Senate HELP Committee Holds Hearing on Food Safety Reform Legislation


Introductory Remarks

Senator Tom Harkin (D-IA), Chairman of the Senate HELP Committee opened the hearing, which focused on food safety reform legislation and specifically S. 510, “FDA Food Safety Modernization Act.” S. 510 was introduced by Assistant Majority Leader, Senator Dick Durbin (D-IL) in March of 2009 and currently has 11 co-sponsors\(^1\). Chairman Harkin noted that food safety is a major domestic policy issue and must be a part of health care reform because “unsafe food is yet another strain on our health care system.” Chairman Harkin commended President Obama for creating the Food Safety Working Group to develop recommendations for “bringing our food safety system into the 21st Century.” Chairman Harkin, like many of the other Senators who spoke, cited statistics from the Centers for Disease Control and Prevention (CDC) that illustrate the consequences of food safety\(^2\) and called for modernization of the food safety system, including a focus on prevention, improved response to outbreaks, and increased funding for the Food and Drug Administration (FDA) to carry out its increased duties under the proposed bill.

Senator Michael Enzi (R-WY), Ranking Member of the Senate HELP Committee also gave a statement emphasizing the non-partisan nature of food safety. He applauded S. 510 for containing some of the needed solutions for modernizing the authorities of the FDA and stressed the importance of funding such efforts. He also expressed concern about provisions in the bill related to the FDA’s relationship with farms and state officials.

Senators Christopher Dodd (D-CT), Sherrod Brown (D-OH), Robert P. Casey Jr. (D-PA), Kay Hagan (D-NC), Jeff Merkley (D-OR), Al Franken (D-MN), Judd Gregg (R-NH), and Johnny Isakson (R-GA) all participated in at least a portion of the hearing. In general, the Senators who spoke stressed the importance of preventing adulterated food from getting to consumers, monitoring imported food, traceability of adulterated food, a better system of recalling such food and mandatory recalls.

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\(^1\) Senator Lamar Alexander (R-TN), Senator Richard Burr (R-NC), Senator Roland Burris (D-IL), Senator Saxby Chambliss (R-GA), Senator Christopher Dodd (D-CT), Senator Kirsten Gillibrand (D-NY), Senator Judd Gregg (D-NH), Senator Johnny Isakson (R-GA) Senator Edward M. Kennedy (D-MA), Senator Amy Klobuchar (D-MN) Senator Tom Udall (D-NM).

\(^2\) CDC estimates that food-borne disease causes approximately 76 million illnesses in the United States each year, including 325,000 that result in hospitalization and 5,000 that result in death.
Many of the Senators used illustrative examples of people (often their constituents) who had been seriously injured or killed by food-borne illness. Senator Dodd, whose daughter has a severe allergy to peanuts, emphasized the need to improve allergen labeling on food labels as another critical food safety measure. In addition to the health consequences of consuming adulterated food, some of the Senators raised concerns for farmers and producers, many of whom suffer the economic consequences of recalls even when their products are not responsible for the food-borne illness, largely because there is no good system for tracing food-borne illness back to the adulterated food source.

**Testimony**

**Senator Durbin** gave brief testimony emphasizing that our food safety system is inadequate to protect Americans, citing the CDC statistics mentioned earlier. He also told the story of Mary-Ann, an elderly woman who nearly died of food-borne illness after eating contaminated spinach. Durbin also stressed the importance of food safety to our economy because of the devastating effects on producers, citing two recent examples: (1) the peanut butter recall where people stopped buying safe peanut butter just because some peanut butter was contaminated (estimated loss of $1 billion); and (2) the tomato recall where the true source of the salmonella was actually jalapeno peppers from Mexico (estimated loss of $150 million).

Next, **FDA Commissioner, Dr. Margaret A. Hamburg** testified. The FDA oversees the safety of the food supply except for meat, poultry, and processed egg products, which are overseen by the U.S. Department of Agriculture (USDA). She stressed the FDA’s commitment to a safe food supply as a core public health issue. She noted that the main challenges are an increasingly global food supply and that food can be contaminated at many different steps between the farm and the consumer’s home. President Obama is also committed to improving food safety. He established the President’s Food Safety Working Group, which recommended a new public-health approach to food safety based on three core principles: (1) prioritizing prevention; (2) strengthening surveillance and enforcement; and (3) improving response and recovery. Modernizing the food safety statutes to provide key tools to the FDA, USDA Food Safety Inspection Service (FSIS), and other components of the federal government. She highlighted the following legislative authorities as key to improving food safety:

- Enhanced ability to require sanitation and preventive controls at food facilities based on scientific hazard analysis;
- Ability to access basic food safety records at facilities;
- Enhanced ability to use resources flexibly to target food at the highest risk;
- Enhanced ability to establish performance standards to measure the implementation of proper food safety measures; and
- The ability to require mandatory recalls.

A food safety bill recently passed by the House of Representatives, H.R. 2749, “The Food Safety Enhancement Act of 2009,” addresses all of the above authorities and includes many of the other recommendations of the working group. S. 510 likewise addresses many of the priorities identified by the President’s Working Group, including preventive measures and mandatory recall authority. Dr. Hamburg noted that food safety legislation has broad support from the President, consumer groups, and major sectors of the food industry, but this support will be meaningless if Congress does not modernize food safety statutes.
The FDA believes there are three key questions to ask about food safety legislation, and Dr. Hamburg analyzed S. 510 within each of the following questions:

1. **Does the legislation refocus the system to put greater emphasis on prevention?**

   The bill would transform FDA’s approach to a preventive one by requiring companies to understand risks and implement measures to prevent contamination, and then holding them accountable for doing so.

   Key provisions in the bill are sections 103 (requires facilities to conduct hazard analyses and develop and implement a preventive controls plan) and 105 (requires adherence to science-based safety standards for fresh produce to minimize risks of serious adverse health consequences or death).

   FDA is eager to further develop this modern system by working with the CDC, USDA, industry, consumers, states, localities, and other key stakeholders to make this approach more consistent across government.

2. **Does the legislation provide FDA with the legal tools necessary to match existing and new food safety responsibilities?**

   S. 510 provides important tools for the FDA to oversee the primary new responsibility of overseeing and verifying the implementation of preventive measures as well as continue to protect the public during an outbreak. For example, section 301 (Foreign Supplier Verification Program) would help FDA monitor and control the quality of imports with an effective enforcement mechanism; and section 207 revises the existing standard for administrative detention to allow the FDA time to investigate a product's potential to cause significant harm.

   However, some provisions of the bill need to be strengthened by incorporating effective enforcement mechanisms and other tools. For example:
   - S. 510 does not provide FDA with authority to access food records during routine inspections, which is essential to identify problems before an outbreak and ensure that facilities are keeping proper records, and also one of the most significant gaps in FDA’s existing authority.
   - S. 510 does not provide for information sharing, a critical element of an integrated federal state system for expediting investigation and tracing the source of the illness to protect consumers and help industry recover faster. FDA recommends adding language to S. 510 that is similar to section 112(b) of H.R. 2749. This section provides FDA with the authority to provide, receive, and disclose (when necessary) confidential and commercial trade secret information relating to food with provisions to ensure its confidentiality.
   - Section 103 (outlining requirements for conducting a hazard analysis and implementing risk-based controls) and Section 105 (authorizes mandatory safety standards for fresh produce) both address enforcement by making violation a “prohibited act.” Enforcement could be strengthened if the bill would deem foods that violated these sections “adulterated.”
   - Section 204 (enhanced trackback and recordkeeping) lacks any enforcement mechanism.

3. **Does the legislation provide or anticipate resources for the FDA to carry out its responsibilities under the legislation?**

   FDA is concerned that there are important provisions of S. 510, such as mandatory inspections at specified frequencies based on risk and required inspection of foreign food facilities. However, FDA is worried that the funds won’t be adequate to carry out inspections with the required frequency and that foreign facility inspections could be more cost-effective if FDA had the flexibility to work with foreign governments.
Registration fees will help with the costs, but a reliable funding source is needed, as currently the inspection mandate of the bill will far outstrip resources.

It is also important to provide resources to build capacity of state and local food safety partners and the FDA supports section 205(d) which would reauthorize food safety capacity-building grants.

Dr. Hamburg concluded by saying that this legislation is a major step in the right direction and a historic moment for food safety. Success means fewer hospitalizations and deaths, fewer economically devastating recalls, and greater health for the American people.

The Question & Answer session following Dr. Hamburg’s testimony brought out the following points:

- Dr. Hamburg could not speak to the 1996 FDA pilot study referenced by Chairman Harkin, but said that a producer’s ability to identify points of vulnerability and eliminate risks along the food production process is a critical preventive food safety measure.

- Real-time on-site testing is also an important preventive measure. Dr. Hamburg knows that the bill’s mandates outstrip current FDA resources. While she does not know how much money will be needed to keep pace with the inspection responsibilities in the bill, she is committed to working with Congress and experts to making this determination.

- In order to meet the staffing requirements necessary to implement the FDA’s responsibilities in the bill, the agency is restructuring and realigning its food safety staff/departments and also expanding the workforce, getting more inspectors, and shifting their paradigm to prevention (versus reaction to outbreaks). Dr. Hamburg expects to add 350 inspectors into food safety protection and enhance border protection staff (even without the mandates of the bill) and believes that S. 510 would require even more. Again, she is committed to working with experts to estimate the needs.

- FDA is committed to working with small/organic farms to build in flexibility to the regulations that will allow those farms to comply with the bill and ensure consumers are protected. Senator read provision from the bill that exempts small/organic farmers from the bill.

- Senator Gregg expressed concern about provisions that would require sharing confidential information and about the FDA’s ability to “seize” inventory over “having the wrong paper or something” and that it would encourage people to not keep records. Dr. Hamburg stressed the difference between “adulteration” and “prohibited act” and assured Senator Gregg that a wrong paper would not result in seizure.

- Although Dr. Hamburg did not know the exact amounts, she said the costs associated with unsafe food are very important and include costs to the health care system and to industry, and that unsafe food can have an impact on the economy in general. Senator Franken would like a cost-benefit analysis of food safety measures against the cost of unsafe food. He would additionally like to see severe criminal penalties for facility operators who knowingly send out contaminated food, like the Peanut Corporation of America.

- Coordination is key and Dr. Hamburg noted that at present time there is extraordinary coordination between federal, state, and local agencies. FDA is still working to improve international collaboration.

- Senator Isakson stressed his concern over smaller farms and possible seizure of product.

After Dr. Hamburg testified, a second panel of the following people testified:

- **Caroline Smith DeWaal**, Director of Food Policy, Center for Science in the Public Interest
- **Michael Roberson**, Food Marketing Institute
- **Daniel Ragan**, Director, North Carolina Dept. of Agriculture & Consumer Services, Food & Drug Protection Division
- **Thomas Stenzel**, President and CEO, United Fresh Produce Association
Caroline Smith DeWaal is the Director of Food Policy at the Center for Science in the Public Interest, a nonprofit that does not accept money from government or industry, but is primarily funded through individual memberships and grants from foundations. They work closely with the Make Our Food Safe coalition.

Successive outbreaks caused by numerous healthy foods make food safety legislation more critical than ever. These outbreaks are the result of “an antiquated legal system that ties the hands of the FDA when seeking food safety information form plants and limits the effectiveness of the agency to enforce the laws.” FDA laws concerning food safety are 50 to 100 years old and inadequate to deal with modern-day food safety hazards. The FDA has compensated through rule-making, but this is inefficient.

Ms. DeWaal repeated earlier-quoted CDC statistics about the illness and death caused by food-borne illness and noted that economists have calculated the costs of unsafe food to rage from $40 billion to well over $100 billion. Consumer confidence in food safety has declined. Consumers who rely on the food safety system daily are the ones who bear the consequences of the broken system. She told the story of Michael who was poisoned by salmonella-tainted peanut butter in 2007, and yet there was another outbreak in 2009.

Safety must be built into the food safety system, and it must be in the form of prevention, not reaction. Hazard analysis and preventive control plans should be a prerequisite for all food processors that want to sell food in the United States. S. 510 establishes the industry's fundamental responsibility for ensuring food safety and provides a foundation for government inspections, but the bill must also give the FDA the authority and funding to enforce compliance. FDA also needs authority to set performance standards for the most hazardous pathogens and required food producers to meet those standards. Ms. DeWaal recommends three changes to strengthen S. 510:

1. **Risk-based inspection and inspection frequency.** Establish three categories of risk and set inspection frequencies based on these categories with a minimum frequency of once every 6 to 12 months for high-risk facilities and prohibit FDA from using certification by a private entity as a factor in setting the frequency of inspection for a domestic facility.

2. **Testing and reporting requirements, affirmative reporting of positive results.** Food companies must be required to test for contamination most common to their products and be required to promptly report to FDA any positive results from its testing program.

3. **Imports and Imported Produce.** S. 510 language on imported food regulation should be strengthened by requiring government-to-government certification for high-risk foods; clarifying that FDA has principle responsibility for accrediting import programs of foreign governments and that private accrediting bodies must be under strict FDA oversight; and adding language requiring FDA establish a system to determine whether safety standards for imported produce are at least equal to standards for domestic produce.

Ms. DeWaal also noted that accessibility of plant records is crucial to identifying problems before an outbreak. She closed by saying that “not acting now [on food safety legislation] is setting the table for the next outbreak.”

Michael Roberson is the Director of Corporate Quality Assurance for Publix Super Markets and was testifying as a representative of the Food Marketing Institute (FMI), a national trade association of 1,500 food retailers and wholesalers in the United States. FMI and its member companies share the goal of enacting food safety legislation this year. Recalls have not only caused death and illness, but have also had devastating impact on food retailers, wholesalers and producers. Consumer confidence is a critical factor in the debate because of the impact it can have on purchasing decisions.

Supermarkets have many prevention programs in place at the retail level, and Publix is committed to working with the supplier community to constantly improve the safety of the food they manufacture and process. Mr. Roberson
described these programs, including the Safe Quality Food Program, programs within each supermarket, and consumer education programs (including “Fight BAC!”). But these programs are not enough. S. 510 is consistent with retailers focus on preventive measures, a need to focus on products with greatest risk of contamination that will cause illness. Any changes should be supported by science, have measurable benefits, be affordable, be realistic, be implemented without unintended consequences, and mitigate risk.

Specifically, FMI particularly supports the following sections of S. 510

- Section 102 (hazard analysis and risk-based preventive controls);
- Section 105 (standards for produce safety);
- Section 201 (targeting inspection resources), but encourages that the FDA be allowed to develop a separate classification for warehouse facilities that only hold foods that are not exposed to environment (as is allowed in section 103);
- Section 204 (enhancing traceback and recordkeeping), with a pilot approach being critical to developing best practices and collaboration with the FDA to ensure industry initiatives will better assist in the event of a food safety outbreak;
- Section 205 (surveillance), and encourages that this section incorporate S. 1269, which would enable the CDC to better coordinate food-borne illness surveillance systems and better support state laboratories in outbreak investigations;
- Section 206 (mandatory recall), stressing the importance of the the procedural limitations on recalls, including mandatory direction for FDA to work with state/local public health officials and that the authority only be exercised by the Commissioner;
- Section 301 (foreign supplier verification program);
- Section 302 (voluntary qualified importer program);
- Section 306 (building capacity of foreign governments with respect to food);
- Section 308 (accreditation of third-auditors and audit agents), but encouraging an amendment to this section to ensure that the terminology is consistent with internationally recognized language and terms. Additionally, FMI would stress that such programs cannot replace government oversight or “attempt to deputize private-sector auditors as enforcement agents of the federal government.”

Daniel Ragan is the Director of the North Carolina Dept. of Agriculture & Consumer Services’ Food & Drug Protection Division. He stressed the importance of coordination in three critical areas: (1) developing a national standard; (2) training; and (3) quick response to outbreaks.

More than 3,000 federal, state, and local regulatory and public health agencies have a role in food safety. FDA has entered into collaboration agreements with many states and about 90 percent of all food safety inspections are performed by states. Mr. Ragan described how North Carolina handled a recent listeria contamination and how state action in North Carolina prevented illness in several states.

Mr. Ragan also noted that North Carolina hosted a listening session for FDA and USDA where small and medium sized farmers could voice their concerns about food safety legislation. Farmers are committed to ensuring the safety of their produce, but are concerned about scalability and need indemnity for farmers damaged by fresh-produce linked outbreaks (for example, the salmonella outbreak initially linked to tomatoes when jalapenos were ultimately responsible).
He stressed that food safety must be built into the entire life cycle of a food and that preventive measures are key. The food industry and regulatory agencies must also build trust so that food safety programs are most effective. Collaboration of all agencies allows a state to quickly and effectively minimize the public health and economic consequences of a food incident.

**National Standards**

- **Leverage Existing Resources:** FDA should take full advantage of existing state inspection and surveillance resources.
- **Equivalency:** Uniform standards and programs with a demonstrated equivalency should be used to achieve the same level of public health protection even if states use different approaches. Mr. Ragan described the Manufactured Food Regulatory Program Standards (MFRPS), an FDA program to ensure equivalency in regulatory programs, as a means of developing such standards. MFRPS should be implemented in all states. Retail food standards are another important tool in standardization.
- **Oversight and Accountability:** Regular program oversight and accountability at all levels is needed to maintain system integrity and credibility.
- **National risk-based planning:** Federal and state inspections should be based on a national work plan driven by public health risk. Multiple risk factors would drive inspection frequency (such as type of food, population served, compliance history of the firm).
- **Laboratory Accreditation:** Regulatory programs should be supported by accurate and defensible laboratory results.

**Training**

- **International Food Protection Training Institute:** This institute in Michigan is the foundation for the certification of food regulatory specialists.
- **Industry Training:** Food safety experts agree that a measurable matrix must be developed to evaluate industry partners and effectively train them to prevent food safety problems, detect and respond to outbreaks, and protect food supply from deliberate and natural contamination.

**Response and Recovery**

- **Traceability:** FDA should provide guidance for uniform traceability requirements and systems for food manufacturers and distributors that is scalable and can meet the needs of the entire industry.
- **Market Recovery:** Legislation should include market recovery assistance for industries that are adversely affected by food safety scares, consumer advisories, recalls, and peripheral events.
- **Unified Rapid Response:** North Carolina’s Incident Command System (ICS) has been an effective tool for a unified rapid response.

Mr. Ragan also noted that information sharing is critical and that real-time information sharing should be available to all federal, state, and local food protection agencies. Additionally, legal barriers (such as states not having access to the Bioterrorism Act food facility registry) should be removed.

On the matter of funding, Mr. Ragan made several suggestions. FDA contracts with state regulatory programs on an annual basis to conduct inspections and sample analysis. If these contracts were instead carried out through multi-year funding (instead of annually), this would facilitate long-term success. Congress should also provide dedicated line-item funding from the federal level to the state and local levels. The USDA’s Talmadge-Aiken program may provide a good model for doing so. An analogous FDA program could be administered by the Secretary of HHS based on compliance with MFRPS. Finally, Congress should increase funding for the food protection training institutes affiliated with land-grant colleges and universities to develop comprehensive food safety education and training program for industry.
Thomas Stenzel is the President and CEO of the United Fresh Produce Association (UFPA), which represents more than 1,500 growers, packers, shippers, fresh-cut processors, distributors, and marketers of fresh produce accounting for the majority of the produce sold in the United States. UFPA works to develop industry-wide consensus on the best overall policies and practices to serve the American consumer and food safety is the industry’s top priority.

Mr. Stenzel described the industry’s efforts to tackle food safety issues, including responding to outbreaks with evaluation and reforms in production and handling, developing the Produce Traceability Initiative, continued updating of its Food Safety Guidelines, harmonizing global good agricultural practices. Produce is safer today than it ever has been.

UFPA adopted the following policy principles for food safety reform that would best protect public health and promote consumer confidence. Food safety reform must:

- Allow for a commodity-specific approach, based on the best available science;
- Be consistent and applicable to the identified commodity or commodity sector regardless of where the commodity is grown-packaged or whether it is imported; and
- Be federally mandated with sufficient federal oversight of compliance.

These principles were incorporated into H.R. 2749 and are largely present in S. 510, and Mr. Stenzel described in greater detail the importance of each.

Prevention is paramount, but federal, state, and local management of outbreak investigations also provide some important lessons for improving the system, these include:

- Lack of centralized responsibility for investigations results in a lack of leadership and coordinated response. UFPA suggests Congress put in place an outbreak investigation structure with clear chain of command and HHS should mandate and provide resources for nationally consistent training.
- The current system does not use industry expertise. Congress and agencies should find a proper and transparent way to bring industry experts into investigations. UFPA suggests creating a panel from various produce commodity sectors and vetting them ahead of time so that a credible panel could immediately be convened during an emergency.
- Risk communication is unacceptably broad and harms the industry by creating unreasonable fear in the public (such as fear of all spinach products when only one brand was contaminated).

UFPA supports S. 510 as an aggressive and comprehensive approach to food safety reform. Specifically, they support the bill’s commodity-specific approach, the requirement that FDA collaborate with USDA and states to implement compliance measures, and mandate for expedited entry program imports that can demonstrate compliance with U.S. safety standards. UFPA opposes “watering down” of food safety requirements for small farms, organic farms, or others because size is not related to food safety and everyone needs to be compliant to inspire consumer confidence. Technical assistance, training, and financial support (including reduced fees) are more appropriate ways to assist small farmers.

The Question & Answer session following the testimony of experts on the second panel brought out the following points:

- The provisions to certify foreign countries are complicated because of the large number of products imported from many different countries and may need to be revised so that even if a country cannot be certified (there are clearly countries where this will be the case), perhaps a facility within that country could be certified. This system is already working in the private sector (FMI’s Safe Quality Food Program).
- Education of the general population on safe food handling and preparation are also important and should be continued. FMI’s Fight Bac! program is an example. Nevertheless, consumers are last line of defense and food safety should be implemented throughout the food production chain. Senator Hagan also
mentioned that she thought safe food handling and preparation should be taught in school as a part of the basic curriculum.

- In response to Senator Enzi’s concern that reporting every positive contamination test result to the FDA could become incredibly burdensome, particularly when contaminated food can often be treated and made safe, Ms. DeWaal said that a computer based system would allow for data collection without FDA officials reviewing every individual piece of information. This data would then be available and useful in case of an outbreak to trace contamination to potential sources.

- Mr. Ragan said that FDA’s cooperation with state and local officials is better than it has ever been, but still needs improvement in order to accomplish inspection goals.

- Senator Hagan expressed concern about economic consequences to farmers who ultimately aren’t responsible (such as the tomato recall), and Senator Merkely emphasized that traceability is key and strongly supports the pilot project included in S. 510 on this issue.

- Congress should consider requiring mandatory reporting requirements not only for third-party auditors and certifiers, but also for laboratories with positive test results for contaminated food.

- Senator Franken highlighted three critical areas to detect contamination: (1) frequency of inspections adjusted for levels of risk; (2) mandatory testing reporting built into the bill; and (3) making imports safe. He believes S. 1269 is a good start to outbreak control.

In closing, Chairman Harkin said that the committee would mark up the bill soon and that Congress would hopefully get food safety legislation to the President’s desk by the end of the year.

More Information

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