Food Safety—Council

PHOTOCOPY
PRESERVATION

# President's Council on Food Safety

U.S. Department of Agriculture | Department of Health and Human Services | Environmental Protection Agency | Department of Commerce

# *Draft Preliminary Food Safety Strategic Plan for Public Review*

**January 7, 2000**

***Background and Introduction:*** As announced in the Federal Register on December 15, 1999, the President's Council on Food Safety will host a meeting on January 19, 2000 to discuss the Council's development of a federal Strategic Plan for food safety. The Federal Register Notice included a synopsis of the draft plan in order to provide examples of the types of objectives and actions that will be included in the Strategic Plan document, and to stimulate thinking and public comment about the essential components of an effective food safety strategy. In the Federal Register Notice, the Council also announced that an expanded draft of the Strategic Plan, titled "Preliminary Food Safety Strategic Plan for Public Review," would be available prior to the public meeting.

The document presented here is the preliminary Strategic Plan for public comment. As indicated in the Federal Register Notice, the Council wants to engage all interested stakeholders in a further discussion about the draft goals, objectives, and action items for the U.S. food safety system, as well as whether organizational or other changes would facilitate achievement of the goals. The Council also is interested in suggestions for additional objectives and action items, as well as comments on the priorities, ways to measure progress and mechanisms for successful implementation of the plan. Participants in the upcoming public meeting and other interested parties are strongly encouraged to read both the Federal Register Notice and the preliminary Strategic Plan before attending the public meeting or submitting comments.

Following the public review and comment process, the preliminary Strategic Plan will be refined. The final plan will include evaluation strategies to determine whether public health goals are met, and whether mid-course corrections to the plan are needed. Mechanisms for measuring progress and public health impact of the Strategic Plan will be developed in each goal area. The plan will also include an examination of whether organizational, statutory, or other changes can contribute to implementation of the plan and achievement of the goals.

The Council is particularly interested in comments on the following issues related to the draft Strategic Plan. These questions will be the starting point for discussion at the public meeting sessions on the overall framework for the plan, and on the three draft goals .

General / Cross-cutting Question Regarding the Draft Plan:

1. Is the overarching goal and overall framework of the plan well-focused and comprehensive? What modifications would you suggest? What issue or concern would your modification address?

Questions Regarding Each Draft Goal:

1. What additional objectives or specific action steps would improve the plan? What issue or concern would these address?

2. What objectives and action items should be given priority? Why?

3. What is your expectation of success? How do we measure success of the plan?

4. Are there organizational, statutory, or other changes that you suggest we consider to achieve this goal? How would these changes promote public health and food safety? What barriers would need to be addressed?

The following pages present the preliminary food safety Strategic Plan starting with an outline of the Goals and Objectives.

---

# *Preliminary Food Safety Strategic Plan for Public Review*

## *Vision Statement*

Consumers can be confident that food is safe. We protect public health through a seamless food safety system that uses farm-to-table preventive strategies and integrates research, surveillance, inspection, enforcement, and education. We use science- and risk-based approaches and work with public and private partners. We are vigilant to new and emergent threats and consider the needs of vulnerable populations. Food is safe because everyone understands and fulfills their responsibilities.

## *Overarching Goal*

To protect public health by significantly reducing the prevalence of foodborne hazards, thereby reducing acute and chronic illnesses and injuries through science-based and coordinated regulation, inspection, enforcement, research, and education programs.

## *SCIENCE AND RISK ASSESSMENT GOAL*

***The United States' food safety system is based on sound science and risk assessment.***

*OBJECTIVE 1:*
*Strengthen the scientific basis for food safety policies and regulatory decisions through expanded surveillance and rigorous assessments of risk.*

*OBJECTIVE 2:*
*Expand surveillance and data collection capabilities for adverse human health outcomes related to the food supply.*

*OBJECTIVE 3:*
*Develop and implement a unified, risk-based problem-solving research agenda particularly aimed at bridging identified gaps.*

*OBJECTIVE 4:*
*Identify emerging and potential high-risk food safety threats.*

*OBJECTIVE 5:*
*Enhance scientific infrastructure and skills at Federal, state, and local levels.*

*OBJECTIVE 6:*
*Evaluate research, risk assessment, and surveillance programs for their effectiveness in providing the scientific knowledge needed to develop and implement programs that assure maximum public health.*

## *RISK MANAGEMENT GOAL:*

***The United States system for managing food safety is effective from farm to table.***

*OBJECTIVE 1:*

*Identify areas where risk management gaps exist in the current food safety system*

*OBJECTIVE 2:*

*Promote development and implementation of preventive techniques and controls using risk-based approaches and establishment of national standards, including performance standards, where appropriate.*

*OBJECTIVE 3:*

*Expand and enhance effective monitoring, surveys, inspections and surveillance of foodborne illness and other health effects resulting from food safety hazards.*

*OBJECTIVE 4:*

*Identify food safety risks and violations of food safety standards through inspections*

*OBJECTIVE 5:*

*Protect the food supply through consistent training and consistent enforcement of food safety laws and established regulatory requirements.*

*OBJECTIVE 6:*

*Encourage the implementation of risk based, voluntary approaches for improving food safety, where appropriate.*

*OBJECTIVE 7:*

*Promote the development and transfer of new technologies and approaches to risk management directed at improving food safety.*

*OBJECTIVE 8:*

*Identify and respond to food safety emergencies rapidly and effectively*

*OBJECTIVE 9:*

*Develop an improved system of assuring that foods being exported to the U.S. from other countries are produced under food safety measures that the US concludes meet or otherwise achieve the appropriate level of public protection specified by the U.S.*

*OBJECTIVE 10:*

*Evaluate management of food safety risks.*

## *RISK COMMUNICATION GOAL*

***The United States food safety system openly and effectively provides information on food safety risks, and education on how to control those risks.***

*OBJECTIVE 1:*

*Sustain public confidence through effective, open, transparent, and timely information exchange regarding food safety risks, prevention strategies and decision making.*

*OBJECTIVE 2:*

*Develop state-of-the-art science-based education and training programs for growers, producers, transporters, retailers, consumers, regulators, public health workers, medical care providers -- all persons along the farm to table chain -- focused on prevention of foodborne illness and hazards.*

*OBJECTIVE 3:*

*Provide rapid access to information about food safety surveillance, hazards, outbreak actions,*

*enforcement and other food safety emergency activities through active outreach efforts.*

*OBJECTIVE 4:*
*Monitor and evaluate information and education programs to maximize public health.*

---

# *Draft Preliminary Food Safety Strategic Plan for Public Review*

## *FOOD SAFETY: THE NATION'S CHALLENGE*

Today's challenges with respect to public health and the food supply are exceedingly complex. While the American food supply is among the safest in the world, each year millions of people in the United States are stricken by illness caused by the food they consume, and some -- mostly the very young, elderly, and immune-compromised -- die every year as a result. Hospitalization costs for these illnesses are estimated at more than $3 billion a year and costs from lost productivity are much higher. Moreover, the causes of many of these illnesses are unknown, and research continues to raise new concerns about emerging threats from microorganisms and chemicals.

In recent years, much has changed in what we eat and where we eat. Americans are eating a greater variety of foods, particularly poultry, seafood and fresh fruit and vegetables. This is beneficial to our health, but presents new food safety challenges. More consumers demand these foods year round, making safety issues surrounding transportation and refrigeration increasingly important. As international trade expands, shifting regional commerce and products to a global marketplace, the challenge of ensuring the safety of food expands as well. Americans are eating more of their meals away from home. In fact, fifty cents of every food dollar is spent on food prepared outside the home. This food is purchased not only from grocery stores and restaurants, but also is consumed in institutional settings such as schools, hospitals, nursing homes and day care centers. The result is that, as fewer people are involved in preparing their own meals, the chance for disease-producing errors increases. Our vulnerable populations are growing, with increased longevity and increasing numbers of immune-compromised individuals. Now nearly a quarter of the population is at higher risk for foodborne illness. These forces make extremely urgent the need for a comprehensive, coordinated, forward-looking Strategic Plan for strengthening the systems that ensure the safety of the nation's food supply.

## *FOOD SAFETY REGULATION TODAY*

The Administration has adopted a farm-to-table approach that looks at food safety as an integrated and interdependent system, which is important because of the historical split jurisdictions and differing statutory authorities and responsibilities across several Federal agencies.

Three agencies currently have the major regulatory responsibilities for food safety at the Federal level: the Food Safety and Inspection Service (FSIS) within the U.S. Department of Agriculture (USDA); the Food and Drug Administration (FDA) within the Department of Health and Human Services (HHS); and the Environmental Protection Agency (EPA). FSIS ensures the safety of meat, poultry, and some egg products in interstate and international commerce. FDA regulates all domestic and imported foods that are marketed in interstate commerce except for meat, poultry, and some egg products. EPA licenses pesticide products and establishes maximum limits for pesticide residues (tolerances) in food and animal feed while FDA and FSIS enforce those pesticide tolerances in the commodities under their jurisdiction. EPA also establishes standards for surface, and drinking water.

Since 1906, the Food and Drug Administration (FDA), now within HHS, and its predecessor agencies, and the Food Safety and Inspection Service (FSIS), within USDA, and its predecessor agencies, have been authorized by Congress to protect the nation's food supply. While these agencies have a common purpose of protecting the safety of the food supply, the laws establishing each agency's authority differ considerably and, in some cases, dictate the agency's approach to implementation. For example, in

determining the acceptability of food products, the FDA and FSIS apply comparable statutory standards -- the adulteration provisions of the Federal Meat Inspection Act; the Poultry Products Inspection Act; the Egg Products Inspection Act, and the Federal Food, Drug and Cosmetic Act. However, under its three statutes, FSIS is *required* to maintain a continuous inspection program for meat, poultry and egg products, and establishments producing these products must inform the agency prior to production. The burden under those acts is that FSIS inspectors must make a determination that products are *not* adulterated *before* the mark of inspection can be applied and the products permitted to move in commerce. There is no similar requirement in the Federal Food, Drug and Cosmetic Act - FDA has the burden of proving that food is adulterated. Congress obviously took a different approach to food safety when formulating these Acts.

The Environmental Protection Agency (EPA) also plays an important role in food safety through its authorities to protect water and regulate pesticide products used in this country. EPA's regulation of pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) has historically been science-based, using risk assessment principles to determine whether a pesticide should be licensed for use on designated crops and to establish maximum allowable residue levels in/on food. This was further strengthened by the 1996 Food Quality Protection Act (FQPA) which mandates that EPA look, among other things, at aggregate exposure, cumulative risk, and the potential need for additional factors to protect infants and children.

Based on the authorizing language and their history, the agencies have developed different systems for protecting the food supply, and bring different strengths and shortcomings to the current system.

These regulatory agencies are supported by a number of other organizations. The Centers for Disease Control and Prevention (CDC), in DHHS, plays a critical and unique role as a disease monitoring, investigative, and advisory agency that is separate from -- but works closely with -- food regulatory agencies. CDC leads Federal efforts to gather data on foodborne illness and investigate outbreaks, and monitors the effectiveness of prevention and control efforts. Through its on-going public health efforts, CDC also plays a pivotal role, building state and local health department epidemiology and laboratory capacity to support foodborne disease surveillance and outbreak response. The Agricultural Research Service (ARS), the Cooperative State Research, Education and Extension Service (CSREES), and the Economic Research Service (ERS) of USDA as well as the National Institutes of Health (NIH), which is part of DHHS, play important roles in conducting food safety research, in addition to the research done by some of the food safety agencies. The National Marine Fisheries Service (NMFS) within the Department of Commerce (DOC) conducts a voluntary seafood inspection and grading program to ensure the quality and safety of commercial seafood; mandatory regulation of seafood processing is under FDA's jurisdiction.

The Strategic Plan under development proposes to build on the existing public health and regulatory systems, strengthen them, and promote coordination whenever possible. In addition, the draft plan takes into account the strengths that various state food safety systems may bring to the protection of food, and makes recommendations about how the federal government might build on those systems as well. As part of the Strategic Planning process, evaluations are being made of the current statutes and regulations impacting food safety as well as the organizational structure of the federal food safety program. The initial part of the organizational assessment is presented later in this draft to support discussion of additional ways that efficiency might be achieved over the longer term.

## *PRESIDENT'S FOOD SAFETY INITIATIVE*

In January 1997, President Clinton set a course to strengthen the nation's food safety system. The Food Safety Initiative (FSI) initially focused on the goal of reducing the number of illnesses caused by microbial contamination of food and water. Under the President's leadership, federal and state agencies have enhanced surveillance of foodborne disease and better coordinated our response to outbreaks. We have improved coordination of food safety programs, issued science-based regulations, and targeted important new research and risk assessment to critical scientific gaps. And, working collaboratively with industry, agencies have strengthened education and training, especially for those who handle food at

critical points from the retail setting to the home. Much has been accomplished. As the challenges to our food safety system continue to evolve, however, the system must adapt to meet these changing needs. The food safety system must be capable of responding to and preventing foodborne illness and food hazards through the most effective means possible.

At the request of Congress, the National Academy of Sciences (NAS) conducted a study of the current food safety system and issued its report on "Ansuring Safe Food from Production to Consumption" in August 1998. The scope of the NAS study was broader than that of the Food Safety Initiative. The report focused on microbial, chemical and physical hazards from "substances that can cause adverse consequences" in domestically-produced and imported foods, including additives, pesticides and animal drug residues. The NAS report defined the operational charge or mission of an effective food safety system *"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."* The NAS report also recommended that a comprehensive, national food safety plan be developed and listed 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.

Recognizing the broad scope of current hazards and emerging threats to the food supply and building on the recommendations of the NAS report, the President issued Executive Order 13100 creating the Council on Food Safety. The Council's goal is to make the food supply safer through a seamless, science-based food safety system supported by well-coordinated research, risk assessment, standards, surveillance, inspection, enforcement, education and strategic planning. The President specifically directed the Council to develop a comprehensive federal strategic food safety plan to improve the current system and to anticipate future needs.

## *PRESIDENT'S COUNCIL ON FOOD SAFETY - STRATEGIC PLANNING*

To address the President's directive, the Council established an interagency Strategic Planning Task Force. The Strategic Plan will address the full range of food safety issues, long- and short-term, to further ensure the health and safety of the nation's food supply. It 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 Plan's overarching goal is to protect public health.

The Plan under development aims to establish priorities on the basis of risk and to create an integrated seamless food safety system. It has three broad and complementary goals: The United States' food safety system is based on sound science and risk assessment; the United States system for managing food safety is effective from farm to table; and the United States food safety system openly and effectively provides information on food safety risks, and education on how to control those risks. Each goal includes major objectives to be addressed, along with some specific action items. As part of the strategic planning process, the Council is also examining whether organizational, statutory, or other changes to the federal food safety system will facilitate achievement of public health and food safety goals.

### Guiding Themes

Six major themes have emerged in developing the draft Preliminary Food Safety Strategic Plan presented here for discussion. First, as recommended by the NAS report, " the food safety system must rest on sound science". Thus, a critical dimension of each aspect of the Strategic Plan (science and risk assessment, risk management, and risk communication) is to collect, analyze, disseminate, and fully use objective, reproducible, scientific information about the nature and extent of food safety hazards and the means of preventing them.

Second, the plan proposes the need to select priorities based on where the scientific data show the greatest food safety risks. As it has in the past, risk-based priority setting will continue to shape budget choices, research agendas, risk management targets - indeed will guide every aspect of the effort to

strengthen programs to protect the food supply.

Third, the Strategic Plan recognizes that, ultimately, what matters is its impact on public health: has it made the food supply safer; have we reduced foodborne illnesses and hazards? Therefore, the Strategic Plan consistently includes objectives to measure the results of ongoing programs and new initiatives in terms of improvement of public health.

A fourth theme shaping the direction of this Strategic Plan is prevention. The old maxim, "an ounce of prevention is worth a pound of cure," holds especially true in the arena of food safety. Science is only beginning to assess the burden of microbially-caused food-borne illness and the potential risks of chemicals, contaminants and other hazards in foods are also inadequately characterized. Decades of experience have taught us that it is more effective, and less expensive, to prevent food safety problems than to respond to outbreaks after they have occurred. By swiftly applying our science-based understanding of the causes of foodborne hazards, government can direct the adoption of practices that will prevent harm, rather than responding only after people become ill as a result of something they ate.

The fifth theme to emerge during this planning focuses on the regulatory approaches that are used to protect the food supply. A major obligation of the federal, state, tribal and local agencies is oversight of the regulated industry and the enforcement of their laws and regulations. This not only ensures a safe food supply, but builds a fair and even playing field for all who choose to enter the food industry for commercial purposes. Fair and evenhanded enforcement of the various laws and implementing regulations has to be a key element of any food safety plan. This will also contribute to the acceptance of United States' food products both within the U.S. and outside its borders, wherever they may be consumed.

Finally, coordination of everyone's efforts is essential to the Plan's success. Given the breadth of the farm to table continuum -- from tens of thousands of farms to millions of restaurants and supermarkets to hundreds of millions of homes -- assuring the safety of the nation's food supply must be everyone's shared responsibility. Particularly, the federal agencies and their state, local, and tribal counterparts must work more closely together to assure comprehensive, efficient, consistent, and equitable regulation of the food industry and to create an integrated, seamless food safety system that protects the U.S. consumer. Partnerships among governments, including governments of other countries, academia, and the private sector are also vital to the success of the Plan.

**Draft Framework**

In the Fall of 1998, the Council held a series of public meetings to obtain the public's view on a long-term vision for food safety in the U.S., to identify the important food safety challenges for the Strategic Plan and to solicit public comment on the NAS report. Based on these meetings, the Strategic Planning Task Force developed draft Strategic Plan goals and objectives. The original draft goals and objectives were the basis for a public meeting in July 1999, and for discussions with stakeholders at scientific and professional meetings during the latter part of 1999. Federal interagency working groups were established to revise the draft plan based upon comments from stakeholders. At this time, the Council wants to engage all interested stakeholders in a discussion of the revised goals, objectives and action items being presented here. The Council also is interested in suggestions for additional objectives and action items, as well as comments on the priorities, ways to measure progress and mechanisms for successful implementation of the plan.

The goal of the Strategic Plan is to make the food supply even safer than today as proposed in the Vision Statement and reaffirmed in the Overarching Goal:

## *Vision Statement*

> Consumers can be confident that food is safe. We protect public health through a seamless food safety system that uses farm-to-table preventive strategies and integrates research, surveillance, inspection, enforcement, and education. We use science- and risk-based approaches and work with public and private partners. We are vigilant to new and emergent

threats and consider the needs of vulnerable populations. Food is safe because everyone understands and fulfills their responsibilities.

### *Overarching Goal*

To protect public health by significantly reducing the prevalence of foodborne hazards, thereby reducing acute and chronic illnesses and injuries, through science-based and coordinated regulation, inspection, enforcement, research, and education programs.

The following sections of this document present the three broad and complementary Strategic Plan goals:

The United States' food safety system is based on sound science and risk assessment;

The United States system for managing food safety is effective from farm to table; and

The United States food safety system openly and effectively provides information on food safety risks, and education on how to control those risks.

Each goal section also includes major objectives to be addressed, along with some specific action items.

## *SCIENCE AND RISK ASSESSMENT*

From developing new tools to identify, prevent, or eliminate food hazards, to performing basic research on pathogens and their impact on humans and animals, to developing risk assessment methodologies for multiple chemical exposures, to researching and conveying important information for consumers about safe food handling methods, food safety science and research play an integral role in the Administration's food safety strategy. An effective food safety system must not only be based on sound science, but also be capable of dealing with current and emerging public health concerns on the basis of the risk they present to the consumer. Thus, the Strategic Plan incorporates the NAS report's focus on the use of scientific risk assessment to guide the development of rules, policies and other approaches that will have the most positive

influence on public health. Risk analyses, including an assessment of risks and benefits, are helpful in defining the extent of scientific certainty and in helping decision-makers make the tough decisions a science-based food safety system requires.

There are, however, a number of challenges to improving the scientific base of the food safety system. For example, gaps exist in our knowledge of microbial pathogens and in our ability to measure their impact on human health; the assessment of the total impact on health of multiple chemicals from multiple sources presents a major challenge; the limited existing body of knowledge about microbial contamination limits the ability to develop on-farm preventive controls and systems of testing; insufficient data exist on the entire range of infectious and non-infectious foodborne hazards, including emerging hazards such as endocrine disruptors. Therefore, the foundation underlying any food safety system includes the articulation and implementation of a unified research agenda to provide the scientific knowledge needed for prevention, monitoring, surveillance, inspection, regulation, and education programs. The application of this knowledge in a systematic manner requires the ability to conduct qualitative and quantitative risk assessments. This research agenda must be flexible to meet new food safety challenges and support the needs of regulatory agencies for research that leads to appropriate enforceable regulations and other actions.

## *SCIENCE AND RISK ASSESSMENT GOAL*

***The United States' food safety system is based on sound science and risk assessment.***

***OBJECTIVE 1:***

***Strengthen the scientific basis for food safety policies and regulatory decisions through expanded surveillance and rigorous assessments of risk.***

**Action Items**

Identify and coordinate priority research activities needed to support risk assessment related to all aspects of food safety including microbial, chemical and pesticide related risks.

Such efforts need to address the impact on health, including effects on sensitive sub-populations and the impact of multiple chemicals from multiple sources.

Develop and update priority risk assessments that are needed for scientifically sound, risk-based food safety policies and regulatory decisions.

Develop protocols to insure that the latest scientific information is used consistently in development of risk assessments.

***OBJECTIVE 2:***

***Expand surveillance and data collection capabilities for adverse human health outcomes related to the food supply.***

**Action Items**

Use surveys, surveillance and other tools and data from public and private sources to identify adverse health outcomes related to foods.

Encourage data sharing among all relevant sources of food safety information.

***OBJECTIVE 3***

***Develop and implement a unified, risk-based problem-solving research agenda particularly aimed at bridging identified gaps.***

**Action Items**

Complete and periodically update a comparative risk analysis of acute and chronic foodborne risks from microbial, chemical and physical hazards.

Use risk analysis to identify gaps and establish priorities for a unified food safety research agenda.

This agenda should provide the basis for scientifically sound food safety policies and programs. The scope of the unified program should include: microbial hazards; chemical contaminants; regulated, pre-market approved ingredients and processes; pesticides; physical hazards; water used for food production and processing; animal feed; and veterinary drugs and biologics and drug and biologic residues.

***OBJECTIVE 4:***

***Identify emerging and potential high-risk food safety threats.***

**Action Items**

Develop enhanced identification and surveillance systems, microbial and chemical risk evaluation methods, and related technologies that effectively anticipate and prevent new public health/food safety problems.

Facilitate the development of rapid tests for pathogenic microorganisms and chemical agents in food and clinical specimens.

Develop new risk assessment methods, such as those for determining aggregate exposures and

cumulative risks, as well as consideration of sensitive sub-populations, and apply them in decision-making.

***OBJECTIVE 5:***

***Enhance scientific infrastructure and skills at federal, state, and local levels.***

**Action Items**

Enhance communication and the coordination of activities among the laboratories at local, state and federal levels performing work related to food safety and public health.

Develop programs (1) to provide opportunities for government regulatory and research scientists to maintain their academic credentials (e.g., adjunct professorship programs), and (2) to encourage scientists from academic institutions, including schools of medicine and public health, to participate in governmental food safety and public health activities (e.g., food safety policy or review sabbaticals; IPA positions).

Establish extramural programs (e.g., Centers of Excellence) to conduct targeted research and develop training programs linked to food safety and public health.

Through new and available mechanisms (*e.g.,* public/private/academic consortia, cooperative research and development agreements), provide targeted research programs linked to priority needs of food safety public health professionals and train present and future generations of food safety scientists.

***OBJECTIVE 6:***

***Evaluate research, risk assessment, and surveillance programs for their effectiveness in providing the scientific knowledge needed to develop and implement programs that assure maximum public health.***

**Action Items**

Use surveillance and monitoring data regarding food product composition and public health to examine trends over time in foodborne illnesses, pathogens and chemicals.

Evaluate the current system for establishing priorities in and deciding the allocation of funding for food safety research. Based on that evaluation, undertake steps to achieve overall program goals.

Perform periodic scientific peer reviews of federal food safety research and risk assessment programs.

## *RISK MANAGEMENT*

Foodborne illnesses and injuries have many causes. Food can become contaminated at many points from farm to table. Many factors make some groups of people more susceptible than others. No single preventative measure and no single regulatory or enforcement strategy will ensure the safety of all foods. To protect health and manage risk in the food safety system, effective production, marketplace and disease surveillance, monitoring, and other basic public health functions are essential. Public health and food safety data must be gathered, analyzed and provided to public health and regulatory agencies to aid them in identifying immediate and longer term conditions or hazards that can threaten public health.

Public health, production, and marketplace surveillance play important roles in risk management. Public health surveillance estimates the number of specific illnesses that may be related to food, defines the burden of disease, and provides early warning of disease outbreaks so they can be investigated and controlled. Public health, production and marketplace surveillance combined with epidemiologic investigations can define which foods or food production, processing, or handling practices are sources of illness or expose people to risk. Rapid public health and regulatory agency response to foodborne outbreaks, including enforcement actions, is critical to limit public health consequences. As risk

management steps are implemented, surveillance helps to document whether regulatory and other prevention efforts are working.

There are a number of important challenges to be addressed in managing the risks from foodborne hazards. Once risks or adulteration have been identified, consideration must be given to (1) prevention strategies, (2) the availability of tools to control the risks, including, where appropriate, performance standards, (3) assessment programs to monitor and survey activities directed at prevention and control, (4) surveillance to assess the effectiveness of these activities, and (5) inspection and enforcement of regulatory requirements address the risks or immediate hazards. Another challenge is to allocate resources where risk is high. Allocation of resources based on risk influences what is emphasized in the areas of research, regulation, inspection and enforcement as well as education and training. There are many roles to be fulfilled if risk management is to be effective. Everyone in the chain needs to understand the hazards being addressed and the tools for their prevention and control.

The federal agencies currently use a number of approaches to assure food safety, many are mandatory and some are voluntary. There are mandatory obligations, both statutory and regulatory, that are placed on the food industry. The food safety system relies on inspection, monitoring, and surveys of the food supply as tools to measure whether foods are meeting safety standards and expectations. If unacceptable food safety risks such as adulteration are identified the system uses enforcement provisions of the laws to correct or improve the situation. An effective system for managing food safety includes national, risk-based standards and baseline expectations for risk reduction that will help prevent or control foodborne hazards.

Programs that create incentives to improve food safety can effectively complement, direct and build upon regulation through national standards. These programs, both regulatory and voluntary, fill a variety of needs. Most importantly, they transform the levels of protection accomplished by regulatory measures from a "ceiling" into a "floor." Incentive programs encourage the regulated community to move beyond the minimum efforts required to achieve compliance and to reach higher levels of assurance and protection. They also allow the government and regulated community to gain experience with emerging technology and to design programs for areas where regulation either is inappropriate or does not exist.

An effective system needs to monitor for gaps in food safety data and to support coordination among everyone in the farm to table system having a role in prevention of food safety hazards and in responding to foodborne hazards that do occur. When food safety emergencies or new emerging food risks are identified, the system must respond quickly and effectively to protect public health. The system should coordinate activities at all levels (federal, state, tribal and local) to minimize food safety risks and use resources wisely. The system also includes a strategy for imported foods. Finally, the system will incorporate program evaluation to determine the effectiveness of the system in meeting all of its objectives for managing food safety risks.

## *RISK MANAGEMENT GOAL:*

***The United States system for managing food safety is effective from farm to table.***

### *OBJECTIVE 1:*

***Identify areas where risk management gaps exist in the current food safety system***

**Action Items**

Using risk criteria determine where standards are needed or need to be harmonized between state and federal and among federal programs and develop a plan to meet these needs.

Identify national, state and local standards and regulations that are in place to address these areas and assess their potential to be the basis for national standards.

Build the infrastructure required to support a seamless, federal/state/local food safety system.

Near-term work includes a gap analysis and identification of criteria to improve effectiveness of programs at all levels.

***OBJECTIVE 2:***

***Promote development and implementation of preventive techniques and controls using risk-based approaches and establishment of national standards, including performance standards, where appropriate.***

**Action Items**

Facilitate industry adoption of preventive controls, as appropriate based on risk, throughout the farm-to-table continuum.

Maintain performance standard based, HACCP programs and expand the use of this concept where appropriate.

Promote targeted labeling strategies to provide consumers the information necessary for them feel confident in their selection of foods processed by enhanced safety technologies, such as irradiation.

***OBJECTIVE 3:***

***Expand and enhance effective monitoring, surveys, inspections and surveillance of foodborne illness and other health effects resulting from food safety hazards.***

**Action Items**

Monitor hazards and prevention practices.

Include microbial, chemical and physical hazards as well as current prevention practices. Programs could include federal and state public health, food safety and animal health data collection; surveys of "high risk" raw agricultural products (e.g., sprouts) and foods at processing; and targeted surveys of agricultural and manufacturing practices. Such monitoring, surveys and surveillance could provide baseline data for risk assessment, detect emerging pathogens, etc. for risk management (including standards and enforcement), and evaluate the effectiveness of hazard reduction programs (quality assurance programs).

Upgrade the ability at all levels (federal, state, tribal, and local) to conduct public health surveillance of foodborne illnesses and hazards in a timely and efficient way.

Expand the capacity of public health laboratories, including the nationwide network of State Health Department laboratories.

The principal foodborne hazards should be reliably identified and "fingerprinted" with the best new technologies and staff trained to use them.

Increase special surveillance efforts.

These efforts should address a broader range of foodborne illnesses and hazards, including those illnesses affecting special populations, and the longer-term effects of foodborne illness and hazards.

Develop a network of animal diagnostic laboratories to enhance national, systematic monitoring in animal feeds and feed-stuffs for microbial, chemical and other hazards that pose a food safety risk.

Upgrade food laboratory standards and infrastructure at federal, state and local levels.

This would improve and strengthen the ability to conduct rapid targeted surveys of pathogens and chemical and physical hazards in foods and increase the consistency of laboratory methods.

***OBJECTIVE 4:***

***Identify food safety risks and violations of food safety standards through inspections***

**Action Items**

Prioritize for inspection those categories of foods determined by risk assessment to pose a "high risk" to

public health.

For example: meat and poultry, eggs and egg products, seafood, ready-to-eat food.

Promptly report identified outbreaks, safety risks and violations of food safety standards to all appropriate federal, state, tribal and local regulatory agencies for investigation and possible enforcement actions.

Expand the capacity of the entire system to monitor and inspect for "high risk" pesticides and other chemical contaminants at critical points in the farm-to-table continuum to decrease food safety risks and identify violations.

This would help to ensure a level playing field for pesticide residues on domestic and foreign grown food.

Develop an analytic framework for constructing algorithms for risk-based inspections at all levels; federal, state, tribal and local.

Design approaches that can be tailored to the needs of different agencies at different levels of government, to guide agencies in targeting prevention and enforcement activities.

***OBJECTIVE 5:***

***Protect the food supply through consistent training and consistent enforcement of food safety laws and established regulatory requirements.***

**Action Items**

Maintain and augment, where necessary, trained enforcement and compliance officers and, based on foodborne risks, utilize these individuals to maintain a high level of compliance with U.S. food safety laws for both domestic and imported foods.

Develop additional national training and job standards where such standards do not exist.

The program could include a credentialing system for food safety inspectors, investigators, and program reviewers. As a result, core competency requirements and training elements appropriate for a given area of food safety and level of expertise would be uniform throughout the country. Credentials would encourage better communications between agencies and cross-utilization of personnel. Consider new types of training that could deliver low cost, easily accessible training to all government inspectors, investigators, and program reviewers (e.g., training materials and even testing over the Internet, supplemented by more traditional courses). Training could also be open to all, including industry employees, to foster better communications and increased industry use of HACCP-based controls.

Allocate enforcement resources on the basis of greatest risks.

Target compliance inspections; e.g. inspections targeted at the foods most frequently associated with illnesses and hazards; at facilities with a history of non-compliance and at the most critical points in the farm-to-table chain for occurrence of hazard-producing or hazard-controlling events.

***OBJECTIVE 6:***

***Encourage the implementation of risk based, voluntary approaches for improving food safety, where appropriate.***

**Action Items**

Develop and/or implement programs to address areas where mandatory standards do not exist.

Use federal interagency task forces, federal/state agreements, and public/private partnerships in this effort.

Promote voluntary "best practices" and quality assurance programs developed and implemented by industry and/or government.

For example, encourage implementation of the current Good Agricultural Practices (GAPs) and

Good Manufacturing Practices (GMPs) by domestic producers and foreign trading partners.

Promote integrated pest management, biologically integrated farming systems, and sustainable agricultural practices to reduce risks from pesticide use.

Use incentive programs to improve food safety.
Examples of such programs could include preferential entry into Federal programs, information-sharing, or financial incentives.

***OBJECTIVE 7:***
***Promote the development and transfer of new technologies and approaches to risk management directed at improving food safety.***

**Action Items**

Expedite licensing and encourage the development and use of new technologies and safer pesticides.
Such products are alternatives to older riskier pest control methods and products that may be lost due to new risk standards and requirements under FQPA.

Expedite the review of food additive and pesticide petitions that are intended to decrease the incidence of foodborne illnesses through their antimicrobial actions against microbial hazards that may be present in food.

Expedite review of new animal drugs that are intended to reduce food safety risks.

Promote development and use of preventive techniques and controls at all levels to ensure that inputs such as fertilizers and water will not adversely affect the food supply.

***OBJECTIVE 8:***
***Identify and respond to food safety emergencies rapidly and effectively***

**Action Items**

Upgrade the ability, at all levels (federal, state, tribal, and local), to conduct outbreak investigation and response in a timely and efficient way.

Strengthen coordination between federal, state, tribal and local health departments, and increase feedback on multi-state foodborne outbreaks through the use of interagency outbreak coordination teams.

Facilitate a seamless local, state and federal response system
Develop national protocols for initiating and conducting source tracing and recalls, and assure adequate communication with industry and with the public during recalls.

Make the conduct of trace-back easier.
Working with appropriate industry groups, improve product identification, tracking systems, and access to records where statutory authority is not available. By determining the source and distribution chain for foods, it would be easier to conduct trace-back, to know where a product has been distributed, and to recall it selectively when necessary.

Expand the electronic information system for public health officials for reporting potential foodborne outbreaks and increase coordination between reporting systems.
This would include automated analysis and notification of possible links between outbreaks, and rapid dissemination of summaries.

***OBJECTIVE 9:***
***Develop an improved system of assuring that foods being exported to the U.S. from other***

***countries are produced under food safety measures that the US concludes meet or otherwise achieve the appropriate level of public protection specified by the U.S.***

**Action Items**

Strengthen assessments of foreign systems and conduct additional assessments of foreign regulatory systems, as appropriate, to determine if the foreign country provides the appropriate level of protection specified by the U.S. for domestic foods.

Coordinate Federal activity in all international inter-governmental settings for dealing with food safety issues.

The coordination would focus on developing policy through the direct participation of policy level individuals from the food safety regulatory agencies, agricultural trade policy agencies and agencies dealing, either directly or indirectly, with international development and assistance.

Provide technical assistance, as appropriate, to help developing countries improve their systems to meet U.S. standards. This may be done by:

Developing, coordinating, and sharing information among those U.S. agencies involved in international development and technical assistance aspects of food safety;

Sharing information on international food safety technical assistance activities and resources from U.S. and foreign governments, industry and consumer sources, and international organizations; and

Entering into MOUs with international organizations to further coordinate technical assistance.

Improve and expand, where needed, risk-based port-of-entry inspections that focus on chemical, microbiological, and physical hazards as well as labeling issues to promote public health.

***OBJECTIVE 10:***

***Evaluate management of food safety risks.***

**Action Items**

Evaluate and upgrade the food safety system periodically.

Assessment studies could (1) Identify areas for improvement in existing and newly developed programs, including possible mid-course corrections; and (2) Identify areas where new program activity is needed.

Incorporate evaluation plans when developing major standards and regulatory programs for food safety and use national surveillance and outbreak investigation data and risk analysis to demonstrate the impact of better science-based food safety management.

## *RISK COMMUNICATION*

To create effective food safety policies and programs and build public confidence in the food safety system, requires open, transparent decision making and accurate, timely exchange of information and ideas among stakeholders. It is critical to ensure that all points of view are heard and considered as the policies and programs are developed. Efficient collection of the best information from all appropriate sources must be brought to bear on decision making, particularly as federal agencies deal with emergencies and emerging new threats to food safety. Science based information and education programs need to be developed and continually evaluated and updated to ensure maximum impact on public health.

Information and education play a critical role in ensuring that everyone involved meets their responsibilities for food safety. Everyone involved in the global farm-to-table chain --" producers and

growers, transporters, workers in various segments of the food processing industry, retail food service workers and consumers, regulators, and health professionals -- needs to be informed of food safety risks and their role in reducing those risks. As research and experience reveal new information on the characteristics and transmission of foodborne hazards, food safety agencies must rapidly incorporate new information into education and information programs.

Information and education also play an important role when surveillance and inspections reveal a threat to the public health. An effective food safety system needs the capacity to transmit information and adapt messages rapidly and to provide communication tools and training programs to the appropriate people and institutions to help minimize public health threats. This flow of information must occur in an open and candid way to ensure the public's trust in the food safety system.

## *RISK COMMUNICATION GOAL*

***The United States food safety system openly and effectively provides information on food safety risks, and education on how to control those risks.***

### *OBJECTIVE 1:*

***Sustain public confidence through effective, open, transparent, and timely information exchange regarding food safety risks, prevention strategies and decision making.***

**Action Items**

Create a state-of-the-art national information network.

This network could link federal food safety departments and agencies (USDA, HHS, and EPA) with state, tribal and local public health, food safety, agricultural, and environmental agencies.

Promote development of knowledgeable food safety communicators.

Knowledgeable communicators, such as journalists and reporters, developed through workshops, seminars, professional meetings, etc. could assist agencies in providing accurate information to the public.

Establish opportunities for public/private partnerships to promote effective transparent communication about food safety risks, prevention strategies and enforcement actions.

Launch a nationwide public information/education campaign.

Such a campaign would widely disseminate food safety messages in multiple formats and languages. For example, this campaign could put critical food safety messages in the public eye by focusing on commercial network, cable, and satellite television, radio, billboards on highways, subways, advertisements in magazines reaching diverse ages and cultural groups.

Communicate frequently with stakeholders on food safety.

Such communication throughout the country would create opportunities for conversations about food safety policies, actions, and educational needs and to engage in an ongoing dialogue for meeting food safety goals.

### *OBJECTIVE 2:*

***Develop state-of-the-art science-based education and training programs for growers, producers, transporters, retailers, consumers, regulators, public health workers, medical care providers--all persons along the farm to table chain--focused on prevention of foodborne illness and hazards.***

**Action Items:**

Develop consistent and coordinated food safety messages and programs.

Identify and promote public-private educational partnerships.

Such partnerships could a) build the capacity to extend available resources, b) capitalize on unique

opportunities for reaching the public, and c) remove barriers between groups and organizations that might otherwise have conflicting food safety concerns and training needs.

Expand opportunities to utilize virtual technologies for providing online distance learning courses.
Courses could include interactive seminars, self-study curricula, live discussions with experts, etc. in order to enhance traditional educational sessions and provide the opportunity for training the greatest number of consumers and professionals at times and places convenient to them.

Create professional development opportunities for science teachers.
Such programs would promote enhanced understanding of the science of food safety and identify career opportunities in food science. This effort would complement completion of the school-based food safety curricula at the elementary, middle and secondary school levels.

Evaluate university curricula related to food safety fields and provide support for the development of appropriate professional programs so the programs are in place to train the workforce of the future.

***OBJECTIVE 3:***
***Provide rapid access to information about food safety surveillance, hazards, outbreak actions, enforcement and other food safety emergency activities through active outreach efforts.***

**Action Items**

Establish active outreach strategies to provide rapid public access to information about food safety emergencies.

Assure consistency and accuracy of information about food safety emergencies.
Include chemical contamination, foodborne illness outbreaks, and other food safety emergencies addressed by federal, state, tribal and local officials. Utilize new and emerging networks for sharing information to ensure that the public has rapid access to accurate information about microbial and chemical contamination risks in the food supply.

Develop public health education kits in multiple formats and languages.
These kits would support federal, state, tribal, and local health departments, Cooperative Extension offices, and other appropriate government offices in the dissemination of the latest information on prevention strategies for food safety risks in the event of an emergency.

***OBJECTIVE 4:***
***Monitor and evaluate information and education programs to maximize public health.***

**Action Items**

Evaluate the effectiveness of information campaigns and education programs.
Utilize local, state, and tribal health departments, Cooperative extension offices and other appropriate offices in these efforts. Disseminate results throughout the national food safety system to strengthen existing programs and develop new ones.

Expand the use of interactive web sites.
Web-sites could provide the public with a means to comment on the effectiveness of the various federal food safety programs in relation to their (a) responsiveness to priority public health concerns, (b) focus on perceived high risk food safety problems, © effectiveness in problem solving, and (d) timeliness. Included should be a means for recommending future directions for the nation's food safety programs.

## ORGANIZATIONAL CONSIDERATIONS

As outlined previously, the overarching goal of the food safety system is "to protect public health by

significantly reducing the prevalence of foodborne hazards...". As the Strategic Plan goals, objectives, and action items are being developed, the Council is analyzing whether existing structures and approaches may need to be refined, strengthened, or changed. Organizational options, facilitating mechanisms, and other potential changes are being examined for their ability to achieve the Plan's goals. With this interconnectedness in mind, the Council is presenting a wide range of organizational options which are under review. Public input is being solicited on whether and how structural changes will facilitate achievement of Strategic Plan's goals.

There are a number of dimensions or variables to be considered in examining the federal food safety system. These include:

- the numerous agency functions (e.g., research, surveillance, standard setting, enforcement) and the interdependence of both food and non-food functions in order to make food safe;
- the breadth of the farm-to-table production system that brings food to the American consumer;
- the different types of food (e.g., meat, fruits and vegetables, beverages);
- the multiple hazards that can be present in food (e.g., pathogens, chemicals, pesticides, metals, glass);
- the differing approaches to determining food safety and who bears the burden of that determination under the various statutes (e.g., MPIA, FFDCA, FQPA);
- the various agencies which make up the current U.S. food safety system; and
- the different mechanisms available for creating a seamless food safety system (e.g., stronger executive leadership, facilitating mechanisms such as MOUs, partnerships, and reorganization).

**Evaluation Criteria**

The food safety system must be seamless and must facilitate the integration of research, surveillance, inspection, enforcement, and education functions of the federal government. In order to ensure food safety and public health protection, the federal food safety system must also facilitate the implementation of the science- and risk-based strategies being developed in the Strategic Planning process.

In addition to meeting public health and food safety goals, the federal food safety system must be *effective, efficient, science-based,* and *comprehensive,* and *instill public confidence.*

Other considerations with both long- and short-term consequences must be weighed. For example, there are a number of implementation issues that must be considered in determining the strengths and weaknesses of the organizational options. These include: long- and short-term costs to full implementation; short-term disruptions and lapses in efficiency; the potential for short-run adverse impacts on public health due to disruptions, confusion and delay; and the impact on state, tribal and local food safety agencies and on other constituencies.

**Options**

A broad range of organizational options have been identified as well as a few options that will not be considered at this time and the rationale for that decision. The options are based on the NAS report *Ensuring Safe Food from Production to Consumption,* legislative proposals in the last few years, food safety consolidation efforts in other countries, General Accounting Office (GAO) and Congressional Research Service (CRS) reports, public comments and testimony, and other sources.

The options consider regulatory responsibilities for food safety, and in some cases food safety research and surveillance funded by the U.S. government. They were chosen to ensure breadth and examine the key variables described above. The major options represent a continuum from strengthening the current system, to consolidating specific overlapping functions, to designating a lead agency, to creating a consolidated agency for most or all food safety functions. Within the options, there are alternatives or sub-options; to some extent the options and sub-options represent a menu from which alternatives could be combined to create a strengthened food safety system to achieve the Strategic Plan's goals. Some of the options can be implemented within existing structures and with current legislation, while others may

require legislation and/or reorganization. The options focus on organizational structures for the federal food safety system, and not on vertical integration of food safety, although which structures provide better integration with state, tribal and local food safety regulatory agencies will be considered in evaluating the options.

## I. Coordinated Federal Food Safety System

This option would provide centralized executive leadership (including a "single voice" for food safety), and improved coordination to facilitate achievement of food safety and public health goals. There are alternative ways to accomplish this. The alternatives differ in terms of the nature of the executive leadership as well as whether there is coordination and oversight of not only planning, budgeting and research, but also policy and/or operations. The option assumes development of a comprehensive federal food safety Strategic Plan and unified annual budgets. The Joint Institute for Food Safety Research (JIFSR) would initially coordinate microbial research, and could coordinate other food safety research in the future. There would be no organizational changes with this option. It could be implemented alone or in combination with Option II, some Lead Agency alternatives under Option III, or the less expansive forms of a consolidated agency in Options IV and V.

A. Modified President's Council on Food Safety: This sub-option would modify the current Council structure for coordination and leadership. Specifically, the President's Council would be modified by designating a single chair appointed by the President, establishing a small dedicated staff, and/or broadening the Council's members to include representatives from the Federal Trade Commission (FTC), the Department of Treasury (DOT), and the Department of Defense (DOD).

B. Joint Chiefs of Staff: In this sub-option, a Board of Directors or Joint Chiefs of Staff would be established with a neutral Chairman appointed by the President and representatives from all the food safety regulatory agencies (USDA/FSIS, DHHS/FDA, EPA, DOC/NMFS). Each agency would retain its core mission, but would be obliged to plan and coordinate in areas where their missions coincide.

## II. Specific Consolidations of Food Safety Functions

This option would consist of streamlining or consolidating specific federal food safety functions, particularly those where there are jurisdictional overlap, perceived duplication, or public confusion, in order to more efficiently achieve the goals of the Strategic Plan. In this option, full responsibility for certain food products or for specific points in the farm-to-table chain would be housed in one place within an existing organization. The option would also examine agency programs where there may be functional overlaps that cause confusion for the public or industry. Such streamlining has already been initiated for seafood with the Administration proposal to consolidate federal seafood inspection activities by transferring the National Oceanic and Atmospheric Administration (NOAA) Seafood Inspection Program from DOC to FDA.

Examples of areas which might be examined for the possibility of streamlining or consolidation include:

A. Certain Food Products: game meats and USDA-regulated meats; pizza (cheese and pepperoni); and sandwiches (open-faced and closed-faced).

B. Specific Points in Farm-To-Table Continuum: food production on farms; egg safety; and federal guidance for retail establishments.

C. Functional Overlaps: inspections at jointly-regulated facilities; pre-market approval of antimicrobials; animal drugs and biologics; and food safety labeling.

An in-depth analysis could result in specific areas being consolidated (e.g., oversight of all meats with USDA; all federal guidance for retail food operations with DHHS), or food safety responsibilities for certain points in the farm-to-table chain being placed with one agency (such as discussed in the Egg Action Plan regarding packer/distributors).

## III. Lead Agency Approach

As in Option I, the Lead Agency Approach provides centralized executive leadership and a "single voice" for all or discrete parts of the food safety system. It differs from Option I in that one agency becomes the lead for all or for specific food safety functions rather than vesting the "single voice" for food safety in a Council or Joint Chiefs. This option could be implemented in combination with Option II and the Canadian Model might also be combined with Option I.

A. Single Lead Agency: Designate one agency as the lead agency (USDA or DHHS) and have the head of that agency be responsible for achieving food safety goals, including determining the strategic direction of federal food safety planning, budgeting, and policy. This agency would also have the lead for coordinating foodborne outbreaks, similar to the role that the Federal Emergency Management Agency (FEMA) plays in natural disasters. The current food safety agencies would implement their operational responsibilities in accordance with the strategic direction provided by the Lead Agency and their own laws.

B. Canadian Model: This option would establish two lead agencies, and each would have specific areas of responsibility under all the food safety laws for achievement of the Strategic Plan goals. For example, one agency could be responsible for monitoring, inspection, recall, enforcement and outbreak response for all foods and components of food (e.g., food additives, pesticides). Another agency could be responsible for research, risk assessment, surveillance, standards and regulations for all food products (meat, poultry, eggs, and other foods). EPA would continue to register and set tolerances for pesticides. This would be similar, but not identical, to the recently reorganized Canadian food safety system.

## IV. Consolidated Agency within Existing Department/Organization

This option would consolidate most food safety regulatory functions--i.e., policy, guidance, standard setting, inspection, enforcement, and education--in one agency reporting to either a current Cabinet Secretary, or the management of an existing independent agency. The consolidated agency would be responsible for standard setting, food safety labeling, education, information dissemination, inspection, enforcement, and coordination of outbreak response for all foods and substances in food. This consolidated agency would also oversee research and surveillance conducted by DHHS, USDA, and others. A variation on this would consolidate only USDA and DHHS regulatory functions -- i.e., it would exclude pesticide licensing and tolerance setting.

A. Under DHHS: Combine food safety responsibilities within DHHS, headed by a Presidential-appointed, sub-Cabinet level official, such as the Commissioner for Food and Drugs. This sub-option is similar, but not identical, to Great Britain's consolidation.

B. Under USDA: Combine food safety responsibilities within USDA, headed by a Presidential-appointed sub-Cabinet level official, such as the Under Secretary for Food Safety.

C. Under EPA: Consolidate food safety regulatory responsibilities with EPA, forming the Food and Environmental Protection Agency. This organization would continue to be an independent agency managed by a Presidential-appointed Cabinet-level official.

D. Under an Existing Commission (e.g.,CPSC) Consolidate food safety regulatory responsibilities in an existing Commission, such as the Consumer Product Safety Commission (CPSC) Transfer all food safety standard setting, monitoring, inspection, labeling and enforcement functions of FSIS, the Agricultural Marketing Service (AMS), FDA, EPA, and NMFS to CPSC or a similar-type Commission.

## V. New Consolidated, Stand Alone Food Safety Agency

Different from Option IV which consolidates food safety functions within an existing organization, this

option would create a new stand alone Cabinet-level food safety agency to facilitate achievement of food safety and public health goals. It would create an agency with its own executive leader or Cabinet-level Administrator (analogous to EPA or FEMA). Alternatively, the new agency could be managed by a five or seven member Presidential-appointed, Senate-confirmed Commission, with a Chairman who manages the day-to-day business of the Agency.

There are many ways to design a new stand-alone food safety agency. The following alternatives for a separate, stand alone agency take a functional approach. The first sub-option reflects an agency focused on a single function (inspections). With each subsequent sub-option, additional functions are added until all functions related to food safety are consolidated within one agency.

Alternatively, a new, stand alone agency could be formed on the basis of: 1) specific types of foods (all meats, all produce); 2) specific points in the farm-to-table spectrum (production, processing, etc.); or 3) different types of risks (microbial, chemical). Given the integrated nature of the food industry and food consumption as well as the fact that all types of hazards may be present in food products, these alternatives were not outlined for further analysis.

A. Consolidate food safety inspections: Consolidate the food safety inspection functions of USDA/FSIS, DOC/NMFS, and parts of FDA's Office of Regulatory Affairs (ORA) into a new stand-alone agency.

B. Consolidate food safety regulatory functions (Sub-Option A above plus standards, labeling, and education): Combine the "core" standard-setting, food safety labeling, education, inspection and enforcement functions for meat, poultry, eggs, seafood and other FDA-regulated foods and animal feed --i.e., USDA/FSIS, DOC/NMFS, and FDA's food safety offices: the Center for Food Safety and Applied Nutrition (CFSAN), the Center for Veterinary Medicine (CVM), and a part of the field operations of ORA-- into a new, independent food safety agency.

C. Consolidate food safety regulatory and research functions (Sub-Option B above plus research): Combine the functions outlined in Sub-option B above with food safety research that supports FSIS, FDA and NMFS (i.e., food safety research in ARS, CSREES, ERS, FDA, NIH, and DOC).

D. Consolidate food safety regulatory functions including pesticides (Sub-Option B above plus pesticides): Combine policy-setting and operational food safety functions for all food products and substances in food (Sub-option B above plus pesticides) into a separate, stand alone agency. This option would combine: FSIS, the Animal and Plant Health Inspection Service (APHIS) and some functions of AMS (e.g., Pesticide Data Program) at USDA; CFSAN, CVM and a portion of the ORA inspection staff at DHHS/FDA; NMFS at DOC; and EPA's Office of Pesticide Programs (OPP) as well as EPA's enforcement program that supports the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). It would put in one place all standard-setting, labeling, inspection, enforcement, and education, but not research and CDC's surveillance, for foods.

E. Consolidate food safety regulatory, research and surveillance responsibilities: Combine food safety regulatory functions for all food products and substances in food (e.g., pesticides, food additives) as well as research and surveillance supporting those regulatory activities into a new, stand alone agency. This would combine all the functions in Sub-option D above with research directly supporting food safety. It would put in one place: FSIS, APHIS, some responsibilities of AMS (e.g., Pesticide Data Program), research supporting food safety at ERS, ARS, CSREES, and the Office of Risk Assessment and Cost Benefit Analysis (ORACBA) from USDA; CFSAN, CVM, and some inspection staff from ORA at FDA; food safety research, surveillance, outbreak response, training and education from CDC; NMFS and food safety research at DOC; and the pesticide regulatory, research and enforcement programs of EPA.

F. Merge All Food Safety and Related Functions: Consolidate all food safety and food safety related functions from USDA (FSIS, ARS, CSREES, ERS, ORACBA, AMS, and APHIS -- as described above -- and the Office of Pest Management Policy or OPMP), DHHS (some parts of FDA and CDC, and NIH food safety research), EPA (pesticides and some water functions), DOC (NMFS

including related research), FTC (advertising and labeling), and DOT's Bureau of Alcohol, Tobacco and Firearms' responsibilities for beverages into a new, stand alone food safety agency. This agency would be responsible for food and beverage "core" and "collateral" food safety functions including research, surveillance, outbreak response, regulation, inspection, enforcement, education, labeling, and advertising; it would also be responsible for water used in food production, processing and for drinking.

## AFTERWORD

This draft plan and the public meeting on January 19, 2000, are intended to focus the public discussion on important food safety issues and their solutions. At the meeting, discussion will be facilitated by the questions which appear on page 1 of this document. To provide an opportunity for participation in writing, the agencies have established public dockets for the President's Council on Food Safety Strategic Plan. Comments should be submitted by February 14, 2000. It is important that comments submitted to the dockets are identified with the appropriate docket number. For those comments directed to USDA, use Docket No. 98-045N; for comments directed to FDA, use Docket No. 97N-0074; and for EPA, use Docket No. OPP-00550. Commenters are encouraged to submit a disk with their written comments in WordPerfect 6.1/8.0 or ASCII file format. Submit written comments (in triplicate) to: USDA/FSIS Hearing Clerk, 300 12th St., SW., Rm.102 Cotton Annex, Washington, DC 20250-3700; FDA/Dockets Management Branch (HFA-305), 5630 Fishers Lane, Rm.1061, Rockville, MD 20852. Comments may also be submitted electronically to: oppts.homepage@epa.gov. All comments and data in an electronic format 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.

Following the public review of this draft, the Strategic Plan will be refined. The final plan will include an examination of whether organizational, statutory, or other changes can contribute to implementation of the plan and achievement of the goals.


Webmaster | Last updated on 2000-JAN-09 by cjm/dms

FOOD SAFETY COUNCIL

**PRESIDENT'S COUNCIL ON FOOD SAFETY**
**QUARTERLY MEETING**
**NOVEMBER 10, 1999**
✦✦✦✦✦✦
**9:00 A.M. - 10:00 A.M.**
**WILLIAMSBURG ROOM**
**JAMIE L. WHITTEN BUILDING**
**U.S. DEPARTMENT OF AGRICULTURE**

IN AUGUST, 1998, THE PRESIDENT CREATED BY EXECUTIVE ORDER THE PRESIDENT'S COUNCIL ON FOOD SAFETY AND DIRECTED IT TO UNDERTAKE SEVERAL TASKS. AS MEMBERS, HE NAMED THE SECRETARIES OF AGRICULTURE (USDA), COMMERCE, AND HEALTH AND HUMAN SERVICES (HHS), THE ENVIRONMENTAL PROTECTION AGENCY (EPA) ADMINISTRATOR, DIRECTORS OF THE OFFICES OF MANAGEMENT AND BUDGET (OMB) AND NATIONAL PARTNERSHIP FOR REINVENTING GOVERNMENT (NPR), AND ASSISTANTS TO THE PRESIDENT FOR SCIENCE AND TECHNOLOGY POLICY (OSTP) AND DOMESTIC POLICY (DPC).

THE COUNCIL MEETS QUARTERLY, AND THE AGENDA FOR THE NEXT MEETING AT USDA (MEETING SITES ARE ROTATED) INCLUDES COUNCIL DECISIONS ON THE FRAMEWORK FOR A NATIONAL FOOD SAFETY SYSTEM AND AN ACTION PLAN FOR IMPROVING THE LEVEL OF EGG SAFETY. ADDITIONALLY, THE COUNCIL WILL RECEIVED UPDATES ON THE STATUS OF THE JOINT INSTITUTE FOR FOOD SAFETY RESEARCH, WHICH THE PRESIDENT ANNOUNCED IN 1998, AND PROGRESS THE COUNCIL'S TASK FORCE IS MAKING TO DEVELOP A UNIFIED FEDERAL FOOD SAFETY BUDGET. SHORT PAPERS DESCRIBING THE ISSUES WILL BE DISTRIBUTED PRIOR TO THE MEETING, ALONG WITH ATTACHMENTS.

ALL AGENDA ITEMS ARE TIED TO DIRECTIVES SPELLED OUT IN THE PRESIDENT'S EXECUTIVE ORDER.

**THE PRESIDENT'S COUNCIL ON FOOD SAFETY**

USDA - SECRETARY GLICKMAN (CO-CHAIR)
HHS - SECRETARY SHALALA (CO-CHAIR)
OSTP - DR. NEIL LANE, ASSISTANT TO THE PRESIDENT FOR SCIENCE AND TECHNOLOGY (CO-CHAIR)

**MEMBERS**
SECRETARY OF AGRICULTURE
SECRETARY OF HEALTH AND HUMAN SERVICES
SECRETARY OF COMMERCE
DIRECTOR OF OMB
ADMINISTRATOR OF EPA
ASSISTANT TO THE PRESIDENT FOR SCIENCE AND TECHNOLOGY
ASSISTANT TO THE PRESIDENT FOR DOMESTIC POLICY
DIRECTOR OF THE NATIONAL PARTNERSHIP FOR REINVENTING GOVERNMENT

DEPARTMENT OF AGRICULTURE | DEPARTMENT OF COMMERCE

# PRESIDENT'S COUNCIL ON FOOD SAFETY

DEPARTMENT OF HEALTH & HUMAN SERVICES | ENVIRONTAL PROTECTION AGENCY

## Quarterly Meeting Agenda

November 10,1999

**Location**: Williamsburg Room
Jamie L. Whitten Building
U.S. Department of Agriculture

**Time**: 9am to 10am

**THE PRESIDENT'S COUNCIL ON FOOD SAFETY**

USDA - SECRETARY GLICKMAN (CO-CHAIR & HOST)
HHS - SECRETARY SHALALA (CO-CHAIR)
OSTP - DR. NEIL LANE, ASSISTANT TO THE PRESIDENT FOR SCIENCE AND TECHNOLOGY (CO-CHAIR)

**Agenda**:

| | |
|---|---|
| Welcome | |
| Strategic Planning Process | Decision Issue |
| Egg Safety Action Plan | Decision Issue |
| Joint Institute for Food Safety Research | Informational Issue |
| Budget Accomplishments and Plans | Informational Issue |
| Closing | |

# DISCUSSION PAPER: Process for developing a Food Safety Strategic Plan for all Federal agencies.

November 10,1999

**ACTION REQUIRED**: Approval of 1) a process and direction for preparing a food safety strategic plan and 2) discussion of the plan and criteria and options for the organizational analysis and legislative analysis with constituents at the public meeting in January 2000.

The President's Council is responsible for development of a 5-year Federal food safety strategic plan. 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 strengthen and enhance prevention and intervention strategies, and develop performance measures to show progress. The scope of the plan will include microbial, chemical, physical, regulated pre-market approved substances (e.g., pesticides and food additives), and water used in food production and processing.

The food safety agencies under the direction of the Council have convened an interagency Strategic PlanningTask Force consisting of representatives from the following agencies: HHS, USDA, EPA, OSTP, DPC, and OMB. This Strategic Planning Task Force has taken a number of steps to develop the comprehensive food safety strategic plan.

The committee developed a draft set of goals and objectives and engaged a wide range of stakeholders in an interactive public meeting in July to discuss this first draft. In addition, Task Force members have participated in a number of scientific and professional meetings to share the plan as it is evolving and engage the widest possible audience in the process of developing the plan. As a result of the written and oral input the Task Force has received to date, the draft goals have been revised into a three-goal format that focuses on the risk and science basis for the food safety system in the 21st century. The Task Force has further elaborated objectives needed to accomplish these goals. The Task Force believes this format is both useful for government program managers and understandable one for stakeholders all along the farm-to-table continuum.

**RECOMMENDATION:** Prior to the next public meeting to be held in mid-January, the Task Force is now seeking the Council's views on the content of the draft strategic plan and on the process outlined below:

- The Task Force strategic plan includes the following Overarching Goal:

*To protect the public health by significantly reducing the number of foodborne illnesses through science based and coordinated surveillance, regulation, inspection, enforcement, research, and education programs*

In addition, the plan will include the following three risk and science-based goals with objectives. Issues related to the analysis of organizational structure and legislative changes will be handled as separate, supporting components of the planning document. These are discussed in greater detail below.

The draft goals and objectives are:

1. ***The United States has an effective system for managing food safety from farm-to-table.***

*Objectives:*

a) *The US food safety system establishes national, uniform, risk-based standards and risk reduction for control of food safety risks.*

b) *The US food safety system develops, promotes and requires preventive techniques and controls including new technologies, which apply national standards.*

c) *The US food safety system encourages the use of non-regulatory approaches for improving food safety.*

d) *The US food safety system conducts effective and efficient monitoring, inspection, and comprehensive surveys of the food supply to identify food safety risks or violations of food safety standards .*

e) *The US food safety system protects our food supply through uniform enforcement of local, state, and US statutes.*

f) *The US food safety system conducts effective surveillance of foodborne illness or other health effects resulting from food safety hazards.*

g) *The US food safety system responds to food safety emergencies rapidly and effectively.*

h) *The US food safety system incorporates a comprehensive strategy to ensure the safety of imported food products.*

i) *The US food safety system assesses the success of its management of food safety using evaluative techniques.*

2. ***The United States food safety system is based on sound science and risk assessment.***

*Objectives:*

a) *Identify and control new emerging food safety hazards.*

b) *Develop and implement a unified, problem-solving research agenda to provide the knowledge needed to identify and control food borne hazards.*

c) *Enhance scientific infrastructure and the skills of research and regulatory scientists at the Federal, state, and local levels.*

d) *Enhance the scientific basis for food safety policies and regulatory decisions through rigorous assessments of risk.*

e) *Research, risk assessment, and surveillance programs are evaluated for their effectiveness in providing the scientific knowledge needed to develop and implement programs that assure maximum public health.*

3. ***Information on food safety risks and how to reduce them is honestly and effectively communicated.***

*Objectives:*

a) *Timely access is provided to information about food safety through active outreach efforts.*

b) *Open access is provided to food safety information and frequent opportunities for information exchange.*

c) *Science-based education, and training programs are available for consumers, producers, retailers, regulators, public health workers, medical care providers in order to prevent health risks.*

d) *Information, education, and training activities are evaluated to ensure maximum public health.*

- Action items, performance measures, and narrative material needed to articulate a clear food safety strategy for the future are under development. Action items will be specific to each objective and implementable over a five year period.

- The Task Force will continue to engage stakeholders in the development process to obtain their input on the draft goals and objectives during November and December including special meetings with consumers, industry associations, as well as state and local officials. Their views will be reflected in a more complete draft plan including organizational and legislative analysis for public review and comment in January 2000.

- The Task Force will review the public comments and submit a final draft of the strategic plan to the Council in July 2000 for approval.

## ORGANIZATIONAL ANALYSIS:

Over the last few years, there have been a number of proposals for changing the structure of the Federal food safety system. The intent of these proposals has been to reduce foodborne hazards by strengthening and creating a more seamless food safety system. As a result of these proposals and recommendations from the National Academy of Sciences (NAS), the President's Council on Food Safety agreed to "conduct an assessment of structural models that could strengthen the Federal food safety system". Earlier this year, the Food Safety Strategic Planning Task Force established a workgroup to conduct this assessment. This paper outlines the status of this task.

## Methodology

The Organizational Analysis Workgroup (the group) identified four basic steps for conducting the assessment. First, the group established a baseline by identifying the roles and responsibilities of both the food safety and non-food safety functions of the various Federal agencies. Second, criteria for evaluating the options were developed based on the attributes of a desirable food safety system, as well as other relevant implementation issues. Third, the group identified a broad range of options for analysis. The criteria and options will be further refined based on public comment. In the fourth and final step, the group will identify the strengths and weaknesses of each option.

## Criteria/Attributes

The five major criteria are listed below in no particular order of priority.

1. The federal food safety system must be ***effective***
2. The federal food safety system must be ***efficient***.
3. The federal food safety system must be ***science-based with a strong emphasis on risk analysis.***
4. The federal food safety system must ensure ***comprehensive coverage***.
5. The federal food safety system must instill ***public confidence.***

Each of these criteria encompasses a number of attributes of a desirable food safety system. These include but are not limited to: increased consistency and uniformity, elimination of gaps, and ease of public interaction. Some of the attributes can effectively be used as criteria to discriminate amongst the structural options; others are better addressed through the strategic plan. For example, the structure of the Federal food safety system must ensure adequate interaction between food safety and non-food safety responsibilities. There also must be strong, focused leadership and clear lines of authority. In order to be efficient, the Federal food safety structure should eliminate unnecessary duplication, and coordinate budgets to ensure full funding of food safety needs.

## Implementation Considerations

There are a number of implementation issues that also must be considered in determining the strengths and weaknesses of the organizational options. These include but are not limited to: the costs of making changes to the system (e.g., loss of employees and expertise, physical/facility costs, cultural barriers); potential public health impacts due to disruption, confusion, and delay; legislative implications; ripple effects on State/local agencies and industry; etc.

## Organization Options

The group identified a range of options for analysis by examining previous proposals and developing some new ones. The options vary from strengthening executive leadership to streamlining overlapping functions, to massive reorganization of food safety and food safety-related responsibilities. Within the options, there are alternatives or sub-options. The major options are described below.

1. ***Coordinated Federal Food Safety System***

This option continues or strengthens the status quo by providing stronger executive leadership (including a "single voice" for food safety) and improved coordination mechanisms for a variety of functions. It includes the development of a comprehensive Federal food safety strategic plan and unified annual budgets. The

Joint Institute for Food Safety Research would coordinate food-related microbial research and might coordinate other food safety research in the future. There would be no structural changes with this option. Sub-options include an expanded and strengthened President's Council on Food Safety with the possibility of establishing a single chair and a few dedicated staff. Another sub-option would create a Joint Chiefs of Staff.

2. ***Streamlined Federal Food Safety Responsibilities***

This option consists of streamlining or consolidating specific Federal food safety responsibilities, particularly those where there are jurisdictional overlap, perceived duplicative functions or public confusion. In this option, full responsibility for certain food products (e.g., eggs, meats), or for specific points in the farm-to-table chain (e.g., retail, imports) would be housed in one place within an existing organization. The option would also examine "streamlining" agency programs where there may be functional overlaps that cause confusion for the public or industry (e.g., fish contaminant levels, antimicrobials). This option could be combined with some other options under consideration.

3. ***Lead Agency***

As in Option 1, the Lead Agency approach provides centralized executive leadership and a "single voice" for all or discrete parts of the food safety system. It differs from option 1 in that one agency or official becomes the lead for all or for specific food safety functions rather than vesting the "single voice" in a Council or Joint Chiefs. Sub-options include designating one agency/official as the lead with responsibility for the strategic direction of Federal food safety planning, budgeting, and policy, including guidance and standard-setting. Another sub-option would be based on the Canadian system, where all food safety inspection, enforcement, outbreak response, and recall would be consolidated within USDA and standard setting, risk assessment, research, and surveillance would be consolidated at HHS.

4. ***Consolidated Agency within Existing Department/Organization***

This option would consolidate most or all food safety functions in one agency reporting to either a current Cabinet Secretary or the management of an existing independent agency. Food safety responsibilities could be combined either within an existing agency (e.g., FDA, FSIS, EPA), within the existing food safety mission area at USDA or a newly created food safety agency at HHS, or under a Commission such as CPSC.

5. ***New Consolidated, Stand Alone Food Safety Agency***

This option would create a new independent food safety agency established by law or Executive Order. Such a separate, stand alone agency would be distinct from all previous food safety organizations, with its own Cabinet-level Administrator, or managed by a five or seven member Commission. The sub-options take the approach of consolidating similar functions, and reflect a range from a single function (inspections) to all functions related to food safety.

**RECOMMENDATION**:

The Strategic Planning Task Force recommends that comments be solicited on the criteria and options at the upcoming public meeting; the meeting would also be used to identify some of the strengths and weaknesses (pros and cons) of the options. At the same time, in parallel with preparations for the public

meeting, the Task Force recommends that the group begins the final step in the analysis, to identify the pros and cons along with data to support the evaluation.

## LEGAL AUTHORITIES ANALYSIS OF FEDERAL FOOD SAFETY STATUTES

Under the direction of the Strategic Planning Task Force, an interagency team of senior staff is charged with preparing an analysis of the strengths and weaknesses of the current federal food safety statutes. The paragraphs below describe the approach and scope of the analysis.

Scope: The interagency team is reviewing the six major food safety statutes:

- The Federal Food, Drug and Cosmetic Act (FFDCA)
- The Public Health Service Act (PHSA)
- The Federal Meat Inspection Act (FMIA)
- The Poultry Products Inspection Act (PPIA)
- The Egg Products Inspection (EPIA)
- The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)

As appropriate, the team is including information about other federal statutes such as the Clean Water Act, Safe Drinking Water Act, Toxic Substances Control Act, or the laws that the Customs Service administers. The analysis, however, will not touch to any significant extent on the multiple authorities under which states, tribal governments, and localities carry out food safety programs.

Approach: The team has focused its efforts on producing a cross-cutting assessment of the federal food safety laws by analyzing existing statutes in 10 issue areas:

1. Safety Standards
2. Procedures
3. Prevention Authorities
4. Outbreak Control, Remedial & Enforcement Authorities
5. Federal, Tribal, State & Local Relationships
6. Information-Related Authorities
7. Research Authorities
8. Jurisdiction & Administrative Flexibility
9. Authorities Affecting Imports
10. Incentives to Produce Safer Food

A summary of the different laws for each area is being prepared and will be presented in chart form. The charts are designed to be understood easily by a lay audience. Thus, they are fairly general in their explanations of the agencies' authorities, but they are also designed to be technically accurate overviews of the laws. The summary will also include as an Appendix more detailed descriptions of the food safety provisions of the major federal laws. Following each chart, the text provides a brief assessment of the legal authorities, highlighting the gaps and weaknesses in existing law.

Finally, the team is providing a set of options for possible changes to existing law that could strengthen or streamline the federal food safety laws. The group is preparing a range of choices which include not only changes that appear in the Administration's current legislative initiatives, but also ideas which would be considerably more far-reaching.

**RECOMMENDATION**:

The Strategic Planning Task Force recommends that comments not be solicited on the legislative analysis at the upcoming public meeting.

# DISCUSSION PAPER: Action Plan to Improve Egg Safety in the United States.

November 10, 1999

**ACTION REQUIRED**: Approval of the Egg Safety Action Plan and release of the document for public comment.

Under the auspices of the President's Council on Food Safety, the Strategic Planning Task Force commissioned an Egg Safety Task Force composed of designees of the federal food safety agencies responsible for egg safety to develop an action plan to eliminate egg-associated *Salmonella* Enteriditis (SE) illnesses. Those agencies are DHHS' Food and Drug Administration and Centers for Disease Control and Prevention and USDA's Food Safety and Inspection Service, Animal and Plant Health Inspection Service, Agriculture Marketing Service, and Agriculture Research Service.

The Egg Safety Task Force has worked diligently to develop an aggressive plan by identifying the systems and practices necessary to achieve its food safety public health goal. The agencies held a public meeting on August 26, 1999 to receive input from the egg industry, consumer groups, the States, and the general public during the Plan's development.

On October 19,1999, the Egg Safety Task Force presented to the Strategic Planning Task Force an action plan to achieve a 50-percent reduction of SE illnesses by 2005 and, ultimately, eliminate eggs as a source of SE infections. The comprehensive farm-to-table Egg Safety Action Plan presented in the report under cover, lays out an ambitious, coordinated federal, State, industry and consumer initiative.

**RECOMMENDATIONS**: In summary, the Strategic Planning Task Force recommends the following implementation plan:

Industry

- Egg producers and processors select one of two equivalent SE reduction strategies that focus on two different stages of the farm-to-table continuum. Strategy I emphasizes on-farm preventive controls at the producer. Strategy II emphasizes a HACCP-based program with a pathogen reduction step, such as in-shell pasteurization, at the packer/processor.

Government

- Development of consistent, nationwide standards by the Federal agencies.

- Inspection and enforcement to achieve compliance. FDA will contract with the States to inspect, with Federal oversight, and enforce the "on-farm" preventive controls. FSIS will inspect and enforce standards at the packer/processor.

- Enhancement of existing surveillance systems to measure performance toward meeting the overall public health goal.

- Educational programs targeted at at-risk populations to ensure safe practices and healthy choices.

- Research to develop new food safety technologies, e.g. vaccines and in-shell pasteurization, and better prevention and intervention strategies.

Enclosure

# EGG SAFETY

## FROM PRODUCTION TO CONSUMPTION:

# AN ACTION PLAN

## TO ELIMINATE SALMONELLA ENTERITIDIS

## ILLNESSES DUE TO EGGS

November 8, 1999

## TABLE OF CONTENTS

# EGG SAFETY FROM PRODUCTION TO CONSUMPTION: AN ACTION PLAN TO ELIMINATE SALMONELLA ENTERITIDIS ILLNESSES DUE TO EGGS

## EXECUTIVE SUMMARY

PURPOSE. The President's Council on Food Safety has identified egg safety as one component of the public health issue of food safety that warrants immediate federal, interagency action. The Egg Safety Action Plan presented in this report identifies the systems and practices that must be implemented to reduce and, ultimately, eliminate eggs as a source of human *Salmonella* Enteritidis (SE) illnesses. The overarching public health goal of the Council is to eliminate SE illnesses associated with the consumption of eggs. The interim goal of the Egg Safety Action Plan is a 50 percent reduction in egg-associated SE illnesses by 2005.

BACKGROUND. Americans consume an average of 234 eggs per person per year. While eggs are an important source of protein in the diet, an estimated 1 in 20,000 eggs in the U.S. supply will contain the SE bacteria and can cause illness if eaten raw in foods or not thoroughly cooked before consumption. Because eggs can become contaminated internally from the hen, common egg-handling practices are now considered to be unsafe. These practices include temperature abuse (i.e. holding eggs and egg-containing foods at room temperature instead of under refrigeration), inadequate cooking, and pooling eggs to prepare a large volume of an egg-containing food that is subsequently temperature abused or inadequately cooked.

The SE risk assessment model for shell eggs and egg products, developed jointly by the Food Safety and Inspection Service (FSIS) and Food and Drug Administration (FDA) in 1998, predicted that using multiple interventions could achieve a more substantial reduction in SE illnesses than using any one intervention alone. This finding suggests that a broadly based policy is likely to be more effective in eliminating egg-associated SE illnesses than a policy directed solely at one stage of the egg production to consumption continuum.

On August 26, 1999, the President's Council held a public meeting to obtain input during the development of the action plan to address egg safety. A single theme resounded from representatives of the consumer groups and the egg industry: The federal government needs a set of mandatory national standards. These standards should: (1) provide consumers an assurance that all eggs are subject to the same safety standards across the U.S. and (2) provide egg producers and processors a "level playing field" industry-wide.

RECOMMENDATIONS. The Action Plan presented in this report clearly lays out the components for an effective program to prevent human SE infections resulting from consumption of contaminated eggs. The Action Plan reflects our current understanding of the steps needed to reduce egg-associated SE illness. As we move forward with the Plan and develop the proposals, we will assess the impact of the individual action items, consult with stakeholders, and refine the Plan to reflect the best information available to achieve our public health goal.

At each stage of the egg production-to-consumption continuum, the Plan identifies the systems and activities necessary to achieve our food safety public health goals. The Plan offers industry the flexibility to choose from two equivalent SE reduction strategies, each delivering eggs into distribution and to the consumer at an equivalent level of safety. The strategy selection by egg producers and packer/processors determines the point at which the pathogen reduction steps are taken:

- Strategy I: SE testing-egg diversion system on farm
- Strategy II: Lethal treatment, or "kill step" at packer/processor

For the distribution and retail stages, the Plan specifies the safe handling practices necessary to ensure consumers receive a safe food product. Furthermore, the Plan clearly describes the surveillance, research, and education activities that must also be conducted to achieve the elimination of egg-associated SE illnesses.

This Action Plan can be accomplished irrespective of the organizational structure under which its objectives must be carried out. In its recommendations, the Task Force seeks to consolidate egg safety oversight responsibilities to one set of players for each stage of the farm-to-table continuum to provide clarity, efficiency, and effectiveness in

striving toward our food safety public health goals. First, FDA develops standards for the producer and the States provide inspection and enforcement on the farm. Second, FSIS develops standards for both shell egg packers and egg products processors and provides inspection and enforcement for both. Third, FDA and CDC conduct surveillance activities.

The performance measures that will be used to assess the progress of the Plan toward its goal are the numbers of SE cases, isolates, and outbreaks annually. The data will be collected using the following existing systems: (1) Foodborne Diseases Active Surveillance Network (FoodNet), (2) National Salmonella Surveillance System (via PHLIS), and (3) National SE Outbreak Surveillance System and Foodborne Diseases Outbreak Surveillance System. The new data will be compared to the 1998 baseline values of: (1) 1.9 cases per 100,000 persons; (2) 5,900 SE isolates; and (3) 45 SE outbreaks, respectively.

Under current estimates, the cost of implementing all of the activities described in this report would be between $45 and $78 million. These estimates have not been cleared by the Office of Management and Budget.

**Table 1. COMPARISON OF PROGRAM STRATEGIES FOR ACTION PLAN**

| *Activity* | Strategy I | Strategy II |
|---|---|---|
| **PRODUCTION (On-Farm): Objective 1.1** | | |
| Chicks from SE-free breeder flocks | √ | √ |
| SE Environmental Testing (chicks, pullets, layers) | √ | |
| SE Environmental Testing (at depopulation) | √ | √ |
| SE Egg Testing (w/positive environmental results) | √ | |
| Diversion of shell eggs to pasteurization | √ | |
| Biosecurity | √ | √ |
| Rodent/Pest control | √ | √ |
| Decontamination (Cleaning & Disinfection) | √ | √ |
| **PACKING[1]: Objective 1.2** | | |
| Prerequisite programs | √ | √ |
| HACCP system with a "kill" step | | √ |
| **PROCESSING[1]: Objective 1.3** | | |
| Prerequisite programs | √ | √ |
| HACCP system with a "kill" step | √ | √ |
| **DISTRIBUTION[2]: Objective 1.4** | | |
| Refrigeration during transport and storage | √ | √ |
| **RETAIL: Objective 2** | | |
| Food Code (egg-relevant provisions) | √ | √ |
| **SURVEILLANCE: Objectives 3-6** | | |
| Monitoring human and poultry SE infections | √ | √ |
| **RESEARCH: Objective 7** | | |
| | √ | √ |
| **EDUCATION: Objective 8** | | |
| | √ | √ |

[1] Prerequisite programs must address: basic sanitation of facilities and premises; rodent and pest control; employee hygiene and health; safety of water and food packing materials; and washing, sanitizing, and packaging.

[2] FSIS Final rule; FDA Proposed Rule

# EGG SAFETY FROM PRODUCTION TO CONSUMPTION: AN ACTION PLAN TO ELIMINATE SE ILLNESSES DUE TO EGGS

## INTRODUCTION

Americans consume an average of 234 eggs per person per year. While eggs are an important source of protein in the diet, an estimated 1 in 20,000 eggs in the U.S. supply will contain the *Salmonella* Enteritidis (SE) bacteria and can cause illness if not thoroughly cooked before consumption. The federal agencies responsible for ensuring the safety of eggs, under the auspices of the President's Council on Food Safety, have jointly developed an Action Plan to eliminate SE illnesses due to the consumption of contaminated eggs.

The Action Plan presented in this report is an aggressive, comprehensive approach to address egg safety that will reduce the number of SE illnesses attributed to eggs in the United States by 50 percent by the year 2005. The Plan identifies systems that must be designed and implemented and activities that must be conducted at each stage of the farm-to-table continuum to reach the overarching goal of eliminating egg-associated SE illnesses. The Plan also recognizes and encompasses federal, state, and local systems already in place and industry activities already occurring. The Action Plan reflects our current understanding of the steps needed to reduce egg-associated SE illness. As we move forward with the Plan and develop the proposals, we will assess the impact of the individual action items, consult with stakeholders, and refine the Plan to reflect the best information available to achieve our public health goal.

## SCOPE

This comprehensive, science-based plan contains elements identified by the National Academy of Sciences' Committee to Ensure Safe Food from Production to Consumption as necessary components of an effective food safety system.[3]

[3] Institute of Medicine/National Research Council, NAS. *Ensuring Safe Food: From Production to Consumption.* National Academy Press, Washington, DC, 1998.

- To promote consistency, the Plan calls for a consistent, nationwide program that addresses each stage of the farm-to-table continuum, including on the farm, at the packer or processor, during distribution, as well as for proper handling and preparation practices at retail. The Plan also highlights the proposed and final rules requiring refrigeration at retail and during distribution, respectively, as well as a proposed rule that would require a safe handling statement on the package.
- To provide a science-based foundation, the development of the Plan began with a review of the comprehensive, quantitative risk assessment of SE for shell eggs and egg products. The findings and research needs identified in the risk assessment report were incorporated into the Plan.
- The Plan identifies promising developments in science and technology, such as SE vaccines and in-shell pasteurization, for further research including field and pilot studies.
- The Plan recognizes the need for adequate surveillance, including active surveillance of SE illnesses in regions of the country where the most contaminated eggs are produced and consumed, and calls for expansion of FoodNet activities.
- The Plan identifies gaps in the scientific understanding of the SE bacterium and its route of on-farm transmission to SE-free chicks. The Plan also highlights the federal government's current education efforts focused on the use of safe egg handling practices by food preparers at retail and at home.
- The Plan itemizes the personnel and funds necessary to implement and maintain the specific systems and activities listed, through FY2005. Under the federal agencies' current authorities and available resources, the federal government cannot carry out these activities alone. The Plan highlights existing partnerships and encourages the formation of new ones.
- The Plan clearly identifies the agencies currently responsible for the safety of eggs. Moreover, the Plan provides options for consideration in

determining which agency or agencies should be used to implement and maintain the specific responsibilities proposed.

The Egg Safety Action Plan presented in this report clearly and concisely describes a way to reduce the number of SE-contaminated eggs in the marketplace and to eliminate SE illnesses caused by consumption of eggs. By combining new and existing systems and activities targeted at both eggs and illnesses, the plan presents a comprehensive, integrated nationwide strategy to address an important food safety and public health concern so that Americans can continue to enjoy one of the safest food supplies in the world.

## BACKGROUND

*President's Food Safety Initiative.* On January 25, 1997, the President directed the Secretaries of Agriculture and Health and Human Services and the Administrator of the Environmental Protection Agency to identify specific steps to further improve the safety of the food supply and to further reduce the incidence of foodborne illness to the greatest extent feasible.[4] In May 1997, they presented the President with a report entitled, "Food Safety from Farm to Table: A National Food Safety Initiative." Under this initiative, the federal government, in concert with state and local governments, industry and academia, are conducting research, risk assessments, and cost-benefit analyses to determine how foodborne illnesses occur and can be prevented or controlled in the most efficient and cost-effective manner. The federal government is also improving surveillance and investigative efforts to locate and monitor illnesses caused by food, updating its approach to inspections of food processors to monitor the safety of the food supply, and reinvigorating education of food preparers focusing on the use of safe practices.[5]

*President's Council on Food Safety and Its Strategic Plan.* In August 1998, the President established a Council on Food Safety under Executive Order No. 13100 to

[4] EPA/HHS/USDA. *Food Safety From Farm To Table: A National Food-Safety Initiative.* A Report to the President. May 1997.

protect the health of the American people by preventing foodborne illness using science-based regulation and well-coordinated surveillance and investigation, inspection, enforcement, research, and educational programs.[6] In the Order, the President directed the Council to "develop a comprehensive strategic food safety plan for Federal food safety activities" and "advise Federal agencies in setting priority areas for investment in food safety."[7] He also ordered the Council to make recommendations to him on how to implement a comprehensive science-based strategy to improve the safety of the food supply and enhance coordination among Federal agencies, State, local, and tribal governments, and the private sector. The Council's Food Safety Strategic Plan will focus on "core food safety activities" including activities intended to enhance the safety of the nation's food supply and to protect public health by reducing the annual incidence of acute and chronic foodborne illness. The strategic plan will include Federal programs for research, monitoring, surveillance, regulation, prevention, voluntary and mandatory certification and inspection, enforcement, labeling, and education.[8] The plan will be used to set priorities, improve coordination and efficiency, identify and close gaps in the current food safety system, enhance and strengthen prevention and intervention strategies, and develop performance measures to monitor progress.[9]

*Council's Egg Safety Action Plan.* The President's Council on Food Safety has identified egg safety as one component of the overall public health issue of food safety that warrants immediate federal, interagency action. Under the auspices of the President's Council, the Strategic Planning Task Force commissioned an Egg Safety Task Force composed of designees of the federal food safety agencies responsible for egg safety to develop an action plan to eliminate egg-associated SE illnesses. Those agencies are DHHS' Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) and USDA's Food Safety and Inspection Service (FSIS),

---

[5] Ibid.
[6] President's Council on Food Safety. *Charter.* Dec. 16, 1998.
[7] President Clinton. *Executive Order 13100: President's Council of Food Safety.* Aug. 25, 1998.
[8] President's Council on Food Safety. *Scope of the Council's Comprehensive Strategic Food Safety Plan.* Dec. 16, 1998.

Animal and Plant Health Inspection Service (APHIS), Agriculture Marketing Service (AMS), and Agriculture Research Service (ARS). The Egg Safety Action Plan developed by the Task Force and presented in this report identifies the systems and practices that must be implemented to reduce and, ultimately, eliminate eggs as a source of SE illnesses.

*Salmonella Enteritidis Contamination of Eggs.* *Salmonella* of various serotypes are commonly found in the digestive tracts of animals and frequently contaminate our environment. Originally, *Salmonella* contamination of shell eggs was believed to occur primarily when organisms present on the egg passed through the shell into the egg's contents. However, more recently transovarian SE contamination of egg contents has been determined to occur from SE-infected laying hens. The rate of transovarian egg contamination has been estimated at about 1 SE-positive egg in every 20,000 eggs produced in the U.S.[10]

*Human SE illnesses.* From 1985 to 1998, there have been a total of 794 SE outbreaks reported to CDC involving 28,644 illnesses, 2,839 hospitalizations, and 79 deaths.[11] In 1997 alone, an estimated 300,000 infections may have occurred.[12] A typical case of salmonellosis is characterized by diarrhea, abdominal cramps, nausea, vomiting, fever, and headache. Symptoms usually begin within 6 to 72 hours after consuming food, last 4 to 7 days, and resolve without antibiotic treatment for most people who do not have underlying health problems. However, the infection can enter the bloodstream leading to severe and fatal illness. The invasive, life-threatening form of the disease is more likely in highly susceptible populations, including children, the elderly, and persons with weakened immune systems. CDC reported that 54 of the 79 deaths associated with outbreaks of SE between 1985 and 1998 were of individuals in

---

[9] President's Council on Food Safety. *Discussion Paper: Process for developing a Food Safety Strategic Plan for all Federal food safety agencies.* Dec. 16, 1998.

[10] Food Safety and Inspection Service, USDA. *Salmonella Enteritidis Risk Assessment for Shell Eggs and Egg Products.* Final Report. June 12, 1998.

[11] Potter, M.E. Testimony before the Subcommittee on Oversight of Government Management, Restructuring, and the District of Columbia, Committee on Governmental Affairs, United States Senate. July 1, 1999.

[12] Ibid. Based on 7,924 cases, reported to CDC, multiplied by a factor of 38. The estimated degree of underreporting of nontyphoidal *Salmonella* is 38-fold. Ref: Mead, P.S. et al, 1999. *Food-related Illness and Death in the United States.* Emerging Infectious Diseases 5(5): 619.

nursing homes.[13] In addition, about 2 percent of those who recover from salmonellosis may later develop recurring joint pains and arthritis.

CDC surveillance data show that the rate of isolation of SE from infected humans increased throughout the U.S. during 1976-1994 from 0.5 to 3.9 per 100,000 population. Evaluation of regional trends for the years 1990-1994 actually indicates a decrease in the SE isolation rate from 8.9 to 7.0 per 100,000 population in the Northeast, where egg quality assurance efforts had been the most intensive. In contrast, the rate increased approximately threefold in the Pacific region, with California reporting an increase in SE isolates from 11% in 1990 to 38% in 1994.[14]

The benefits associated with preventing human salmonellosis, there are also: (1) the economic benefits of reducing loss of productivity associated with human illness, (2) reduced pain and suffering, and (3) reduced expenditures on medical treatment. The costs associated with human salmonellosis due to SE are estimated to range from $150 million to $870 million annually.[15]

*Egg-Handling Practices.* Traditionally, practices such as the use of raw eggs in foods and the undercooking and non-refrigeration of eggs were not considered unsafe. More recently, however, the potential for internal SE contamination of eggs has been established and egg-handling practices have been reevaluated. Common egg-handling practices now considered to be unsafe include: temperature abuse (i.e. holding eggs and egg-containing foods at room temperature instead of under refrigeration); inadequate cooking; and pooling eggs to prepare a large volume of an egg-containing food that is subsequently temperature abused or inadequately cooked. The presence of SE bacteria in a raw egg, alone, does not guarantee illness upon consumption. However, the likelihood of developing an SE infection increases when the egg is not handled safely by permitting the bacteria to multiply and a greater number of bacteria to

---

[13] U.S. General Accounting Office. *Food Safety: U.S. Lacks a Consistent Farm-to-Table Approach to Egg Safety.* GAO/RCED-99-184. July 1999.

[14] Centers for Disease Control and Prevention. *Outbreaks of Salmonella Serotype Enteritidis Infection Associated with Consumption of Raw Shell Eggs--United States, 1994-1995.* Morbidity and Mortality Weekly Report 45(34). Aug. 30, 1996.

[15] Food Safety and Inspection Service, USDA. *Salmonella Enteritidis Risk Assessment: Shell Eggs and Egg Products.* Final Report. June 12, 1998.

be ingested with the food. Investigations of SE outbreaks show that the consumption of foods prepared with SE-contaminated eggs that are not cooked or are undercooked or that are held at room temperature is a common scenario. In fact, many of the SE outbreaks that occurred between 1985 and 1998 were attributed to commercial establishments, such as restaurants, hospitals, nursing homes, schools, and prisons, and greater than 75 percent of those SE outbreaks with an identified source were associated with foods containing undercooked eggs. In addition, the 1996-97 Food Consumption and Preparation Diary Survey showed that 27 percent of all egg dishes consumed were undercooked, described as being runny or having a runny yolk or runny white.[16] On average, each person in the survey consumed undercooked eggs 20 times a year. Within those subgroups at risk, women over 65 and children under 6 consumed undercooked eggs 21 times a year and 8 times a year, respectively.

*U.S. Egg Industry.* On a per capita basis, Americans consume about 234 eggs per year. In 1998, the U.S. table egg industry produced 67.3 billion eggs, up 3 percent from 1997.[17] U.S production is relatively stable and has increased only slightly from about 60 billion eggs in 1984. The total value of the table eggs (eggs produced for human consumption, not hatching) produced in the U.S. in 1995 was estimated at $3.96 billion.[18] Generally, about 70 percent of the table eggs produced are sold as shell eggs while the remainder are processed into liquid, frozen or dried pasteurized egg products. The majority of egg products are destined for institutional use or further processing into foods such as cake mixes, pasta, ice cream, mayonnaise, and bakery goods.

Flocks associated with egg production fall into three categories: breeders (grandparents), multipliers (parents), and laying flocks (including both immature hens, or pullets, and laying hens, or layers). There were roughly 300,000 breeding hens, 3 million multipliers, and 300 million layers. The value of laying flocks alone is estimated

---

[16] Lin, C-T., R.A. Morales, and K. Ralston. *Raw and Undercooked Eggs: A Danger of Salmonellosis.* Food Review 20:27-32, 1997.

[17] National Agricultural Statistics Service, USDA. *Layers and Egg Production 1998 Summary.* January 1999.

[18] Food Safety and Inspection Service, USDA and Food and Drug Administration, HHS. *Salmonella Enteritidis in Eggs.* Federal Register, Vol. 63, No. 96. Proposed Rules. May 19, 1998.

to be nearly $1 billion.[19] Geographically, commercial egg production in the western U.S. is concentrated in California and in the eastern U.S. is centered in Ohio, Indiana, and Pennsylvania. Other states in which major producers are located include Iowa, Texas, Minnesota, and Georgia. About 5,000 producers have 3,000 or more layers, representing 99 percent of all domestic egg-laying hens and accounting for 99 percent of total egg production.[20] An additional 65,000 farms have less than 3,000 egg-laying hens accounting for the balance of eggs produced.[21]

*Current Regulation of Shell Eggs.* Federal authority to regulate egg safety is shared by the Department of Health and Human Services' (HHS') Food and Drug Administration (FDA) and the United States Department of Agriculture's (USDA's) Food Safety Inspection Service (FSIS). In addition, USDA's Animal and Plant Health Inspection Service (APHIS) conducts a control program that certifies poultry breeding stock and hatcheries are SE-free and USDA's Agricultural Marketing Service (AMS) conducts a surveillance program to ensure proper disposition of restricted shell eggs. (See Figure 1.)

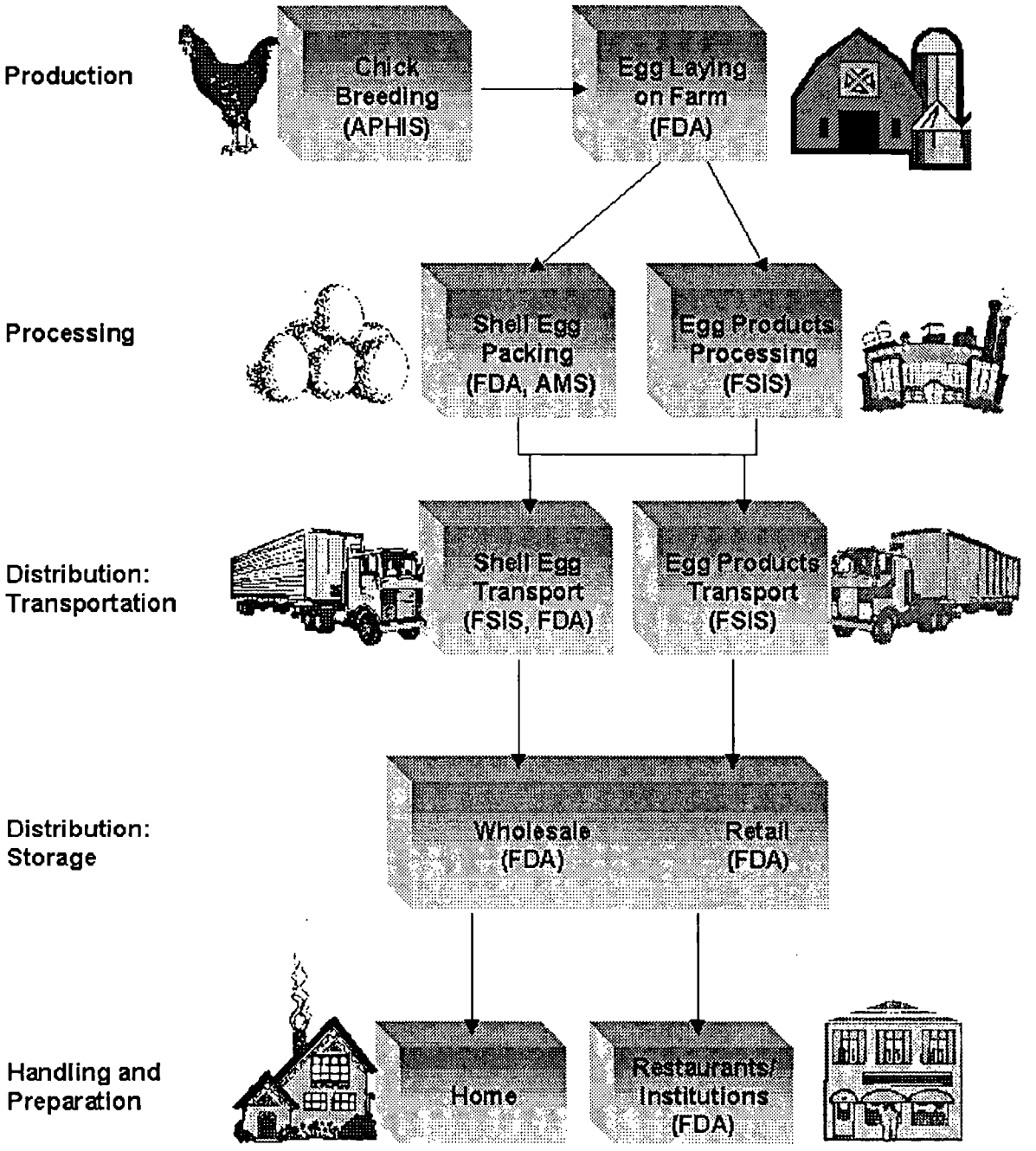
FDA has jurisdiction over the safety of foods generally, including shell eggs, under the Federal Food, Drug, and Cosmetic Act (FFDCA; 21 U.S.C. 301 *et seq.*). Under the Public Health Service Act (PHSA; 42 U.S.C. 201 *et seq.*), FDA also has the authority to prevent the spread of communicable diseases, including the authority to regulate foods when the foods may act as a vector of disease, as in the case of SE and eggs. FDA is responsible for: (1) investigating SE outbreaks, reported by CDC and State/local health departments, due to foods in interstate commerce, (2) performing trace backs to identify the source of the implicated eggs, (3) testing flocks, (4) diverting eggs from SE-positive flocks, (5) collecting flock data to help track the spread of SE among layer flocks, and (6) promoting better quality control.

USDA has primary responsibility for implementing the Egg Products Inspection Act (EPIA; 21 U.S.C. 1031 et seq.). Under EPIA, FSIS has primary responsibility for the

---

[19] Ibid.
[20] AMS correspondence with FDA. 10/1/99.
[21] National Agricultural Statistics Service, USDA. *1997 Census of Agriculture.* Poultry Inventory and Sales.

Figure 1. Egg Safety from Production to Consumption



inspection of processed egg products to prevent the distribution of adulterated or misbranded egg products. Also under EPIA, AMS conducts a surveillance program to ensure proper disposition of restricted shell eggs and visits producer/packers periodically to ensure: (1) that eggs packed for commercial sale contain no more restricted eggs than permitted for US Consumer Grade B, (2) that restricted and inedible product is properly labeled, and (3) that the disposition of these products are handled accordingly. Under current federal regulations, all major commercial egg producers are required to register with AMS and are subject to periodic onsite inspections by AMS. In FY1998, 698 producer/packers were registered with AMS, with a balance of about 4,300 producers that do not process (pack).[22]

*Quantitative Risk Assessment of SE in Eggs.* In December 1996, FSIS and FDA jointly began a comprehensive risk assessment in response to an increasing number of human illnesses associated with the consumption of eggs.[23] A team of scientists developed a quantitative model to characterize the risks associated with the consumption of eggs contaminated internally with SE, using information obtained from academic, government, and industry sources and scientific literature. The risk assessment model consists of discrete modules that may be used independently to evaluate the effect of variable changes during a particular stage of the farm-to-table continuum. However, the overall model encompasses the entire continuum, from the chicken through egg production, to egg consumption and human illness. The model continues to serve as a quantitative tool for FSIS and FDA decision-makers to use in the design of a comprehensive, integrated risk reduction strategy.

The risk assessment of SE in eggs: (1) established the unmitigated risk of foodborne illness from SE; (2) evaluated potential risk reduction strategies; and (3) identified knowledge gaps where future research is needed. First, the model predicted the risk of a hen laying an SE-contaminated egg to be 1 in 20,000. Second, two interventions showed great promise in reducing the number of SE illnesses associated with contaminated egg consumption: (1) lowering the temperature at which shell eggs

[22] AMS correspondence with FDA. 9/20/99.

are maintained and (2) diverting eggs produced by SE-positive flocks from the shell egg market to the pasteurized, egg products market. In addition, the model predicts that the probability of any cases of SE illness resulting from the consumption of pasteurized egg products is low. However, the risk of illness may be further reduced by basing the egg product pasteurization time-temperature standards on: (1) the amount of bacteria in the raw product, (2) the specific process used to treat the raw product, and (3) the intended use of the finished egg product. Third, several research needs were identified and have been incorporated into the research objective of this Action Plan. Overall, the model predicted that while using any one intervention could achieve a modest reduction in human SE illnesses, using multiple interventions could achieve a more substantial reduction for those interventions tested. This finding suggests that a broadly based policy is likely to be more effective in eliminating egg-associated SE illnesses than a policy directed solely at one stage of the egg production to consumption continuum.

*FDA and FSIS Egg Safety Regulations.* As a result of the risk assessment findings, FDA has proposed a rule to require: (1) safe handling statements on labels of shell eggs that have not been treated to destroy *Salmonella* bacteria and (2) that shell eggs be stored and displayed under refrigeration at a temperature of 7.2°C (45°F) or less when held at retail establishments.[24] These proposed actions complement FSIS' final rule that requires: (1) shell eggs be stored and transported at a temperature of 7.2°C (45°F) or less and (2) consumer containers of shell eggs be labeled to indicate that refrigeration is required.[25] The label statements are intended to ensure that consumers have the information necessary to protect themselves from eggs contaminated with SE. The refrigeration requirements are intended to ensure that eggs be held at temperatures that restrict pathogen growth. Careful coordination of these efforts in the overall strategy presented in the SE Action Plan will amplify their individual impact and will provide early progress toward meeting the public health goals of the Action Plan.

---

[23] Food Safety and Inspection Service, USDA. *Salmonella Enteritidis Risk Assessment for Shell Eggs and Egg Products.* Final Report. June 12, 1998.

[24] Food and Drug Administration, HHS. *Safe Handling Label Statement and Refrigeration at Retail Requirements for Shell Eggs.* Federal Register, Vol. 64, No. 128. Proposed Rules. July 6, 1999.

[25] Food Safety and Inspection Service, USDA. *Refrigeration and Labeling Requirements for Shell Eggs.* Federal Register, Vol. 63, No. 166. Final Rule. Aug. 27, 1998.

## AN ACTION PLAN FOR EGG SAFETY

On August 26, 1999, the President's Council held a public meeting to obtain input during the development of the action plan to address egg safety. A single theme resounded from representatives of the consumer groups and the egg industry. The federal government needs a set of national, mandatory standards. These standards should: (1) provide consumers an assurance that all eggs are subject to the same safety standards across the U.S. and (2) provide egg producers and processors a "level playing field" industry-wide.

With this in mind, the Task Force has developed a comprehensive Action Plan that identifies the sum of activities necessary to reach the overarching public health goal of the elimination of SE illnesses associated with the consumption of eggs. While the Plan focuses on SE and eggs, major components of the Plan offer food safety benefits well beyond the specific goal of eliminating egg-associated human SE illnesses. For example, upgrading the information systems at public health departments will contribute to reductions in all foodborne illnesses.

The Action Plan consists of 8 objectives, each with at least one performance measure, covering all stages of the farm-to-table continuum as well as support functions. The farm-to-table continuum encompasses: egg production, shell egg processing (or packing), egg products processing, egg distribution, and egg handling and preparation. The support functions are surveillance of human and poultry SE infections (including outbreak and traceback investigations) and eggs, research, and education.

*Regulatory approach.* The Action Plan presented in this report clearly lays out the components for an effective program to prevent human SE infections resulting from consumption of contaminated eggs. At each stage of the egg production-to-consumption continuum, the Plan identifies the systems and activities necessary to achieve our food safety public health goals. The Plan offers industry the flexibility to

choose from two equivalent SE reduction strategies, each delivering eggs into distribution at an equivalent level of safety. The strategy selection by egg producers and packer/processors determines the point at which the pathogen reduction steps are taken:

- Strategy I: SE testing-egg diversion on farm
- Strategy II: Lethal treatment, or "kill step" at packer/processor

For the distribution and retail stages, the Plan specifies the safe handling practices necessary to ensure consumers receive a safe food product. Furthermore, the Plan clearly describes the surveillance, research, and education activities that must also be conducted to achieve the elimination of egg-associated SE illnesses.

Both Strategies I and II require an on-farm regulatory presence and a packer/ processor regulatory presence; therefore, an industry shift over time from one strategy to the other should not change the overall human resource needs. Because reaching our public health goals requires that each stage of the farm-to-table continuum achieve its objectives, oversight and enforcement at every stage will be key to the Plan's success.

*Organizational structure.* This Action Plan can be accomplished irrespective of the organizational structure under which its objectives must be carried out. The Plan identifies a number of administrative frameworks that could assure egg safety. The Task Force, in its recommendations, seeks to consolidate egg safety oversight responsibilities to one set of players for each segment of the farm-to-table continuum to provide clarity, efficiency, and effectiveness in striving toward our food safety public health goals. The Task Force makes three recommendations for assigning egg safety responsibilities.

- First, FDA develops standards for the producer and the States provide oversight and enforcement on the farm.
- Second, FSIS develops standards for both shell egg packers and egg products processors and provides inspection and enforcement for both.

- Third, FDA and CDC conduct surveillance and monitoring activities. CDC focuses on human health and FDA on the food supply.

The performance measures that will be used to assess the progress of the Plan toward its goal are the numbers of SE cases, isolates, and outbreaks annually. The data will be collected using the following existing systems: (1) Foodborne Diseases Active Surveillance Network (FoodNet), (2) National Salmonella Surveillance System (via PHLIS), and (3) National SE Outbreak Surveillance System and Foodborne Diseases Outbreak Surveillance System. The new data will be compared to the 1998 baseline values of: (1) 1.9 cases per 100,000 persons; (2) 5,900 SE isolates; and (3) 45 SE outbreaks, respectively.

Under current estimates, the cost of implementing all of the activities described in this report would be between $45 and $78 million. These estimates have not been cleared by the Office of Management and Budget.

# EGG SAFETY ACTION PLAN

## OVERARCHING GOAL:

**To eliminate SE illnesses associated with the consumption of eggs. The Egg Safety Action Plan has set an interim goal of a 50% reduction in egg-associated SE illnesses by 2005.**

Performance measures: Numbers of SE cases and outbreaks decrease annually. Data from: (1) Foodborne Diseases Active Surveillance Network (FoodNet), (2) National Salmonella Surveillance System (via PHLIS), and (3) National SE Outbreak Surveillance System and Foodborne Diseases Outbreak Surveillance System.

1998 Baseline data: (1) 1.9 cases per 100,000 persons; (2) 5,900 SE isolates; and (3) 45 SE outbreaks, respectively.[26]

**Objective 1:**
**Reduce the number of SE-containing eggs marketed to the consumer.**

Performance measure: Number of production sites testing positive for SE reduces annually, according to agency and producer data. (Proxy measure for eggs marketed baseline to be determined.).

1.1 Establish a consistent, nationwide SE reduction program for egg production that includes components such as:

- 1.1.1 SE environmental testing
  (For example, chick papers; pullets at 12-14 weeks and layers at 25-30 weeks of age; post-molt, if molted; 2-4 weeks prior to de-population.)
- 1.1.2 Restricting access and movement of personnel and equipment
- 1.1.3 Using SE-negative feed
- 1.1.4 Using chicks from SE-negative breeders
- 1.1.5 Cleaning and disinfection of poultry houses and equipment
- 1.1.6 Improving rodent and pest control in houses
- 1.1.7 Diverting of eggs to pasteurization if SE testing yields a positive.
  (With option to test eggs and sell SE-negative eggs as shell eggs.)
- 1.1.8 Training agency inspection force

[26] CDC correspondence with FDA. 10/27/99.

Timeline: Proposed rule - FY2000; final rule - FY2001; implementation following.

1.2 Establish a HACCP-based system for shell egg processing and prerequisite programs that includes components such as:

1.2.1 Basic sanitation of premises and facilities
1.2.2 Rodent and pest control
1.2.3 Employee hygiene and health
1.2.4 Safety of water and food packing materials
1.2.5 Washing, sanitizing, grading, packaging, cooling, and repackaging

Timeline: Proposed rule - FY2002; final rule - FY2003; implementation following.

1.3 Establish a HACCP-based system for egg products processing and prerequisite programs that includes components such as:

1.3.1 Basic sanitation of premises and facilities
1.3.2 Rodent and pest control
1.3.3 Employee hygiene and health
1.3.4 Safety of water and food packing materials
1.3.5 Washing, sanitizing, packaging

Timeline: Proposed rule - FY2000; final rule - FY2001; implementation following.

1.4 Finalize and implement refrigeration and labeling regulations for eggs from processor to consumer.

Timeline: Final rule - FY2000; implementation following.

**Objective 2:**
**Reduce exposure of consumers to SE-containing foods.**

Performance measure: Number of egg-associated SE illnesses due to unsafe handling practices at the retail stage decreases annually.

2.1 Establish safe egg handling and preparation practices using egg-relevant sections of FDA's 1999 Food Code, specifically practices such as:

2.1.1 Acquisition

2.1.2 Storage
2.1.3 Preparation
2.1.4 Service

Timeline: Proposed rule - FY2000; final rule - FY2001; implementation following.

2.2 Identify and address barriers to implementing Food Code provisions in facilities serving high-risk populations, through the collaborative efforts of interagency Federal Food Safety Coalition. These facilities include:

2.2.1 Child and adult day care centers
2.2.2 Senior centers and home-delivered meals
2.2.3 Preschools and elementary schools
2.2.4 Nursing homes
2.2.5 Hospitals
2.2.6 Detention and penal facilities

Timeline: Ongoing

**Objective 3:**
**Expand and upgrade surveillance systems for human SE infection**

Performance measures: Number of public health laboratories that rapidly report SE isolates and SE outbreak surveillance data electronically increases; number of SE isolates phage-typed increases

3.1 Conduct active surveillance in a location where SE is prevalent. (Requires an additional FoodNet site.)

Timeline: By FY2005

3.2 Upgrade information systems, at State and local public health departments, for electronic reporting of laboratory-confirmed SE isolations (via Public Health Laboratory Information System) and SE outbreak surveillance data.

Timeline: By FY2005

3.3 Maintain CDC's role as the national SE phage typing reference and support center for human isolates. Continue phage-typing SE isolates submitted through

the National Antimicrobial Resistance Monitoring system-Enteric Bacteria (NARMS-EB).

Timeline: Ongoing

3.4 Begin phage typing human SE isolates from FoodNet sites.

Timeline: By 2001

3.5 Conduct SE case-control studies at FoodNet sites to monitor changes in risk factors for human SE infection and association with egg consumption.

Timeline: By FY2005

**Objective 4:**
**Expand surveillance and upgrade surveillance systems for poultry SE infection**

Performance measures: Availability of data on prevalence of SE infections in poultry increases; number of SE-isolates phage-typed increases.

4.1 Monitor SE prevalence in layer breeding flocks.

Timeline: Ongoing

4.2 Complete USDA NAHMS Layers '99 Study.

Timeline: By FY2000. (Repeat survey in FY2005.)

4.3 Phage-type SE isolates submitted through Layers '99 Study.

Timeline: By 2001

4.4 Define, assess and enhance surveillance capacities and data at industry and animal health agencies.

Timeline: By 2005

4.5 Maintain USDA's National Veterinary Services Laboratories (NVSL) role as the national SE phage typing reference and support center for feed and animal isolates.

Timeline: Ongoing

**Objective 5:**

**Accelerate SE outbreak detection and initiation of outbreak investigations and improve completeness of outbreak investigations.**

Performance measures: Number of SE outbreaks investigated completely increases; number of egg-associated outbreaks in which source of eggs is identified increases.

5.1 Develop and implement new outbreak detection algorithms. Use Salmonella Outbreak Detection Algorithm (SODA) to analyze SE surveillance data.

Timeline: Ongoing

5.2 Identify and address reasons for delayed investigation and reporting of SE outbreaks from state agencies.

Timeline: By FY2005

5.3 Assess practices and environmental circumstances during outbreak investigations to identify common contributing factors.

Timeline: By FY2005

5.4 Establish product identification and tracking system requirements to facilitate identification of egg sources during outbreaks.
(Note: May require new statutory authority to access product records.)

Timeline: By FY2005

5.5 Establish national egg traceback procedures.

Timeline: By FY2005

**Objective 6:**
**Improve communication among Federal, State, and local agencies involved in SE outbreak and traceback investigations and by agencies with industry and the public about outbreaks.**

Performance measure: Number of days to notify other relevant government agencies of outbreaks decreases.

6.1 Establish a listserve to communicate SE outbreak information among public health authorities and other partners.

Timeline: By FY2001

6.2 Conduct an SE outbreak information needs assessment with industry and the public.

Timeline: By FY2001

6.3 Develop and maintain an internet site for posting SE surveillance and outbreak data for industry and public access.

Timeline: By FY2001

**Objective 7:**
**Ensure adequate, current information is available to make decisions about SE preventive controls, surveillance, and education based on sound science.**

Performance measure: Number of research questions answered increases.

7.1 Conduct research to develop and evaluate on-farm intervention strategies or technologies including:

7.1.1 Forced molting and other stress factors
7.1.2 Vaccines and immunomodulators
7.1.3 Competitive exclusion
7.1.4 Ion air scrubbers in hatcheries

Timeline: By FY2005

7.2 Conduct research to provide additional information about commercial processing technologies and practices including:

7.2.1 In-shell pasteurization of eggs
7.2.2 Rapid cooling before and after processing
7.2.3 Continuous rewashing
7.2.4 Repackaging
7.2.5 Pasteurization of egg products with additives

Timeline: By FY2003

7.3 Conduct research to improve testing methodologies for SE on the farm and in eggs, including the identification of virulence factors and development of rapid tests, screening tests, sampling protocols, and molecular methods for subtyping SE isolates.

Timeline: By FY2005.

7.4 Conduct research to understand the ecology and epidemiology of SE in the hen and farm environment, including:

7.4.1 Sources of SE in the environment
7.4.2 Mechanism of colonizing the layer house
7.4.3 Factors affecting infection of the hen and contamination of the egg
7.4.4 Characteristics of SE that promote infection in hens and humans
7.4.5 Biochemical characteristics of SE strains causing variations in virulence
7.4.6 Immunological and other factors in humans that affect infectivity
7.4.7 Risk factors associated with the on-farm presence of SE isolates.

Timeline: By FY 2008

**Objective 8:**
**Educate individuals throughout the production to consumption continuum using science-based materials.**

Performance measures: Number of partnerships increases; number of education materials available increases; percentage of consumers using unsafe egg-handling practices decreases.

8.1 Develop and distribute materials for the egg, retail, and foodservice industries, using partnerships:

8.1.1 For egg producers and processors/packers about their role in egg safety, using egg industry organizations.
8.1.2 For retailers and food service workers about regulations and adoption of the Food Code, using retail and institutional organizations.
8.1.3 For food packages including safe food handling tips, using food industry representatives.

Timeline: FY 2000-2005

8.2 Develop and distribute materials for target audiences of:

8.2.1 Healthcare practitioners, including physicians, about diagnosing and treating foodborne illness, through professional organizations, such as the AMA.
8.2.2 Patients and at-risk populations, about safe handling and preparations of foods, including eggs, through professional organizations, such as the AMA.
8.2.3 Food preparers at facilities serving highly susceptible populations, including nursing homes, daycare centers, and hospitals, about proper egg handling and preparation practices.
8.2.4 Under-served populations, including Hispanics and African-Americans, about proper egg handling and preparation practices, through magazines and newspapers.
8.2.5 Senior citizens, about proper egg handling and preparation practices, using the Food Safety Information for Seniors, the Senior food safety website, the Senior food safety video, and the Senior food safety publication.
8.2.6 Women and men, about proper egg handling and preparation practices, through women's, men's, and health magazines.
8.2.7 Students and parents, advice on not eating foods containing uncooked eggs, such as homemade raw cookie dough.

Timeline: FY 1999-2000

8.3 Conduct a nationwide telephone survey to assess consumer knowledge about and proper practices of egg handling and consumption, including:

8.3.1 Consume raw or undercooked (runny) eggs, by age group
8.3.2 View eggs as a high-risk food
8.3.3 Awareness of safe handling and warning label statements

8.3.4 Cooking time-temperatures
8.3.5 Pooling

Timeline: FY 1999-2000

8.4 Conduct a survey at retail establishments (e.g. restaurants, institutions) to assess food preparer knowledge and proper practices of egg handing, as in 8.3.

Timeline: FY 2001-2002

[End of Action Plan]

## REGULATORY AND PROGRAM SUPPORT OPTIONS

The Food Safety Task Force considered the following options for meeting the food safety public health goal, including agency responsibilities. This section of the report provides the Task Force recommendations along the farm-to-table continuum.

- First, FDA develops standards for the producer and the States provide inspection and enforcement on the farm.
- Second, FSIS develops standards for both shell egg packers and egg products processors and provides inspection and enforcement of both.
- Third, CDC and FDA conduct surveillance and monitoring activities. CDC focuses on human health and FDA and USDA on the safety of the food supply.

Under current estimates, the cost of implementing all of the activities described in this report would be between $45 and $78 million. These estimates have not been cleared by the Office of Management and Budget (OMB).

This page is not for public distribution

## Inspection of Egg Producers (Farms)

This report is not for public distribution

Scope of Program: Annual inspections of 5,000 producers with 3,000 or more layers.

Recommended Option

*Option 1:* **FDA** develops standards;
**States** inspect and enforce standards. **$12.6-17.6M**

- Inspection force:
  - FDA contracts with the States (4,000) $5.0M
  - FDA for States electing not to contract (1,000) $5.0M
- Audit force $3.2M
- Program management and evaluation $1.9M
- Training, equipment and operations $2.5M

Alternative Options Considered

*Option 2:* **FDA** develops standards;
**FDA** inspects and enforces standards. **$40.5M**

- Inspection force $36.0M
- Program management and evaluation $1.9M
- Training, equipment and operations $2.5M

*Option 3:* Requires new statutory authority.
**FDA** develops standards;
**FSIS** inspects and enforces standards. **$14.5M**

- Inspection force: Reallocated meat and poultry inspectors $9.1M
- Standards development $1.0M
- Program management and evaluation $1.9M
- Training, equipment, operations $2.5M

***NOT CLEARED BY OMB***

## Inspection of Shell Egg and Egg Products Processors

*Scope of Program:* Annual inspections of 700 shell egg processors (packers) and 80 egg products processors.

Recommended Option

*Option 1:* USDA and HHS are reviewing their statutory authority to determine whether the necessary authority can be conferred upon FSIS using administrative means or whether a transfer of authority from FDA to FSIS must be done legislatively.

Packers and Processors: **FSIS** develops standards;
**FSIS** inspects and enforces standards. **$9.1M**

- Inspection force $4.9M
- Program management and evaluation $1.9M
- Training, equipment, and operations $2.3M

Alternative Options Considered

*Option 2:*

Packers: **FDA** develops standards;
**States** inspect and enforce standards.
Processors: **FSIS** develops standards;
**FSIS** inspects and enforces standards. **$9.2M**

- Inspection force: State contracts $5.3M
- Program management and evaluation $1.9M
- FDA training, equipment, and operations $1.0M
- FSIS training, equipment, and operations $1.0M

*Option 3:*

Packers: **FDA** develops standards;
**FDA** inspects and enforces standards.
Processors: **FSIS** develops standards;
**FDA** inspects and enforces standards. **$9.7M**

***NOT CLEARED BY OMB***

This page is not for public distribution

- Inspection force $5.8M
- Program management and evaluation $1.9M
- FDA training, equipment, and operations $1.0M
- FSIS training, equipment, and operations $1.0M

This page is not for public distribution

## Inspection of Retail Establishments

*Scope of Program:* Annual inspections of 1 million retail establishments covering Food Code provisions and FDA proposed temperature and safe handling statement rules.

**FDA** develops standards;
**States** inspects and enforces standards. **$9.5-11.5M**

- Inspection force: FDA contracts with the States
  - States with >20,000 establishments, $200,000 (20) $4.0M
  - States with <20,000 establishments, $100,000 (30) $3.0M
  - FDA for States electing not to contract $2.0M

- Program management and evaluation and audit force $2.5M

## Surveillance

*Scope of Program:* CDC monitors human SE illnesses and conducts epidemiological investigations including testing methodologies. FDA monitors the food supply for SE-contaminated products and conducts traceback investigations.

Recommended Option

*Option 1:* **CDC** monitors human illness and **FDA** monitors food supply **$4.5M**

- CDC $2.5M
- FDA $2.0M

***NOT CLEARED BY OMB***

Alternative Option Considered

*Option 2:* **CDC** only **$2.5M**

This page is not for public distribution

## Research

*Scope of Program:* Conduct research to support inspection and surveillance.

**FDA, ARS,** and **CDC** conduct research **$7.5M**

- FDA technology, SE virulence, environmental factors $2.5M
- ARS vaccines, technology $5.0M

## Education

*Scope of Program:* Develop and implement a national egg safety education and outreach campaign.

**FDA** and **USDA** develop and implement education programs. **$3.0M**

- FDA $2.5M
- USDA $0.5M

## APPENDIX 1. SUMMARY OF REGULATORY OPTIONS AND RESOURCE REQUIREMENTS

| *Activity* | In Millions |
|---|---|
| **PRODUCER (On-Farm)**[27] | |
| *Option 1*: FDA develops standards, States inspect and enforce | $12.6-17.6 |
| *Option 2*: FDA develops standards, FDA inspects and enforces | $40.5 |
| *Option 3*: FDA develops standards, FSIS inspects and enforces | $14.5 |
| **PROCESSOR/PACKER**[28] | |
| *Option 1*: FSIS develops standards, FSIS inspects and enforces at packer and processor | $9.1 |
| *Option 2*: FDA develops standards, States inspect and enforce at packer; FSIS develops standards, FSIS inspects and enforces at processor | $9.2 |
| *Option 3*: FDA develops standards, FDA inspects and enforces at packer; FSIS develops standards, FSIS inspects and enforces at processor | $9.7 |
| **DISTRIBUTION** | |
| FSIS enforces its rule; FDA completes and enforces its rule | n/a |
| **RETAIL** | |
| FDA develops standards and States inspect and enforce | $9.5-11.5 |
| **SURVEILLANCE** | |
| CDC monitors human illnesses; FDA monitors food supply | $4.5 |
| CDC monitors human illnesses | $2.5 |
| **RESEARCH** | |
| FDA, ARS, and CDC conduct research | $7.5 |
| **EDUCATION** | |
| FDA and USDA develop education and outreach campaigns | $3.5 |
| | |
| **TOTAL** | $44.7-77.2 |

*****NOT CLEARED BY OMB*****

[27] Approximately 5,000 producers with 3,000 or more layers.
[28] Approximately 700 shell egg processors (packers) and 80 egg products processors.

# Appendix 2. Action Plan Timeline

## APPENDIX 3. GLOSSARY

**Biosecurity.** The term refers to procedures designed to prevent SE from being carried into poultry houses from outside sources and may include all or some of the following: use of chicks from SE-negative breeder flocks, use of SE-negative feed ingredients; proper use of medications and pesticides; and restricted access and movement of personnel and equipment in/out of hen houses.

**Eggs.** The term is used in this document to include both shell eggs and egg products.

**Egg products processing.** The processing of shell eggs into egg products involving breaking, filtering, mixing, stabilizing, blending, pasteurizing, cooling, freezing or drying, and packaging.

**Egg production.** The on-farm activities of egg-laying and collection.

**Egg products.** The term refers to eggs that have been removed from their shells and processed. The term applies to whole eggs, whites, yolks, and various blends with or without non-egg ingredients, regulated by FSIS. The term does not apply to freeze-dried products, imitation egg products, and egg substitutes which are the responsibility of FDA.

**Federal Food Safety Coalition.** The interagency working group consists of members from: Department of Veterans Affairs, Veterans Health Administration; USDA, Food and Nutrition Service's School Lunch Program, WIC Program, and Infant Formula Program; Department of Justice, Bureau of Prisons; HHS, Head Start Program, Administration on Aging, Indian Health Service, Health Care Financing Administration, and CFSAN.

**Food Code.** A reference document for regulatory agencies responsible for overseeing food safety in retail outlets, such as restaurants, grocery stores, and institutions (including nursing homes and daycare centers), consisting of recommendations for adoption by local, state, and federal governmental jurisdictions, offered by FDA.

**FoodNet (Foodborne Diseases Active Surveillance Network).** A network consisting of 8 sites that conduct active surveillance, investigations, and epidemiologic studies. The information is used to: (1) determine the frequency and severity of foodborne diseases; (2) determine the proportion of common foodborne diseases that result from eating specific foods; (3) describe the epidemiology of new and emerging foodborne pathogens; and (4) assess the effectiveness of new food safety control measures. It is a collaborative project among CDC, the 8 sites, FSIS and FDA.

**HACCP (Hazard Analysis-Critical Control Points).** The process of identifying the hazards (hazard analysis) present in a process and determining critical points

throughout the process (critical control points) at which loss of control would result in the presence of a hazard posing a serious risk to human health.

**Layers.** Hens (including those being molted) or pullets producing table or commercial type shell eggs, usually at least 20 weeks of age.

**"Layers 99" NAHMS Survey.** A study to: (1) describe baseline health and management practices used by the U.S. layer industry; (2) estimate the national prevalence of SE in layer flocks by testing the environment and at layer operations; (3) identify potential risk factors associated with the presence of SE; and (4) describe biosecurity practices.

**Molt**. A process during which hens stop laying and shed their feathers, occurring naturally every 12 months. May be artificially induced by withholding feed or water for a period of time. Forced molting is done to improve egg production.

**National Animal Health Monitoring System (NAHMS).** An animal health monitoring system, established by APHIS in 1990, (1) to help government officials and industry organizations define public risks and identify research needs and (2) to identify opportunities for producers and veterinarians to improve management and product quality.

**National Antibiotic Resistance Monitoring System (NARMS).** A system for monitoring emerging resistance to antibiotics in foodborne pathogens, established in 1996 as an interagency cooperative activity.

**National Poultry Improvement Plan (NPIP).** A program that certifies that poultry breeding stock and hatcheries are free from egg-transmitted and hatchery-disseminated diseases, including SE.

**National Veterinary Services Laboratories (NVSL).** A national laboratory providing veterinary diagnostic, laboratory support, and reference services related to domestic and foreign livestock and poultry diseases for programs, including NAHMS and NPIP, and administered by APHIS.

**Outbreak.** Two or more people having a similar illness that has been traced to eating a common food.

**Public Health Laboratory Information System (PHLIS).** An electronic reporting system used by State public health laboratories to report isolates of *Salmonella* from human sources to CDC's National Salmonella Surveillance System.

**Pullet.** A female chicken that has not yet started to lay eggs.

**Restricted eggs.** Eggs with cracks or checks in the shell, dirty eggs, incubator rejects, and inedible, leaker, or loss eggs which must be either destroyed or diverted from use as human food.

**Salmonella Enteritidis (SE).** A bacterium of the genus *Salmonella*, species *enterica*, and serotype Enteritidis.

**"Sell by" period.** The time within which retailers must sell shell eggs.

**Shell eggs.** The term refers to eggs still in their shells.

**Shell egg handlers.** Firms that grade and pack shell eggs for commercial distribution (packing plants) and hatcheries.

**Shell egg processing.** The phase of processing involving the washing, segregation and packaging of shell eggs for distribution to retail, institutional, and other commercial users.

**Shell Egg Surveillance program.** A quarterly inspection program, mandatory for shell egg handlers, to verify that: (1) restricted eggs are properly disposed of and (2) no more restricted shell eggs than permitted in U.S. Consumer Grade B are sold to the consumer

**Salmonella Outbreak Detection Algorithm (SODA).** A statistical algorithm designed to detect unusual clusters of isolates of Salmonella infection and to compare current Salmonella isolates reported through PHLIS by serotype to an historical baseline for that serotype, implemented in 1996.

**Spent Hen.** A breeder or commercial type egg hen that no longer performs at desired production levels.

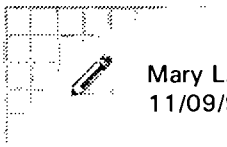
**Undergrade.** Any edible shell eggs that does not meet the requirements (standards) for the indicated grade, Grade AA, Grade A, or Grade B.

**Whole Eggs.** Consist of yolk (yellow portion) and albumen (white or clear portion). For the various types of egg products - liquid, frozen, and dried - the yolks and albumen are separated during the breaking. Customers may request whole eggs (entire contents of egg) or a combination of yolks and albumen to produce egg product for specific uses.

# # #

**APPENDIX 4.** Egg Safety Task Force Members

| | |
|---|---|
| Arthur Baker | USDA-FSIS |
| Krista Baldwin | USDA-FSIS |
| Marilyn Balmer | FDA-CFSAN |
| Bessie Berry | USDA-FSIS |
| Nancy Bufano | FDA-CFSAN |
| Lou Carson | FDA-CFSAN |
| Marjorie Davidson | FDA-CFSAN |
| Don Edwards | USDA-FSIS |
| Laura Fox | FDA-CFSAN |
| Richard Gast | USDA-ARS |
| Roger Glasshoff | USDA-FSIS |
| Kathy Gombas | FDA-CFSAN |
| Thomas M. Gomez | USDA-APHIS |
| Thomas Hammack | FDA-CFSAN |
| Jim Holt | USDA-OGC |
| Charles Johnson | USDA-AMS |
| Geraldine June | FDA-CFSAN |
| Leslie Kux | FDA-OGC |
| Victoria Levine | USDA-FSIS |
| Arthur P. Liang | CDC-FSI |
| Daniel McChesney | FDA-CVM |
| Thomas J. Myers | USDA-APHIS |
| Tammy O'Conner | USDA-FSIS |
| Eileen Parish | FDA-CFSAN |
| Clifford Purdy | FDA-CFSAN |
| Richard Raybourne | FDA-CFSAN |
| Andrew Rhorer | USDA-APHIS |
| Judy Riggins | USDA-FSIS |
| Stephanie A. Smith | FDA-CFSAN |
| David Swerdlow | CDC |
| Michael Thaggard | USDA-FSIS |
| Alice Thaler | USDA-FSIS |
| Irving Weitzman | FDA-ORA |
| Patsy White | USDA-FSIS |
| Richard Whiting | FDA-CFSAN |
| Nora E. Wineland | USDA-APHIS |



Mary L. Smith
11/09/99 10:17:40 AM

Record Type: Record

To: See the distribution list at the bottom of this message

cc:
Subject: essence will be out today

Message Sent To:

Leanne A. Shimabukuro/OPD/EOP@EOP
Deanne E. Benos/OPD/EOP@EOP
Thomas L. Freedman/OPD/EOP@EOP
Paul J. Weinstein Jr./OPD/EOP@EOP
Cathy R. Mays/OPD/EOP@EOP

# ORGANIZATIONAL OPTIONS

## INTRODUCTION

There have been a number of proposals for major structural changes in the Federal food safety system in the last 30 years. The intent of these proposals has been to reduce foodborne hazards by strengthening and creating a more seamless food safety system. As a result of these proposals and recommendations from the National Academy of Sciences (NAS), the President's Council for Food Safety agreed to "conduct an assessment of structural models ... that could strengthen the Federal food safety system..." This draft paper outlines several options which will be the subject of that analysis.

## BACKGROUND

Four agencies currently have the major regulatory responsibilities for food safety at the Federal level: the Food Safety and Inspection Service (FSIS) within the U.S. Department of Agriculture (USDA); the Food and Drug Administration (FDA) within the Department of Health and Human Services (DHHS); the Environmental Protection Agency (EPA); and the National Marine Fisheries Service (NMFS) within the Department of Commerce (DOC). FSIS ensures the safety of meat, poultry, and some egg products in interstate and international commerce. FDA regulates all domestic and imported foods that are marketed in interstate commerce except for meat, poultry, and some egg products. EPA licenses pesticide products and establishes maximum limits for pesticide residues (tolerances) in food and animal feed while FDA and FSIS enforce those pesticide tolerances in the commodities under their jurisdiction. EPA also establishes standards for surface, ground and drinking water. The NMFS conducts a voluntary seafood inspection and grading program to ensure the quality and safety of commercial seafood; mandatory regulation of seafood processing is under FDA's jurisdiction.

These regulatory agencies are supported by a number of other organizations. The Centers for Disease Control and Prevention (CDC) within DHHS conducts surveillance activities and investigates outbreaks associated with food and water consumption. The Agricultural Research Service (ARS), the Cooperative State Research, Education and Extension Service (CSREES), and the Economic Research Service (ERS) of USDA as well as the National Institutes of Health (NIH), which is part of DHHS, play important roles in conducting food safety research.

## OPTIONS

There are a number of dimensions or variables to be considered in examining the Federal food safety system:

* the numerous agency functions needed to make food safe (e.g., research, surveillance, enforcement);
* the breadth of the farm-to-table production system that brings food to the American consumer;
* the different types of food (e.g., meat, fruits and vegetables, beverages);
* the multiple hazards that can be present in food (e.g., pathogens, chemicals, pesticides);
* the various agencies which make up the current U.S. food safety system; and

* the different mechanisms available for creating a seamless food safety system (e.g., stronger executive leadership, reorganization).

The organizational options selected for analysis in this paper take into consideration these variables. They are also based on the NAS report *Ensuring Safe Food from Production to Consumption,* legislative proposals in the last few years, food safety consolidation efforts in other countries, General Accounting Office (GAO) and Congressional Research Service (CRS) reports, public comments and testimony, and other sources.

We have attempted to select a range of reasonable options for analysis. The options consider regulatory responsibilities for food safety, and in some cases research and surveillance funded by the Federal government. They were chosen to ensure breadth in the analysis and examine the key variables. The major options represent a continuum from the status quo to designating a lead agency to creating a single agency for most or all food safety functions. The single agency could be created either within an existing organization or as a new, independent agency. Within the options, there are alternatives or sub-options; the options and sub-options in essence represent a menu from which alternatives could be combined to create a strengthened food safety system. The options focus on organizational structures for the Federal food safety system, and not on vertical integration of food safety, although which structures provide better integration with state and local food safety regulatory agencies will be considered in evaluating the options. They are described below.

## I. Coordinated Federal Food Safety System

This option strengthens the Federal food safety system by providing stronger executive leadership and improved coordination mechanisms for a variety of functions. There are alternative ways to accomplish this. The alternatives differ in terms of the nature of that executive leadership as well as whether there is coordination and oversight of not only planning, budgeting and research, but also policy and/or operations. This option assumes the development of a comprehensive Federal food safety strategic plan (including a joint vision, goals, and actions) and unified annual budgets to guide Federal food safety activities. The Joint Institute for Food Safety Research (JIFSR) would also coordinate microbial research, and might coordinate other food safety research in the future. This option could be implemented alone or in combination with streamlining (Option II), some Lead Agency alternatives (Option III), or the less expansive forms of a "single" agency (Options IV and V).

**A. President's Council for Food Safety (status quo):** This option reflects the current structure and system for coordination and leadership. The President's Council for Food Safety coordinates strategic planning and budgeting as well as overseeing JIFSR. The Council is chaired by the Secretaries of Agriculture and Health and Human Services, and the Director of the Office of Science and Technology Policy (OSTP), and has members from EPA, DOC, the Office of Management and Budget (OMB), the Domestic Policy Council (DPC), and the National Partnership for Reinventing Government (NPR). Variations on this option could include designating a single, neutral chair appointed by the President, establishing a small staff with an Executive Director, and/or broadening the Council's members to include representatives from the Federal Trade Commission (FTC), the Department of Treasury (DOT), and the Department of Defense (DOD).

B. **Joint Chiefs of Staff:** Establish a Board of Directors or Joint Chiefs of Staff, similar to the military, with a neutral Chairman appointed by the President and representatives from all the food safety regulatory agencies (USDA/FSIS, FDA, EPA, NMFS). Each agency would retain its core mission, but would be obliged to plan and coordinate in areas where their missions coincide. The Chairman of the "Joint Chiefs for Food Safety" would also have authority over policies where the missions are similar or overlap. One variation on this option would provide the Joint Chiefs with line operational authority over the deployment and exercise of agency resources (e.g., over the deployment of inspection resources) and another would include the research and surveillance agencies as part of the "Joint Chiefs".

## II. Streamline Certain Federal Food Safety Responsibilities

This option consists of streamlining or consolidating specific Federal food safety responsibilities, particularly those where there are jurisdictional overlap, perceived duplicative functions or public confusion. In this option, full responsibility for certain food products (e.g., eggs, meats) or for specific points in the farm-to-table chain (e.g., retail, imports) would be housed in one place within an existing organization. The option would also examine streamlining agency programs where there may be functional overlaps that cause confusion for the public or industry (e.g., fish contaminant levels, antimicrobials). Such streamlining has already been initiated for seafood with the Administration proposal to consolidate federal seafood inspection activities by transferring the National Oceanic and Atmospheric Administration (NOAA) Seafood Inspection Program from DOC to FDA.

Examples of areas to be examined for the possibility of future streamlining include:

A. Certain Food Products: eggs and egg products; game meats and "regular" meats; food additives; and bottled water and drinking water.

B. Specific Points in Farm-To-Table Continuum: food production on farms; imports; and Federal guidance for retail establishments.

C. Functional Overlaps: inspections at jointly-regulated facilities; pre-market approval of antimicrobials; animal drugs and biologics; determination of "safe" levels for fish contamination; and food safety labeling.

This option would examine the strengths and weaknesses of streamlining, and would analyze in more detail some of the above candidates for consolidation. The analysis could result in certain specific areas being identified for consolidation of responsibility (e.g., oversight of all meats with USDA; all Federal guidance for retail food operations with DHHS; responsibility for all water with EPA).

It should be noted that this option by itself does not create a single voice for food safety, but does target overlaps and issues which have caused inefficiencies, confusion, and the perception of a fragmented system. The option could be implemented in combination with changes in executive leadership (Option I or III), or at least partially with some of the reorganizations identified in Options IV and V. It would not have merit with the more expansive alternatives under Option V when all or most food safety and related functions are consolidated in a single agency.

## III. Lead Agency Approach

As in Option I, the Lead Agency Approach provides centralized executive leadership and a " single" voice for all or discrete parts of the food safety system. It differs from Option I in that one agency becomes the lead for all or for specific food safety functions rather than vesting the single voice for food safety in a Council or Joint Chiefs. Further, with the Lead Agency Approach there would be no need to consider establishing a small staff or an Executive Director. This option could be implemented in combination with Option II and the Canadian Model might also be combined with Option I.

A. **Single Lead Agency:** Designate one agency as the lead agency (USDA or DHHS) and have the head of that agency be responsible for the strategic direction of Federal food safety planning, budgeting, and policy, including guidance and standard-setting. This agency could also have the lead for coordinating foodborne outbreaks, similar to the role that the Federal Emergency Management Agency (FEMA) plays in natural disasters. The current food safety agencies would implement their operational responsibilities in accordance with the strategic direction provided by the Lead Agency and their own laws.

B. **Canadian Model:** Consolidate all food safety inspection, enforcement, outbreak response and recall at USDA and standard setting, risk assessment, research and surveillance at DHHS. In essence, this option would establish two lead agencies, and each would have responsibility for specific functions such as inspection or standards under all the food safety laws. FSIS would be responsible for monitoring, inspection, recall, enforcement and emergency response for all foods and components of food (e.g., food additives, pesticides). DHHS would set safety standards for all food products (meat, poultry, eggs, and other foods). EPA would continue to register and set tolerances for pesticides. A variation on this option would place EPA's pesticide program within DHHS. This option is similar to the recently reorganized Canadian food safety system.

## IV. "Single", Consolidated Agency within Existing Organization

This option would consolidate most or all food safety regulatory functions -- policy, guidance, standard setting, inspection, enforcement, education, and other responsibilities -- in a single agency reporting to either a current Cabinet Secretary, or the management of an existing independent agency. A variation on this option would include research in the consolidated agency.

A. **Under DHHS:** Establish a Food Safety Administration within DHHS headed by a Presidential-appointed, sub-Cabinet level Administrator. The Food Safety Administration would be responsible for standard setting, food safety labeling, education, information dissemination, inspection, enforcement and coordination of outbreak response for all foods and substances in food. The Food Safety Administration would also oversee research and surveillance conducted by DHHS, USDA, and others. A variation on this would consolidate only USDA and DHHS regulatory functions -- i.e., it would exclude pesticide licensing and tolerance setting from the new agency. [Note: This option is similar to Great Britain's consolidation.]

B. **Under USDA:** Same as above except the Food Safety Administration or Food Safety Service would be established within USDA, under a Presidential-appointed

sub-Cabinet level Administrator.

C. **Under EPA:** Consolidate food safety regulatory responsibilities with the EPA, forming the Food and Environmental Protection Agency. This organization would continue to be an independent agency managed by a Presidential-appointed Cabinet-level official, and its Office of Food Safety would be managed by a sub-cabinet level Presidential Appointee.

D. **Under a Commission (e.g., CPSC):** Consolidate food safety standards, inspection and enforcement with the Consumer Product Safety Commission (CPSC), an independent agency managed by a Commission. Transfer all food safety regulatory functions, including standard setting, monitoring, inspection, labeling and enforcement of the USDA (FSIS and AMS), FDA, EPA, and DOC to CPSC. [Note: This is similar to the Metzenbaum bill (1993) and proposals in the early 70s.]

## V. "Single", Independent Food Safety Agency

This option would create a new independent food safety agency established by law or Executive Order and lead by a Presidential-appointed Cabinet-level Administrator. It would establish a separate, independent agency distinct from all previous food safety organizations, with its own executive leader. A variation on this option would have the independent agency managed by a Presidential-appointed Commission rather than an Administrator. The functional responsibilities of the single agency could vary as described below.

The following alternatives for a "single", independent agency take the approach of consolidating similar functions, and reflect a range from a single function (inspections) to all functions related to food safety. Conceptually, a single agency could be also formed on the basis of: 1) specific types of foods (all meats, all produce); 2) specific points in the farm-to-table spectrum (production, processing, etc.); or 3) different types of risks (microbial, chemical). Given the integrated nature of food as well as of food production and processing, and the fact that all types of hazards may be present in food products, these conceptual alternatives were not considered reasonable and therefore are not examined in this analysis.

A. **Consolidate food safety inspections:** Consolidate the food safety inspection functions of USDA/FSIS, DOC/NMFS, and parts of FDA's Office of Regulatory Affairs (ORA) into a "single" agency with an Administrator appointed by the President.

B. **Consolidate food safety regulatory functions (Sub-Option A above plus standards, labeling, and education):** Combine the "core" standard-setting, food safety labeling, education, inspection and enforcement functions for meat, poultry, eggs, seafood and other FDA-regulated foods and animal feed (i.e., USDA/FSIS, DOC/NMFS, and FDA's food safety offices: CFSAN, CVM, and a part of the field operations of ORA) into a "single", independent food safety agency. The Agency would be managed by an Administrator appointed by the President. [This option is similar to Denmark's consolidation.]

C. **Consolidate food safety regulatory and research functions (Sub-Option B above plus research):** Combine the functions outlined in Sub-option B above with food

safety research that supports FSIS, FDA and NMFS (i.e., food research in ARS, CSREES, ERS, FDA and DOC). Variations on this option would also include research done at NIH and CDC as well as CDC's surveillance functions into this new agency.

**D. Consolidate food safety regulatory functions including pesticides (Sub-Option B above plus pesticides):** Combine policy-setting and operational food safety functions for all food products and substances in food (Sub-option B above plus pesticides) into a "single", independent agency. This option would combine: FSIS, APHIS and some functions of AMS (e.g., Pesticide Data Program) at USDA; CFSAN, CVM and a portion of the ORA inspection staff at FDA; NMFS at DOC; and EPA's Office of Pesticide Programs as well as EPA's enforcement program that supports the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). It would put in one place all standard-setting, labeling, inspection, enforcement, and education, but not research and CDC's surveillance, for foods.

**E. Consolidate food safety regulatory, research and surveillance responsibilities:** Combine food safety regulatory functions for all food products and substances in food (e.g., pesticides, food additives, etc.) as well as research and surveillance supporting those regulatory activities into a single, independent agency. This would combine all the functions in Sub-option D above with research directly supporting food safety. It would put in one place: FSIS, the Animal and Plant Health Inspection Service (APHIS), some responsibilities of AMS (e.g., Pesticide Data Program), research supporting food safety at ERS, ARS, CSREES, and the Office of Risk Assessment and Cost Benefit Analysis (ORACBA) from USDA; CFSAN, CVM, and some inspection staff from ORA at FDA; food safety research, surveillance, outbreak response, training and education from CDC; NMFS and food safety research at DOC; and the pesticide regulatory, research and enforcement programs of EPA.

**F. Merge All Food Safety and Related Functions (the Blue Sky option):** Consolidate all food safety and food safety related functions from USDA (FSIS, ARS, CSREES, ERS, ORACBA, AMS, and APHIS -- as described above -- and the Office of Pest Management Policy or OPMP), DHHS (FDA, CDC, NIH research), EPA (pesticides and water), DOC (NMFS including research), FTC (advertising and labeling), and DOT's Bureau of Alcohol, Tobacco and Firearms (beverages) into a "single", independent food safety agency (the complete, truly "single" agency). This agency would be responsible for food and beverage "core" and "collateral" food safety functions including research, surveillance, outbreak response, regulation, inspection, enforcement, education, labeling, and advertising; it would also be responsible for water used in food production, processing and for drinking.