Proposed changes in US food safety legislation and its potential impact

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PROPOSED CHANGES IN US FOOD SAFETY LEGISLATION AND ITS POTENTIAL IMPACT

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MANAGEMENT SUMMARY

The United States Congress is considering legislation to modernize the country's food safety system. The House of Representatives has approved a food safety bill (HR 2749), and the US Senate has agreed in committee on its own bill, which may soon be considered by the Senate as a whole. Both bills would substantially transform food safety requirements for companies producing and distributing food, and would provide authority to the Food and Drug Administration (FDA) to enforce both existing laws and new provisions.

This research is to obtain an in-depth understanding of the context of the US food safety regulatory system, the proposed legislation and its likelihood of passage, and its potential implications and consequences.

THE BIG PICTURE: FOOD SAFETY IN THE US

The United States is the world's largest market for food products in terms of value and volume. According to the USDA, American consumer expenditures on food exceed $1.2 trillion annually, of which a little more than half is spent at home, and the remainder away from home.[1] Each year the FDA or state and local authorities regulate "more than 2 million farms, about 935,000 restaurants and institutional food service establishments, and 114,000 supermarkets, grocery stores, and other food outlets."[2] Approximately 140,000 registered domestic food facilities and 220,000 foreign food facilities supply US consumers. Given the expansive scale, diversity, and volume of US food production as well as the varied number of domestic and foreign food production sources, US government officials and food industry representatives frequently testify before Congress that the US has one of the world's most plentiful, safest, and affordable food supplies.

Due to the scale of the food production, distribution, and marketing system in the US, however, foodborne illness outbreaks occur frequently, causing an estimated 5,000 deaths, 325,000 hospitalizations, and 76 million illnesses each year. Moreover, outbreaks have increased in frequency and scale, from 1 or 2 per year a decade ago to 1 or 2 *per month* today. Some of the food recalls have cost an estimated $1 billion, and a recent study suggests that the cost of foodborne illness in the US is $152 billion annually (approximately $500 per person), once medical expenses, loss of wages and life, and other costs are factored in.

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[1] USDA, Economic Research Service, http://www.ers.usda.gov/briefing/CPIFoodAndExpenditures/Data/2007table97.htm

[2] Food Protection Plan (2007), US Department of Health and Human Services, Food and Drug Administration, November.

The regulatory system

The US food safety system is a patchwork of 15 federal agencies and 2,700 state and local health agencies that administer the overlapping monitoring, surveillance, inspection, enforcement, outbreak response, research, and education responsibilities defined by more than 30 food safety laws.

The primary agencies responsible for food safety are the FDA and the United States Department of Agriculture (USDA, which regulates meat and poultry products through its Food Safety and Inspection Service). Although the FDA is responsible for a larger percentage of foods, in comparison with the USDA it is underfunded and lacks authority. **The food safety legislation discussed in this report pertains to FDA-regulated products only.**

The FDA currently has 1,900 food inspectors in field offices around the country, and an additional 900 inspectors in the Washington, DC area, who inspect more than 44,000 food manufacturers and more than 100,000 registered food facilities. The FDA also coordinates inspection and regulatory activities with over 400 state agencies.

PROPOSED FOOD SAFETY LEGISLATION

The US Congress has debated and proposed several legislative measures to improve the food safety system in the United States. In this session of the House of Representatives, The Food Safety Enhancement Act (HR 2749) was introduced and passed. A similar bill, The Food Safety Modernization Act (S 510), was introduced in the Senate, approved in Committee, and is now awaiting action from the full Senate.

Should the Senate approve its bill, it will then be taken along with HR 2749 into conference, where differences between the two bills will be eliminated, a single bill will be approved by both chambers, and the President will sign it.

Both bills expand the authority of the FDA to regulate the 80% of the nation's food that falls under its jurisdiction. Food facilities exempt from the legislation's provisions include those already under USDA regulation, alcohol related facilities, farms, private residences, retail and foodservice establishments, fishing vessels, and aquaculture.

Common provisions

Both House and Senate bills have many common provisions; these are the ones most likely to make it through conference and become law:

Preventive control systems

- **Expanded access to records** – both bills give the FDA increased access to records.
- **Hazard Analysis and Prevention Control Systems** – both bills call for participants in the distribution chain to have food safety plans.
- **Inspections** - both bills call for an increase in the number of FDA inspections.
- **Mandatory inspections frequencies** – both bills set mandatory inspection frequencies.
- **Imported food specific provisions** – both bills have provisions specific to imported foods.
- **Certification for high-risk food products** – both bills task the FDA with requiring certification for high risk food products, according to origin or food classification.
- **Traceback system** - both bills require the FDA to work on traceability of food products.

Intervention

- **Mandatory recall authority** – Both bills give the FDA mandatory recall authority. Currently, the FDA relies on voluntary cooperation.
- **Administrative detention authority** – both bills give the FDA the ability to order the detention of food shipments.

Response

- **Civil penalties for non-compliance** – Both bills increase penalties for food safety violations.
- **Enforcement mechanisms for non-compliance** – both bills identify circumstances under which companies and products are deemed non-compliant.

Key differences between the bills

The bills also have provisions unique to one bill but not the other:

Prevention

- **Registration fees** – The House bill assesses a $500 annual registration fee for every qualified facility, domestic or international, which handles food destined for consumption in the United States. The Senate bill does not mandate a fee, but directs the HHS Secretary to collect fees for re-inspections and recalls
- **Trace-back systems** – The House bill mandates a national tracing system (but provides no funding); the Senate bill mandates pilot programs for produce and

processed food (based on recent outbreaks, most likely peanuts, other nuts, tomato products, and/or frozen meals).

Intervention

- **Seizure** - In the House bill, the FDA is given authority to seize and detain misbranded or adulterated food; in the Senate version, the FDA has authority to administratively detain non-compliant food, but not the authority to seize it.

Response

- **Criminal Penalties** - In the House bill, the FDA can impose criminal penalties (increased from a maximum of 1 year to a maximum of 10 years) and/or levy fines; the Senate bill does not grant the FDA the ability to impose criminal penalties.

Miscellaneous

- **Country-of-Origin Labeling (COOL)**; The House bill has a COOL provision for FDA-regulated foods; the Senate version does not.
- **Foreign Supplier Verification Program** – In the Senate bill, the importer is responsible for compliance of all its foreign suppliers with US food safety laws. The House bill lacks this provision.
- **Voluntary Qualified Importer Program** - In the Senate bill, there is a voluntary program to certify and demonstrate compliance with US food safety laws, a program which is supposed to provide expedited product movement. There is no VQIP in the House bill.

US FOOD IMPORTS AND FOOD SAFETY REGULATORY AUTHORITY

The volume of food imported in the US has increased each year over the past decade, from approximately $44 billion in 1999 to nearly $90 billion in 2007, more than doubling in value and nearly doubling in volume. In 2007, imported food products accounted for 15% of the US food supply. An even greater share of fresh fruits and vegetables (60%) and seafood products (75%) are imported. Each day the US receives approximately 25,000 food shipments from more than 100 countries at more than 300 ports of entry. The largest foreign suppliers of food to the US are Canada, Mexico, China, France, and Italy. Japan is ranked 29th, shipping approximately $660 million in 2009.

Despite the dramatic increase in food import shipments, food safety measures for imports are not handled uniformly.

The Department of Agriculture (USDA), the Food and Drug Administration (FDA), and the US Department of Homeland Security, Bureau of Customs and Border Protection (CBP)

inspect and certify that foreign food imports are free from pathogens, pests, disease, and filth.

For decades, the FDA has relied on an import food safety program focused on random inspections and laboratory sampling at production sources, limited ports of entry, and in response to ongoing outbreaks. The FDA currently manages imported food products according to a prevention program relying on electronic screening, customs procedures for imports, physical inspection, and sampling. However, an overwhelming majority of FDA-regulated products are not managed according to current legal statutes due to a lack of resources, limited legislative authority granted to the FDA, and poor information sharing between the FDA, USDA, and CBP.

FDA food safety inspections overseas are conducted according to the risk-profile for individual trading partners. On average, the FDA conducts over 100 inspections per year (through its Office of Regulatory Affairs, ORA). Of the 1,286 inspections conducted from 2001 to 2008, only two took place in Japan.

Potential impact of new food safety legislation on import authority, process, and products

The legislation proposes changes to FDA's approach to food safety oversight in three critical areas: Prevention, Intervention, and Response. Overall, proposed changes to FDA legislative authority is directed at improving accountability for food facilities, foreign suppliers, and importers.

Changes to FDA's approach to Prevention

- **Registration and registration fees:** Registration provisions in the legislation will ensure that each facility is documented and accounted for by the FDA, competent authorities in the country-of-origin, or third-party certification firms. The FDA will also be granted legal authority to levy and collect fees.
- **Hazard Analysis, Prevention Control, and Food Safety Plans**: The legislation grants the FDA authority to direct and review registered food facility Hazard Analysis, Prevention Control, and Food Safety plans.
- **Risk-based inspections**: The FDA will expand the frequency of inspections for all food classification groups, as well as the specialization of inspections conducted for particular food products according to risk assessments defined by product classification, area/region of origin, food facility history, and for imported products, the importer and broker history.
- **Enhanced access to records:** The FDA will be granted enhanced access to records for food facilities. The bill will require FDA access to records within 24 hours of the initial request.

Changes to FDA's approach to Intervention

- **Surveillance and monitoring**: The legislation directs additional funding to improve monitoring and surveillance programs administered by the CDC.
- **Traceability systems**: The legislation proposes a tracing system for pilot projects for specific food products determined by the FDA or a national tracing system for all US consumer food products.

Traceability in the current food safety system is limited to recordkeeping requirements which require food facilities to maintain documentation of their supply-chain for the previous food facility where the product originated, and the subsequent food facility where the product is shipped. Under current statutes, recordkeeping and dedicated investigator teams respond to foodborne illness outbreaks. The legislation proposes traceability pilot projects and a national program for all food products.

Additionally, the House version of the legislation may require traceability of food products within two business days, and for imported food products, the reporting of the entire supply chain.

Changes to FDA's approach to Response

The legislation grants the FDA enhanced authority to enforce regulations, punish repeat violators, and restrict potentially harmful food products from the public.

- **Mandatory recall authority**: The FDA will be granted mandatory recall authority for products which are deemed to be a potential risk to public health.
- **Enforcement**:

- **Seizure and Detention** - In the House version of food safety legislation, the FDA is granted authority to seize and detain adulterated or misbranded food products.
- **Civil Penalties** - The FDA is granted authority to impose more stringent civil penalties for non-compliance with registration, inspections, recalls, and recordkeeping.
- **Criminal Penalties** – The FDA is granted authority to impose criminal penalties for violators who knowingly distributing food products which pose a risk to public health.

Food safety regulations and US trade obligations

The overarching goal of the food safety legislation is to improve food safety in the US and strengthen the country's food safety laws. In addition, the provisions for the most part apply equally to both domestic and international suppliers to the market. Nevertheless, there is concern, particularly on the part of other exporters – but also within the USTR and certain legislative circles – that some of the provisions in the proposed laws may not be consistent/compliant with the US obligations under the WTO Sanitary/Phytosanitary (SPS) agreements.

Specifically, the concerns regard **registration fees**, which are not associated in the legislation with specific services, and **equivalence,** which is the language used by SPS for recognition of foreign food safety systems, but is not the language used in the US legislation.

PERSPECTIVES ON THE LEGISLATION

Perspectives – Foreign exporters

The larger US trade partners (e.g., Canada, Mexico) are following the legislation very closely and have a well-defined list of issues they are working to address. Smaller trading partners are less active, not quite as involved, and tracking developments more loosely.

Overall, there is support in the international community for the US to upgrade its food safety laws. Each country, however, is concerned with the actual rules that will be put in place and their potential impact on trade. Common concerns include:

- That the legislation provide equal treatment (nondiscriminatory principle)
- Avoiding unnecessary duplication in the name of food safety; e.g., certification and inspection requirements
- Avoiding trade disruption

The primary issues raised by foreign exporters were

- **Registration fees**. Exporters felt that registration fees are a blunt instrument, possibly in violation of the US WTO commitments. The primary objection to the fee is that there are no identifiable services provided in return.
- **Certification**. Most exporters already have certification systems for riskier food categories, and they understand the use of certification to promote food safety. The primary concern regarding certification is recognition of other countries' existing food safety systems. Other countries would prefer that the FDA deal with regulatory authorities overseas, rather than directly with companies, and

expressed a preference for FDA accreditation of foreign government agencies over independent commercial/nongovernmental ones (the legislation as written can be read as allowing independent, commercial 3rd parties to be responsible for approving other governments' accreditation systems).

- **Equivalence**. They also want the FDA to recognize their own equivalent systems (based on food safety outcomes), where possible. They are comfortable with the language of "equivalence," not with the current "meets or exceeds" (US safety standards) language in the Senate bill.
- **Inspections**. Exporters expressed concern regarding the inspection frequency/timetable required in the legislation, as well as the potential for unnecessary duplication. In addition, there was concern about "unreasonable" requirements that US-based importers inspect their suppliers (in the Foreign Supplier Verification Program).
- **Traceability**. Codex Alimentarius only requires "1 up / 1 down." Full traceability was cited several times as being a problem / unrealistic.
- **Food defense**. This was raised as an issue several times. Food defense focuses on reducing intentional adulteration of food. Interviewees said it "has nothing to do with food safety," that the mentality and concerns overseas were different than they are in the US, and they were concerned with the costs of compliance with food defense provisions.
- **Country of origin labeling (COOL)**. Exporters are not happy with the House bill's COOL provision, but generally acknowledged that consumer-ready products already have to meet Consumer and Border Protection (CBP) requirements.
- **Voluntary importer programs**. Exporters appreciated the provisions allowing for expedited trade. However, they also expressed concern that these programs will become essential to remain competitive.

Perspective – FDA

The FDA has taken the position that it will not comment on implementation of the rules until the legislation is signed into law by the President. However, the FDA Commissioner, Dr. Margaret Hamburg, provided official statements regarding each of the two bills, indicating how, from the FDA's perspective, the bills fall short or could be improved.

Overall, the FDA was strongly supportive of the House bill, but indicated that the Senate bill should be strengthened to more closely resemble the House bill:

- **On the House bill**: The FDA called for modification of provisions to take into account the operational challenges involved, flexibility to modify [reduce] the inspection requirements based on the best available data on risk, and allowing the FDA to authorize certification by accredited third parties, especially overseas.
- **On the Senate bill**, the FDA suggested multiple changes, specifically those granting more authority and enforcement capability to the FDA, as well as more funding and flexibility in terms of inspections.

Perspectives – Others

Consumer groups expressed a preference for the House bill over the Senate bill, but noted that both are "much" better than the current system. The primary objective of these groups is to bring the legislation to a vote in the Senate, after which passage would become very likely. The other key issues of importance to consumer groups are a preference for government-to-government dealings in the international arena (rather than reliance on non-governmental parties), as well as increased funding for the FDA to ensure that it has the resources necessary to carry out its mission.

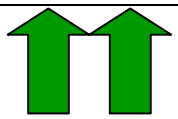
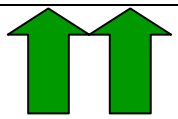
Food processors and importers expressed the most concern for avoiding overly burdensome and/or duplicative requirements. They said that certification and inspections requirements, particularly for samples and/or small product volumes, could lock potential suppliers out of the market.

Finally, **other observers** closely tracking the legislation offered (and generally agreed) on a number of other issues:

- Establishing full traceability systems is not something that can be tackled successfully, near term.
- Many of the rules will only become clear in the rulemaking process.
- The final bill is likely to be a watered down (i.e., weaker) version of the House bill.
- Funding will be a challenge and will limit what the FDA can accomplish.
- The general expectation is that legislation will pass this year, but that progress will happen regardless of passage.

The following table summarizes the relative positions of various groups, with respect to the proposed legislation:

Interest group support for food safety legislation

Interest group	Support level	Summary
Consumer groups		Very active support; in favor of tight food safety regulations, with real enforcement power and penalties; want to strengthen Senate bill
Industry groups		Very supportive, given high cost of recalls
Agencies (FDA)		Pushing for stronger enforcement power and funding; want to strengthen Senate bill but weaken inspection timetables
Legislators		The legislation provides some/many with political capital; some may oppose it due to special interests and/or cost
Foreign exporters		Generally in favor of the improvements, but have numerous concerns
Small producers		Concerned with cost of compliance, regressive fees, and overall, the adverse impact on their ability to compete

Most groups involved in the food safety issue are in favor of it. The most significant groups in opposition are (small) producers – many of which are exempt from its provisions anyway.

Potential obstacles and complications

Despite the broad interest group support, there are several factors which may contribute to prevent the legislation from passing this year:

- **Committee leadership changes** – Leadership in both committees approving the bills has changed since the bills were introduced. There is potential for the leadership of these committees to change their agenda to some degree.
- **Time** – This is an election year. The longer the legislation goes without Senate approval, the less likely it is to become law in 2010.
- **Loss of Democrat supermajority** – In the fall, the Democrats had a 60-seat supermajority in the Senate, guaranteeing passage of their legislation. The bill itself is not particularly partisan, but could become caught up in other legislative struggles.

- **Budget considerations** – With the US economy apparently stabilizing, concerns about the federal budget deficit have been mounting. An unwillingness to fund new FDA responsibilities would render them infeasible.

Despite these potential obstacles, prospects for passage of food safety legislation this year are good. Food safety continues to occupy headlines, with several large recalls in the past several weeks and months; several lawmakers continue to call for passage of the legislation.

OVERALL CONCLUSIONS

- **This legislation has a strong chance of passing**. There is broad support for the passage of this legislation. The FDA, consumer and industry groups, and both political parties all support for it. Congressional deadlock and legislative inertia are the strongest obstacles, but will likely be overcome this year, possibly by mid-year.
- **Changes will happen regardless of legislative outcome; passage will accelerate the process**. The primary consequences of the legislation will be to bolster FDA's authority and possibly provide more and more secure funding for food safety activities. In practice, many items called for by the legislation are already underway, albeit slowly. With passage of the legislation, change will accelerate, but even if it is not passed, change will continue.
- **A lot of changes will be incremental**, building on existing/current initiatives (see previous conclusion).
- **Many important details will be decided later**, following passage of the law. Although they have broad requirements, both food safety bills leave many of the details to FDA rulemaking, which will take years. Implementation will taken even longer.
- **Funding will have a strong impact** on exactly how much regulators will be able to ask for and manage. The legislation will only be as successful as the funding allocated for the FDA to follow through on its provisions.
- **Legislation is unlikely to significantly affect Japanese food exporters**. Japan already has a sophisticated food safety system; consequently, very little of FDA's international food safety activity has involved Japan or its exports. This is unlikely to change after the law passes, as FDA will necessarily have to tailor its resources to managing higher-risk sources of food. However, companies must still meet compliance requirements (e.g. registration, inspections) and importers may require proof of compliance / additional documentation.

SPECIFIC CONCLUSIONS FOR THE FOOD TRADE

Likely changes

Based on our research, the following changes are likely:

- **Hazard analysis and prevention control plans will be required** for all food handling facilities – This is a common provision in both bills, and a key component of a preventive food safety system. Sooner or later, it will be required throughout the food chain.
- **Importers will be held more accountable** for their suppliers – Given the FDA's limited international reach, both bills seek to make importers more accountable for the products they introduce into the US food supply. Exactly how burdensome new requirements will be remains to be seen.
- **Inspections will increase in frequency** based on risk. Increased inspections are a centerpiece of the House bill and are a key requirement from consumer groups.
- **The cost of food safety compliance will increase**. It is safe to say that if the legislation is enacted, compliance with the new rules will add costs to food trade.
- **Civil and criminal penalties for food safety violations will be enacted/increase** – penalties for unwitting and intentional food safety violations are extremely limited today. If anything like the House provisions are enacted, consequences for such violations will increase substantially.
- **Risk-based testing** will continue to be refined. The new PREDICT system appears to be an incremental improvement over OASIS. Expect algorithms to continue to be improved over time, allowing inspections to focus on the highest-risk shipments.
- **Product specific inspections procedures will be developed**. The FDA will be tasked with continuing to expand and improve inspections procedures.

Possible changes

The following developments are possible:

- **Food defense plans**: These are seen as an important element ensuring bi-partisan support for the legislation, and may well be required in the near future, should the legislation pass. In deference to the potential burden of this requirement, however, the required plans may be relatively modest.
- **Import certificates and/or fees may expand**: The number of food categories (and possibly countries) subject to certification requirements may increase.
- **Electronic recordkeeping will be required**. Either piecemeal or in substantial moves, data gathering and reporting will shift to electronic formats. How quickly

will be a function of legislation and the resources devoted to supporting compliance.

- **Participation in voluntary importer programs may become necessary** to remain competitive. As these programs create opportunities for expedited shipping, they may ultimately become a pre-requisite for effectively competing in the US food market.
- **Mandatory reporting of all laboratory results** - Companies heretofore have had the luxury of resubmitting samples and "gaming the system" by shopping around for favorable results and sending authorities only the best results. These possibilities may be eliminated, requiring that ALL laboratory results be reported, regardless of outcome.
- **Partial traceability**: implementation and enforcement. Traceability may be put in place, either "1 up / 1 down" across the board, and/or fully in select distribution chains.

Unlikely

- **Full traceability** – It is unlikely that the resources will be available for enforcement of full traceability in the foreseeable future, regardless of what the legislation may say. Moreover, the more stringent House version (full traceability) is inconsistent with WTO's "1 up / 1 down" traceability agreement.

SECTION 1: INTRODUCTION AND OBJECTIVES

The United States Congress is considering legislation to modernize the country's food safety system. The House of Representatives has approved a food safety bill (HR 2749), and the US Senate has agreed in committee on its own bill (S 510), which may soon be considered by the Senate as a whole. Both bills would substantially transform food safety requirements for companies producing and distributing food, and would provide expanded authority to the Food and Drug Administration (FDA) to enforce both existing laws and new provisions.

This research is to obtain an in-depth understanding of the context of the US food safety regulatory system, the proposed legislation and its likelihood of passage, and its potential implications and consequences.

Specifically, we were asked to research and report back on the following:

Background on food safety in the US

- History and scope
- Government action: legislation and enforcement

The food safety legislation (currently HR 2749 and S 510)

- Provisions
- Changes mandated by the provisions, especially in the following areas
  - Inspections
  - COOL
  - Registration of food facilities
  - Traceability requirements
  - Mandatory recalls
- Similarities and differences between the bills
- Details on the legislative process
- Concerns, reactions, potential alliances with other exporters

In this report we address each of these topics, as well as an in-depth examination of a number of other food safety issues. The study provides our detailed findings, including information and insights collected from nearly two dozen interviews conducted with influential and expert individuals observing or involved in food safety, including legislative staff, food safety experts, lobbyists and congressional observers, import specialists, consumer and industry group representatives, and Washington-based agricultural counselors from several countries with substantial food exports to the US.

In **Section 2**, we describe the US food safety system in detail, describing the magnitude of the food safety challenge, the agencies responsible for food safety, the nature of outbreaks and regulatory response in recent history, and recent agency initiatives.

The primary subject of this report, the food safety legislation pending in the US Congress, is the subject of **Section 3**. In it we describe the legislative process, the specifics of the House and Senate bills, as well as similarities and differences between the bills. We also include information relating the bills to specific issues.

In **Section 4**, we describe the current import environment for foods in the US, as it relates to food safety. We describe the role imports play in the food system and the authorities that regulate imports. We then itemize the ways the proposed legislation would impact the import process. We conclude by looking closely at the FDA-regulated products the US imports from Japan, identifying other exporters of similar products (i.e., potential legislative/rulemaking allies), as well as at the impact legislation would have on specific food categories.

Section 5 shares the many perspectives on the legislation that were uncovered in interviews. We highlight in particular the key issues of concern to other food exporters. We also provide the perspective of the FDA itself, as well as those of consumer groups, companies involved in food trade, and others.

Section 6 summarizes the outlook for the proposed legislation, identifying the forces that are creating pressure for its passage, as well as the obstacles that might keep it from being approved in the near term.

Our conclusions, both overall and specific for importers, are the subject of **Section 7.** In it we also include specific recommendations.

Finally, we have included several **appendices** to this study, among them outlines for the Senate and House bills, information about the import process, further details from our interviews with exporters, and a selection of links to key sources of information.

SECTION 2: FOOD SAFETY IN THE UNITED STATES

The United States is the world's largest market for food products in terms of value and volume. According to the USDA, American consumer expenditure for food exceeds $1.2 trillion annually, of which a little more than half is spent at home, and the remainder away from home.[3] Each year the FDA or state and local authorities regulate "more than 2 million farms, about 935,000 restaurants and institutional food service establishments, and 114,000 supermarkets, grocery stores, and other food outlets."[4] Approximately 140,000 registered domestic food facilities and 220,000 foreign food facilities supply US consumers. Given the expansive scale, diversity, and volume of US food production as well as the varied number of domestic and foreign food production sources, US government officials and food industry representatives frequently testify before Congress that the US has one of the world's most plentiful, safest, and affordable food supplies.

Nevertheless, waning consumer confidence about the overall safety of food consumed in the US has prompted public scrutiny and various responses from the White House, Congress, and food safety agencies. A June 2008 study by the Harvard School of Public Health, Project on the Public and Biological Security, reported that in a polling sample a majority of Americans (58%) stated that they believe that food produced in the US is "somewhat" safe and 4% believe US produced food is unsafe. In 2007, the Food Marketing Institute's annual survey indicated that ongoing food safety news negatively affected consumer attitudes as the percentage of shoppers who were confident in the safety of supermarket food declined from 82% in 2006 to 66% in 2007, a year-on-year decline of 16% percentage points.

The overall risk profile of food safety to public health in the United States has increased in recent decades. The aging US consumer population is becoming more susceptible to foodborne illnesses. According to the US Census Bureau, more than 20% of the US population will be 60 years or older by 2015. Secondly, US food consumption patterns have shifted to include a greater share of foods consumed away from home, processed convenience foods consumed at home, and imported foods.[5] US imports of food products have increased from 4.9 million entry lines in 2002 to more than 9.5 million entry lines in 2007, nearly doubling in volume.[6] Overall, approximately 15% of the US food supply is imported. An even greater share of fresh fruits and vegetables (60%), and seafood products (75%) are imported.

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[3] USDA, Economic Research Service, http://www.ers.usda.gov/briefing/CPIFoodAndExpenditures/Data/2007table97.htm

[4] Food Protection Plan (2007), US Department of Health and Human Services, Food and Drug Administration, November.

[5] *Ibid.*

[6] *Ibid.* Note that each entry line represents individual tariff lines included in a shipment.

The importance of imports and concerns about food safety of imports from some origins underlined the need for comprehensive coverage of the foods circulating in the United States. Consequently, legislative initiatives have included provisions that will tighten food safety screening of imports. Currently a reform of food safety laws and regulation is in progress (and is the focus of this report).

2.1 US Food Safety Agencies and responsibilities

The US food safety system is a patchwork of 15 federal agencies and 2,700 state and local health agencies that administer the overlapping monitoring, surveillance, inspection, enforcement, outbreak response, research, and education responsibilities defined by more than 30 food safety laws.[7] The following is an introduction to these agencies, beginning with the two most prominent ones, the FDA and USDA's FSIS.

2.1.1 Food and Drug Administration (FDA)

The FDA is one of two agencies largely responsible for safe, wholesome, and properly labeled domestic and imported food products, with the exception of major meat, poultry, and processed egg products regulated by the USDA's Food Safety and Inspection Service (FSIS). FDA regulates approximately 80% of all domestic and foreign foods consumed in the US including produce, dairy products, seafood, processed foods and meats from animals not regulated by the USDA, and establishments which serve or make products from eggs. According to the Federal Food, Drug, and Cosmetics Act of 1938, the term food includes:

- Articles used for food and drink for man or other animals
- Chewing gum
- Articles used for components of any such article

The FDA estimates that in 2003, it regulated $417 billion of domestic food and $49 billion of imported food.[8]

The FDA has 1,900 food inspectors in field offices around the country and an additional 900 inspectors in the Washington, DC area, who inspect more than 44,000 food

[7] Shames, Lisa (2008), "Federal Oversight of Food Safety," US Government Accountability Office, Testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, US House of Representatives, January 28.

[8] FDA, CFSAN, http://www.fda.gov/AboutFDA/CentersOffices/CFSAN/WhatWeDo/default.htm

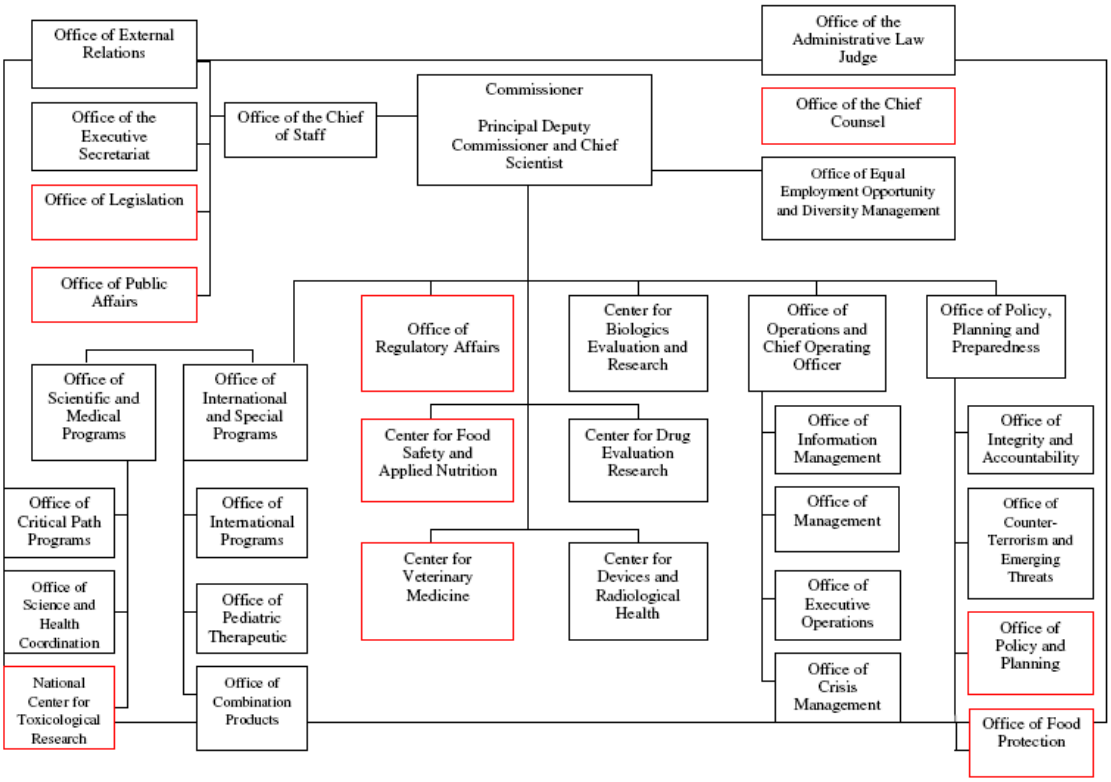
manufacturers and more than 100,000 registered food facilities. The FDA also coordinates inspection and regulatory activities with over 400 state agencies.[9]

Because foodborne pathogen contamination is often difficult to detect and manage once an outbreak has occurred, the FDA relies on a prevention principle. The FDA fulfills its food safety mandate by setting safety and sanitation standards, inspecting manufacturing facilities in over 136,000 domestic registered food facilities and approximately 60,700 other domestic food facilities, reviewing records, and inspecting foreign imports once every five years.[10] The FDA also inspects selected animal feeds used in human food-producing animals, and monitors pesticide residue levels, maintaining the Pesticide Monitoring Database.

Within the FDA, three agencies are charged with administering food safety regulatory oversight—the Center for Food Safety and Applied Nutrition (CFSAN), the Center for Veterinary Medicine (CVM), and the Office of Regulatory Affairs (ORA), as indicated in the accompanying chart. CFSAN is charged with researching and supporting food safety issues, developing and overseeing food safety and quality regulations, coordinating and evaluating FDA food safety surveillance programs, and developing food safety and regulatory information to educate consumers and the industry. The CVM is responsible for overseeing the development and monitoring of regulations for animal drugs, feeds, and veterinary devices, labels, and their effect on human health when used for animals in human food production.

[9] Becker, Geoffrey (2009), "Federal Food Safety System: A Primer," Congressional Research Service, April 8.
[10] Becker, Gary (2009),

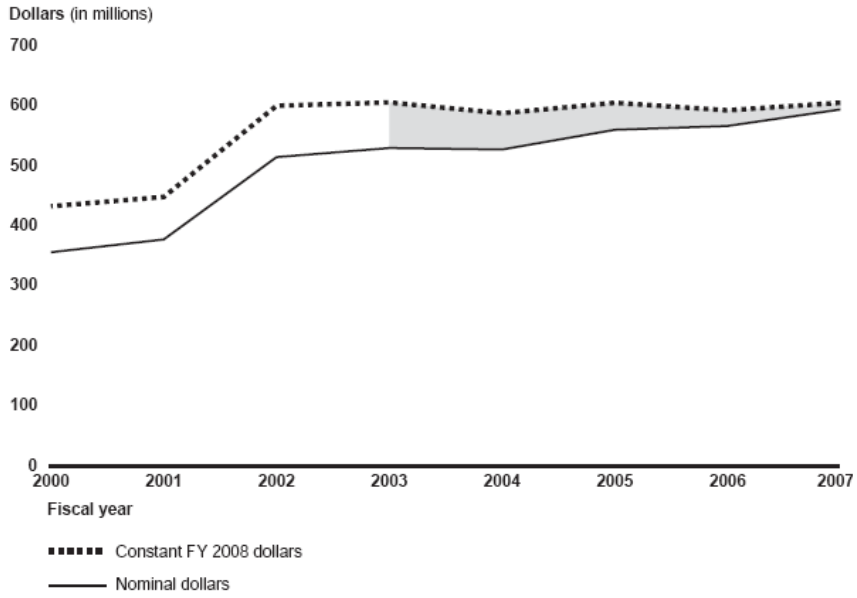
Food and Drug Administration Organizational Chart



Source: Robert Wood Johnson Foundation/Trust for America's Health
Note: The boxes outlined in red represent FDA offices with food-related responsibilities.

Despite the increasing volume of activity the FDA most monitor, its funding levels (below) have been stagnant, and staffing levels (at bottom) have declined in recent years.

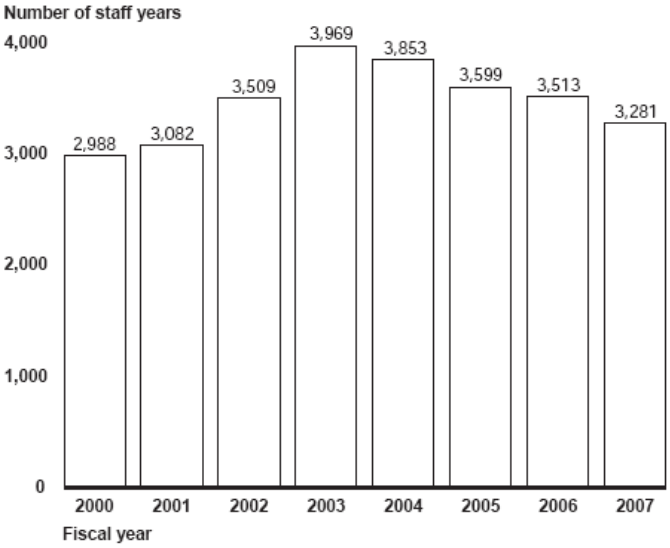
Figure 1: FDA Food Safety Spending in Constant and Nominal Dollars, Fiscal Years 2000 through 2007



Source: GAO analysis of FDA data.

Note: Annual totals include some non-FDA funding from collaborations between the National Center for Toxicological Research and non-FDA entities.

Figure 2: FDA's Total Food Safety Staffing Levels, Fiscal Years 2000 through 2007



Source: FDA data.

Note: Staff years are rounded to the nearest whole number.

The statutes governing FDA authority include the Federal Food, Drug, and Cosmetic Act of 1938, the Public Health Service Act of 1944, and the Egg Products Inspection Act of 1970.[11]

2.1.2 USDA, Food Safety Inspection Service (FSIS)

The other primary agency that regulates US food safety is the USDA, through its Food Safety and Inspection Service, which is charged with ensuring the safety, wholesomeness, and proper labeling of most commercial domestic and foreign meat and poultry products. The FSIS manages food safety for meat, poultry, and processed egg products, and inspects and certifies that foreign imports are free of pathogens, pest and disease.

The FSIS currently manages around 9,400 staff, of which approximately 7,865 are in-plant inspectors and 1,000 are veterinarians posted in approximately 6,300 meat slaughtering or processing facilities nationwide. FSIS personnel are present in the facilities at all times during all hours of operation. About 5,300 of the plants are slaughtering and processing facilities, and about 1,000 are warehouses and distribution facilities. The FSIS is also responsible for ensuring that the standards for 27 independent state meat/poultry inspection agencies meet minimum USDA requirements. About two dozen states have agreements with the USDA that certify state inspectors as qualified federal inspectors, allowing their inspected products to be available for interstate commerce. Although inspection is not required on the production line for each product, daily inspections account for continual inspection of plant operation, sanitation, ingredient levels, packaging, and statistical sampling and testing for laboratory inspection.

FSIS also has independent responsibility for foreign imported meat and poultry products. The FSIS first requires foreign processing facilities for meat and poultry products to meet US inspection standards, as an equivalency system, and certifies foreign facilities as safe for handling products for US consumers. The FSIS, in cooperation with the US Bureau of Customs and Border Protection, also conducts statistical sampling and inspection of imported meat, poultry, and egg products at all US ports of entry. The agency conducts enhanced inspections of documentation, sampling, and preparation and cooking regulations of imports from countries that harbor livestock and poultry diseases. Some exotic species, such as frog legs, are inspected by the FDA.

The statutes governing USDA, FSIS authority include the Federal Meat Inspection Act (FMIA) of 1906, which directs meat inspection before and after slaughter, and during their processing into food products; the Poultry Products Inspection Act (PPIA) of 1957; the Egg Products Inspection Act (EPIA) of 1970, specifically granting regulatory authority for the

[11] *Ibid.*

oversight of liquid, frozen, and dried egg products; and the Federal State Cooperation Act of 1962, otherwise known as the Talmadge-Aiken Act, which allows the use of state inspectors to be used instead of FSIS employees.[12]

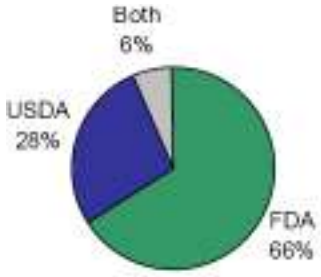
Together, the FDA and USDA have a mainly preventative role in the food safety system. They are charged with ensuring sanitation and food handling procedures promote food safety. However, the FDA and USDA have significant disparities in funding and staffing. Despite its large regulatory responsibility, the FDA has significantly lower funding and staffing levels than FSIS.

Resource allocations for major food safety agencies

Agency	Acronym	% of food	FY 2008 Funding	Staff
			-million-	
Food and Drug Administration (food)	FDA	80%	$510	2,700
Food Safety and Inspection Service	FSIS	20%	$930	9,400

It has been noted that foodborne illness is more likely to occur with USDA regulated products. From 1998 to 2007, the FDA was responsible for regulating approximately 66% of all foodborne illness outbreaks, and 80% of the total food supply, whereas the USDA was responsible for 28% of all foodborne illness outbreaks and about 20% of the US food supply. Yet, despite the large disparity in incidences of foodborne illness and authority, the USDA receives nearly 14% greater funding than the FDA.

Outbreaks related to FDA and USDA regulated foods, 1998-2007



Food Safety Budget for FY 2010[13]

[12] *Ibid.*

[13] "Outbreak Alert!: Analyzing Foodborne Outbreaks 1998 to 2007, Closing Gaps in Out Federal Food-Safety Net," Center for Science in the Public Interest.

2.1.3 USDA, Food and Nutrition Service (FNS)

The Food and Nutrition Service is charged with administering USDA nutrition assistance programs, and food safety issues are an important component of the agency's overall mandate for nutrition assistance as well as the National School Lunch Program. The FNS operates and administers the USDA/FNS Commodity Alert System to notify program participants about particular food safety issues with significant public health impacts for USDA commodity programs.[14]

2.1.4 USDA, Grain Inspection, Packers, and Stockyards Administration

The Department of Agriculture, Grain Inspection, Packers, and Stockyards Administration (GIPSA) is charged with facilitating US marketing programs for grain, oilseed, meat, and poultry products. GIPSA also manages the Federal Grain Inspection Service (FGIS) on a user-fee basis. GIPSA is administered by one federal/state office, 9 field offices, and 57 state and private agencies authorized to provide services for GIPSA. In FY 2006, GIPSA conducted nearly 2,000 regulatory actions and investigations on livestock marketers and dealers. In the same fiscal year, GIPSA conducted nearly 3 million inspections of over 286 million MT of grain.[15]

GIPSA regulates marketing for grains, oilseeds, meat, and poultry products in the US under the Grain and Stockyards Act of 1921.

2.1.5 Centers for Disease Control and Prevention (CDC)

The Department of Health, and Human Services, Centers for Disease Control and Prevention (CDC) is the lead agency charged with conducting disease surveillance and outbreak investigations. Working with the FDA, the USDA, FSIS, and the NMFS, and state and local health departments, the CDC launched the Foodborne Diseases Active Surveillence Network (FoodNet) in 1995, a data collection and communication system for 7 bacterial and 2 parasitic pathogens related to foodborne illness outbreaks in a population of 20.5 million Americans.[16] FoodNet is a surveillance system which compiles and analyzes clinical microbiology laboratories to ensure accurate accounting for foodborne illness results. The CDC also manages PulseNet, and OutbreakNet, a network

[14] http://www.fns.usda.gov/fns/food_safety.htm
[15] Link, James E. (2008), "Statement of James E. Link, Administrator," Grain Inspection, Stockyards, and Packers Administration.
[16] Mead, Paul S. et al. (2009), "Food related illnesses and death in the United States," Centers for Disease Control and Prevention, 5:5, http://www.cdc.gov/ncidod/eid/vol5no5/mead.htm

of public health officials who investigate outbreaks of enteric illnesses from food or water, nationwide.[17]

The CDC is granted legislative authority under the Public Health Service Act of 1944.

2.1.6 US Bureau of Customs and Border Protection (CBP)

The Department of Homeland Security, Bureau of Customs and Border Protection is charged with inspecting and enforcing US import and export laws and regulations. The CBP and the FSIS jointly work to inspect, sample, monitor, and enforce laws and regulations pertaining to food imports at US ports of entry.

Civil penalties for violating US import and customs laws include:

- First offense carries a $300 fine
- Second offense carries a $500 fine

The CBP also seizes unauthorized agricultural imports, and estimates that each day it seizes approximately 1.81 metric tons (2 short tons) of prohibited meat, plant, and animal products.[18]

The CBP is granted authority over food safety and security for imported food products under the Tariff Act of 1930, the Bioterrorism Act of 2002, and the Security and Accountability for Every Port Act of 2006.

2.1.7 National Marine Fisheries Service (NMFS)

The Department of Commerce, National Marine Fisheries Service (NMFS) conducts a voluntary user-fee paid service for marketing and grading fish and shellfish. The NMFS employs approximately 160 seafood safety and quality inspectors.

The National Marine Fisheries Service inspects and grades the marking and grading attributes of fish and shellfish under the legislative authority of the Agricultural Marketing Act of 1946. [19]

[17] Becker, Geoffrey (2009), "Federal Food Safety System: A Primer," Congressional Research Service, April 8.
[18] *Ibid.*
[19] *Ibid.*

2.1.8 Environmental Protection Agency (EPA)

The Environmental Protection Agency, Office of Pesticide Programs monitors and registers pesticide usage on food crops by establishing federal regulations, and is responsible for the registration of new pesticides. The EPA determines maximum residue tolerance levels for regulatory purposes, reviews and evaluates health data on pesticides, and analyzes the costs and benefits of pesticide use. Separately, state level environmental health agencies can set additional pesticide regulations.

The EPA has statutory authority under the amended statutes of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) of 1947 and the Federal Food, Drug, and Cosmetic Act of 1938.[20]

2.1.9 Consumer Product Safety Commission (CPSC)

The US Department of Commerce, Consumer Product Safety Commission jointly share responsibility with the Food and Drug Administration (FDA) to establish food safety standards, conduct investigations into potential public health threats, and issue recalls and warnings for domestic and foreign products.[21]

2.1.10 State and Local Food Safety Agencies

State and local food safety agencies conduct over 90% of all US food safety inspections. Over 100,000 state and local food safety agencies coordinate with federal agencies to manage pubic health threats from foodborne illness outbreaks. States currently conduct 40,000 state inspections under state law, and more than 10,000 inspections under contract for the FDA and USDA.

2.1.11 Alcohol, Tobacco, and Trade Bureau (ATT)

The Department of Treasury, Alcohol, Tobacco, and Trade Bureau regulates the commercial import of alcoholic beverages, distilled spirits, wines, and beer. The ATT also levies and collects taxes for alcohol and liquor imports. The ATT is granted legislative authority under the Federal Alcohol Administration Act of 1935.

2.2 US food safety outbreaks

Food safety monitoring and evaluation are established practices in the US public health system. It is common to hear claims from within the industry that the United States has one of the world's safest food supplies. However, due to the scale of the food production, distribution, and marketing system in the US, foodborne illness outbreaks occur frequently.

[20] *Ibid.*

[21] *Ibid.*

Each year foodborne illnesses are estimated to cause up to 5,000 deaths, 325,000 hospitalizations, and 76 million illnesses.[22] Moreover, foodborne illness outbreaks have increased in frequency and scale over the past decade. In the early part of 2000, one or two foodborne illness outbreaks occurred each year. Ten yeas later, it is common for one or two foodborne illness outbreaks to occur *each month*.

Much of this increase is attributable to improvements in the science and understanding of foodborne illness detection as well as increases in food diversity and imports in recent decades. It is difficult to accurately document the entire history of foodborne illness in the US in recent years due to the nature of food safety data, as outbreaks may be limited to as few as two cases of illness or as many as thousands. Reliable food safety data are based on population surveys, physician surveys, laboratory surveys, and public health surveillance by national agencies such as the CDC. Foodborne illnesses are subject to irregular incubation periods, widely dispersed geographic distribution, specific pathogens which are difficult to identify or diagnose, and underreporting due to mild cases of illness where patients may not seek medical attention.

The overall prevalence of foodborne pathogen contamination in the United States is low, given the large scale and diversity of the US food industry. Less than 0.2% of US ground beef is contaminated with E. coli 0157:H7 and less than 0.65% of US ready-to-eat meat and poultry products are contaminated with listeria monocytogenes.[23] Yet, despite the seemingly low rates of food contamination, frequent and large-scale episodes of illness outbreaks from meat, fresh fruit and vegetables, nuts, and processed foods demonstrate the numerous gaps that remain in regulatory oversight and understanding of food safety. In 2007, the USDA's Economic Research Service conducted a study on the societal costs of food safety risks, and concluded that although consumer concern about food safety in supermarkets and restaurants is high, enforcement tools to achieve the desirable level of food safety are limited.[24]

The CDC estimates that more than 200 different pathogens and contaminants sicken consumers each year. Agents of foodborne illness include bacteria, viruses, parasites, toxins, chemical contaminants, and metals present in food products. According to the CDC, the most common bacterial pathogens are related to *Vibrio*- and *Shiga*-toxin producing Escherichia coli (STEC) 0157 (or E. coli 0157:H7), *Salmonella*, *Campylobacter*, *Norwalk-like viruses,* and *Listeria monocytogenes*. The most common viral pathogens are

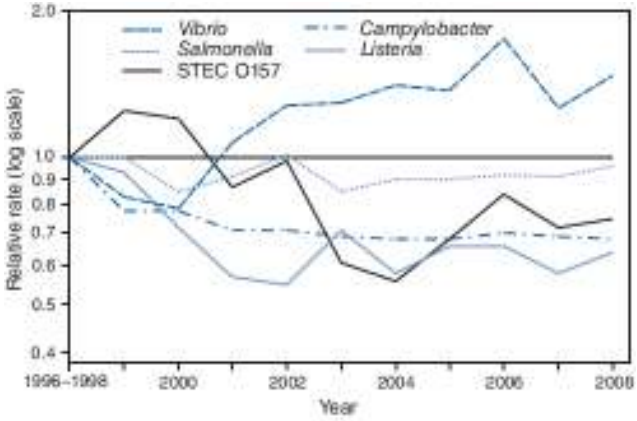
[22] Mead, Paul S. et al. (2009), "Food related illnesses and death in the United States," Centers for Disease Control and Prevention, 5:5, http://www.cdc.gov/ncidod/eid/vol5no5/mead.htm

[23] *Ibid.*

[24] Roberts, Tanya (2007), "Willingness to Pay Estimates of the Societal Costs of US Food-borne Illness," American Journal of Agricultural Economics, 89:5, 1183-1188, November 5.

Norwalk-like viruses, which account for approximately two-thirds of known foodborne illness cases. More recently, chemical contaminants such as melamine in bulk protein product ingredients from China worried US pet food and dairy consumers. Other contaminants include unapproved dyes for food products or metal shavings. However, the incidence of chemical or foreign matter contaminants as a source of widespread foodborne illness is rare and undocumented.

Relative rates of laboratory-confirmed infections with *Vibrio*, *Salmonella*, *STEC* O157*, *Campylobacter*, and *Listeria* compared with 1996-1998 rates, by year—Foodborne Diseases Active Surveillance Network, United States 1996-2008†



* Shiga toxin-producing *Escherichia coli*.
† The position of each line indicates the relative change in the incidence of that pathogen compared with 1996–1998. The actual incidences of these infections can differ. Data for 2008 are preliminary.

Source: Centers for Disease Control and Prevention (CDC) 2008

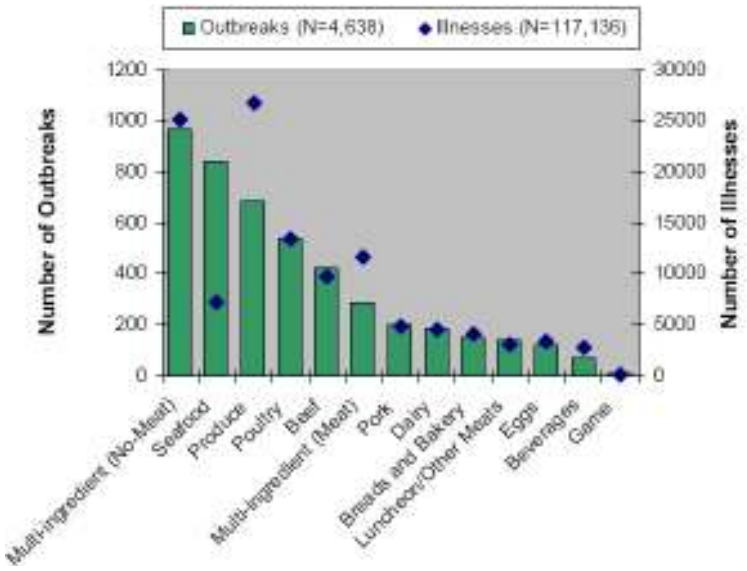
According to the CDC data in the chart above, the FDA attributes recent stabilization or declines in bacterial infection rates of *E. Coli*, *Salmonella*, *Campylobacter*, and *Listeria* to improved food safety outbreak prevention and management. Note that CDC data indicate laboratory-confirmed infections from all potential vectors of contamination including food, water, and cross-contamination. However, the incidence of cholera, or *Vibrio*-related illnesses, has not been effectively mitigated in recent years. *Vibrio*-related cases are commonly associated with consumption of contaminated oysters and shellfish from the Gulf of Mexico.

Foodborne illness outbreaks categorized according to food type in the next chart suggest that specific food product and pathogen combinations can be ranked in terms of risk based on the number of outbreaks. This may serve as an indicator of which products should receive increased scrutiny from the legislative and regulatory proposals under consideration. The left-axis measures the *number of outbreaks* as a bar chart distributed among food commodity groups and sample size of 4,638 outbreaks from 1998 to 2007.

The right-axis measures the *number of illnesses* as a scatter plot distributed across the same food commodity groups over the same 10-year period.

Multi-ingredient processed foods (not containing meat) represent the food commodity group with the greatest number of outbreaks and the second greatest number of reported illnesses. Seafood is the second-leading commodity group in terms of outbreaks, followed by produce, poultry, beef, multi-ingredient processed foods (containing meat), and pork.

Outbreaks and Illnesses in Food Commodities, 1998-2007[25]



Source: Center for Science in the Public Interest

Under current statutes and regulations, multi-ingredient foods are regulated by the FDA. Because multi-ingredient foods contain several ingredients, it is important to note that the products included may or may not include eggs or egg products.

Seafood products are considered one of the most highly regulated food commodities, and remain a leading source of foodborne illness outbreaks, although the overall number of confirmed cases of foodborne illness associated with seafood is relatively low in comparison to food commodities with similar rates of outbreak reporting. Seafood products are jointly regulated by statute under the Food and Drug Administration, and the US Department of Commerce, National Marine Fisheries Service. In the Gulf of Mexico, the incidence of *Vibrio*-toxin remains a commonly reported illness, and has led the FDA to establish the Gulf Coast States *Vibrio* Surveillance System, and consider specific post-

[25] "Outbreak Alert!: Analyzing Foodborne Outbreaks 1998 to 2007, Closing Gaps in Out Federal Food-Safety Net," Center for Science in the Public Interest.

harvest processing procedures for shellfish harvested from the Gulf of Mexico during summer months.

Produce is estimated to account for the third-highest number of foodborne illness outbreaks, and the highest number of reported foodborne illnesses. The CDC reports that a sample of illness reports indicate that fresh produce was associated with 7% of all foodborne illness outbreaks that were traced back to a specific source but 14% of *overall foodborne illnesses* from 1998 to 2004.[26]

Poultry products are commonly associated with Salmonella contamination. The regulation of poultry meat and poultry products is under the authority of the USDA, Food Safety and Inspection Service and the Poultry Products Inspection Act of 1957.

Beef products have been associated with *E. Coli 0157:H7* and *Salmonella* contamination in recent years, and are commonly associated with large volume and widespread recalls, as beef products are commonly ground and mixed to produce hamburger meat. Beef products are also regulated under the authority of the USDA, Food Safety and Inspection Service, and the Federal Meat Inspection Act of 1906.

2.3 Major food borne illness outbreak events in recent years

Major foodborne illness outbreaks featuring large numbers of cases, widely dispersed cases, and large industry costs, often prompt public scrutiny and responses from the White House, Congress, and food safety agencies. This section will detail the causes of major recent outbreaks and the government's response to these outbreaks.

The table below identifies recent high profile food safety events; details on some of the most influential cases follows the table.

[26] Shames, Lisa (2008), "Food Safety: Improvements needed in FDA Oversight of Fresh Produce," Government Accountability Office, September.

Recent high profile US food safety recalls by dollar amount or number of victims

Year	Case	Pathogen	Product	No. of States	Point source	Illnesses	Deaths	Est. Industry Cost millions
2009	Peanut Corp of America	Salmonella typhimurium	Peanuts	46	GA	714	9	$1,000
2009	Pistachios	Salmonella Montevideo	Pistachios	31	CA	-	-	$1,000
2008	Tomato and Peppers	Salmonella Saint Paul	Peppers	43	MEX	1,443	2	$150
2008	Hallmark/Westland beef	BSE (sus.)	Beef	46	CA	-	-	$117
2007	ConAgra Pot Pies	Salmonella	Pot Pies	31	MO	272	-	$30
2007	Peter Pan peanut butter	Salmonella Tennessee	Peanut Butter	47	GA	628	-	$78
2006	Taco Bell Lettuce	E. coli 0157:H7	Lettuce	7	CA/AZ	71	-	$76
2006	Spinach	E. coli 0157:H7	Spinach	26	CA	227	3	$200
1997	Mexican Strawberries	Hepatitis A	Strawberries	13	MEX	1,000	-	$20
1993	Jack-in-the-Box Burgers	E. coli 0157:H7	Ground beef	4	Multiple	700	4	$210

Source: FDA and CDC

1993 Jack-in-the-Box E. Coli Case

In summer 1993, hamburger meat from the Jack-in-the-Box hamburger chain sickened nearly 600 and caused 4 deaths related to E. Coli 0157:H7 infections in Washington, Idaho, California, and Nevada. The incident was widely publicized and led to estimated federal, state, and company losses of $210 million.

The outbreak was first identified and reported by a Seattle pediatrician, who notified Washington State health officials. The CDC epidemiologists investigated the case and concluded that the E. Coli 0157:H7 contamination was caused by errors in meat processing at approximately five facilities in the Western US, and cooking procedures at approximately 73 Jack-in-the-Box restaurants, Previously, epidemiologists hypothesized that sulfa and penicillin antibiotics would eliminate the risk of widespread enteric infectious diseases. However, the Jack-in-the-Box case demonstrated that safe processing and handling procedures remain critical elements of public health management for food safety.

Response

The federal government reacted to the Jack-in-the-Box food safety outbreak in several ways. At the Executive level, the US Secretary of Agriculture testified before a Washington State Legislature panel on food safety. The FDA revised handling and cooking guidelines for ground beef, and recommended that the internal temperature for hamburgers in restaurants should be cooked to 155˚F. The USDA, FSIS initiated several new programs in the wake of the outbreak event, including safe handling labels and instructions on retail supermarket labels, an educational campaign for school children, and sampling and testing procedures for federally inspected retail and food service establishments. Additionally, the outbreak spurred legislative resolve and funding to expand the CDC FoodNet monitoring and surveillance program for foodborne pathogens and illness, as well as efforts to modernize the Pathogen Reduction and Hazard Analysis and Critical Control Point Program (PR/HACCP), which was subsequently implemented in 1996.[27]

The Jack-in-the-Box case also mobilized private groups such as Safe Tables Our Priority (STOP) to lobby Washington to improve federal food safety standards, and spurred industry efforts to investigate the matter. In 1993, the Washington Beef Commission funded research on E. Coli 0157:H7 detection and monitoring methods for beef processing and handling. The National Cattleman's Beef Association (NCBA) established a task force to fund research on sampling, testing, and detection methods to identify and reduce E. Coli 0157:H7 in live cattle and at slaughterhouses. Today, the NCBA spends approximately $2.5 million annually on food safety research and technology. In 2003, the NCBA helped establish the Beef Industry Food Safety Council (BIFSCo) to develop and establish "industry-wide, science-based strategies to solve the problem of E. Coli 0157:H7 and other foodborne pathogens in beef."[28]

2006 Spinach E. Coli Case

In fall 2006, bagged fresh spinach grown in the Salinas Valley of California contaminated with E. coli 0157:H7 led to approximately 227 confirmed illnesses and 3 deaths. News of the outbreak led to a 61% decline in weekly bagged spinach purchases during the third-week of the outbreak, and cost the Western US spinach industry approximately $200 million. The incident led to a widespread national recall and public health investigation by multiple federal, state, and local authorities. FDA authorities partnered with the California Department of Public Health to form the California Food Emergency Response Team (CalFERT). The state and federal investigators have previously coordinated and

[27] Roberts (2007)

[28] Golan, Elise, Tanya Roberts, et al. (2004), "Food Safety Innovation in the United States: Evidence from the Meat Industry," USDA, Economic Research Service, April.

trained together, but the partnership of jointly administering a food safety outbreak improved the utilization of staffing and funding resources for the outbreak investigation. The investigation concluded that irrigation water contaminated by residual livestock waste or a nearby wild boar population was used to raise the affected fields of spinach. However, the investigation inconclusively identified the specific point source of pathogen contamination.

California state and federal investigators from the CDC, FDA, USDA, and the Government Accountability Office (GAO) each conducted investigations into the regulatory accountability for the 2006 Spinach outbreak. The GAO concluded that the FDA has limited resources and authority to effectively administer fresh produce safety programs, and that in light of agency focus on counterterrorism and foodborne illness outbreak efforts, the fresh product safety program has been overlooked, understaffed, and underfunded relative to the overall food safety program. FDA officials at the Center for Food Safety and Applied Nutrition (CFSAN) cite that the center's priorities for fresh produce safety have been delayed by 6 years to attend to immediate efforts to improve counterterrorism and foodborne illness response issues. As a result, in 2008, the GAO estimated that the FDA inspected about 2,000 domestic fresh produce firms twice on average over a seven year period from 2000 to 2007. The GAO credited the FDA for partnering with the California Department of Public Health to improve emergency response and trace-back for the point source of contamination. The report also cited several factors which have hampered efforts to quickly identify and contain the contamination and the outbreak. First, the GAO notes that because fresh produce is highly perishable, there is often no physical sample of the product remaining after the normal trace back process has been completed, which usually takes about two weeks. Other challenges include poor labeling of fresh produce between various tiers of the supply and value chain, variable record keeping for financial and logistical business tasks, as well as added complexity when fresh produce is commingled with other fresh produce from multiple sources in fresh bagged produce products. The FDA initiated a pilot program to post labels of recalled perishable products, such as fresh produce, to assist consumer identification of fresh produce products.

Response

In response, the USDA, Agricultural Marketing Service and the FDA have jointly promoted the "National Leafy Greens Marketing Agreement" and have publicly engaged industry and public comments for improving product tracing practices for foods to prevent a similar outbreak event. The initiative promotes voluntary science-based guidelines for leafy greens producers, handlers, shippers, and processors to improve water quality, test tissues for pathogens, keep records, and conduct audits. The Leafy Greens Marketing Agreement binds voluntary participants to adhering to best-practices guidelines to improve food safety, lower the number of audits for marketing, and improve

accountability for food safety issues. The Product Tracing Initiative is aimed at improving outbreak response by investigating the feasibility and food safety aspects of standardized product labeling and tracing systems. In addition, in August 2008, the FDA published a rule allowing irradiation of iceberg lettuce and fresh spinach.

Opponents of the Leafy Greens Marketing Agreement and the trace back program criticize the initiative as a "one-size-fits-all" approach which discriminates against small, mid-sized, and organic leafy greens producers, which would need to meet the same regulations and make the same investments as competitors with large-scale operations, creating barriers to entry for smaller and independent, nonintegrated producers. Critics also attribute widespread pathogen contamination and distribution to production, handling, and marketing practices by large-scale producers, and argue that fresh-cut, bagged plant products are inherently at risk to harbor and spread food borne pathogens as they break the surface of produce allowing pathogens to enter. A similar program to issue guidelines for good agricultural practices to reduce pathogen contamination when growing, packing, and transporting fresh produce in 1998 did not prevent subsequent foodborne illness outbreaks in fresh produce in 2000 (raspberries from Guatemala), 2002 (cantaloupes from Mexico), 2003 (scallions from Mexico), 2006 (spinach from California), and other more recent outbreaks in fresh produce. A 2008 GAO report on fresh produce notes federal and state inspectors found problems in approximately 41% of the fresh produce inspections conducted from 2000 to 2007.

2008 Peppers Salmonella Saintpaul Case

Serrano peppers grown and contaminated with Salmonella Saintpaul by agricultural irrigation water in Mexico were imported into the United States in early 2008, causing a Salmonella outbreak which left 1,443 people sick, hundreds hospitalized, and 2 dead in more than 43 states in the US and Canada. An investigation by the CDC and the FDA concluded that Salmonella-contaminated Serrano peppers were shipped to a US packer which distributed fresh produce from Mexico. The peppers then cross-contaminated separate lots of jalapeño peppers handled in the same facility. The contaminated peppers sickened consumers directly and were also used as ingredients in tomato-containing products causing a multi-state Salmonella outbreak.

Response:

In April 2008, the CDC and the FDA collaborated with state and local health and regulatory agencies and industry representatives to investigate. The CDC identified tomatoes and peppers as the potential source of contamination. In June 2008, the FDA issued a confusing advisory notice instructing consumers to avoid raw red plum, red Roma, and red round tomatoes, as well as tomato containing products unless the tomatoes originated from areas unassociated with the outbreak. The FDA also notified consumers

that it was safe to consume cherry tomatoes, grape tomatoes, and tomatoes with the vine still attached. The FDA noted that tomatoes are often commingled from multiple growers to market lots of tomatoes of similar size and quality, but that this hampers efforts to identify sources of contamination. A month later the FDA withdrew the advisory notice and concluded that tomatoes were *not* the origin of contamination for the outbreak. However, the economic association with salmonella led to massive consumer pull-back and to approximately $100 million in losses for the tomato industry.

Back at square one, the FDA, the CDC, and state and local agencies worked to determine if jalapeño and Serrano peppers associated with the outbreak were a possible source of contamination. Further investigation linked the genetic sample of contaminated jalapeño peppers to a sample in an infected person's home, and a previously sampled warehouse which contained the same genetic sample. The FDA promptly issued an advisory for consumers to avoid Serrano and jalapeño peppers grown, harvested, or packed in Mexico. In August 2008, the CDC announced that epidemiological trends indicated that the *Salmonella* Saintpaul outbreak was over, and the FDA then lifted the advisory ban on Serrano and jalapeño peppers.

In response to the outbreak, which affected tomato and pepper producers in Florida, California, and Mexico, state and local authorities blamed federal officials for improperly identifying the source of the outbreak, and causing unnecessary economic harm to the tomato industry. However, given the perishable nature of fresh tomatoes and other produce, the scope of the outbreak, and the lack of uniform standards for labeling and identifying lots of potentially contaminated produce, federal investigators erred on the side of caution to limit the potential harm to the public health. Tomato industry leaders responded by convening a Harvard University School of Public Health, Executive Session on Food Safety with specific emphasis on the US tomato industry. The Executive Session identified potential methods to improve product trace back and trace forward in the event of an outbreak, as well as ways to collaborate within the industry to develop a food safety program to respond to potential future outbreaks. State legislators in Florida also responded by passing new legislative guidelines for Tomato Good Agricultural Practices for greenhouse and field producers and Tomato Best Management Practices for packinghouses and post harvest handlers.

2009 Peanut Corporation of America Case

In late 2008 and early 2009, contaminated peanuts, peanut butter, and peanut paste processed and manufactured at a Peanut Corporation of America (PCA) processing plant in Blakely, Georgia sickened 714 people and may have caused as many as 9 deaths in 43 states in one of the largest food recall events in history. The Blakely facility primarily manufactured peanut paste for commercial ingredient users, and served over 300 industrial consumers, which in turn processed the peanut product into hundreds of

other products, including cookies, cereal, candy, and ice cream. The subsequent product recall included hundreds of products, and the estimated industry cost was approximately $1 billion in lost revenue and marketing costs. Although, the investigators cannot identify the exact point source of contamination, they attribute the principal cause to poor facility management.

Response

In November 2008, more than 30 local and state health agencies reported several confirmed cases of an identical strain of *Salmonella* typhimurium illness, and required further testing to identify the source of contamination. The data was forwarded to be compiled by the CDC's FoodNet database for outbreak reports and the PulseNet database for pathogen reports. Following a lead by the Minnesota Department of Health, the FDA separately investigated a nursing home which reported a cluster of cases of *Salmonella* infection from contaminated peanut butter. With the assistance of the CDC PulseNet, FDA investigators confirmed that the *Salmonella* strain in the Minnesota case matched similar cases appearing nationwide.

The FDA traced the Minnesota case sample of King Nut peanut butter to a PCA plant in Blakely, Georgia, and in January 2009, issued a product recall for King Nut peanut butter advising distributors, retailers, and consumers to identify and dispose of suspected products produced at the facility from July 2008 to January 2009 (there is no way to sanitize peanut butter of *Salmonella* once it is contaminated). Further on-site investigation of the facility revealed that plant equipment and in products were contaminated with the same strain of *Salmonella*, and indicated that several potential risks and problems existed at the plant, including potential contamination from tainted water entering the facility from outside, bird and rodent droppings, and cross-contamination from plant equipment. The FDA then promptly issued an expanded recall for all products made at the facility from January 2007 to January 2009.

Numerous warning signs were disregarded or were not followed up by the FDA and state regulators. Federal investigators in cooperation with the Georgia Department of Agriculture reviewed the facility's records and discovered that in-house food safety sampling tests conducted by the PCA on 12 occasions in 2007 and 2008 found salmonella contamination in products. On each occasion the firm retested suspect samples to obtain negative *Salmonella* contamination test results, then shipped the contaminated products, failed to notify the FDA about potential contamination, and took no further action to clean the facility or address cross-contamination. During the same period, Georgia state inspectors examined the facility under contract for the FDA, and were unable to identify contaminated products or equipment. A FDA scientist commented in news reports that state inspectors lacked specialization to inspect and identify risks for a peanut processing plant, and that state and federal inspectors generally may not be fully

prepared to inspect every type of food processing facility.[29] In April 2008, the Canadian officials denied entry for peanut butter from the Blakely facility, and the FDA reported that the shipment "appears to be in whole or in part of a filthy, putrid, or decomposed substance, or is otherwise unfit for food in that it appears to contain foreign objects." FDA Administrator Dean Acheson later identified the foreign objects as metal fragments. The shipment was destroyed by the FDA on November 17, 2008. A subsequent follow-up inspection by Georgia state inspectors failed to identify a source for the fragments.[30]

On January 30, 2009, the US Department of Justice and the FDA jointly opened a criminal investigation into violations of America of the Food, Drug, and Cosmetics Act of 1938 by the Peanut Corporation of America. Penalties for violation of the Act include imprisonment for one year or a $1,000 fine, or both, which are relatively insignificant for a firm with annual revenues of approximately $17.5 million.[31]

FDA and regulatory failures in this case include ineffective inspections and oversight with inspections of each facility occurring once every 10 years on average; a lack of financial resources and personnel to inspect food commodity processing and handling facilities; ineffective penalties for enforcement mechanisms to deterring violations of the law; and lastly, a lack of FDA authority to intervene and respond to ongoing outbreaks – the FDA does not require traceability systems, nor does it have the authority to detain and recall food which may potentially cause harm to the public health.

Each of these cases illustrates systemic failures of US food safety oversight and highlight challenges facing the safety of the US food supply. As the number of the food safety outbreaks becomes more publicized and prevalent, political pressure mounts for the US Congress and federal agencies to enact and implement comprehensive food safety reform.

2.4 Recent agency and legislative initiatives

Over the past 10 years, the US Congress has conducted more than 32 legislative hearings on food safety, following outbreaks caused by *E. Coli* 0157:H7 contaminated spinach, peanut butter contaminated with *Salmonella* Tennessee, the threat of Mad Cow Disease,

[29] Harris, Gardiner (2009), "Peanut Product Recall Grows in Salmonella Scare," New York Times, January 28.
[30] Stark, Lisa and Kate Barrett (2009), "Criminal Investigation Launched in Salmonella Outbreak," ABC News Online, January 30, http://abcnews.go.com/Health/story?id=6770594&page=1, Accessed January 21, 2010.
[31] DeWaal, Caroline (2009), "Testimony of Caroline Smith DeWaal before the Senate Committee on Agriculture, Nutrition, and Forestry," Center for Science in the Public Interest, February 5.

and imported food products, as well as regulatory agency shortfalls in food safety oversight and inspections.

The US government has also passed or implemented the following agency or legislative initiatives:

Public Health Security and Bioterrorism Preparedness and Response Act (2002)

In July 2002, Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act, also known as the Bioterrorism Act, to amend the Food, Drugs, and Cosmetics Act of 1938, and direct the FDA to establish new regulations to protect the public from food safety (unintentional) and food defense (intentional) threats. The Bioterrorism Act provisions stipulate that domestic and foreign facilities that "manufacture, process, pack, or hold food for human or animal consumption in the United States" must be registered with the FDA, exporters must register and file a *Prior Notice of Imported Food* with the FDA before exports enter US ports of entry, and that food facilities that are registered must maintain records to identify the origin of a food product at the stage before handling by a particular facility and also identify the destination of a food product at one stage after handling by a particular facility. The FDA and the Bureau of Customs and Border Protection work to jointly monitor, inspect, and survey food products entering into the United States. The Prior Notice rule is part of the effort to establish preventative measures for foodborne illness outbreaks originating from foreign food facilities.

Food and Drug Amendments Act (2007)

In September 2007, the US Congress passed the Food and Drug Amendments Act. Title X, the food safety title of the Act, directs the FDA to establish improved regulations for ingredient, processing, and labeling standards and definitions; supplement the FDA Consumer Complaint Reporting System (CCRS) with the MedWatch Plus surveillance tool for pet food products; establish the Partnership for Food Protection with federal, state, and local food safety authorities; establish a food safety registry for reporting potentially adulterated foods; prepare an enhanced Aquaculture and Seafood Inspection Report; and prepare Pesticide Residue Monitoring Reports to the US Congress.

Action Plan for Import Safety (2007)

In November 2007, the George W. Bush administration established the Intragency Working Group on Import Safety, which ultimately produced the "Action Plan for Import Safety." The plan recommended mandatory recall authority for the FDA (but not for the USDA/FSIS), electronic certification of imports, and the levy and collection of user fees to offset inspection and administrative costs for program management.

FDA Food Protection Plan (2007)

In November 2007, the FDA released a comprehensive Food Protection Plan (FPP) to implement risk-based prevention, intervention, and response to domestic and imported food safety threats for humans and animals. The FPP recommended legislative authorization, as well as regulatory changes within the FDA with additional appropriations funding in the FY 2008 budget to improve food safety oversight. The FPP recommended that the FDA take a risk-based approach to food safety by evaluating and tracking each part of the product lifecycle to prevent foodborne illness. The FPP directed the FDA to intervene in the case of potential foodborne illness outbreaks by identifying and assessing risks, and expanding the use of effective risk mitigation measures such as inspections, sampling, and surveillance. The FPP requested FDA authority to increase the number and frequency of inspections, FDA bi-annual registration of food facilities, resources to provide technical assistance to foreign trade partners to comply with FDA standards, and the establishment of a risk-based inspection and import surveillance database on food inspections and food quality from foreign partners. The measures were aimed to improve the FDA's capacity to collect, interpret, and conduct research related to risk-based prevention activities, and to develop monitoring and detection tools to identify food contamination in domestic and foreign produced food. The FPP also planned to expand the inspection force for FDA domestic and foreign inspections and examinations. The FPP proposed a Risk-Based Steering Committee to evaluate FDA progress.

To improve foodborne illness outbreak response, the FPP focused on the rapid reaction of public health agencies and effective communication between the CDC, FDA, FSIS, and other food safety partners.

FDA Science Board report, "FDA Science and Mission at Risk" (2007)

As an advisory board to the agency, the FDA Science Board in December 2007 released a report entitled "FDA Science and Mission at Risk." This report cautions agency managers that the agency is under staffed and underfunded, threatening the efficacy and capacity of the FDA as an institution. The report highlights the overall increase and expansion of FDA food safety responsibilities and challenges, meanwhile also marking the declining and inadequate resources of the FDA. Congressional testimony by the advisory board estimated that implementation costs would require a $755 million increase in the FDA annual budget by FY 2013 over a five-year period.

FDA Emergency Appropriations and Hiring Increases (2008)

In April 2008, the FDA announced that the $150 million in emergency supplemental funds granted by Congress for FY 2008 would be appropriated for hiring 1,300 additional scientists, medical officers, statisticians, and investigators, with $72.8 million allocated exclusively for food safety responsibilities.

The FDA has a three-year plan to increase the number of State inspections, and to expand the Office of Regulatory Affairs to add an additional 125 food inspectors in the field, bringing the total number of inspectors to about 3,000. The expanded force will conduct 9,000 inspections each year.

Food, Conservation, and Energy Act (2008)

Title XIV, the Miscellaneous provisions title of the 2008 Farm Bill, directs the USDA, FSIS to update notification procedures for adulterated or mislabeled meat and poultry, to require meat and poultry processing and handling facilities to prepare and submit recall and HAACP response plans, and to grant the USDA unlimited authority to request and assess meat and poultry facility documents, as amended in the Federal Meat Inspection Act of 1906 and the Poultry Products Inspection Act of 1957.

The title also directs the USDA, Grain Inspection, Packers, and Stockyards Administration to report the number and details of livestock and poultry investigations, as amended in the Grain and Stockyards Act of 1921.

Title XI, the Livestock title of the 2008 Farm Bill directs the USDA to establish classifications for Country-of-Origin Labeling (COOL) US and foreign meat and poultry products, and the country in which livestock or poultry was born, raised, and slaughtered. The title also extends COOL to fresh and frozen fruits and vegetables, ginseng, peanuts, pecans, macadamia nuts, and wild and farm-raised fish.

President's Working Group on Food Safety (2009)

In March 2009, the Obama administration established a Food Safety Working Group headed by Vice President Joseph Biden to investigate and propose measures to improve US food safety. The FSWG reported that the US population will become at higher risk for foodborne illness as it ages. The report cites that nearly 20% of all Americans will be over the age of 60 in 2015. To meet this challenge, the FSWG recommends the US pursue a flexible and coordinated approach to manage food safety issues in the US. The plan focuses on mitigating obvious threats such as salmonella infection in poultry and eggs, and E. coli infection in beef products, as well as institutional reforms such as a national product traceability and response system, improved federal food safety policy coordination and accountability, and review and modernization of dated federal legislation for food safety.

FDA Final Shell Egg Rule (2009)

On July 9, 2009, the FDA released a public notice and Final Rule on the prevention of *Salmonella Enteritidis* (SE) in shell eggs during production, storage, and transportation. The FDA has identified shell eggs as a primary source of human SE infections, and recognizes

SE as a leading bacterial cause of foodborne illness in the United States. To mitigate the threat of SE to public health, the Final Shell Egg Rule was released. The rule became effective on September 8, 2009. The rule outlines on-farm measures to prevent SE contamination, such as biosecurity and pest control programs, environmental and egg testing requirements, refrigerated storage requirements for shell egg producers, and diversion of eggs which have tested positive for SE from the table egg market. Further, the rule requires refrigeration measures to limit further growth of SE bacteria during storage and transportation.

FDA Reportable Food Registry (2009)

In September 2009, in accordance with the Food and Drug Amendments Act of 2007, the FDA issued a rule requiring the responsible party of a food facility to register contact information with the FDA Reportable Food Registry (RFR). The rule requires responsible parties to report food products which may potentially cause serious adverse health consequences or death to humans or animals to the FDA RFR, as soon as possible and no later than 24 hours after the party determines the risk is imminent. The rule requires responsible parties to submit the following data elements to the FDA:

- Food Facility Registration Number
- Date the article of food was determined to be reportable
- Description of the food, including quantity and amount
- Extent and nature of the adulteration
- Results of investigation of the cause of the adulteration if it may have originated with the responsible party, when known
- Disposition of the article of food, when known
- Product information typically found on packaging sufficient to identify the article of food

Responsible parties are also required to notify immediate previous sources, and investigate the source of adulteration of a reportable food. Responsible parties are also required to maintain records of reports and notifications for at least 2 years.

Beyond our Borders (2009)

In July 2009, the FDA announced the Beyond Our Borders program to establish overseas FDA offices for expanded inspections and liaison activities with major US export partners for FDA-regulated products. Beyond our Borders is aimed at developing an overseas presence in areas or regions which have indicated high risk for food imports to the US, a

resource built either through local liaison offices with foreign government food safety counterparts, or locally based foreign inspections staff.

PREDICT system (2010)

The FDA is currently rolling-out the Predictive Risk-Based Evaluation of Dynamic Import Compliance Targeting (PREDICT) system, a successor program to the legacy Operational and Administrative System for Import Support (OASIS) program. PREDICT is being touted as a substantial modernization of the FDA and CBP's operational capability to electronically compile, review, and screen the ever-increasing volume of US food imports at the port of entry.

SECTION 3: PROPOSED FOOD SAFETY LEGISLATION

The US Congress has debated and proposed several legislative measures to improve the food safety system in the United States. Following a series of highly publicized food safety outbreaks related to ground beef, peppers, pistachios, and peanut products, the House of Representatives Committee on Energy and Commerce held a hearing in March 2009 entitled, "How do you fix our ailing food safety system?" Several proposals to amend the Food and Drug Administration legislative authority were soon introduced; however, only one proposal was widely supported and subsequently passed by the House of Representatives.

In the 111th session of the House of Representatives in June 2009, Congressman John Dingell (D-MI), then chairman of the Committee on Energy and Commerce introduced and sponsored House Resolution 2749 (HR 2749), the Food Safety Enhancement Act, to amend the Federal Food, Drug, and Cosmetic Act to improve the safety of food in the global market, and for other purposes. The bill was co-sponsored by five other Democratic members of the House of Representatives, including Rep. Diana DeGette (D-CO), Rep. Frank Rep. Pallone (D-NJ), Rep. Bart Stupak (D-MI), Rep. Betty Sutton (D-OH), and Rep. Henry Waxman (D-CA). HR 2749 subsequently was introduced to the Subcommittee on Health. Nearly two months later, after two attempts, the bill passed the House of Representatives on July 31, 2009 by a margin of 283-183. HR 2749 was reported to the Senate in August 2009.

Meanwhile, in March 2009, Senator Richard Durbin (D-IL) introduced a similar but different legislative proposal to the US Senate Committee on Health, Education, Labor, and Pensions (HELP), as Senate Resolution 510 (S 510), the Food Safety Modernization Act, a bill to amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of the food supply. S 510 was co-sponsored by 15 Democrat and Republican Senators, giving the bill balanced bipartisan support and strong legislative backing. It was passed by the HELP Committee in November 2009, but has not advanced to further consideration.

Both the HR 2749 and S 510 expand FDA regulatory powers and authority to regulate the safety of the 80% of nation's food supply which falls under its jurisdiction under the Food, Drug, and Cosmetics Act of 1938. This bill closely follows many of the recommendations of the President's Working Group on Food Safety, the FDA's "Food Protection Plan," and specific provisions in the Bioterrorism Act of 2002. The Food Safety Enhancement Act is modeled after the Customs-Trade Partnership Against Terrorism (CTPAT) as a layered food safety system for the FDA, and aims to increase the security of food safety protection, and address the need to improve the overall efficiency of food safety oversight, given increasing import volumes of food products.

3.1 Food safety legislation: The House (HR 2749) and Senate (S 510) bills

The food safety legislation in the US Congress is currently contained in two separate legislative bills, the Food Safety Enhancement Act of 2009 (HR 2749) and the Food Safety Modernization Act (S 510).

The Food Safety Enhancement Act of 2009 (HR 2749). The House of Representatives version of the bill is divided into two separate titles. Title I specifies prevention, intervention, and response measures similar to the proposed recommendations of the FDA Food Protection Plan published in November 2007. Title II specifies provisions for country-of-origin-labeling, export certificate programs, registration for commercial importers, foreign inspection offices, and Bisphenol A content in food and beverage containers. The Food Safety Enhancement Act is drafted to enter into force 18 months following enactment.

The Food Safety Modernization Act (S 510). The Senate version of the Act is divided into four separate titles. Title I specifies provisions to improve the capacity of the FDA to prevent food safety problems. Title II specifies provisions to improve the capacity of the FDA to detect and respond to food safety problems. Title III specifies provisions to improve the safety of food. Title IV specifies miscellaneous provisions including budgetary funding.

3.2 Exceptions

The law is meant to update the Federal Food, Drug, and Cosmetic Act, and as such affects only FDA-regulated areas. In addition, there are a number of other entities to which the proposed food safety legislation does not apply, particularly facilities selling direct to consumers.

3.2.1 USDA-regulated food and entities

The proposed legislation explicitly excludes entities and products regulated by the USDA, those covered under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act:

- Livestock and poultry
- USDA regulated and inspected meat, poultry, egg, and dairy products
- Farms that raise animals from which USDA-regulated foods are derived
- Other USDA-regulated facilities

3.2.2 Other exempt facilities

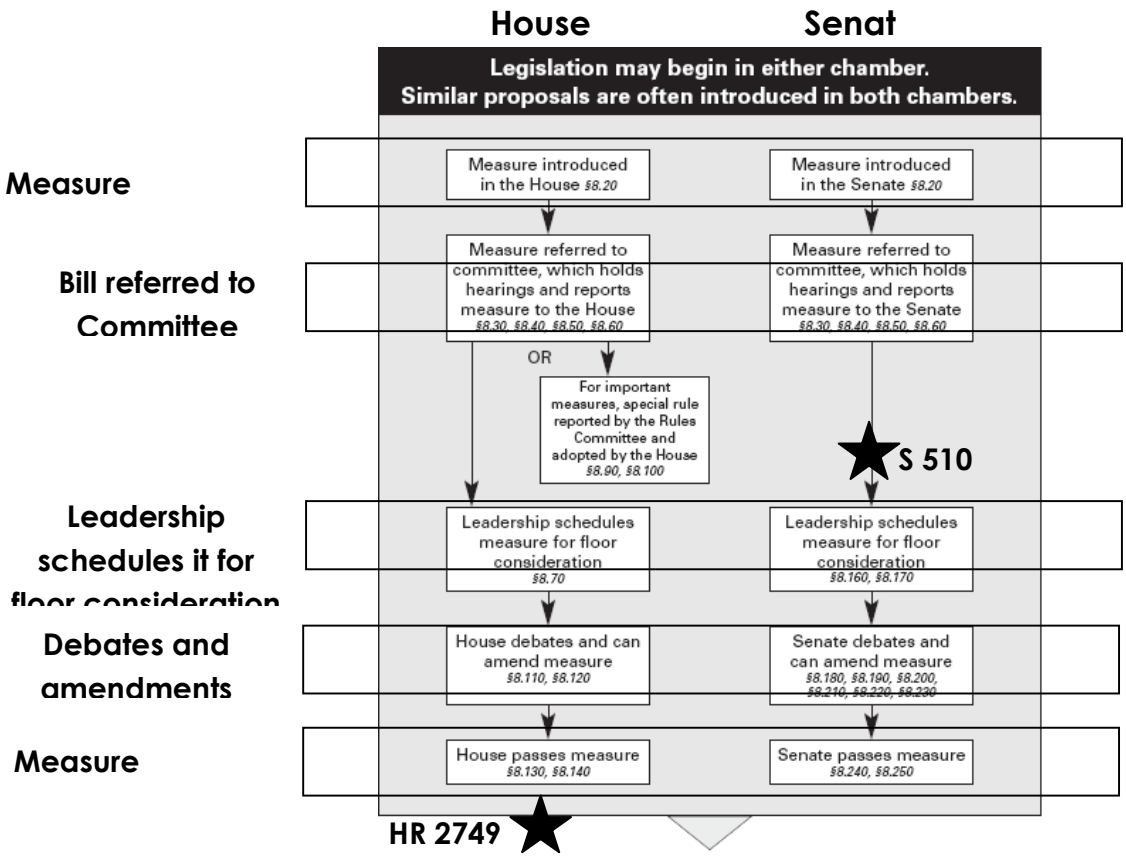
The following are also exempt:

- Alcohol related facilities regulated by the Alcohol, Tobacco, and Trade Bureau

- Farms where food is grown, raised, harvested, and even packed, manufactured, or processed food on farm or a separate farm under the same ownership Private residences
- Farms where direct sales to consumers exceeds sales to all other buyers
- Private residences
- Restaurants
- Other retail food establishments, supermarkets and grocery stores;
- Foodservice operations selling direct to consumers
- Fishing vessels
- Marine or freshwater fisheries, aquaculture operations, or beds

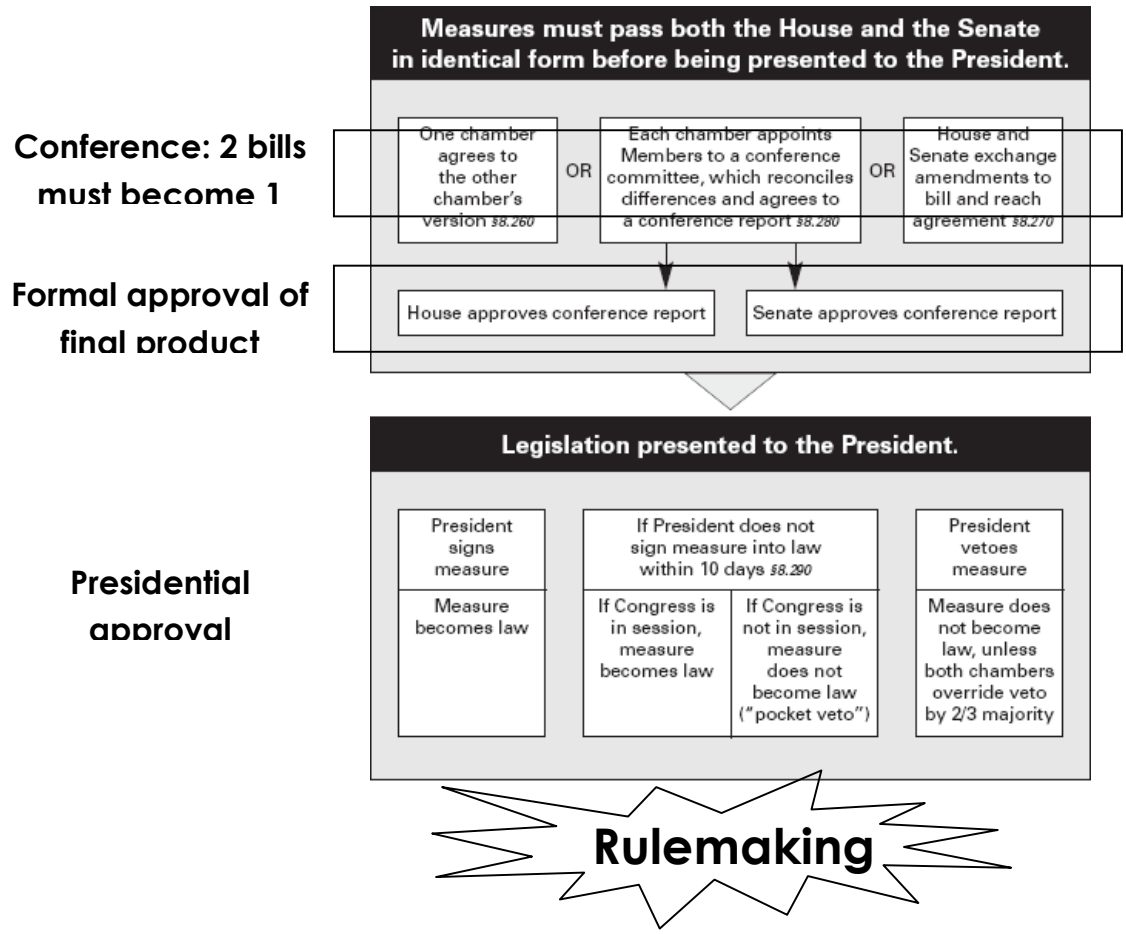
3.3 Legislative process

The following diagrams detail the legislative process in the US Congress, and the current status of the legislation in each chamber.



As indicated in the flowchart above, when a bill is introduced to Congress it is introduced in both the House and Senate for committee negotiations, amendments, and consideration.

Once bills have approved by both chambers (see the diagrams on the next page), the differences between them must be resolved in conference, yielding a single piece of legislation which must then be formalized by each chamber. The bill then requires the President's signature (or if he refuses to approve the legislation, "vetoing it", the Congress must override the veto) for it to become law.



3.4 Legislative provisions

In the pages that follow, we identify the key provisions contained in the House and Senate bills, with references to the sections (and page numbers) where they are found (complete

tables of contents for the bills are included in appendices A1 and A2). Following the references, we describe key provisions in greater detail. We also briefly indicate the miscellaneous (but less relevant) provisions in each bill.

Following descriptions of these provisions, we identify, in summary form, those common to both bills, as well as significant differences between the two bills.

3.4.1 Registration of facilities

House	Senate
Changes in registration of food facilities Section 101 (pp. 7-16)	***Registration of food facilities*** Section 102 (pp. 123-128)

House provisions

Title I, section 101 of the bill defines an FDA registry of food facilities that manufacture, process, pack, or hold food that is consumed in the US is designed to establish a foundation for product traceability, increase the frequency of inspections, improve product traceability, and generate a funding resource to support oversight of food safety. Registration is considered the first step towards establishing a food safety compliance and enforcement system for food producers and processors who market to US consumers. Registration is available electronically at http://www.access.fda.gov. Registration is available by paper using Form FDA-3537. ***Registration with the FDA would be required on an annual basis on or before December 31 of each year.*** This provision overlaps with similar provisions in the Bioterrorism Act of 2002.

Registration of a food facility would require:

(a) the name, address, and emergency contact information of the facility being registered
(b) the primary purpose and business activity of the facility, including dates of operation if the facility is seasonal
(c) The general food category of each food manufactured, processed, packed, or held at the facility
(d) All trade names under which the facility conducts business related to food.
(e) The name, address, and 24-hour emergency contact information of the United States distribution agent for the facility, which would have access to information required to be maintained by a food manufacturing, processing, packing, or handling facility for presentation upon request by the FDA
(f) Foreign facilities require the name, address, and emergency contact information of an agent in the United States
(g) The unique facility identifier of the facility
(h) Additional information pertaining to the facility as the Secretary may require by regulation

The Unique Facility Identifier will be developed as a numerical identifier system and integrated with CBP's computerized import scanning systems, including the Automated Commercial Environment (ACE), and the International Trade Data System (ITDS).

If there is a food facility's information, such as new name or address, the facility must submit updated information to the FDA within 30 days.

Food from a facility which has failed to register or improperly registered will be considered "misbranded," and cannot be marketed for human consumption in the US.

Registration may be suspended under the FSEA if a violation of the Act could result in serious adverse health consequences or death to humans or animals. The suspension process includes a formal notice of suspension, an opportunity for an informal hearing, and a request to the Secretary of Health and Human Services to vacate the suspension.

Registration may be cancelled when a notice of cancellation is served no sooner than 10 days following notice of suspension. The registration may be updated or corrected 7 days following notice of cancellation.

Foreign food facilities producing food for export and consumption in the United States require the addition of a US agent to their FDA registration information. The "US agent" must be "a person residing or maintaining a place of business in the United States whom a foreign facility designates as its agent." The US agent can also be an individual, a partnership, business partner, corporation, parent company, broker, lawyer, or association.

Senate provisions

The Senate version of the bill also requires the e-mail address of the owner, operator, or agent of the food facility. It also requires that changes to the food manufacturing, processing, packing, or handling activities conducted at a facility, changes that create reasonable potential for a new hazard or the increase of a previous hazard, that these must be reanalyzed, and the updated changes submitted to the FDA.

The Senate version would require registration every 2 years, between October 1st and December 31st.

3.4.2 Risk-based inspections

House	Senate
Risk-based inspection schedule Section 105 (pp. 53-58) ***Reportable food registry*** Section 112 (p. 99-106) ***Prohibition against delaying, limiting, or refusing inspection*** Section 207 (p. 143)	***Targeting of inspection resources*** Section 201 (p. 185-191) ***Inspection of foreign food facilities*** Section 307 (pp. 234-235)

House provisions

Each registered facility shall be inspected by an agent of the Department of Health and Human Services, or a federal, state, or local official recognized by the Secretary, or an agent of a foreign country recognized to conduct equivalent inspection standards as those specified under US law. The FDA may recognize federal, state, local, or foreign inspection agents for specific commodities or food types.

Inspections are to be conducted with a frequency that appropriately matches a certain facility's risk profile. Proposed schedules for facility inspections are as follows:

- **Category 1** facilities manufacture or process food. Category 1 food facilities are considered high-risk facilities and will be randomly inspected at least every 6 to 12 months.
- **Category 2** facilities manufacture or process food. Category 2 food facilities are considered low-risk facilities and will be randomly inspected at least every 18 months to 36 months.
- **Category 3** facilities handle or hold food. Category 3 facilities are considered very low-risk facilities and will be randomly inspected at least once every 60 months.

Reportable Food Registry (Section 112) - The House bill directs the FDA to maintain the Reportable Food Registry initially established in September 2009, and to require reporting of analytical laboratory and environmental test results.

The bill directs the FDA and the Bureau of Customs and Border Protection to jointly develop a program which requires certification and verification of food facility inspection standards, as specified in the previous section, as well as additional factors such as:

- Personnel of the individual company importing food
- Physical and procedural safety and security of an importer's food supply chain
- Sufficiency of preventative controls for food and ingredients purchased by an importer
- Vendor and supplier information
- Other programs for certification and verification by a qualified certifying entity used by the importer
- Additional factors determined by the FDA

Each of the Title I provisions specified above are subject to "science-based" regulatory standards established by the Secretary of Health and Human Services; international standards for hazard analysis and prevention control; restricted authority for facilities producing food for animals other than humans; storage of packaged foods that are not exposed to the environment; storage of raw agricultural commodities for "further distribution or processing"; review of the regulatory impact of federal hazard analysis and prevention control analysis under the proposed legislation on small business; existing Hazard Analysis Control Certification Prevention authorities including Juice HACCP, Thermally Processed Low-Acid HACCP, and HACCP points program standards; and other relevant federal programs including the Customs-Trade Partnership Against Terrorism.

Prohibition Against Delaying, Limiting, or Refusing Inspection (Section 207) – Food from a facility which delays, limits, or refuses inspection will be considered as "adulterated" unless corrective action to prove otherwise is taken.

Senate provisions

The Senate version of the inspections provision directs the FDA to inspect food facilities according to the assessment of a risk-base profile for particular food products. The risk profile for imported food products under the provision includes the following considerations:

- Risk profile of food commodity produced and handled at a specific facility
- Facility compliance history (recalls, outbreaks, and violations)
- Rigor and effectiveness of Hazard Analysis and Preventive Controls.

High-risk facility inspections criteria

- Inspection once during the first 2 years following enactment of legislation
- Inspections once a year, after the first two years following enactment

Non-high-risk facility inspections criteria

- Inspections once every 4 years

Inspection of foreign food facilities (Section 307) – Directs the Secretary to both increase capacity for foreign inspections and to work with other governments to facilitate the process. *Foreign food facilities failing to honor an inspection within 48 hours will have their exports denied admission to the United States*.

3.4.3 Food safety planning

House	Senate
Hazard analysis, risk-based preventative controls Section 102 (pp. 25-33) ***Food safety plan*** Section 102 (pp. 33-34) ***Food defense plan*** Section 102 (pp. 41-46)	***Hazard analysis and risk-based preventive controls*** Section 103 (pp. 128-132) ***Food safety plan*** Section 103 (p. 131) ***Food defense*** Section 106 (p. 147-151) ***National agriculture and food defense strategy*** Section 108 (p. 161-167)

House provisions

Hazard Analysis: The bill specifies that food facilities must submit a hazard analysis plan to the FDA which identifies hazardous contaminants occurring naturally, unintentionally, or intentionally, which may affect the safety wholesomeness, or sanitation of food from a food facility include:

- Biological, chemical, physical, and radiological hazards
- Natural toxins
- Pesticides
- Drug residues
- Filth
- Decomposition
- Parasites
- Allergens
- Unapproved food and color additives
- Naturally occurring hazards which may be unintentionally introduced.

HACCP plans have been in place for seafood products since 1995, juice products since 2001, and thermally processed low-acid canned foods since 2001. However, the FDA rule for thermally processed low-acid canned foods was recently withdrawn in May 2009. The language for safe and sanitary conditions for food products, as well as the condition of producing, marketing, or distributing food products is consistent with existing requirements present in the Food, Drug, and Cosmetics Act of 1938, as well as the "Good Manufacturing Practices for Foods" (GMPs) contained in Part 110 of Title 21, "Food and Drugs" of the US Code of Federal Regulations.

Furthermore, the FDA has established "Defect Action Levels" (DALs) for specific food commodities which are subject to natural and unavoidable defects as the nature of the product, including mold, insect filth, and mammalian excreta. DALs are established to specify maximum allowable amounts of defects for a given product.

Preventative controls: All food facilities processing US food consumer products must submit and receive approval for safety plans that identify and implement effective preventive controls which prevent, eliminate, or reduce the occurrence of food safety hazards to acceptable levels through an environmental or product testing program. The FDA is granted authority to establish rule-making for minimum food safety plan requirements, and audit food facility hazard plans.

Food facility managers may submit alternative preventive controls to the one established by the Secretary of Health and Human Services.

Title I of the bill requires the owner, operator, or agent of a facility to develop and implement a food safety plan:

(a) Conduct hazard analysis
(b) Identify and implement effective preventive controls
(c) Institute corrective actions when monitoring shows preventive controls have not been properly implemented, or monitoring and verification show that such controls were ineffective
(d) Conduct verification activities
(e) Maintain records of monitoring, corrective action, and verification
(f) Reanalyze for hazards

Monitoring: The implementation of preventative controls must be monitored to identify partial or incomplete implementation, or verification indicates that preventative controls are ineffective. The food facility management must institute corrective actions when monitoring indicates preventive controls have not been properly implemented, or monitoring and verification show that such controls were ineffective. Therefore,

monitoring procedures must be in place to identify failures of preventative controls and identify potential sources of contamination from a food facility.

Corrective actions: Facility managers must establish and implement procedures to either restrict products originating from a facility with ineffective preventative controls from entering commerce, or such that appropriate procedures are taken to reduce the likelihood of future failures of preventative controls. Therefore, a food facility must also have a food safety management plan to remedy food safety problems and risks the event of a faulty risk prevention plan, and to revise preventative controls which are not effective.

Verification: The risk prevention plan must be validated as scientifically and technically sound such that the hazards identified in the hazard analysis are prevented, eliminated, or reduced to an acceptable level of risk.

Requirement to Reanalyze and Revise: The legislation directs food facilities to review the scientific and technical evaluation of their risk prevention plan at least every 2 years, and take appropriate measures to remedy or revise hazard analysis and risk prevention measures if necessary.

Recordkeeping: The bill requires that food facility managers maintain accurate and organized records documenting hazard analysis, risk prevention controls, monitoring, corrective actions, verifications, and revisions over a minimum of a 2 year period.

Food facilities are required to maintain records to identify immediate previous sources of food products or food ingredients for tracing purposes.

These documents for a given facility must be accessible by FDA officials upon request either physically, remotely, or electronically.

Food from a facility without the necessary hazard analysis, prevention control, and food safety plan above will be considered "adulterated" and subject to an Order to Cease Distribution, Recall, or seizure, in addition to criminal and civil penalties for violators.

Senate provisions

Hazard Analysis (Section 103): The Senate bill identifies the same set of hazards associated with food facilities. The Senate bill differs from the House bill in that it will require food facilities to notify the FDA of any substantial changes to food production or handling processes which will create a reasonable risk for a new hazard.

Preventive Controls, Monitoring, Corrective Action, Verification: The Senate legislation specifies comparable language and provisions for preventive controls as the House version of the legislation.

However, the Senate version of the bill has no requirement to reanalyze and revise hazard analysis and preventive control measures in the case of a non-compliance event, such as a food safety outbreak.

Comments

Juice and Seafood products must already meet HACCP requirements, so there is no effective change for them.

Opponents to the hazard analysis and prevention control plan provisions argue that detailed FDA rule-making authority and technical requirements will be prohibitively burdensome for food facilities and producers, and establish barriers to entry for nonintegrated producers, including small, minority and disadvantaged food facility operators and producers.

3.4.4 Food safety and trade

Certification

House	Senate
Certification and accreditation Section 109 (p. 77-88) ***Exportation certificate program*** Section 203 (p. 127-129)	***Authority to require import certifications for food*** Section 303 (pp. 229-231)

House provisions

To determine adequate government controls, the bill specifies several steps.

Process – The FDA must define a regulatory process to allow foreign countries and territories to demonstrate that their respective government controls are adequate to export food for consumption in the United States. This requirement places accountability on the government certification agency of an exporting country as well as the food facility.

Demonstration – the bill does not require certification for food products exported from a country or territory which has demonstrated that their respective government controls are adequate to export food for consumption in the United States.

The bill proposes on-site auditing of prospective and qualified accreditation bodies to evaluate the adequate procedural standards for export certification. FDA inspection officials are also granted authority to randomly conduct on-site inspection and audits of any food facility and product, which has been certified by a qualified accreditation body, at reasonable times and within reasonable limits permission. This on-site audit authority also includes access to copy and verify record-keeping for a foreign food facility.

Notice of cancellation or suspension of certification – The bill requires qualified certifying entities to notify the FDA when a particular food facility fails to comply with certification provisions in the bill.

The FDA can also make a determination to refuse to accept a certification as no longer valid or reliable.

The bill also specifies regulations for laboratory accreditation, sampling procedures, and reporting of laboratory analytical sampling results to the FDA.

Import certification and qualified certification agency: According to the legislation, imports of food which are misbranded, adulterated, or lack certification of compliance with the requirements of the Act, or are not in compliance with the requirements of food products in the Act, will be refused admission by US Customs and Border Protection agents, FDA, or USDA inspectors. Failure to register or improperly registered food products will be considered "misbranded" and prohibited for importation into the United States.

The FDA has authority to require that qualified certifying agents of a government where a product originates can conduct inspections and sampling procedures to certify that a certain food product complies with the requirements of the Act. Factors which may require certification include:

- Scientific or risk-based evidence indicates that imports of certain food products from a particular country, territory, or region may be susceptible to inadequate government controls for food safety
- Scientific evidence indicates that a particular food item presents a threat of risk to public health or death
- Certification requirements are predetermined between the government of a particular country or territory and the FDA

Certification in the bill is defined broadly to include particular information about the product, or the facility in which a product was manufactured, processed, packed, held, grown, harvested, sorted, or transported.

The bill directs the FDA and the Bureau of Customs and Border Protection to issue formal rule-making and procedural guidance on how to file import entry filings.

The bill will require that customs brokers register and provide documentation of certification for food processing facilities of imported foods to the FDA. Customs brokers will also be required obtain a unique facility identifier under the proposed legislation as other food facilities. Although brokers are not technically handlers of food products and will not require on-site facility inspections, brokers will require oversight for documentation, recordkeeping, and serve as a deterrent to avoid the provisions of the Act through the agency of brokers. Unlike similar registration requirements for other food facilities, brokers will not need to pay a user-fee. Brokers will be required to maintain and submit records upon request by the FDA.

Export certificate program (Section 203) – In the bill, the FDA is granted authority to develop regulations and procedural guidelines for an Export Certification program for food exports, and also collect an annual fee for the export certificate as determined by the FDA. The user fees from the export certification program will be used to administer the program.

Senate provisions

Section 303 gives the Secretary authority to require import certificates, provided either through an agency of foreign government, or another accredited certifying agency. The bill does not create a requirement to demand import certificates, but rather leaves the decision making to the Secretary as to which countries and products must supply them:

"The Secretary, based on public health considerations, including risks associated with the food or its place of origin, may require as a condition of granting admission to an article of food imported or offered for import into the United States, that an entity…provide a certification or such other assurances as the Secretary determines appropriate that the article of food complies with some or all applicable requirements of this Act, as specified by the Secretary." (Section 303(b))

Importer registration and programs

House	Senate
Registration for Commercial Importers Section 204 (p. 129-134) ***Registration for Customs Brokers*** Section 205 (p. 138-141) ***Unique Identification Numbers for Food Facilities, Importers, and Customs Brokers*** Section 206 (p. 141-142)	***Foreign Supplier Verification Program*** Section 301 (pp. 222-226) ***Voluntary Qualified Importer Program*** Section 302 (pp. 226-228)

House provisions

Registration for Commercial Importers (Section 204): Commercial importers will be required by the Act to register to import or held for import food products. The registered food importer must also provide information of a **unique food facility identifier (Section 206)**. Importers of food will also be assessed an annual fee of $500, which will be adjusted annually for inflation and necessary import administration fees. This fee is waived for importers registered in the FDA food registry.

Good importer practices: The provision also specifies that maintenance of registration is conditional upon compliance with "Good Importer Practices," which are to be developed and specified at a later date by the US Bureau of Customs and Border Protection. Food importers will be required to:

- Retain adequate information about the food, its hazards, and the requirements of the Act
- Develop and implement adequate procedures to verify the origin and responsible party for food products
- Develop and implement adequate procedures for corrective action, for tracing, control of distribution, and recall of food products not in compliance with the provisions of the Act

Registration of a commercial importer can be suspended after initial notice of suspension and an informal hearing which establishes that an importer violated the Act, or knowingly or repeatedly made inaccurate or incomplete statements and documentation to the FDA in compliance with the Act.

A commercial importer whose registration has been suspended may request the FDA to vacate the suspension of registration once the importer has taken corrective action to remedy violations which were the basis of suspension.

The FDA can vacate a suspension of registration under the discretion of the Secretary of Health and Human Services.

Registration of a commercial importer can be cancelled 10 days following a notice to suspend registration, if an import does not update registration, or provides false, incomplete, or inaccurate information.

If a commercial importer updates or corrects information within 7 days of notice of cancellation, the registration shall not be cancelled.

In addition to registration for importers, **customs brokers must also register with the FDA (Section 205)** and provide unique facility identifiers, as appropriate.

Senate provisions

The Foreign Supplier Verification Program (Section 301) establishes accountability for importers to verify the compliance of all foreign suppliers with US food safety laws. This proposal divides the responsibility of foreign food facility verification to the importer, the foreign supplier/exporter, and the FDA foreign inspectorate. Participants in the program will be posted online on the FDA agency website.

"Verification activities under a foreign supplier verification program under this section **may include** monitoring records for shipments, lot-by-lot certification of compliance, annual on-site inspections, checking the hazard analysis and risk-based preventive control plan of the foreign supplier, and periodically testing and sampling shipments."

The FSVP creates requirements for food importers, some of which could in theory be substantial and burdensome. The potential requirements are preceded by the expression "may include," however, so there is plenty of room for the FDA to be judicious in its requirements and apply them only in higher-risk situations, as warranted.

Timing and details: The Secretary would be required to issue guidance on the program within one year of the law's passage, and it would go into effect 2 years after passage. Failure to have a program in place is a prohibited act, and importers would be required to keep records and have them readily available for 2 years.

Note: Seafood, juice, and low-acid canned foods already in compliance with FDA's HACCP requirements are deemed by the legislation to be in compliance with Foreign Supplier Verification Program.

The Voluntary Qualified Importer Program (Section 302) offers incentives such as expedited customs clearance and regulatory review and crediting of registration fees for importers to register, comply, and certify compliance with US food safety laws. This program would allow participants to realize improved margins for import costs and/or allow participants to charge consumers a pricing premium for supplying consumers with a supply of more regulated imported food products. The Voluntary Qualified Importer Program does have different criteria for importer participation including:

- Nature of food to be imported
- Compliance history of the foreign supplier
- Capability of the regulatory system of the country to export to ensure compliance with US food safety standards
- Recordkeeping, testing, inspections and audits of facilities, traceability of articles of food, temperature controls, and sourcing practices of the importer
- Potential risk for intentional adulteration of food
- Other factors considered by the FDA at the Secretary of Health Human Services discretion
- Re-evaluation once every 3 years.

This section directs the Secretary to "establish a program, in consultation with the Secretary of Homeland Security, to provide for the expedited review and importation of food offered for importation by importers who have voluntarily agreed to participate in such program," and to issue a related guidance document on the program. The goal is to provide an expedited process to those willing to spend the time and effort necessary to minimize food safety risks.

In reviewing applications and participation, the Secretary may consider any relevant factors, including but not limited to the risk level of the food and potential risks for adulteration; the compliance history and procedures of the importer; and the exporter's track record and the capability of the exporting country's regulatory system.

Other trade issues

For other trade issues, we will detail first the provisions of the House bill, then those of the Senate bill.

House
Dedicated foreign inspectorate
Section 208 (p. 144)
Country of origin labeling (COOL)
Section 202 (pp. 125-127)
Improper Import Entry Filings
Section 136 (pp. 123-124)
Extraterritorial jurisdiction
Section 213 (p. 155)

Dedicated foreign inspectorate: The bill directs the FDA to establish and maintain a corps of inspectors to conduct inspections of foreign food facilities. The bill further directs the FDA to sufficiently staff and fund the foreign inspectorate to achieve the frequency of inspections for the appropriate number of facilities described in the Act.

Country of origin labeling (COOL): Processed food products must be labeled to include the country of origin, identifying the country in which the final processing of food occurs. This provision overlaps and supports existing regulations which require country of origin marking requirements of the US Bureau of Customs Border and Protection.

Non-processed food products must be labeled to identify the country of origin of the food. This provision overlaps and supports existing regulations which require country of origin marking requirements of the US Department of Agriculture.

COOL provisions for USDA regulated muscle cut and ground meat products, wild and farm-raised fish and shellfish, fresh and frozen fruits and vegetables, peanuts, pecans, and macadamia nuts, and ginseng roots entered into force on March 19, 2009. COOL provisions for fish and shellfish entered into force in 2005. The labeling requirements in this provision are set to enter force 2 years following the enactment of the bill. However, actual enforcement of the provision may take as long as 6 years as was the case in the protracted and litigious implementation process for the 2002 Farm Bill provisions for meat and fish labeling.

The Senate bill does not address COOL.

Improper import entry filings (Section 136) – Failure to provide accurate or complete information on submissions related to food is a prohibited act.

Extraterritorial jurisdiction (Section 404) – This provisions says that extraterritorial jurisdiction applies to violations of the Act in connection with foods intended for distribution in the United States.

Senate provisions

The Senate legislation directs the FDA to establish overseas offices to assist and conduct risk-based inspections of food facilities where appropriate to facilitate compliance with the legislation.

Review of a regulatory authority of a foreign country (Section 305) – This section has been of particular interest to several foreign governments, concerned about how the bills address the recognition of their own food safety regulatory regimes. The language does not compel the Secretary to review other country's regulatory authority, but delegates the decision to the Secretary to do so:

Senate
Foreign offices of the Food and Drug Administration Section 309 (pp. 249-250)
Review of a regulatory authority of a foreign country Section 305 (p. 232)
Building capacity of foreign governments with respect to food Section 306 (pp. 233-234)
Accreditation of third-party auditors and audit agents Section 308 (pp. 235-249)
Compliance with international agreements Section 404 (p. 265)

The Secretary may review information from a county outlining the statues, regulations, standards, and controls of such country, and conduct on-site audits in such country to verify the implementation of those statues, regulations, standards, and controls. Based on such review, the Secretary shall determine whether such country can provide reasonable assurances that the food supply of the country meets or exceeds the safety of food manufactured, processed, packed, or held in the United States."

Building capacity of foreign government with respect to food (Section 306) – This provision directs the FDA to work with foreign governments to build their capacity in the area of food safety; also, to work with them in a number of areas, including towards mutual recognition of inspections, and harmonization of processes and recordkeeping/sharing.

Accreditation of third-party auditors and audit agents (Section 308) – The Secretary has 2 years to establish a system to recognize accreditation bodies, whether they be foreign governments or third party organizations. Once the system is set up, if no accrediting bodies have been recognized within 1 year, then the Secretary my directly accredit third party auditors (hence becoming the accrediting agency).

Standards used for accreditation are supposed to follow existing practices. "In developing model standards, the Secretary shall look to standards in place on the date of the

enactment of this section for guidance, to avoid unnecessary duplication of efforts and costs." (Section 308(8)(2))

To accredit foreign governments as an accrediting agent, the Secretary is responsible for performing reviews and audits to ensure that the accrediting agency is "capable of adequately ensuring that the eligible entities certified by them meet the requirements of the Food Safety Act with respect to food manufactured, processed, packed or held for import into the United States."

To accredit foreign cooperatives or other third parties as accrediting agents, the Secretary is responsible for performing reviews and audits of the training and qualifications of auditors used by that cooperative or party and conduct reviews of internal systems as necessary to meet the requirements of the Act.

Audit agents must agree to issue written and electronic certificates. Audit requirements include

- Identity of persons at the audited entity responsible for food safety
- Dates of the audit
- Scope of the audit
- Any other information required by the Secretary

Consultative audits: In addition to regulatory audits, accredited auditors may perform consultative audits; these are only for internal use by the audited entity.

Agents may not perform a regulatory audit of an entity if they have performed any audit (regulatory or consultative) within the previous 24 month period. Agents may not be owned, managed, or controlled by any person or entity that owns or operates an eligible entity to be certified by such an agent. There are also provisions to ensure a lack of financial conflicts of interest on the part of auditing agents as well.

Compliance with international agreements (Section 404) – This variance clause attempts to reconcile the bill's provisions with the United States's international obligations:

> *Nothing in this Act (or an amendment made by this Act) shall be construed in a manner inconsistent with the agreement establishing the World Trade Organization or any other treaty or international agreement to which the United States is a party.*

3.4.5 Traceability

Traceability is the ability to identify and follow the movement of a product through the supply chain, through all stages of production, processing, and distribution.

House	Senate
Traceability of food Section 107 (p. 67-75)	***Enhanced traceback and recordkeeping*** Section 204 (pp. 198-201) ***Pilot project to enhance traceback and recordkeeping with respect to processed food*** Section 205 (pp. 201-202)

House provisions

The bill requires the FDA to implement a tracing system to trace the previous origin and full distribution history of food products, the subsequent distribution of the products, and assess the costs and benefits with the adoption of tracing technologies and methodologies.

Food products which cannot satisfy the tracing requirement will be considered "adulterated." However, implementation of a tracing system is considered distant as the law requires a study/pilot phase of review and rule-making, then a secondary tentative phase of final rule-making, and implementation.

Senate provisions

The Senate version of the traceback provision proposes pilot projects to enhance traceback and recordkeeping: three for produce and at least one for processed food. All are supposed to be products which have been subject of food safety outbreaks within the 5 years preceding the enactment of the Act.

The Senate bill does not include enforcement mechanisms for traceback and recordkeeping.

Comments

Under the Food, Drug, and Cosmetics Act the FDA must maintain "standards of identity" for a minimum quantity of ingredients composing of a processed food product. The standards of identity are specified in Parts 130 to 169 in Title 21, Food and Drugs, of the US Code of Federal Regulation. Furthermore, an FDA rule requires "low acid canned foods

(LACF), a thermally processed canned product with a pH above 4.6, and "acidified foods" (AF) to be registered with the LACF office of the FDA, at lacf@fda.gov.

Furthermore, additives used in food products must be approved or reviewed by the FDA prior to marketing. The FDA maintains a list of food additives called the "Everything Added to Food in the United States" (EAFUS).

The provisions of the recordkeeping and traceability of food closely follow similar provisions in the Bioterrorism Act of 2002. The FDA and the USDA, FSIS which are jointly working to develop preliminary rules and guidance for a national food product tracing system. In 2005, the FDA implemented rules to require recordkeeping guidelines for certain food facilities.

However, the implementation of the Bioterrorism Act of 2002 and the FDA rule issued in 2005 have not been effective. A 2009 study by the Department of Health and Human Services, Office of the Inspector General concluded that 12.5% of a random sample of 40 food products could be completely traced through each stage of the supply chain. For 78% of the products sampled, the survey was able to identify food facilities that likely handled the product. However, for 22% of the products sampled, the survey was unable to identify the food facilities that likely handled the product. Yet, in a wider context of food products, other than the 40 randomly sampled products in the study, a separate survey of 118 food facilities in the same report indicates that 59% of food facilities did not maintain records in compliance with FDA regulations, approximately 20% of respondents to the survey did not properly maintain information about their sources, approximately 52% did not maintain information about their recipients, and approximately 46% did not provide information about their transporters. Lastly, the report concludes that 25% of survey respondents were not aware of FDA recordkeeping requirements. The survey identifies that awareness of recordkeeping requirements declines from a primary sources of food products to retail and food service establishment levels of recordkeeping requirements. Approximately 13% of managers at processing, packing, and manufacturing facilities, 21% of managers at distributors, wholesalers, and storage facilities, and 50% of managers at retail facilities were unaware of retail requirements.

A separate study conducted by the Institute of Food Technologists, under contract for the FDA, Center for Food Safety and Applied Nutrition, concluded that although most firms believe that they are in compliance with the Bioterrorism Act of 2002 requirements for a one step back and one step ahead approach, in fact, many food facilities do not maintain common data elements needed to complete product tracing in the supply chain. The study also concluded that traceability costs vary among food production facility types and food classes, as well as capabilities for different firms. The report also noted that traceability costs are often inaccurately estimated.

3.4.6 FDA Authorities

The FDA currently has no enforcement mechanism besides inspections and certification procedures to enforce FDA regulations. The bills grant the FDA unprecedented enforcement authority to seize, impose administrative detention, and prohibit or restrict the movement of food.

Authority to recall

House	Senate
Notification, nondistribution, and recall of adulterated or misbranded food Section 111 (pp. 93-99)	***Mandatory recall authority*** Section 207 (pp. 208-212)

House provisions

Voluntary recalls: If a food facility has reason to believe that misbranded or adulterated food products have entered interstate commerce, or held for sale, and pose a reasonable probability of consumption and risk to public health or death to humans or animals, that food product should be voluntarily recalled, restricted from distribution, and subject to notification to the FDA and other appropriate authorities.

Mandatory recalls: If a food manufacturer refuses to voluntarily remove contaminated food products from the marketplace, then the FDA has authority to issue a mandatory detention, cease of distribution, recall, and notification of potentially affected consumers.

The FDA is also granted authority to seize, prohibit, or restrict movement of adulterated or misbranded food as a necessary protection of the public health from the imminent threat of serious or adverse health consequences or death to humans or animals.

The FDA will notify the Governor or other appropriate official, issue a public announcement and notify agents of a food facility about recall or seizure of food products and imminent food safety outbreak threats posed by a food product in question. The bill directs the FDA to take the least drastic action feasible to prevent adverse health consequences or death to humans or animals.

Following 14 days after initial actions to protect the public health have been taken, the FDA will notify the governor or appropriate official of the State affected by a food safety incident, issue a pubic announcement, and publish details in the Federal Register.

Appeals: The bill grants the FDA authority to issue an Order to Cease Distribution to a food facility to immediately limit further distribution and sale of a misbranded or adulterated

food product. An Order to Cease of Distribution can be appealed within 24 hours by an informal hearing as soon as possible, but not after more than 5 calendar days.

Following an Order to Cease Distribution, the FDA can issue an Order to Recall affected food products suspected to be misbranded or adulterated.

Senate provisions

Mandatory recall authority (Section 207) – The Senate bill grants the FDA mandatory recall authority based on information collected through the reportable food registry, or other means, indicating that there is a reasonable probability that a food product is adulterated, or misbranded, and the product will cause a public health risk or death to humans or animals.

Authority to restrict, detain, dispose

House	Senate
Authority to prohibit or restrict movement of food Section 133 (p. 118-121) ***Administrative detention*** Section 132 (p. 116-117)	***Administrative detention of food*** Section 208 (p. 212-213) ***Decontamination and disposal standards and plans*** Section 209 (p. 213-215)

Administrative detention of food (Section 208) – The Senate bill grants the FDA authority to administratively detain food products if there is "reason to believe' potential adulteration or misbranding and the potential risk of adverse public health consequences.

Decontamination and disposal standards and plans (Section 209) – The Senate legislation requires federal agencies such as the Department of Health and Human Services, Department of Homeland Security, and the Department of Agriculture to collaborate with local and state governments to prepare for the assessment, recovery, and decontamination of an agriculture or food emergency.

Comments

Food facilities and the food and agriculture industry are concerned that the legislative authority to Order to Cease Distribution, Order to Recall, and Seizure impose extraordinary risks on the responsible parties of a food facility in the case of an unwarranted recall which has the potential to cause significant material harm to the income, reputation, brand equity, and public good will for a particular company. Responsible parties for food facilities would like to be granted legal or compensatory tort protections against unwarranted recall and seizure actions taken by the FDA.

Access to records and subpoena authority

House	Senate
Access to records Section 106 (pp. 58-67) ***Subpoena authority*** Section 211 (pp. 145-150)	***Access to records ("Inspection of records")*** Section 101 (p. 121-123)

Both bills provide for increased FDA authority to access records. The House bill is more comprehensive and provides access to records, including during routine inspections (with advance notice), as well as subpoena authority. The Senate bill does not grant the FDA authority to access records during routine inspections – the FDA would like this authority.

3.4.7 Fees and penalties

The two bills include specifics on certain fees, while delegating other fee assessments to the FDA. The fees enumerated in the legislation are insufficient to fully fund the requirements called for by either bill.

Registration fees (facilities)

House	Senate
Changes in registration of food facilities Section 101 (p. 17-24)	*(No facility registration fees)*

House provisions

The House of Representatives version of the bill proposes a $500 annual fee per facility. Owners of multiple facilities are limited to an aggregate total of $175,000 in annual registration fees.

Senate provisions

The Senate version of this provision does not require registration fees.

Comments

A recent study by the Department of Health and Human Services, Office of the Inspector General, found that the registration of food facilities defined under similar provisions of the Bioterrorism Act of 2002 have not achieved effective and complete implementation. However, it is also important to note that the Bioterrorism Act of 2002 did not include criminal or civil penalties to enforce participation. The study concluded that as many as 7% of selected facilities regulated by the FDA failed to register with the agency as

required by the statute, an additional 2% of the selected facilities failed to cancel their registration, nearly 48% of the selected facilities failed to properly provide information for the registry, and 52% of the facility managers surveyed were unaware of the FDA's registry requirements.

Furthermore, critics of the provision challenge the funding structure and scope for an expanded inspection and registration program by the FDA. They argue that the proposed flat-rate registration fees of $500, which are estimated to generate funds of $200 million per year, are insufficient to properly fund the program. They also claim that to be fair, that the user-fee schedule should be more closely associated with the costs of a particular food facility (for FDA personnel and their administration of re-inspections, food recalls, and investigations), and not levied on a universal basis to all food facilities. The CBO estimates that the bill will generate $10 million in user-fees from 2010-2014, and $20 million in user fees from 2010 to 2019.

Registration fee (importers)

House	Senate
Registration for commercial importers of food; fee Section 204 (p. 135-138)	*(Does not specify fees for importers)*

House provision

The House bill assesses a $500 fee for commercial importers of food; *this fee is waived in the event the importer has facilities for which it is already paying a registration fee*.

Penalties for violations, and reinspection, and recall fees

House	Senate
Civil Penalties for violations relating to food Section 135 (p.122-123) ***Criminal penalties*** Section 134 (p. 121-122)	***Mandatory recall authority*** Section 207 (p. 208-212) *(Senate has no criminal penalties)*

House provisions

If a food facility commits a violation of any requirement of the Act related to food, including Good Manufacturing Practice guidelines, and the violation requires additional inspections to be conducted by the FDA, or products from the food facility undergo a food product recall, then the food facility management is responsible for fully covering the costs of additional inspections, conducting recall activities, technical assistance, and public notifications.

Civil penalties for violations related to food:

- $20,000 for an individual, not exceeding $50,000 for a single proceeding
- $250,000 for any other individual, not exceeding $1,000,000 for a single proceeding

Civil penalties for known violations related to food:

- $50,000 for an individual, not to exceed $100,000 for a single proceeding
- $500,000 for any other individual, not exceeding $7,500,000 for a single proceeding

Each violation and each additional day during which a facility continues to violate the act constitutes a separate offense.

In addition to civil penalties, the House Bill also specifies criminal penalties of up to 10 years for intentional violations of the act.

Senate provisions

The Senate bill grants the FDA authority to collect re-inspection and recall fees. It specifies civil penalties for failure to comply with an ordered recall.

3.4.8 Common miscellaneous provisions

Performance standards

House	Senate
Performance standards Section 103 (pp. 46-48)	***Performance standards*** Section 104 (p. 140)

The House bill specifies that the FDA must review and evaluate toxicological and epidemiological data at least once every 2 years to identify significant food-borne contaminants and hazards, and then develop and issue contaminant-specific and science-based guidance and performance standards to facilities handling food or food classes to minimize to acceptable levels, prevent, or eliminate hazards.

The bill also directs the FDA and the USDA to issue joint guidance regarding science-based minimum standards for the production and harvesting of fruits and vegetables,

meanwhile establishing a flexible rule to accommodate small businesses, entities that sell directly to consumers as specified in the exemptions portion of the description of the bill, and non-conflicting provisions with certified organic production requirements.

The House version of the provision extends specific direction to the FDA and USDA to establish similar science-based guidance for nuts and fungus as well.

The Senate legislation directs the Secretary of HHS to develop "contaminant specific and science based guidance documents, action levels, or regulations."

Produce safety standards

House	Senate
Safety standards for produce and certain other raw agricultural commodities Section 104 (pp. 48-52)	***Standards for produce safety*** Section 105 (p. 140-147)

These provisions direct the FDA to establish standards and procedures to improve the safety of produce (and in the House bill, other raw commodities such as nuts as well).

Surveillance

House	Senate
Surveillance Section 121 (pp. 110-113)	***Surveillance*** Section 206 (pp. 202-208)

Both the House and Senate bills direct the CDC to enhance food-borne illness surveillance systems.

Whistleblower protections

House	Senate
Whistleblower protections Section 212 (pp. 150-154)	***Whistleblower protections*** Section 402 (pp. 253-263)

These provisions protect explicit protection to individuals alerting authorities to violations of the food safety legislation.

3.4.9 Bill-specific miscellaneous provisions

Each bill also has specific and unique miscellaneous provisions of limited relevance to food trade. We list them here for thoroughness.

House miscellaneous provisions

- Public Education and Advisory System (Section 122, p. 114)
- Research (Section 123, p. 115)
- Food Generally Recognized as Safe (Section 201, p. 124)
- Infant formula (Section 114, p. 108)
- Support for training institutes (Section 214, p. 155)
- Bisphenol A in Food and Beverage Containers (Section 215, p. 156)
- Lead content labeling requirement for ceramic tableware and cookware (Section 216, p. 157)

Senate miscellaneous provisions

- Food and agriculture coordinating councils (Section 109, p. 167)
- Building domestic capacity (Section 110, p. 168)
- Sanitary transportation of food (Section 111, p. 173)
- Food safety and anaphylaxis management (Section 112, p. 173)
- Recognition of laboratory accreditation for analyses of food (Section 202, p. 191)
- Integrated consortium of laboratory networks (Section 203, p. 196)
- Improving the training of state, local, territorial, and tribal food safety officials (Section 210, pp. 215-218)
- Grants to enhance food safety (Section 211, p. 218)
- Smuggled food (Section 310, p. 250)
- Upgrading guidance relating to fish and fisheries products hazards and controls (Section 405, p. 265)

3.5 Most important common provisions

Here we identify provisions common between the two bills; provided the Senate passes the bill, these are provisions that would be most likely to make it through conference. Note that the two bills are not structured identically, so provisions may be located in different sections or even under different headings.

Both House and Senate bills have many common provisions; these are the ones most likely to make it through conference and become law:

Preventive control systems

- **Expanded access to records** – both bills give the FDA increased access to records.
- **Hazard Analysis and Prevention Control Systems** – both bills call for participants in the distribution chain to have food safety plans.
- **Inspections** - both bills call for an increase in the number of FDA inspections.

- **Mandatory inspections frequencies** – both bills set mandatory inspection frequencies.
- **Imported food specific provisions** – both bills have provisions specific to imported foods.
- **Certification for high-risk food products** – both bills task the FDA with requiring certification for high risk food products, according to origin or food classification.
- **Traceback system** - both bills require the FDA to work on traceability of food products.

Intervention

- **Mandatory recall authority** – Both bills give the FDA mandatory recall authority. Currently, the FDA relies on voluntary cooperation.
- **Administrative detention authority** – both bills give the FDA the ability to order the detention of food shipments.

Response

- **Civil penalties for non-compliance** – Both bills increase penalties for food safety violations.
- **Enforcement mechanisms for non-compliance** – both bills identify circumstances under which companies and products are deemed non-compliant.

3.6 Key differences between the bills

The bills also have provisions unique to one bill but not the other:

Prevention

- **Registration fees** – The House bill assesses a $500 annual registration fee for every qualified facility, domestic or international, which handles food destined for consumption in the United States. The Senate bill does not mandate a fee, but directs the HHS Secretary to collect fees for re-inspections and recalls
- **Trace-back systems** – The House bill mandates a national tracing system (but provides no funding); the Senate bill mandates pilot programs for produce and processed food (based on recent outbreaks, most likely peanuts, other nuts, tomato products, and/or frozen meals).

Intervention

- **Seizure** - In the House bill, the FDA is given authority to seize and detain misbranded or adulterated food; in the Senate version, the FDA has authority to administratively detain non-compliant food, but not the authority to seize it.

Response

- **Criminal Penalties** - In the House bill, the FDA can impose criminal penalties (increased from a maximum of 1 year to a maximum of 10 years) and/or levy fines; the Senate bill does not grant the FDA the ability to impose criminal penalties.

Miscellaneous

- **Country-of-Origin Labeling (COOL)**; The House bill has a COOL provision for FDA-regulated foods; the Senate version does not.
- **Foreign Supplier Verification Program** – In the Senate bill, the importer is responsible for compliance of all its foreign suppliers with US food safety laws. The House bill lacks this provision.
- **Voluntary Qualified Importer Program** - In the Senate bill, there is a voluntary program to certify and demonstrate compliance with US food safety laws, a program which is supposed to provide expedited product movement. There is no VQIP in the House bill.

3.7 Food commodity specific provisions

Produce and certain other raw agricultural commodities including fruits, vegetables, nuts, and fungus may be subject to specific regulatory guidelines for growing, harvesting, packing, sorting, transporting, and storage operations. Regulatory standards may be implemented for manure use, water quality, employee hygiene, sanitation and animal control, temperature controls, and other reasonable standards.

Many produce and agricultural producers oppose the measure and argue that the US Department of Health and Human Services, Food and Drug Administration does not have authority or technical expertise to advise agricultural producers on good agriculture practices (GAP) and good management practices (GMP).

The bill specifies that standards will take into consideration reasonable enforcement measures for public health protection, and the impact of standards on small-scale and diversified farms, wildlife habitat, conservation practices, watershed protection efforts, and organic production methods.

3.8 Carbon monoxide provisions

Although in the original version of the House bill, the miscellaneous provision related to carbon monoxide was removed.

3.9 Alternative approaches

A number of alternative approaches to food safety reform have been considered in recent years. We provide these here to present some of the viewpoints that have been introduced as potential legislation.

3.9.1 Single independent food safety agency

Some would like to see the patchwork of responsibility for food safety consolidated under a single agency and/or the flip side of the coin, separating out non-food responsibilities from the FDA. Examples:

HR 875 sponsored by Rep. Rosa DeLauro (D-CT) and HR 1332 sponsored by Rep. Costa (D-FL)
- Sponsors, Government Accountability Office, USDA Secretary Tom Vilsack, DHS Secretary Tom Ridge, Sen. Richard Durbin (D-IL)
Canada, Denmark, Germany, Ireland, the Netherlands, New Zealand and the United Kingdom
- Splits the FDA into Food Safety Administration and Federal Drug Administration

Consumer group advocates indicated in interviews that this would be a desirable solution, but do not believe it realistic at this point in time.

3.9.2 Reform FDA oversight of food and other imports

HR 759 sponsored by Rep. John Dingell (D-IL)

Impose new requirements on food manufacturers, handlers, and producers, including risk-based safety plans, recordkeeping regulations for product tracing purposes, more rigorous registration requirements, and performance standards.

SECTION 4: POTENTIAL CHANGES IN THE US IMPORT ENVIRONMENT

This section explores the food safety legislation as it relates to imports. First we summarize the role of imports in the food supply, followed by a description of the authorities and procedures as they relate to food imports. We then identify changes to the system in the proposed legislation, and take a close look at how these changes would impact specific food categories of importance to Japanese exporters. We conclude by highlighting a couple of inconsistencies identified between the legislation and US trade obligations.

4.1 Role of imports in the food supply

US demographics consumer preferences have been driving an increase in food imports. US consumers demand imported foods for their quality, variety, and seasonal availability. According to USDA data, in 2007, imported food products accounted for 15% of the US food supply. An even greater share of fresh fruits and vegetables (60%) and seafood products (75%) are imported.

US food imports have increased from $44 billion in 1999 to nearly $90 billion in 2008, more than doubling in value and nearly doubling in volume.[32] Each day the US receives approximately 25,000 food shipments from more than 100 countries at more than 300 ports of entry.

The top five suppliers of food imports are Canada, Mexico, China, France, and Italy. Japan ranked 29th, accounting for about $660 million in food imports for consumption by value.[33]

The following sections define existing US agency authorities and procedures for administering US food imports.

4.2 US food import agency authorities and procedures

The Department of Agriculture (USDA), the Food and Drug Administration (FDA), and the US Department of Homeland Security, Bureau of Customs and Border Protection (CBP) inspect and certify that foreign food imports are free from pathogens, pests, disease, and filth.

Despite the dramatic increase in food import shipments, food safety measures for imports to the US are not handled uniformly.

[32] *Ibid.* Note that each entry line represents individual tariff lines included in a shipment.
[33] USDA, ERS, "U.S. food imports, value by food group and sector"

4.2.1 FDA's approach to Prevention

For decades the FDA has relied on an import food safety program focused on random inspections and laboratory sampling at production sources, limited ports of entry, and in response to ongoing outbreaks. The FDA currently manages imported food products according to a prevention program relying on electronic screening, customs procedures for imports, physical inspection, and sampling. However, an overwhelming majority of FDA-regulated products are not managed according to current legal statutes due to a lack of resources and limited legislative authority granted to the FDA.

a) Registration

Under current federal statutes, food facilities producing or handling products for export to the United States must be registered with the FDA. However, as discussed previously, compliance issues with the registration provisions of the Bioterrorism Act of 2002 and the Food and Drug Amendments Act of 2007 remain problematic for foreign food product suppliers to importers in the United States.

b) Prior Notice

Prior Notice of Incoming Shipments is required under the Bioterrorism Act of 2002 and the Food and Drug Amendment Act of 2007. The provisions require electronic notification of shipment of food products to the FDA through the FDA Prior Notice website at http://www.cfsan.fda.gov/~pn/pnoview.html, or through the Bureau of Customs and Border Protection (CBP) Automated Commercial System (ACS).

Prior notice information about the product shipment is compiled and reviewed electronically in the FDA import database, the Operational and Administrative System for Import Support (OASIS), and its successor program, the Predictive Risk-Based Evaluation of Dynamic Import Compliance Targeting (PREDICT) system.

The PREDICT system generates a manufacturer's identification number, which is used to generate an establishment identifier, or FDA firm identification number.

c) Customs and Border Protection agency holds imported products in-bond

Upon the unloading of a product at a port of entry, an importer purchases a bond from the Bureau of Customs and Border Protection. This bond is refunded once the shipment clears a US port of entry. The bond allows the shipment to remain in the custody of the importer, and is in place to deter release of a shipment of food into commerce prior to clearance by the CBP. If the shipment is transported within the United States to clear Customs through another port of entry at an in-land port, such as Michigan, then the shipment is considered in-bond.

4.2.2 FDA's approach to Intervention

a) OASIS and PREDICT

Although FDA is not able to physically inspect a large percentage of import entries, FDA electronically screens all import entries through the Operational and Administrative System for Import Support (OASIS) and its successor program, the Predictive Risk-Based Evaluation of Dynamic Import Compliance Targeting (PREDICT) system, for a variety of risk factors including:

- Manufacturer history
- Country of Origin
- Product history
- Recall history
- Security risk

The FDA uses Prior Notice information to target resources for additional review for products with the greatest potential for causing harm to public health. OASIS is an automated system for processing and helping FDA make admissibility determinations for FDA-regulated products offered for import. Each business day the FDA currently receives approximately 33,400 Prior Notice submissions.

b) Foreign Inspections and the Beyond our Borders program

The FDA has maintained foreign inspections capacity for decades under the Office of Regulatory Affairs (ORA). Prior to the Beyond our Borders program, FDA officials traveled overseas to conduct inspections, causing significant delays in personnel activity due to travel, acclimation, time change, and logistics. FDA inspectors frequently visited food facilities which demonstrated high risk (through border inspections or agency records).

Following the events of September 11, 2001, and the establishment of the Department of Homeland Security, all foreign imports have entered the country under the dual supervision of the Customs and Border Protection agency and the USDA Animal and Plant Inspection Service (APHIS). For many high-volume exporters to the United States, such as Mexico, Chile, Haiti, Thailand, and New Zealand, APHIS inspects and certifies export products prior to shipment. In certain extreme cases, products are quarantined and investigated further by FDA inspectors at foreign processing facilities.

FDA food safety inspections are conducted according to the risk-profile for individual trading partners. On average, the ORA conducts over 100 inspections per year. The primary targets for foreign inspections by the FDA have been NAFTA-countries, and Asian and Latin American trading partners. This is largely related to the significant volume and

variety of products originating from NAFTA trading partners. Of the 1,286 inspections conducted from 2001 to 2008, just two of these took place in Japan.

FDA Inspections of Food Firms in Foreign Countries, Fiscal Years 2001 through 2008

		2001	2002	2003	2004	2005	2006	2007	2008	Total
1	Mexico	17	15	8	15	7	16	26	29	133
2	Ecuador	8	0	11	24	0	11	10	0	64
3	Thailand	4	10	0	10	0	22	0	12	58
4	Chile	13	0	15	6	7	11	0	5	57
5	Peru	13	0	0	18	1	9	9	4	54
6	Brazil	0	12	6	7	21	0	0	7	53
7	China	0	9	2	6	16	0	0	13	46
8	Taiwan	9	7	0	9	0	7	0	7	39
9	Canada	13	0	13	1	0	7	4	0	38
10	Costa Rica	0	11	0	4	5	7	0	7	34
	Total number of countries that had firms inspected by FDA during the specific fiscal year listed above	26	22	22	20	16	15	11	24	56
	Total inspections	211	169	148	153	132	125	95	153	1,186

Source: GAO and FDA

Institutionally, the FDA and the USDA are jointly moving towards a more active and systemic approach to regulate and monitor food safety risks at the point of production, domestically and abroad. FDA administrators are moving away from the costly expenditure of funding and personnel resources for a select number of high-risk areas or regions of origin for food safety concerns. Instead, FDA officials are now focusing efforts on a joint program with the USDA, other US food safety authorities, and foreign governments to promote food safety oversight at points of production, as well as institutional capacity-building efforts at the local and regional level for under-resourced areas and regions.

The new FDA approach includes the strategic deployment of resources including:

- Collaborative working agreements with more than 30 trade partners to improve food inspections oversight.
- Strengthening importer accountability
- Developing a risk-based imported food monitoring program using Prior Notice and monitoring systems (discussed in further detail below).

4.2.3 FDA's approach to Response

a) Enforcement

If the inspection and PREDICT evaluation does not indicate a need for further review, the shipment is given a "may proceed" designation.

Under current statutes, the FDA is granted limited authority based on information gathered from an examination or prior history of the product, manufacturer or country to:

- Refuse entry for a food product, which appears to be adulterated or misbranded at the border, and mark the container "UNITED STATES REFUSED ENTRY."
- Give notice advising the owner or consignee of the appearance of a violation and the right to provide evidence (such as a laboratory analysis by an independent laboratory) to rebut the appearance of the violation.
- Issue an administrative detention of food products which are identified as originating from a food facility which fails to register.

See Appendix A3 for FDA import procedure details.

At this time, the FDA does not have the authority to require equivalent inspection standards for food products administered by the USDA. With limited resources, the FDA manages food safety inspections at 18 of 300 ports of entry, and estimates that in 2007 less than 1.3% of the $49 billion of imported foods under the agency's jurisdiction were inspected.

In contrast, the USDA FSIS, APHIS, and GIPSA have more authority and funding to meet their food safety mandates. The USDA is authorized to require that nations which export meat, poultry, processed egg products, grains, oilseeds, fruit, vegetables, and plant products to the US maintain equivalent inspection standards. With the USDA's legislative authority to establish standard equivalence, the agency cooperates with 37 foreign trading partners and manages approximately 121 import stations at US ports of entry to ensure that USDA inspected import products are safe, wholesome, and properly labeled.

4.2.4 FDA challenges

The GAO has identified four specific gaps in the US food safety system for imported products.

a) The FDA, USDA, and CBP import screening systems do not share key information

The FDA maintains the Prior Notice program, and is implementing the Predictive Risk-based Evaluation for Dynamic Impact Compliance Targeting (PREDICT) system.

The USDA, FSIS maintains the Automated Import Information System (AIIS), and is developing the Public Health Information System, a web-based information technology application which will replace many of FSIS's legacy systems and allow electronic submission of foreign health certificates, and allow more secure, timely, and advanced notice of foreign shipments certified by a foreign government.

The CBP maintains four systems: the Automated Commercial System (ACS), a legacy computerized screening system; its successor, the Automated Commercial Environment (ACE); the Automated Broker Interface; and the International Trade Data System (ITDS).

The three agencies operate with legacy systems which do not interact, and are shifting to modern information technology systems which are not designed to operate jointly either. The lack of interaction causes gaps in the import screening process. For example, the CBP, ACS, and ACE systems to not provide access to time-of-arrival information at US ports for shipments under the authority of the FDA and USDA, FSIS. These agencies are then unable to conduct examinations or re-inspections of incoming food products. The agencies are currently working on interagency agreements to facilitate screening. However, the operation of the import screening process remains incomplete, as an agreement between the CBP and the FDA does not extend to the USDA, FSIS.

b) The FDA has limited authority to ensure importer compliance

The FDA lacks enforcement mechanisms to enforce laws under its authority. Under current statutes, importers can retain import shipments during the FDA review process. FDA relies on the assumption that the bond paid by importers to the CBP provides sufficient deterrence to restrict unapproved import shipments from entering commerce.

c) CBP and FDA do not provide unique identification numbers to firms.

Previous violators of FDA regulations are able to import high-risk foods to the United States under current statutes and regulations. Because the current CBP-FDA OASIS and PREDICT system generates a unique establishment identifier for each unique manufacturer identification number, any given food importer or broker could potentially receive multiple unique establishment identification numbers for multiple manufacturers identification numbers, complicating registration and tracing efforts.
A recent GAO report estimates that on average an individual firm will have three "unique" identification numbers. One firm is reported to have as many as 75 "unique"

identification numbers. In the case of foreign firms, the FDA estimated in 2008 that many of the 189,000 foreign firms registered with the FDA as food facilities may be duplicates.

d) CBP faces challenges in managing in-bond shipments.

The CBP does not effectively track in-bond shipments, which due to reporting and registration procedures can potentially be used to divert consumer food products from their specified destination and sell them illegally in the US market.

4.3 Proposed changes to US food import agency authorities and procedures

The legislation proposes changes to FDA's approach to food safety oversight in three critical areas: Prevention, Intervention, and Response. Overall, proposed changes to FDA legislative authority is directed at improving accountability for food facilities, foreign suppliers, and importers.

4.3.1 Changes to FDA's approach to Prevention

a) Registration and registration fees

Registration provisions in the legislation will ensure that each facility is documented and accounted for by the FDA, competent authorities in the country-of-origin, or third-party certification firms. The FDA will also be granted legal authority to levy and collect fees.

b) Hazard Analysis, Prevention Control, and Food Safety Plans

The legislation grants the FDA authority to direct and review registered food facility Hazard Analysis, Prevention Control, and Food Safety plans.

c) Risk-based inspections

The FDA will expand the frequency of inspections for all food classification groups, as well as the specialization of inspections conducted for particular food products according to risk assessments defined by product classification, area/region of origin, food facility history, and for imported products, the importer and broker history.

d) Enhanced access to records

The FDA will be granted enhanced access to records for food facilities. The bill will require FDA access to records within 24 hours of the initial request.

4.3.2 Changes to FDA's approach to Intervention

a) Surveillance and monitoring

The legislation directs additional funding to improve monitoring and surveillance programs administered by the CDC.

b) Traceability systems

The legislation proposes a tracing system for pilot projects for specific food products determined by the FDA or a national tracing system for all US consumer food products.

Traceability in the current food safety system is limited to recordkeeping requirements which require food facilities to maintain documentation of their supply-chain for the previous food facility where the product originated, and the subsequent food facility where the product is shipped. Under current statutes, recordkeeping and dedicated investigator teams respond to foodborne illness outbreaks. The legislation proposes traceability pilot projects and a national program for all food products.

Additionally, the House version of the legislation may require traceability of food products within two business days, and for imported food products, the reporting of the entire supply chain.

4.3.3 Changes to FDA's approach to Response

The legislation grants the FDA enhanced authority to enforce regulations, punish repeat violators, and restrict potentially harmful food products from the public.

a) Mandatory recall authority

The FDA will be granted mandatory recall authority for products which are deemed to be a potential risk to public health.

b) Enforcement

- **Seizure and Detention** - In the House version of food safety legislation, the FDA is granted authority to seize and detain adulterated or misbranded food products.
- **Civil Penalties** - The FDA is granted authority to impose more stringent civil penalties for non-compliance with registration, inspections, recalls, and recordkeeping.
- **Criminal Penalties** – The FDA is granted authority to impose criminal penalties for violators who knowingly distributing food products which pose a risk to public health.

4.4 Legislative impact on imports of Japanese food

As discussed above, the proposed provisions of the Food Safety Enhancement Act are drafted to provide food safety measures for US products according to a risk-based approach for each food product and each area or country of origination. Therefore, in practice, the legislation is intended to have varying impacts for trading partners with different food safety risk profiles to be defined by the FDA at a later date in the rule making process.

a) Japanese food exports to the US

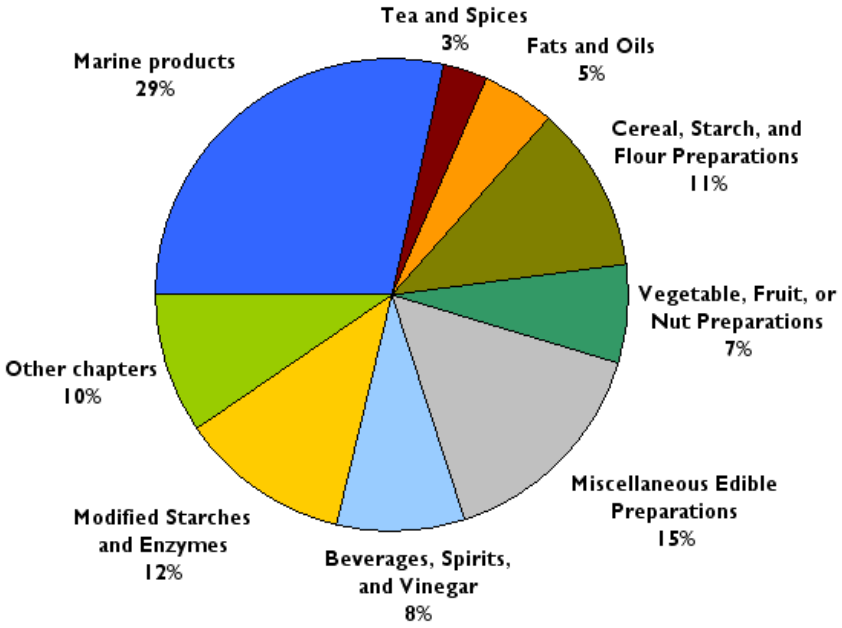
Japanese food exports to the United States are primarily limited to processed food products. Processed foods include 116 food commodity categories including meat and poultry products, food ingredients, consumer packaged products, produce, and alcoholic beverages. In aggregate by value, these products represent less than 10% of US imported food products.

Japanese food exports to the US total approximately $670 million. These exports fall primarily into 8 major Harmonized Tariff Schedule chapters, and are grouped according to USDA data:

Major Japanese Export Chapters by Value (2009)

HTS Code	Description	--$1,000s--	% of total
Chapter 3	Marine products	$191,441	29%
Chapter 21	Miscellaneous Edible Preparations	$102,981	15%
Chapter 35	Modified Starches and Enzymes	$77,702	12%
Chapter 19	Cereal, Starch, and Flour Preparations	$75,568	11%
Chapter 22	Beverages, Spirits, and Vinegar	$56,317	8%
Chapter 20	Vegetable, Fruit, or Nut Preparations	$43,885	7%
Chapter 15	Fats and Oils	$33,006	5%
Chapter 9	Coffee, Tea, and Spices	$20,400	3%
	Other chapters	$65,339	10%
Total		**$666,639**	**100%**

Major Japanese Exports -- Chapter Distribution by Value (2009)



Source: USDA. FAS, Global Agricultural Trade System

Japan competes with several major US exporters to the United States for a variety of products specified in the description above. Below are chapter level descriptions of Japanese product exports to the United States. Note that although Japan is not a substantial player in the overall US import market, Japan is a leader in a few select product classifications at the HTS-10 digit level. Incorporating specific notable product categories identified from USDA data as well as specific categories identified as products of interest by MAFF, the following group of chapter level descriptions aims to define the overall context of Japanese exports to the US, as well as the likely impacts of pending legislative proposals and regulatory developments in the United States. At the end of each product description, the product category is generally classified according to the product risk classification indicated by food outbreak and illness data in Section 2.2 of this report, as well as the risk-inspection schedule defined in Section 105 of the House of Representatives Resolution 2749, the Food Safety Enhancement Act.

Fish and shellfish products (HTS Ch. 3)

Marine products are Japan's largest export categories by value to the United States, accounting for more than $190 million or nearly 30% of total exports. As before the Act, fish and shellfish products have been subject to the FDA Seafood Hazard Analysis Critical Control Points Program, and risk prevention, intervention and response provisions for import. Fish and shellfish are under the regulatory oversight of the Food and Drug

Administration, and to a lesser degree the Department of Commerce, National Marine Fisheries Service. Fish and shellfish products are one of the highest reported food commodities associated with foodborne illness. Current regulations specify unique processing and handling requirements for specific varieties of fish. For example, imports of the highly poisonous torafugu (tiger puffer fish) are required to enter the United States through one importer, Wako International, which imports from licensed processing facilities in Japan to New York for FDA inspection and sampling, and then shipped to consumers. Other potential contaminants for fish and shell fish include bacterial and viral pathogens, chemicals or heavy metal residues.

Under the new bill, in a similar manner to the procedural and inspections regime for tiger puffer fish, a high-risk fish or shellfish product would require certification by food safety authorities in the country of origin, an export certificate by the exporter, and import certificate and registration by the importer, as well as enhanced inspection and laboratory sampling analysis by the FDA. The bill would also require that each step of the harvesting, processing, packing, handling, and shipping of fish and shellfish be subject to hazard analysis, prevention control, monitoring, corrective action, verification, tracing, and recordkeeping.

The use of carbon monoxide in packaging for seafood products, or other products – and area of interest to MAFF – is not addressed in either the House or Senate versions of the bill.

Category 1 food facility and inspection by the FDA foreign inspectorate every 6 to 12 months

Processed food products (including meat extract and/or eggs as ingredients, HTS Ch. 19 - 21)

Processed food products, Chapters 19, 20, and 21, are regulated under the authority of the Food and Drug Administration and are subject to regulations from the FDA, regardless of the content of meat extract or egg ingredients. This category is comprised of Consumer Packaged Products including various sauces, baked goods, blended teas, steamed fish-meat pastes, instant noodles, dried noodles, sports drinks, packaged milk tea, and candies. Combined, these products account for more than $222 million, or more than one-third, of Japanese food exports to the US.

According to the pathogen or contaminant risks for specific ingredients in a processed food product or the associated status of compliance of food facilities which manufacture, process, pack, or hold a particular product, FDA inspectors will assign an appropriate risk-based assessment of a food product and will consider import specification accordingly. In general as an overall group, processed food products are one of the leading food

commodity groups associated with foodborne illnesses and outbreaks, and accordingly are likely to be a food commodity group subject to additional scrutiny as a high risk food group.

The Senate version of the legislation specifies that the FDA may define separate requirements for compliance for the storage of packaged foods that are not exposed to the environment.

Category 1 food facility and inspection by the FDA foreign inspectorate every 6 to 12 months

Sauces (HTS Ch. 20 - 21)

Soy sauce, fish sauces, and other sauces (mixed condiments) are classified as a part of either as Chapter 20 or Chapter 21 products and are regulated under the authority of the FDA as processed food products. Chapter 20 and 21 exports account for nearly $150 million of food exports to the United States, or approximately 22% of total exports. Japan supplies US consumers with approximately $17.2 million (7%) of all imported sauce preparations; it is the third largest exporter by value.

Due to the large number of ingredients in sauces, it is likely that enhanced HACCP regulatory provisions apply to sauce manufacturing facilities. Sauces containing fish products may be considered higher risk products based on the historically higher incidence of contamination for fish and fish products, and may require specific preparation and handling procedures during manufacture, as well as specific laboratory sampling procedures and reporting to the FDA. Other sauces such as Tonkatsu sauce, which may include fruit and vegetable ingredients, may require enhanced hazard analysis and prevention control plans to accommodate traceability and emergency response requirements in the bill.

Category 1 food facility and inspection by the FDA foreign inspectorate every 6 to 12 months

Baked goods (HTS Ch. 19)

Baked goods are classified as a part of Chapter 19 products and are regulated under the authority of the Food and Drug Administration as processed food products. Chapter 19 exports account for nearly $76 million or 11% of Japanese food exports to the US. Japan ranks as the 5th largest exporter of sweet baked goods to the US, accounting for approximately $6 million in total landed goods.

Baked goods are not considered high-risk products and are not likely to require enhanced scrutiny. In the case of baked goods using dairy powder, enhanced hazard analysis and prevention control plans for traceability and emergency response may be required.

Teas (HTS Ch. 9)

Tea are classified as Chapter 9 exports, in addition to coffee and spices, and account for nearly $20.5 million or 3% of total Japanese exports to the US. Japan represents a relatively small share of the total US market for tea products by value with only $8.2 million in exports and ranking as the 11th highest exporter overall; however, among fermented green tea and green tea products, Japan ranks as the 1st and 2nd largest exporter to the US, respectively. Japan exports approximately $13.6 million in fermented green tea or, approximately $7.4 million in green tea in 2009.

All tea products, including minimally processed Japanese teas, such as green tea, are subject to FDA regulation. The USDA, APHIS, Plant Protection and Quarantine section, import manual on miscellaneous and processed products indicates that "solely green tea" products do not require APHIS import permits.[34] In the case of teas, which are either fermented or roasted, such as black teas, or roasted and blended with other ingredients such as rice and seaweed, such as genmaicha, the manufacturing process is more complex and is considered classified as a processed food product, which places them under the authority of the Food and Drug Administration

Teas may be considered moderate to high risk products given the potential adulteration of the plant-based product from chemicals used in the production of tea. Tea products may require enhanced hazard analysis and prevention control measures to accommodate traceability and emergency response requirements in the bill, as well as laboratory sampling procedures and reporting measures specific for tea products. imported tea products are also likely to subject to laboratory sampling test for traces of pesticide residue for FDA analysis, as well as EPA regulations.

Category 1 food facility and inspection by the FDA foreign inspectorate every 6 to 12 months

Vegetables, Fruits and Nuts (HTS Ch. 7-8)

Fresh produce products are classified as subject to regulatory oversight by the USDA, Animal and Plant Health Inspection Service. Chapter 7 and 8 exports of fresh vegetables, fruits, and nuts account for nearly $8 million of total Japanese exports to the US, or just

[34] "Miscellaneous and Processed Products, Import Manual," USDA, APHIS, Plant Protection and Quarantine, March 2010, Reference Table 3-317.

over 1% of the total by value. Japan is a high-value exporter of mushrooms to the United States, ranking 8th among the top US suppliers of mushroom products by value.

According to historical data, fruits and vegetables account for significant percentage of foodborne illness and outbreaks over recent years. In a sample period from 1998 to 2004, fruit and vegetables accounted for 7% of all foodborne illnesses trace back to a source, and 14% of foodborne illnesses overall. As a high-risk food product, fresh produce is likely to be subject to enhanced hazard analysis and prevention control measures, similar to those implemented in the Good Agricultural Practices and Good Marketing Practices established in the Leafy Greens Marketing Agreement, as well as laboratory sampling analysis and reporting to the FDA.

Category 1 food facility and inspection by the FDA foreign inspectorate every 6 to 12 months

Sesame oil (HTS Ch. 15)

Vegetable and animal fats and oils such as sesame oil are defined as Chapter 15 exports, and account for approximately $33 million in Japanese exports to the US, or 5% of the total export value. Japan is the US market's largest exporter of sesame oil, whether or not refined, accounting for nearly $25 million in landed goods.

Sesame oil is a processed food product, and is regulated under the authority of the Food and Drug Administration. Sesame oil is not a common source of foodborne pathogens and is considered a relatively low-risk food product. However, cross contamination from processing in a plant handling similar products may be subject to facility-specific food safety controls.

Category 1 food facility and inspection by the FDA foreign inspectorate every 6 to 12 months

Soft drinks (HTS Ch. 22)

Soft drinks are classified as Chapter 22 products in the Harmonized Tariff Schedule of the United States, and account for approximately $56 million, or 8% of total Japanese exports to the US. Under the bill, soft drinks are considered as processed food products and are subject to regulation by the Food and Drug Administration.

As a product with either few or numerous ingredients, soft drinks may be subject to varying degrees of scrutiny by FDA regulators. Whereas products from Coca Cola may be considered as "Generally Regarded as Safe" substances and with clean food safety

records, However, beverage products containing dairy products, such as milk tea, may be subject to more stringent risk profiling and subject to additional inspections criteria.

Category 1 food facility and inspection by the FDA foreign inspectorate every 6 to 12 months

Alcoholic beverages (HTS Ch. 22)

Alcoholic beverages are also classified under Chapter 22 export products. Alcoholic beverages are not regulated by either the FDA or the USDA, but instead the US Department of Treasury, Bureau of Alcohol, Tobacco, and Trade. Therefore, the jurisdiction of alcohol related products are not under the legislative authority of the FDA, and accordingly are exempt from the provisions of the legislation.

b) Other major food exporters of similar products to the United States

The following countries are major US export market competitors of product categories which are similar to the products described in the previous section, and are also potential policy allies for developing a coherent and unified foreign exporter position on policy developments in the United States Congress.

Even within HTS categories, products can be quite different (i.e., not direct substitutes). Nevertheless, if they are treated the same way by food safety regulations, then exporters of these products should have a common interest in influencing the regulations affecting these products. The table below shows other primary exporters in categories of importance to Japanese exporters.

Exporters to the US in key categories of interest to MAFF, ranked by value (those in top 5)

Product	Canada	Mexico	China	Germany	S. Korea	*Japan*
Sauces	1	2				*3*
Teas / Green teas	1	3	2	5		*4*
Soybean-based foods, miso products			1			*2*
Starches	1	3				*2*
Sesame oil		2	4			*1*
Pasta products	2	3	1			*5*
Other consumer packaged goods	1	2			4	*3*

Source: USDA, Foreign Agricultural Service, Global Agricultural Trade System

Note: The full presentation of export data is available in the Appendix

For the purpose of product-driven alliances, therefore, some of the key foreign exporters that should be considered are Canada, Mexico, China, Germany, and South Korea.

4.5 Legislation and US trade obligations

The overarching goal of the food safety legislation is to improve food safety in the US and strengthen the country's food safety laws. In addition, the provisions for the most part apply equally to both domestic and international suppliers to the market. Nevertheless, there is concern, particularly on the part of other exporters – but also within the USTR and certain legislative circles – that some of the provisions in the proposed laws may not be consistent/compliant with the US obligations under the WTO Agreement of Sanitary and Phytosanitary Measures.

The primary issues raised in interviews, when related to the WTO SPS agreements, were the issues of registration fees and equivalence.

Registration fees. The primary issue here relates to the following passage in the WTO SPS agreement:

> "(f) any fees imposed for the procedures on imported products are equitable in relation to any fees charged on like domestic products or products originating in any other Member and should be no higher than the actual cost of the service;"
>
> - WTO SPS Agreement, Annex C(1.)(f)

Several exporters commented that the registration fees are not related to any corresponding service (they don't even relate to actual shipments/exports – and thus they are not consistent with WTO requirements.

Equivalence. This was the other item cited repeatedly by foreign exporters; it relates to the following article in the SPS agreement:

> *Article 4*
> *Equivalence*
>
> *1. Members shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection. For this*

> *purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.*
>
> *2. Members shall, upon request, enter into consultations with the aim of achieving bilateral and multilateral agreements on recognition of the equivalence of specified sanitary or phytosanitary measures.*

The Senate bill originally had "equivalence" in its language, but US legislators and regulators removed it, ostensibly because it would **require** the FDA to elaborately review food safety systems across the globe in order to pronounce them "equivalent." As several interviewees described to us, the US interprets equivalence to mean *equivalence of process*, whereas most other nations consider equivalence to mean *equivalence of outcomes*. The language, therefore, was changed to read "meets or exceeds" US safety standards, which more clearly implies equivalent outcomes.

Furthermore, under the provisions in Section 105, Standards for Produce Safety of the Senate Food Safety Modernization Act, the FDA is directed to develop a variance request process for states or foreign countries from which food is imported and is subject to local growing conditions, procedures, practices, and processes that satisfactorily meet the requirements in the Food, Drug, and Cosmetics Act as amended in the current legislation.

Given the variance language in the legislation with respect to produce, it is reasonable to assume that future FDA rules for other high risk products may consider the equivalency in outcomes for alternative procedures, practices, and practices defined by foreign government inspection services. For example, FDA rules have adopted variances for irradiation and other processes are currently used to ensure food safety for spices, produce, and a variety of other imported products. Similar processes may be defined in the FDA rulemaking process or during the conference negotiations of the legislation.

SECTION 5: PERSPECTIVES ON THE LEGISLATION

In this section, we share findings the views of:

- Foreign food exporters
- The FDA
- Others:
  - Consumer groups
  - Congressional observers and lobbyists
  - Food processors and importers

5.1 Perspective: Foreign exporters

These foreign exporter perspectives come exclusively from personal interviews, primarily with Agricultural Counselors of embassies in Washington, DC. Many of these diplomats have been working as a group, to better understand and track the legislation and influence the legislative process.

Here we offer both the broad perspective of this group on important shared themes, as well as specific issues as they relate to the legislation. There are many areas of agreement, but some differences as well, particularly with regard to issue priority. Here, we summarize the views; in the Appendices, we provide more detail on each exporting country's priority issues and other thoughts.

The larger US trade partners (e.g., Canada, Mexico) are following the legislation very closely and have a well-defined list of issues they are working to address. Smaller trading partners are less active, not quite as involved, and tracking developments more loosely.

5.1.1 Broad perspectives

Overall, there is support in the international community for the US to upgrade its food safety laws. Each country, however, is concerned with the actual rules that will be put in place and their potential impact on trade. Common concerns include:

- That the legislation provide equal treatment (nondiscriminatory principle)
- Avoiding unnecessary duplication in the name of food safety; e.g., certification and inspection requirements
- Avoiding trade disruption

The primary issues raised by foreign exporters are listed here.

5.1.2 Issue #1: Registration fees

We found a range of reactions to registration fees, from "we don't like it but can live with it," to "we expect others to fight our fight for us," to those that feel that the registration fees are a blunt instrument, possibly in violation of the US WTO commitments.

The primary objections to the fee are

- There are no identifiable services provided in return for the fee (i.e., payment is demanded where no service is provided), and therefore may not be in compliance with the WTO Sanitary/Phytosanitary agreement:
  - Fee appears to simply go into a general fund, unmatched to any expense.
  - Registration fees are required simply to enable the *opportunity* to ship to the US, even if no shipments are ever sent
- It disproportionately hits small companies and/or those with multiple facilities

5.1.3 Issue #2: Certification

For most exporters, given that they already have certification systems for riskier food categories, the certification requirements were not seen as a problem. They appear ready and able to adapt to reasonable food safety-based requirements.

There are issues, however, concerning recognition of other countries' existing food safety systems. Where possible, other countries would prefer that the FDA deal directly with governmental authorities, rather than dealing directly with individual companies, as has been the FDA's behavior. Moreover, there is concern about non-governmental 3rd parties being responsible for accreditation of auditors/agents – particularly when those auditors are part of a sovereign government (the legislation as written can be read as allowing independent, commercial 3rd parties being responsible for approving other governments' accreditation systems).

As of the writing of this report, there was an indication that some significant changes were being made to the certification provisions/language in the Senate bill, changes that would suit the perspective of exporters.

5.1.4 Issue #3: Equivalence

Countries also want the FDA to recognize their own equivalent systems (based on food safety outcomes), where possible. They "are comfortable with the language of equivalence," the language used in the WTO Sanitary / Phytosanitary (SPS) agreements. Congress, however, has favored using the language "meets or exceeds" US safety standards (changing it from "equivalence" in the Senate bill).

The rationale given for the change is that "equivalence" is a technical term that requires an extensive process of comparing systems – which many fear will be impossible for the FDA to complete in a timely fashion.

5.1.5 Issue #4: Inspections

Exporters expressed concern regarding the inspection frequency/timetable required in the legislation, as well as the potential for unnecessary duplication. In addition, there was concern about "unreasonable" requirements that US-based importers inspect their suppliers (in the Foreign Supplier Verification Program).

5.1.6 Issue #5: Traceability

Codex Alimentarius only requires "1 up / 1 down." Full traceability was cited several times as being a problem / unrealistic.

5.1.7 Issue #6: Food defense

This was raised as an issue several times. Food defense focuses on reducing intentional adulteration of food. Interviewees said it "has nothing to do with food safety," that the mentality and concerns overseas were different than they are in the US, and they were concerned with the costs of compliance with food defense provisions.

5.1.8 Issue #7: Country of origin labeling (COOL)

Exporters are not happy with the House bill's COOL provision, but generally acknowledged that consumer-ready products already have to meet Consumer and Border Protection (CBP) requirements.

5.1.9 Issue #8: Voluntary importer programs

Exporters appreciated the provisions allowing for expedited trade. However, they also expressed concern that these programs will become essential to remain competitive.

5.2 Perspective: FDA

The FDA has taken the position that it will not comment on implementation of the rules until the legislation is signed into law by the President. However, the FDA Commissioner, Dr. Margaret Hamburg, provided official statements regarding each of the two bills, indicating how, from the FDA's perspective, the bills fall short or could be improved.

Overall, the FDA was strongly supportive of the House bill, but indicated that the Senate bill should be strengthened to more closely resemble the House bill.

5.2.1 FDA perspective on the House bill (HR 2749)

The FDA expressed strong support for the House bill and its provisions, with the exception of Section 105, regarding inspections. The FDA asked for three additional items:

- modification of provisions to take into account the "operational challenges involved"
- the flexibility to modify the inspection requirements based on the best available data on risk
- that it allow the FDA to authorize certification by accredited third parties, especially overseas.

5.2.2 FDA perspective on the Senate bill (S 510)

Beyond general support for the bill and most of its provisions, the FDA's feedback on the Senate bill fell into two categories: not enough authority, and not enough funding or flexibility for inspections:

Not enough authority:

- **Records access** - Does not provide FDA with explicit authority to access food records during routine inspections, but should
- **Information sharing** - The FDA wants explicit authority to provide federal agencies, state and local government agencies, foreign government agencies, and certain international organizations both confidential commercial and trade secret information relating to food with provision to ensure its confidentiality, consistent with international obligations.
- **Stronger enforcement mechanisms**
    - related to the implementation of hazard analysis, risk-based controls - Section 103 outlines requirements for hazard analysis and implementing risk-based controls... effectiveness of this provision would be greatly strengthened if it deemed food that is in violation of this section as "adulterated" (creation of a prohibited act - currently in the bill - would support an injunction but would not provide a legal basis for a seizure, administrative detention, or refusal of admission of imported food from a facility that is not in compliance with the requirements).
    - Similarly, stronger enforcement mechanisms related to fresh produce (Section 105)
    - Traceback and record keeping (Section 204) provides no enforcement mechanism, but should

Not enough funding or flexibility for inspections:

- "...we are concerned that the bill does not provide a guaranteed consistent funding source to help FDA fulfill its new responsibilities.
- The Administration supports inclusion of a registration fee...which could be used, in part to fund this inspection mandate.
- We also suggest [giving the] FDA flexibility to adjust the inspection frequencies.
- [We suggest] adding language to authorize FDA to use accredited third parties, such as foreign regulatory agencies, to meet the inspection frequency for foreign facilities.
- "We note that the current inspection mandate in the bill will far outstrip our current resources.

> "We think we can achieve cost-effective oversight of imports by working with foreign governments, using the bill's new tools for import oversight, supporting a strong accredited third-party inspection program, and increasing targeted, risk-based foreign inspections, consistent with the United States' international trade obligations."
> - FDA Commissioner Hamburg, 22 Oct 2009

5.3 Perspectives: Others

Based on our interviews and research, we also uncovered the following issues relevant to the legislation.

5.3.1 Consumer groups

Consumer groups are a major force driving the food safety legislation through Congress. Broadly speaking, they are in favor of the creation of substantial new regulations to make the food supply safer, and in favor of allotting the funding needed to enforce the regulations.

> "The House bill was a big breakthrough. A big breakthrough. It has a lot of really important things in it. The mandatory inspection frequency is, for us, the absolute centerpiece of this. Requiring high-risk facilities to be inspected once a year...that just has to happen, we can't have this once-every-ten-years set up that we have now, or we will just keep getting Peanut Corporation of America repeats."
> - Jean Halloran, Consumer Policy Institute

Several interviewees expressed a preference for the House bill over the Senate bill, but indicated that both are "much better than what we have." Their primary objective is to bring the bill to a vote in the Senate, and move from there. They mentioned a number of countries which they felt already have stronger safety

legislation in place, i.e., New Zealand, Japan, a lot (but not all) of EU countries, and Canada.

Consumer groups expressed a strong **preference for government involvement** rather than delegation to third party organizations, whether commercial or not.

Domestically, this reflects a preference for government certification/inspections, and internationally, that dealings be government-to-government (this "should be a basic principle," we were told), rather than having the FDA delegate responsibilities to private 3rd party accreditation bodies (to accredit agencies and auditors), or deal directly with companies overseas.

Another issue high on the agenda for domestic groups is **funding for the FDA**. They are very supportive of anything increasing/guaranteeing funding for the FDA to fulfill its missions. Hence, they are supportive of the facility registration fees in the House, to be used for "food safety activities."

Consumer groups acknowledged that many of the most important details will surface in the rulemaking.

5.3.2 Food processors / importers

One large multinational food company we contacted provided us with some very specific comments, collated by three multi-billion dollar food multinational companies, based on their detailed analysis of the legislation. We include their detailed comments here.

Their comments fall into three basic issues:

- The legislation calls for overlapping / duplicative requirements
- The legislation is unclear in places and potentially unreasonably burdensome
- The legislation adds significant burdens on importers without providing any measurable easing of the trade process

1. The legislative proposals do not build off the existing importer identification, liability, security, and penalty regimes that are in place under DHS/Customs and Border Protection (CBP) rules. The legislative
proposals create confusing, duplicative and sometimes conflicting requirements which burden legitimate importers without enhancing food safety. For example, concordance between FDA and CBP practice for
importer identification. Both should use same system for identifying the Importer of Record (IOR) which is EIN +2 (to distinguish business units under the same legal entity). This is

particularly important if the risk profile of a product is to be based on "the history of food recalls, outbreaks, and violations of food safety standards of the food importer."

2. Proposals need to avoid the imposition of requirements on importers that cannot realistically be delivered. For example, each US importer is to perform risk based foreign supplier verification. Failure to maintain such a program is a prohibited act. The legislation is silent on the standard against which the foreign supplier is to be measured. Is this simply a verification of exporters' status such as the current FDA registration requirement or is this a requirement to hire a third party to inspect foreign facilities? If this requirement is to be left open for future rule making then some form of consultation with importers, prior to Federal Register notice, is necessary to ensure unrealistic demands are not imposed. United States trade obligations could also be in the equation.

Importers of food products are already responsible for complying with FDA regulations, including providing facility registration and other PN information. Requirements are enforced through customs bonds and both Customs and FDA can issue penalties and liquidated damages if there is an error.

Within GMA more than 60% of the companies responding to a survey last year report importing raw materials for use in food production. Legislative focus needs to be on facilitating the import process not just layering on more regulations and procedures.

3. Importer registration requirement is redundant with existing CBP registration requirements. CBP has a robust importer registration program backed by an established bond process.

4. The penalty regimes appear to focus sole responsibility on the importer of record if there is an in-market problem. FDA is authorized to impose up to $20 million in fees on the importer of record to recover the cost of recall activities, technical assistance, follow up checks, public notifications etc.

5. FDA and USDA already have a system of import certification for food products that may present a risk. Dairy, meat, and canned goods are examples. Products cannot enter the country without this certificate. Usually within the existing system, an original certificate is required which adds cost and delay. A constructive legislative step would be to fund electronic certification at FDA and USDA instead of continuing with paper certificates.

6. Penalty provisions are severe for what can often be a simple clerical error that is easily corrected. Once again, the goal should be trade facilitation rather than a layering of regulations that unnecessarily burden legitimate importers.

7. The legislation currently requires that even prospective suppliers be certified. We often import samples of raw materials and finished products to see if they work in our systems or to do quality evaluation. Having to validate suppliers you may not use is a tremendous burden. Regarding the time and cost of getting a supplier 'vendor assured:' An audit day takes approximately 8 hours to complete. An audit trip is generally three days. That said, there is the VA time that is spent coordinating the audit with the supplier which can eat up approximately an additional 4 hours, so in total, about 28 to 30 hours for each audit when planned individually. As for cost to review each new supplier, a rough approximation is around $3500 U.S. for the three day audit trip, not including time from all the parts of the business that are involved in evaluating new suppliers.

5.3.3 Other observers / lobbyists

As part of our research, we interviewed lobbyists, reporters, and food safety specialists, and got their perspectives as well. We highlight key findings and thoughts from these interviews here.

- **Traceability:** Though the technology for full traceability exists today, the costs of compliance make it unrealistic. We are many years away from having reasonable domestic traceability, let alone full traceability which would require a global system.
- **Devil will be in the details**: The rulemaking process will determine many of the true outcomes of the legislation.
- **Watering down the House bill:** Consumer group desires notwithstanding, observers expect reality to prevail: for the House bill provisions to be weakened, rather than the have the Senate bill strengthened.
- **Funding:** Funding is already a challenge for the FDA; how much of the legislation gets implemented will depend on how much funding gets allocated.
- **Timing:** Generally, observers expect the legislation to pass this year, but point out that regulations on many of these food safety issues are moving forward regardless of passage.

SECTION 6: OUTLOOK FOR THE LEGISLATION

In this section, we provide an update on the status of the food safety legislation, describe the forces influencing the process, and provide a prognosis.

6.1 Food safety bills – Status summary

At the time of this writing, the Senate bill was expected to be considered (and approved) by the full Senate in the near future, after which point it would be reconciled in conference with the House bill. The following table summarizes details on each of the two bills.

House bill HR 2749	Senate bill S 510
• Introduced June 8, 2009 • Reported by Committee on Energy and Commerce, June 17, 2009 • Amendments • Passed House of Representatives on July 30, 2009 (283-142)	• Introduced March 3, 2009 • Reported by Senate Committee on Health, Education, Labor, and Pensions, November 18, 2009 • Placed on Senate Calendar December 18, 2009

6.2 Factors influencing the legislative process

Here we outline the primary factors, both interest groups and other forces, influencing this process.

6.2.1 Legislature / Politicians

The House bill was approved in a 283-142, modestly bipartisan vote (9 out of every 10 Democrats and 3 of 10 Republicans voting for the bill). The Senate bill is more bipartisan with a roughly even split in Democratic/Republican co-sponsors. A complete list of bill co-sponsors is provided in the following table.

Food safety legislation – Sponsors

House bill HR 2749	Senate bill S 510	
Diana DeGette [D-CO1]	Jeff Bingaman [D-NM]	Lamar Alexander [R-TN]
Frank Pallone [D-NJ6]	Roland Burris [D-IL]	Richard Burr [R-NC]
Bart Stupak [D-MI1]	Christopher Dodd [D-CT]	Saxby Chambliss [R-GA]
Betty Sutton [D-OH13]	Kirsten Gillibrand [D-NY]	Michael Enzi [R-WY]
Henry Waxman [D-CA30]	Thomas Harkin [D-IA]	Judd Gregg [R-NH]
	Edward Kennedy [D-MA] †	Orrin Hatch [R-UT]
	Amy Klobuchar [D-MN]	John Isakson [R-GA]
	Tom Udall [D-NM]	

† Senator Kennedy died in late 2009

In the course of our research and interviews, the following were identified as key individuals to watch, regarding the legislation:

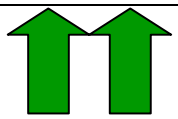
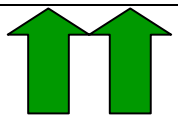
- Senator Tom Harkin (Senate HELP Committee Chair); he was recently quoted as saying that the goal was to get the bill on the President's desk by late May;
- Senators Enzi and Burr, key Republican co-sponsors who may introduce amendments of their own (and receive priority consideration) when the legislation is considered by the full Senate;
- Senator Richard Durbin (D-IL), a long-time proponent of food safety legislation;
- Senator Harry Reid (D-NV), the Senate majority leader who has been under political pressure;
- Senator Sherrod Brown [D-OH], who last year introduced a bill on traceability / recall authority, may introduce amendments to strengthen the bills provisions; and
- Senator Debbie Stabenow [D-MI], who might introduce an amendment favoring small producers.

Other "actors" of interest indicated in interviews were the Grocery Manufacturers Association and consumer and victim's groups.

6.2.2 Interest groups – summary

In Section 5 we presented detailed perspectives from a number of groups following the food safety legislative process. Most groups are in favor of passage, for various reasons. In the table below, we summarize the position of these and other groups, with regard to the legislation.

Interest group support for food safety legislation

Interest group	Support level	Summary
Consumer groups		Very active support; in favor of tight food safety regulations, with real enforcement power and penalties; want to strengthen Senate bill
Industry groups		Very supportive, given high cost of recalls
Agencies (FDA)		Pushing for stronger enforcement power and funding; want to strengthen Senate bill but weaken inspection timetables
Legislators		The legislation provides some/many with political capital; some, however, may oppose legislation due to special interests and/or cost
Foreign exporters		Generally In favor of the improvements, but have numerous concerns
Small producers		Concerned with cost of compliance, regressive fees, and overall, the adverse impact on their ability to compete

6.2.3 Potential obstacles and complications

Despite the strong coalition supporting food legislation, there are a number of issues which might contribute to preventing passage of the legislation this year.

Committee leadership changes. Political leadership in both the House and Senate committees which originated the legislation has changed in recent months. In August 2009, Senate HELP Committee Chair Edward Kennedy (D-MA) died due to complications related to cancer. His absence opened the Chairmanship to former Senate Agriculture Committee Chair, Tom Harkin (D-IA). Separately, the primary sponsor of the House version of the bill, Rep. John Dingell (D-MI), lost his 28-year chairmanship of the House Committee of Energy and Commerce to Rep. Henry Waxman (D-CA) in November 2009. Rep. Waxman, an ally of House Speaker Nancy Pelosi (D-CA), was one of the original co-sponsors of the House bill. With the changes in Chairmanship of the committees of origin for HR 2749 and S 510, it is possible that the successors may promote (their own) divergent agenda, and drop elements from previous legislative proposals defined by their predecessors, either on the Senate floor or in conference.

Time, the enemy. With the passage of time, the likelihood that the Senate bill will pass necessarily diminishes. Other legislative priorities such as health care and finance reform may continue to squeeze food safety from the agenda. Also, given that it is an election year, the 1/3 of Senators who must run for re-election may also be reluctant to push new legislation as fall approaches. (Though all representatives in the House must run for re-election, the House bill already passed.)

Loss of Democrat supermajority. Following the election of Republican Senator Scott Brown (MA) in early January, the Democratic Party lost a 60-seat super-majority in the 100-seat Senate. The loss of this supermajority, given the current partisan climate, makes it more challenging for Democrats to push their legislative agenda, and has weakened the Democratic Party leadership, bringing the passage of several other key pieces of legislation into question.

Budget considerations. Funding will have an enormous impact on what the FDA will be able to accomplish. With the US economy apparently stabilized, there have been renewed calls for fiscal discipline from many quarters – pressure to reign in the federal deficit. This could limit the expansion of federal programs generally, and the prospects for food safety legislation specifically.

The registry and inspection programs defined in the legislation would substantially expand the size of FDA. They would require substantial budgetary increases to accommodate the number of qualified inspectors and certification agents necessary to achieve the level of food safety called for in the legislation.

Although the House bill charges a $500 annual registration fee and is estimated to generate $200 million in funding, the operating budget to fund expansive increases in inspection capacity is likely to substantially exceed that amount. The Congressional Budget Office (CBO), estimated that implementing the House version of the bill would cost $2 billion over five years ($400m/year) subject to appropriations. The unfunded mandate portion of the bill would cost private entities $139 million annually starting in 2010.

6.3 Prognosis

Senator Tom Harkin (D-IA) said food safety legislation could reach the Senate floor around Easter and be "on the president's desk by May."
– "A Jumpstart for the Food Safety Bill, *Wall Street Journal*, 3 March 2010.

Prospects for passage of food safety legislation this year are good. Food safety continues to occupy headlines, with several large recalls in the past several weeks and months; several lawmakers continue to call for passage of the legislation. In addition, there is a broad coalition of interest groups, all backing passage.

Implementation would take a long time. The bills themselves specify fairly long timelines for the FDA to accomplish its tasks – timelines typically measured in years. FDA must go through proposing rules, factoring in feedback, making final rules and allowing time for their implementation. It would have to build and train a foreign inspectorate. And funds will have to be specified and allocated.

The core needs addressed in the bill – providing the FDA with additional food safety mandates and expanded authority to create and enforce regulations – will not go away if the legislation is not approved during this session of Congress. In the event it fails to pass this year, it is very likely that legislation would be reintroduced in future sessions, rather than abandoned.

"In short, we don't know what will emerge, but suspect it will look a lot like the Senate bill. Challenges will be more FDA inspections, compliance re: recordkeeping, traceability, ensuring adequacy of food safety systems. When will be determined by the bill requirements, but in general we expect FDA to conduct rulemakings for regulations that will take effect 1 to 3 years after enactment...we're anxiously awaiting the completion of the process so we'll know better ourselves."

– Congressional Relations Director, multinational food company

Moreover, progress on food safety regulations will continue, regardless of what happens with the legislation, albeit at a slower pace. The primary effects of passage would be to accelerate change and provide authority to the FDA and a likely increase in regulations and enforcement over the next several years.

SECTION 7: CONCLUSIONS

In this section, we provide conclusions from our research.

7.1 Conclusions

We have divided conclusions into our broad findings, along with specific conclusions for companies involved in the food trade.

7.1.1 Broad conclusions

- **This legislation has a strong chance of passing**. There is broad support for the passage of this legislation. The FDA, consumer and industry groups, and both political parties all support for it. Congressional deadlock and inertia are the strongest obstacles, but will likely be overcome this year, possibly by mid-year.
- **Changes will happen regardless of legislative outcome; passage will accelerate the process**. The primary consequences of the legislation will be to bolster FDA's authority and possibly provide more and more secure funding for food safety activities. In practice, many items called for by the legislation are already underway, albeit slowly. With passage of the legislation, change will accelerate, but even if it is not passed, change will continue.
- **A lot of changes will be incremental**, building on existing/current initiatives (see previous conclusion).
- **Many important details will be decided later**, in the years following passage of the law; implementation will take years. Although they have broad requirements, both food safety bills leave many of the details to FDA in rulemaking. The process of rulemaking and implementation will take years.
- **Funding will have a strong impact** on exactly how much regulators will be able to ask for and manage. The legislation will only be as successful as the funding allocated for the FDA to follow through on its provisions.
- **Legislation is unlikely to significantly affect Japanese food exporters**. Japan already has a sophisticated food safety system; consequently, very little of FDA's international food safety activity has involved Japan or its exports. This is unlikely to change after the law passes, as FDA will necessarily have to tailor its resources to managing higher-risk sources of food. However, companies must still meet compliance requirements (e.g. registration, inspections) and importers may require proof of compliance / additional documentation.

7.1.2 Conclusions for the food trade

Likely changes

Based on our research, the following changes are likely:

- **Hazard analysis and prevention control plans will be required** for all food handling facilities – This is a common provision in both bills, and a key component of a preventive food safety system. Sooner or later, it will be required throughout the food chain.
- **Importers will be held more accountable** for their suppliers – Given the FDA's limited international reach, both bills seek to make importers more accountable for the products they introduce into the US food supply. Exactly how burdensome new requirements will be remains to be seen.
- **Inspections will increase in frequency** based on risk. Increased inspections are a centerpiece of the House bill and are a key requirement from consumer groups.
- **The cost of food safety compliance will increase**. It is safe to say that if the legislation is enacted, compliance with the new rules will add costs to food trade.
- **Civil and criminal penalties for food safety violations will be enacted/increase** – penalties for unwitting and intentional food safety violations are extremely limited today. If anything like the House provisions are enacted, consequences for such violations will increase substantially.
- **Risk-based testing** will continue to be refined. The new PREDICT system appears to be an incremental improvement over OASIS. Expect algorithms to continue to be improved over time, allowing inspections to focus on the highest-risk shipments.
- **Product specific inspections procedures will be developed**. The FDA will be tasked with continuing to expand and improve inspections procedures.

Possible changes

The following developments are possible:

- **Food defense plans**: These are seen as an important element ensuring bi-partisan support for the legislation, and may well be required in the near future, should the legislation pass. In deference to the potential burden of this requirement, however, the required plans may be relatively modest.
- **Import certificates and/or fees may expand**: The number of food categories (and possibly countries) subject to certification requirements may increase.
- **Electronic recordkeeping will be required**. Either piecemeal or in substantial moves, data gathering and reporting will shift to electronic formats. How quickly

will be a function of legislation and the resources devoted to supporting compliance.

- **Participation in voluntary importer programs may become necessary** to remain competitive. As these programs create opportunities for expedited shipping, they may ultimately become a pre-requisite for effectively competing in the US food market.
- **Mandatory reporting of all laboratory results** - Companies heretofore have had the luxury of resubmitting samples and "gaming the system" by shopping around for favorable results and sending authorities only the best results. These possibilities may be eliminated, requiring that ALL laboratory results be reported, regardless of outcome.
- **Partial traceability**: implementation and enforcement. Traceability may be put in place, either "1 up / 1 down" across the board, and/or fully in select distribution chains.

Unlikely

- **Full traceability** – It is unlikely that the resources will be available for full traceability in the foreseeable future, regardless of what legislation may say. Moreover, the more stringent House version (full traceability) is inconsistent with WTO's "1 up / 1 down" traceability agreement.

APPENDICES

In this section, we include items which may serve as useful references, including:

- A table of contents for the House bill (HR 2749)
- A table of contents for the Senate bill (S 510)
- Diagrams describing the current procedures for FDA-regulated food imports
- Exporter perspectives
- A list of sources / resources

A1. House bill (HR 2749): "Food Safety Enhancement Act of 2009" – Contents

AN ACT
To amend the Federal Food, Drug, and Cosmetic Act to improve the safety of food in the global market, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.
This Act may be cited as the 'Food Safety Enhancement Act of 2009'.

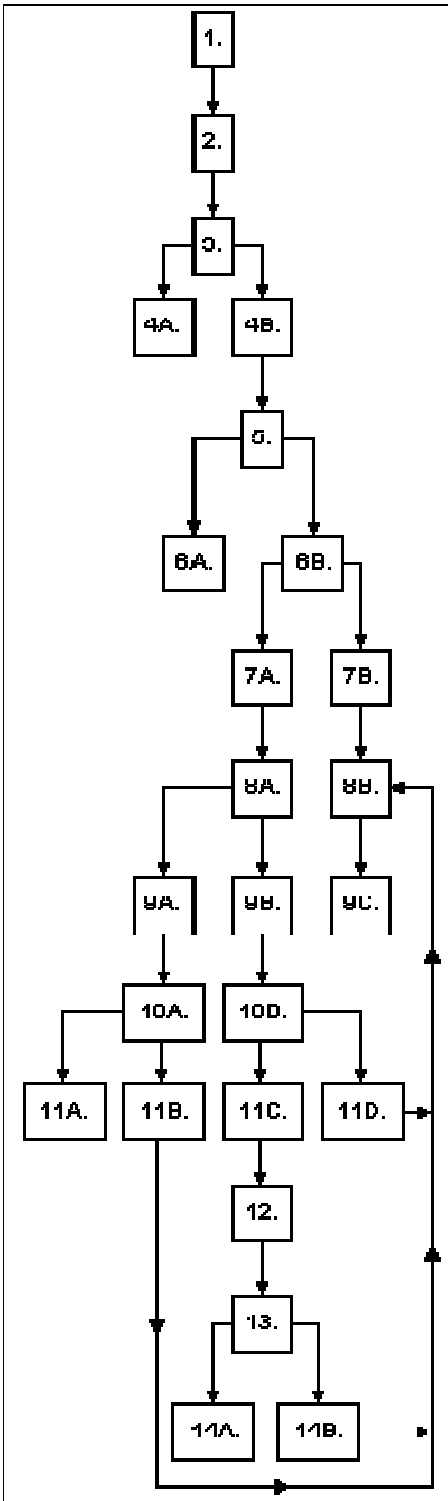
SEC. 2. TABLE OF CONTENTS.
The table of contents of this Act is as follows:

A2. Senate bill (S 510): "Food Safety Modernization Act" – Contents

SECTION 1. SHORT TITLE; REFERENCES; TABLE OF CONTENTS.
(a) SHORT TITLE.—This Act may be cited as the ''FDA Food Safety Modernization Act''.
(b) REFERENCES.—Except as otherwise specified, whenever in this Act an amendment is expressed in terms of an amendment to a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act (2110 U.S.C. 301 et seq.).
(c) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

A3. Import flow charts

FDA Import process



1. Importer or agent files entry documents with U.S. Customs Service within five working days of the date of arrival of a shipment at a port of entry.

2. FDA is notified of an entry of a regulated food through:

   - Duplicate copies of Customs Entry Documents (CF 3461, CF 3461 ALT, CF 7501 or alternative),
   - Copy of commercial invoice, and,
   - Surety to cover potential duties, taxes and penalties.

3. FDA reviews Importer's Entry Documents to determine if a physical examination, wharf examination, sample examination should be made.

4A. Decision is made not to collect a sample. FDA sends a "May Proceed Notice" to U.S. Customs and the importer of record. The shipment is released as far as FDA is concerned.

4B. Decision is made to collect a sample based on:

   - Nature of the product,
   - FDA priorities, and,
   - Past history of the commodity.

   FDA sends a "Notice of Sampling" to U.S. Customs and the importer of record. The shipment must be held intact pending further notice. A sample will be collected from the shipment. The importer of record may move the shipment from the dock to another port or warehouse (contact U.S. Customs for details).

5. FDA obtains a physical sample. The sample is sent to an FDA District Laboratory for analysis.

6A. FDA analysis finds the sample to be in compliance with requirements. FDA sends a Release Notice to U.S. Customs and the importer of record.

6B. FDA analysis determines that the sample "appears to be in violation of the FD&C Act and other related

	Acts." FDA sends U.S. Customs and the importer of record a Notice of Detention and Hearing which: • Specifies the nature of the violation, and, • Gives the importer of record 10 working days to introduce testimony as to the admissibility of the shipment. The hearing is the importer's only opportunity to present a defense of the importation and/or to present evidence as to how the shipment may be made eligible for entry.
	7A. Consignee, true owner, importer of record, or a designated representative responds to the Notice of Detention and Hearing. The response permits the introduction of testimony, either orally or written, as to the admissibility of the shipment.
	7B. Consignee, true owner, importer of record, or a designated representative neither responds to the Notice of Detention and Hearing nor requests an extension of the hearing period.
	8A. FDA conducts a hearing concerning the admissibility of the product. The hearing is an opportunity to present relevant matters and is confined to the submission of pertinent evidence.
	8B. FDA issues a Notice of Refusal of Admission to the importer of record. This is the same person or firm who was sent a Notice of Sampling. All recipients of the Notice of Sampling and the Notice of Detention and Hearing are sent a copy of the Notice of Refusal.
	9A. Importer of record presents evidence indicating that the product is in compliance. Certified analytical results of samples, examined by a reliable laboratory and which are within the published guidelines for levels of contaminants and defects in food for human use, may be presented.
	9B. Importer of record submits an Application for Authorization to Recondition or to Perform Other Action (FDA Form FD 766). The form requests

	permission to try to bring a food that is adulterated or misbranded into compliance by relabeling or other action, or by converting to a non-food use. A detailed method to bring the food into compliance must be given. 9C. FDA receives verification of the exportation or destruction of the shipment from U.S. Customs. The exportation or destruction of the merchandise listed on the Notice of Refusal of Admission is carried out under the direction of U.S. Customs. 10A. FDA collects follow-up sample to determine compliance with guidelines. 10B. FDA evaluates the reconditioning procedure proposed by the importer. A bond is required for payment of liquidated damages. 11A. FDA finds that the sample is "in compliance." A Release Notice with the statement "Originally Detained and Now Released" is sent to U.S. Customs and the importer. 11B. FDA finds that the sample is not in compliance. The importer may either submit an Application for Authorization to Recondition or to Perform Other Action (see 9B), or, FDA will issue a Notice of Refusal of Admission (see 8B). 11C. FDA approves importer's reconditioning procedures. The approved application contains the statement "Merchandise Should Be Held Intact Pending the Receipt of FDA's Release Notice." 11D. FDA disapproves applicant's reconditioning procedure if past experience shows that the proposed method will not succeed. A second and final request will not be considered unless it contains meaningful changes in the reconditioning operation to ensure a reasonable chance of success. The applicant is informed on FDA Form FD 766. 12. Importer completes all reconditioning procedures and

	advises FDA that the goods are ready for inspection/sample collection. 13. FDA conducts follow-up inspection/sample collection to determine compliance with the terms of the reconditioning authorization. 14A. FDA analysis finds that the sample is in compliance. A Release Notice is sent to the importer and to U.S. Customs. The charges for FDA supervision are assessed on FDA Form FD 790. Copies are sent to U.S. Customs which is responsible for obtaining total payment including any expenses incurred by their personnel. 14B. FDA analysis finds that the sample is still not in compliance. Charges for FDA supervision are assessed on FDA Form FD 790. Copies are sent to U.S. Customs which is responsible for obtaining total payment including expenses incurred by their personnel.

Source: A multinational food company

A4. FDA overseas inspections data

The following table lists the number of FDA-conducted overseas inspections, by country, during the period 2001-2008. The FDA typically conducts 100-200 inspections per year. Only two of the inspections conducted during this 8-year period were in Japan.

FDA: International Food Firm Inspections, 2001-2008

	2001	2002	2003	2004	2005	2006	2007	2008	Total
Mexico	17	15	8	15	7	16	26	29	133
Ecuador	8	0	11	24	0	11	10	0	64
Thailand	4	10	0	10	0	22	0	12	58
Chile	13	0	15	6	7	11	0	5	57
Peru	13	0	0	18	1	9	9	4	54
Brazil	0	12	6	7	21	0	0	7	53
China	0	9	2	6	16	0	0	13	46
Taiwan	9	7	0	9	0	7	0	7	39
Canada	13	0	13	1	0	7	4	0	38
Costa Rica	0	11	0	4	5	7	0	7	34
Honduras	9	8	0	0	7	0	0	8	32
Vietnam	0	9	0	10	8	0	0	4	31
Argentina	7	5	0	0	0	0	19	0	31
India	6	0	10	0	7	7	0	0	30
South Korea	14	0	0	1	7	0	6	0	28
Australia	12	0	6	0	0	9	0	0	27
Jamaica	2	6	0	3	0	3	0	8	22
Fiji	0	0	8	0	0	0	13	0	21
Guatemala	0	10	0	0	6	0	0	5	21
Singapore	10	0	0	8	0	0	0	3	21
Nicaragua	0	8	0	0	0	7	0	4	19
El Salvador	0	0	8	0	6	0	0	4	18
Germany	5	4	4	0	0	1	1	2	17
Estonia	8	0	0	8	0	0	0	0	16
Panama	0	0	7	0	0	0	0	9	16
South Africa	5	0	11	0	0	0	0	0	16
Malaysia	0	0	0	0	9	0	0	6	15
Countries with FDA inspections	26	22	22	20	16	15	11	24	56
Total inspections	**211**	**169**	**148**	**153**	**132**	**125**	**95**	**153**	**1,186**
28 additional countries									

Source: GAO

A5. Sources/Resources

Agencies and organizations involved in food safety issues, as well as other food safety resources.

A5.1. By organization

Consumer organizations

Center for Science in the Public Interest
http://www.cspinet.org/

Consumer Federation of America
http://www.consumerfed.org/

Pew Trusts – Food Safety
http://www.pewtrusts.org/our_work_detail.aspx?id=582

Industry

Institute of Food Technologists
http://www.ift.org/cms/

Alliance for a Stronger FDA
http://strengthenfda.org/

Grocery Manufacturers Association
http://gmaonline.org/

Government agencies

Centers for Disease Control (CDC) - Food Safety
http://www.cdc.gov/foodsafety/

Congressional Research Service
The Federal Food Safety System: A Primer
http://www.nationalaglawcenter.org/assets/crs/RS22600.pdf

Congressional Budget Office (CBO)
Cost assessments
Legislation – Estimated cost of House bill (from Congressional Budget Office)

Department of Health and Human Services (HHS)
HHS FY 2011 Budget in Brief
http://dhhs.gov/asfr/ob/docbudget/2011budgetinbrief.pdf

Food and Drug Administration (FDA)
http://www.fda.gov
Beyond our Borders (2009)
http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/ucm103044.pdf
Food Defense
http://www.fda.gov/Food/FoodDefense/default.htm
FDA Science Board report, "FDA Science and Mission at Risk" (2007)
http://tinyurl.com/yvnk28
FDA Final Shell Egg Rule (2009)
http://tinyurl.com/lhrhuh
Food and Drug Amendments Act (2007)
http://tinyurl.com/yj9nu4l
Food Protection Plan
http://tinyurl.com/ydpj3pl
Food Safety
http://www.fda.gov/Food/FoodSafety/default.htm
PREDICT
http://www.fda.gov/ForIndustry/ImportProgram/ucm172743.htm
FDA Reportable Food Registry (2009)
http://rfr.fda.gov/
Food Safety and Inspection Service (FSIS)
http://www.fsis.usda.gov
FSIS, Regulations and policies
http://www.fsis.usda.gov/regulations_&_policies/index.asp

Government Accounting Office (GAO)
Fresh Produce Safety
http://www.gao.gov/new.items/d081047.pdf
Federal Oversight of Food Safety
http://www.gao.gov/new.items/d08435t.pdf

A5.2. By topic

Food-borne illness and outbreaks

CDC Outbreak data using FoodNet: 2006 2008

Center for Science in the Public Interest, Analysis of outbreaks, 1998-2007
CSPI
http://cspinet.org/new/pdf/outbreakalertreport09.pdf

Costs of food-borne illness, by state, estimates
Make our food safe coalition
http://www.makeourfoodsafe.org/cost_map

Food safety guidelines

HACCP website, food safety links
http://haccpalliance.org/sub/food-info.html

President's Food Safety Working Group
http://www.foodsafetyworkinggroup.gov

Imported food safety / trade

Action Plan for Import Safety (2007)
http://www.importsafety.gov/report/actionplan.pdf

Food Safety Import-Export compliance
http://foodsafety.gov/compliance/importexport/index.html

International agreements

WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)
http://www.wto.org/english/tratop_E/sps_e/spsagr_e.htm

Legislation

Bioterrorism law:
Public Health Security and Bioterrorism Preparedness and Response Act (2002)
http://tinyurl.com/y8g68v5

House bill (HR 2749)
http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h2749rfs.txt.pdf

Library of Congress – THOMAS legislation database
http://thomas.loc.gov/

Senate bill (S 510)
http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:s510rs.txt.pdf