

The Regulatory Structure and the Role of Risk Analysis in the United States' Food Safety Agencies

미국의 식품 위해분석 조직체계 및 기관별 역할

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미국에서 식품안전의 책임은 연방정부와 주정부에 모두 부여되고 서로 영향을 받는다. 연방 수준에서 식품안전은 30종의 법률에 의해 관리되고, 약 15개의 기관들이 관여한다. 이들 중 가장 큰 규모의 기관이 식품의약품안전청(FDA)이다. FDA는 156,008개소의 관리업체(IOC 2010년), 연4.5천억불의 식품가치, 미국 식품공급의 약80%, 2,000건의 FDA 허가 서류 추가 등의 복합시스템에 대해 책임을 지고 있다. 나머지 국내식품공급의 20%는 농업부에서 관리하고 있다.

식품안전에 대한 1차적인 책임은 아래와 같은 8개 기관들에 있다: 보건복지부 산하의 FDA와 CDC, 농업부 산하의 FSIS, AMS, ARS, NIFA 및 국토안보부와 환경보호국.

미국의 식품안전체계에는 전략적인 디자인이 다소 결여되어있다. 예를 들면 닭육수는 생산업체는 FDA에 의해 몇 년에 한번 감시되는 반면, 소육수 생산업체는 USDA에 의해 매일 감시된다. 또한, 냉동치즈피자는 FDA에

서, 냉동페퍼로니피자는 USDA에서 관리되고 있다.

식품생산업체의 감시는 주정부에서 관할하고 있고, 50개 주정부 중 44개 주정부는 FDA와의 계약 체결을 통해 협력을 강화하고 있다. 각 주정부는 식품안전과 표시 프로그램을 보유하고, 연방정부와 주정부는 GMPs와 HACCP과 같은 식품안전프로그램을 실행한다. 또한 식품접객업소, 편의점, 기타 식품판매점 등을 감시한다. 그들은 식중독조사와 식품회수를 지휘하고, 주정부는 소비자불만에 대한 대응활동을 하며, 때로는 연방정부기관과 독립적으로 일을 하기도 하고, FDA 및 CDC와 밀접하게 협력하기도 한다.

이번 원고에는 위해분석 분야에서의 USDA와 FDA의 역할이 구체적으로 기술되어 있다.

미국의 식품안전체계는 복잡하고 다원화되어 있으나, 효율적인 시스템의 많은 속성들을 보유하고 있으며, HACCP 및 위해분석과

같이 과학에 근거한 접근을 위해 의도적으로 움직이고 있다. 그러나 어떤 경우에는 모니터링조사, 감시, 실행, 집단사고관리, 연구와 교육 등의 중요한 식품 관련 기능을 가진 기관에서 특유한 입법역사에 의해 과학에 근거한 실행력과 행정력이 제한받기도 한다.

1998년 IOM위원회는 미국의 식품안전체계에 대한 연구결과를 바탕으로 아래와 같이 제안하였다.

첫째, 효과적이고 능률적인 식품안전체계는 과학에 근거해야 한다.

둘째, 과학에 근거를 둔 식품안전체계를 달

성하기 위하여 식품안전 관련 규정과 관리에 대한 현재 법령은 수정되어야 한다.

셋째, 과학에 근거한 체계를 실행하기 위하여 연방의 식품안전 노력의 개편이 요구된다.

결론적으로 IOM위원회는 현재의 문제를 해결하기에는 미국의 다원화된 조직구조가 부적합하다는 것을 표명하였다. 위원회는 기관의 일원화까지는 권장하지는 않더라도 이를 위한 노력에 대한 연방정부의 책임을 요구하였고, 식품안전에 할당된 자원관리를 제안하였다. 즉, 식품안전에 대한 한 목소리의 필요성이 강조되었다.

Introduction

Food safety responsibilities in the United States have been shaped and affected by its Federal/State/Local government structure. Each level of government has assumed different responsibilities in a bewildering array of variations. At the Federal level of government, the focus of this paper, there are about fifteen agencies that administer at least 30 laws related to food safety. The largest of these is the Food and Drug Administration (FDA). They have responsibility for a complex system of more than 156,008 FDA-regulated firms (IOC, 2010) producing \$450 billion worth of food annually, about 80 percent of the U.S. food supply and an additional 2,000 FDA licensed feed mills (Behnke, 2009). The remaining 20 percent of the domestic food

supply is regulated by the other agencies, the more significant of those being in the U.S. Department of Agriculture. Food protection in the US, which includes food quality, food safety, and food defense (Yoe, et al, 2009), involves many parties, however, including suppliers, farmers, food handlers, processors, wholesalers and retailers, food service companies, consumers, and third-party organizations, as well as government agencies in the United States and abroad.

The major agencies and their responsibilities are summarized in Table 1 below. Eight of the listed agencies have primary responsibility for ensuring food safety. Two of them are under the Department of Health and Human Services (DHHS); they are the FDA and the Centers for Disease Control and Prevention (CDC). Four

agencies come under the Department of Agriculture (USDA); they are the Food Safety and Inspection Service (FSIS), the Agricultural Marketing Service (AMS), the Agricultural Research Service (ARS), and the National Institute of Food and Agriculture (NIFA). The

Table 1: U.S. Government Food Safety Agency Responsibilities

Federal Agency	Responsibility
<p>○ FDA Food and Drug Administration (under the Department of Health and Human Services [DHHS])</p>	<p>Oversees all domestic and imported food sold in interstate commerce, including shell eggs, but not meat and poultry, bottled water, and wine beverages with less than 7 percent alcohol. Also 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 the safety of food and color additives before marketing; reviewing animal drugs for the safety of animals that receive them and humans who eat food produced from the animals; monitoring the safety of animal feed used for 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 (e.g., the model Food Code, a reference for retail outlets and nursing homes and other institutions on how to prepare food to prevent foodborne illness); establishing good food manufacturing practices and other production standards, such as plant sanitation and packaging requirements and Hazard Analysis and Critical Control Points (HACCP) programs; working with foreign governments to ensure the 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; and educating industry and consumers on safe foodhandling practices. FDA uses risk-based practices.</p>
<p>○ CDC Centers for Disease Control and Prevention (under the Department of Health and Human Services [DHHS])</p>	<p>Prevents disease, disability, and death caused by a wide range of infectious diseases and:</p> <ul style="list-style-type: none"> • Investigates with local, state, and other federal officials sources of foodborne disease outbreaks. • Maintains a nationwide system of foodborne disease surveillance (designs and puts in place rapid, electronic systems for reporting foodborne infections; works with other federal and state agencies to monitor rates of

〈Table 1〉

Federal Agency	Responsibility
	<p>and trends in foodborne disease outbreaks; develops state-of-the-art techniques for rapid identification of foodborne pathogens at the state and local levels).</p> <ul style="list-style-type: none"> • Develops and advocates for public health policies to prevent foodborne diseases. • Conducts research to help prevent foodborne disease. Trains local and state food safety personnel.
○ USDA Department of Agriculture	Primarily responsible for meat, poultry, and egg products; see descriptions that follow.
– USDA/AMS Agricultural Marketing Service	Provides standardization, grading, and market news services for five commodities: dairy, fruits and vegetables, livestock and seed, poultry, and cotton and tobacco. Enforces such federal laws as the Perishable Agricultural Commodities Act and Country-of-Origin-Labeling. AMS’s National Organic Program develops, implements, and administers national production, handling, and labeling standards for organic agricultural products.
– USDA/APHIS Animal and Plant Health Inspection Service	Responsible for monitoring/surveillance of egg products; risk assessment and data collection for pesticides; inspections/enforcement for the pesticide record-keeping program, including border quarantine activities to detect and eliminate animal health problems and exotic organisms that might harm U.S. agriculture, many of which also pose potential food safety threats. APHIS uses risk-based approaches for import quarantine.
– USDA/ARS Agricultural Research Service	Provides data for food products and contaminants (fruits and vegetables, dairy products, eggs/egg products, meat/poultry, seafood, grain/rice/related products, imported foods, animal drugs/feeds, and pesticide residues) to support risk assessment by the Food Safety and Inspection Service (FSIS), the Economic Research Service (ERS), the Office of Risk Assessment and Cost-Benefit Analysis (ORACBA), the FDA, and EPA; broad support of Land Grant Universities for research and education across all product areas; and education in the form of information to the National Agricultural Library (NAL) and educational workshops.
– USDA/NIFA National Institute of Food and Agriculture	Advances knowledge for agriculture, the environment, human health and well-being, and communities by supporting research, education, and extension programs in the Land Grant University System and other partner organizations. Does not perform actual research, education, and extension but helps fund them at the state and local levels and provides program leadership in these areas.

(Table 1)

Federal Agency	Responsibility
– USDA/ERS Economic Research Service	Provides risk assessment for meat and poultry and data collection to support the pesticide risk assessment process, as well as technical assistance to identify education needs and to analyze the effectiveness of food safety education programs
– USDA/FSIS Food Safety and Inspection Service	<p>Oversees domestic and imported meat and poultry and related products, such as meat– or poultry–containing stews, pizzas, and frozen foods, as well as processed egg products (generally liquid, frozen, and dried pasteurized egg products). Also enforces food safety laws governing domestic and imported meat and poultry products by:</p> <ul style="list-style-type: none"> • Inspecting food animals for diseases before and after slaughter; • Inspecting meat and poultry slaughter and processing plants; • Monitoring and inspecting processed egg products with USDA's Agricultural Marketing Service; • Collecting and analyzing samples of food products for microbial and chemical contaminants and infectious and toxic agents; • Establishing production standards for the 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 of unsafe products by meat and poultry processors; • Sponsoring research on meat and poultry safety; and • Educating industry and consumers on safe food–handling practices. <p>As of April, 2010, FSIS is responsible for mandatory inspection of catfish and catfish products. FSIS uses risk–based approaches.</p>
– USDA/GIPSA Grain Inspection, Packers, and Stockyards Administration	Through its oversight activities, including monitoring programs, reviews, and investigations, fosters fair competition, provides payment protection, and guards against deceptive and fraudulent trade practices that affect the movement and price of meat animals and their products. Protects consumers and members of the livestock, meat, and poultry industries. Its Federal Grain Inspection Service (FGIS) facilitates the marketing of U.S. grain and related agricultural products by establishing standards for quality assessments; regulating handling practices; and managing a network of federal, state, and private laboratories that provide impartial, user fee–funded official inspection and weighing services.

〈Table 1〉

Federal Agency	Responsibility
– USDA/ORACBA Office of Risk Assessment and Cost-Benefit Analysis	Reviews USDA risk assessments that relate to a major regulation that concerns human, health, safety or the environment and has an annual economic impact of at least \$100 million in 1994 dollars. Provides technical assistance to identify education needs and to analyze the effectiveness of food safety education programs.
– USDA/NAL National Agricultural Library/ USDA/FDA Foodborne Illness Education Information Center	Collects information on human nutrition and food to support USDA programs. These programs encompass areas as diverse as human nutritional needs, food production, safety and inspection, distribution, economics, and consumer education. Because of USDA's responsibility for food safety and inspection, NAL comprehensively collects works addressing risk analysis, foodborne illness, food toxicology, and food inspection. In addition, in support of USDA's close relationship and regulatory role with the food industry, NAL collects information on the food industry and technology, including food irradiation and biotechnology.
– USDA/NASS National Agricultural Statistics Service	Performs data collection for risk assessment of pesticides.
○ EPA Environmental Protection Agency	Oversees drinking water and certain aspects of 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 the quality of drinking water and finding ways to prevent contamination of drinking water; and determines the safety of new pesticides, sets tolerance levels for pesticide residues in foods, and publishes directions on the safe use of pesticides.
– EPA/OECA Office of Enforcement and Compliance Assistance	Responsible for inspection/enforcement of pesticide regulations, including the misuse of pesticides.
– EPA/OPPTS Office of Prevention, Pesticides and Toxic Substances	Responsible for risk assessment of pesticide residues in food, pesticide registration.
– EPA/ORD Office of Research and Development	Provides scientific support for pesticide-related public health issues.
○ DHS Department of Homeland Security	Leverages resources within federal, state, and local governments, coordinating the transition of multiple agencies and programs into a single, integrated agency focused on protecting the American people and their homeland.

(Table 1)

Federal Agency	Responsibility
– DHS/CBP Customs and Border Protection	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.
– DHS/OHA Office of Health Affairs	<ul style="list-style-type: none"> • Serves as DHS' s principal agent for all medical and health matters. • Leads veterinary and agro–defense activities, addressing animal and zoonotic diseases, as well as livestock, food, and water security issues.
○ DOJ Department of Justice	<ul style="list-style-type: none"> • Prosecutes companies and individuals suspected of violating food safety laws. • Through the U.S. Marshals Service, seizes unsafe food products not yet in the marketplace, as ordered by courts.
○ FTC Federal Trade Commission/Bureau of Consumer Protection	Protects consumers against unfair, deceptive, or fraudulent practices, including advertising claims for foods, drugs, dietary supplements, and other products promising health benefits.
○ NOAA/NMFS National Oceanic and Atmospheric Administration/ National Marine Fisheries Service (under the Department of Commerce [DOC])	Through its voluntary fee–for–service Seafood Inspection Program, inspects and certifies fishing vessels, seafood processing plants, and retail facilities for federal sanitation standards. Provides scientific oversight and system surveillance of the DOC inspection program and seafood HACCP training.
○ US DOT/BATF U.S. Department of the Treasury/Bureau of Alcohol, Tobacco, and Firearms	Oversees alcoholic beverages except wine containing less than 7 percent alcohol, enforces food safety laws governing the production and distribution of alcoholic beverages, and investigates cases of adulterated alcoholic products, sometimes with help from the FDA.

Source: Adapted from IOC (2010)

two remaining primary agencies are the Department of Homeland Security and the Environmental Protection Agency (GAO, 2004b,c, 2005, 2008a, 2009a).

The U.S. lacks an overall strategic design to its food safety system. The laws that govern food safety activities were based on issues as they arose or were recognized historically and the system developed in a rather ad hoc manner.

The Government Accounting Office of the U.S. Government says this circumstance has resulted in a fragmented and overlapping (e.g., inspections) system (GAO, 2004c). Not only are there overlaps, but significant gaps (e.g., FDA' s lack of mandatory recall authority) and contradictions have resulted as well.

For example, beef broth may be produced in a plant inspected by USDA on a daily basis while

Role of State and Local Government

States conduct inspections of food-manufacturing firms under contract to the FDA in 44 of the 50 states. Every state has both food safety and labeling programs. State and local governments implement food safety standards like Good Manufacturing Practices (GMPs) and Hazard Analysis and Critical Control Points (HACCP). They also inspect restaurants, grocery stores, and other retail food establishments. States collect and analyze many food product samples. They conduct foodborne outbreak investigations and participate in food recall events. States are most likely to act on consumer complaints. Their duties are sometimes independent of the Federal agencies but they also work in close cooperation with FDA and CDC.

chicken broth may be produced in a plant inspected by FDA once every several years. Frozen cheese pizza is regulated by FDA while frozen pepperoni pizza is regulated by USDA. All fish except catfish (USDA) fall under the jurisdiction of FDA. USDA considers a product with any *Listeria monocytogenes* to be adulterated. FDA has favored tolerance levels (below 100CFUs/gram of food) in foods that do not support growth of *Listeria monocytogenes* (FDA, 2008). The remainder of this paper will

describe the role of risk analysis in the two major food safety agencies, USDA and the FDA.

United States Department of Agriculture

The USDA has responsibilities far beyond the food safety responsibilities of the Food Safety Inspection Service (FSIS) and the Animal Plant Health Inspection Service (APHIS). The range of risk assessments conducted by USDA is rather broad and includes:

- Food Safety Risk
- Nutrition Risk
- Pest/Disease Risk
- Programmatic Risk Assessments for Pest Control Programs (human health and ecological risk)
- Biotechnology Risk Assessments
- Fire Risk
- Urban Tree Risk
- Pesticide, Nutrient Enrichment, Erosion Risk, Engineering failure

Risk assessments are required for all major USDA regulations affecting human health, safety or the environment. A major regulation is one that creates an annual economic impact of greater than \$100 million (measured in 1994 dollars). The Office of Risk Assessment and Cost-Benefit Analysis (ORACBA) reviews all of these risk assessments. The Federal Crop

Insurance Reform and Departmental Reorganization Act of 1994, which created ORACBA, requires regulatory risk assessments to analyze:

- The risk the proposed regulation addresses, including health and safety risks to persons disproportionately exposed or particularly sensitive;
- The costs of compliance with the proposed regulation;
- Comparison of the risk relative to other similar risks;
- Reduction or prevention of the risk due to the regulation;
- Cost effectiveness of proposed risk mitigation.

Food Safety and Inspection Service

The roles and responsibilities for risk analysis within FSIS are shown in Figure 1. The three key components of the risk analysis process along with the FSIS office responsible for implementing each component are shown. Risk assessments are conducted by risk assessors in the Risk Assessment Division, Office of Public Health Science. They will often receive support and help from other offices within FSIS and USDA. The Agricultural Research Service and the Economic Research Service, for example, provide risk assessment support to all of USDA including FSIS.

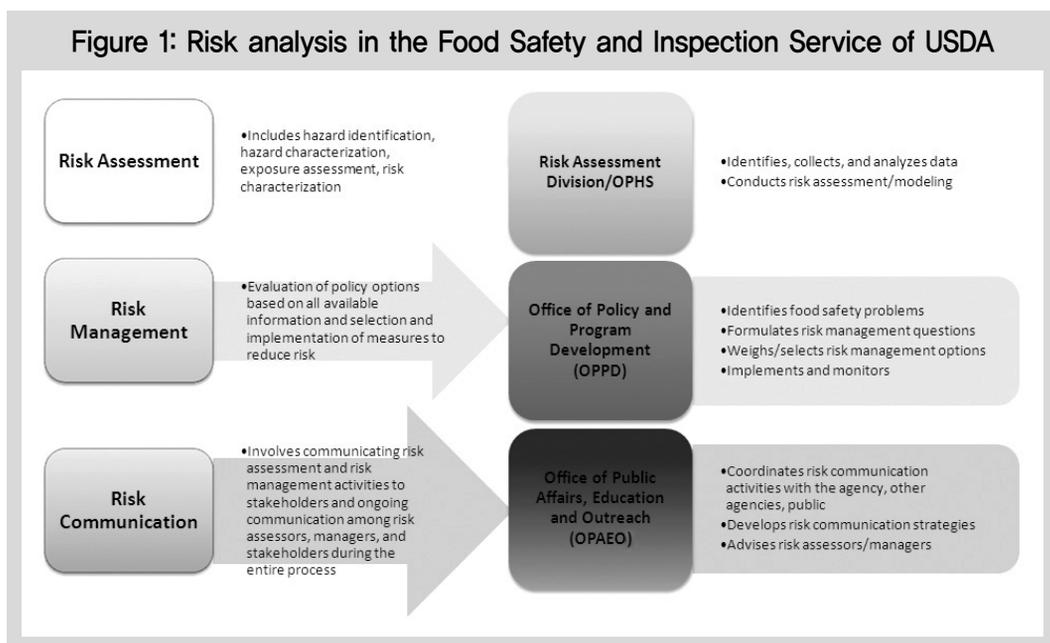
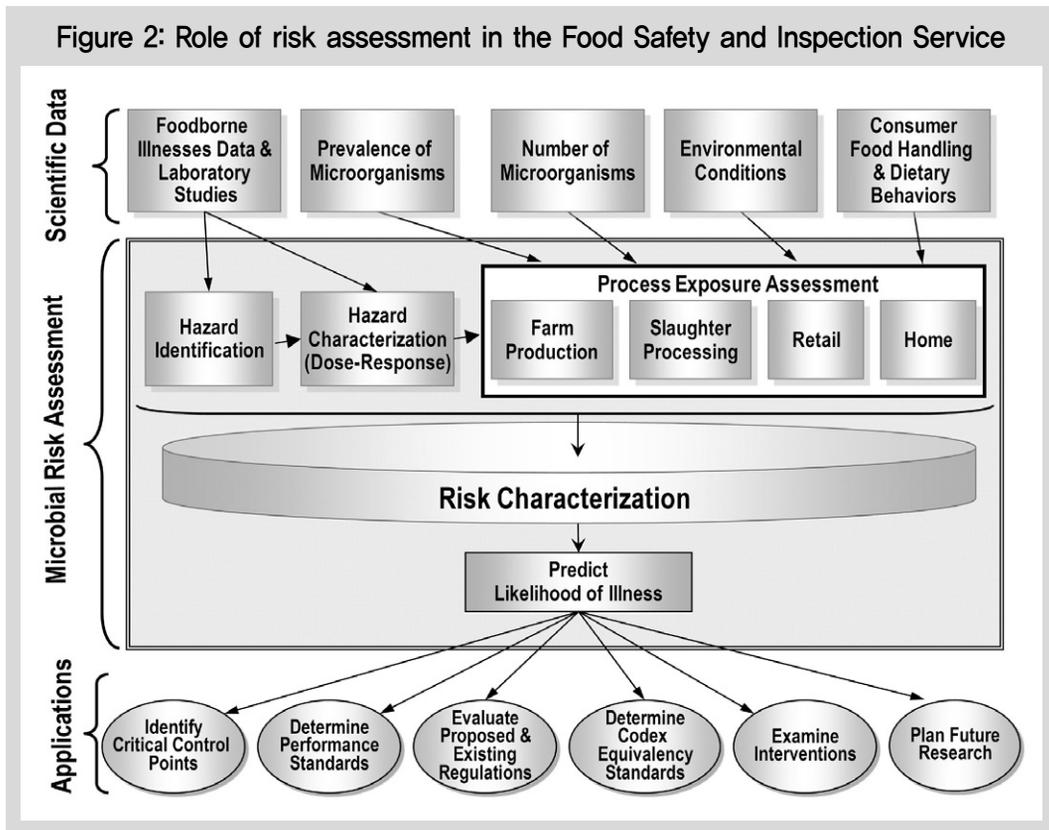


Figure 2: Role of risk assessment in the Food Safety and Inspection Service



Risk assessment plays a critical role in the work of FSIS. Figure 2 illustrates this role. Microbial risk assessment is supported by scientific data, much of which will be provided by other services within USDA. The steps of a typical risk assessment are shown in the center of the figure. The risk characterization, which usually presents a risk estimate, often in the form of a prediction of illnesses forms the basis for many of FSIS's functions. These include identifying such things as critical control points (CCPs) for processes, developing performance

standards, supporting regulations, and identifying future research needs. ORACBA will conduct a review of any FSIS risk assessment used to support a major regulation.

The risk managers from the Office of Policy and Program Development play a key role in risk management. These staff identify food safety problems, formulate the risk management questions to be addressed by the risk assessment, evaluate and select the risk management option or options, and implement and monitor any policy changes. Staff from the Office of Public

Affairs, Education, and Outreach coordinate risk communication activities within the agency, with other agencies, and with the public. They develop risk communication strategies, education, and outreach programs and also advise risk assessors and risk managers with regard to risk communication. Inspectors play a very important role in the risk analysis process in terms of collecting data that are used for risk assessments and implementing the agency's risk-based sampling algorithms.

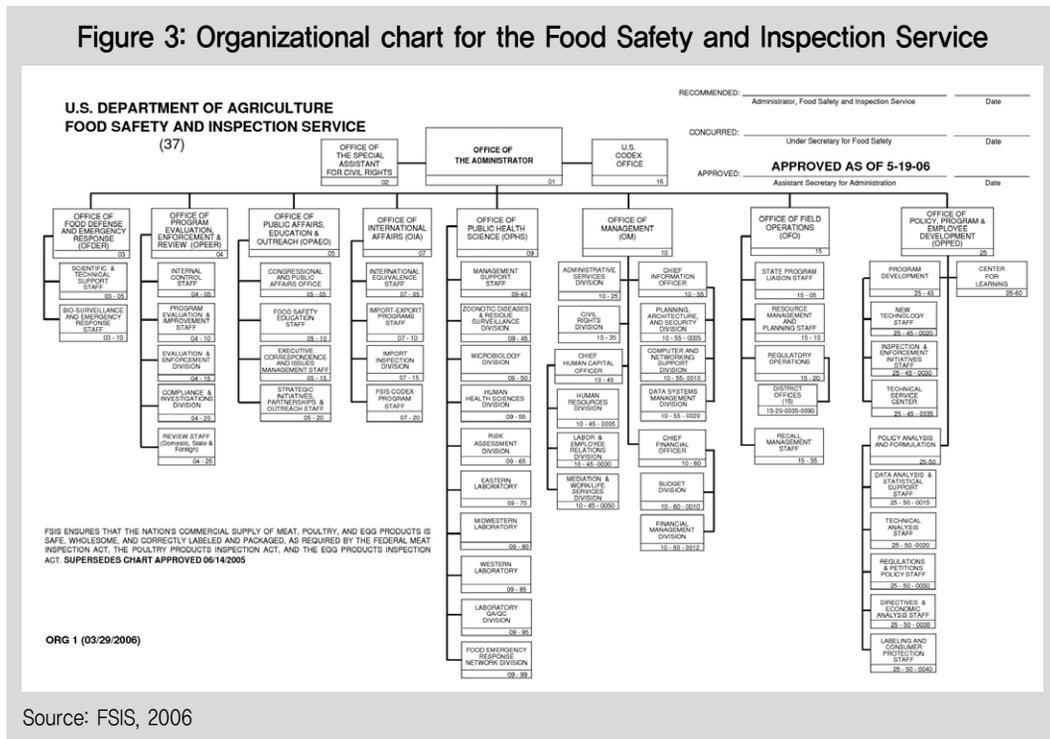
Figure 3 shows the structure of FSIS in 2006, the latest publicly available organizational chart. Notice that the primary responsibility for each of

the three risk assessment tasks rests in three different Offices.

Animal Plant Health Inspection Service (APHIS)

Broadly speaking APHIS protects American agriculture through a variety of programs including plant protection and quarantine, veterinary services, animal care, wildlife services, biotechnology regulatory services, and international services. This paper focuses on their responsibility to safeguard American agriculture

Figure 3: Organizational chart for the Food Safety and Inspection Service



Source: FSIS, 2006

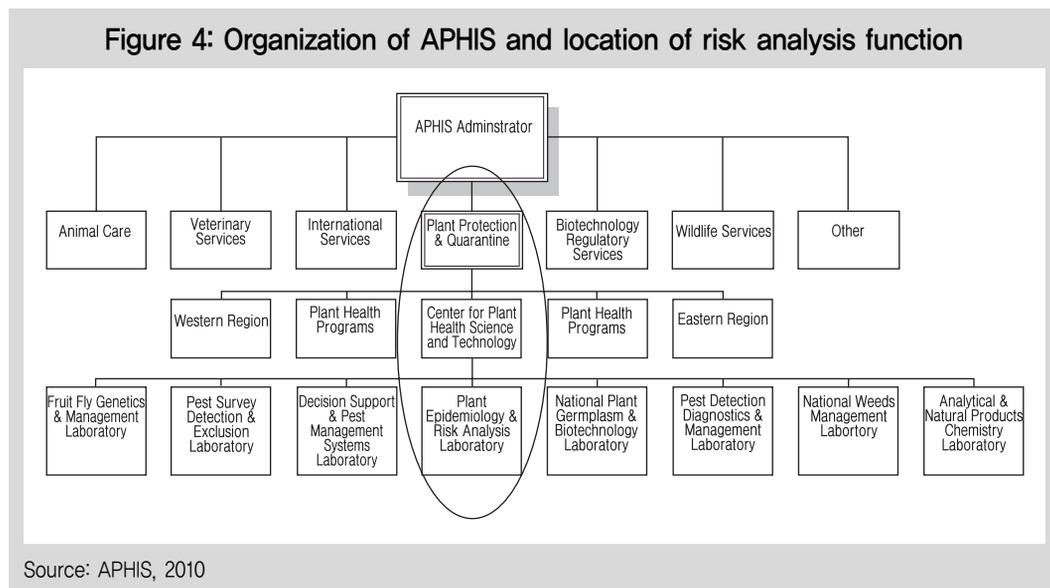
and natural resources from the risks associated with the entry, establishment, or spread of plant pests and noxious weeds. This is accomplished primarily through the use of pest risk assessments consistent with the guidance of the International Plant Protection Convention, which includes but is not limited to the guidance found in ISPM 2, ISPM 11, ISPM 14, and ISPM 5.

The basic organization of APHIS is shown in Figure 4. The activities of interest in this paper are conducted in Plant Protection and Quarantine (PPQ) where CPHST is primarily responsible for the risk analysis activity. PERAL is where most of the risk analysis is actually done. Some of their duties include:

- Develop/review pest risk analyses (PRA) for APHIS–PPQ;

- Analyze risk–based operational questions;
- Provide scientific support to facilitate exports;
- Evaluate new pests & imminent threats – New Pest Advisory Group;
- Identify and evaluate risk mitigation measures;
- Collect and manage pest risk information.

The language of risk analysis is not standardized across the many agencies that use the risk analysis framework. PPQ in essence parses risk management into two distinct functions using the terms “risk mitigation” and “risk management.” Risk mitigation is the term used to describe the identification and evaluation of measures to reduce risks while risk management is used to describe the negotiation

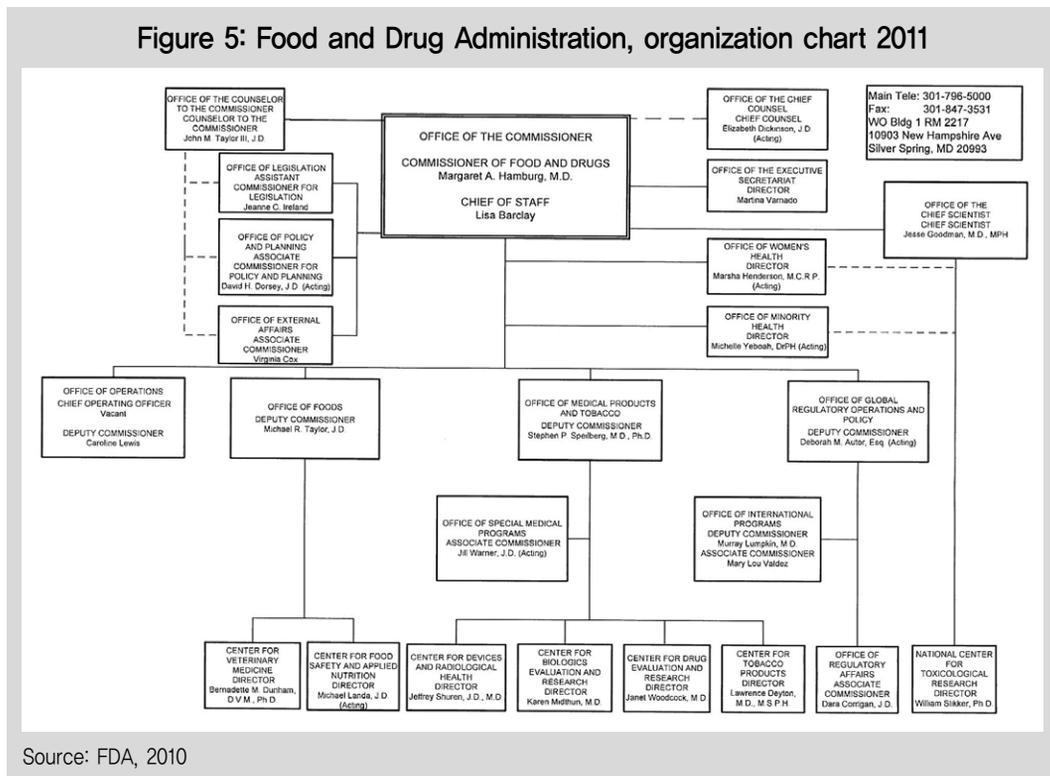


and decision-making process. The risk mitigation work is done within PERAL and PPQ. Within PPQ, the Phytosanitary Issues Management group, which is part of Plant Health Programs, is responsible for trade negotiations on behalf of APHIS-PPQ. This is where the Trade Directors work. Trade discussion and negotiations may, at times, take the risk management responsibility out of PPQ where it can go all the way up to the US Trade Representative.

Food and Drug Administration

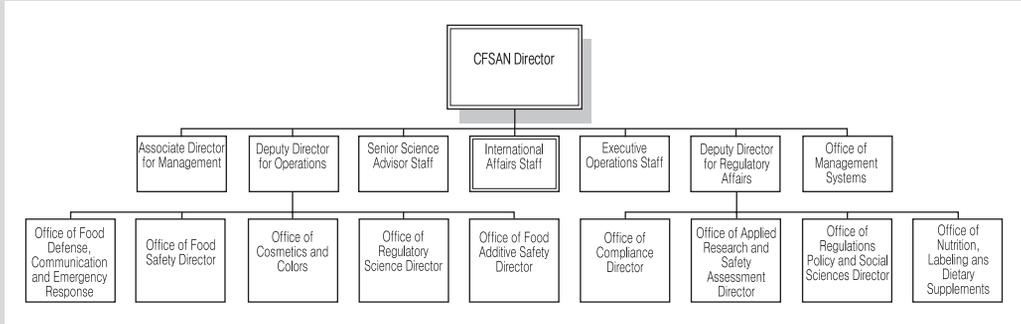
The FDA is a complex organization that is part of the Department of Health and Human Services. Figure 5 shows the basic organization of FDA. At the bottom of the chart are seven centers, which are the heart of the organization. One of these is the Center for Food Safety and Applied Nutrition (CFSAN), where FDA's food safety responsibilities are concentrated. Figure 6 shows the organization of CFSAN. The Center for Veterinary Medicine also has some responsibility for food safety, CVM's mission is

Figure 5: Food and Drug Administration, organization chart 2011



Source: FDA, 2010

Figure 6: Center for Food Safety and Applied Nutrition organization chart 2010



Source: Generated from information accessed on October 13, 2010 and found at <http://www.fda.gov/AboutFDA/CentersOffices/OrganizationCharts/ucm183491.htm>

protecting animal and human health.

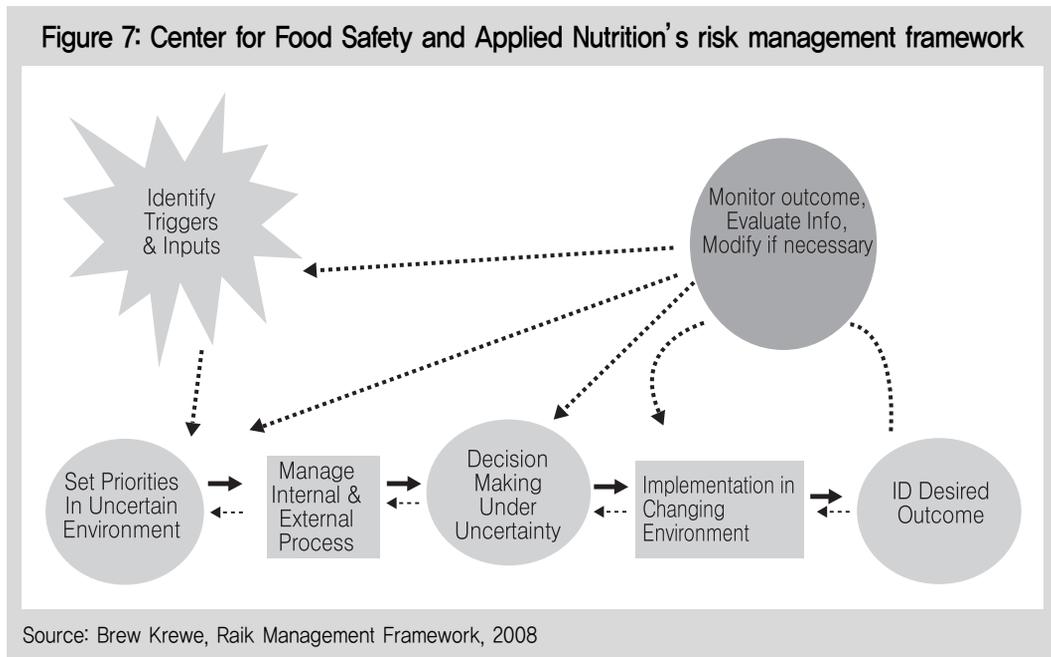
FDA CFSAN

CFSAN has been formally using risk-informed methods to manage food safety for over a decade. Less formal applications of risk-informed methods and techniques stretch back substantially longer than that. In 2009 the Office of Foods (see Figure 5) was created with a direct line of authority over both CFSAN and CVM. It is too soon to know exactly how that will impact the functioning of these units and the ultimate implementation of a risk-based food safety approach.

CFSAN has been conducting safety assessments for food additives for a long time. Food additive safety assessments have been characterized as risk assessments by Codex, the

Food Agricultural Organization (FAO) and the World Health Organization (WHO) since they first began discussing risk-based methods for food safety. In 2002 CFSAN took the major step of producing an internal report, Initiation and Conduct of All Major Risk Assessments within a Risk Analysis Framework. This report marks the first formal written commitment of CFSAN to engage in and conduct more complex quantitative microbial risk assessments. It followed the center's first quantitative risk assessment for pathogens completed in 1999. Based on the food safety community of practice principles of risk analysis (these are generally consistent with the principles as espoused by Codex, FAO, and WHO) it describes the CFSAN risk analysis framework and how to prioritize and conduct risk assessments within that framework.

In 2003 the center published CFSAN's Risk



Management Framework illustrated in Figure 7.

This, second internal document, describes the components of the risk management framework. All of the Center's employees were trained in the elements and use of this framework at the time it was initially introduced to the Center. CFSAN was quite aggressive in formalizing its commitment to risk analysis as a central part of its food safety strategy.

Risk-based activities are spread throughout the offices within CFSAN. The Risk Assessment Coordination Team (RACT) in the Office of Food Defense, Communication, and Emergency Response coordinates and manages risk profiles and assessments that require representation from different offices within CFSAN. They sometimes

coordinate efforts that reach outside of CFSAN and at times, the FDA.

Risk assessments are often performed by "virtual" teams formed to work on a specific risk issue. These teams are overseen by RACT, which also serves as a liaison to external stakeholders and partners which may include: federal, state, and local government; industry; consumer groups; and academia. RACT guides efforts to plan food safety risk analysis activities and related research. It also provides directions for the conduct and coordination of risk analysis activities related to food.]

The Chemical Hazards Assessment Team, housed in the Office of Food Safety, conducts safety and risk assessments of elemental and

organic industrial chemicals. This includes both naturally occurring contaminants and allergens.

Economists in the Office of Regulations, Policy and Social Sciences conduct economic impact analyses of and cost/benefit analyses for risk management decisions. These analyses are integrated with risk assessments to inform risk management decisions.

The Division of Field Programs and Guidance in the Office of Compliance coordinates and provides oversight for risk-related initiatives that impact field work planning, e.g. risk-based sampling. The Office of Food Additive Safety and the Office of Nutrition, Labeling, and Dietary Supplements are other offices at CFSAN that perform science-based food safety/risk assessments.

All of the risk analysis tasks (management, assessment, and communication) take place within the Center. The Center routinely produces safety assessments, risk profiles, qualitative and quantitative risk assessments, and risk/benefit analyses. Perhaps the most comprehensive effort to date is the joint FDA (CFSAN)-USDA (FSIS) (CFSAN/FSIS, 2003). Action items resulting from this risk assessment are still being developed and implemented. CFSAN provides a high level of support to international organizations, such as the Food and Agriculture Organization (FAO)/World Health Organization (WHO) and the Codex Alimentarius Commission. Its members have participated on the risk assessments they have

produced.

The FDA has also used risk assessments conducted by other agencies in formulating regulations. A recent example is the Shell Egg Rule, based on USDA's "Risk Assessments for Salmonella Enteritidis in Shell Eggs and Salmonella spp. in Egg Products." U.S. Environmental Protection Agency's (EPA) risk assessments have been used by the FDA to manage chemical contaminants in the food supply.

FDA is pioneering three applications of risk-based activities. These are:

- Public Health Risk Ranking
- Risk-Based Inspection
- Risk-Based Management of Imported Foods

In a cooperative agreement with the Institute of Food Technologists (IFT) FDA has developed a prototype risk-ranking methodology (iRisk) to produce a prediction of the relative level of risk to human health of selected hazard-food pairs based on a semiquantitative characterization of the disease burden, which can be used for comparison (ranking) purposes.

Like the FSIS, the FDA is developing models to help allocate resources to inspections. By identifying high-risk food categories field inspections and sample collection resources can be targeted to domestic food products and manufacturers that pose the greatest risk to public health. The Office of Regulatory Affairs (ORA)

has recently prioritized its inspection resources based on three categories: category 1, high-risk firm inspections; category 2, inspected plants with compliance issues; and category 3, low-risk industry blitzes.

The FDA has recently begun to develop a risk-based approach to managing the safety of food imports. The Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) is an import screening tool that is intended to automate decisions currently made by import entry reviewers by utilizing intelligence information from numerous sources so as to direct resources to products presenting the greatest risks to public health in a streamlined manner.

The CFSAN Risk Management Framework has established a process that relies on monitoring the effectiveness of risk management decisions through risk reduction outcomes. The DHHS Strategic Plan (2009) includes several Foodsafety-Related Outcome Indicators. These are:

- Reduce the incidence of infection with key foodborne pathogens: *Campylobacter* species. 2010. 12.3 cases/100,000 by December, 2011
- Reduce the incidence of infection with key foodborne pathogens: *Escherichia coli* O157:H7. 2010. 1.0 cases/100,000 by December, 2011
- Reduce the incidence of infection with key

foodborne pathogens: *Listeria monocytogenes*. 2010. 24 cases/100,000 by December, 2011

- Reduce the incidence of infection with key foodborne pathogens: *Salmonella* species. 2010 6.8 cases/100,000 by December, 2011

FDA CVM

The Center for Veterinary Medicine uses risk ranking and risk assessment in its regulatory process (Hartogenesis, 2009). One of the Center's risk management strategies is to prioritize activities aimed at reducing or mitigating risks according to the ranking of the risks as constrained by the limits of their authority and resources. Unlike CFSAN, CVM does not yet have a standardized process for conducting risk assessments (or rankings) for potential contaminants in feed or specific guidelines for risk ranking or prioritization.

The Office of New Drug Evaluation (ONADE), which reviews information and approves new drugs is also responsible for evaluating human health impacts that might result from the consumption of drug residues present in the tissues of food animals. In the past couple of years ONADE has been attempting to formalize a risk-based manner to perform this evaluation. In 2003, CVM began its Animal Feed Safety System (AFFS), a first step toward making

the agency's animal feed safety program more comprehensive and risk-based.

CVM sponsored one of the first known quantitative risk assessments for antimicrobial resistance (2001). They have continued their interest in antimicrobial resistance risk assessment and have developed a qualitative method for approaching the problem. Like CFSAN, CVM is very active in working with international organizations to affect guidance for veterinary-risks to humans.

Summary

The food safety system in the US is complex, fragmented and to a very great extent uncoordinated. It has many attributes of an effective system and is moving intentionally toward a more science-based approach with

HACCP and risk analysis. In some instances it is limited in its ability to implement practices and enforcement based in science by the peculiar legislative histories of the 15 or so agencies involved in key food functions of monitoring, surveillance, inspection, enforcement, outbreak management, research and education.

There is a long history of studies on food safety in the US since the middle of the last century. No less than eight studies¹⁾ have examined the desirability of uniting food safety under a single, independent agency. Each of these recommended revampings, most recommended federal food safety authority be concentrated in a single agency. The need for more coordination is universally recognized in the food safety community, if not yet throughout the food chain.

The 1998 study of the Institute of Medicine (IOM) offered three overriding conclusion to the

1) GAO (U.S. Government Accountability Office). 2004a. Federal Food Safety and Security System: Fundamental Restructuring is Needed to Address Fragmentation and Overlap. Washington, DC: GAO.

GAO. 2004b. Food Safety: USDA and FDA Need to Better Ensure Prompt and Complete Recalls of Potentially Unsafe Food. Washington, DC: GAO.

GAO. 2005. Oversight of Food Safety Activities: Federal Agencies Should Pursue Opportunities to Reduce Overlap and Better Leverage Resources. Washington, DC: GAO.

GAO. 2008a. Federal Oversight of Food Safety: FDA Has Provided Few Details on the Resources and strategies Needed to Implement its Food Protection Plan. Washington, DC: GAO.

GAO. 2008b. Federal Oversight of Food Safety: FDA's Food Protection Plan Proposes Positive First steps, but Capacity to Carry Them Out is Critical. Washington, DC: GAO.

IOM (Institute of Medicine). 2009. HHS in the 21st Century: Charting a New Course for a Healthier America. Washington, DC: The National Academies Press.

IOM. 2010. Enhancing Food Safety: The Role of the Food and Drug Administration. Washington, DC: National Academy Press.

IOM/NRC (IOM/National Research Council). 1998. Ensuring Safe Food: From Production to Consumption. Washington, DC: National Academy Press.

U.S. Congress as a result of its study of the U.S. food safety system. They were:

1. An effective and efficient food safety system must be based on science. (Risk analysis was recognized as the cornerstone of such a science-based system.)
2. To achieve a food safety system based on science, current statutes governing food safety regulation and management must be revised.
3. To implement a science-based system, reorganization of federal food safety efforts is required.

Importantly, for this paper, the IOM committee found the current fragmented regulatory structure of the US was not well-equipped to meet the current challenges. The committee, perhaps a bit too-intimated by the failure of previous efforts, stopped short of recommending single agency. They did, however, recommend that one official be responsible for federal efforts in food safety and that official ought to have control of the resources allocated to food safety. Food safety needs to speak with a single voice.