Food Safety Reform:

What's Coming and How to Prepare

by Elizabeth B. Fawell

Take the spate of food borne illness outbreaks in recent years (think spinach, melamine, tomatoes/peppers and peanut butter), combined with a federal statute that dates back to 1906, add in a President interested in food safety and you have the perfect recipe for food safety reform. Although the Senate has been focused on healthcare this winter, food safety legislation is still on its plate.

As of this writing, the Senate Committee on Health, Education, Labor, and Pensions (HELP) has passed S. 510, the FDA Food Safety Modernization Act (FDAMA), but the bill has not yet been considered by the full Senate. Nonetheless, with the passage of H.R. 2749, the Food Safety Enhancement Act of 2009, in the House of Representatives last summer, we can look at the similarities between the two bills and have a pretty good idea of what food safety reform will look like. Accordingly, there are several things that food companies can start doing now to prepare for what is coming.

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What's Coming

First, what can food companies expect to see if food safety legislation is enacted? Although the details remain to be seen and differences between the bills will need to be worked out, the two bills moving through Congress contain four basic components: new responsibilities for food companies, enhanced enforcement authorities for the Food and Drug Administration (FDA), increased oversight of imports, and user fees. The substantial similarities between the bills in these areas signal what is most likely to become law.

New Responsibilities for Food Companies

Many of the potential new responsibilities for companies will likely impact daily operations at food facilities. The most significant new requirement is a provision found in both the House and Senate bills that would require, with limited exemptions, each registered food facility to have a food safety plan.

Specifically, both bills would require each facility to conduct an analysis of potential contamination hazards and to implement preventive controls to prevent or mitigate those hazards. Preventive controls include sanitation procedures, employee training, good manufacturing practices (GMPs), allergen control programs, supplier verification activities, and environmental testing programs. H.R. 2749 and S. 510 would require food facilities to monitor the preventive controls in place to ensure they are working and take appropriate corrective actions, if necessary. All of these activities would need to be documented. These records and the contents of the plan would be made available to FDA during inspections.

In a similar fashion, both bills would require food facilities to have food defense plans—plans to protect food against intentional contamination. Facilities would need to evaluate potential hazards and implement measures such as processing security, material security, utility security and storage security to protect against such hazards. Facilities would be required to check to ensure that those measures are in place and are working and periodically test the plan. Like with food safety plans, facilities would need to document the monitoring procedures and any corrective actions and assessment activities.[1]

Additionally, FDA is likely to receive expanded records access. Under the House bill, the agency would have access to all records bearing on whether food is adulterated or misbranded, including food safety plans. A written request for records would not be required. FDA also would have remote access to food safety plans and, during an emergency, remote access to all other records. FDA would

have the authority to review accredited laboratory records and would have access to testing results when testing must be conducted by an accredited laboratory. FDA would have access to any related records of an importer or customs broker, as well as access to records at a facility certified by a third-party auditor in order to verify the auditor's performance. Finally, FDA would have the authority to require facilities to maintain additional records.

The Senate bill has a more narrow records access provision. It would expand FDA's current records access (access to records relating to an article of food when there is a reasonable probability that it will cause serious adverse health consequences or death), to give FDA access to records for any other article of food that may be similarly affected. It would also give FDA access to a company's food safety plan, including records of monitoring and corrective actions, as well as any testing or other means used to verify the plan.

Additionally, FDA would have access to any records regarding an importer's foreign supplier verification program and FDA would have access to inspection reports and other documentation gathered by third party auditors during the auditing process, as well as access to accredited laboratory records.

Under both H.R. 2749 and S. 510, FDA also would be required to establish standards for the safe production, harvesting, and handling of produce. Both bills also would require FDA to establish performance standards for specific food-borne contaminants. Food companies would need to ensure that their food meets such standards. Finally, food facilities would be required to register with FDA on a regular basis—every two years under the Senate bill and every year under the House bill.

New or Enhanced Authorities for FDA

Not only can food companies expect to see increased responsibilities, but they can also expect to see an FDA with new or enhanced enforcement authorities. Both the House and Senate bill would establish a risk-based inspection frequency for food establishments. In particular, facilities warranting closer federal oversight would be inspected at least every year.

Under the House bill, other food processing establishments would be inspected at least every three years, and warehouses would be inspected every five years. In S. 510, these other facilities would be inspected every four years. Regardless, facilities that, in the past, have received an FDA inspection as infrequently as once every 10 years, can expect to see FDA inspectors more regularly.

In addition, both the House and Senate bills would provide FDA with mandatory recall authority when an article of food may cause serious adverse health consequences or death. Albeit with different timeframes, both bills also would provide for a hearing on the mandatory recall order. However, the House bill would allow FDA to issue a mandatory recall order without a hearing during emergencies.

Similarly, the House and Senate bills would allow FDA to suspend the registration of a food facility if the agency determines that food from that facility has a reasonable probability of causing serious adverse health consequences or death. This is an authority analogous to the withdrawal of inspection by the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA). Suspension of registration would be preceded by notice and an opportunity for an informal hearing. The House bill also would allow FDA to cancel a registration that is not updated appropriately or contains false or incomplete information.

Furthermore, S. 510 and H.R. 2749 would broaden the authority granted under the Bioterrorism Act of 2002 and provide FDA with the authority to administratively detain food when the agency has reason to believe that it is adulterated or misbranded.

Increased Oversight of Imports

Reflecting the 2007 melamine scare, both the House and Senate food safety bills contain several provisions aimed at increasing the oversight of imported foods. Both S. 510 and H.R. 2749 would require importers to have programs in place to ensure that food imported meets the requirements of the Federal Food, Drug, and Cosmetic Act (FDCA).

In the Senate bill, this would be called a "foreign supplier verification program." In the House bill, importers would be required to comply with "good importer practices" issued by FDA. Although there are some differences between these two approaches, both programs would require importers to conduct due diligence on their foreign suppliers.

Both bills would also allow FDA to require imports to have a certification due to risks associated with the food or its place of origin, or if FDA has an agreement with another country to provide a certification. Moreover, each bill contains a provision that would establish a procedure for accreditation of third-party auditors to certify that foreign entities in the import supply chain are in compliance with the Act.

The House and Senate bills also contain similar provisions that would require product testing for certain imports to be conducted at an accredited laboratory and the results sent directly to FDA.

Finally, both bills would allow FDA to establish a program for expedited entry of imported foods if the importer meets FDA food safety and security guidelines—a "fast lane" for certain imports.

User Fees

One significant difference between the House and Senate bills is that the House bill would impose a fee of $500 on each registered food facility and each importer, with a per company cap of $175,000, to help fund food safety activities at FDA. The Senate bill does not contain a registration fee.

Under both pieces of legislation, FDA would collect fees from each facility that undergoes an additional inspection to reimburse the agency for the cost of the inspection. Similarly, FDA would collect fees from companies conducting product recalls to cover the agency's costs monitoring the recall activities.[2] Also, FDA would impose a fee for issuing export certificates, similar to fees already in place for other FDA-regulated products. S. 510 additionally allows FDA to impose a user fee for participation in the "fast lane" program for imports.

Outstanding Differences between House and Senate Versions

Despite the significant similarities between the House and Senate bills, there are some crucial differences that will need to be worked out before a final bill becomes law. These outstanding issues include the registration fee mentioned above, traceability, finished product testing, additional enforcement authorities for FDA, and country of origin labeling (COOL).

The House bill would require FDA to establish a food tracing system that would enable the agency to identify each person who handles an article of food within two business days. Before establishing such a system, the agency would be required to review available technologies, hold public meetings, and conduct a pilot project. FDA would have the discretion to require the use of lot numbers, a standardized format for pedigree information, and the use of common nomenclature for food.

In contrast, the Senate bill contains a much more limited traceability provision. FDA would be required to conduct a pilot project and issue a proposed rule to establish standards to improve the tracking and tracing of fresh produce. In addition, FDA would be required to establish a pilot project for tracing processed food, but the agency would not be required to issue any regulations establishing a tracing system.

Under H.R. 2749, FDA also would conduct a pilot project and feasibility study in order to determine which results from finished product testing would be required to be reported to the agency. As passed by the HELP Committee, the Senate bill does not contain a similar provision regarding the reporting of test results.

The House and Senate bills also differ when it comes to enforcement authorities. Unlike the Senate bill, H.R. 2749 would increase the criminal penalties available to FDA, provide FDA with subpoena authority, and provide FDA with quarantine authority. Notably, S. 510 would only impose civil money penalties against food companies for failure to comply with a mandatory recall order, and the penalty would be capped at $500,000 per company.

In contrast, the House bill would establish a two-tiered system of civil penalties. Civil money penalties would be capped at $1 million per company for unintentional violations of the Act, and would be capped at $7.5 million for intentional violations.

Finally, the House bill contains a provision requiring country-of-origin labeling for all foods. S. 510 as passed by the HELP Committee does not contain a similar provision.

Several of these issues are an outgrowth of the Peanut Corporation of American (PCA) peanut product recall last year. Indeed, as these bills have moved through Congress, they have been revised to reflect those perceived gaps revealed by the most recent foodborne illness outbreak. Therefore, it would not be unexpected to see additional provisions added to the final piece of legislation should we see another foodborne illness outbreak or other food safety crisis prior to final passage of the bill.

How to Prepare

Despite the uncertainty as to the exact content of food safety reform as enacted, there are three provisions that are expected to be a part of any final bill. These are the requirement that food facilities have food safety plans, expanded FDA records access during inspections and the requirement that food companies verify the quality of their suppliers. Importantly, there are steps that companies can take now to prepare for these likely new requirements.

Food Safety Plans

Companies should not underestimate the significance of the proposed requirement that each facility have a food safety plan, as that is a main cornerstone of the entire legislation. Although many, if not most, food companies may think they are already in compliance with such a provision, it would be prudent even for companies with comprehensive food safety plans to pause and review those plans with a critical eye.

For example, companies should ask: When was the last time we analyzed the potential hazards for food in this facility? Do we have any critical control points? What preventive controls are we using? Have we verified that these controls are effective? What monitoring activities are we performing? Are these appropriately documented? Do we have procedures in place to determine when corrective action is necessary and what kind of corrective action to take? Is this documented?

We can expect that FDA will have access to a facility's food safety plan during inspections. Thus, companies should be prepared to engage in discussions with FDA over their plans. For example, FDA and a facility may disagree over what hazards are reasonably likely to occur in that facility, and whether the identified preventive controls are sufficient to control the hazard.

Second, FDA may receive the authority to establish preventive controls by product type. Companies can prepare for this by ensuring they have the necessary scientific data to support their food safety plan-related decisionmaking. That is, food companies can begin now to solidify and document the necessary scientific substantiation for their food safety plans.

As part of this review, companies also should look to ensure that they have the right employees, such as microbiologists, toxicologists and quality managers, to help with this process, as well as areas where outside scientific consultants could be useful. Likewise, companies should think about which personnel should be in charge of the food safety plans in place, and who should be the point of contact for discussions with inspectors. Further, companies can begin to assess where additional employee training might be beneficial.

The rigor of FDA oversight is likely to be much greater under the new legislation than has been the case historically under the agency's good manufacturing practice (GMP) regulations. Those food companies with either FDA-regulated seafood or juice facilities, or FSIS-regulated meat or poultry facilities, can look to the lessons learned during the implementation of the respective Hazard Analysis and Critical Control Point (HACCP) programs as a good place to start.

Company Maintenance of Records

Although the scope of the records access provisions differ in the Senate and House versions, food companies can expect that FDA will not only have access to food safety plans, but also to additional plant records. This could include documents such as environmental and finished product testing records, audits of suppliers and co-manufacturers, certificates of analysis and manufacturing records, as well as records regarding foreign suppliers and imported goods.

FDA likely will have full access to all records regarding a facility's food safety plan, which may include some of the types of documents noted above. For those companies that currently restrict FDA's records access to that specified for many years in the existing statute, this will be a dramatic change. Notably, failure to maintain required records and the failure to provide FDA records access will be a violation of the Act.

To prepare, food companies can ask: What are our record maintenance and retention policies? Where are records maintained and who has access to those records? What kind of training do we need to do to educate our employees about the upcoming change in policy? Do our records clearly reflect our food safety plans? Are corrective actions well documented? Who will be responsible for reviewing plant records with inspectors? In addition, companies can also review their current recordkeeping policies and consider whether to conduct training in record creation practices, such as making sure that changes to records are properly documented and that there is no missing data or information.

The shift will be significant, but companies can take steps now to make sure that their records are complete and accessible.

Supplier Verification

Both the H.R. 2749 and S. 510 would require food companies to engage in supplier verification activities for domestically produced food and for imports. Specifically, under the House bill, the preventive controls used in a facility's food safety plan must include verification procedures for suppliers and incoming ingredients, which may include onsite auditing of suppliers. In addition, the food safety plan must include a description of the facility's procedures for ensuring a safe and secure supply chain for the ingredients used in the facility. The Senate bill states that supplier verification activities may be among those preventive controls employed by a facility.

Furthermore, the Senate bill would require importers to perform risk-based foreign supplier verification activities to verify that imported food is produced in accordance with U.S. requirements. Verification activities could include, among other things, lot-by-lot certification of compliance, annual on-site inspections or periodic testing of shipments. Similarly, the House bill would require importers to follow good importer practices, including measures to ensure that each person that handled the imported article of food and its components is in compliance with the Act.

Companies can prepare for these new requirements by examining their current supplier verification procedures. What are our procedures to qualify ingredient suppliers? Do we know who our suppliers are, even if brokers are used? What do we do to audit our suppliers? What auditing procedures do we have for our co-manufacturers? Do we know who their suppliers are? Do we require them to use only company-approved suppliers? Do we test incoming ingredients? Importantly, companies need to ask these same questions for imported materials and foreign co-manufacturers. Supplier verification procedures may be more complicated for foreign suppliers, but they are just as essential.

Conclusion

As food safety legislation makes it way through Congress and to the President's desk, we will likely continue to see changes made. Regardless, there are core provisions that we can expect to see in any final bill, as these provisions are directly tied to some of the major food borne illness outbreaks in recent years. The good news is that companies can start preparing for these new requirements today, by engaging in a critical review of their food safety plans, record creation and retention practices, and supplier verification activities. If companies gather the right people, ask the hard questions and put actions plans in place where needed, they will be ready for the new requirements to come.

1 H.R. 2749 contains a separate section for food defense plans, whereas S. 510 would require intentional contamination hazards to be assessed as part of the facility's food safety plan analyzing and preventing against unintentional and foreseeable hazards.

2 The Senate bill would only impose such a fee if the company is subject to a mandatory recall order, whereas under the House bill, the fee would be imposed for all food recalls.