Food Research Institute

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, permanent 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.

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-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 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