



Government Relations

Representing the produce supply chain, from field to fork

Analysis of the Food Safety Modernization Act

The U.S. Congress passed the Food Safety Modernization Act in December. The congressional process was neither fast nor pretty. First caught behind health care reform and then squeezed into the post-election congressional wrap up, President Barack Obama signed food safety bill in early January 2011. Long after the tortured process that produced the final bill is forgotten, the statutory language and the U.S. Food and Drug Administration's (FDA) implementation of it will remain. Though the bill often specifies timelines for the rulemaking process and while the agency has already begun working on the rules, the actual date that the implementing regulations will go into effect. Stay tuned to PMA for the latest information.

The following are key components of the bill that will affect PMA members. The next step is that FDA will implement the new law with regulations, and this summary will give companies a sense of what is to come from FDA.

Produce Standards. Within one year of enactment of the law, FDA must issue proposed regulations on produce standards. The science-based standards are to be issued for those types of fruits and vegetables (including specific mixes or categories) the agency determines need standards in order to minimize risk to human health. Before becoming effective one year after the close of the comment period on the proposed rules, the agency must conduct public hearings across the country and the rules must take into account environmental, organic, and possibly even regional differences. FDA must prioritize the implementation based on known risks, including the history of outbreaks.

Food Safety Plans. Each food facility must have a written food safety plan that includes hazard analysis and preventive controls, a description of verification and recordkeeping, and procedures for monitoring, recall, and tracing. The plans, which are available to FDA during an inspection, must also address risks from intentional contaminations such as terrorism. A facility must update its plan every three years or when it makes a significant change in the facility.

Traceability and Recordkeeping. After several studies and pilots (including a fruit and vegetable pilot), FDA shall establish a system that improves the capacity to effectively track and trace food. In addition, FDA must issue regulations requiring enhanced recordkeeping for what it determines and makes public to be "high-risk foods." The system must be science-based and technologically neutral and have benefits that outweigh the burdens of the additional requirements. It is not required to contain the full pedigree of information or require product tracing to the case level. Grocery stores

buying directly from farms are exempted from recordkeeping requirements for those products, other than retaining for 180 days records documenting the source of the food.

Access to Records. During an inspection, FDA (or its agent) may view and copy records bearing on whether the facility's food is adulterated or misbranded. This includes food safety plans, testing results, corrective actions taken, and monitoring of supply chain.

Registration. Under existing law, facilities that process, pack, or hold food (excluding farms, restaurants, and retail) must register with FDA. The new law does not change who must register, but it does require a registration renewal every two years, with no cost for registration.

Laboratory Accreditation and Testing. Within two years, FDA shall issue regulations on food testing as well as on accrediting laboratories to standardize and increase the number of laboratories eligible to perform testing. Laboratories, U.S. and non-U.S., private and governmental, may receive accreditation, and FDA will establish a registry of accredited labs (though distribution of the list may be restricted). The testing is to occur when otherwise required, including upon entry into the country, or when the Secretary determines it is appropriate to address a food safety problem. FDA is to receive the test results, unless the agency determines that receipt of particular tests do not contribute to public health protection.

Small and Local Farms and Facilities. The bill exempts from the food safety plans and the produce standards facilities or farms that meet certain qualifications:

- Food from "very small facilities" which FDA will define, or
- The food at the facility or farm has an annual value of \$500,000 or less and a majority of the food is sold:
 - directly to consumers (without limitation on geography), or
 - directly to restaurants or retail establishments that are less than 275 miles away from the farm or facility or are in the same state.
- If these conditions are met, then the entire facility or farm is exempt – even the food that goes to other sources. For a facility, it avoids the requirement to have a food safety plan that FDA may review. For a farm, it is exempt from produce standards. FDA may lift the exemption for a particular facility or farm if there is a direct link to a food outbreak or when necessary to protect public health.

Importer Verification of Foreign Suppliers. Importers will be required to verify that food imported is produced in compliance with U.S. food safety laws. Importers (the owner/consignee at the time of importation or the U.S. agent of a foreign owner/consignee) must verify that food he or she handles was produced in compliance with applicable U.S. laws and is not adulterated. The records relating to verification must be made available to FDA upon request. The types of verification activities may include monitoring records, lot certification, annual on-site inspections, checking food safety plans, and periodic testing or sampling. Under the new law, FDA will provide guidance on developing a foreign supplier verification program within one year and the requirement is to take effect two years after the law's enactment.

Fast Track Entry. Beginning within 18 months, FDA shall establish expedited entry for importers that participate in a voluntary certification program. Importers will pay a fee for this service. Because the program will rely on accredited certifiers, the fast track program will not begin until after FDA completes its work on that program.

Accreditation of Third Party Auditors. FDA must establish a program to accredit third-party auditors for inspections of foreign facilities. Such audits may either be “regulatory” to meet a legal requirement such as the foreign supplier verification or “consultative” which is for purposes internal to the company. The records of regulatory audits are available to FDA upon request but consultative records are available only as part of an inspection. Whether conducting a consultative or regulatory inspection, an auditor must immediately disclose to FDA any conditions that could cause serious risk to public health.

FDA Inspections. The legislation increases inspections and mandates the frequency of inspection. It creates categories of facilities that FDA will determine based on known risk factors, the history of the facility, and the rigor of its preventive controls. Like time deadlines for issuing rules, the ambitious schedules set forth in the bill may make it difficult for the agency to achieve these goals. FDA may utilize other federal or state agencies for inspections.

- **High-risk facilities** must be inspected within the next five years and every three years thereafter.
- **Non high-risk facilities** must be inspected within the next seven years and every five years thereafter.
- **Foreign facilities** (non-U.S.) are to be inspected at an increasing rate; the bill sets a goal of doubling the number of inspections over each of the next five years.

Evaluation of Foreign Regulatory Programs. The law broadens FDA’s ability to refuse entry into the United States food from a country with a food safety system FDA has found to be inadequate. Food from those countries may be permitted entry with certifications from accredited third parties.

Recall and Outbreak Response. The bill beefs up FDA’s authority to require recalls. When senior FDA officials have a reasonable belief that food presents an imminent threat of serious harm, FDA may request a voluntary recall by a company. If the company refuses, the bill sets out a procedure by which the Secretary orders a recall. The bill also calls for improved collection and usefulness of data relating to outbreaks and mandates better cooperation between and training of FDA, the U.S. Centers for Disease Control and Prevention, and state and local officials.

Posting of Recall. The bill requires FDA to draft rules requiring the posting of recall notices at grocery chains with at least 15 stores, which must display a recall notice in a “prominent and conspicuous location” in the store. Within one year, FDA will promulgate a list of acceptable locations. The notice must be posted within 24 hours of when it appears on FDA website.