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Food Safety Legislation Passed Congress...Now What?

After a memorable trip through Congress, the Food Safety Modernization Act is on President Obama's desk awaiting the final signature. Once signed, several key provisions of the bill will immediately go into effect, including:

- Expanded records access
- Increased inspection frequencies
- Mandatory recall authority
- Authority to require import certifications for food

For a complete summary of the implementation timelines for all provisions, please see our [Food Safety Modernization Act Implementation Timeline](#).

Expanded Records Access

What is new? Access to all records related to the manufacturing, processing, packing, transportation, distribution, receipt, holding, or importation of an article of food for which there is a reasonable probability that exposure will cause serious adverse health consequence or death and all records relating any food that is likely to be affected in a similar manner must be provided to FDA upon request.

What will be different? Prior to the new legislation, FDA could only access records relating to articles of food believed to be adulterated. Under the new law, if there is a reasonable belief that an article of food handled by a facility is adulterated, FDA can request access to records relating to other food handled by the facility.

Who is impacted? Anyone who manufactures, processes, packs, distributes, receives, holds or imports food must comply with this provision. Farms and restaurants are excluded from the requirement.

What does this mean? In effect, this means that there is a "lower bar" for FDA to access records, but there still has to be a reasonable belief that an article of food will cause a serious adverse health event or death, and exactly how that is subsequently defined will be important.

Increased Inspection Frequencies

What is new? The new legislation includes increased inspection frequencies for all registered facilities, which includes any factory, warehouse, or establishment that manufactures, processes, packs or holds food.

FDA must target inspection resources to high-risk facilities, based on the known safety risks of the food, the compliance history of the facility, the rigor and effectiveness of the facility's hazard analysis and risk-based preventive controls, and if the food or facility has meet certification requirements for imported food.

Domestic high-risk facilities must be inspected at least once in the first five years following enactment and at least once every three years thereafter.

Domestic non-high risk facilities must be inspected at least once in the 7 years following enactment and at least once every 5 years thereafter.

In the first year following enactment, FDA must inspect at least 600 foreign facilities and must double the number of inspections every year compared with the previous year for the next 5 years. Thus, FDA has to inspect 600 foreign facilities in 2011 and increase the number of foreign inspections to 19,000 in 2016.

What will be different? With current resources, it will be nearly impossible for FDA to meet inspection frequencies. The Agency will likely look to other Federal, State, or Local inspectors to assist FDA in meeting the inspection frequency requirements for domestic firms.

The Agency may explore the use of third party auditors to assist with meeting the foreign facility inspection frequency requirements. The legislation authorizes FDA to enter into agreements with foreign governments to facilitate inspection of foreign firms. Foreign firms that refuse an FDA inspection may not be allowed to import product into the U.S.

Who is impacted? This provision will impact all domestic and foreign facilities required to register under section 415 of the Food, Drug and Cosmetic Act. Under the current definition, farms, restaurants, and retail facilities are exempt from the registration requirement. Under the new legislation, FDA must develop regulations defining what constitutes on-farm packing, holding, manufacturing, and processing. Some facilities that are only engaged in specific types of on-farm manufacturing, processing, packing or holding activities that are determined to be low-risk may be exempt from inspection frequency requirements.

What does this mean? Expect to see FDA inspectors, or their representatives in the form of State or Local inspectors more often than in the past. For foreign firms this will have a major impact as FDA ramps up their focus on imported foods.

Mandatory Recall Authority

What is new? The new legislation gives FDA authority to require a mandatory recall of product for which there is a reasonable probability that the product is adulterated or misbranded and will cause a serious adverse health consequence or death. The responsible party must be given an opportunity to voluntarily cease distribution and recall the affected product.

If the responsible party does not voluntarily cease distribution or recall the product, FDA can order them to immediately cease distribution and notify all persons manufacturing, processing, packing, transporting, distributing, receiving, holding, importing, and selling the product to immediately cease distribution of the product. Following the order, FDA will provide the responsible party an opportunity for an informal hearing within 2 days. Failure to comply with the recall order is a prohibited act and the responsible party may be subject to civil penalties.

If FDA confirms that the recall is necessary during the hearing, the Agency will establish a timeframe for the recall and will require submission of periodic reports. If it is determined that the recall is not necessary, FDA will vacate or modify the order.

What will be different? Prior to the new legislation, if a firm refused to recall product, FDA could issue a consumer notification and press informing people not to purchase or consume the product and pursue a court order, in each applicable jurisdiction, to seize the product. Currently, it is rare for a firm to not agree to do a voluntary recall when "pressured" by FDA. The new regulation gives FDA the ability to take action without having to receive prior approval from a court, but likely will only be used in extreme cases.

Who is impacted? This provision will impact registered facilities that manufacture, process, pack, distribute, receive, hold or import food. This provision will not directly impact farms that are not engaged in on-farm packing, holding, manufacturing and processing and are exempt from registering under Section 415 of the Food, Drug, and Cosmetic Act.

What does this mean? This will likely have little direct day to day impact on recalls. The vast majority of recalls occur voluntarily and quickly because no respectable food firm wants to risk making consumers sick. It fills a gap in the current FDA authority that the Agency will use rarely but when they do use it, it will be much faster and easier than the current approach.

Authority to require import certifications for food

What is new? Under Section 303 of the new legislation, FDA may require that imported food be certified to ensure compliance with U.S. laws. Certifications can apply to a specific shipment of food or to a facility that manufactures, processes, packs, or holds food.

The requirement for an article of food to be certified will be based on the known safety risks associated with the food and the known safety risks associated with the country, territory, or region in which the article of food originated. Certification can be required if the food safety programs of the country, territory, or region of origin are found to be inadequate to ensure that food is as safe as a similar article of food that is manufactured, processed, packed or held in the U.S.

Certifications can be provided by a FDA designated agency or representative of the government of the country from which the food originates or a person or entity accredited as a third party auditor.

What will be different? Entry into the U.S. may be delayed until certification is obtained. If it is determined that a food article or facility requires certification.

Who is impacted? Foreign manufacturers, processors, packers, holders and importers will be impacted by this provision.

What does this mean? This new authority potentially gives FDA a great deal more leverage against imported high risk foods. How FDA defines high risk will be important, but will likely include those foods with a history of problems or countries that have consistently had problems controlling the safety of exported foods. This will likely take a little while to gain full effect, despite the immediate authority, but we may see this being used fairly soon for selected foods.