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U.S. Food and Drug Administration

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## 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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