Driving the Fox from the Henhouse

Improving Oversight of Food Safety at the FDA and USDA

The Scientific Integrity Program of the
Union of Concerned Scientists

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Union of Concerned Scientists
Citizens and Scientists for Environmental Solutions

The Union of Concerned Scientists (UCS) is the leading science-based nonprofit working for a healthy environment and a safer world.

The UCS Scientific Integrity Program mobilizes scientists and citizens alike to defend science from political interference and restore scientific integrity in federal policy making. To learn more, visit *www.ucsusa.org/scientific_integrity*.

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Contents

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Chapter 1. Introduction

A Serious and Worsening Problem

Americans are fortunate to enjoy a food supply that is among the safest in the world—the result of decades of advances in public health practice and technological innovations in the food industry. Yet there is significant room for improvement, as attested by the August 2010 recall of shell eggs because of Salmonella contamination as well as by other headline-raising events in recent memory, such as the 2006 outbreak of illness due to *Escherichia coli* in spinach. Yet these events are merely the tip of the iceberg; large nationwide food recalls are an ever-present experience for consumers.

It is difficult to measure the overall burden of foodborne disease, as illnesses often remain unreported and untreated, but that burden is believed to be substantial. While many of the annual estimated 76 million cases of foodborne illness in the United States are mild, they cause more than 300,000 hospitalizations and some 5,000 deaths (Mead et al 1999).[*] Tragically, severe cases often involve the most vulnerable members of our society—the young, the elderly, and those with suppressed immune systems.

Dozens of pathogens are known to cause foodborne illness, which vary widely in their prevalence and the seriousness of their consequences. They include bacteria (such as *Campylobacter*), viruses (norovirus, for example), and parasites (e.g., *Giardia*). Most people affected by foodborne pathogens experience mild nausea, diarrhea, and stomach cramps. But in severe cases, the infection can lead to complications such as intestinal bleeding and kidney failure (CDC 2010b). These pathogens may contaminate a food at any point in the production process (CDC 2010a).

Foodborne illnesses create not only a physical burden; they also have a significant economic impact on society. A 2000 study of the U.S. Department of Agriculture (USDA) estimated that the "economic costs of medical care, productivity losses, and premature deaths" from five major pathogens amounted to $6.9 billion annually (Golan et al. 2005, ERS 2000). A more recent study by a former Food and Drug Administration (FDA) economist puts the total price tag of foodborne illnesses in the United States at $152 billion annually (Scharff 2010).

In many respects, the problem is getting even worse. In the United States, our food system is increasingly industrial and global. Without a doubt, this trend has increased the variety of available foods—imports now make fresh produce available year-round—but the trend has also complicated the origins of what we find on store shelves. That processed TV dinner, representing the tail end of a very long global supply chain, could contain ingredients from hundreds of locations. This increasing globalization creates foodborne outbreaks today that are more widespread and difficult to contain than in the past. In 2009, when peanut butter paste was contaminated with *Salmonella*, 3,918 food products had to be recalled nationwide (CDC 2009a).

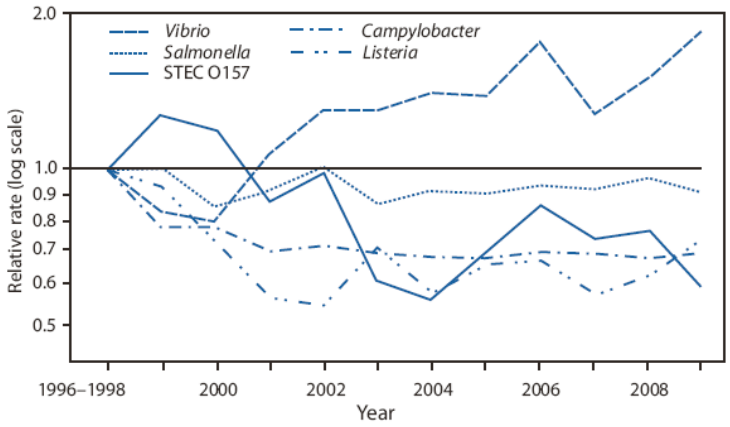
Toward a Safer Food Supply

The threat of unsafe food is an issue that crosses all political lines, and food policy experts agree that the market has a limited ability to police itself. Some food producers put profits before

[*] An updated analysis by the U.S. Centers for Disease Control and Prevention (CDC) of the total burden of U.S. foodborne illnesses, using data from CDC monitoring systems, is expected later this year (Scallan 2010).

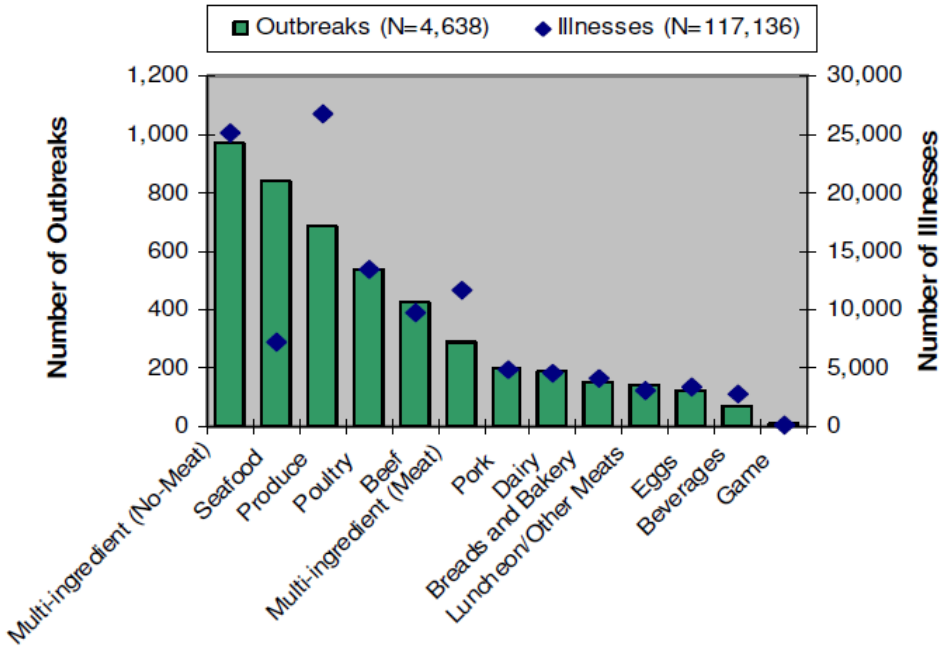
public health, and consumers typically do not have the ability to identify contaminated food by sight or smell. The resulting effects, moreover, are underreported. Although the U.S. Centers for Disease Control and Prevention (CDC) is in charge of the nationwide monitoring of foodborne illnesses, the primary reporting responsibility lies with state and local agencies, where there often are wide variations in the quality and completeness of the surveillance systems. For this reason the CDC developed a special surveillance system—the Foodborne Diseases Active Surveillance Network (FoodNet) system—to get more information about infections that are diagnosed but not reported (CDC 2010a). The FoodNet system involves active surveillance of foodborne illness at 10 sites across the country. Using the data thus acquired, the CDC releases an annual report card on food safety that calculates the yearly incidences of laboratory-confirmed infections for nine common foodborne bacteria and parasites. Figure 1 shows FoodNet trends over the past decade in the relative rates of infection incidence from five common pathogens (CDC 2010c).

Figure 1: Relative Rates of Laboratory-Confirmed Infections with *Vibrio, Salmonella, Campylobacter, Listeria,* and Shiga-Toxin-Producing *Escherichia coli* O157, by Year. Source: FoodNet, 1996–2009 (CDC 2010c)



Research on attributing public health burdens to specific food commodities is ongoing (Tauxe 2005, Griffin 2010). But an analysis of outbreak data by the Center for Science in the Public Interest (CSPI), which provides numbers of outbreaks and illnesses for the major food commodity categories from 1998 to 2007, is indicative (DeWaal et al 2009). That analysis is summarized in Figure 2.

Figure 2: Number of Outbreaks and Illnesses according to Food Commodity Category. Source: CSPI 2009



In any case, government could do a much better job of preventing contaminated food from reaching Americans' plates in the first place. In order to document the present state of affairs and determine specific needs, the Union of Concerned Scientists (UCS), working with researchers at Iowa State University, sent a 44-question survey in March 2010 to some 8,000 employees with food safety responsibilities at the FDA and U.S. Department of Agriculture (USDA), which together oversee our food supply. More than 1,700 responded. Their answers reveal a food safety system where, far too often, special interests and public officials inhibit the ability of government scientists and inspectors to protect us. The respondents also provide useful recommendations, informed by hard experience, on what must be done to correct this problem.

Executive branch reforms—aimed at protecting government scientists, increasing transparency and accountability, and restoring scientific integrity—are needed to combat the political and corporate interference at the FDA and USDA. In addition, the laws governing the system badly need to be updated to meet 21st century challenges. Congress should give the FDA and USDA additional authority, such as the ability to: mandate food recalls, establish a science-based system for detecting harmful pathogens in the food supply, require food manufacturers to disclose more information to the government, and increase government surveillance of food imports. Congress also should provide adequate resources to more effectively police the food supply. Only then can the frequency and scale of foodborne disease outbreaks decline.

Chapter 2. Federal Food Safety Efforts, Past and Present

History

The current federal food safety system in the United States is a fragmented legal and organizational structure that has "emerged piecemeal, over many decades, typically in response to particular health threats or economic crises" (GAO 2004). Its central pillars are the FDA, within the Department of Health and Human Services (HHS); and the Food Safety and Inspection Service (FSIS), within the USDA. But in addition nearly a dozen other federal agencies are responsible for smaller components of the food safety system. This complex national enterprise is supplemented by many state and local food safety programs, which often serve as the front line for enforcement and response.

In 1862, President Abraham Lincoln founded the USDA to support American farmers and advance the nation's agricultural system. By the turn of the century, the USDA housed two bureaus that would eventually grow into the FDA and FSIS, although federal authority over the food system at that time was very weak. The USDA Bureau of Chemistry was tasked with investigating "the adulteration of foods, drugs, and liquors" while the Bureau of Animal Industry (BAI) focused on preventing diseased animals from being used as food, eradicating animal diseases, and improving livestock quality.

After the Civil War, the expansion of railroads, refrigerator cars, and electricity led to a flourishing of the livestock and meatpacking industries and of the international food trade. The growing problem of livestock disease led Congress to pass quarantine laws and to give the USDA limited responsibility over certain food products, but prior to 1906 all attempts to implement systematic regulation of food safety were defeated in Congress.

However, by the turn of the century serious problems with the safety and quality of the nation's food supply had become apparent. The publication of Upton Sinclair's *The Jungle*, which exposed the unsanitary conditions in Chicago's meatpacking industry, led to a public outcry. A subsequent government report corroborated Sinclair's claims, and those two documents were crucial in convincing President Theodore Roosevelt to support comprehensive legislation. A coalition of labor unions, consumer groups, and doctors was successful in overcoming opposition from industry and in 1906 the Pure Food and Drug Act (PFDA) and the Federal Meat Inspection Act (FMIA) were signed into law (Merrill 2005).

The PFDA for the first time gave the USDA the ability to regulate adulterated and misbranded foods (and drugs) in interstate commerce. The FMIA improved sanitary conditions, placed federal inspectors in every meat-processing plant, and established a system of continuous meat inspection that still exists today. The Bureau of Chemistry was charged with implementing the PFDA until 1927, when Congress created the Food, Drug, and Insecticide Administration (FDIA—the "I" was dropped in 1930, thereby creating the organization known today as the FDA).

In the wake of a legally marketed drug that killed 107 people, most of whom were children, Congress enacted the Food, Drug, and Cosmetic Act (FDCA) of 1938. The FDCA overhauled the public health system, expanded the FDA's powers, and largely redesigned the regulatory system set in place by the PFDA. The new law authorized the FDA to demand evidence of safety

and efficacy for new drugs, to issue standards for foods, and to conduct factory inspections. In 1939, the first food standards were issued—for canned tomatoes, tomato purée, and tomato paste. Such standards established a food's common name, defined the food's nature in terms of mandatory ingredients, and provided label requirements.

In 1940, President Franklin D. Roosevelt moved the FDA out of the USDA to the Federal Security Agency (FSA), thus separating the two primary food safety agencies. At the time, some had advocated for this move as a way of insulating the FDA's public health function from conflicts with the agricultural mission of the USDA (Merrill 2005). The FDA was moved again in 1953 from the FSA to the Department of Health, Education, and Welfare—the precursor agency to the HHS—where the FDA has remained ever since. However, it was only in 1988 that Congress officially established the FDA as an agency of the HHS, with a commissioner appointed by the president and confirmed by the Senate.

Even with the removal of the FDA, the USDA's authority over food safety inspections continued to expand. The 1946 Agricultural Marketing Act expanded the scope of the USDA's inspections and gave the department the authority to grade agricultural products for quality in addition to safety. Demand for poultry skyrocketed during World War II, and in 1957 the Poultry Products Inspection Act extended the USDA's inspection system to cover poultry products. USDA's food safety inspection function has been reorganized numerous times, moving from the Bureau of Animal Industry to the Agricultural Research Service (ARS) in 1953, to the Animal and Plant Health Inspection Service in 1971, to the Food Safety and Quality Service in 1977, and finally to FSIS in 1981.

Organization of the Food Safety System

The fragmentation of the federal food safety system has continued since the FDA was split off from the USDA. To give one example, in 1970 President Richard M. Nixon transferred responsibility for setting pesticide tolerances on food from the FDA to the newly created Environmental Protection Agency (EPA), with the FDA still responsible for the enforcement of those tolerances. Such partitions have led to numerous regulatory absurdities—such as the fact that pizza with meat toppings are regulated by the USDA while cheese pizzas are handled by the FDA—and near-constant calls for reform.

A 1998 Institute of Medicine (IOM) study, *Ensuring Safe Food*, criticized this fragmentation as one of the central impediments to creating a truly science-based food safety system. The IOM recommended that Congress establish "a unified and central framework for managing federal food safety programs, one that is headed by a single official and which has the responsibility and control of resources for all federal food safety activities" (IOM 1998).

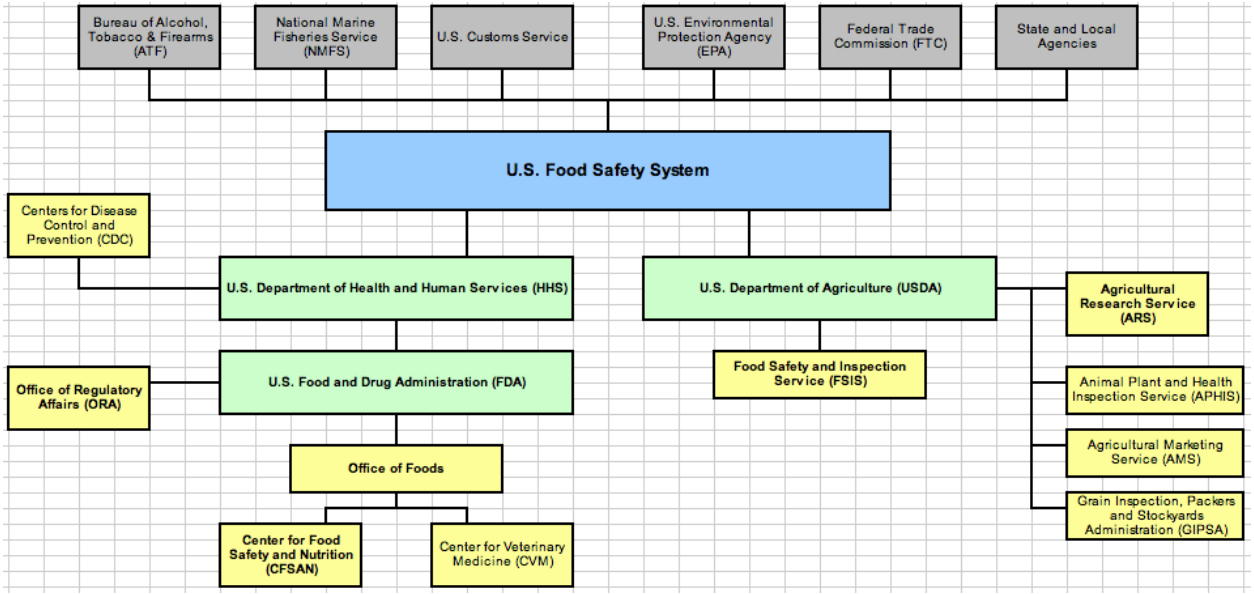
In January 2007, the U.S. Government Accountability Office (GAO) added the food safety system to its list of troubled and "high-risk" government programs "that are in need of broad-based transformation." The GAO identified a number of problems with the food safety system, directing particular attention to fragmentation as a main cause of that system's inefficiency and inconsistency (GAO 2007).

This fragmentation has also fostered periodic attempts by numerous administrations to enforce some level of unity in the area of food safety. President Clinton created a President's Council on Food Safety, announced in August 1998. President George W. Bush announced in November

2007 two initiatives to improve food safety: the FDA's Food Protection Plan and an Interagency Working Group on Import Safety. In March 2009, President Barack Obama announced the creation of a new Food Safety Working Group, chaired jointly by the Secretary of Agriculture Tom Vilsack and the Secretary of Health and Human Services Kathleen Sebelius, to advise him on how to upgrade the U.S. food safety system.

Figure 3 provides a flow chart of the major federal agencies charged with protecting the nation's food supply. In the discussion that follows, we briefly summarize the chief responsibilities of these agencies, as well as those of several others involved in food safety (also, see Becker 2010a).

Figure 3: U.S. Food Safety System Organization



U.S. Department of Agriculture

The USDA is a large department with broad responsibilities to promote American farmers and agriculture, and food safety has been only a small part of its mandate. In order to enhance the stature of food safety within the USDA, the position of Under Secretary for Food Safety was created in 1994. President Obama's nominee for this position, Dr. Elisabeth Hagen, was given a recess appointment by the Senate in August 2010.

USDA sections have responsibilities that touch on food safety include the following:

- The Food Safety and Inspection Service (FSIS) is charged with ensuring that meat, poultry, and processed egg products are safe, wholesome, and properly labeled.

  The FSIS has a staff of 9,400, of which approximately 8,000 are inspectors who continuously oversee 6,300 meat-slaughtering and -processing establishments nationwide. FSIS inspectors are required by law to inspect every slaughtered carcass of meat or poultry, and at least one inspector must be present during all hours of operation. Inspectors also check each processing plant's sanitary conditions and compliance with other regulations. Similarly, FSIS employees monitor the plant's adherence to its HACCP

plan (see Science and Food Safety section below) and conduct microbial testing of products.

In addition to its extensive in-plant inspection responsibilities, the FSIS is responsible for enforcing compliance with other food safety regulations and for conducting emergency response operations such as the detention and voluntary recall of adulterated foods. The FSIS shares with the FDA the authority to enforce meat adulteration standards once products have left USDA-regulated processing plants, and it also coordinates U.S. participation in international standard-setting processes, certifies that imported meat has been inspected under an equivalent system, and provides safety information and outreach to food handlers and consumers.

- The Agricultural Research Service (ARS) performs in-house scientific research in support of USDA programs. The Food Safety division of the ARS conducts research into a number of food safety topics and areas, often in support of FSIS activities or objectives.

- The Agricultural Marketing Service (AMS) is responsible for establishing standards and grading a number of food products for quality. The grading process is voluntary, paid for by user fees, and used for marketing purposes. While the quality grading is not formally a safety inspection, the AMS does consider some safety-related factors, such as cleanliness, in its standards.

- The Animal and Plant Health Inspection Service (APHIS) is responsible for protecting animal and plant health in the United States by carrying out tests for the presence of invasive pests and diseases, such as bovine spongiform encephalopathy (BSE, or "mad cow" disease). APHIS also regulates certain genetically engineered organisms through the Biotechnology Regulatory Service.

- The Grain Inspection, Packers, and Stockyards Administration (GIPSA) implements a national quality-inspection system for grain and related products. GIPSA has no regulatory responsibility for food safety, however. It reports to the FDA when its inspections uncover objectionable food products.

- The Food and Nutrition Service (FNS) is responsible for the USDA's nutrition assistance programs, including the Food Stamp Program and the National School Lunch Program. The FNS also houses a Food Safety Unit, which coordinates food safety and security efforts within all FNS activities, including the school lunch program.

- The National Institute of Food and Agriculture (NIFA). Formerly the Cooperative State Research, Education, and Extension Service, NIFA supports projects and research into food safety, among many other subject areas, through the administration and coordination of federal grants to universities, nonprofits, small businesses, and others.

U.S. Food and Drug Administration

The FDA—housed in the Department of HHS—is responsible for the safety, nutrition, wholesomeness, and accurate labeling of all domestic and imported human food products sold in interstate commerce, except for those regulated by the FSIS (i.e., meat, poultry, and processed

egg products). In addition, a significant fraction of the FDA's budget goes toward implementing its drug safety responsibilities.

Roughly 80 percent of national food purchases are of products under the FDA's jurisdiction; they include seafood, produce, dairy products, and processed foods. The FDA also has jurisdiction over meats from animals or birds, such as game animals, that are not under the regulatory jurisdiction of the FSIS; and it shares responsibility for the safety of eggs with that agency. Because the FDA does not have an inspection capacity comparable to that of the USDA, it relies more heavily on pursuing legal enforcement of the provisions of the various laws that it administers.

The FDA Foods Program includes three major units—the Center for Food Safety and Applied Nutrition, the Center for Veterinary Medicine, and the foods-related activities of the Office of Regulatory Affairs. The Foods Program also draws on the resources and expertise of the National Center for Toxicological Research, the Office of Crisis Management, the Office of Criminal Investigations, and several other FDA offices.

- The Center for Food Safety and Applied Nutrition (CFSAN) is the central coordinator of the FDA's food safety activities. It conducts research on relevant topics, oversees the compliance and enforcement of food safety regulations, coordinates international food standard and harmonization work, and does outreach to businesses and the public. Being responsible for the FDA's response to outbreaks of foodborne illness, the CFSAN conducts trace-back investigations to identify which products should be recalled and how contamination has occurred. The center has approximately 1,000 employees, a large percentage of whom are scientists.

- The Center for Veterinary Medicine (CVM) is responsible for ensuring that animal drugs, feeds, and veterinary devices are safe, effective, and properly labeled, and that foods from animals that have received drugs or additives are safe for human consumption.

- The Office of Regulatory Affairs (ORA) is responsible for all FDA field activities, which can include inspections of products and manufacturers, sample analysis, review of imported products, and enforcement of regulations. The ORA's inspection responsibilities include all FDA-regulated products—drugs, medical devices, foods, and cosmetics—both pre- and post-market. The ORA's food safety work force numbers around 1,900 spread across numerous field offices in five regions, as well as another 900 located in Washington, DC (Becker 2010a).

In August 2009, the Office of Foods was created to bring several of the FDA's food program components under one management structure. At the same time, Michael R. Taylor was named as the first Deputy Commissioner for Foods at the FDA.

Centers for Disease Control and Prevention

The CDC—also housed in the HHS—is charged with protecting the nation's public health and is the central authority on foodborne-disease surveillance and epidemiology. The CDC is responsible for running the various foodborne-disease monitoring networks—such as FoodNet and the National Outbreak Reporting System (NORS)—and it takes the lead on coordinating

state responses to multistate foodborne-disease outbreaks. Scientists at the CDC work to develop new epidemiological and laboratory techniques to better identify and respond to such outbreaks.

Other Departments and Independent Agencies

A number of other federal authorities maintain responsibility for small pieces of the food safety system.

- The Environmental Protection Agency (EPA) is responsible for regulating all pesticide products sold or used in the United States. Part of this responsibility involves setting tolerances for pesticide residues on foods, which are enforced by the FDA.

- The Bureau of Alcohol, Tobacco, Firearms, and Explosives, a part of the Department of Justice, is responsible for regulating the production of alcoholic beverages and resolving any related safety issues that arise.

- National Marine Fisheries Service, a part of the Department of Commerce, conducts voluntary safety and quality inspections of seafood, although the FDA retains regulatory authority.

- U.S. Customs and Border Protection, a part of the Department of Homeland Security, is responsible for enforcing customs; and it works with both the FSIS and the FDA to enforce various regulations on imported foods.

- The Federal Trade Commission is tasked with regulating unfair or deceptive advertising practices, including those involving food products.

- State and local agencies. A wide variety of state and local health, agriculture, and consumer departments play crucial roles in the food safety system. These agencies typically take the lead on inspecting food establishments such as restaurants, grocery stores, and other retail outlets, while federal inspectors concentrate on food production and processing plants. The FDA also contracts with local agencies to help extend their limited inspection workforce.

Key Food Safety Laws

A few key laws, along with many amendments, govern the U.S. food safety system:

- The *Federal Meat Inspection Act* (FMIA, passed in 1906) requires FSIS to examine and inspect live cattle, swine, goats, sheep, and horses, as well as their carcasses and processed products. The FMIA also mandates improved sanitary conditions for slaughter and production. The FMIA does not technically confer authority on FSIS to order recalls of tainted food, but its requirement that a federal inspector be present during all hours of operation at slaughter facilities does give the agency enforcement leverage.

- The *Pure Food and Drug Act* (PFDA, 1906) prohibited the sale of adulterated or mislabeled foods and drugs in interstate commerce, and it regulated the use of color additives in food. The PFDA did not give the government pre-market approval but only allowed it to assess products after they were available for sale. There were some other weaknesses in the law as well, notably a provision that allowed the marketing of

otherwise illegal products so long as they had a "distinctive name." The PFDA was largely superseded by the 1938 enactment of the FDCA, described below.

- The *Federal Food, Drug, and Cosmetic Act* (FDCA, 1938) greatly expanded the FDA's ability to regulate foods, drugs, and (for the first time) cosmetics. Under the FDCA's food provisions, the FDA is responsible for ensuring that all foreign and domestically produced foods (except those regulated by FSIS) are safe, wholesome, and properly labeled. The FDCA also mandates that all drugs and feeds for animals are safe, properly labeled and, when used in food-producing animals, do not endanger human health.

  The FDCA eliminated the PFDA's distinctive-name provision, instead requiring standard names on labels. The law also strengthened the FDA's enforcement authority by allowing it to inspect facilities, establish safety tolerances for certain additives, correct abuses in food packaging and quality, and create quality standards.

  The FDCA has been amended numerous times since its enactment. Amendments include requirements that manufacturers prove the safety of pesticide residues on food (1954), new food additives (1958), and color additives (1960) before they may be marketed. Two categories of food additives are exempt from the 1958 rules: (1) additives "generally recognized as safe" (GRAS); and (2) substances that had been approved for use in foods prior to the passage of the amendment (such as potassium nitrite and sodium nitrite).

  Two major amendments to the FDCA greatly expanded food-labeling requirements to provide more information to the public about the nutritional content of foods (*Nutrition Labeling and Education Act* of 1990) and potential allergens in foods (*Food Allergy Labeling and Consumer Protection Act* of 2004). (Like other consumer protection agencies, FDA is also charged with enforcing the *Fair Packaging and Labeling Act* of 1966, which requires that retail products be honestly and informatively labeled.)

  Other amendments to the FDCA have addressed the safety and efficacy of animal drugs (1968, 1994) and set higher standards of control and testing for infant formula (1980). The *FDA Modernization Act* of 1997 and the *FDA Amendments Act* of 2007 updated the FDA's mission and attempted to reform some of its practices. For example, measures to increase the transparency of the regulatory process were mandated.

- The *Poultry Products Inspection Act* (PPIA, 1957) extended the federal meat-inspection system to include poultry animals. In 1906, poultry was not a sufficiently popular food item to be included in the FMIA; it was not until World War II that poultry production had expanded enough to warrant government oversight. The PPIA requires the FSIS to inspect any domesticated birds being processed for human consumption, including chickens, turkeys, ducks, and a number of other fowl. The law also requires that plant facilities be sanitary and that product labels be accurate.

- The *Egg Products Inspection Act* (1970) required continuous FSIS inspection of the processing of liquid, frozen, and dried egg products (i.e., eggs that have been removed from their shells for processing). The FDA remains responsible for the safety of shell eggs under the FDCA.

- The *Agricultural Marketing Act* (1946) authorized the USDA and other agencies to create quality-inspection systems in order to promote the marketing of a wide variety of food products, including dairy, meat, poultry, eggs, fruits, vegetables, and seafood.

Food safety activities in the federal government are also subject to provisions in broader pieces of legislation:

The *Public Health Service Act* of 1944 consolidated many of the government's public health agencies and services, and it also provided some regulatory authority to the FDA. Under this act, the FDA may take steps that it judges necessary to prevent the spread of communicable diseases, including foodborne illness. Areas of this act enforced by the FDA include the regulation of biologics (medical products created by biological processes), pasteurized milk and shellfish handling, and food service sanitation.

Tolerances for pesticide residues on foods—which are set by the EPA and enforced by the FDA—are governed by the *Federal Insecticide, Fungicide, and Rodenticide Act* (1972) and its 1996 update, the *Food Quality Protection Act* (FQPA). The FQPA officially replaced the Delaney Clause of the 1958 FDCA Amendments (which had set a "zero cancer risk" standard for pesticide residues in some foods) with a single "safe" standard connoting a reasonable certainty of no harm to consumers. The FQPA also instructed the EPA to consider the greater vulnerabilities of children when setting standards for pesticide exposure.

The *Public Health Security and Bioterrorism Preparedness and Response Act* (Bioterrorism Act, 2002) expanded the FDA's authority over food imports by requiring food producers to register with the FDA, give prior notice before importing food, and maintain adequate records. The Bioterrorism Act also expanded the FDA's ability to detain food that it suspects as presenting a threat to humans or animals.

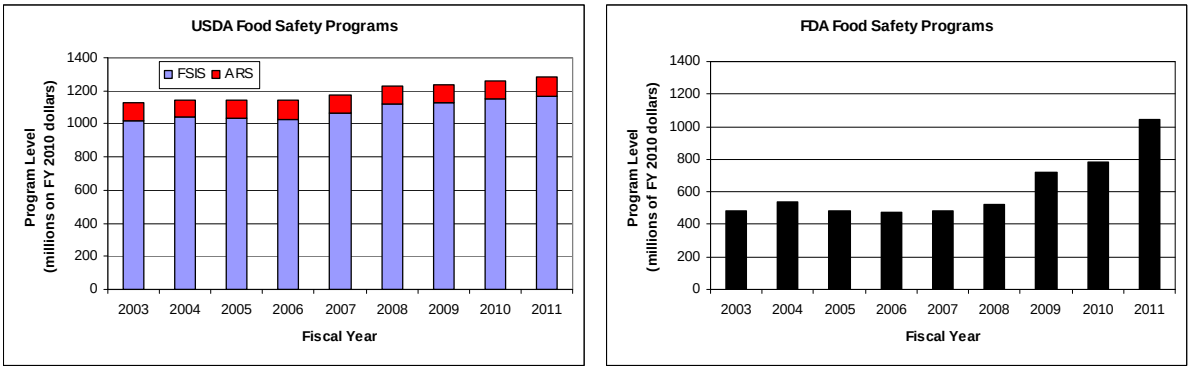
Funding Trends

Historically there has been a serious imbalance in the resources provided to the two primary food safety regulatory agencies. Prior to the 2009 fiscal year, funding for the FDA's food safety programs amounted to less than half of the total allocation to the USDA's FSIS and the food safety research line item at the ARS. This disparity persisted for many years, despite the fact that nationwide some 80 percent of all food purchases and 85 percent of known foodborne illnesses are associated with foods regulated by the FDA (Dyckman 2005).

The funding imbalance has been most clearly manifested in the number of inspections carried out by each agency. While the FSIS has the resources for daily inspections of 6,300 slaughter and processing facilities, the FDA is responsible for oversight of approximately 44,000 food manufacturers and over 100,000 additional food facilities (Becker 2010a). The mismatch between the agency's responsibilities and resources has led some to estimate that the average domestic facility is visited by the FDA only once every 10 years. Indeed, an investigation by the HHS's inspector general found that at the end of FY2008, 56 percent of food facilities had not been inspected at all in the previous five years (HHS 2010a). Problems such as these have led the FDA Science Board to "state unequivocally that the [food safety system] cannot be fixed 'within available resources'" (FDA 2007).

In recent years, proposed and enacted resources for the FDA have risen, but they are not yet at the level of USDA funding (see Figure 4). The president's FY2011 budget includes $1.168 billion for the FSIS (of which $131 million comes from user fees), $114 million for food safety research at the ARS, and $1.042 billion for food safety at the FDA (of which $194 million would be in the form of new user fees that have been proposed but not yet enacted by Congress). (USDA 2010, HHS 2010b)

Figure 4: USDA and FDA Food Safety Budgets, FY2003–2011. Budgets for 2003 to 2010 are presented in millions of constant FY2010 dollars. FY2011 reflects the president's budget request. Sources: USDA and FDA budget summaries



Science and Food Safety

As the foodborne threats to public health have changed over the decades since 1906, the FDA and FSIS have struggled to keep pace. Yet government regulators have also had some successes at eliminating threats to the food supply. The 1906 laws were written at a time when animal diseases such as trichinosis, tuberculosis, and brucellosis were common, and the system of organoleptic (related to sight, touch, and smell) inspection of meat and poultry processing plants—as specified by the Federal Meat Inspection Act—proved to be an effective defense against those diseases. Similarly, in the 1970s botulism outbreaks from low-acid canned foods became a troubling problem; subsequent FDA regulations (in 1974) and strengthened industry precautions have now largely eliminated this disease (IOM 2009).

Yet the FSIS's organoleptic meat inspection methods came to be criticized by many as ineffective against microbial contamination. In 1971, the American Public Health Association (APHA) brought suit against the USDA to force it to address the fact that a significant percentage of meat bearing the USDA seal of approval was in fact contaminated with *Salmonella*. The APHA sought to require that meat products have a warning label that included cooking instructions. In this controversial case (*APHA v. Butz* 1974), an appeals court ruled that the 1906 legislation was not intended to cover bacterial contamination and hence a USDA inspection seal did not imply the product would be free of bacteria (Nestle 2003).

It was not until 1993, with the "Jack in the Box" outbreak and the public outcry that followed it, that USDA was forced to reconsider standards for microbial contamination. The FSIS began to modernize its inspection program, shifting its focus toward science-based testing with a goal of preventing contamination in the first place. In 1994, the FSIS initiated a testing program for *Escherichia coli* O157:H7 in federally inspected establishments and retail stores, declaring that any ground beef found with this pathogen would be considered adulterated. This was the first

time that a foodborne pathogen in a raw product was declared an adulterant under the meat inspection law. An even bigger step was taken in July 1996, when the FSIS issued a rule requiring meat and poultry plants to put in place Hazard Analysis and Critical Control Point (HACCP) systems.

HACCP is a process that was originally developed in 1959 by the Pillsbury Company and the National Aeronautics and Space Administration to ensure the safety of the food provided to astronauts during space missions. HACCP played a central role in the 1974 FDA regulation of low-acid canned food and was later endorsed by the World Health Organization and the National Academies. Since then, HACCP has become a widely accepted method for food safety assurance. A seven-step plan for reducing the risk of microbiological hazards in food, it requires plants to:

(1) Conduct a hazard analysis
(2) Determine the critical control points
(3) Establish critical limits for those points
(4) Implement and monitor control procedures for those points
(5) Institute corrective actions should the critical limits be exceeded
(6) Create procedures to verify the adequacy of the system
(7) Maintain records of the process (NACMCF 1998).

The 1996 FSIS rule paired the HACCP requirements with a "pathogen reduction standard" for *Salmonella* in ground beef— meaning that if meat from a given facility tested positive for *Salmonella* and the percentage exceeded a certain threshold, FSIS would take action. However, a 2001 lawsuit successfully challenged this standard, and after the court ruling (*Supreme Beef Processors v. USDA* 2001) the USDA was unable to use test results as a reason for withdrawing inspectors from a plant (thereby forcing a shutdown). Nevertheless, the USDA continues to use test results in evaluating a plant's HACCP plan (Nestle 2003; Hoffman 2005).

The new HACCP rule was intended to operate in parallel with the traditional methods of inspection, which are still mandated by law. Nevertheless, it represented a significant change in the FSIS's regulatory philosophy and led to a shift in resources from visual inspection toward risk- and science-based regulation. The GAO identified a number of early problems with HACCP implementation, however, including failure to document and enforce violations of the rule and a lack of scientific expertise among staff charged with reviewing the plans (GAO 2002).

The rule has attracted criticism not only from industry but also from consumer advocates and labor unions, which saw it as an abdication of government responsibility by giving too much discretion to industry (Mattera 2004, Nestor and Hauter 2000). Others have criticized the movement to expand HACCP into new sectors, arguing that HACCP is most successful when there is a "definitive critical control point"—a condition that is not always fulfilled at each stage from "farm to fork" (e.g., Sperber 2005).

Despite the controversy, the HACCP rule has generally been seen as a public health success. An Institute of Medicine report concluded that "the balance of progress in food safety after implementation of HACCP in various sectors of the food industry is decidedly favorable and commendable" (IOM 2003). In addition to meat and poultry, the FDA and FSIS have finalized HACCP regulations for seafood (1995) and fresh juice (2001), and they have issued voluntary guidance for other food products.

Legislation under Consideration in Congress

In response to the rash of foodborne illnesses and deaths among people and animals during the past decade—and to growing concerns that the food safety system is outdated—several bills addressing food safety are currently under consideration by Congress. These bills focus on improving the FDA's food safety efforts and reorienting that agency toward a more preventive (and less reactive) model; the current bills do not propose any reforms at FSIS.

As reported by the Congressional Research Service (Becker 2010b), the issues currently being debated in Congress include:

- Giving the FDA authority to require HACCP (or more general food safety) plans for all food facilities.
- Giving the FDA authority to issue science-based performance standards for pathogens that represent a threat to public health.
- Strengthening requirements for facilities to register with the FDA.
- Strengthening requirements for facilities to maintain adequate records and to provide access to government inspectors in response to an outbreak.
- Increasing the frequency of FDA inspections and using risk-based methods to target scarce inspection resources.
- Extending FDA authority to farms (in addition to processing facilities), with a special emphasis on produce safety.
- Strengthening certification and verification of food imports.
- Expanding the use of third-parties in import inspections and laboratory accreditations.
- Giving the FDA authority to mandate recalls of adulterated foods and impose penalties if the recalls are not honored. This authority would also require companies to notify the FDA when such foods have been distributed and to put in place a system to trace adulterated foods to their source.
- Improving the collection of surveillance data on outbreaks of foodborne illnesses.
- Collecting fees from industry to pay for expanded inspections of facilities.
- Reorganizing the federal food safety system under one (possibly Cabinet-level) entity or implementing a more limited reorganization of food safety within HHS (Becker 2010b).

Two related bills, one in the Senate (S 510) and one in the House (HR 2749), are the likely vehicles for food safety reform in the present (111th) Congress. Both the Senate and House bills address most of the reform proposals mentioned above, although details vary considerably between the two (Becker 2010b). On July 30, 2009, the House passed HR 2749 by a vote of 283-142. Its Senate counterpart, S 510, has passed out of committee, but at the time of this writing it had not been considered by the full Senate.[†]

[†] The current status of this bill can be found online at *http://thomas.loc.gov/cgi-bin/bdquery/z?d111:s.00510:*

Chapter 3. Research Methods

In March 2010, the Union of Concerned Scientists (UCS) sent a 44-question survey to 8,122 individuals working on food safety at the FDA and USDA. The survey inquired about political interference in their work, corporate influence on agency actions, the use of science in agency decision making, agency effectiveness, employee morale, and other topics. The 1,710 employees who responded came from all levels of the food safety system, with more than half having worked at their agency for 11 years or longer.

UCS contracted with the Center for Survey Statistics and Methodology (CSSM) at Iowa State University to conduct the survey, through an online questionnaire, and to tabulate and analyze the resulting data. Survey recipients received an initial email containing an anonymous login and unique password, as well as a hard copy mailed to their place of work (if a mailing address was available). CSSM also sent up to three reminder emails to those who had not responded, with the aim of boosting the response rate.

To allow survey respondents to freely express their opinions about their work, confidentiality and anonymity were assured. Thus while UCS provided the sample of scientists that received the survey, we did not have access to any links between a given survey response and personal information, such as a name or email address. CSSM maintained such links solely to send out reminders during the data collection period, and it destroyed all such links once it closed the survey.

Creating the Survey Mailing List

The mailing list for the survey was created from information available on the websites of the FDA and the USDA:

- The HHS employee directory provides full names, job titles, organizational chart information, duty station, and (with an additional click) email and phone information for department employees. The search form returns up to 500 employee records per request. Using this webpage, we obtained a full list of employees from the FDA offices concerned with food safety, namely the Center for Food Safety and Nutrition (CFSAN), the Office of Regulatory Affairs (ORA), and the newly created Office of Foods.

- The USDA email directory provides full names and email addresses for department employees and returns up to 100 employee records per request. Using this webpage, we obtained a list of employees of the Food Safety and Inspection Service (FSIS), although we were unable to identify in advance which employees were scientists, inspectors, or support staff. The online list of FSIS employees contained about 8,000 names.

  Aggregate statistics from the U.S. Office of Personnel Management (OPM) indicated that the FSIS has about 9,000 employees, with an approximate breakdown of 15 percent scientists, 75 percent inspectors, and 10 percent support staff and management. It was not clear what caused the difference in total number between the online list and the OPM statistics, though conversations with the FSIS leadership indicated that some field inspectors may not be in the email system and that others may check their email only occasionally.

- USDA officials indicated that there are also a number of scientists in the Agricultural Research Service (ARS) working on food safety who regularly interact with the FSIS. We were consequently able to identify a sample of 253 researchers who were listed on the ARS website as being assigned to a food safety project, and we obtained email addresses for these names from the USDA email directory.

The lack of job-title information for FSIS employees in the USDA directory meant we were unable to identify the 15 percent who are scientists. Similarly, while we did have job title information for FDA employees, the missions for the two targeted FDA offices are not exclusively related to food safety, and certain individuals in the sample may spend some or all of their time on topics such as nutrition (CFSAN) or drug safety (ORA).

Given these constraints, we opted to send the survey to a large sample of recipients at the FDA, FSIS, and ARS and to ask respondents to self-identify regarding their job duties, the percentage of their time spent on scientific work, and the percentage of their time spent on food safety issues. Respondents who indicated that they were involved with food safety but did no scientific work were not asked several science-specific questions; respondents who indicated that they their work was neither scientific work nor related to food safety were dropped from the survey (see *www.ucsusa.org/assets/documents/scientific_integrity/food-safety-survey-methodology.pdf* for details).

From this universe of names, CSSM drew a sample of 5,248 USDA employees and 2,874 FDA employees. The USDA sample included all 253 ARS names plus a random sampling of 4,995 FSIS names. The FDA sample included all 1,221 employees identified as scientists by their job title plus a random sampling of other job categories (including managers and inspectors but excluding support staff).

Table 1 describes the sample sizes of the various groups surveyed and the response rates.

Table 1. Sample Sizes and Response Rate, by Agency

	FDA	USDA		TOTAL
		FSIS	ARS	
Total Sample	**2874**	**4995**	**253**	**8122**
Ineligible	144	66	1	211
Total Eligible Sample	**2730**	**4929**	**252**	**7911**
Refusals	49	35	2	86
Unable to respond	0	0	1	1
Non-Response	2155	3795	164	6114
Partial surveys	44	67	7	118
Complete surveys	482	1032	78	1592
Total Surveys	**526**	**1099**	**85**	**1710**
Response Rates	**19.3%**	**22.3%**	**33.7%**	**21.6%**

Survey Questionnaire

The survey questionnaire consisted of 44 multiple-choice questions and two open-ended essay questions. After posing some demographic questions the survey asked about institutional support for scientists, agency culture and openness, employee morale and job satisfaction, agency resources and effectiveness, and the extent to which the policy-making process relied on science.

The survey also asked about agency staff members' personal experiences with various forms of political interference in scientific work, the influence of outside entities on agency decision making, and the likely effect of such interventions on food safety reforms being considered in Congress. One of the essay questions asked about how to improve the integrity of science at the agency and the safety of the food supply, while the other offered space for general feedback on the survey. (See Appendix for the questionnaire and a summary of its responses, and *www.ucsusa.org/assets/documents/scientific_integrity/food-safety-survey-methodology.pdf* for further analysis of the statistics in this report.)

Survey Demographics

CSSM mailed paper letters about the survey to the sample of FDA employees on March 26, 2010, and the survey went live on the website on that date (no paper letters were sent to USDA employees because we were unable to obtain their mailing addresses). The first email announcement was sent both to FDA and USDA employees on April 5, 2010, and response data were collected until May 20, 2010.

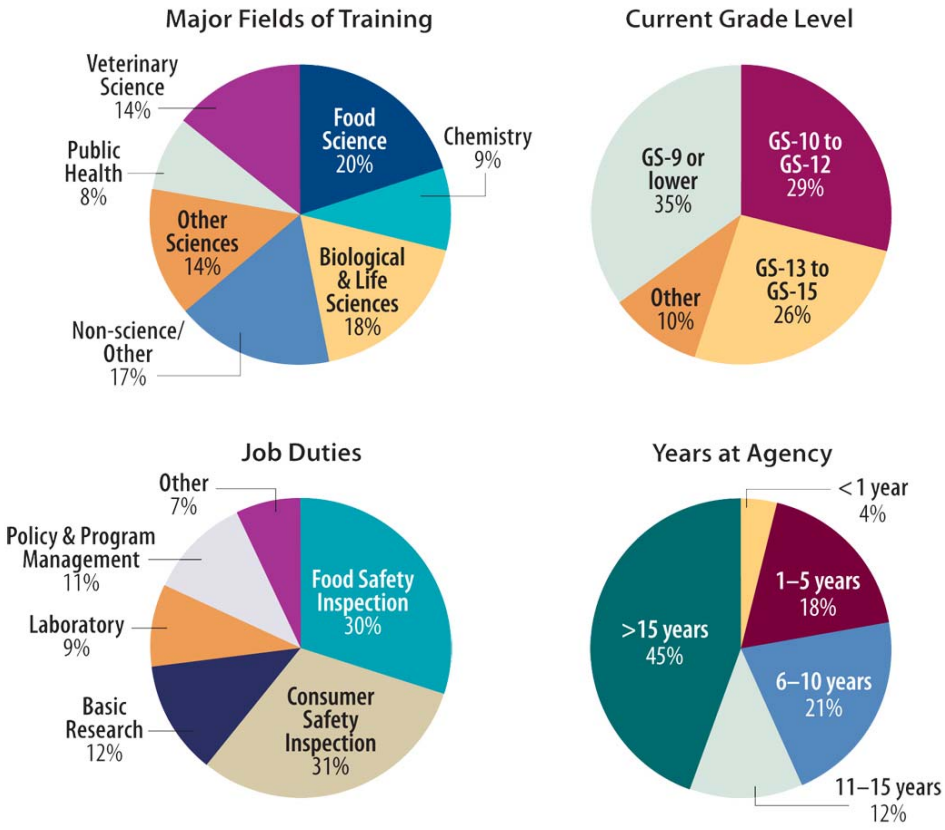
Approximately 500 email addresses were bounced back as undeliverable. We attempted to locate correct email addresses for those names and resend the survey whenever possible. CSSM excluded 211 survey recipients judged to be ineligible based on a personal communication, survey response, or confirmed absence from the online database (possibly because the recipient stopped working at the agency after the initial list was compiled).

After these exclusions, the eligible sample totaled 7,911 individuals (see *www.ucsusa.org/assets/documents/scientific_integrity/food-safety-survey-methodology.pdf* for a full methodology report from CSSM). CSSM received completed surveys from 1,710 of these individuals, for a response rate of 21.6 percent (see Table 1).

The survey was designed to measure raw numbers of scientists who experienced political interference in their scientific work. Because of unknown selection effects in creating the sample and the self-selection of respondents, it is difficult to extrapolate these raw numbers to a percentage of the total workforce. In our analysis of the results, we rely on raw numbers of respondents when discussing most questions; we report the percentage of respondents primarily when comparing two groups of uneven size. For example, comparing responses between USDA and FDA employees can be done under the assumption that whatever unknown selection effects might be present in our data, those effects are approximately the same from agency to agency.

To prevent anyone from identifying individual respondents from the data, we report results only for offices or divisions where 100 or more employees received the survey. Figure 5 shows some of the demographics of the survey respondents.

Figure 5: Survey Demographics



Agency Response

We met with agency leadership both at the FDA and the USDA during the planning stages of the survey work. Given some of our past experiences with agency leaders, who at times prohibited surveys from being filled out or inadvertently sowed confusion about them, we sought to avert such outcomes by first obtaining official approval. Leaders at both agencies were interested in the survey and generally supportive, though they were unable to officially endorse it or (in the case of USDA) provide a targeted list of scientists who work on food safety.

Leaders at both agencies did send emails to staff, informing them that survey recipients could complete the survey on their own time, though the USDA sent its email nearly a month before the FDA did. (See *www.ucsusa.org/assets/documents/scientific_integrity/food-safety-survey-methodology.pdf* for full text of emails sent to USDA and FDA employees.)

Chapter 4. Survey Results

The survey results paint a complex picture of the federal food safety system. On the one hand, the reported levels of political and corporate interference both at the USDA and FDA are troublingly high, many scientists claim that they are not free to discuss their findings with the media or to speak out about their agency's work, and FDA respondents often cite insufficient resources to meet their mission. On the other hand, most survey respondents feel that the agencies are moving in the right direction and acting effectively to protect the public health.

Survey results from the two agencies are remarkably similar. In all but four questions, responses are virtually indistinguishable. Respondents from the USDA are more likely to say they had sufficient resources and were acting effectively to protect the public from foodborne illnesses than their colleagues from the FDA. Respondents from the FDA are more likely to report instances of businesses withholding necessary information from investigators and more likely to report members of Congress forcing the withdrawal or significant modification of policy.

Our analysis of the survey's responses is presented below. We provide the overall raw numbers of respondents who, for example, report personally experiencing incidents of political or corporate interference, and we also provide the corresponding percentages (in parentheses). When comparing results between groups of different sizes (such as a comparison of FDA and USDA responses to a given question) we report them in percentages only.

Political Interference in Science

A series of questions asked survey recipients how often they had personally experienced various forms of political interference in their work, both over the past year and the five-year period preceding, from agency leadership. (Response options included Frequently, Occasionally, Seldom, Never, and Not Applicable.) Large numbers of respondents both at the FDA and USDA reported such interference in their work over the past year (see Figure 6):

- One hundred and five respondents (10 percent) had frequently or occasionally received requests from agency decision makers to "inappropriately exclude or alter technical information or conclusions in an agency scientific document." One hundred and thirty three respondents (13 percent) seldom received such requests. We interpret these results to mean that a total of 238 respondents (23 percent) reported that the requests occurred at least once (not "Never"), indicating at least some experience with this egregious form of interference.

- Ninety-eight respondents (9 percent) had frequently or occasionally received requests from agency decision makers to "provide incomplete, inaccurate, or misleading information to the public, regulated industry, media, or elected/senior government officials." One hundred and eighteen respondents (11 percent) seldom received such requests. We interpret these results to mean that a total of 216 respondents (20 percent) reported that the requests occurred at least once.

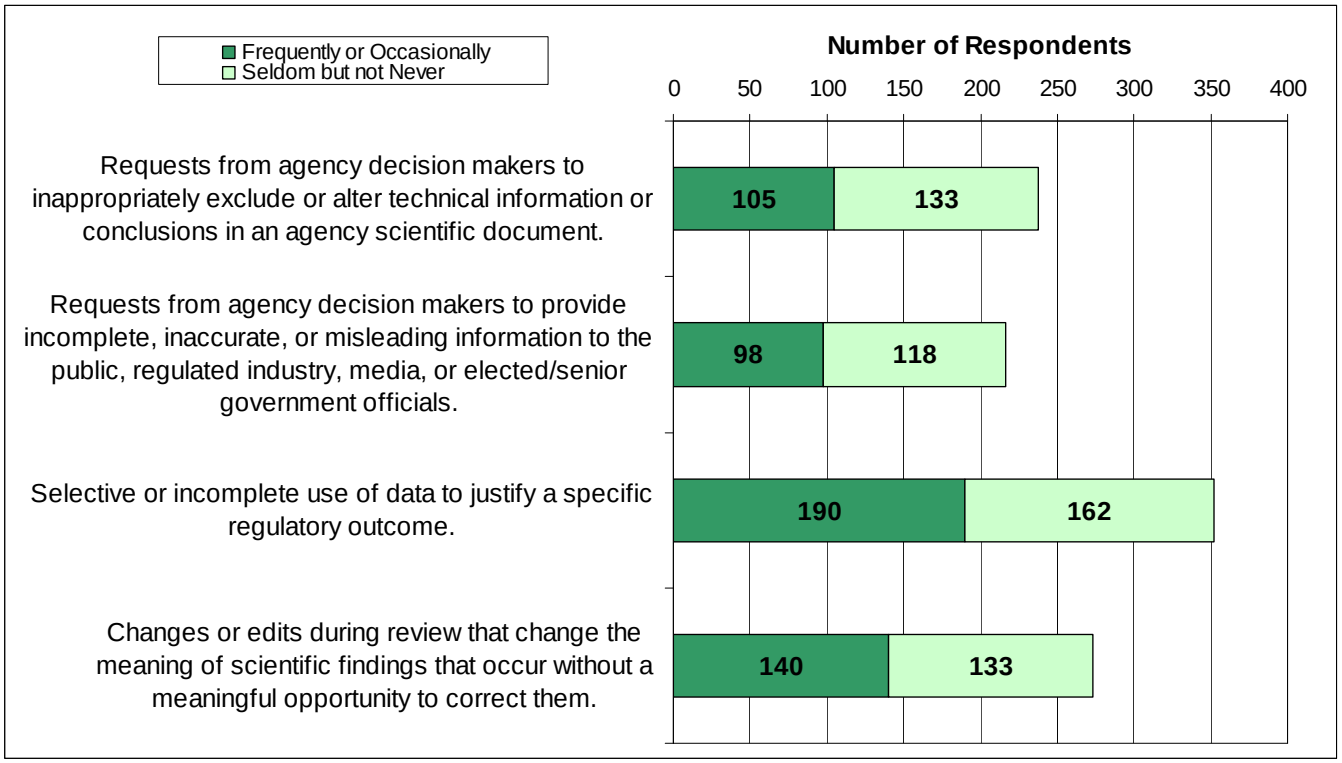
- One hundred and ninety respondents (16 percent) had frequently or occasionally experienced "selective or incomplete use of data to justify a specific regulatory outcome." One hundred and sixty two respondents (14 percent) seldom had such

experiences. We interpret these results to mean that a total of 352 respondents (30 percent) reported that the experience occurred at least once.

- One hundred and forty respondents (13 percent) had frequently or occasionally experienced "changes or edits during review that change the meaning of scientific findings that occur without a meaningful opportunity to correct them." One hundred and thirty three respondents (13 percent) seldom had such experiences. We interpret these results to mean that a total of 273 respondents (26 percent) reported that the experience occurred at least once.

Recipients were also asked to specify the number of incidents of political interference they had experienced over the past year (0, 1–5, 6–10, 11–20, or more than 20). A total of 507 respondents (34 percent) had personally experienced one or more such incidents during that period.

Figure 6: Number of Respondents Reporting Various Forms of Political Interference over the Past Year



In comparing survey responses for the past year with those covering the five previous years, there is evidence that the rate of political interference has declined slightly under the new administration:

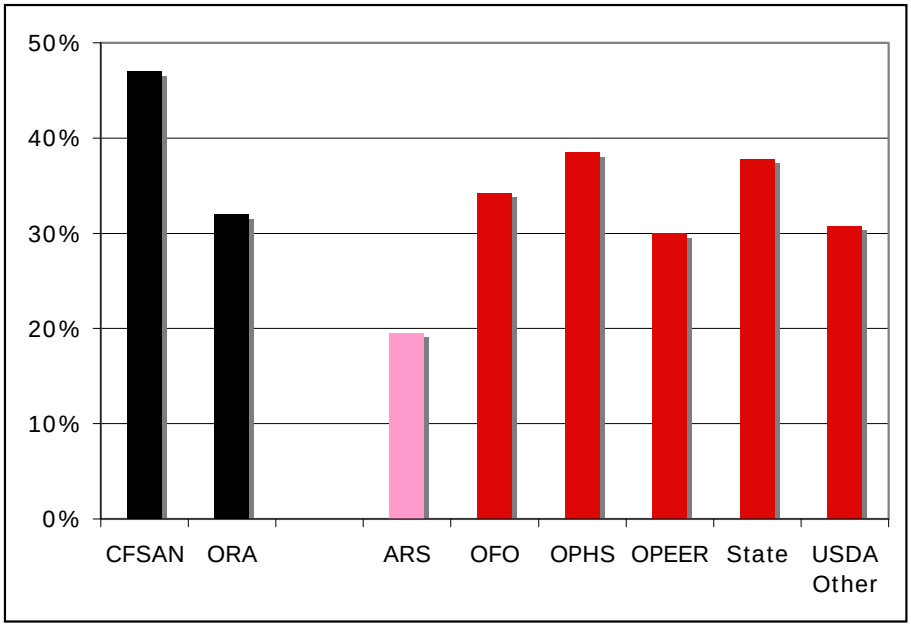
- Restricting our analysis to agency veterans with more than 10 years experience at the agency, we found that survey respondents were more likely to say that interference had declined (17 percent) rather than increased (7 percent). However, even more said that interference had remained constant (26 percent) or that they didn't know (49 percent).

- In each of the categories of political interference, fewer agency veterans reported experiences of interference over the past year than over the five years previous (Figure 10). This trend was consistent across all questions, although the decline was smaller than 10 percentage points in each case.

Given the small size of these trends, the inherent difference in agency activity between the first year and the final five years of an administration, and the difference in length of time, it is difficult to interpret these numbers as strong evidence of a decline in political interference. However, we can also compare these survey results against a similar survey of FDA scientists conducted in 2006 (See Box 1.)

Some of the political interference reported by survey respondents is likely to represent normal disagreements that occur in any organization. However, by comparing rates of interference between different offices and subdivisions in the agencies we see that political interference is not an unavoidable consequence of scientific work but rather is associated with the intersection of science and the regulatory process. Figure 7 shows the percentage of employees reporting at least one incident of political interference in science over the past year in two divisions of the FDA (CFSAN and ORA) and six groupings of the USDA (ARS, four offices of FSIS—OFO, OPHS, OPEER,* and Other—and employees assigned to work with state agencies).

Figure 7: Rates of Reported Political Interference by Agency Subdivision



* These three FSIS offices are the Office of Field Operations, Office of Public Health and Science, and Office of Program Evaluation, Enforcement, and Review.

Box 1: Comparison with 2006 FDA Survey

In 2006, UCS and Public Employees for Environmental Responsibility (PEER) sent a survey to nearly 6,000 scientists at the FDA working on a number of topics including, but not limited to, food safety (UCS and PEER 2006). Many of the questions posed by the 2006 survey are sufficiently similar to those of the present survey to permit rough comparisons, which show significant improvement in agency effectiveness and working conditions from 2006 to 2010, except in the area of direct political interference.

Because the 2006 survey included respondents who also worked on topics other than food safety, we restrict our analysis here to respondents from the FDA's Center for Food Safety and Nutrition (CFSAN). Notable differences in the two surveys include:

- While only 12 percent of 2006 CFSAN respondents agreed or strongly agreed that the FDA had "sufficient resources" to adequately perform its mission, that number among the 2010 CFSAN respondents rose to 40 percent.

- Only 32 percent of 2006 CFSAN respondents agreed or strongly agreed that FDA was "moving in the right direction," but in 2010 that number was 74 percent.

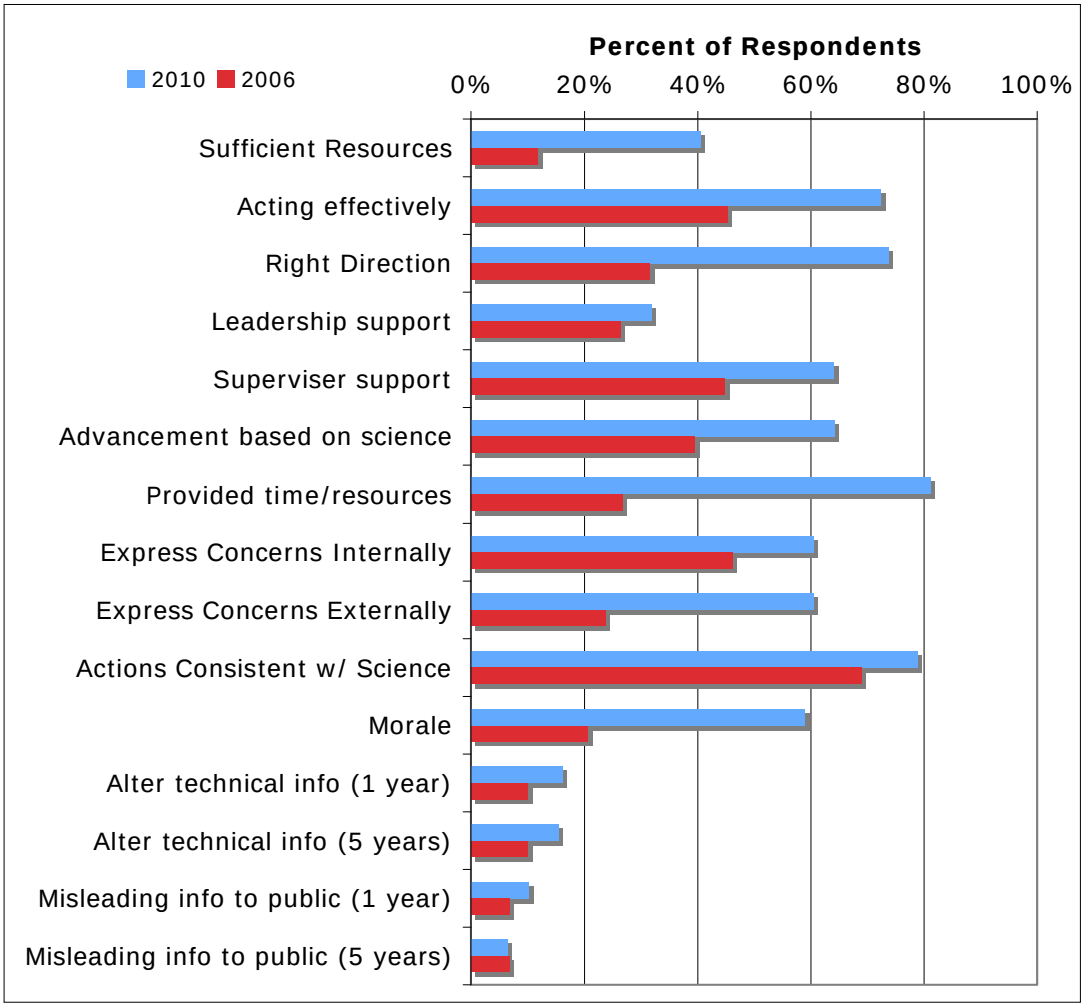
- In 2006, only 21 percent of CFSAN respondents reported good or excellent morale within their center or office, while in 59 percent did so in 2010.

- While 10 percent of 2006 CFSAN respondents had frequently or occasionally been asked to inappropriately exclude or alter technical information or conclusions in an FDA scientific document over the past year, 16 percent of 2010 CFSAN respondents had been asked to do so.

- Seven percent of 2006 CFSAN respondents had frequently or occasionally been asked explicitly by FDA decision makers to provide incomplete, inaccurate, or misleading information to the public or other entities in the past year, while 10 percent of 2010 CFSAN respondents had been so requested.

It is important to state that a number of unknown factors may influence these differences in results. We have no way of knowing, for example, whether the demographic profiles of those who responded to the 2006 and 2010 surveys were divergent. Similarly, the questions' wordings in the two surveys were not identical and could have accounted for some of the differences in outcome. Figure 8 summarizes the comparisons between 15 pairs of similar questions.

Figure 8: Comparison of 2006 and 2010 FDA Surveys



The ARS, which functions more as a pure research agency, reported notably lower levels of political interference in science than did all sections of the FSIS and FDA, which are responsible for using science in crafting regulations. If we take the ARS results as reflecting a rough "control" group, the results of the other groups show some evidence that the levels of interference found by our survey are not expressive of normal agency operations.

The responses to these questions, over both the one- and five-year time frames, were of the same order of magnitude as the level of political interference reported by scientists at the EPA in response to similar questions in 2007 (Donaghy et al. 2008b).

Outside Interference

A series of questions asked about the prevalence of outside entities—specifically corporate interests, nongovernmental organizations (NGOs), and members of Congress—influencing agency policies. In certain respects, this outside influence was even more widespread than internal political interference.

Most troubling, 330 respondents (27 percent) reported frequently or occasionally experiencing "instances where the public health has been harmed by businesses withholding food safety information from agency investigators" in the past year, as shown in Figure 9. Two hundred and seventy three respondents (22 percent) seldom reported such experiences. We interpret these results to mean that a total of 603 respondents (49 percent) had the experience at least once. A similar number—621 respondents (38 percent)—agreed or strongly agreed that "public health has been harmed by agency practices that defer to business interests."

In response to questions about the sources of outside influence:

- Three hundred and one respondents (25 percent) had frequently or occasionally experienced "situations where corporate interests have forced the withdrawal or significant modification of an agency policy or action designed to protect consumers or public health" in the past year. Two hundred and seventy seven respondents (23 percent) seldom reported such experiences. We interpret these results to mean that 578 respondents (48 percent) reported that the experience occurred at least once during that period.

- Two hundred and forty-three respondents (22 percent) had frequently or occasionally experienced "situations where nongovernmental interests [such as advocacy groups] have forced the withdrawal or significant modification of an agency policy or action designed to protect consumers or public health" in the past year. Two hundred and twenty five respondents (20 percent) seldom reported such experiences. We interpret these results to mean that 468 respondents (42 percent) had the experience at least once during that period.

- Two hundred and sixty-six respondents (24 percent) had frequently or occasionally experienced "situations where members of Congress have forced the withdrawal or significant modification of an agency policy or action designed to protect consumers or public health" in the past year. Two hundred and twenty nine respondents (21 percent) seldom reported such experiences. We interpret these results to mean that 495 respondents (45 percent) had the experience at least once during that period.

Finally, in each of the four questions about outside influence, fewer agency veterans reported experiences of interference over the past year than over the five years previous (Figure 9). As with the trend in political interference, this was consistent across all four questions, although in each case the decline was small and again difficult to interpret.

Figure 9: Number of Respondents Reporting Various Forms of Outside Influence in the Past Year

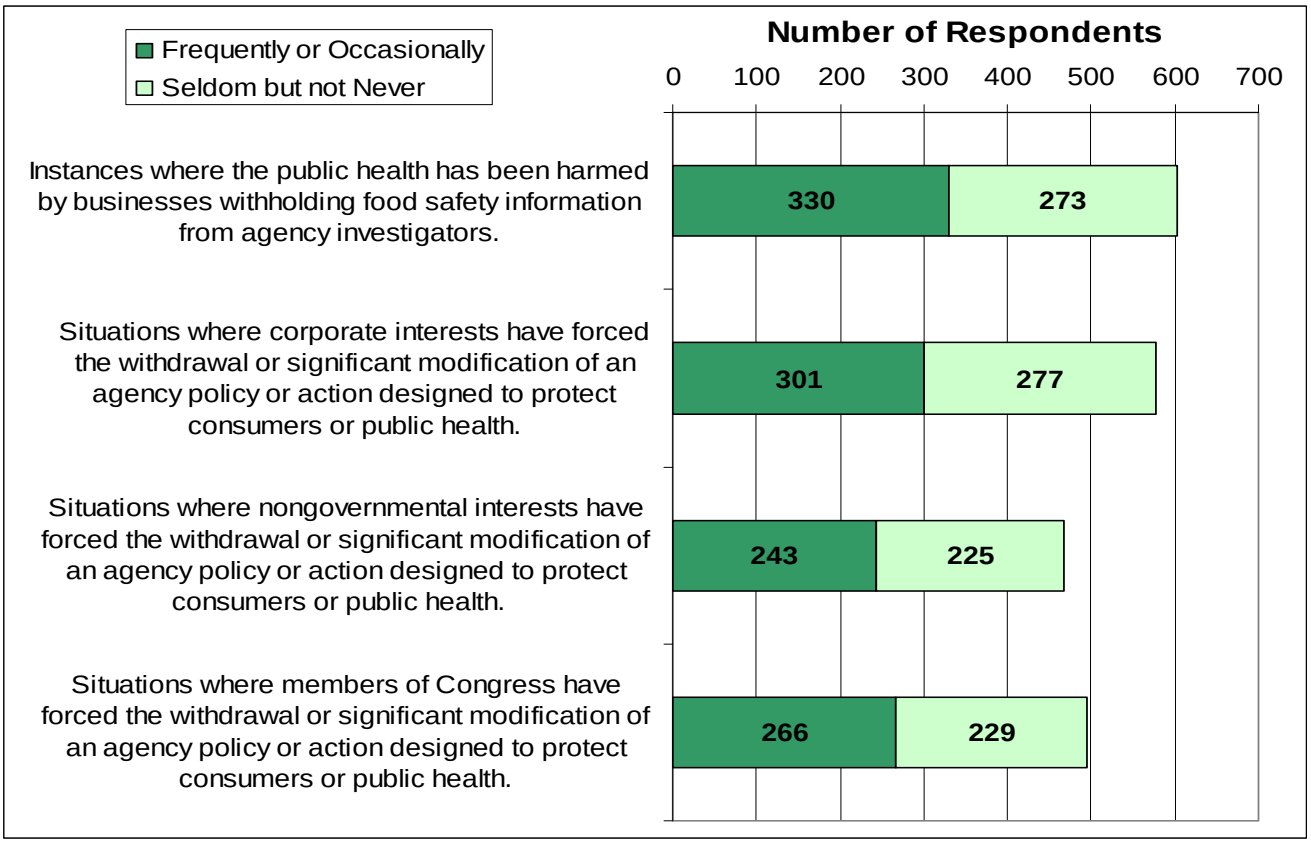
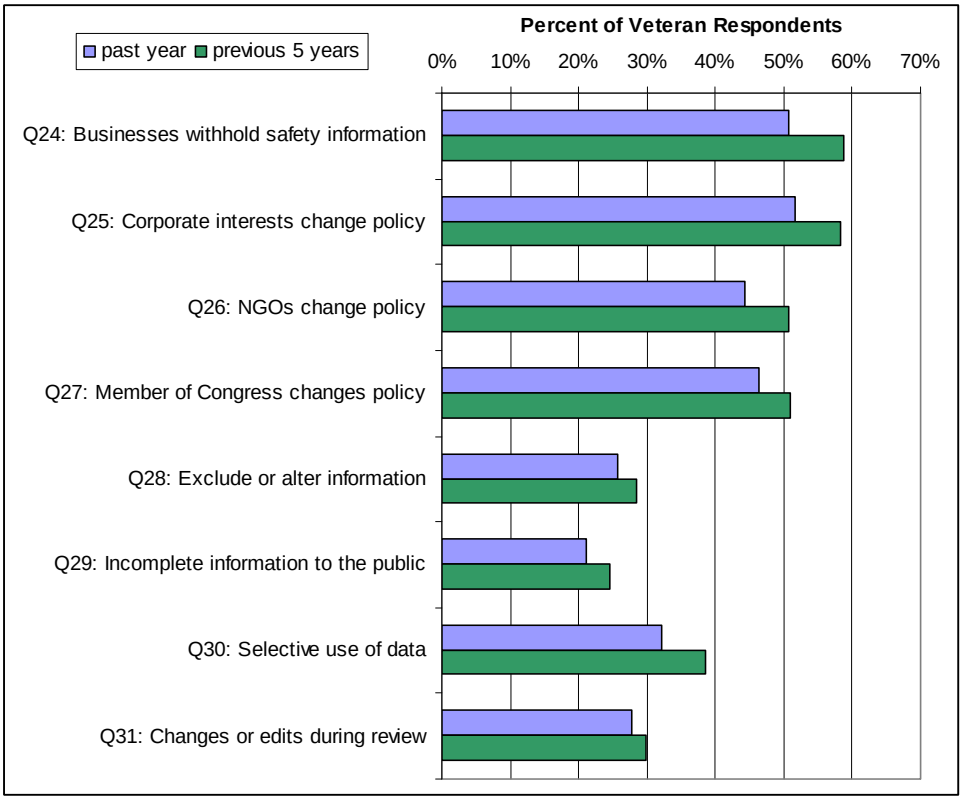


Figure 10. Trends in Political and Outside Interference Over Time



Respondents were also asked to rate how much weight was given to four factors—*public health*, *political interests*, *consumer interests*, and *business interests*—in agency decisions. Responses indicated that all four factors play some role. *Public health* was seen as being given "a lot of weight" or "much weight" by 75 percent of respondents, while 58 percent said the same of *political* and *consumer interests*. Forty-four percent of respondents said that business interests were given a lot of weight or much weight in agency decisions.

A separate question asked whether the weight given to each factor was "Too low," "About right," or "Too high." While *public health* and *consumer interests* were both described as heavily weighted factors, only small numbers of respondents thought these weights were too high (5 and 6 percent, respectively). For both categories, 20 percent of respondents thought these weights were too low.

Conversely, while *political interests* were also seen as playing a significant role in agency decisions, 54 percent of respondents thought this level was too high, with only 2 percent judging it too low. Similarly for *business interests*, whose influence on agency decisions was seen as mixed; 34 percent of respondents thought this level was too high, 41 percent about right, and 6 percent too low.

The Revolving Door?

Media reports and watchdog groups have often criticized the FDA and USDA regarding top agency leaders who worked for their regulated industries either before their government employment or after. The answers to two survey questions paint a complicated picture of this "revolving door" phenomenon.

When asked whether the presence of top agency decision makers who have come from the food or agriculture industry "inappropriately influences the decisions made by the agency," a plurality (43 percent) of respondents said they were undecided, while 31 percent agreed or strongly agreed.

Among survey respondents from FSIS, a majority (51 percent) had previously worked for "a food producer, processor, distributor, or trade organization." That percentage was 20 percent at the FDA and 10 percent at the ARS. Among respondents who had been in industry, around half had been there for more than five years, although a majority (65 percent) had worked longer at their agency than for industry.

In their opinions about political and corporate interference in agency actions, survey responses from individuals with industry experience were virtually identical to those without industry experience.

Specific Food Threats

A series of questions explored individuals' confidence in the safety of various classes of foods. All recipients were asked to rate the safety of imported foods, USDA recipients were asked about meat and poultry, and FDA recipients were asked about eggs, seafood, fruits, vegetables, and processed foods. Respondents rated their confidence in the safety of each food category as "Completely confident," "Mostly confident," "Somewhat confident," "Not at all confident," or "Don't know."

- Both FDA and USDA respondents rated the safety of imported foods lower than the safety of the other categories. Only 35 percent of respondents were completely or mostly confident in the safety of imported foods, while 21 percent were not at all confident.

- Only 45 percent of FDA respondents were completely or mostly confident in the safety of fruits and vegetables, with 10 percent expressing no confidence.

- Seafood and eggs fared slightly better, with 49 and 50 percent of FDA respondents respectively reporting they were completely or mostly confident in the safety of both categories. Five and 10 percent of FDA respondents respectively reported that they were not at all confident in these food categories.

- Processed foods received the highest marks among FDA respondents, with 62 percent reporting that they were completely or mostly confident in processed food safety and only 6 percent reporting that they were not at all confident.

- Meat and poultry received a vote of confidence from USDA respondents, with 75 percent reporting that they were completely or mostly confident in these foods' safety and only 5 percent reporting that they were not at all confident.

Proposed Policy Changes

A series of questions asked for recipients' opinions about the likely effectiveness of various food safety reforms that have been proposed and debated. They were asked whether each of five potential reforms, if properly funded and implemented, would improve or worsen food safety in this country. Strong majorities of respondents favored the implementation of four of these reforms, but they were roughly split about the effectiveness of the fifth reform (consolidation of food safety activities into one government agency).

- By a margin of 41 percent ("would improve or greatly improve") to 25 percent ("would worsen or greatly worsen"), survey respondents approved of consolidating "all government food safety activities into a new Food Safety Administration." Fifteen percent predicted no significant change in food safety from such a reform and 18 percent said they didn't know.

- By a margin of 71 percent to 5 percent, survey respondents said that "requiring each food production facility to conduct a science-based hazard analysis and implement preventive controls" would improve rather than worsen food safety. This outcome appears to support an HACCP-based food safety system, which has been controversial.

- By a margin of 75 percent to 3 percent, survey respondents said that "increasing the frequency of food safety inspections conducted by the FDA" would improve rather than worsen food safety. The same question about FDA inspections was asked of USDA and FDA recipients alike: FDA respondents were more supportive than USDA respondents, although the concept had wide support in the USDA as well.

- By a margin of 73 percent to 3 percent, survey respondents said that "establishing a comprehensive electronic system to trace food products through the production and distribution system" would improve rather than worsen food safety.

- By a margin of 70 percent to 2 percent, survey respondents said that "establishing strong whistleblower protections for private or public employees who report problems affecting the food supply" would improve rather than worsen food safety.

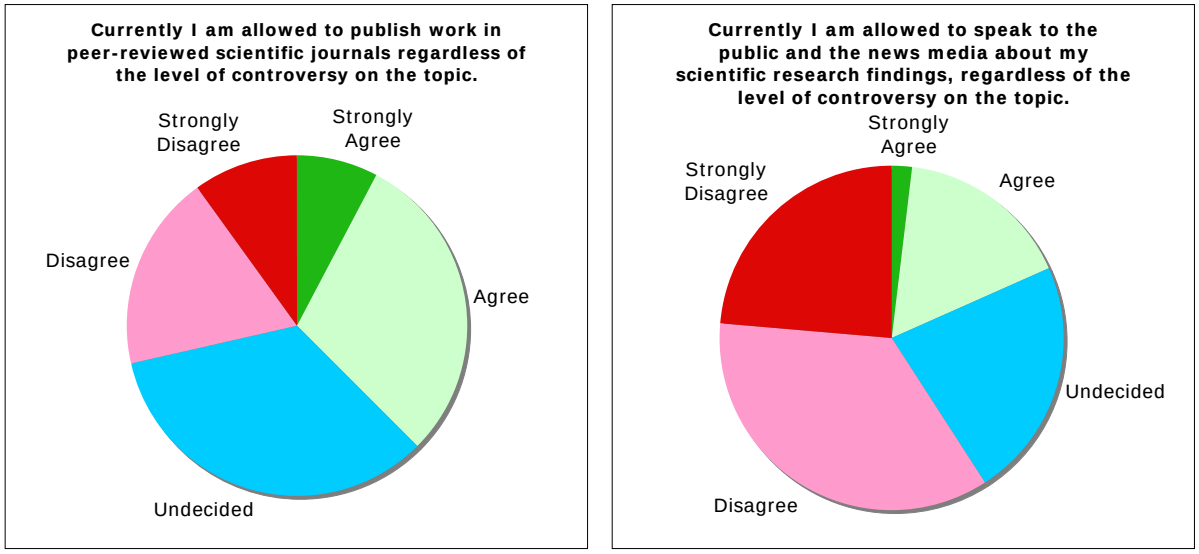
Professionalism and Candor

Scientists and employees at other federal agencies have often reported barriers to publishing results in peer-reviewed journals and communicating their scientific findings to the public. Corresponding staff at the USDA and FDA also noted such problems:

- Among survey respondents with advanced degrees,[‡] a majority (217 respondents, or 59 percent) disagreed or strongly disagreed that they were currently "allowed to speak to the public and the news media about my scientific research findings, regardless of the level of controversy on the topic." Only 67 respondents (18 percent) agreed or strongly agreed.

- In comparison, survey respondents with advanced degrees reported somewhat greater freedom in being "allowed to publish work in peer-reviewed scientific journals regardless of the level of controversy on the topic." However, only 139 respondents (37 percent) agreed or strongly agreed with that statement, while 106 respondents (28 percent) disagreed or strongly disagreed (see Figure 11).

Figure 11. Freedom to Speak and Publish among Respondents with Advanced Degrees



Overall, a majority of respondents agreed that they could "openly express any concerns about the mission-driven work of my agency without fear of retaliation," though a significant minority (448 respondents, or 26 percent) stated that they could not.

[‡] Defined here as a master's degree, Ph.D., M.D., J.D., or D.V.M. Percentages do not include those who responded "Does not apply."

Use of Science

Both agencies received overall positive marks on the use of science in decision making.

- Nine hundred and seventy-nine respondents (62 percent) said that their agency always or frequently "collects the scientific and monitoring information needed to effectively meet its mission."

- Eight hundred and ninety respondents (57 percent) said that agency determinations and actions are always or frequently "consistent with the scientific findings contained in agency documents and reports."

- Eight hundred and twenty-two respondents (52 percent) said that agency scientific documents always or frequently "make use of the best judgment of its scientific staff."

- Six hundred and ninety-three respondents (44 percent) said that expert advice from scientific advisory committees is always or frequently "heeded and incorporated into regulatory decisions," while a large number of respondents (540, or 34 percent) said that they didn't know.

Agency Mission and Management

A large majority (1,150 respondents, or 67 percent) agreed or strongly agreed that their agency is "moving in the right direction," a result that was slightly stronger at the FDA (72 percent) than at the USDA (65 percent).

Given the FDA's lower budget, it is unsurprising that FDA respondents were more likely than their USDA counterparts to question whether their agency has "sufficient resources to effectively perform its mission." Forty-seven percent of FDA respondents disagreed or strongly disagreed with that statement, while only 39 percent agreed or strongly agreed. In contrast, only 22 percent of USDA respondents disagreed or strongly disagreed, while 67 percent of agreed or strongly agreed.

Both groups of respondents strongly felt that their agency was "acting effectively to protect the public from foodborne illnesses." Eighty percent of USDA respondents agreed or strongly agreed with that statement, compared with a smaller but still significant number (67 percent) at the FDA.

Job Satisfaction and Morale

Both FDA and USDA respondents reported positive work environments.

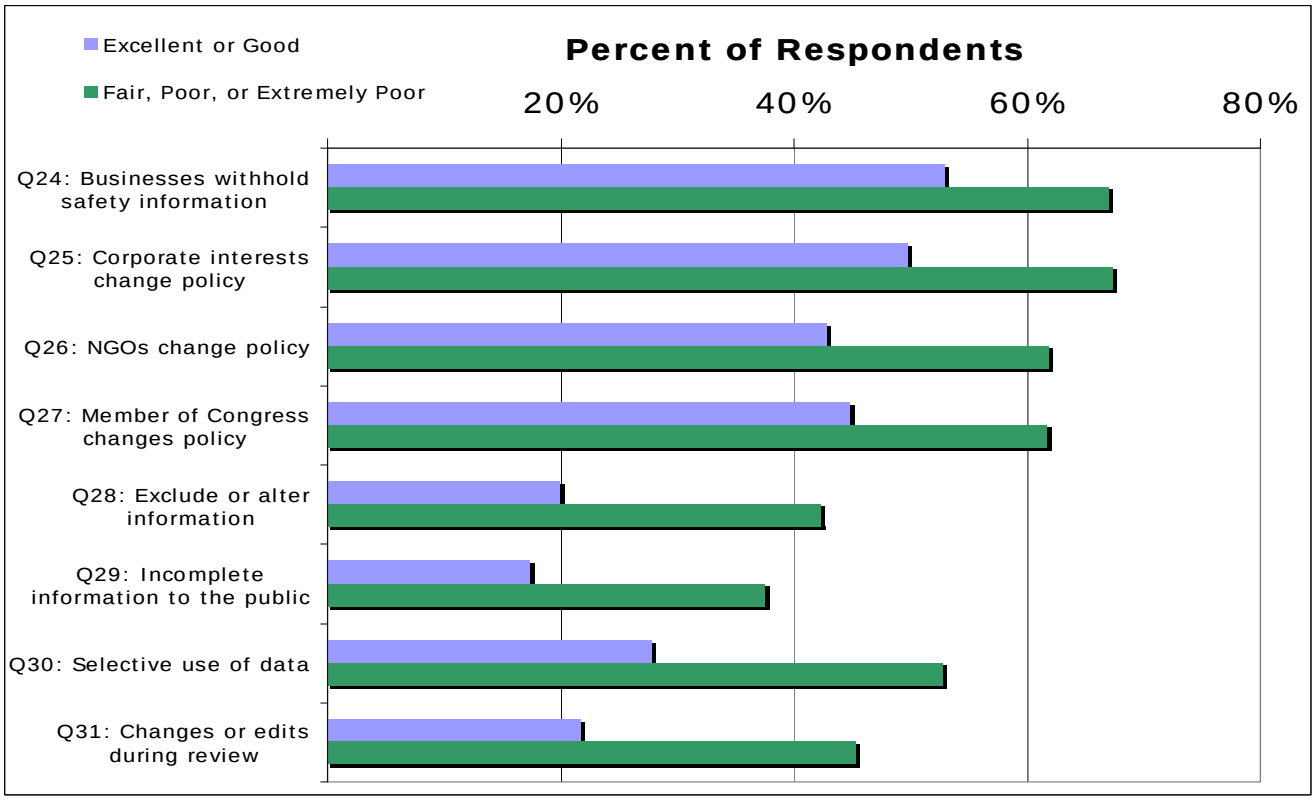
- Strong majorities at both agencies reported that their personal job satisfaction was either "Good" or "Excellent"—70 percent at the FDA and 72 percent at the USDA—with only 10 percent of respondents reporting "Poor" or "Extremely Poor" job satisfaction.

- Smaller majorities reported that morale in their center, office, or service was either good or excellent—54 percent at both agencies. Nineteen percent of respondents described morale in their office as poor or extremely poor.

These strong numbers for morale and job satisfaction give confidence that a broad cross-section of FDA and USDA staff responded to our survey—not just employees with grievances. Further analysis did uncover a negative correlation between job satisfaction and experience of political and corporate interference. However, such a link does not provide information about causation.

Among employees reporting at least one incident of political interference in the past year, a majority (284 respondents, or 56 percent) also reported good or excellent job satisfaction, while 221 respondents (44 percent) reported fair, poor, or extremely poor job satisfaction. Figure 11 shows the percentages of these two groups who reported various forms of interference, again suggesting that such reports are not fully explained by dissatisfaction with one's job (although they could serve as one significant cause).

Figure 12: Job Satisfaction and Political Interference



Conclusions

The results of this survey indicate that political and corporate interference is far too common in the food safety system, with serious consequences for government accountability and public health.

Calls to base decision making on "sound science" or the "best available science" are nearly universal in and around government, and they come from all parts of the political spectrum. According to the Institute of Medicine, the GAO, and many other informed observers, there is good reason to believe that a food safety system more grounded in science would work better than the present system in reducing the incidence of foodborne illness across the country (IOM 2010). Indeed, the rise of HACCP and the microbial testing of food products—a trend that may

be accelerated with the passage of a strong food safety reform bill—represent a slow though as yet incomplete shift toward a more science-based system.

But paradoxically, the high level of respect accorded science also leads to a constant temptation on the part of policy makers, corporations, and others to meld it to fit a desired policy outcome. All parties want to have science on *their* side. Further, evidence suggests that recent and widespread occurrences of political and corporate interference in regulatory issues were most the intense when science was the deciding factor—for example, Clean Air Act pollution standards, FDA drug approvals, and endangered species listings (De Angelis, Donaghy, and Grifo. In preparation).

This trend was echoed in the food safety world during the late 1990s, when the USDA attempted to use microbial testing as a basis for regulation. In that situation the battleground was the court system, but in the future the fight may shift to the processes by which tests are conducted, the levels at which regulatory actions are triggered, or even the test results themselves. Thus as the food safety system moves toward a more science-based approach, it is crucial that safeguards be put in place to prevent such abuses.

Our survey results indicate that interference in science can range from the explicit (but rare) rewriting of scientific conclusions to subtler but more common abuses such as the selective use of data or the editing of agency documents so as to weaken them. Survey respondents also reported that public health had been harmed by corporate influence in particular—either through the withholding of needed information from government or through industry's lobbying to withdraw or modify certain agency actions.

There is no silver bullet for this type of abuse. Any system of fact-based decision making that is flexible enough to incorporate new scientific findings or data is vulnerable to political or corporate manipulation. Fortunately, a number of mechanisms exist that could make such abuses of science more difficult to perpetrate and easier to discover, thereby helping to preserve the system's scientific integrity. Any congressional reforms of the food safety system should include such safeguards.

The similarities of responses from two very different agencies suggest the need for *system-wide* reforms. Toward that end, changes throughout the executive branch—aimed at protecting government scientists, increasing transparency and accountability, and restoring scientific integrity—could combat the political and corporate interference at the FDA and USDA. These are just the sorts of reforms outlined in President Obama's memo on scientific integrity, released in March 2009. Unfortunately, concrete plans for implementing the memo's principles, much less specific benchmarks and guidance, have not yet been released, despite the urgency.

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Appendix: Selected Survey Results

The tables below provide detailed data on responses to survey questions referenced in the main text. The first set of tables shows the total number of responses to questions, broken down by offices or centers within the FDA and USDA. The second set of tables provides cross-comparisons between two survey questions. Additional survey data and analyses are available online at *www.ucsusa.org/surveys*.

Selected Responses by Office and Location

These tables break down survey questions based on respondents' office or center within the FDA and USDA. The leftmost column lists the response options for the given question. The column labeled "total" lists the total number of respondents who chose the available option. The row labeled "total" lists the number of respondents answering the question, and the total respondents from each office or center.

The breakdown into individual offices and centers for each question is not complete because of the large number of FDA and USDA offices and centers. For simplicity, we analyze only the results for offices or locations specifically mentioned in the main text. The values in the right-hand columns therefore do not add up to the value in the "total" column.

The percentages in each table are based on the total number of scientists from each office or center who answered each question.

Cross-Comparisons of Selected Responses

These tables compare responses to two survey questions. The two columns on the left side list the first survey question, the available responses, and the total number of scientists who chose each option. The row labeled "total" provides the total number of respondents on the first question, and the total number of respondents for each option on the second question. The totals for the first question will not always equal the sum of respondents for the second question because a given respondent may not have answered both questions.

Acronyms

ARS	Agricultural Research Service
CFSAN	Center for Food Safety and Applied Nutrition
FDA	Food and Drug Administration
FSIS	Food Safety Inspection Service
OFO	Office of Financial Operations
OPEER	Office of Program Evaluation, Enforcement and Review
OPHS	Office of Public Health and Science
ORA	Office of Regulatory Affairs
USDA	United States Department of Agriculture

Questions 12 and 13 were completed only by individuals whose job duties involve science. Scientific work may include, but is not limited to, basic research, laboratory testing, data collection, risk assessment, veterinary medicine, economic analysis, and science policy. Advanced degree is defined as a masters degree, Ph.D., M.D., J.D. or D.V.M. Numbers do not include those who responded "Does Not Apply."

Questions 9, 14–17, and 32 were completed only by individuals whose job duties involve science. Scientific work may include, but is not limited to, basic research, laboratory testing, data collection, risk assessment, veterinary medicine, economic analysis, and science policy.

For Questions 24–27, numbers do not include those who responded "Does Not Apply."

Questions 28–31 were completed only by individuals whose job duties involve science. Scientific work may include, but is not limited to, basic research, laboratory testing, data collection, risk assessment, veterinary medicine, economic analysis, and science policy. Numbers do not include those who responded "Does Not Apply."

Question 34 was completed based on agency regulatory responsibilities. A respondent from one agency could not respond about a product regulated by a different agency.

Job Duties.

QUESTION 1: **Approximately what percentage of your job duties are related to food safety?**

	FDA		FSIS		ARS		TOTALS	
None	22	4%	4	0%	5	6%	31	2%
1-25%	55	10%	33	3%	13	15%	101	6%
26-50%	61	12%	40	4%	4	5%	105	6%
51-75%	64	12%	166	15%	10	12%	240	14%
76-100%	324	62%	856	78%	53	62%	1233	72%
TOTAL RESP	526		1099		85		1710	

QUESTION 2: **Approximately what percentage of your job duties involves science?**
(Note: Scientific work may include, but is not limited to, basic research, laboratory testing, data collection, risk assessment, veterinary medicine, economic analysis, science policy and other topics.)

	FDA		FSIS		ARS		TOTALS	
None	15	3%	85	8%	0	0%	100	6%
1-25%	55	10%	293	27%	1	1%	349	20%
26-50%	49	9%	247	22%	2	2%	298	17%
51-75%	117	22%	264	24%	4	5%	385	23%
76-100%	290	55%	210	19%	78	92%	578	34%
TOTAL RESP	526		1099		85		1710	

[If none, Q9, 12, 13, 14-17, and 28-32 are skipped.]
[If Q1 and Q2 are both none, go to close]

QUESTION 3: **Which one of the following categories best describes your work at the FSIS/FDA?**

	FDA		FSIS		ARS		TOTALS	
Basic Research	73	14%	2	0%	70	82%	145	8%
Laboratory Testing	131	25%	27	2%	1	1%	159	9%
Modeling	5	1%	2	0%	0	0%	7	0%
Risk Assessment	21	4%	20	2%	0	0%	41	2%
Science Policy	21	4%	3	0%	0	0%	24	1%
Other Science	22	4%	14	1%	9	11%	45	3%
Food Safety Inspection	44	8%	427	39%	0	0%	471	28%
Consumer Safety Inspection	108	21%	421	38%	0	0%	529	31%
Program Management	38	7%	67	6%	4	5%	109	6%
Administrative & Office Support	11	2%	39	4%	0	0%	50	3%
Other	39	7%	46	4%	1	1%	86	5%
(new) Compliance, Enforcement, Investigation	11	2%	30	3%	0	0%	41	2%
TOTAL RESP	524		1098		85		1707	

Mission.

Please indicate the extent to which you agree or disagree with each of the following statements.

QUESTION 4: **The FSIS/FDA has sufficient resources to effectively perform its mission of [FILL].**

	FDA		FSIS		ARS		TOTALS	
Strongly Agree	49	9%	228	21%	6	7%	283	17%
Agree	156	30%	524	48%	33	39%	713	42%
Undecided	73	14%	112	10%	15	18%	200	12%
Disagree	187	36%	191	17%	26	31%	404	24%
Strongly Disagree	61	12%	43	4%	5	6%	109	6%
TOTAL RESP	526		1098		85		1709	

QUESTION 5: **The FSIS/FDA is acting effectively to protect the public from food borne illnesses.**

	FDA		FSIS		ARS		TOTALS	
Strongly Agree	84	16%	321	29%	14	16%	419	25%
Agree	264	50%	551	50%	58	68%	873	51%
Undecided	74	14%	90	8%	7	8%	171	10%
Disagree	90	17%	110	10%	4	5%	204	12%
Strongly Disagree	11	2%	26	2%	2	2%	39	2%
TOTAL RESP	523		1098		85		1706	

QUESTION 6: **The FSIS/FDA is moving in the right direction.**

	FDA		FSIS		ARS		TOTALS	
Strongly Agree	110	21%	259	24%	11	13%	380	22%
Agree	269	51%	450	41%	51	60%	770	45%
Undecided	81	15%	201	18%	17	20%	299	17%
Disagree	49	9%	137	12%	6	7%	192	11%
Strongly Disagree	16	3%	52	5%	0	0%	68	4%
TOTAL RESP	525		1099		85		1709	

Management.

QUESTION 7: **FSIS/FDA leadership stands behind agency employees or managers who make decisions that may be controversial.**

	FDA		FSIS		ARS		TOTALS	
Strongly Agree	22	4%	76	7%	4	5%	102	6%
Agree	146	28%	396	36%	16	19%	558	33%
Undecided	192	37%	319	29%	43	51%	554	33%
Disagree	109	21%	211	19%	19	22%	339	20%
Strongly Disagree	49	9%	83	8%	3	4%	135	8%
TOTAL RESP	518		1085		85		1688	