

Essentials of a Public Health Regulatory Agency

This module covers an overview of the essentials of a public health regulatory agency. FSIS is a public health regulatory agency.

OBJECTIVES

After completing this module, you will be able to:

1. Describe what makes FSIS a public health regulatory agency.
2. Describe your role as a Public Health Veterinarian in FSIS.

RESOURCE MATERIALS

- Veterinary Recruiting video
- FSIS Leadership Public Health Competencies
- Enhancing Public Health: Strategies for the Future 2003 FSIS Food Safety Vision
- A Description of the U.S. Food Safety System
- Food Safety: A Team Approach
- Milestones in U.S. Food and Drug Law History

Basis for FSIS as a Public Health Regulatory Agency: Statutes

The work that you do is based on three statutes that were enacted by Congress.

- Federal Meat Inspection Act (FMIA)
- Poultry Products Inspection Act (PPIA)
- Egg Products Inspection Act (EPIA).

The FMIA was enacted first, in 1906 after the public outrage stirred up by the writings of Upton Sinclair's book, "The Jungle." The book contained graphic and detailed descriptions of the insanitary and abhorrent conditions that existed in meat plants at the turn of the century in the city of Chicago, which was the heart of the meat processing industry at the time. Excerpts from the book were published in newspapers. Due to public concern, Congress enacted a statute to ensure that public health was protected. The statute provided for a federal inspection service in livestock slaughter establishments.

The PPIA was modeled after the FMIA. The PPIA enacted in 1957 based on the growing poultry industry. Initially, there were two separate Agencies – one responsible for enforcing the provisions of the FMIA and one responsible for enforcing the provisions of the PPIA. This explains why, in some cases, establishments that process both meat and poultry products have two establishment numbers. But today, these statutes form the basis of one public health regulatory agency focused on ensuring food safety. We will not be covering the EPIA because of the small number of plants and the large volume of material we must cover.

The Acts provide for the basis for FSIS's ability to perform as a public health agency. In Section 602 of the FMIA, Congressional statement of findings, the first sentence reads:

“Meat and meat food products are an important source of the Nation’s total supply of food. It is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products distributed are wholesome, not adulterated and properly marked, labeled, and packaged. It is hereby in found that all articles and animals which are regulated under this chapter are either in interstate or foreign commerce or substantially affect such commerce, and that regulation by the Secretary and cooperation by the States and other jurisdictions as contemplated by this chapter are appropriate to prevent and eliminate burdens upon such commerce, to effectively regulate such commerce, and to protect the health and welfare of consumers.”

These three things - verifying that meat or poultry products are (1) wholesome, (2) not adulterated, (3) properly marked/labeled, and packaged – are the essentials of the job you have in protecting public health. All of your activities focus around one or more of these things.

The Congressional statement of findings in the Poultry Products Act (Section 451) is almost identical to that of the FMIA. Again, it emphasizes public health, and it emphasizes the four essentials – wholesome, not adulterated, properly marked/labeled, and packaged.

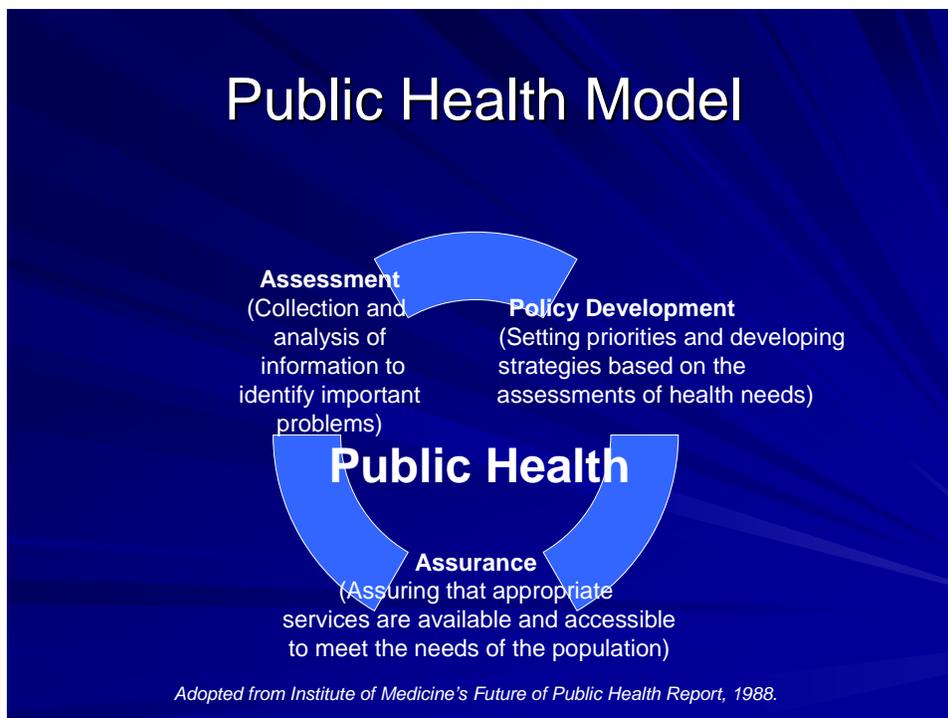
Another foundation principle is outlined in Section 452 of the PPIA which indicates that inspection is authorized to prevent products from entering commerce that are adulterated or misbranded. Remember, ***all the things you do or you supervise as part of your job that can be traced back to the statutes to make sure that any meat, poultry, or egg product that is adulterated or misbranded does not enter commerce to protect the public health.*** You will do that through the enforcement authorities that you will learn about later.

The Public Health Model

There are some key features of a public health agency. These features are outlined in the public health model. This model applies to all types of public health institutions – such as the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), the Centers for Disease Control (CDC) – as well as to FSIS.

The 3 parts of the public health model are:

- Assessment
- Policy Development; and
- Assurance.



The Assessment component:

The first area, "Assessment", is the activity by which known or potential public health problems are identified and assessed with respect to the magnitude of the problem and the potential impact on public health. Assessment is carried out using the latest surveillance and testing methods to gather data for conducting the analyses, including quantitative risk assessments, forecasting models, data-mining, and trend analysis. The assessment component is focused on gathering, analyzing, and interpreting data about public health problems using science. Some examples of the activities in FSIS related to assessment include surveillance, identifying needs, analyzing the causes of problems, collecting and interpreting data, case-finding, monitoring and forecasting trends, research, and evaluation of outcomes.

The part of FSIS that has primary responsibility for assessment in FSIS is the Office of Public Health Science, or OPHS. However, you will do some of this in your daily work as well.

The Policy Development component:

The second area is "Policy Development". The word "policy" includes legal regulations, guidance and other rules, documents and strategies issued by FSIS. Policy development is defined as the process by which society makes decisions about problems, chooses goals and the proper means to reach them, handles conflicting views about what should be done, and allocates resources to deploy those policies. The Agency's policies serve to translate issues affecting public health into a course of action that minimizes the risk of foodborne illnesses. Some examples of policy development activities include planning and priority-setting, the development of regulations, directives

and other policy vehicles, mobilizing resources, training, constituency building and distribution of public information, and encouragement of public and private sector cooperation.

The Office of Policy and Program Development has the major responsibility for policy development in FSIS. Some examples of policy documents and policy guidance include regulations, Directives, and Notices. When there is an emerging issue affecting public health, such as the discovery of a cow that tested positive for BSE in January of 2004, FSIS must develop a policy that responds to that issue. Therefore, FSIS policies are dynamic and change to meet the challenges facing public health. You will be responsible for carrying out the policies in your day to day activities. You can provide input into policy development by commenting on interim regulations.

The Assurance component:

The third area is “Assurance”. Assurance is the activity that verifies FSIS performance measures and targets and validates that the Agency is effective in achieving the desired results. This is the function of providing services and implementing Agency policies and procedures to meet public health needs. One aspect of this is done through policy evaluation and the enforcement of established statutory and regulatory responsibilities which hold industry accountable for ensuring that meat, poultry, and processed egg products are safe, secure, wholesome, and accurately labeled. FSIS assurance also occurs through domestic and import inspection activities and verification testing. We must assure the American public that the USDA mark of inspection found on meat, poultry, and egg products means what it says – that product is safe, wholesome, and properly labeled.

The Office of Field Operations (OFO) has the primary role for assurance in FSIS. You, as a PHV, are assigned to work within OFO.

Vision and Goals for FSIS as a Public Health Regulatory Agency

As part of the U.S. Department of Agriculture, FSIS reports to the Undersecretary for Food Safety. The Undersecretary has identified 3 themes incorporating 8 goals for FSIS to achieve. These goals are outlined in the FSIS Strategic Plan FY 2011-2016, which can be found on the FSIS website.

The vision is for FSIS to become a trusted public health regulatory agency committed to preventing foodborne illness.

Theme number one: Prevent Foodborne Illness. Preventing foodborne illness and protecting public health is FSIS’ primary purpose. FSIS continually strives to become more adaptable to changing food safety risks, educates consumers on food handling best practices, and works closely with other public health partners to present a comprehensive approach to preventing illness.

- Goal 1 – Ensure that food safety inspection aligns with existing and emerging risks
- Goal 2 – Maximize domestic and international compliance with food safety policies
- Goal 3 – Enhance public education and outreach to improve food-handling practices

- Goal 4 – Strengthen collaboration among internal and external stakeholders to prevent foodborne illness

Theme number two: Understand and Influence the Farm-to-Table Continuum. FSIS cannot improve its ability to prevent foodborne illness, develop new policy or regulation, or effectively collaborate with other food safety organizations without first understanding the epidemiology of foodborne illness outbreaks and factors influencing food safety issues. To gain this insight, FSIS optimizes its use of science and data to fully understand the environment in which FSIS operates.

- Goal 5 – Effectively use science to understand foodborne illness and emerging trends
- Goal 6 – Implement effective policies to respond to existing and emerging risks

Theme number three: Empower People and Strengthen Infrastructure. All FSIS employees deserve to take pride in the fact that what they do helps prevent foodborne illness. FSIS hires the appropriate people, trains them correctly, and ensures that they have the right tools and technology to perform their jobs. Each FSIS employee contributes to the success of the entire Agency.

- Goal 7 – Empower employees with the training, resources, and tools to enable success in protecting public health
- Goal 8 – Based on the defined Agency business needs, develop, maintain, and use innovative methodologies, processes, and tools, including PHIS, to protect public health efficiently and effectively and to support defined public health needs and goals

FSIS: Part of the Food Safety System

In the Appendix of this handout, the last attachment covers the food safety system. This document identifies FSIS, along with FDA, APHIS and EPA as the primary food safety agencies that are supported by a number of other agencies that have food safety responsibilities. You will learn that as part of the food safety system, at times, you may work with others outside of FSIS in your role as a PHV.

Public Health Competencies

FSIS will be using the Public Health Competencies in leadership development, job descriptions, and performance elements. The Public Health Competencies were adopted by the Council on Linkages on April 11, 2001. This list will be reviewed for potential revision, taking into consideration its use by the public health practice and academic communities and the changing nature of public health practice. It is the currently accepted standard of core public health competencies.

It should also be noted that public health, by definition, places a strong emphasis on the “community” and community development. This is reflected in the developed FSIS competencies, as well. Within the context of FSIS, the working definition of “community” will be based on the area of responsibilities of the person(s) the competencies are being applied to. For example, the inspection team at a facility, or the inspection team and the establishment’s workforce within a duty location could be viewed as “communities.” Your work will require you to use many if not all of these competencies. You will see that your training covers most of them as well.

The public health competencies include:

- Effective Communication
- Values Diversity
- Leadership and Empowerment
- Coalition and Team building
- Analysis and Assessment
- Systems Thinking
- Program Development, Planning and Execution
- Resource Planning and Management
- Basic Public Health Science

Summary

FSIS has an important role to play to protect public health. As a PHV, you are on the front line of our public health workforce.

FSIS Leadership Public Health Competencies

In an effort to further the evolution of FSIS to a premier world class regulatory public health agency, the existing leadership competencies needed to be reviewed and updated to include currently accepted public health aspects. The review resulted in the development of the following nine competencies. This was achieved by combining the following two existing sets of *previously validated* competencies:

- The current “**FSIS Leadership Competency Development Resource Guide**” (Version 1, April 2002); and
- The “**Core Competencies for the Public Health Professionals**” (Council on Linkages between Academia and Public Health Practice¹).

The Council on Linkages adopted the utilized final list of Core Competencies for Public Health Professionals on April 11, 2001 for a three-year period. This list will be reviewed for potential revision by April 2004, taking into consideration its use by the practice and academic communities and the changing nature of public health practice. It is the currently accepted standard of core public health competencies.

It should also be noted that public health, by definition, places a strong emphasis on the “community” and community development. This is reflected in the developed FSIS competencies, as well. Within the context of FSIS, the working definition of “community” will be based on the area of responsibilities of the person(s) the competencies are being applied to. For example, the inspection team at a facility, or the inspection team and the establishment’s workforce within a duty location could be viewed as “communities.”

¹ <http://www.trainingfinder.org/competencies/list.htm>

The following nine FSIS Public Health Leadership Competencies have been identified:

1. Effective Communication
2. Values Diversity
3. Leadership and Empowerment
4. Coalition and Team building
5. Analysis and Assessment
6. Systems Thinking
7. Program Development, Planning and Execution
8. Resource Planning and Management
9. Basic Public Health Science

Essential functions and skills of each LPHC

1. EFFECTIVE COMMUNICATION

Essential Functions:

- Ensures the free flow of timely, accurate, and pertinent information and communications throughout the organization.
- Effectively communicates and achieves agreement with a broad range of people internally and externally.
- Communicates the Agency's message effectively to both professional and non-professional audiences.

Skills:

- Communicates effectively, in writing, orally, and/or in other ways throughout the organization as well as externally to build effective partnerships
- Leads and participates in groups to address specific issues
- Articulates viewpoints in a way that positively influences the conversation
- Solicits input from individuals and organizations
- Promotes an open exchange of views and information with and among others, demonstrating own commitment to a "right to know" rather than a "need to know" philosophy
- Uses relevant data or information to persuade others and build a common understanding among stakeholders with differing viewpoints
- Distills ideas into focused messages that inspire support or action from others.
- Advocates for public health programs and resources
- Effectively presents accurate demographic, statistical, programmatic, and scientific information for professional and lay audiences
- Uses the media, advanced technologies, and community networks to communicate information, when applicable

2. VALUES DIVERSITY

Essential Functions:

- Works Effectively with a wide range of people from varying backgrounds and with different skill levels.
- Demonstrates sensitivity to individual differences in terms of culture, ethnicity, age, organizational or program affiliation, disability, or personal style.
- Views differences as an asset and takes personal action to maximize diversity in order to achieve the vision and mission of the Agency, including public health.
- Develops and adapts approaches to problems that take into account cultural differences.
- Understands the dynamic forces contributing to cultural diversity.
- Understands the importance of a diverse public health workforce.

Skills:

- Encourages others to seek out and use diverse views in order to improve the effectiveness of the organization

- Solicits input from a wide variety of people and functions, e.g., through the establishment of diverse teams and work groups, as well as surveys and focus groups
- Integrates perspectives from others when making decisions
- Takes action to address intolerant or prejudiced behavior, including disciplinary or corrective action
- Challenges organizational policies and actions that may be exclusionary even at the risk of own self-interest
- Utilizes appropriate methods for interacting sensitively, effectively, and professionally with persons from diverse cultural, socioeconomic, educational, racial, ethnic and professional backgrounds, and persons of all ages and lifestyle preferences
- Identifies the role of cultural, social, and behavioral factors in determining the delivery of public health services

3. LEADERSHIP AND EMPOWERMENT

Essential Functions:

- Creates a structure and policies that enable employees to continuously upgrade their capabilities.
- Provides others with feedback, information, and support to help them develop enhanced capacity.
- Enables others to reach higher levels of performance through trust, delegation, participation, and coaching.
- Demonstrates high levels of honesty and personal ethics in representing the Agency and conducting its business.
- Consistently seeks to achieve results in the best interests of the Agency rather than to further own self career or self-interests.
- Models and reinforces ethical behavior in self and others.
- Helps others adapt and remain effective during the times of internal or external change.
- Demonstrates a personal commitment to changing one's own behavior as required to make change initiatives successful.

Skills:

- Convinces others to change by linking their personal future success to the results of the change.
- Acts to resolve team breakdowns that result from the change.
- Provides an anchor for others in times of stress or change by reaffirming key goals or values.
- Motivates others to change by providing facts, scientific information and financial data.
- Creates a culture of ethical standards within organizations and communities
- Helps create key values and shared vision and uses these principles to guide action
- Contributes to development, implementation, and monitoring of organizational performance standards

4. COALITION AND TEAM BUILDING

Essential Functions:

- Develops constructive and effective relationships with colleagues at all levels.
- Commits to the development of a stronger team to enhance team spirit.
- Develops teams in order to achieve the agency's mission.
- Shifts appropriately among multiple roles, such as leader, contributor, or facilitator, to support the work of the team.
- Facilitates collaboration with internal and external groups to ensure participation of key stakeholders

Skills:

- Directs the efforts of the team toward closing the gap between the present and the desired future.
- When assigning work, balances the need to achieve results with the opportunity to improve team members' performance and capabilities.
- Works with the team to establish a common vision rather than trying to create the vision for the team.
- Encourages participation and dialogue within the team.
- Promotes team and organizational learning
- Establishes and maintains linkages with key stakeholders
- Utilizes leadership, team building, negotiation, and conflict resolution skills to build community partnerships
- Collaborates with community partners to promote the health of the population
- Identifies how public and private organizations operate within a community
- Accomplishes effective community engagements
- Identifies community assets and available resources

5. ANALYSIS AND ASSESSMENT

Essential Functions:

- Critically evaluates information to promote the agency's mission.
- Assesses and analyzes the implications of own decisions on employees, the organization, stakeholders, citizens and other customers, prior to making a decision.
- Calculates and evaluates the short- and long-term consequences of decisions.

Skills:

- Forms ideas that bring clarity to the many possibilities in a complex situation.
- Gathers and considers multiple sources of information and weighs them appropriately to make decisions.
- Defines a problem
- Determines appropriate uses and limitations of both quantitative and qualitative data
- Selects and defines variables relevant to defined public health problems
- Identifies relevant and appropriate data and information sources
- Evaluates the integrity and comparability of data and identifies gaps in data sources

- Applies ethical principles to the collection, maintenance, use, and dissemination of data and information
- Partners with communities to attach meaning to collected quantitative and qualitative data
- Makes relevant inferences from quantitative and qualitative data
- Obtains and interprets information regarding risks and benefits to the community
- Applies data collection processes, information technology applications, and computer systems storage/retrieval strategies
- Recognizes how the data illuminates ethical, political, scientific, economic, and overall public health issues

6. SYSTEMS THINKING

Essential Functions:

- Makes timely and sound decisions.
- In the absence of clear knowledge, is able to work within existing framework to make a decision.
- Reacts decisively to changing conditions in the agency or for its customers.
- Integrates information and perspectives from colleagues when making decisions.
- Conceptualizes and clarifies the forces that are affecting or are being affected by the situation at hand.

Skills:

- Acts decisively in a crisis.
- Takes ownership for decisions by standing by them and accepting responsibility for resulting consequences.
- Identifies internal and external issues that may impact delivery of essential public health services (i.e., strategic planning)
- Makes logical and pragmatic decisions in the best interest of the agency.
- Makes connections between and among seemingly unrelated events that reveal key issues or opportunities.
- Takes specific action on emerging opportunities in a rapidly changing, ambiguous environment.

7. PROGRAM DEVELOPMENT, PLANNING AND EXECUTION

Essential Functions:

- Actively promotes change as necessary to the current and future success of the agency.
- Considers and integrates agency priorities and such factors as policies, regulations, the applicable science, safety standards, quality issues, and ethics when making decisions.
- Identifies, interprets, and implements public health laws, regulations, and policies related to specific programs
- Articulates the health, fiscal, administrative, legal, social, and political implications of each policy option
- Develops a plan to implement policy, including goals, outcome and process objectives, and implementation steps

Skills:

- Takes personal initiative to remedy barriers to implementing change.
- Ensures that short-term activities support long-term organizational goals.
- Translates broad strategies into specific actions, goals, objectives, and responsibilities to ensure a safe food supply.
- Uses the legal and political system to effect change
- Applies theory of organizational structures to professional practice
- Collects, summarizes, and interprets information relevant to an issue
- States policy options and writes clear and concise policy statements
- States the feasibility and expected outcomes of each policy option
- Utilizes current techniques in decision analysis and health planning
- Decides on the appropriate course of action
- Translates policy into organizational plans, structures, and programs
- Prepares and implements emergency response plans
- Develops mechanisms to monitor and evaluate programs for their effectiveness and quality
- Develops, implements, and evaluates a community public health assessment
- Describes the role of government in the delivery of community health services

8. RESOURCE PLANNING AND MANAGEMENT

Essential Functions:

- Develops and presents a budget
- Demonstrates the ability to gain maximum leverage from the available financial resources.
- Sponsors, leads, and/or manages initiatives in a manner that manages costs without sacrificing quality of the core values of the agency.
- Effectively manages, deploys, and leverages resources including capital, equipment, and people.
- Uses own budgetary discretion as a means for ensuring that agency initiatives achieve maximum impact.
- Gains approval for new initiatives (e.g., investment in technology, cultural change, skills development) by providing appropriate analysis, including return-on-investment analysis, in terms of the government's budget and cost management processes.

Skills:

- Analyzes a wide range of financial and program reports by applying analytical tools, as they become available, such as cost management, statistical analysis, and performance budgeting to leverage and prioritize resources.
- Considers and integrates the financial and programmatic implications of decisions in terms of both costs and expected benefits.
- Focuses own efforts and those of others on projects and programs that produce bottom-line impacts in alignment with agency priorities.
- Manages programs and projects in an integrated manner to assure resources are effectively leveraged to reach goals.
- Manages programs within budget constraints and applies budget processes
- Develops strategies for determining budget priorities

- Monitors program performance
- Prepares proposals for funding from external sources
- Applies basic human relations skills to the management of organizations, motivation of personnel, and resolution of conflicts
- Manages information systems for collection, retrieval, and use of data for decision-making
- Negotiates and develops contracts and other documents for the provision of population-based services
- Conducts cost-effectiveness, cost-benefit, and cost-utility analyses

9. BASIC PUBLIC HEALTH SCIENCE

Essential Functions:

- Identifies the individual's and organization's responsibilities within the context of the Essential Public Health Services and core functions
- Understands the historical development, structure, and interaction of public health and the Agency's mission
- Identifies and retrieves current relevant scientific evidence
- Identifies the limitations of research and the importance of observations and interrelationships

Skills:

- Defines, assesses, and understands the health status of populations, determinants of health and illness, factors contributing to health promotion and disease prevention, and factors influencing the use of health services
- Identifies and applies basic research methods used in public health
- Applies the basic public health sciences including behavioral and social sciences, biostatistics, epidemiology, environmental public health, and prevention of chronic and infectious diseases and injuries
- Develops a lifelong commitment to rigorous critical thinking

Enhancing Public Health: Strategies for the Future 2003 FSIS Food Safety Vision

[PDF version, best for printing](#)*(17 pp.)

ABSTRACT

On March 19, 2003, Agriculture Secretary Ann Veneman challenged the Food Safety and Inspection Service (FSIS) to reach the next level of food safety. Secretary Veneman's challenge called for creative and effective ways to modernize the FSIS' ability to continue to improve the safety of U.S. meat, poultry, and egg products to better protect public health. This vision document identifies goals and strategies to be pursued by FSIS.

Americans enjoy the safest food supply in the world. This is due in part to efforts by the U.S. Department of Agriculture (USDA) to follow a scientific approach in administering its food safety programs. This approach has resulted in tangible public health benefits for consumers, as seen by the 16 percent decline in foodborne illness over the last 6 years. The Centers for Disease Control and Prevention ([CDC](#)) attributes these results in part to the implementation of the Hazard Analysis Critical Control Point ([HACCP](#)) system in all meat and poultry plants in the United States.

Over the past two years, the Food Safety and Inspection Service (FSIS) has been implementing a 5-point strategy to further reduce the incidences of foodborne illness using HACCP as the foundation. This strategy includes: improved management of inspectors, application of science in crafting regulations, better coordination with other agencies, an aggressive education campaign for food handlers, and protection of the food supply against terrorist attack.

In this document, FSIS presents a list of accomplishments achieved over the past two years that further enhance the safety of the food supply. In order to continue on the road to improving public health, FSIS will be implementing several new initiatives. These new initiatives, which are outlined in this document, are focused on improved training for inspectors, the use of effective technologies in processing plants to address harmful bacteria, and on scientific research directed and applied to address food safety from the farm to the table.

In addition to these ongoing efforts, the Agency must examine how it can best utilize its resources and authorities to further enhance its systems while providing incentives for compliance. A brief description of these challenges is also presented in this document, laying the groundwork for directions that FSIS may take in the future. The Agency welcomes the input of all interested parties, and encourages the free exchange of ideas, as it continues to work to enhance the safety of the food supply.

Introduction:

Americans enjoy the safest food supply in the world, and it is getting safer. This is evidenced by an overall 16 percent decline in foodborne illnesses from 1996 to 2002, as reported by the Centers for Disease Control and Prevention (CDC). [Preliminary FoodNet data](#) for that 6-year period were released April 18, 2003. The preliminary data demonstrate a sustained decrease in major bacterial foodborne illnesses caused by *Campylobacter* and *Listeria*, indicating progress toward meeting the Agency's health objectives of reducing the incidence of foodborne infections. In addition, data from FSIS show a continuing decline in the prevalence of *Salmonella* in regulatory samples of meat and poultry.

In spite of these positive trends towards a safer food supply, FSIS recognizes that intensified efforts are needed to further reduce the incidence of foodborne illnesses related to meat, poultry, and egg products in

the United States. For example, preliminary FoodNet data do not show a sustained decline in foodborne infections caused by *E. coli* O157:H7 and *Salmonella*. Eradicating foodborne illness is an evolving challenge affected by many factors. These factors include changes in food distribution and preparation habits, increases in the average lifespan and the number of immune-compromised individuals, and the emergence and virulence of new pathogens. As the [Institute of Food Technologists](#) states in its report titled, "Implications for Control in the 21st Century," food safety issues change over time and so too must the management strategies and regulatory framework.

FSIS is committed to anticipating the changes by incorporating into policymaking the many advances that have been made in food safety research and technologies. These advances will enable FSIS to predict trends in food contamination, and in hazard survivability and growth, thereby enabling the Agency to protect the public's health to the greatest extent possible. An added benefit to such a preventive and anticipatory approach to food safety is the impact that various management practices can have on risk mitigation. Applying risk assessment can enable us to focus efforts on the highest-risk problems, resulting in a more efficient use of resources.

The continued mission of FSIS is to ensure that consumers have the safest possible food supply. To fulfill this vision, FSIS must use science-based practices to diminish the incidence of foodborne illness associated with meat, poultry and egg products. This document outlines recent FSIS accomplishments in combating foodborne illness, describes new initiatives FSIS is undertaking in pursuing its mission, and presents the challenges that must be overcome in order to realize the FSIS vision for food safety. Input from all interested parties on ideas presented in this document is encouraged.

Goals in Pursuit of the FSIS Mission:

The following five core goals best articulate the road map for FSIS' food safety mission:

Goal #1: Improve the management and effectiveness of regulatory programs. In order for policies and programs to be successful, they must be uniformly and correctly applied. Thus, proper training of the workforce is essential. In addition, communication to field personnel needs to be timely and accurate, with proper supervision from the district and from headquarters in order to foster accountability in the system.

Goal #2: Ensure that policy decisions are based on science. Science allows for policy decisions to be continually updated based on technological advances and to respond to emerging threats to public health. Science-based decision-making is objective and preventive in nature, and thus, it offers the best foundation for the development of policies that will achieve the desired result of improving public health, both in the short term and the long term. In terms of developing science-based policies, the threats to public health need to be understood and addressed within the context of the best available research and risk analysis. With input from the scientific community, FSIS can develop practical policies that allow the industry to implement new technologies as food safety interventions.

Goal #3: Improve coordination of food safety activities with other public health agencies. This coordination includes all Federal, State, and other food safety agencies to better utilize resources. All of these agencies share the same mission and their activities and programs should be complementary, so that the maximum benefit can be realized without duplication of efforts.

Goal #4: Enhance public education efforts. Everyone has a responsibility for food safety. Food preparers must know clearly and understand basic food-handling practices. Therefore, FSIS needs to enhance public education efforts. These efforts must be broad enough to ensure that no segment of the public is uninformed about safe food handling practices. Communicating with the public about food safety must be accomplished in a manner that is easily understandable so that it is useful to every segment of the population. The food safety messages must also be targeted to various segments of the population to

improve receptivity, and messages should be focused on positively influencing those behaviors that pose the greatest potential risk. These messages must be distributed to as broad an audience as possible to ensure an effective use of resources. Thus, FSIS must consider innovative and collaborative methods for delivering the food safety message.

Goal #5: Protect meat, poultry, and egg products against intentional contamination. In the aftermath of September 11, 2001, there is recognition that threats to the well being of the Nation's citizens can come in the form of terrorist attacks, including the intentional contamination of food. Thus, FSIS must do everything possible to protect meat, poultry, and egg products against such threats. As with food safety, protection of the food supply against intentional contamination must be coordinated with all relevant agencies.

Accomplishments Within Each Goal:

FSIS has made great strides in achieving its vision through the pursuit of its five stated goals. The following is a summary of some of the most significant efforts made since 2001.

Goal #1: Improve the management and effectiveness of regulatory programs.

FSIS field employees are in every meat, poultry, and egg products plant, ensuring that the plants are producing products that are safe, wholesome, and accurately labeled. These frontline employees are responsible for making the critical determination that products are not adulterated and therefore are safe to eat. Therefore, it is essential to have a scientifically and technically trained workforce that is dedicated to ensuring a safe supply of meat, poultry, and egg products.

A key to improving the management and effectiveness of food safety regulatory programs is having a workforce that understands the scientific basis behind its programs. Having a workforce more grounded in science enables the Agency to better assess the soundness of food safety programs implemented at slaughter and processing establishments, and to enhance its ability to conduct epidemiological investigations. Therefore, the agency created the [Consumer Safety Officer \(CSO\)](#) series to reflect increasing reliance on science and technology. CSOs have a scientific and technical background and receive additional Agency training that enables them to use a disciplined methodology to assess and verify the design of food safety systems. FSIS has trained 107 employees as CSOs in FY 2002, and plans to train almost 200 additional employees in the CSO methodology in FY 2003. In addition, the agency is extending CSO training to its Veterinary Medical Officers.

Because accountability is crucial in delivering programs in a consistent and effective manner, FSIS implemented the In-Plant Performance System (IPPS). This system establishes a formal process so frontline supervisors can be sure that inspection personnel carry out their assigned job responsibilities. All field supervisors have been trained to use this system. The IPPS review helps the supervisor to: identify and address the need to improve an employee's knowledge about his or her responsibilities, encourage correlation with employees to ensure consistency in methods and applications of methods, help identify and address performance problems, and recognize and reward on-target employee performance.

In addition to these efforts, FSIS is finalizing a plan for reorganization to prepare the Agency to better meet its public health and food safety goals. The specific objectives of this reorganization are to increase accountability, enhance communication, strengthen appropriate agency action on HACCP issues as they occur, and improve overall efficiency at FSIS. The changes have strengthened the bonds between the FSIS offices and have made operations more coherent and responsive.

To improve efficiency, the reorganization includes four new offices with cross-cutting purposes. For example, the assistant administrator for Food Security and Emergency Preparedness ties together all

Homeland Security activities within the Agency, so that FSIS policy makers, scientists, field staff, and management are all working together to ensure that FSIS is prepared to prevent and respond to any bioterrorist attack.

The reorganization also includes an Office of Program Evaluation, Enforcement and Review (PEER) to serve as the Agency's quality control team. This office's mission is to ensure that effectiveness, efficiency, consistency, and accountability become the rule at FSIS. The PEER quality assurance program ensures that FSIS functions, such as reviews of plants for compliance and food safety investigations, are carried out in a way most conducive to protecting the public health. This office also conducts audits of foreign country inspection systems, reviews, assessments, and program evaluations in an effort to ensure that the programs are performing as needed. PEER is the Agency's liaison with the General Accounting Office and the Office of the Inspector General; this uniquely positions PEER to focus on key areas in need of improvement. PEER retains the role of ensuring prompt and appropriate enforcement of the inspection laws. The work of the field Program Investigators in PEER places them on a daily basis in close proximity to performance and compliance problems and concerns at the in-plant level, which affords the Agency the ability to deal with necessary adjustments and problems in a much more immediate and direct fashion than in the past. PEER was formed because a strong quality assurance program that uses reviews, evaluations, and audits as its tools can have a significant impact on management effectiveness, efficiency and policy development.

In addition, FSIS recently consolidated all of the communication functions under the Office of Public Affairs, Education and Outreach to increase the efficiency and strength of FSIS' internal and external communications, outreach, and partnerships. This is a cross-cutting office that combines traditional communications activities, such as those conducted by the Agency's Congressional and Public Affairs, Food Safety Education, and Executive Management Staff, with outreach conducted by the Strategic Initiatives, Partnerships and Outreach Staff (SIPOS). SIPOS includes the Meat and Poultry Advisory Committee Staff, the Planning Staff, small and very small plant outreach, and works with members of Federal, State and local governments.

The new Office of International Affairs centralizes the Agency's activities related to regulation of imported meat, poultry and egg products and certification of exports. This includes representation in international settings where FSIS influences and directs activities that establish food safety standards and promotes improved food safety practices worldwide.

In addition to the new offices, FSIS has instituted new information systems to assist in achieving its mission. In FY 2002, FSIS introduced the [new Automated Import Information System \(AIIS\)](#), which directs port-of-entry sampling of imported shipments. The new AIIS system focuses on a foreign country's inspection system as a whole, rather than on individual plants. The system randomly selects shipments of meat and poultry imports for reinspection based on the annual volume of shipments from the exporting country. Previously, reinspection was based only on an establishment's compliance history. The new system is user-friendly for inspectors, provides managers with instant access to inspection reports, and permits better tracking of shipments once they enter the United States. The next step is for FSIS to integrate its system with other key systems in order to further protect the food safety system against intentional attacks. Such systems include those of USDA's [Animal and Plant Health Inspection Service](#) and the Bureau of Immigration and Customs Enforcement within the [U.S. Department of Homeland Security](#).

Goal #2: Ensure that policy decisions are based on science.

The food safety system employed by FSIS to accomplish its mission has evolved from a purely inspection program, in which visual and other organoleptic examination was the cornerstone, to one in which a science-based framework is used to identify and prevent food safety problems. This framework is known as

the Pathogen Reduction/Hazard Analysis and Critical Control Points (PR/HACCP) system. PR/HACCP allows for the use of science, research, technology, and data disclosure in the development of improved food safety. HACCP identifies hazards for the purpose of establishing critical control points. It is a preventive approach.

PR/HACCP is working. Evidenced by a 16 percent overall decrease in foodborne illnesses between 1996 and 2002, and by a decrease from 5.0 percent to 4.3 percent in the prevalence of *Salmonella* in regulatory samples (from 2001 to 2002), this system has become an effective tool to minimize the entry of pathogens into the food supply.

In addition, a strong system of checks and balances is essential to continued improvements in food safety. In the last two years, FSIS has taken decisive and concrete actions to modernize this system. For example, FSIS has used its authority to issue regulations for specific pathogens to impose additional data requirements on establishments producing ready-to-eat products where the pathogen *Listeria monocytogenes* is a concern. New audit initiatives have produced significant improvements to HACCP controls in raw beef product producing plants. In-depth reviews of establishments failing to meet *Salmonella* performance standards are also producing results, including increased use of suspension authorities pending correction.

As stated above, FSIS continuously reviews its existing authorities and regulations to ensure that emerging food safety challenges are adequately addressed. In addition, FSIS is committed to continuing its emphasis on the use of science, research, and technology in the development of improved food safety policies, focused on prevention whenever possible. Risk assessment is one tool that can provide FSIS with the solid scientific foundation on which to base regulatory and policy decisions. In fact, the Agency has used risk assessment to estimate the likelihood of exposure to various hazards, and to estimate the resulting public health impact. For example, in February 2003, FSIS released a draft of a quantitative risk assessment conducted on *Listeria* in ready-to-eat (RTE) meat and poultry products. On February 26, 2003, FSIS held a public meeting to discuss the design of the risk assessment, the results, and conclusions that could be drawn from it regarding the risk of contamination of RTE products with this pathogen during processing.

The [risk assessment](#), in conjunction with a previously released Food and Drug Administration (FDA)/FSIS risk ranking, peer review and public comment, provided important data enabling FSIS on June 6 to publish a [final *Listeria* rule](#) proposed in early 2001. This risk-based regulation will serve as the cornerstone of the FSIS efforts to prevent listeriosis from RTE meat and poultry products. The rule requires all establishments that produce RTE products that are exposed to the environment after cooking to develop written programs to control *Listeria monocytogenes* and to verify the effectiveness of those programs through testing. Establishments must share testing data and plant generated information relevant to their controls with FSIS. The rule also encourages all establishments to employ additional and more effective *Listeria monocytogenes* control measures. The new rule is accompanied by a verification testing program under which intensified testing is conducted at high-risk plants that produce high-risk products, as identified by the previously released FDA/FSIS risk ranking.

In addition to the new *Listeria* regulation, additional policies that have been implemented include:

***Salmonella* Notice.**

In August 2002, FSIS issued [new procedures](#) emphasizing the use of *Salmonella* testing. Establishment failure to meet the *Salmonella* performance standard triggers an immediate review of an establishment's entire food safety system.

Establishments that do not meet food safety requirements, as determined during these in-depth reviews, are subject to enforcement actions. In fact, in-depth reviews have resulted in an increase in suspensions of

inspection from 2.3 percent in 1998 to 4.8 percent in 2002. The new procedures also emphasize coordination between consumer safety officers, district managers, circuit supervisors, compliance officers and inspection personnel to ensure that plants identify and correct problems in their food safety systems that are resulting in noncompliance. Increased coordination also helps FSIS ensure that it addresses performance problems regarding inconsistent inspection and related issues. These can be measured through audits of verification activities carried out by FSIS inspectors.

***E. coli* O157:H7 Reassessment.**

Data from the Agricultural Research Service (ARS) as well as FSIS' draft risk assessment for *E. coli* O157:H7, indicate that *E. coli* O157:H7 is more prevalent in cattle than previously believed. Based on this data, in October 2002, FSIS announced a series of new measures to further prevent contamination in ground beef with the pathogen *E. coli* O157:H7.

In an October 7, 2002, [Federal Register Notice](#), FSIS informed manufacturers of beef products of the Agency's views about the application of the HACCP system regulations to contamination with *E. coli* O157:H7. The Notice informed all establishments producing raw beef products that they must reassess their food safety plans, based on evidence indicating that *E. coli* O157:H7 is a hazard reasonably likely to occur at all stages of the process (unless they had already reassessed their plans in light of this data). If establishments determine from these reassessments that *E. coli* O157:H7 is a hazard reasonably likely to occur, they (or for grinders, their suppliers) must incorporate one or more critical control points designed to prevent or eliminate contamination with this pathogen.

FSIS is in the process of reviewing these establishment reassessments, through audits being conducted by CSOs. As of mid-May, 63 percent of all plants reviewed, and 87 percent of large plants reviewed, have revised their HACCP plans to include better controls for *E. coli* O157:H7, in an effort to prevent contamination of products with this pathogen.

***E. coli* O157:H7 Testing.**

In April 2003, FSIS issued an [FSIS Notice](#) to clarify that FSIS will now collect a sample of ground beef for *E. coli* O157:H7 analysis regardless of the measures that plants take to reduce or eliminate this pathogen. FSIS announced this new procedure in order not to exempt any processor and to recognize that the prevalence of this pathogen begins to rise in April and May of each year. FSIS is in the process of developing a risk-based verification testing program for *E. coli* O157:H7, and expects to issue a revised Directive 10,010.1 in August 2003.

AMR Sampling Program.

On March 3, 2003, FSIS released the [results](#) of a blind survey of beef products produced using Advanced Meat Recovery (AMR) systems. The survey of 34 establishments was conducted to determine the frequency of products containing central nervous system (CNS) tissue, including spinal cord tissue, produced with this equipment. The results showed that approximately 35 percent of the final product samples tested positive for CNS tissue (spinal cord) and CNS-associated tissues.

As a result of the survey, FSIS began implementing a [verification program](#) to verify that establishments using AMR systems to produce beef are following regulations designed to prevent spinal cord from entering the food supply. The sampling program specifically requires inspection personnel to take samples of AMR product on a routine basis. If the tests identify the presence of spinal cord tissue in the product, then inspection personnel are to withhold marks of inspection from the establishment's AMR product and tag the AMR system itself. This means that neither the product nor the equipment can be used until

satisfactory corrective action has been taken and verified.

In response to the survey results and the sampling program, establishments with beef AMR systems have implemented numerous changes to reduce the likelihood of spinal cord tissue entering the final product. The changes range from discontinuing the use of their AMR systems altogether, to retraining employees and employing new equipment and procedures to ensure that spinal cord is fully removed from the vertebral column prior to entry into the AMR system for processing. As a result, the percent of samples testing positive for CNS tissue has decreased by over 50 percent.

As a means to consider possible strategies for addressing food safety issues, FSIS has aggressively sought the input of the scientific community and others. The Agency has sponsored many public meetings and scientific symposia that allow the agency to share information with, and gather input from, stakeholders on food safety and public health topics.

A public meeting entitled "[Applied Epidemiology – A Public Health Tool to Inform Food Safety Inspection](#)," was held on January 29-30, 2002, to discuss the Agency's use of epidemiological data, scientific principles and techniques, and the use of other public health tools. The meeting was designed to help develop a framework for how FSIS will conduct public health investigations and integrate the scientific principles of applied epidemiology into in-plant activities.

FSIS also sponsored a major symposium entitled "[Pathogen Reduction: A Scientific Dialogue](#)," in May 2002. The symposium brought together leading experts from government and academia to discuss scientific data and issues associated with pathogen reduction and HACCP. From this meeting, FSIS has been able to gather information on how pathogens enter the food chain, options for constructing statistically sound performance sampling strategies, new trends in microbiology and microbial ecology, and new technologies to remove or inactivate pathogens on carcasses.

The Second National Conference for Food Safety Educators, "[Thinking Globally--Working Locally: A Conference on Food Safety Education](#)," was held in Orlando, Florida, from September 18-20, 2002. More than 600 food safety educators from across the United States and around the world attended the conference. This conference enabled the exchange of successful educational approaches among the participants.

On November 18, 2002 FSIS held a "[Listeria Summit](#)." This forum allowed government, academia, industry, advocacy groups and the public to present the Agency with up-to-date research data as well as comments on actions that best address *Listeria monocytogenes*. This summit was helpful in obtaining additional scientific analysis, information and public input to finalize a proposed rule on *Listeria* to enhance current policies.

FSIS also held a [public meeting December 12, 2002](#), to discuss improving the process for recalls of meat, poultry and egg products. This public meeting provided an opportunity for public input on how to further improve the recall process. Suggestions and ideas derived from this meeting are currently being considered by the Agency, as it seeks to enhance these systems to better protect public health.

On February 26, 2003, FSIS held a [public meeting](#) to discuss and gather input on the draft risk assessment for *Listeria*. The draft risk assessment was an important step in finalizing regulations for addressing *Listeria monocytogenes*. Comments and discussions held at this meeting aided the Agency in determining how the risk assessment could be improved, and was the first step towards seeking further input through a peer review conducted by university experts soon thereafter.

FSIS held a [public meeting on March 27, 2003](#), to share perspectives and discuss strategies for improving global food safety. The meeting allowed discussion of the challenges faced by the international food safety

community, and provided an opportunity to share ideas and perspectives on food safety issues, discuss strategies to improve food safety worldwide, and foster relationships to promote food safety.

Finally, a [second public meeting on applied epidemiology](#) was held on April 29, 2003, to discuss the use of epidemiological data, principles, techniques and other tools to help it achieve its public health goals. This meeting was designed as a follow-up to a meeting held in early 2002, with the purpose of helping FSIS develop a framework for how the Agency will conduct public health investigations and integrate the scientific principles of applied epidemiology into its in-plant activities.

On April 28, 2003, FSIS implemented the [Food Safety Regulatory Essentials Training Program](#) under which FSIS will retrain the entire workforce in HACCP. The training is based on revised [Directive 5000.1](#), issued May 21. Directive 5000.1 serves as a handbook that contains instructions for FSIS field personnel on how they are to protect the public health by properly verifying an establishment's compliance with the pathogen reduction, sanitation, and HACCP regulations. It guides the consumer safety inspector (CSI) and the CSO on the verification procedures, documentation instructions and enforcement actions for specific food safety activities. It provides a framework to assist the CSI in understanding the thorough process to be followed in performing the inspection methodology and making regulatory decisions.

Goal #3: Improve coordination of food safety activities with other public health agencies.

An example of the progress in coordinating efforts was an unprecedented investigation conducted with the CDC and State and local public health agencies on the Northeastern listeriosis outbreak that occurred in 2002. FSIS dispatched seven teams beginning in early September to affected Northeastern States and used information provided by CDC to test products and visit plants that were suspected of being linked to the outbreak. FSIS collected more than 400 samples of product and the environment for analysis in the course of the investigation. When it was first suspected that a turkey product caused the outbreak, FSIS took immediate, focused steps to identify the plant. After identifying the plant, FSIS immediately requested a [recall](#) and sent a team of specialists to the establishment to help identify any problems in the plant. Functioning as a true public health agency, FSIS spent an enormous amount of time and resources investigating this outbreak, including creating a team of more than 50 laboratory scientists, regional epidemiologists, CSOs, compliance officers, field personnel and headquarters management to work closely with CDC and State and local public health officials to locate the source. CDC has publicly commended FSIS for its successful public health role in identifying and addressing the source of the outbreak.

In addition, the cadre of FSIS epidemiologists, including several who are Public Health Service (PHS) Commissioned Officers, enhanced public health agency coordination. The ability of FSIS to utilize these PHS Officers results from a [Memorandum of Agreement](#) (MOA) with the U.S. Department of Health and Human Services' PHS Commissioned Corps signed on April 17, 2003. The addition of these PHS Commissioned Officers will enhance FSIS capabilities for rapid response during heightened security alerts or in the event of an actual threat to food security.

Another area in which FSIS is making strides involves cooperation with States through the sharing of product recall information. In July 2002, FSIS published a [final rule](#) allowing the Agency to share a firm's distribution list with State and Federal agencies in the event of a meat or poultry recall through a Memorandum of Understanding. This change allows for better communication and coordination between FSIS and the numerous State and Federal agencies that are involved in product recalls.

Goal #4: Enhance public education efforts.

Food safety education is a critical element of the risk analysis framework, which includes risk assessment, risk management, and risk communication. It is a risk management strategy because educating food

preparers – in the home, in institutions, and in food service -- is an important way to reduce the risk of foodborne illness. Education is also a risk communication function because it serves to alert the public about a hazard that exists and can be addressed by safe food handling and food selection.

FSIS has been conducting an aggressive educational campaign of public events and media interviews with national and regional media organizations in order to reach more of the population with important public health messages. Recent events were held in Atlanta, Miami, Detroit, Austin, and Nashville. National television interviews have been conducted with major television networks, including *Fox News*, *Telemundo* and *Univision*. National celebrities, such as [former Miss America Heather Whitestone](#) and country singer [Wynonna Judd](#), have also been recruited to help FSIS reach even larger audiences with food safety messages through special events and the filming of Public Service Announcements.

FSIS is developing a comprehensive and sustainable mass media campaign that leverages traditional and non-traditional media outlets throughout the country to get this important message out.

FSIS is sending the [USDA Food Safety Mobile](#) to strategic locations throughout the country to research and develop this important food safety education campaign. Through a partnership with university extension agents and private industry, the Mobile has hosted numerous demonstrations for food handlers of all ages. While delivering important food safety messages to the public, the Mobile is providing valuable first hand insight on how future mass media messages and education campaigns should be constructed and delivered.

Keeping in mind the changing demographics of the Nation, FSIS has also taken important steps to provide food safety education to citizens whose first language is not English. The Agency has [translated](#) its most popular consumer publications into Spanish and this year the FSIS Meat and Poultry Hotline is answering – in Spanish – the food safety questions of Spanish-speaking Americans. FSIS is making progress on translating key materials into other languages as well.

Goal #5: Protect meat, poultry, and egg products against intentional contamination.

Close coordination with other public health agencies is important in [protecting the food supply against intentional harm](#). Since the attacks on September 11, 2001, FSIS has strengthened coordination and preparation efforts to prevent, detect, and respond to food-related emergencies resulting from acts of terrorism, and ensure the safety of meat, poultry, and egg products that come to us from other countries. With a strong food safety infrastructure already in place, FSIS has been able to focus on strengthening existing programs and improving lines of communication, both internally and externally.

Also, the formation of PEER provides FSIS with a strong enforcement program with significant surveillance capacity. While much of the Agency's focus is properly at the in-plant level, strong surveillance is critical to the ability to control product at retail, in distribution and in transit. The FSIS enforcement program also addresses intentional contamination of products.

FSIS has made important progress on the scientific front. FSIS laboratories have enhanced analytical capability for compounds of concern, and developed surge capacity. FSIS is represented on the interagency Laboratory Response Network and worked to develop the Food Emergency Response Network for potential foodborne contamination incidents. FSIS has hosted a laboratory workshop for food and drug officials on integrating laboratory resources for national food security. The Agency has also begun construction of a Bio Security Level 3 facility. In order to respond rapidly to possible intentional contamination, field employees must diligently monitor all plants and other facilities where products are stored, handled and transported to ensure that there is no intentional biosecurity breach that could harm the Nation's food supply. Coordination with other agencies is one of the Agency's goals.

FSIS has strengthened its controls to protect the public from the entry of contaminated product from abroad. FSIS continually assesses foreign country inspection systems to ensure that they maintain food safety standards and operations equivalent to the U.S. inspection system. These assessments include in-country [audits](#) and [port-of-entry reinspection](#) of all shipments entering the country.

To augment the efforts of traditional FSIS import inspectors, FSIS has also added 20 new import surveillance liaison inspectors who are on duty at ports of entry. Where traditional FSIS import inspectors examine each shipment and conduct reinspection activities, these new import surveillance liaison inspectors conduct a broader range of surveillance activities at each import facility and serve as liaisons to improve coordination with other agencies concerned with the safety of imported food products, such as the Department of Homeland Security.

Besides initiatives to screen imported products, FSIS has conducted a vulnerability assessment to be used as a tool for determining the most vulnerable products, likely agents, and potential sites for deliberate adulteration of domestically produced meat, poultry, and egg products. The assessment was conducted using a farm-to-table approach based on current knowledge of the industrial processes used in the production of these products and the potential biological and chemical agents that could be introduced. The assessment was concluded in June 2002, and the information obtained is being used to develop risk management strategies, including ensuring that FSIS laboratories are equipped with the methods and personnel necessary for detecting agents of concern.

FSIS has also developed a vulnerability assessment of the import system to identify points in the production of imported products where biological, chemical, and radiological contaminants could be intentionally added to foods being brought into the United States. FSIS used the risk analysis framework to conduct a relative risk ranking to be used to allocate resources to monitor U.S. ports of entry for those food commodities that pose the greatest risk, examine different intervention strategies for preventing or reducing risks, develop biohazard identification protocols, and target training of personnel and develop educational campaigns to increase awareness. This assessment is expected to be completed in September 2003.

FSIS has taken preparation for food safety emergencies to a higher level with simulation exercises. Earlier this year, an exercise known as "Crimson Winter" was conducted to familiarize managers and staff with the operating environment that would exist during an outbreak of foodborne disease – the cause being intentional or unintentional. This exercise was very constructive for FSIS' senior management, its emergency response team, its partners in the Food Threat Preparedness Network, and other relevant Federal and State agencies.

New Initiatives for 2003:

FSIS is implementing several new initiatives in order to continue toward its vision for food safety.

Train to the Vision.

FSIS recognizes that to successfully implement consistent enforcement of its regulations, it needs to support the most critical component of FSIS effectiveness -- its workforce. Thus, one of the Agency's top priorities is to aggressively address the training and education of its workforce. The Agency must ensure it is training employees to fulfill its vision. In order to ensure consistent and accurate inspection, FSIS has made a strong commitment to recruiting scientifically educated employees and retooling its entire training and education programs for all employees.

FSIS has crafted a two-fold plan on how it will enhance its workforce training capability. First, all training programs for all employees will be updated to incorporate a public health focus by integrating scientific and technical principles, including HACCP validation, with training on technical and regulatory approaches to inspection, and use of enforcement responses, such as suspension of inspection, where appropriate.

Second, FSIS is moving to a system of delivering training that is as close to the employee's worksite as possible. This will involve regional training and regional trainers, as well as interactive sessions near the employee's work site and on-site training programs. Training and education programs must be easily accessible for both headquarters and field personnel.

FSIS is developing long-term strategies to build a more knowledgeable and empowered workforce. The program will incorporate both technical and managerial aspects so that FSIS has employees who can function well in a science-based environment. In addition, some of the training, particularly training involving new technologies and methodologies, must be carried out in conjunction with the regulated industry, so that both processors and inspectors share in the knowledge gained about the science behind the FSIS regulations, and how they must be applied to improve public health.

Food Safety Technologies.

The Agency is working to encourage the regulated industry to target microbial interventions at appropriate control points to best protect public health. FSIS is establishing a technology review staff that will review interventions in order to expedite the implementation of safe interventions at slaughter and processing establishments. The Agency is refining guidance documents for industry on how to seek review of new technologies under an expedited review process. These enhancements follow earlier steps to facilitate the review process, including implementing a simultaneous review process (with FDA) for new ingredients. On April 29, 2003, FSIS issued a [direct final rule](#) to permit the use of any safe and suitable binder or antimicrobial agent in the production of meat and poultry products that are subject to a standard of identity or composition that provides for the use of such ingredients. This rule, effective June 30, will provide food processors with much more flexibility in using antimicrobial agents in standardized meat and poultry products.

Risk Assessment Coordination.

In order to better focus its resources in food safety risk assessment activities, FSIS is planning the establishment of a risk assessment coordination team with USDA-wide membership. The goals are to strategically plan these activities and to improve coordination with researchers within and outside FSIS so that risk assessments are conducted more efficiently and utilizing the best science. As an added benefit, the Agency anticipates that such a focused approach will better enable use of risk assessments as tools to help identify future research needs.

Research Agenda.

FSIS is working with the Research, Education, and Extension mission area at USDA to coordinate food safety research priorities and needs, including elucidating the ecology of various pathogens from farm to table. This research agenda will include a mechanism by which research needs in food safety are prioritized and conducted by the Agricultural Research Service ([ARS](#)) and the Cooperative State Research, Education, and Extension Service ([CSREES](#)), with input from other government agencies, academia, and stakeholders, in order to improve efficiency in the use of resources, and effectiveness in application of research results to better improve food safety.

In order to improve coordination with ongoing research efforts in food safety, the Research, Education, and

Economics ([REE](#)) mission area of USDA is planning to host a food safety research agenda symposium. The symposium will help initiate the development of a unified research agenda to complement industry and academic research as well as encourage external research directed toward this unified agenda. FSIS has created a new position of Strategic Manager for Research and Technology Transfer. The Agency has also recruited and hired a senior ARS scientist-veterinarian into this position. This new FSIS scientist will greatly facilitate FSIS communication and coordination with its USDA and other research partners.

Best Practices for Animal Production.

In consultation with livestock producers, researchers, and other stakeholders, FSIS is developing a list of best management practices for animal production facilities such as feedlots to provide guidance in reducing pathogen loads before slaughter. FSIS is planning a symposium in coming months as a foundation for the development of guidelines that can be followed at the feedlot by producers to minimize carriage of human pathogens by food animals.

Baseline Studies.

FSIS is making plans to conduct continuous baseline studies to determine the nationwide prevalence and levels of various pathogenic microorganisms in raw meat and poultry. In the past, limited baseline studies have been used to establish performance standards. While these performance standards have not been directly correlated with public health outcomes, they are an important part of verifying the sanitary operation of meat and poultry establishments.

The new baseline studies will take into account regional variation, seasonality and other critical factors. The continual nature of the baseline studies will provide both benchmark information on the national trends and a tool to assess performance of initiatives designed to reduce the level and prevalence of pathogens in meat and poultry products. These baseline studies will also provide important information for conducting risk assessments that support regulatory initiatives for reducing foodborne illness. These surveys will be important in establishing the link between foodborne disease and ecological niches, as well as levels and incidence of pathogens in meat and poultry. The net result will be more targeted interventions and effective elimination of sources of foodborne microorganisms.

Modernization of Enforcement Activities.

A strong system of checks and balances is important to an effective food safety system. FSIS will continue to review authorities and regulations and will continue to work with interested parties to modernize and further enhance its compliance efforts.

Achieving the Next Level of the Food Safety Vision:

Emergence of previously unrecognized human pathogens, as well as new trends in food distribution and consumption, have prompted FSIS to consider the need for novel strategies to reduce the health risks associated with pathogenic microorganisms in meat, poultry, and egg products. Although great strides have been made in accomplishing FSIS' vision for food safety, it is necessary for us to pursue a course of action that will help us attain the next level of prevention, which is to predict, or anticipate, problems as much as possible before they arise. Toward this effort, FSIS intends to identify hazards early by analyzing prevalence and enforcement data, coupled with ensuring that the right corrective actions are taken promptly to minimize risks to public health.

Through analysis and discussions with stakeholders, FSIS has identified three issues that need to be addressed if FSIS is to attain this next level of public health protection.

Issue #1: Anticipate/Predict risk through enhanced data integration.

To anticipate hazards involving meat and poultry products, FSIS must have the best available data to clearly identify the extent and nature of these hazards, in order to determine and calibrate an effective response. These data consist of FSIS' regulatory samples, as well as samples collected by food processing establishments. Thus, there is a need to improve access to, and analysis of food safety data from all reliable sources. This must be achieved in a responsible manner that serves public health.

Issue #2: Improved application of risk into regulatory and enforcement activities.

FSIS recognizes the need to better document food safety problems as they occur, in order to analyze conditions that should be corrected in its science-based approach to pathogen reduction. For example, a better understanding of the prevalence and causes of food safety failures could allow FSIS to assess how best to address them. Data regarding the causes of food safety violations, either within a specific establishment, or within a class, can be utilized in order to better focus prevention and regulatory enforcement strategies.

Issue #3: Better association of program outcomes to public health surveillance data.

FSIS has made great strides in preventing foodborne illness, which CDC has attributed in part to the implementation of HACCP. For example, the preliminary FoodNet report for 1996-2002 notes that the decline in the rate of *S. Typhimurium* infections in humans coincided with a decline in the prevalence of *Salmonella* isolated from FSIS regulated products to levels below baseline levels before HACCP was implemented.

However, there still is a need to determine how specific policies affect public health. In order to accomplish this, data that links foodborne illness outbreaks with specific foods needs to be obtained and documented, so that it may be linked with prevalence data of specific pathogens in specific foods. The latter activity can be best accomplished through an ongoing commitment to conducting baseline studies for various foodborne hazards. As previously mentioned in this document, such an activity is one of the initiatives currently being pursued by FSIS. However, to complete the linkage with public health outcomes, a strong connection with human health surveillance data is needed.

Accomplishing this task will help point FSIS regulatory efforts towards focusing its inspection and enforcement on those practices where risk is deemed to be highest, resulting in a more efficient use of government resources. Toward this goal, FSIS is working with [CDC's National Center for Infectious Diseases](#) to design and support studies that enable definite connections to be made between occurrence of specific pathogens in specific foods and the occurrence of human foodborne illness.

The Agency intends to engage the scientific community, public health experts and all interested parties in an effort to identify science-based solutions with public health outcomes. It is FSIS' intention to pursue such a course of action in the coming months, in as transparent and inclusive a manner as possible. The resulting strategies should help FSIS continue to pursue its goals and achieve its mission of reducing foodborne illness.

**U.S. Food and Drug Administration
U.S. Department of Agriculture
March 3, 2000**

A Description Of The U.S. Food Safety System

The following interagency paper was prepared as the U.S.'s March 2, 2000 submission to the Organization for Economic Cooperation and Development (OECD), which requested descriptions of member countries' food safety systems. The documents will be used to prepare an international food safety paper for OECD use.

- This page is a mirror of the page at <http://www.foodsafety.gov/~fsg/fssyst2.html>
- **Annex 1** and **Annex 2** are now available at <http://www.foodsafety.gov/~fsg/fssystem.html>.
- Any updates or additional information will be posted on the U.S. Codex Office "[What's New?](#)" page .

I. Synthesis: The United States Food Safety System

The United States Constitution prescribes the responsibilities of the government's three branches: executive, legislative and judicial, which all have roles that underpin the nation's food safety system. Congress, the legislative branch, enacts statutes designed to ensure the safety of the food supply. Congress also authorizes executive branch agencies to implement statutes, and they may do so by developing and enforcing regulations. When enforcement actions, regulations, or policies lead to disputes, the judicial branch is charged to render impartial decisions. General U.S. laws and statutes and Presidential Executive Orders establish procedures to ensure that regulations are developed in a transparent and interactive manner with the public. Characteristics of the U.S. food safety system include the separation of powers among these three branches and transparent, science-based decision-making, and public participation.

The U.S. food safety system is based on strong, flexible, and science-based federal and state laws and industry's legal responsibility to produce safe foods. Federal, state, and local authorities have complementary and interdependent food safety roles in regulating food and food processing facilities. The system is guided by the following principles: (1) only safe and wholesome foods may be marketed; (2) regulatory decision-making in food safety is science-based; (3) the government has enforcement responsibility; (4) manufacturers, distributors, importers and others are expected to comply and are liable if they do not; and (5) the regulatory process is transparent and accessible to the public. As a result, the U.S. system has high levels of public confidence.

Precaution and science-based risk analyses are long-standing and important traditions of U.S. food safety policy and decision-making. U.S. food safety statutes, regulations, and policies are risk-based and have precautionary approaches embedded in them.

The agencies' well-qualified science and public health experts work cooperatively to ensure the safety of U.S. food. Scientists from outside government are regularly consulted to provide additional recommendations regarding technical and scientific methods, processes, and analyses used by regulators. The cutting-edge science that informs U.S. regulators is routinely shared internationally through interactions with organizations like the Codex Alimentarius Commission, World Health Organization, and the Food and Agriculture Organization.

The U.S. routinely and effectively deals with technological advances, emerging problems, and food safety incidents. It is enhancing early warning systems about pathogens in food. The legislation granting authorities to agencies generally enables them to revise regulations and guidance consistent with advances in technology, knowledge, and need to protect consumers.

U.S. food agencies are accountable to the President, to the Congress which has oversight authority, to the courts which review regulations and enforcement actions, and to the public, which regularly exercises its right to participate in the development of statutes and regulations by communicating with legislators, commenting on proposed regulations, and speaking out publicly on food safety issues.

II. United States Food Safety System

Introduction

The U.S. food safety system is based on strong, flexible, science-based laws and industry's legal responsibility to produce safe foods. Coordinated interactions among federal authorities having complementary and interdependent food safety missions, in partnership with their state and local government counterparts, provide a comprehensive and effective system. The implementation of the statutes and the food safety system over many years has resulted in very high levels of public confidence in the safety of food in the U.S.

Principal federal regulatory organizations responsible for providing consumer protection are the Department of Health and Human Services' (DHHS) Food and Drug Administration (FDA), the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) and Animal and Plant Health Inspection Service (APHIS), and the Environmental Protection Agency (EPA). The Department of Treasury's Customs Service assists the regulatory authorities by checking and occasionally detaining imports based on guidance provided. Many agencies and offices have food safety missions within their research, education, prevention, surveillance, standard-setting, and/or outbreak response activities, including DHHS's Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH); USDA's Agricultural Research Service (ARS); Cooperative State Research, Education, and Extension Service (CSREES); Agricultural Marketing Service (AMS); Economic Research Service (ERS); Grain Inspection, Packers and Stockyard Administration (GIPSA); and the U.S. Codex office; and the Department of Commerce's National Marine Fisheries Service (NMFS).

The FDA is charged with protecting consumers against impure, unsafe, and fraudulently labeled food other than in areas regulated by FSIS. FSIS has the responsibility for ensuring that meat, poultry, and egg products are safe, wholesome, and accurately labeled. EPA's mission includes protecting public health and the environment from risks

posed by pesticides and promoting safer means of pest management. No food or feed item may be marketed legally in the U.S. if it contains a food additive or drug residue not permitted by FDA or a pesticide residue without an EPA tolerance or if the residue is in excess of an established tolerance. APHIS' primary role in the U.S. food safety network of agencies is to protect against plant and animal pests and diseases. FDA, APHIS, FSIS, and EPA also use existing food safety and environmental laws to regulate plants, animals, and foods that are the results of biotechnology.

A. Laws And Implementing Regulations

The three branches of U.S. government -- legislative, executive, and judicial -- all have roles to ensure the safety of the U.S. food supply. Congress enacts statutes designed to ensure the safety of the food supply and that establish the nation's level of protection. The executive branch departments and agencies are responsible for implementation, and may do so by promulgating regulations, which the U.S. publishes in the *Federal Register* and which are also electronically available. Characteristics of the U.S. food safety system are the separation of powers and science-based decision-making. Agency decisions under U.S. food safety laws can be appealed to the courts which are empowered to settle such disputes.

Food safety statutes enacted by Congress provide regulatory agencies with broad authority but also set limits on regulatory actions. The statutes are drafted to achieve specific objectives. Food safety agencies then develop regulations that give specific direction and establish specific measures. When new technologies, products, or health risks must be addressed, agencies have the flexibility to revise or amend regulations generally without need for new legislation. Agencies are able to maintain their state-of-the-art scientific methods and analyses because changes of this type can be made at the administrative/technical level.

Major U.S. food safety authorizing statutes include the Federal Food, Drug, and Cosmetic Act (FFDCA), the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), the Egg Products Inspection Act (EPIA), Food Quality Protection Act (FQPA), and Public Health Service Act.

Procedural statutes, which regulatory agencies must follow, include the Administrative Procedure Act (APA), the Federal Advisory Committee Act (FACA), and the Freedom Of Information Act (FOIA). The APA specifies requirements for rulemaking (i.e., the process by which federal agencies formulate, amend, or repeal a regulation and the process permitting any interested party to petition for the issuance, amendment, or repeal of a regulation). Substantive regulations promulgated by an agency under the APA have the force and effect of law. FACA requires that certain kinds of groups whose advice is relied upon by the government be chartered as advisory committees, that they be constituted to provide balance, to avoid a conflict of interest, and to hold committee meetings in public with an opportunity for comment from those outside the committee. The FOIA provides the public with a statutory right to access federal agency information.

U.S. food safety programs are risk-based to ensure the public is protected from health risks of unsafe foods. Decisions within these programs are inherently science-based and involve risk analyses. Risk assessment is useful in understanding the magnitude of the problem faced, and it assists the agency in determining an appropriate risk management response.

The regulatory development process is conducted in an open and transparent manner. Regulations are developed and revised in a public process that not only allows, but encourages, participation by the regulated industry, consumers, and other stakeholders throughout the development and promulgation of a regulation. In developing new regulations and revising existing regulations, the agencies often provide the public a preliminary discussion and opportunity for comment by publishing an Advance Notice of Proposed Rulemaking (ANPR). It lays out the issues, presents the agency's suggested resolution, and solicits alternative solutions. The information received from the public is used by the agency to decide whether and how to pursue rulemaking further. All significant public comments must be addressed in the final regulation. The next steps are publication of a proposed regulation and publication of a final regulation, which is enforceable, with opportunities for public comment. The APA requires that the final regulation be justified by policy rationale, scientific bases, and legal authority.

When confronted by a particularly complex issue where advice is needed from experts who are not part of the agency, the regulatory agency may choose to hold a public meeting or convene an advisory committee meeting. Open, public meetings, structured according to the agency's needs, bring together experts and stakeholders via an informal process. These meetings are used to receive the public's input on a specific subject area or on the agency's future programs. An advisory committee meeting is structured more formally. Public meetings and advisory committee meetings are announced in the *Federal Register* and the meetings are held in public unless an exempt issue, such as trade secrets, confidential commercial information, or personal medical information, is being discussed.

If a person or organization wishes to challenge an agency decision, the complainant may take the agency to court. Thus, even after an agency issues a final regulation which responds to all comments received, an individual or organization may still challenge the agency decision. This legal action involves the third branch of the federal government, the judicial branch. The judiciary (the federal court system) plays a critical role in the regulatory process in that it reviews an agency's action in light of the substantive law and procedural requirements. An independent judge or panel examines the whole agency record of activity detailing what the agency did and why. If the court finds that the agency did not follow its statutory mandates, fulfill the procedural requirements, or have a rational basis for its action, the judicial system can overturn the agency's action. The judicial system also serves as a forum for agency-initiated enforcement actions.

Just as it is the responsibility of the food industry to sell only safe food, it is likewise its responsibility to obey applicable laws and regulations.

B. Risk Analysis And the U.S.'s Precautionary Approach

1. Risk Analysis

Science and risk analysis are fundamental to U.S. food safety policymaking. In recent years, the federal government has focused more intently on risks associated with microbial pathogens and on reducing those risks through a comprehensive, farm-to-table approach to food safety. This policy emphasis was based on the conclusion that the risks associated with microbial pathogens are unacceptable and, to a large extent, avoidable; and that multiple interventions would be required throughout the farm-to-table chain to make real progress in reducing foodborne pathogens and the incidence of

foodborne disease. This effort followed many years of concentration on managing chemical hazards from the food supply by regulation of additives, drugs, pesticides, and other chemical and physical hazards considered potentially dangerous to human health. It reflects the recognition that the approaches to analyses and review of biological hazards and safety concerns differ from those presented by chemicals.

The President's Food Safety Initiative, announced in 1997, recognized the importance of risk assessment in achieving food safety goals. The Initiative called for all federal agencies with risk management responsibilities for food safety to establish the Interagency Risk Assessment Consortium. The Consortium is charged with advancing the science of microbial risk assessment by encouraging research to develop predictive models and other tools.

The U.S. government has completed a risk analysis on *Salmonella enteritidis* in eggs and egg products which included the first farm-to-table quantitative microbial risk assessment. It is also conducting a risk analysis for *E. coli* 0157:H7 in ground beef and has entered into a cooperative agreement with Harvard University for a risk assessment of the transmission of Bovine Spongiform Encephalopathy by foods. The U.S. is also carrying out a risk analysis for *Listeria monocytogenes* in a variety of ready-to-eat foods.

Regulatory agencies also have made progress in implementing various risk management strategies. An example can be found in Hazard Analysis Critical Control Point (HACCP) regulations. Instead of including in the text of the regulation those specific steps industry must take under a HACCP system, food safety agencies provide general requirements and direct those being regulated to apply the guidelines and develop specific steps to achieve an effective HACCP program. HACCP systems are a risk management tool because they enable the user to identify hazards reasonably likely to occur and to develop a comprehensive and effective plan to prevent or control those hazards.

Performance standards for pathogen reduction and control represent another risk management tool. For example, the U.S. has in place pathogen reduction performance standards for *Salmonella* that slaughter plants and raw ground product must meet, and it also tests product to ensure that these standards are met. In the future, the government may establish performance standards for other pathogens of public health concern and define what food establishments that produce, process, or handle food must achieve.

Fair and objective regulatory decisions regarding food safety standards and requirements rely on risk analysis performed by competent authorities, qualified to make scientifically sound decisions. Risk analysis consists of risk assessment, risk management, and risk communication, which are interdependent.

Risk Assessment – Risk assessments are conducted in an objective manner. However, since data and scientific knowledge on any issue are never totally complete, an assessment of absolute risk is impossible. By explicitly considering uncertainties in the data and analyses, decisions can be made regarding the amount of uncertainty that is acceptable. U.S. policy decisions on procedures used for risk assessment can also ensure that risks are unlikely to be underestimated.

The first component of risk assessment, hazard identification, requires decisions on the effort expended to identify hazards. In the U.S., these are established by law and experience. Laws regarding the use of new food ingredients or pesticides require a

prescribed effort to uncover any hazards before introduction into the food supply. For products already on the market, hazards may be identified by experience (e.g., emerging pathogens) that require efforts to control risk.

The second component, hazard characterization, considers data regarding the potential hazard at different exposure levels and modes, including which data are most relevant for characterizing the hazard. While human data are always most relevant, animal data are usually used to characterize a hazard. The U.S. generally relies on data from the most sensitive species to characterize the risk. Where a safety threshold cannot be assumed, the U.S. may rely on linear mathematical models that are not likely to underestimate a risk. It is important to use the most realistic data and models consistent with current scientifically sound knowledge. When information is not available that can identify which is most realistic, data or models that can be shown not to underestimate hazards are used.

The third component, exposure assessment, must differentiate between short term exposure for acute hazards and long term exposure for chronic hazards. For acute hazards, such as pathogens, data on levels of pathogens causing illness in vulnerable population groups are important. For chronic hazards, such as chemicals that may cause cumulative damage, a lifetime averaged exposure is relevant.

Risk Management – Risk management is exercised by highly qualified regulatory authorities with the sole objective to provide high levels of protection to the U.S. consumer. Management of risk is necessary when much, some, little, or no data are available thus requiring knowledgeable experienced experts capable of making scientifically defensible decisions in the interest of public health. Risk management principles are set by law or by the risk manager's expert judgement to reduce risk to the lowest practical, or achievable, level.

U.S. laws require that the safe use of a food additive, an animal drug, and a pesticide be established before marketing; therefore risk management decisions are based on very substantial scientific evidence. For hazardous substances that are inherent components of foods (e.g., low levels of natural toxicants produced in potatoes) or unavoidable contaminants of food (e.g., mercury in fish, aflatoxin in grains), government intervention occurs when presence of a substance reaches a level known to present significant risk. The quantity and quality of scientific evidence may vary with the type of risk management decision.

As an example of risk management, every year the U.S. federal food agencies work together to develop a comprehensive, risk-based, annual sampling plan to detect drug and chemical residues in U.S. food. Violative residue information is used as the basis for standard-setting and for enforcement and other follow-up activities.

Risk Communication – Routine risk communication is inherent in the transparent regulatory process which is more fully described in Part D entitled, "Transparency." Transparent standards are employed to ensure fairness to all members of the food industry while protecting public health. U.S. law requires the government to allow and consider comment on the factual basis for a decision when it establishes regulations. Anyone can comment, including persons outside the U.S. There must be a substantial basis in law and fact for every rule. Information relied on by the government is made available for anyone to review. Government scientists use public communication media to explain to the public the science behind regulations.

When there is a need for emergency risk communication, alerts are conveyed through a nationwide telecommunication system linking all levels of the food safety system with the nationwide media so all citizens are made aware of the risk, and through global information sharing mechanisms by which international organizations (WHO, FAO, Office of International Epizootics and the World Trade Organization, if appropriate), regions such as EU, and individual countries are informed immediately.

Risk communication is critical during the risk assessment and management stages. The U.S. is committed to openness and transparency of its work to protect the public from food-related health risks. For example, regulatory agencies provide public notification of recalls of food products. Information about recalls is also provided on the agency's website, as are frequent reports of regulatory and enforcement actions taken against regulated food establishments. EPA's pesticides website contains the full risk analysis for specific pesticides, and risk analyses procedures have been made available to the public for comment. Where appropriate, risk analyses processes have been modified in response to these comments.

Another example of risk management are U.S. federal agency activities on the emerging issue of resistance from the use of antimicrobials in animals. Antimicrobial risk management includes establishment of monitoring and resistance thresholds before a drug can be approved; continuous monitoring of resistance in enteric bacteria from humans and food animals; obtaining information on factors responsible for promoting resistance; and taking regulatory actions as needed, including restrictions on a drug or removing it from the market.

2. Precautionary Approach

(This approach is described in detail in the annex on Precaution In U.S. Food Safety Decision Making.)

The genesis of many health, safety, and environmental laws is associated with the prevention of undesirable events and the protection of public health and the environment. Specific prevention and protection measures reflect differing provisions of law, regulation, and circumstances. However, they all are risk-based. The precautionary approach is exercised in a variety of ways.

An example of the U.S. precautionary approach to risk is the control system for ingredients in food and feed, such as the feeding prohibition of certain animal proteins to ruminants to prevent the introduction of BSE in this country. In implementing this prohibition through a regulation, the government followed existing APA procedures to explain in the *Federal Register* why it is proposed to take the action, including a description of the risk, and to evaluate the comments received from industry, academia, private citizens, and government agencies before publishing its final regulation.

Another illustrative example of the precautionary approach is the pre-market approval requirements established by law for food additives, animal drugs, and pesticides. The products are not allowed on the market unless, and until, they are shown by producers to be safe to the satisfaction of the regulatory authorities. When the petition is reviewed, data are evaluated to determine exposure to the additive, including exposure to all likely impurities in the additive. The degree of testing considered necessary depends on the class of chemical and exposure. The data or the lack of data drive a decision for

approval. The evaluation of all is documented. The final decision explaining the basis for all significant conclusions is published in the *Federal Register*. Persons disagreeing with the decision may file an objection with the reasons for disagreeing and request a hearing. After administrative remedies for appeal are exhausted, the government may be challenged in court on its approval or denial of a petition.

C. Dealing With New Technologies, Products, and Responding to Problems

In achieving the nation's farm-to-table food safety objective, the federal government is only one part of the equation. Federal agencies collaborate with state and local agencies and other stakeholders to encourage food safety practices and to offer assistance to industry and consumers on practices that promote food safety.

The U.S. recognizes the regulated industry as a stakeholder and as the party principally responsible for food safety. Establishments are responsible for producing food products that meet regulatory requirements for safety. The government's role is to set appropriate standards and do what is necessary to verify that the industry is meeting those standards and other food safety requirements. Consistent with modernization of inspection systems and the farm-to-table initiatives, federal agencies use their resources as efficiently and effectively as possible to protect the public from foodborne illness. As an extension of HACCP, the U.S. is testing new meat and poultry inspection models to determine whether or not additional protections can be provided consumers through redeployment of some in-plant resources to the distribution segment of the farm-to-table chain, which includes transportation, storage, and retail sale of products.

Federal food safety agencies regularly enter into partnerships with states and others such as grower organizations and public interest groups to encourage improved production practices, to develop and foster food safety measures that can be taken on the farm and in marketing channels to decrease public health hazards in food, to develop and implement safer pest management practices, and to develop good agricultural practices to minimize pesticide residues and microbial risks.

The country's emergency response capability is sound and being enhanced continually. For example, U.S. food safety regulatory agencies participate in FoodNet, a network whose objectives are to determine the frequency and severity of foodborne diseases and the proportion of common foodborne diseases that result from eating specific foods and describe the epidemiology of new and emerging bacterial, parasitic, and viral foodborne pathogens.

Information on possible foodborne disease outbreaks from FoodNet and reports to state and local health departments are followed up by those health departments in cooperation with federal food agency authorities to determine the course and nature of the outbreak. Appropriate public advisories are issued and enforcement actions taken about the products involved as soon as possible.

In addition, a new technique has been developed using pulsed-field gel electrophoresis (PGE), which permits CDC to match distinctive patterns of pathogenic materials that cause foodborne illness. Using these "fingerprinting" techniques, the single casual factor of a foodborne illness outbreak can be traced using epidemiological investigation and PGE. This has led to intervention and, in at least one recent case, cessation of a serious foodborne illness outbreak. Both FoodNet and PulseNet are basic building blocks for the U.S. system of foodborne illness prevention.

D. Transparency

Various U.S. statutes and executive orders establish procedures to ensure that regulations are developed in an open, transparent, and interactive manner and that, as appropriate, the regulatory process is similarly open to the public. Regulations and their implementation must lead to fulfillment of objectives for the public good such as protecting health, safety, and environment.

The APA specifies requirements for rulemaking (i.e., the process by which federal agencies formulate, amend, or repeal a regulation and the process permitting any interested party to petition for the issuance, amendment, or repeal of a regulation). Substantive regulations promulgated by an agency under the APA have the force and effect of law. Under the APA, a notice of proposed rulemaking must be published in the *Federal Register*, an official daily publication which is available through subscription and through the Internet at no cost. All regulations and legal notices issued by federal agencies and the President are published in the *Federal Register*. In addition, though the Internet is not an official publication, U.S. government agencies make extensive use of it to provide information on regulatory activities and enhance the transparency of their processes.

The President issued an Executive Order to strengthen agencies' processes for promulgating regulations. Also, several states require analysis of the impacts of regulations: there are requirements to analyze the impact of the regulation on small business (the Regulatory Flexibility Act); the impact of the regulation on the environment (the National Environmental Policy Act); and the impact of any information collection requirements contained in the regulation (the Paperwork Reduction Act).

FACA requires that certain kinds of groups whose advice is relied upon by the government for establishing regulations be chartered as an advisory committee, be constituted to provide balance and to avoid conflicts of interest, and to hold its advisory meetings in public with an opportunity for comment from those outside the committee.

FOIA's purpose is to expand the areas of public access to information beyond those originally set forth in the APA. Any person residing in the United States has a right of access to a wealth of government information and records, subject only to certain limited exemptions.

To ensure the broadest possible participation by the public, agencies publish their proposals on Internet sites and call attention to the proposed or final rule through press releases. The U.S. news media and interest groups follow the *Federal Register* and agency Internet sites closely and publish information about proposed and final regulations. In addition, U.S. agencies may hold public meetings to solicit input from interested persons. Meetings often include media coverage. For example, numerous public meetings were held to solicit input on the Food Safety Strategic Plan being developed by the President's Council on Food Safety; on the draft Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables; as part of the process to develop the Food Safety Initiative; and on bioengineered foods, among other topics.

Regulatory agencies often offer guidance on ways to achieve compliance with regulatory requirements. Such guidance may describe situations where a food could become adulterated or misbranded or may describe data that would be needed to establish safety. Although such guidance does not have the effect of law (one need not follow it to

demonstrate that a food is safe and lawful, provided that all statutory and regulatory requirements are met), such advice is helpful to the food industry and to the consumer.

The Codex Alimentarius Commission (Codex) is the major international body for promoting the health and economic interests of consumers while encouraging fair international trade in food. Within the United States, Codex activities are coordinated by officials from USDA, HHS, and EPA. The U.S. Codex Office provides information via the *Federal Register* and the Internet concerning the Codex and its activities internationally and in the U.S.

E. System Accountability

U.S. food agencies are highly accountable to government's three branches and to the people:

- U.S. food agencies are accountable to the President – the chief executive – who has constitutional responsibility to assure that laws are faithfully executed; who appoints senior officials, and whose Office of Management and Budget clears significant regulations.
 - U.S. food agencies are accountable to the Congress, the legislative branch of the U.S. government, which provides the food agencies their authority and budget; whole committees hold frequent oversight hearings; and the Senate must confirm the nomination of cabinet officers and senior officials.
 - U.S. food agencies are accountable to the courts, the judicial branch of the U.S. government, which review food agency regulations and enforcement actions.
 - Most importantly, U.S. food agencies are accountable directly to members of the public, who regularly exercise their right to participate in the development of laws and regulations, such as commenting on proposed regulations; whose guidance is sought in frequent public meetings; and who provide strong support for food safety regulation, the nutrition label, and other regulatory initiatives.
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U. S. Department of Health and Human Services
U. S. Food and Drug Administration
FDA Backgrounder
September 24, 1998

(This document also available in [other languages](#).)

Food Safety: A Team Approach

[Food and Drug Administration](#) | [Centers for Disease Control and Prevention](#)
[Food Safety and Inspection Service](#) | [Cooperative State Research, Education, and Extension Service](#)
[National Agricultural Library, USDA/FDA Foodborne Illness Education Information Center](#)
[Environmental Protection Agency](#) | [National Oceanic and Atmospheric Administration](#)
[Bureau of Alcohol, Tobacco and Firearms](#) | [U.S. Customs Service](#)
[U.S. Department of Justice](#) | [Federal Trade Commission](#)
[State and Local Governments](#)

September 24, 1998

The United States maintains one of the world's safest food supplies, thanks in large part to an interlocking monitoring system that watches over food production and distribution at every level-locally, statewide and nationally.

Continual monitoring is provided by food inspectors, microbiologists, epidemiologists, and other food scientists working for city and county health departments, state public health agencies, and various federal departments and agencies. Their precise duties are dictated by local, state and national laws, guidelines and other directives. Some monitor only one kind of food, such as milk or seafood. Others work strictly within a specified geographic area. Others are responsible for only one type of food establishment, such as restaurants or meat-packing plants. Together they make up the U.S. food safety team.

The Clinton administration's Food Safety Initiative, begun in 1997, strengthens the efforts of all the members of the nation's food safety team in the fight against food-borne illness, which afflicts between 6.5 million and 33 million Americans every year. One of the initiative's major programs got under way in May 1998 when the Department of Health and Human Services (which includes FDA), the U.S. Department of Agriculture, and the Environmental Protection Agency signed a memorandum of understanding to create a Food Outbreak Response Coordinating Group, or FORC-G. The new group will:

- increase coordination and communication among federal, state and local food safety agencies
- guide efficient use of resources and expertise during an outbreak
- prepare for new and emerging threats to the U.S. food supply.

Besides federal officials, members of FORC-G include the Association of Food and Drug Officials, National Association of City and County Health Officials, Association of State and Territorial Public Health Laboratory Directors, Council of State and Territorial Epidemiologists, and National Association of State Departments of Agriculture.

The following table offers a closer look at the nation's food safety lineup. The agencies listed in the table also work with other government agencies, such as the Consumer Product Safety Commission to enforce the Poison Prevention Packaging Act, the FBI to enforce the Federal Anti-Tampering Act, the Department of Transportation to enforce the Sanitary Food Transportation Act, and the U.S. Postal Service to enforce laws against mail fraud.

U.S. Department of Health and Human Services *

Food and Drug Administration

Oversees

- All domestic and imported food sold in interstate commerce, including shell eggs, but not meat and poultry
- Bottled water
- Wine beverages with less than 7 percent alcohol

Food Safety Role

Enforces food safety laws governing domestic and imported food, except meat and poultry, by:

- Inspecting food production establishments and food warehouses and collecting and analyzing samples for physical, chemical and microbial contamination
- Reviewing safety of food and color additives before marketing
- Reviewing animal drugs for safety to animals that receive them and humans who eat food produced from the animals
- Monitoring safety of animal feeds used in food-producing animals
- Developing model codes and ordinances, guidelines and interpretations and working with states to implement them in regulating milk and shellfish and retail food establishments, such as restaurants and grocery stores. An example is the model Food Code, a reference for retail outlets and nursing homes and other institutions on how to prepare food to prevent food-borne illness.
- Establishing good food manufacturing practices and other production standards, such as plant sanitation, packaging requirements, and Hazard Analysis and Critical Control Point programs
- Working with foreign governments to ensure safety of certain imported food products
- Requesting manufacturers to recall unsafe food products and monitoring those recalls
- Taking appropriate enforcement actions

- Conducting research on food safety
- Educating industry and consumers on safe food handling practices

For More Information

Consumers: Call toll-free 1-888-INFO-FDA (1-888-463-6332).

Regional FDA offices, listed in the blue pages of the phone book under U.S. Government

Media inquiries: 202-205-4144

Consumers:
FDA's Outreach and Information Center
1-888-SAFEFOOD (1-888-723-3366)

www.cfsan.fda.gov/list.html

www.fda.gov/cvm/

Centers for Disease Control and Prevention

Oversees

- All foods

Food Safety Role

- Investigates with local, state and other federal officials sources of food-borne disease outbreaks
- Maintains a nationwide system of food-borne disease surveillance: Designs and puts in place rapid, electronic systems for reporting food-borne infections. Works with other federal and state agencies to monitor rates of and trends in food-borne disease outbreaks. Develops state-of-the-art techniques for rapid identification of food-borne pathogens at the state and local levels.
- Develops and advocates public health policies to prevent food-borne diseases
- Conducts research to help prevent food-borne illness
- Trains local and state food safety personnel

For More Information

Centers for Disease Control and Prevention
1600 Clifton Rd., N.E.
Atlanta, GA 30333

Media inquiries: 404-639-3286

General public: 404-639-3311

www.cdc.gov

* Also, HHS's National Institutes of Health conduct food safety research.

U.S. Department of Agriculture **

Food Safety and Inspection Service

Oversees

- Domestic and imported meat and poultry and related products, such as meat- or poultry-containing stews, pizzas and frozen foods
- Processed egg products (generally liquid, frozen and dried pasteurized egg products)

Food Safety Role

Enforces food safety laws governing domestic and imported meat and poultry products by:

- Inspecting food animals for diseases before and after slaughter
- Inspecting meat and poultry slaughter and processing plants
- With USDA's Agricultural Marketing Service, monitoring and inspecting processed egg products
- Collecting and analyzing samples of food products for microbial and chemical contaminants and infectious and toxic agents
- Establishing production standards for use of food additives and other ingredients in preparing and packaging meat and poultry products, plant sanitation, thermal processing, and other processes
- Making sure all foreign meat and poultry processing plants exporting to the United States meet U.S. standards
- Seeking voluntary recalls by meat and poultry processors of unsafe products
- Sponsoring research on meat and poultry safety
- Educating industry and consumers on safe food-handling practices

For More Information

FSIS Food Safety Education and Communications Staff
Room 1175, South Building,

1400 Independence Ave., S.W.
Washington, DC 20250

Media inquiries: 202-720-9113

Consumers:

The Meat and Poultry Hotline, 1-800-535-4555
(In Washington, D.C., area, call 202-720-3333.)
TDD/TTY: 1-800-256-7072

www.fsis.usda.gov

Cooperative State Research, Education, and Extension Service

Oversees

- All domestic foods, some imported

Food Safety Role

- With U.S. colleges and universities, develops research and education programs on food safety for farmers and consumers

For More Information

Local cooperative extension services, listed in the blue pages of the phone book under county government

Cooperative State Research, Education and Extension Service
U.S. Department of Agriculture
Washington, DC 20250-0900
202-720-3029

www.reeusda.gov

National Agricultural Library USDA/FDA Foodborne Illness Education Information Center

Oversees

- All foods

Food Safety Role

- Maintains a database of computer software, audiovisuals, posters, games, teachers' guides and other educational materials on preventing food-borne illness

- Helps educators, food service trainers and consumers locate educational materials on preventing food-borne illness

For More Information

USDA/FDA Foodborne Illness Education Information Center
Food and Nutrition Information Center
National Agricultural Library/USDA
Beltsville, MD 20705-2351
301-504-5719

www.nal.usda.gov/fnic/

** Also, a number of other USDA agencies conduct food safety activities.

U.S. Environmental Protection Agency

Oversees

- Drinking water

Food Safety Role

Foods made from plants, seafood, meat and poultry

- Establishes safe drinking water standards
- Regulates toxic substances and wastes to prevent their entry into the environment and food chain
- Assists states in monitoring quality of drinking water and finding ways to prevent contamination of drinking water
- Determines safety of new pesticides, sets tolerance levels for pesticide residues in foods, and publishes directions on safe use of pesticides

For More Information

Environmental Protection Agency
401 M St., S.W.
Washington, DC 20460
202-260-2090

Regional EPA offices, listed in the blue pages of the phone book under U.S. Government

www.epa.gov

U.S. Department of Commerce

National Oceanic and Atmospheric Administration

Oversees

- Fish and seafood products

Food Safety Role

- Through its fee-for-service Seafood Inspection Program, inspects and certifies fishing vessels, seafood processing plants, and retail facilities for federal sanitation standards

For More Information

Seafood Inspection Program
1315 East-West Highway
Silver Spring, MD 20910
1-800-422-2750

seafood.nmfs.gov

U.S. Department of the Treasury

Bureau of Alcohol, Tobacco and Firearms

Oversees

- Alcoholic beverages except wine beverages containing less than 7 percent alcohol

Food Safety Role

- Enforces food safety laws governing production and distribution of alcoholic beverages
- Investigates cases of adulterated alcoholic products, sometimes with help from FDA

For More Information

Bureau of Alcohol, Tobacco and Firearms
Market Compliance Branch
650 Massachusetts Ave., N.W.
Room 5200
Washington, DC 20226
202-927-8130

www.atf.treas.gov/alcohol/index.htm

U.S. Customs Service

Oversees

- Imported foods

Food Safety Role

- Works with federal regulatory agencies to ensure that all goods entering and exiting the United States do so according to U.S. laws and regulations

For More Information

U.S. Customs Service

P.O. Box 7407

Washington, DC 20044

Media inquiries: 202-927-1770

General public: Contact local ports of entry, listed in the blue pages of the phone book under U.S. Government, Customs Services

www.customs.ustreas.gov

U.S. Department of Justice

Oversees

- All foods

Food Safety Role

- Prosecutes companies and individuals suspected of violating food safety laws
- Through U.S. Marshals Service, seizes unsafe food products not yet in the marketplace, as ordered by courts

For More Information

U.S. attorneys' offices in blue pages of phone book under U.S. Government

www.usdoj.gov

Federal Trade Commission

Oversees

- All foods

Food Safety Role

- Enforces a variety of laws that protect consumers from unfair, deceptive or fraudulent practices, including deceptive and unsubstantiated advertising.

For More Information

FTC (Federal Trade Commission)
Consumer Response Center, CRC-240
Washington, DC 20580

Media inquiries: 202-326-2180
TDD: 202-326-2502

Consumers: 202-FTC-HELP
(202-382-4357)

www.ftc.gov

State and Local Governments

Oversees

- All foods within their jurisdictions

Food Safety Role

- Work with FDA and other federal agencies to implement food safety standards for fish, seafood, milk, and other foods produced within state borders
- Inspect restaurants, grocery stores, and other retail food establishments, as well as dairy farms and milk processing plants, grain mills, and food manufacturing plants within local jurisdictions
- Embargo (stop the sale of) unsafe food products made or distributed within state borders

For More Information

City, county and state health, agriculture and environmental protection agencies, listed in the blue pages of the phone book under city, county and state government

*This is a mirror of the page formerly at
<<http://www.fda.gov/opacom/backgrounders/foodteam.html>>*

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FDA Backgrounder
May 3, 1999
Updated August 5, 2002

Milestones in U.S. Food and Drug Law History

From the beginnings of civilization people have been concerned about the quality and safety of foods and medicines. In 1202, King John of England proclaimed the first English food law, the Assize of Bread, which prohibited adulteration of bread with such ingredients as ground peas or beans. Regulation of food in the United States dates from early colonial times. Federal controls over the drug supply began with inspection of imported drugs in 1848. The following chronology describes some of the milestones in the history of food and drug regulation in the United States.

1820

Eleven physicians meet in Washington, D.C., to establish the **U.S. PHARMACOPEIA**, the first compendium of standard drugs for the United States.

1848

DRUG IMPORTATION ACT passed by Congress requires U.S. Customs Service inspection to stop entry of adulterated drugs from overseas.

1862

PRESIDENT LINCOLN appoints a chemist, Charles M. Wetherill, to serve in the new Department of Agriculture. This was the beginning of the Bureau of Chemistry, the predecessor of the Food and Drug Administration.

1880

PETER COLLIER, chief chemist, U.S. Department of Agriculture, recommends passage of a national food and drug law, following his own food adulteration investigations. The bill was defeated, but during the next 25 years more than 100 food and drug bills were introduced in Congress.

1883

DR. HARVEY W. WILEY becomes chief chemist, expanding the Bureau of Chemistry's food adulteration studies. Campaigning for a federal law, Dr. Wiley is called the "Crusading Chemist" and "Father of the Pure Food and Drugs Act." He retired from government service in 1912 and died in 1930.

1897

TEA IMPORTATION ACT passed, providing for Customs inspection of all tea entering U.S. ports, at the expense of the importers.

1898

Association of Official Agricultural Chemists (now AOAC International) establishes a **COMMITTEE ON FOOD STANDARDS** headed by Dr. Wiley. States begin incorporating these standards into their food statutes.

1902

The **BIOLOGICS CONTROL ACT** is passed to ensure purity and safety of serums, vaccines, and similar products used to prevent or treat diseases in humans.

Congress appropriates \$5,000 to the Bureau of Chemistry to study **CHEMICAL PRESERVATIVES AND COLORS** and their effects on digestion and health. Dr. Wiley's studies draw widespread attention to the problem of food adulteration. Public support for passage of a federal food and drug law grows.

1906

The original **FOOD AND DRUGS ACT** is passed by Congress on June 30 and signed by President Theodore Roosevelt. It prohibits interstate commerce in misbranded and adulterated foods, drinks and drugs.

The **MEAT INSPECTION ACT** is passed the same day.

Shocking disclosures of insanitary conditions in meat-packing plants, the use of poisonous preservatives and dyes in foods, and cure-all claims for worthless and dangerous patent medicines were the major problems leading to the enactment of these laws.

1907

First **CERTIFIED COLOR REGULATIONS**, requested by manufacturers and users, list seven colors found suitable for use in foods.

1911

In **U.S. v. JOHNSON**, the Supreme Court rules that the 1906 Food and Drugs Act does not prohibit false therapeutic claims but only false and misleading statements about the ingredients or identity of a drug.

1912

Congress enacts the **SHERLEY AMENDMENT** to overcome the ruling in *U.S. v. Johnson*. It prohibits labeling medicines with false therapeutic claims intended to defraud the purchaser, a standard difficult to prove.

1913

GOULD AMENDMENT requires that food package contents be "plainly and conspicuously marked on the outside of the package in terms of weight, measure, or numerical count."

1914

In *U.S. v. LEXINGTON MILL AND ELEVATOR COMPANY*, the Supreme Court issues its first ruling on food additives. It ruled that in order for bleached flour with nitrite residues to be banned from foods, the government must show a relationship between the chemical additive and the harm it allegedly caused in humans. The court also noted that the mere presence of such an ingredient was not sufficient to render the food illegal.

THE HARRISON NARCOTIC ACT requires prescriptions for products exceeding the allowable limit of narcotics and mandates increased record-keeping for physicians and pharmacists who dispense narcotics.

1924

In *U.S. v. 95 BARRELS ALLEGED APPLE CIDER VINEGAR*, the Supreme Court rules that the Food and Drugs Act condemns every statement, design, or device on a product's label that may mislead or deceive, even if technically true.

1927

The Bureau of Chemistry is reorganized into two separate entities. Regulatory functions are located in the **FOOD, DRUG, AND INSECTICIDE ADMINISTRATION**, and nonregulatory research is located in the **BUREAU OF CHEMISTRY AND SOILS**.

1930

McNARY-MAPES AMENDMENT authorizes FDA standards of quality and fill-of-container for canned food, excluding meat and milk products.

The name of the Food, Drug, and Insecticide Administration is shortened to **FOOD AND DRUG ADMINISTRATION (FDA)** under an agricultural appropriations act.

1933

FDA recommends a complete revision of the obsolete **1906 FOOD AND DRUGS ACT**. The first bill is introduced into the Senate, launching a five-year legislative battle.

1937

ELIXIR OF SULFANILAMIDE, containing the poisonous solvent diethylene glycol, kills 107 persons, many of whom are children, dramatizing the need to establish drug safety before marketing and to enact the pending food and drug law.

1938

THE FEDERAL FOOD, DRUG, AND COSMETIC (FDC) ACT of 1938 is passed by Congress, containing new provisions:

- Extending control to cosmetics and therapeutic devices.
- Requiring new drugs to be shown safe before marketing-starting a new system of drug regulation.
- Eliminating the Sherley Amendment requirement to prove intent to defraud in drug misbranding cases.
- Providing that safe tolerances be set for unavoidable poisonous substances.
- Authorizing standards of identity, quality, and fill-of-container for foods.
- Authorizing factory inspections.
- Adding the remedy of court injunctions to the previous penalties of seizures and prosecutions.

Under the **WHEELER-LEA ACT**, the Federal Trade Commission is charged with overseeing advertising associated with products otherwise regulated by FDA, with the exception of prescription drugs.

1939

FIRST FOOD STANDARDS issued (canned tomatoes, tomato purée, and tomato paste).

1940

FDA TRANSFERRED from the Department of Agriculture to the Federal Security Agency, with Walter G. Campbell appointed as the first Commissioner of Food and Drugs.

1941

INSULIN AMENDMENT requires FDA to test and certify purity and potency of this lifesaving drug for diabetes.

1943

In **U.S. v. DOTTERWEICH**, the Supreme Court rules that the responsible officials of a corporation, as well as the corporation itself, may be prosecuted for violations. It need not be proven that the officials intended, or even knew of, the violations.

1944

PUBLIC HEALTH SERVICE ACT is passed, covering a broad spectrum of health concerns, including regulation of biological products and control of communicable diseases.

1945

PENICILLIN AMENDMENT requires FDA testing and certification of safety and effectiveness of all penicillin products. Later amendments extended this requirement to all antibiotics. In 1983 such control was found no longer needed and was abolished.

1948

MILLER AMENDMENT affirms that the Federal Food, Drug, and Cosmetic Act applies to goods regulated by the Agency that have been transported from one state to another and have reached the consumer.

1949

FDA publishes **GUIDANCE TO INDUSTRY** for the first time. This guidance, "Procedures for the Appraisal of the Toxicity of Chemicals in Food," came to be known as the "black book."

1950

In **ALBERTY FOOD PRODUCTS CO. v. U.S.**, a court of appeals rules that the directions for use on a drug label must include the purpose for which the drug is offered. Therefore, a worthless remedy cannot escape the law by not stating the condition it is supposed to treat.

OLEOMARGARINE ACT requires prominent labeling of colored oleomargarine, to distinguish it from butter.

DELANEY COMMITTEE starts congressional investigation of the safety of chemicals in foods and cosmetics, laying the foundation for the 1954 Miller Pesticide Amendment, the 1958 Food Additives Amendment, and the 1960 Color Additive Amendment.

1951

DURHAM-HUMPHREY AMENDMENT defines the kinds of drugs that cannot be safely used without medical supervision and restricts their sale to prescription by a licensed practitioner.

1952

In **U.S. v. CARDIFF**, the Supreme Court rules that the factory inspection provision of the 1938 FDC Act is too vague to be enforced as criminal law.

FDA CONSUMER CONSULTANTS are appointed in each field district to maintain communications with consumers and ensure that FDA considers their needs and problems.

1953

FEDERAL SECURITY AGENCY becomes the Department of Health, Education, and Welfare (HEW).

FACTORY INSPECTION AMENDMENT clarifies previous law and requires FDA to give manufacturers written reports of conditions observed during inspections and analyses of factory samples.

1954

MILLER PESTICIDE AMENDMENT spells out procedures for setting safety limits for pesticide residues on raw agricultural commodities.

First large-scale **RADIOLOGICAL EXAMINATION OF FOOD** carried out by FDA when it received reports that tuna suspected of being radioactive was being imported from Japan following atomic blasts in the Pacific. FDA begins monitoring around the clock to meet the emergency.

1955

HEW SECRETARY OVETA CULP HOBBY appoints a committee of 14 citizens to study the adequacy of FDA's facilities and programs. The committee recommends a substantial expansion of FDA staff and facilities, a new headquarters building, and more use of educational and informational programs.

The **DIVISION OF BIOLOGICS CONTROL** became an independent entity within the National Institutes of Health, after polio vaccine thought to have been inactivated is associated with about 260 cases of polio.

1958

FOOD ADDITIVES AMENDMENT enacted, requiring manufacturers of new food additives to establish safety. The Delaney proviso prohibits the approval of any food additive shown to induce cancer in humans or animals.

FDA publishes in the Federal Register the first list of **SUBSTANCES GENERALLY RECOGNIZED AS SAFE (GRAS)**. The list contains nearly 200 substances.

1959

U.S. CRANBERRY CROP recalled three weeks before Thanksgiving for FDA tests to check for aminotriazole, a weedkiller found to cause cancer in laboratory animals.

Cleared berries were allowed a label stating that they had been tested and had passed FDA inspection, the only such endorsement ever allowed by FDA on a food product.

1960

COLOR ADDITIVE AMENDMENT enacted, requiring manufacturers to establish the safety of color additives in foods, drugs and cosmetics. The Delaney proviso prohibits the approval of any color additive shown to induce cancer in humans or animals.

FEDERAL HAZARDOUS SUBSTANCES LABELING ACT, enforced by FDA, requires prominent label warnings on hazardous household chemical products.

1962

THALIDOMIDE, a new sleeping pill, is found to have caused birth defects in thousands of babies born in western Europe. News reports on the role of Dr. Frances Kelsey, FDA medical officer, in keeping the drug off the U.S. market, arouse public support for stronger drug regulation.

KEFAUVER-HARRIS DRUG AMENDMENTS passed to ensure drug efficacy and greater drug safety. For the first time, drug manufacturers are required to prove to FDA the effectiveness of their products before marketing them. The new law also exempts from the Delaney proviso animal drugs and animal feed additives shown to induce cancer but which leave no detectable levels of residue in the human food supply.

CONSUMER BILL OF RIGHTS is proclaimed by President John F. Kennedy in a message to Congress. Included are the right to safety, the right to be informed, the right to choose, and the right to be heard.

1965

DRUG ABUSE CONTROL AMENDMENTS are enacted to deal with problems caused by abuse of depressants, stimulants and hallucinogens.

1966

FDA contracts with the National Academy of Sciences/National Research Council to evaluate the **EFFECTIVENESS OF 4,000 DRUGS** approved on the basis of safety alone between 1938 and 1962.

CHILD PROTECTION ACT enlarges the scope of the Federal Hazardous Substances Labeling Act to ban hazardous toys and other articles so hazardous that adequate label warnings could not be written.

FAIR PACKAGING AND LABELING ACT requires all consumer products in interstate commerce to be honestly and informatively labeled, with FDA enforcing provisions on foods, drugs, cosmetics, and medical devices.

1968

FDA BUREAU OF DRUG ABUSE CONTROL and Treasury Department Bureau of Narcotics are transferred to the Department of Justice to form the Bureau of Narcotics and Dangerous Drugs (BNDD), consolidating efforts to police traffic in abused drugs.

REORGANIZATION of federal health programs places FDA in the Public Health Service.

FDA forms the **DRUG EFFICACY STUDY IMPLEMENTATION (DESI)** to implement recommendations of the National Academy of Sciences investigation of effectiveness of drugs first marketed between 1938 and 1962.

ANIMAL DRUG AMENDMENTS place all regulation of new animal drugs under one section of the Food, Drug, and Cosmetic Act-Section 512-making approval of animal drugs and medicated feeds more efficient.

1969

FDA begins administering **SANITATION PROGRAMS** for milk, shellfish, food service, and interstate travel facilities, and for preventing poisoning and accidents. These responsibilities were transferred from other units of the Public Health Service.

The **WHITE HOUSE CONFERENCE ON FOOD, NUTRITION, AND HEALTH** recommends systematic review of GRAS substances in light of FDA's ban of the artificial sweetener cyclamate. President Nixon orders FDA to review its GRAS list.

1970

In **UPJOHN v. FINCH** the Court of Appeals upholds enforcement of the 1962 drug effectiveness amendments by ruling that commercial success alone does not constitute substantial evidence of drug safety and efficacy.

FDA requires the first **PATIENT PACKAGE INSERT**: oral contraceptives must contain information for the patient about specific risks and benefits.

The **COMPREHENSIVE DRUG ABUSE PREVENTION AND CONTROL ACT** replaces previous laws and categorizes drugs based on abuse and addiction potential compared to their therapeutic value.

ENVIRONMENTAL PROTECTION AGENCY established; takes over FDA program for setting pesticide tolerances.

1971

PHS BUREAU OF RADIOLOGICAL HEALTH transferred to FDA. Its mission: protection against unnecessary human exposure to radiation from electronic products in the home, industry, and the healing arts.

NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH is established in the biological facilities of the Pine Bluff Arsenal in Arkansas. Its mission is to examine biological effects of chemicals in the environment, extrapolating data from experimental animals to human health.

Artificial sweetener **SACCHARIN**, included in FDA's original GRAS list, is removed from the list pending new scientific study.

1972

OVER-THE-COUNTER DRUG REVIEW begun to enhance the safety, effectiveness and appropriate labeling of drugs sold without prescription.

REGULATION OF BIOLOGICS-including serums, vaccines, and blood products-is transferred from NIH to FDA.

1973

THE U.S. SUPREME COURT upholds the 1962 drug effectiveness law and endorses FDA action to control entire classes of products by regulations rather than to rely only on time-consuming litigation.

LOW-ACID FOOD PROCESSING regulations issued, after botulism outbreaks from canned foods, to ensure that low-acid packaged foods have adequate heat treatment and are not hazardous.

CONSUMER PRODUCT SAFETY COMMISSION created by Congress; takes over programs pioneered by FDA under 1927 Caustic Poison Act, 1960 Federal Hazardous Substances Labeling Act, 1966 Child Protection Act, and PHS accident prevention activities for safety of toys, home appliances, etc.

1976

MEDICAL DEVICE AMENDMENTS passed to ensure safety and effectiveness of medical devices, including diagnostic products. The amendments require manufacturers to register with FDA and follow quality control procedures. Some products must have pre-market approval by FDA; others must meet performance standards before marketing.

VITAMINS AND MINERALS AMENDMENTS ("Proxmire Amendments") stop FDA from establishing standards limiting potency of vitamins and minerals in food supplements or regulating them as drugs based solely on potency.

1977

SACCHARIN STUDY AND LABELING ACT passed by Congress to stop FDA from banning the chemical sweetener but requiring a label warning that it has been found to cause cancer in laboratory animals.

1980

INFANT FORMULA ACT establishes special FDA controls to ensure necessary nutritional content and safety.

1982

TAMPER-RESISTANT PACKAGING REGULATIONS issued by FDA to prevent poisonings such as deaths from cyanide placed in Tylenol capsules. The Federal Anti-Tampering Act passed in 1983 makes it a crime to tamper with packaged consumer products.

FDA publishes first **RED BOOK** (successor to 1949 "black book"), officially known as Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food.

1983

ORPHAN DRUG ACT passed, enabling FDA to promote research and marketing of drugs needed for treating rare diseases.

1984

FINES ENHANCEMENT LAWS of 1984 and 1987 amend the U.S. Code to greatly increase penalties for all federal offenses. The maximum fine for individuals is now \$100,000 for each offense and \$250,000 if the violation is a felony or causes death. For corporations, the amounts are doubled.

DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT expedites the availability of less costly generic drugs by permitting FDA to approve applications to market generic versions of brand-name drugs without repeating the research done to prove them safe and effective. At the same time, the brand-name companies can apply for up to five years additional patent protection for the new medicines they developed to make up for time lost while their products were going through FDA's approval process.

1985

AIDS TEST FOR BLOOD approved by FDA in its first major action to protect patients from infected donors.

1986

CHILDHOOD VACCINE ACT requires patient information on vaccines, gives FDA authority to recall biologics, and authorizes civil penalties.

1987

INVESTIGATIONAL DRUG REGULATIONS REVISED to expand access to experimental drugs for patients with serious diseases with no alternative therapies.

1988

FOOD AND DRUG ADMINISTRATION ACT of 1988 officially establishes FDA as an agency of the Department of Health and Human Services with a Commissioner of Food and Drugs appointed by the President with the advice and consent of the Senate, and broadly spells out the responsibilities of the Secretary and the Commissioner for research, enforcement, education, and information.

THE PRESCRIPTION DRUG MARKETING ACT bans the diversion of prescription drugs from legitimate commercial channels. Congress finds that the resale of such drugs leads to the distribution of mislabeled, adulterated, subpotent, and counterfeit drugs to the public. The new law requires drug wholesalers to be licensed by the states; restricts reimportation from other countries; and bans sale, trade or purchase of drug samples, and traffic or counterfeiting of redeemable drug coupons.

GENERIC ANIMAL DRUG AND PATENT TERM RESTORATION ACT extends to veterinary products benefits given to human drugs under the 1984 Drug Price Competition and Patent Term Restoration Act. Companies can produce and sell generic versions of animal drugs approved after October 1962 without duplicating research done to prove them safe and effective. The act also authorizes extension of animal drug patents.

1989

FDA issued a nationwide recall of all over-the-counter dietary supplements providing 100 milligrams or more of **L-TRYPTOPHAN**. The recall was instituted because of a clear link between the consumption of L-tryptophan tablets and its association with a U.S. outbreak of Eosinophilia-Myalgia Syndrome (EMS) in 1989. Symptoms of EMS include fatigue, shortness of breath, rash, swelling of the extremities, and in some cases congestive heart failure. By 1990, The Centers for Disease Control and Prevention confirmed over 1,500 cases of EMS with 38 deaths. Officials estimate that there may have been 3,000-10,000 unreported cases. Numerous trace levels of impurities were identified in the L-tryptophan implicated in many of the EMS cases and the links between L-tryptophan and EMS are still being investigated in the laboratory. **In 1990** FDA put an import alert in place prohibiting its importation.

1990

NUTRITION LABELING AND EDUCATION ACT requires all packaged foods to bear nutrition labeling and all health claims for foods to be consistent with terms defined by the Secretary of Health and Human Services. The law preempts state requirements about food standards, nutrition labeling, and health claims and, for the first time, authorizes some health claims for foods. The food ingredient panel, serving sizes, and terms such as "low fat" and "light" are standardized.

SAFE MEDICAL DEVICES ACT is passed, requiring nursing homes, hospitals, and other facilities that use medical devices to report to FDA incidents that suggest that a medical device probably caused or contributed to the death, serious illness, or serious injury of a patient. Manufacturers are required to conduct post-market surveillance on permanently implanted devices whose failure might cause serious harm or death, and to establish methods for tracing and locating patients depending on such devices. The act authorizes FDA to order device product recalls and other actions.

1991

Regulations published to **ACCELERATE THE REVIEW OF DRUGS** for life-threatening diseases.

1992

GENERIC DRUG ENFORCEMENT ACT imposes debarment and other penalties for illegal acts involving abbreviated drug applications.

PRESCRIPTION DRUG USER FEE ACT requires drug and biologics manufacturers to pay fees for product applications and supplements, and other services. The act also requires FDA to use these funds to hire more reviewers to assess applications.

MAMMOGRAPHY QUALITY STANDARDS ACT requires all mammography facilities in the United States to be accredited and federally certified as meeting quality standards effective Oct. 1, 1994. After initial certification, facilities must pass annual inspections by federal or state inspectors.

1994

DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT establishes specific labeling requirements, provides a regulatory framework, and authorizes FDA to promulgate good manufacturing practice regulations for dietary supplements. This act defines "dietary supplements" and "dietary ingredients" and classifies them as food. The act also establishes a commission to recommend how to regulate claims.

FDA announces it could consider **REGULATING NICOTINE** in cigarettes as a drug, in response to a Citizen's Petition by the Coalition on Smoking OR Health.

URUGUAY ROUND AGREEMENTS ACT extends the patent terms of U.S. drugs from 17 to 20 years.

ANIMAL MEDICINAL DRUG USE CLARIFICATION ACT allows veterinarians to prescribe extra-label use of veterinary drugs for animals under specific circumstances. In addition, the legislation allows licensed veterinarians to prescribe human drugs for use in animals under certain conditions.

1995

FDA declares **CIGARETTES** to be "drug delivery devices." Restrictions are proposed on marketing and sales to reduce smoking by young people.

1996

FEDERAL TEA TASTERS REPEAL ACT repeals the Tea Importation Act of 1897 to eliminate the Board of Tea Experts and user fees for FDA's testing of all imported tea. Tea itself is still regulated by FDA.

SACCHARIN NOTICE REPEAL ACT repeals the saccharin notice requirements.

ANIMAL DRUG AVAILABILITY ACT adds flexibility to animal drug approval process, providing for flexible labeling and more direct communication between drug sponsors and FDA.

FOOD QUALITY PROTECTION ACT amends the Food, Drug, and Cosmetic Act, eliminating application of the Delaney proviso to pesticides.

1997

FOOD AND DRUG ADMINISTRATION MODERNIZATION ACT reauthorizes the Prescription Drug User Fee Act of 1992 and mandates the most wide-ranging reforms in agency practices since 1938. Provisions include measures to accelerate review of devices, regulate advertising of unapproved uses of approved drugs and devices, and regulate health claims for foods.

1998

MAMMOGRAPHY QUALITY STANDARDS REAUTHORIZATION ACT continues 1992 Act until 2002.

First phase to **CONSOLIDATE FDA LABORATORIES** nationwide from 19 facilities to 9 by 2014 includes dedication of the first of five new regional laboratories.