



Senate II

US Food Safety Regulation

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Introduction

Every year, 76 million Americans get sick, 325,000 are hospitalized, and 5,000 die from food-borne illnesses caused by **microbial contaminants** and other pathogens. How is this possible? We live in a technologically-advanced, modern society that thrives on progress; how is it that one of the most basic staples of human life—food—is being so horribly neglected? It is a case of government oversight and neglect regarding federal food safety regulations. In January of 2007, the US Government Accountability Office identified America's food safety system as a high-risk area needing special oversight and reform.

Food safety is a scientific discipline describing the handling, preparation, and storage of food in ways that prevent food-borne illness, such as specific routines that should be followed to avoid potentially severe health hazards. Food safety is important because improperly handled food can transmit diseases from person to person and serve as a growth medium for bacteria that cause food poisoning.

Many policymakers have begun to question whether the US food safety system has the resources, authority, and structural organization to safeguard the health of American consumers, who spend more than \$1 trillion on food each year. Also at issue is whether federal food safety laws, first enacted in the early 1900s, have kept pace with the significant changes that have occurred in the food production, processing, and marketing sectors since then. Unfortunately, recent food safety-related incidents make it clear that our system and our laws are outdated, resulting in a food system that poses a serious threat to the health and safety of American citizens.

Aside from direct public health concerns, there are numerous other problems that arise from this lack of adequate food safety regulation. Consumer confidence in food purchased from grocery stores and at restaurants has decreased, thus adversely affecting the agricultural sector of society. Additionally, the economic costs of hospitalizations, lost productivity, and death from deadly food-borne pathogens are massive, costing the country billions of dollars each year. As representatives of the consumers of the United States, it is your duty to restore their confidence in American food safety and protect the public health of this country.

microbial contaminant—*a microorganism that enters a system (the environment, human body, food, etc.) where it is not normally found.*

Explanation of the Problem

Thirty-five years ago, the **US Food and Drug Administration (FDA)** completed annual inspections of roughly half the nation's food-processing facilities. Last year, the agency inspected just 7,000 of the nearly 150,000 domestic food facilities. Its oversight of foreign plants, which provide a growing share of the nation's food supply, was even less thorough. These lowered standards are indicative of the failing state of food safety regulation. To better understand and trace the downward spiral of food safety, we will consider the overarching issues in the following three divisions: structural deficiencies, misallocated resources, and insufficient method of attack.

Structural Deficiencies

A February 2007 Report from the Government Accountability Office (GAO) indicates that US federal regulations governing food safety are both fragmented and complicated. The two primary agencies in charge of food safety are the **US Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS)** (commonly referred to as simply the USDA), which is responsible for the safety of meat, poultry, and processed egg products, and the Food and Drug Administration, which is responsible for virtually all other foods. Though the USDA and the FDA are the primary agencies, there are 13 other agencies that share oversight responsibilities in the food safety system. This results in a chaotic and inefficient system. For example, a frozen cheese pizza is subject to inspection by the FDA, which inspects the average food manufacturing facility only once every 10 years. On the other hand, a frozen pepperoni pizza falls under the jurisdiction of the USDA, which performs daily inspections.

Another example can be found in fresh vegetables. Lettuce and other greens have caused outbreaks from strains of *E. coli* and *Salmonella* that were previously associated with meats. Although the USDA inspectors visit farms, they do not inspect the crops for safety. The FDA, the food safety agency most likely to regulate the safety of leafy greens, will not inspect a farm unless an outbreak occurs. Fresh vegetables of all kinds thus fall through a huge crack in the current food safety system.

The differences in the systems of inspection for the USDA and FDA also contribute to the chaos. The USDA first determines import eligibility, or whether the US can import a product. It does so based on how similar the foreign country's regulations are to US standards, along with on-site **audits** which oversee the regulatory procedures in the foreign country. Once eligibility has been established and imports reach

US Food and Drug Administration (FDA)—A federal agency in the Department of Health and Human Services responsible for regulating and supervising the safety of foods, dietary supplements, drugs, and other similar products.

US Department of Agriculture (USDA)—federal agency responsible for administering programs that address farming issues.

Food Safety and Inspection Service (FSIS)—public health agency responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged.

E. Coli—a group of gram-negative bacteria, *Escherichia*, that reside in the intestinal tracts of humans and many animals.

Salmonella—any of several rod-shaped bacteria of the genus *Salmonella*, that cause food poisoning and other diseases.

audit—examine carefully for accuracy with the intent of verification.

the US, 100% of the products overseen by the USDA must be inspected for certification documents, proper labeling, and overall condition.

Within the FDA system, import eligibility is established on a firm-by-firm basis, disregarding any value that could be derived from taking into consideration evaluations and standards already in place in the foreign country. Consequently, hundreds of thousands of firms from 150 different countries must first become certified by the FDA before they can sell their products on the US market. This, in turn, means that the FDA—an agency that is already underfunded and understaffed—is completely overwhelmed by the scope of its authority. Additionally, FDA inspections of the actual products once they arrive in the country are far less frequent than those performed by the USDA, as the FDA inspects only one percent of the food that it regulates.

Misallocated Resources

Federal food safety efforts are further hampered by inadequate funding, as well as confusion created by the outdated rules and regulations currently in place. While the USDA and FDA share the primary responsibility for food safety, each agency employs different inspection procedures and works with a different budget. Federal food safety expenditures are not distributed evenly across all the high risk foods. Instead, they are concentrated on meat and poultry products regulated by the USDA. While the products regulated by the USDA constitute only one-fifth the food supply and 27% of the outbreaks, Congress currently appropriates twice as much money for the USDA's food safety budget as for the FDA's. This gives the USDA the resources to inspect meat and poultry plants daily, as required by law. In contrast, the FDA, which regulates 80% of the food supply, inspects food facilities it oversees on average just once every 10 years and receives just 25% of the total federal money appropriated for food safety.

Reactive vs. Proactive

It is a growing consensus that the FDA's current programs are not proactive in design or execution. Tasks such as emphasizing prevention, evaluating hazards, and focusing inspection resources on areas of greatest risk to public health are not embedded in the current food safety program. Rather, the FDA has generally been a reactive body, usually stepping in during the aftermath of a problem—such as when **adulterated** or misbranded products are found in commerce, or an illness outbreak is caused by unsafe foods. Because of its widely acknowledged funding and staffing constraints mentioned earlier and the lack of an explicit requirement to conduct frequent inspections, the FDA rarely visits food manufacturing and related facilities to check sanitary and other conditions.

adulterate—*corrupt, debase, or make impure by adding a foreign or inferior substance.*

Virtually all stakeholders agree that the foundations of any new program should be an understanding of what and how hazards can enter the food supply, followed by the implementation of measures to prevent these hazards from manifesting themselves. Many private companies already do this using the Hazard Analysis and Critical Control Point (HACCP) system, a method designed to ensure that a facility is able to prevent hazards from getting into food during the manufacturing process, rather than simply performing safety checks of final products. The HACCP program has been recommended by the Committees of the National Academy of Sciences' National Research Council as an effective food safety approach.

Recent Developments

E. Coli on Spinach

In the fall of 2006, more than 200 confirmed illnesses and three deaths were linked to the consumption of bagged fresh spinach grown in California. The spinach was found to be carrying the bacterium *E. coli*, and was ultimately found in spinach sold in 26 different states. The FDA called for bagged fresh spinach to be removed from shelves and warned people not to eat any kind of spinach or spinach containing products. In California, where three-quarters of all domestically grown spinach is harvested, farmers—even those whose spinach is untainted—could face up to \$74 million in losses due to the *E. coli* outbreak. The incident raised public concerns about the safety of all fresh leafy produce and stimulated a number of industry and government initiatives to limit future contamination.

Salmonella in peanut butter

A major outbreak of *Salmonella* infections has been linked to the consumption of numerous peanut products—including a major institutional brand of peanut butter—which contained peanuts from a single firm, the Peanut Corporation of America in Blakely, Georgia. Between September 1, 2008 and March 17, 2009, the **US Center for Disease Control and Prevention (CDC)** has identified nearly 700 cases of *Salmonella* in the 46 states. The infection may have contributed to the deaths of nine people. A series of expanding recalls was announced by the FDA in early 2009, involving thousands of peanut containing products, such as crackers, peanut-butter cookies, and dog treats from more than 200 different companies.

US Center for Disease Control and Prevention (CDC)—a federal agency in the Department of Health and Human Services that investigates, diagnosis, and tries to control or prevent diseases.

Congressional Action

Pure Food and Drug Act of 1906

This act provided federal inspection of meat products and forbade the manufacture, sale, or transportation of adulterated food products and poisonous patent medicines. It also includes the requirement for prescriptions from licensed physicians before a patient is able to purchase certain drugs, as well as the requirement of label warnings on habit-forming drugs. The law paved the way for the eventual creation of the Food and Drug Administration and is generally considered to be that agency's founding date, though the agency existed before the law was passed and was not named the FDA until later.

Federal Food, Drug, and Cosmetic Act (FFDCA)

The FFDCA is a set of laws passed by Congress in 1938 that give authority to the Food and Drug Administration to oversee the safety of food, drugs, and cosmetics. It sets up a reactive structure in which the agency is truly **empowered** only when food is found to be adulterated or misbranded. It is also significant for its restrictions on poisonous chemicals, as it required the Food and Drug Administration to set maximum tolerance levels for unavoidable poisonous substances in food. Additionally, it prohibits the "misbranding" of food and provides enforcement mechanisms for inaccurate product labeling.

empowered —
possessing power or
authority

Food and Drug Administration Amendments Act of 2007

Signed into law by President George W. Bush, this act was a significant step for the Food and Drug Administration. It reviewed, expanded, and reaffirmed several existing pieces of legislation regulating the FDA. The changes made by the law allowed the FDA access to much needed resources, which enabled it to better protect American consumers by conducting more comprehensive reviews of potential new drugs and devices.

HR—An abbreviation of "House Resolution," and used to refer to bills currently being proposed in the House of Representatives

Food Safety Modernization Act of 2009 (HR 875)

This act has not yet been signed into law; it is a bipartisan bill currently being debated in Congress, sponsored by Congresswoman Rosa DeLauro (D-CT). The bill focuses on four key areas to improve: food-borne illness prevention, food-borne illness detection and response, food defense capabilities, and overall resources. Amidst much support, there is also a substantial amount of opposition towards this bill, most of which comes from the food conscious American public. Opponents feel as though the bill "criminalizes **organic farming**" and has the impact to destroy small family farms and even eliminate backyard vegetable gardens—a point that is hotly disputed by supporters of the bill.

organic farming—A farming method that minimizes the use of chemicals in the production process. It aims to produce crops with a high nutritional value and to improve the long-term fertility and sustainability of farmland.

Focus of the Debate

While most lawmakers agree that Congress should seek to improve the safety of the US food supply, there is much disagreement about the best way to go achieve such a goal. Debate has erupted over the past few months—no doubt spurred on by the recent food recalls and outbreaks—about whether to bolster food oversight at the Food and Drug Administration or assign its responsibilities to a separate agency. Another long debated issue of contention between experts is whether the FDA should increase inspections or rely instead on private auditors and more detailed safety rules.

Conservative View

Conservatives are ready and willing to craft and support a bill that provides the FDA with the necessary tools to ensure the safety of the public food supply, but are very much against supporting new blanket authorities that are designed merely to empower the bureaucracy, and they will not support **user fees**. Conservatives also commonly believe that taxes on food products will show up in increased costs of those products on grocery store shelves—increased costs that must be paid by consumers. Worth also noting is the neoconservative view that the government is neither needed nor useful even regarding food safety regulations. Justification for this view comes in the disdain towards fees on industry which will ultimately hurt consumers.

user fee—A fee paid by food facilities in order to fund the food safety activities of governmental agencies

Liberal view

Liberals are eager to enact food safety legislation, since they feel as though the current US food safety system can no longer play an efficient role in food regulation. It can be generally assumed that liberals will support any initiatives put forth by Democratic President Barack Obama, while looking to achieve conservative support whenever possible.

Presidential View

On the subject of food safety regulation, President Obama has blamed “outdated laws and regulations, inadequate food inspections and lack of resources at the Food and Drug Administration” for the recent mishaps. In order to tackle this issue, Obama has begun by appointing new people to lead the way in food safety regulation. He appointed former New York City health commissioner Margaret Hamburg as FDA Commissioner, and Baltimore health commissioner Joshua Sharfstein as the FDA’s Head Deputy.

Additionally, President Obama plans to create a Food Safety Working Group to advise him on legislation and ways to improve regulations. This multi-agency task force will revise and update food safety

laws and their enforcement by the US government. The group, headed by the secretaries of Health and Human Services and Agriculture, will include cabinet members and senior officials from other federal agencies responsible for food safety. And not least, Obama has pledged to invest a billion dollars in the improvement of both food inspection and testing.

Interest Group Perspectives

The Heritage Foundation

The Heritage Foundation, founded in 1973, is a public policy research institute with a primary focus on formulating and promoting conservative public policies based on principles such as free enterprise, limited government, individual freedom, and traditional American values. The Heritage Foundation believes that Congress and the Administration can best improve US food safety by implementing reforms that follow an unbiased, science-based approach to food safety that allows market forces and competition to weed out unsafe producers. The Foundation warns against injudicious regulations and restrictions that discriminate between food producers or erect unfounded, **protectionist**, non-tariff barriers to trade, arguing that not only would they do little to bolster US food security, but they would also likely violate international trade agreements and harm America's economic relations with developing countries. In line with their overall beliefs and policies, the Heritage Foundation maintains that government should take a balanced approach to food safety by keeping markets free and limiting the scope and cost of government intervention to establishing minimum accepted quality standards and implementing science-based methods of detecting tainted domestic and foreign products before they reach US consumers. As ardent supporters of free enterprise, the Foundations emphasizes that a competitive market environment is what motivates firms to produce and offer safe food for America's families.

protectionism — Policies that “protect” business and workers in an industry by restricting foreign trade, and, thus, competition within that industry

Center for American Progress

The Center for American Progress (CAP) is a think-tank dedicated to improving the lives of Americans through ideas and action. Their foundational beliefs build upon progressive ideals, and the Center is designed to provide long-term leadership and support to the progressive movement. The Center for American Progress recognizes the holes in the US food inspection system, and posits that stronger safeguards and tougher enforcement could reduce the current risk a significant amount. CAP criticizes the Bush administration for allowing food manufacturers significant leeway, essentially putting the interests of these manufacturers above the wellbeing of American consumers. Additionally, CAP warns against catering to special interests rather than the

American people; no chances should be taken when it comes to food safety regulation.

Possible Solutions

While the issue of food safety regulation is admittedly expansive, all facets of this problem deserve your consideration as you strive to enact legislation that will truly enhance the food safety policy of the United States and increase the safety and consumer confidence of millions of Americans. The overall problem can be broken down into separate issues, and it may serve you best to carefully consider each smaller issue before tackling the larger context of revamping the entire food safety regulation policy as it stands today.

Prevention over Reaction

A major issue that has been discussed at length is the problem of prevention. Currently, the food safety system is of a responsive rather than a preventative nature, which inherently creates difficulties and inefficiencies in the regulatory structure. To address this problem, there are various options, a shrewd combination of which will be required in order to build a comprehensive policy.

As senators, you could require food processing, manufacturing, shipping, and other regulated facilities to conduct an analysis of the most likely food safety hazards and to design and implement risk based controls to prevent them. Additionally, an increase in the frequency of plant inspections, taking into account risk factors, might also work towards improving the system. It might also help to strengthen record keeping requirements.

Determination of Authority

While there are those who argue that the FDA and USDA should be **merged** as a single authority, there are also others who see this step as unnecessary. Regardless of the particular path you choose, some agency needs to have a true authority over food safety matters. For example, the ability to mandate product recalls if a firm with suspect product fails to do so voluntarily is a key provision lacking in current legislation.

merge—to join multiple groups as one

Closer Scrutiny of Imports

In order to achieve a greater sense of food safety security, you might draft provisions that call for heightened scrutiny of imports, which comprise an increasing share of US food consumption. For example, requiring documentation for food imports certifying that they are from facilities and establishments that meet safety standards equivalent

to those in the US could play a crucial role in the food regulation process.

Increase Funding

There are numerous ways that legislators create funds to support their legislation. For the specific issue of food safety regulation, ideas such as imposing user fees have been tossed around, though they have been met with apprehension on various fronts. Nevertheless, it pays to consider possible places in which fees could be implemented, such as facilities that must register with the federal government, food import shipments, or those who must undergo re-inspection when problems are detected.

Questions for Policymakers

In considering exactly how to craft effective, beneficial legislation, it is important to keep a few main questions in mind to help you stay on track. Consider your **constituency**—are you representing a state with a large population of small farmers? If so, you must consider how their farming needs will be affected by every piece of proposed legislation you debate. Consider the other party. While increased food safety is a goal supported by the majority of both parties, there may be differences in opinion on how to achieve this goal. Keep in mind that in some cases, you may need to be open to compromise in order to reach a common end.

constituency—A group of people bound by a shared identity or loyalty. In the congressional context, it often refers to the citizens of the district or state that a Congressman or Senator represents

Conclusion

It is undeniable that the current state of US food safety is in dire need of reform. It is up to you, Senators, to debate amongst yourselves and arrive at a solution that works for all involved. Because of the broad scope of the US food safety system, a single bill may not be enough to cover the many needs of the current situation. Take care to truly explore the various pieces of this problem, and devise practical and effective solutions that will help to guarantee Americans' health and confidence in the food we serve our children every day.

Guide to Further Research

www.fda.gov/food/default.htm

The website of the US Food and Drug Administration will allow yourself to familiarize yourself with much of the food safety system and stay up to date on current events and regulations.

www.fsis.usda.gov

The website of the USDA's Food Safety and Inspection Service will allow you to explore the other main agency in charge of food safety in the United States, as well as to compare and contrast the USDA and FDA.

www.who.int/foodsafety/en/index.html

A website provided by the World Health Organization that discusses both methods of food safety and the way health ties into the food supply. It also provides a different perspective on food safety, as much of its work is conducted from an international point of view.

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