorities. Through a series of interagency and stakeholder meetings and consultations, the May 1997 Report to the President entitled "Food Safety from Farm to Table: A National Food Safety Initiative" was developed and issued. (See Appendix B).

While the American food supply is the safest in the world, the Administration directed the National Food Safety Initiative (FSI) because there are still millions of Americans stricken by illness every year caused by the food they eat. The FSI recognized that research provides new information and technologies essential to successful implementation of six key activities: standard setting and rulemaking, inspection and compliance, education, surveillance, and risk assessment. To ensure that current research investments are adequately supporting the six key activities identified by the FSI, Federal research agencies are working on a coordinated, interagency research plan. Federal agencies that conduct food safety research have recently completed a major step in the development of this plan by creating a Federal inventory of food safety research projects, active or planned, for Fiscal Year 1998, including the scientific and fiscal resources that supported the research. DHHS and USDA, in collaboration with NSTC/OSTP, will use this information to identify additional priority food safety research areas that are not currently addressed in the FSI and will develop future food safety initiatives and their budgetary requirements. The Institute will become the vehicle for coordinating these activities to create a seamless, interagency food safety research planning, budgeting, and prioritization mechanism.

The FSI identified five broad areas in which significant knowledge gaps require a concerted interagency research effort:

- Improving detection methods
- Understanding microbial resistance to traditional preservation technologies
- Understanding antibiotic drug resistance
- Developing prevention techniques for pathogen avoidance, reduction, and elimination
- Understanding the contribution of food handling, distribution, and storage to pathogen contamination of food and developing preventions

The FSI also identified the research goal to develop methods and scientific data that would enhance the ability of Federal agencies to conduct microbial risk assessments. Two additional research areas, critical for addressing this goal, are:

- Developing and validating microbial exposure models, based on probabilistic methodology
- Developing and validating dose-response assessment models for use in risk assessment

When the FSI was developed in 1997, these immediate needs were given priority within the research and risk assessment agenda because microbial contamination of foods by pathogens has increasingly been linked to increasing incidence of foodborne illness and to high rates of morbidity and mortality. As these research and risk assessment activities progress and improvements in preventative measures are developed, the Institute will provide leadership for identification of other research and risk assessment priorities, which will receive increased attention from Federal food safety research agencies in future years.

III. NAME AND STRUCTURE OF INSTITUTE

The Secretary of Health and Human Services and the Secretary of Agriculture propose that the official name of the Institute be the "National Institute for Food Safety Research (NIFSR)."[1]

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[1]The Food and Drug Administration of the Department of Health and Human Services (DHHS) already has a research facility and program which is named the Joint Institute for Food Safety and Applied Nutrition (JIFSAN). Several prominent universities also have food safety institutes as part of their research programs. To avoid confusion, DHHS and the Department of Agriculture (USDA) have proposed a new name, the "National Institute for Food Safety Research".

The Institute will report to The President's Council on Food Safety (see Appendix C), which is chaired by the Secretaries of Agriculture and Health and Human Services and the Assistant to the President for Science and Technology/Director of the Office of Science and Technology Policy. The Institute will be led by an Executive Director, who will be a highly recognized food scientist, jointly recruited, appointed, and supported by the USDA and DHHS. The Executive Director will supervise a small, permanent Institute staff of no more than 10 employees, and existing staff resources of USDA and DHHS will support the Institute and its operations.

The Executive Director will report to an Executive Research Committee and be advised by a Federal policy and budget committee and the National Institute for Food Safety Research Advisory Committee. The Executive Research Committee will comprise one senior research official appointed by each of the co-chairs of the President's Council on Food Safety. The Executive Research Committee will report to the President's Council on Food Safety.

The Federal policy and budget committee will be comprised of Federal food safety policy officials and agency heads, representing both research agencies and regulatory agencies. This committee will serve as a mechanism by which the government's chief scientific and public health experts can interact with the Institute Director and the Executive Research Committee to ensure the goals of the Institute are achieved. This committee will also be the vehicle for consultation and coordination across all Federal food safety agencies, and its membership will represent agencies of the USDA, DHHS, the Environmental Protection Agency, the National Science Foundation, and other relevant federal agencies.

The National Institute for Food Safety Research Advisory Committee will have 16 stakeholder members, with 6 members appointed by the Secretary of Agriculture, 6 members appointed by the Secretary of Health and Human Services, and 4 members appointed by OSTP/NSTC. Members of this committee may be chosen from existing advisory committees to the USDA, DHHS, and OSTP/NSTC. USDA, DHHS, and OSTP/NSTC will jointly support the Advisory Committee.

The work of the Institute will be accomplished through temporary interagency task forces that form and close as specific issues are resolved and through a small, pernanent Institute staff, which will provide technical, administrative, clerical and computer support. The Institute will focus initially on microbial pathogens, in keeping with the President's National Food Safety Initiative. In future years, based on the direction of the President's Food Safety Council, advice of the National Institute for Food Safety Research Advisory Committee, and on other public input, the Institute may expand its scope progressively to include other known or potential contributors to foodborne illness and/or food safety, such as chemical contaminants, natural toxins, pesticide residues, animal drug residues, food additives, and

nutritional safety and health. All of these topics already are foci for important food safety research activities that warrant coordination by the Institute. With an expanded scope, the Institute would develop broad-based strategic planning with input from stakeholders and coordinate the resources administered by the numerous Federal agencies that participate in food safety research. (See Appendix D).

IV. ORGANIZING PRINCIPLES

The DHHS and USDA have developed the following principles as the foundation for establishing and operating the Institute.

A. Optimize Current Investment and Infrastructure

The Institute's mission includes optimizing the effectiveness of current food safety research investments and infrastructure to maximize funds going to conduct research, rather than for construction or maintenance of additional research facilities. For this reason, the President's directive is not intended to result in construction of new research or administrative facilities. The Institute will be "virtual," *i.e.*, it will focus on coordinated planning for research programs and budgets and on enhanced communications among existing organizational entities working within existing facilities. The Institute will be supported by a small staff and will draw on current resources within the responsible food safety agencies. The Institute will assist in fulfilling the Administration's farm-to-table strategy by relying on access to existing Federal research laboratories throughout the country.

B. Provide Centralized Communication with Stakeholders

Effective communication between the Federal food safety research providers and the users of the knowledge gained is critical to establishing priority-based research programs that are responsive to national needs. More than a dozen Federal agencies actively contribute to food safety research efforts. Food safety researchers have numerous critical constituencies: (1) regulatory agencies that rely on scientific information for the protection of public health; (2) industry and producers, including retailers, who design and implement effective food safety programs; and (3) consumers. While each agency makes a critical contribution, providing their unique expertise, perspective, and infrastructure, this array of activities can be daunting to stakeholders. Effective interchange--not only among Federal laboratories and the managers of Federally supported extramural research programs, but also their counterparts in industry and academia--is critical to developing cost-effective programs that maximize the benefits to

public health. Therefore, the Institute will serve as a centralized focal point for communication between stakeholders and the appropriate members of the Federal research community by facilitating public input into priorities through public meetings and advice from the National Institute for Food Safety Research Advisory Committee.

C. Use Current Intramural and Extramural Research Programs in Innovative Ways

Leveraging Federal research dollars for maximum public health benefit is critical to effective implementation of the FSI farm-to-table strategy. To better leverage current and future funds, the Institute will foster development of joint program announcements involving multiple Federal research programs and multi-center trials to demonstrate the cost-effectiveness of prevention strategies and technologies. Particular emphasis will be placed on "on-farm" research for the development of new technologies and tools to prevent microbial contamination of raw foods.

D. Mobilize Resources to Minimize the Impact of Current and Emerging Food Safety Problems

Food safety concerns are usually complex, involving the interaction of factors associated with agricultural productivity, public health, food processing and distribution practices, market economies and international trade, and consumer preferences and perceptions. The research needed to solve food safety problems is equally complex, requiring contributions from both basic and applied researchers in physical and biological sciences, and equally important advances in economic and behavioral research, and food technology and engineering. The impact that new food safety problems have, both in relation to threats to public health and the economic well-being of industry, is often dependent on how rapidly research resources can be mobilized. In the absence of a centralized coordinating mechanism to provide leadership, such as the Institute, the timely mobilization of resources among diverse groups of scientific disciplines has historically been a barrier to effective problem identification and resolution. The Institute, through advanced communications and coordination systems, will realize increased efficiencies in bringing to bear research resources when they are needed to minimize the impact of current and emerging food safety problems.

E. Increase Accountability for Federal Research Priorities and Implementation of Strategies to the Public

One of the Administration's highest priorities has been to make Federal agencies more responsive to the needs of the nation through transparent decision-making. To effectively

encompass the nation's food safety research needs, the Administration to date has focused on joint research planning and prioritization, with the participation of numerous Federal agencies. Establishment of the Institute will build on this planning process, thereby increasing the transparency of federal food safety research efforts, to better assure the public that Federal investments are strategic and not redundant.

V. GOALS/OUTCOMES OF THE INSTITUTE

A. Coordination in Research Planning, Budgeting, and Prioritization

The ultimate goal of the Institute's research agenda is to reduce the incidence of adverse human health effects associated with the consumption of food. Research planning, budgeting, and prioritization will be a consultative process among food safety research and regulatory agencies, with a primary purpose being to fulfill the informational needs of food safety regulatory agencies. As stated above, DHHS and USDA will cooperate to lead this effort, in consultation with the National Science and Technology Council of the Office of Science and Technology Policy (NSTC/OSTP). The goals of this effort are: (1) to maximize the public health benefit to the American people for resources devoted to basic and applied research, by assuring that the information acquired is applicable to the development of effective food safety guidance, policy, and regulation; (2) to maximize the return-on-investment to producers, processors, and the public for resources devoted to research by developing cost-effective prevention technologies; (3) to effectively communicate and operate together with Federal, state, and local public health, agriculture and research agencies and government partners; and (4) to develop partnerships among the Federal, state, and local governments and industry or academe to identify and solve, scientifically, food safety issues. The Institute will also coordinate and monitor activities that agencies undertake to further these goals and to provide periodic assessments of research accomplishments.

B. Scientific Support of Food Safety Regulation

The Nation's collective food safety research capabilities must be responsive to the risk-based public health priorities of the food safety regulatory agencies. Science and technology are required to develop effective food safety guidance, policy, and regulation. The Institute will identify research needs to (1) achieve public health goals; (2) support guidance, pathogen reduction regulation, and hazard analysis and critical control points (HACCP) systems approaches to regulation (e.g., meat, poultry, seafood, fresh juice); and (3) shift research orientation to a risk-based approach. Through the Federal policy and budget committee, which advises the Institute Director, food safety regulatory agencies will play an integral role in the Institute's operation and its development of research strategies to foster public health goals.

C. Communication/Links with Other Food Safety Agencies

Through participation in the Institute, all Federal food safety research agencies will coordinate, complement, and bolster research efforts on related and multifaceted food safety issues. The Institute will coordinate the use of existing mechanisms, such as interagency agreements, contracts, and the development of scientific conferences, and the development of new mechanisms, such as jointly funded program announcements and other innovative approaches to further the achievement of the Institute's goals.

D. Communication/Links with Industry and Academic Partners

The Institute will encourage the development of public-private partnerships with industry and academia to efficiently develop and transfer new information and technologies. Technology transfer mechanisms for cooperation between Federal agencies and industry exist through the Cooperative Research and Development Agreement (CRADA) process. This mechanism protects the intellectual property rights of the parties involved and is designed to avoid conflicts of interest, which are of particular concern within regulatory agencies. The Institute will foster and build on existing technology transfer mechanisms.

Several food safety research consortia, which include Federal, state, academic, and industry partners, already exist and are supported in part through competitively awarded Federal extramural research grants. These institutes can optimize and combine resources to perform stronger and more cost-effective research programs in food safety than can a single university. The USDA and DHHS research agencies will continue to use grants, contracts, and cooperative agreements in partnership with academia.

VI. IMPLEMENTATION SCHEDULE

Oct. 1, 1998	Present report to the President
October/November 1998	Announce report in Federal Register for comment and notice of public meeting
November/December 1998	Host public meeting
January 1999	Analyze comments and develop a more detailed draft proposal for the Institute
March/April 1999	Announce draft proposal in Federal Register for comment
April/May 1999	Host public meeting
June 1999	Submit final proposal to National Science and Technology Council for review
July 1999	Announce final report in the Federal Register
August 1999	National Institute for Food Safety Research Advisory Committee Members are appointed by Secretary of Health and Human Services and Secretary of Agriculture and Office of Science and Technology Policy
October 1, 1999	Institute begins operation

Appendix A

THE WHITE HOUSE

WASHINGTON

July 3, 1998

MEMORANDUM FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES
THE SECRETARY OF AGRICULTURE

SUBJECT: Joint Institute for Food Safety Research

Americans enjoy the most bountiful and safe food supply in the world. My Administration has made substantial improvements in the food safety system, from modernizing meat, seafood, and poultry inspections to creating a high-tech early warning system to detect and control outbreaks of foodborne illness.

Our success has been built on two guiding principles: (1) engaging all concerned parties including consumers, farmers, industry, and academia, in an open and far-ranging dialogue about improving food safety; and (2) grounding our efforts in the best science available. We have made progress, but more can be done to prevent the many foodborne illnesses that still occur in our country.

As we look to the future of food safety, science and technology will play an increasingly central role. An expanded food safety research agenda is essential to continued improvements in the safety of America's food. We need new tools to detect more quickly dangerous pathogens, like E. coli O157:H7 and campylobacter, and we need better interventions that reduce the risk of contamination during food production.

Food safety research is a critical piece of my Fiscal Year 1999 food safety initiative; and I have urged the Congress to revise the appropriations bills it currently is considering to provide full funding for this initiative. I also have urged the Congress to pass two critical pieces of legislation to bring our food safety system into the 21st century: (1) legislation ensuring that the Food and Drug Administration halts imports of fruits, vegetables, and other food products that come from countries that do not meet U.S. food safety requirements or that do not provide the same level of protection as is required for U.S. products; and (2) legislation giving the Department of Agriculture the authority to impose civil penalties for violations of meat and poultry regulations and to issue mandatory recalls to remove unsafe meat and poultry from the marketplace.

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At the same time, we need to make every effort to maximize our current resources and authorities. One very important way to achieve this objective is to improve and coordinate food safety research activities across the Federal Government, with State and local governments, and the private sector. Solid research can and will help us to identify foodborne hazards more rapidly and accurately, and to develop more effective intervention mechanisms to prevent food contamination.

I therefore direct you to report back to me within 90 days on the creation of a Joint Institute for Food Safety Research that will: (1) develop a strategic plan for conducting food safety research activities consistent with my Food Safety Initiative; and (2) efficiently coordinate all Federal food safety research, including with the private sector and academia. This Institute, which will operate under your joint leadership, should cooperate and consult with all interested parties, including other Federal agencies and offices -- particularly, the Environmental Protection Agency, the National Partnership for Reinventing Government, and the Office of Science and Technology Policy -- State and local agencies focusing on research and public health, and on consumers, producers, industry, and academia. The Institute should make special efforts to build on efforts of the private sector, through the use of public-private partnerships or other appropriate mechanisms.

These steps, taken together and in coordination with our pending legislation, will ensure to the fullest extent possible the safety of food for all of America's families.

William J. Clinton

APPENDIX B

FOOD SAFETY FROM FARM TO TABLE:

A NATIONAL FOOD SAFETY INITIATIVE

REPORT TO THE PRESIDENT

MAY 1997

EXECUTIVE SUMMARY

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

In his January 25, 1997 radio address, President Clinton announced he would request $43.2 million in his 1998 budget to fund a nationwide early-warning system for foodborne illness, increase seafood safety inspections, and expand food-safety research, training, and education. The President also directed three Cabinet members--the Secretary of Agriculture, the Secretary of Health and Human Services, and the Administrator of the Environmental Protection Agency--to identify specific steps to improve the safety of the food supply. He directed them to consult with consumers, producers, industry, states, universities, and the public, and to report back to him in 90 days. This report responds to the President's request and outlines a comprehensive new initiative to improve the safety of the nation's food supply.

The goal of this initiative is to further reduce the incidence of foodborne illness to the greatest extent feasible. The recommendations presented in this report are based on the public-health principles that the public and private sectors should identify and take preventive measures to reduce risk of illness, should focus our efforts on hazards that present the greatest risk, and should make the best use of public and private resources. The initiative also seeks to further collaboration between public and private organizations and to improve coordination within the government as we work toward our common goal of improving the safety of the nation's food supply.

Six agencies in the federal government have primary responsibility for food safety: two agencies under the Department of Health and Human Services (HHS)--the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC); three agencies under the Department of Agriculture (USDA)--the Food Safety and Inspection Service (FSIS), the Agricultural Research Service (ARS), and the Cooperative State Research, Education, and Extension Service (CSREES); and the Environmental Protection Agency (EPA). Over the last 90 days, these agencies have worked with the many constituencies interested in food safety to identify the greatest public-health risks and design strategies to reduce these risks. USDA, FDA, CDC, and EPA have worked to build consensus and to identify opportunities to better use their collective resources and expertise, and to strengthen partnerships with private organizations. As directed by the President, the agencies have explored ways to strengthen systems of coordination, surveillance, inspections, research, risk assessment, and education.

This report presents the results of that consultative process. It outlines steps USDA, HHS, and EPA will take this year to reduce foodborne illness, and spells out in greater detail how agencies will use the $43.2 million in new funds requested for fiscal year 1998. It also identifies issues the agencies plan to consider further through a public planning process.

The actions in this report build on previous Administration steps to modernize our food-safety programs and respond to emerging challenges. As part of the Vice President's National Performance Review (NPR), the agencies have encouraged the widespread adoption of preventive controls. Specifically, the NPR report urged implementation of Hazard Analysis and Critical Control Point (HACCP) systems to ensure food manufacturers identify points where contamination is likely to occur and implement process controls to prevent it. Under HACCP-based regulatory programs there is a clear delineation of responsibilities between industry and regulatory agencies: Industry has the primary responsibility for the safety of the food it produces and distributes; the government's principle role is to verify that industry is carrying out its responsibility, and to initiate appropriate regulatory action if necessary.

The Administration has put in place science-based HACCP regulatory programs for seafood, meat, and poultry. In late 1995, the Administration issued new rules to ensure seafood safety. In July 1996, President Clinton announced new regulations to modernize the nation's meat and poultry inspection system. The Early-Warning System the President announced in January will gather critical scientific data to further improve these prevention systems. Additional actions outlined in this report will encourage the use of HACCP principles throughout the food industry.

The need for further action is clear. Our understanding of many pathogens and how they contaminate food is limited; for some contaminants, we do not know how much must be present in food for there to be a risk of illness; for others, we do not have the ability to detect their presence in foods. The public-health system in this country has had a limited ability to identify and track the causes of foodborne illness; and federal, state, and local food-safety agencies need to improve coordination for more efficient and effective response to outbreaks of illness. Resource constraints increasingly limit the ability of federal and state agencies to inspect food processing facilities (e.g., years can go by before some plants receive a federal inspection.) Increasing quantities of imported foods flow into this country daily with limited scrutiny. Some food processors, restauranteurs, food-service workers, supermarket managers, and consumers are unaware of how to protect food from the threat of foodborne contaminants. These and other deficiencies will be addressed by key Administration actions outlined in this report and described below.

Enhance Surveillance and Build an Early-Warning System

As the President announced in January, the Administration will build a new national early-warning system to help detect and respond to outbreaks of foodborne illness earlier, and to give us the data we need to prevent future outbreaks. For example, with FY98 funds, the Administration will:

Enhance Surveillance. The Administration will expand from five to eight the number of FoodNet active surveillance sentinel sites. Personnel at these sentinel sites actively look for foodborne diseases. Existing sites are in Oregon, Northern California, Minnesota, Connecticut, and metropolitan Atlanta. New sites will be in New York and in Maryland, with an eighth site to be identified. CDC will also increase surveillance activities for certain specific diseases. For example, CDC will begin a case-control study of hepatitis A to determine the proportion of cases due to food contamination, FDA will strengthen surveillance for Vibrio in Gulf Coast oysters, and CDC will strengthen surveillance for Vibrio in people.

Equip FoodNet sites and other state health departments with state-of-the-art technology, including DNA fingerprinting, to identify the source of infectious agents and with additional epidemiologists and food-safety scientists to trace outbreaks to their source.

Create a national electronic network for rapid fingerprint comparison. CDC will equip the sentinel sites and other state health departments with DNA fingerprinting technology, and will link states together to allow the rapid sharing of information and to quickly determine whether outbreaks in different states have a common source.

Improve Responses to Foodborne Outbreaks

At the federal level, four agencies are charged with responding to outbreaks of foodborne and waterborne illness: CDC, FDA, FSIS, and EPA. States and many local governments with widely varying expertise and resources also share responsibility for outbreak response. The current system does not assure a well-coordinated, rapid response to interstate outbreaks. To ensure a rapid and appropriate response, with FY98 funds, agencies will:

Establish an intergovernmental Foodborne Outbreak Response Coordinating Group. Federal agencies will form an intergovernmental group, the Foodborne Outbreak Response Coordinating Group, to improve the approach to interstate outbreaks of foodborne illness. This group will provide for appropriate participation by representatives of state and local agencies charged with responding to outbreaks of foodborne illness. It will also review ways to more effectively involve the appropriate state agencies when there is a foodborne outbreak.

Strengthen the infrastructure for surveillance and coordination at state health departments. CDC, EPA, FDA, and FSIS will assess and catalogue available state resources, provide financial and technical support for foodborne-disease-surveillance programs, and other assistance to better investigate foodborne-disease outbreaks.

Improve Risk Assessment

Risk assessment is the process of determining the likelihood that exposure to a hazard, such as a foodborne pathogen, will result in harm or disease. Risk-assessment methods help characterize the nature and size of risks to human health associated with foodborne hazards and assist regulators in making decisions about where in the food chain to allocate
resources to control those hazards. To improve risk-assessment capabilities, with FY98 funds, the agencies will:

Establish an interagency risk assessment consortium to coordinate and guide overarching federal risk-assessment research related to food safety.

Develop better data and modeling techniques to assess exposure to microbial contaminants, and simulate microbial variability from farm to table. Such techniques will help scientists estimate, for example, how many bacteria are likely to be present on a food at the point that it is eaten (the end of the food chain), given an initial level of bacteria on that food as it entered the food chain.

Develop New Research Methods
Today, many pathogens in food or animal feed cannot be identified. Other pathogens have
developed resistance to time-tested controls such as heat and refrigeration. With FY98 funds, the agencies will focus research immediately to:

Develop rapid, cost-effective tests for the presence in foods of pathogens such as Salmonella, Cryptosporidium, E. coli O157:H7, and hepatitis A virus in a variety of foods, especially foods already associated with foodborne illness.

Enhance understanding of how pathogens become resistant to food-preservation techniques and antibiotics.

Develop technologies for prevention and control of pathogens, such as by developing new methods of decontamination of meat, poultry, seafood, fresh produce, and eggs.

Improve Inspections and Compliance
With FY98 funds, the agencies will pursue several strategies to increase inspections for higher-risk foods; the agencies will, among other things:

Implement seafood HACCP. FDA will add seafood inspectors to implement new seafood HACCP regulations, and will work with the Commerce Department to integrate Commerce's voluntary seafood-inspection program with FDA's program.

Propose preventive measures for fresh fruit and vegetable juices. 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.

Propose preventive measures for egg products. Based on the best science available, FSIS will propose appropriate regulatory and non-regulatory options, including HACCP, for egg products.

Identify preventive measures to address public-health problems associated with produce such as those recently associated with hepatitis A virus in frozen strawberries and E. coli O157:H7 on lettuce. These measures will be identified through a comprehensive review of current production and food-safety programs including inspection, sampling, and analytical methods.

Improve coverage of imported foods. FDA will develop additional mutual recognition agreements (MRAs) with trading partners, initiate a federal-state communication system covering imported foods, and FDA and FSIS will provide technical assistance to countries whose products are implicated in a foodborne illness.

Further Food-Safety 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 food-safety techniques, such as thoroughly washing hands and cooking foods to proper temperatures, could significantly reduce foodborne illness. The Administration--working in partnership with the private sector--will use FY98 funds to, among other things:

Establish a Public-Private Partnership for Food-Safety Education. FDA, USDA, CDC, and the Department of Education will work with the food industry, consumer groups and the states to launch a food-safety public awareness and education campaign. The Partnership will develop, disseminate, and evaluate a single food-safety slogan and several standard messages. Industry has pledged $500,000 to date to support the partnership's activities and plans to raise additional funds.

Educate professionals and high-risk groups. Agencies will better educate physicians to diagnose and treat foodborne illness; strengthen efforts to educate producers, veterinarians, and state and local regulators about proper animal drug use and HACCP principles; and work with the Partnership to better train retail- and food-service workers in safe handling practices and to inform high-risk groups about how to avoid foodborne illness, e.g., in people with liver disease, illness that may be caused by consuming raw oysters containing Vibrio vulnificus.

Enhance federal-state inspection partnerships. New federal-state partnerships focused on coordinating inspection coverage (particularly between FDA and the states) will be undertaken, in an important step towards ensuring the effectiveness of HACCP and ensuring that the highest-risk food plants are inspected at least once per year.

Continue the Long-Range Planning Process

Through this initiative, and through previous activities, HHS, USDA, and EPA have laid the groundwork for a strategic planning effort. There is a broad recognition of the need to carefully implement the initiative's programs, and to consider how to apply preventive

measures in other areas of concern. A strategic-planning effort is needed to build on this common ground, and to tackle some of the difficult public-health, resource, and management questions facing federal food-safety agencies. The federal food-safety agencies are committed to continuing to meet with stakeholders, ultimately to produce a strategic plan for improving the food-safety system.

August 25, 1998 Placeholder until official version is available

EXECUTIVE ORDER

THE WHITE HOUSE

Office of the Press Secretary
(Martha?s Vineyard, Massachusetts)

For Immediate Release August 25, 1998

EXECUTIVE ORDER

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PRESIDENT'S COUNCIL ON FOOD SAFETY

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to improve the safety of the food supply through science-based regulation and well-coordinated inspection, enforcement, research, and education programs, it is hereby ordered as follows:

Section 1. Establishment of President's Council on Food Safety. (a) There is established the President's Council on Food Safety ("Council"). The Council shall comprise the Secretaries of Agriculture, Commerce, Health and Human Services, the Director of the Office of Management and Budget (OMB), the Administrator of the Environmental Protection Agency, the Assistant to the President for Science and Technology/Director of the Office of Science and Technology Policy, the Assistant to the President for Domestic Policy, and the Director of the National Partnership for Reinventing Government. The Council shall consult with other Federal agencies and State, local, and tribal government agencies, and consumer, producer, scientific, and industry groups, as appropriate.

(b) The Secretaries of Agriculture and of Health and Human Services and the Assistant to the President for Science and Technology/Director of the Office of Science and Technology Policy shall serve as Joint Chairs of the Council.

Sec. 2. Purpose. The purpose of the Council shall be to develop a comprehensive strategic plan for Federal food safety activities, taking into consideration the findings and recommendations of the National Academy of Sciences report "Ensuring Safe Food from Production to Consumption" and other input from the public on how to improve the effectiveness of the current food safety system. The Council shall make recommendations to the President on how to advance Federal efforts to implement a comprehensive science-based strategy to improve the safety of the food supply and to enhance coordination among Federal agencies, State, local, and tribal governments, and the private sector. The Council shall advise Federal agencies in setting priority areas for investment in food safety.

Sec. 3. Specific Activities and Functions. (a) The Council shall

develop a comprehensive strategic Federal food safety plan that contains specific recommendations on needed changes, including measurable outcome goals. The principal goal of the plan should be the establishment of a seamless, science-basec food safety system. The plan should address the steps necessary to achieve this goal, including the key public health, resource, and management issues regarding food safety. The planning process should consider both short-term and long-term issues including new and emerging threats and the special needs of vulnerable populations such as children and the elderly. In developing this plan, the Council shall consult with all interested parties, including State and local agencies, tribes, consumers, producers, industry, and academia.

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(b) Consistent with the comprehensive strategic Federal food safety plan described in section 3(a) of this order, the Council shall advise agencies of priority areas for investment in food safety and ensure that Federal agencies annually develop coordinated food safety budgets for submission to the OMB that sus-tain and strengthen existing capacities, eliminate duplication, and ensure the most effective use of resources for improving food safety. The Council shall also ensure that Federal agencies annually develop a unified budget for submission to the OMB for the President's Food Safety Initiative and such other food safety issues as the Council determines appropriate.

(c) The Council shall ensure that the Joint Institute for Food Safety Research (JIFSR), in consultation with the National Science and Technology Council, establishes mechanisms to guide Federal research efforts toward the highest priority food safety needs. The JIFSR shall report to the Council on a regular basis on its efforts: (I) to develop a strategic plan for conducting food safety research activities consistent with the President's Food Safety Initiative and such other food safety activities as the JIFSR determines appropriate; and (ii) to coordinate efficiently, within the executive branch and with the private sector and academia, all Federal food safety research.

Sec. 4. Cooperation. All actions taken by the Council shall, as appropriate, promote partnerships and cooperation with States, tribes, and other public and private sector efforts wherever possible to improve the safety of the food supply.

Sec. 5. General Provisions. This order is intended only to improve the internal management of the executive branch and is not intended to, nor does it, create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers or any person. Nothing in this order shall affect or alter the statutory responsi-bilities of any Federal agency charged with food safety responsibilities.

WILLIAM J. CLINTON

THE WHITE HOUSE,
August 25, 1998.

APPENDIX D

Federal Food Safety Agencies

Twelve Federal agencies have food safety responsibilities:

Agricultural Marketing Service, (AMS), U.S. Department of Agriculture (USDA)
Animal and Plant Health Inspection Service, (APHIS), USDA
Agricultural Research Service (ARS), USDA
Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS)
Cooperative State Research, Education, and Extension Service (CSREES), USDA
Economic Research Service, (ERS), USDA
Environmental Protection Agency, (EPA)
Food and Drug Administration, (FDA), DHHS
Food Safety and Inspection Service, (FSIS), USDA
Grain Inspection, Packers and Stockyards Administration, (GIPSA), USDA
National Institutes of Health, (NIH), DHHS
National Marine Fisheries Service (NMFS), Department of Commerce

APPENDIX E

Glossary of Acronyms

AMS	Agricultural Marketing Service
APHIS	Animal and Plant Health Inspection Service
ARS	Agricultural Research Service
CDC	Centers for Disease Control and Prevention
CRADA	Cooperative Research and Development Agreement
CSREES	Cooperative State Research, Education, and Extension Service
DHHS	Department of Health and Human Services
EPA	Environmental Protection Agency
ERS	Economic Research Service
FDA	Food and Drug Administration
FSI	National Food Safety Initiative
FSIS	Food Safety and Inspection Service
GAPs	Good Agricultural Practices
GIPSA	Grain Inspection, Packers and Stockyards Administration
GMPs	Good Manufacturing Practices
HACCP	Hazard Analysis Critical Control Point
JIFSAN	Joint Institute for Food Safety and Applied Nutrition
NIFSR	National Institute for Food Safety Research
NIH	National Institutes of Health
NMFS	National Marine Fisheries Service
NPR	National Performance Review
NSTC/OSTP	National Science and Technology Council/Office of Science and Technology
USDA	U.S. Department of Agriculture

CDC system allows officials to track dangerous bacteria

By Fred Bayles
USA TODAY

BOSTON — The disease detectives at Massachusetts' Department of Health wouldn't have seen a pattern among the scattered cases they were investigating earlier this summer if they had been using their old methods.

They wouldn't have known that five Keene, N.H., residents and a few people in Maine and Connecticut were hit by the same intestinal malady that had cropped up in Massachusetts.

Instead, in less than a week, the disparate cases were linked to a batch of hamburger meat contaminated with a potent strain of E. coli bacteria. The tainted meat was quickly removed from stores throughout the Northeast.

"Normally we would have had no clue that all these cases had a common source," says Bela Matyas, Massachusetts' head epidemiologist. "We would have spent weeks trying to figure out why our folks were getting sick."

The difference was PulseNet, a system developed by the Centers for Disease Control and Prevention.

It allows Massachusetts and a growing number of states to compare quickly the genetic fingerprints of the bacteria responsible for the rising number of food-borne illnesses. Just as police find suspects by using all-points bulletins, mug shots and fingerprints, state health officials can now track bacterial quarry by issuing a nationwide alert via computer.

"It's like a criminal investigation, only the bacteria are the crooks," says Sue Hunter, a CDC microbiologist who is compiling a computerized rogues' gallery for investigators to match bacteria against. "It offers the power to share information across states instantaneously," says Michael Osterholm, Minnesota's state epidemiologist and a member of a U.S. Department of Agriculture advisory committee on food safety. "It's like moving from the telegraph to the telephone."

Northwest outbreak

PulseNet's origins go back to 1993, when 500 people were stricken and four children died in the Northwest after eating hamburgers contaminated by the same strain of E. coli bacteria that showed up in Massachusetts this year.

CDC scientists were able to identify it as E. coli O157:H7 by using a DNA fingerprinting method called pulsed-field gel electrophoresis, or PFGE.

The process starts with a bacterial culture. The bacteria's DNA is chemically stripped away in a gelatin-like substance that is placed in a machine that resembles a record turntable.

An electric current zaps the gel, separating bands of DNA by molecular weight. The result is a pattern resembling a supermarket bar code. Because bacteria that cause an outbreak share a specific DNA pattern, samples from patients and suspected foods can be compared. "It is one of the best ways to identify a contaminated food source," and prevent other people from eating it, says Bala Swaminathan, head of the CDC's food-borne disease laboratories.

Traditionally, epidemiologists interview victims to see what they ate and where they ate it. Their answers are then compared to find a common source. Often, there's no easy — or quick — conclusion. Narrowing the search takes valuable time.

"PulseNet technology helps trigger the realization of relationships that would take a while to figure out. It allows you to ask how does this cluster in Georgia relate to a small outbreak in Idaho," says Laurence Slutsker, a CDC epidemiologist.

PFGE was used in last summer's recall of tons of hamburger after the meat, produced by Hudson Foods, caused widespread sickness. Soon the CDC lab in Atlanta was being inundated with state requests to match scores of samples taken from stricken residents.

After that experience, which took quite a bit of time to sort out, Swaminathan and his staff decided critical time could be saved if states could do their own PFGE work, then compare samples through a nationwide database. That's happening now.

"As other labs come on line, the work moves much faster — from three or four days to 24 hours or less," says Tim Barrett, a CDC microbiologist who runs the program. "That's critical in cases where tainted food is still out there."

Presently, 14 states and the cities of Los Angeles, New York and Washington are part of the system. Another 13 states are expected to be on line next year.

Eventually all states will be able to send PFGE patterns directly to a CDC computer that matches DNA fingerprints against a growing database of culprits. If a match is made, the computer sends e-mail warnings to states with cases that share a pattern.

"When there's a widespread outbreak, the system gives us a chance to coordinate with other states," says Steve Dietrich, a Michigan biologist who was in Atlanta recently to train on the system.

Record of success

While the interlinking system is still being built, the fingerprinting technique already has had a number of successes:

▶ In 1996, outbreaks in Illinois and Connecticut seemed unrelated. Some victims were stricken after eating at a restaurant; others ate at home. PFGE tests found the common source, mesclun lettuce grown on a California farm.

▶ An E. coli outbreak in Michigan last summer was traced to alfalfa sprouts believed to be contaminated at a local health food firm. Then an outbreak in Virginia produced the same DNA pattern. The source was tracked to a Kentucky seed company where 6,000 pounds of contaminated seeds were discovered.

▶ This summer, CDC epidemiologists struggled to determine the cause of an outbreak around Alpine, Wyo. When matching PFGE patterns came in from 12 other states, scientists traced the source to the town's water supply, which had been used by residents and by tourists.

PulseNet has been introduced at a time when reports of food-borne illnesses are on the increase. Experts estimate there are now as many as 81 million illnesses and 9,000 deaths a year.

Earlier this summer, the Institute of Medicine and the National Research Council called for better coordination within the maze of agencies charged with preventing contamination and tracking down outbreaks.

The institute released a report that the system was being taxed by virulent new bacterial forms, and by an increasingly global food distribution system that sends processed products and raw produce around the country and around the world.

"That's why PulseNet is so important," says Osterholm, who took part in the study. "It used to be a case where you'd have a dozen people get ill by eating grandma's potato salad. Now the source can be a mass produced product that can show up in seven different states."

USA TODAY · WEDNESDAY, SEPTEMBER 16, 1998

THE WHITE HOUSE

Office of the Press Secretary
(Martha's Vineyard, Massachusetts)

For Immediate Release August 25, 1998

EXECUTIVE ORDER

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PRESIDENT'S COUNCIL ON FOOD SAFETY

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to improve the safety of the food supply through science-based regulation and well-coordinated inspection, enforcement, research, and education programs, it is hereby ordered as follows:

Section 1. Establishment of President's Council on Food Safety. (a) There is established the President's Council on Food Safety ("Council"). The Council shall comprise the Secretaries of Agriculture, Commerce, Health and Human Services, the Director of the Office of Management and Budget (OMB), the Administrator of the Environmental Protection Agency, the Assistant to the President for Science and Technology/Director of the Office of Science and Technology Policy, the Assistant to the President for Domestic Policy, and the Director of the National Partnership for Reinventing Government. The Council shall consult with other Federal agencies and State, local, and tribal government agencies, and consumer, producer, scientific, and industry groups, as appropriate.

(b) The Secretaries of Agriculture and of Health and Human Services and the Assistant to the President for Science and Technology/Director of the Office of Science and Technology Policy shall serve as Joint Chairs of the Council.

Sec. 2. Purpose. The purpose of the Council shall be to develop a comprehensive strategic plan for Federal food safety activities, taking into consideration the findings and recommendations of the National Academy of Sciences report "Ensuring Safe Food from Production to Consumption" and other input from the public on how to improve the effectiveness of the current food safety system. The Council shall make recommendations to the President on how to advance Federal efforts to implement a comprehensive science-based strategy to improve the safety of the food supply and to enhance coordination among Federal agencies, State, local, and tribal governments, and the private sector. The Council shall advise Federal agencies in setting priority areas for investment in food safety.

Sec. 3. Specific Activities and Functions. (a) The Council shall develop a comprehensive strategic Federal food safety plan that contains specific recommendations on needed changes, including measurable outcome goals. The principal goal of the plan should be the establishment of a seamless, science-based food safety system. The plan should address the steps necessary to achieve this goal, including the key public health, resource, and management issues regarding food safety. The planning process should consider both short-term and long-term issues including new and emerging threats and the special needs of vulnerable populations such as children and the elderly. In developing this plan, the Council shall consult with all interested parties, including State and local agencies, tribes, consumers, producers, industry, and academia.

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(b) Consistent with the comprehensive strategic Federal food safety plan described in section 3(a) of this order, the Council shall advise agencies of priority areas for investment in food safety and ensure that Federal agencies annually develop coordinated food safety budgets for submission to the OMB that sustain and strengthen existing capacities, eliminate duplication, and ensure the most effective use of resources for improving food safety. The Council shall also ensure that Federal agencies annually develop a unified budget for submission to the OMB for the President's Food Safety Initiative and such other food safety issues as the Council determines appropriate.

© The Council shall ensure that the Joint Institute for Food Safety Research (JIFSR), in consultation with the National Science and Technology Council, establishes mechanisms to guide Federal research efforts toward the highest priority food safety needs. The JIFSR shall report to the Council on a regular basis on its efforts: (I) to develop a strategic plan for conducting food safety research activities consistent with the President's Food Safety Initiative and such other food safety activities as the JIFSR determines appropriate; and (ii) to coordinate efficiently, within the executive branch and with the private sector and academia, all Federal food safety research.

Sec. 4. Cooperation. All actions taken by the Council shall, as appropriate, promote partnerships and cooperation with States, tribes, and other public and private sector efforts wherever possible to improve the safety of the food supply.

Sec. 5. General Provisions. This order is intended only to improve the internal management of the executive branch and is not intended to, nor does it, create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers or any person. Nothing in this order shall affect or alter the statutory responsibilities of any Federal agency charged with food safety responsibilities.

WILLIAM J. CLINTON

THE WHITE HOUSE,
August 25, 1998.

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ACTIVITIES OF THE COUNCIL (with reference to executive order)

A. Comprehensive strategic plan. This plan is referenced in two sections of the executive order.

1. Section 2 states: "The purpose of the Council shall be to develop a comprehensive strategic plan for Federal food safety activities, taking into consideration the findings and recommendations of the National Academy of Sciences report "Ensuring Safe Food from Production to Consumption" and other input from the public on how to improve the effectiveness of the current food safety system. The Council shall make recommendations to the President on how to advance Federal efforts to implement a comprehensive science-based strategy to improve the safety of the food supply and to enhance coordination among Federal agencies, State, local, and tribal governments, and the private sector. The Council shall advise Federal agencies in setting priority areas for investment in food safety."

2. Section 3(a) states in pertinent part: "The Council shall develop a comprehensive strategic Federal food safety plan that contains specific recommendations on needed changes, including measurable outcome goals. The principal goal of the plan should be the establishment of a seamless, science-based food safety system. The plan should address the steps necessary to achieve this goal, including the key public health, resource, and management issues regarding food safety. The planning process should consider both short-term and long-term issues including new and emerging threats and the special needs of vulnerable populations such as children and the elderly."

B. Budget Activities. The Council will help coordinate the budget for food safety activities in two respects: (1) coordinated food safety budgets; and (2) a unified budget for the President's Food Safety Initiative.

1. Section 3(b) states in pertinent part: "[T]he Council shall advise agencies of priority areas for investment in food safety and ensure that Federal agencies annually develop coordinated food safety budgets for submission to the OMB that sustain and strengthen existing capacities, eliminate duplication, and ensure the most effective use of resources for improving food safety."

2. The Council is also tasked with developing a unified budget for the President's Food Safety Initiative, which is a subset of all the food safety activities that are performed by the agencies.