

Section 101: Inspection of records

What is new?

Upon enactment, the new legislation gave FDA additional access to records. 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 a serious adverse health event 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.

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. 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.

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.

Section 102: Registration of food facilities

What is new?

Within six months of enactment, FDA must issue regulations requiring all facilities to register and update their registration every two years on even numbered years. This provision also gives FDA authority to suspend a facility's registration if food is found to present a reasonable probability of causing serious adverse health consequences or death. If registration is suspended, a facility will have to develop and implement a corrective action plan prior to

registration being reinstated. This means that FDA has additional mechanisms to prevent food from reaching consumers when it is not believed to be safe.

Who is impacted?

Anyone who manufactures, processes, packs, distributes, receives, holds or imports food must comply with this provision.

Section 103: Hazard analysis and risk-based preventive controls

What is new?

All registered facilities will be required to conduct a hazard analysis, implement preventive controls and develop a food safety plan to document monitoring, correction, and verification of preventive controls. The food safety plan and all related documents must be made available to FDA during inspections. As part of its food safety plan, a facility may be required to document sanitation procedures, a recall plan, a food allergen control program, supplier verification activities, and environmental sampling testing

FDA will establish science-based standards for conducting a hazard analysis, and implementing and documenting preventive controls.

Who is impacted?

Anyone who manufactures, processes, packs, distributes, receives, holds or imports food must be in compliance with this provision within 1.5 years of enactment. Small and very small businesses will be given additional time to be in compliance with the new requirements.

Under the current definition, farms, restaurants, and retail facilities are exempt from the registration requirement. Currently, farms are defined as a facility devoted to the growing and harvesting of crops for food and/or the raising of animals for food (including seafood). The current definition includes farms that pack, hold, process, or manufacture food, if all of the food is consumed on that farm or another farm under the same ownership. 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 or subject to modified preventive controls requirements. Additional exemptions apply for qualified facilities that sell under \$500,000 of food annually and sell either directly to consumers or to a restaurant or retail establishments that are located in the same state or not more than 275 miles from the facility.

Section 104: Performance standards

What is new?

At least every two years, FDA will review and evaluate relevant data to determine which foodborne contaminants pose the greatest risk and, as appropriate, issue guidance documents, regulations and action levels. Guidance documents should apply to products or product classes, differentiate between food for human consumption and food intended for consumption by animals other than humans and should not be written to be facility specific.

Who is impacted?

Registered facilities who manufacture, processes, pack, distribute, receive, hold or import food will have to take performance standards into consideration when developing, monitoring, and verifying preventive controls. Laboratories should monitor the development of new performance standards as new laboratory methods may need to be validated to assure compliance with new action levels.

Section 105: Standards for produce safety

What is new?

The legislation requires FDA to establish standards for the safe production and harvesting of produce where FDA has determined that standards would minimize the risk of serious adverse health consequences. FDA is required to publish a proposed rule on the minimum standards and publish updated Good Agricultural Practices within one year. The standards should include science-based minimum standards related to soil amendments, hygiene, packaging, temperature controls, animals in the growing area, water, and intentional and unintentional hazards.

Who is impacted?

This provision will impact anyone who produces or harvests fruits and vegetables, including mixes or categories of fruits or vegetables that are considered raw agricultural commodities.

Section 106: Protection against intentional adulteration

What is new?

FDA is to determine vulnerabilities by conducting an assessment of the food system, identifying the costs and benefits of guarding food at vulnerable points, and determining mitigation strategies that are necessary to protect food. FDA will develop a guidance document within one year of enactment that includes a model assessment, examples of mitigation strategies, and specifies situations in which the mitigation strategies are appropriate. Finally, FDA will develop

regulations within 1.5 years that specify how to assess whether a person is required to implement mitigation strategies and specify appropriate mitigation strategies.

Who is impacted?

Requirements for mitigation strategies will only apply to food with a high-risk of intentional contamination, including food where there are clear vulnerabilities, including short shelf-life or susceptibility at critical controls points and food that is in bulk or batch form prior to being packaged for the final consumer.

Section 107: Authority to collect fees

What is new?

The new legislation gave FDA the authority to collect fees upon enactment to cover the cost of reinspections of domestic and foreign facilities and importers to verify corrective actions have been taken to address non-compliances found during the initial inspection, to cover the cost of recall orders, including technical assistance, follow-up effectiveness checks and public notifications, and to cover administrative costs for each importer participating in the voluntary qualified importer program. This provision shifts the responsibility for covering the cost to the responsible party for domestic and foreign facilities and importers.

FDA is required to publish the fee schedule in the Federal Register 60 days prior to each year. Fees collected can only be used for costs related to the specific activity for which they were collected. For the first five years after the establishment of a voluntary qualified importer program, FDA may include a surcharge to the fee to cover the costs expended to establish and implement the first year of the program.

Who is impacted?

Responsible parties for domestic and foreign facilities and importers will be responsible for paying fees, as required, under the new legislation.

Section 111: Sanitary transportation of food

What is new?

The law requires FDA to write the regulations that were authorized by the Sanitary Transportation Act of 2005 and does not provide FDA with any new authorities beyond what was included in the 2005 law. FDA is required to issue regulations to require that shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in transportation of food to use sanitary practices within the next year and half. Specific requirements will be

outlined in the regulation. In addition, FDA is required to conduct a study of transportation of food in the United States, including transportation by air and an examination of the unique needs of rural areas with regard to the delivery of safe food.

Who is impacted?

This provision will impact transporters. Others in the supply chain will also need to be aware of the new regulations, including processors, manufacturers, distributors, and retailers.

Section 201: Targeting of inspection resources for domestic facilities, foreign facilities, and ports of entry, annual report

What is new?

The new legislation includes increased inspection frequencies, effective upon enactment, 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.

With current resources, it will be nearly impossible for FDA to meet inspection frequencies. The Agency likely will 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.

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.

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.

Section 202: Laboratory accreditation for analyses of foods

What is new?

Within two years, FDA must develop a program for laboratory accreditation. The program will have model standards that include sampling and analytical procedures, internal quality systems and training for individuals conducting sampling and analysis. The goal of the program is to increase the number of qualified laboratories. Both domestic and foreign laboratories are eligible for participation and both must meet the model standards.

Who is impacted?

Two and a half years from the date the law was signed, laboratories will be required to be accredited to conduct any regulatory testing.

Section 204: Enhancing tracking and tracing

What is new?

The legislation requires FDA to conduct product tracing pilots in the processed food and produce sectors within 270 days of enactment. Within 18 months, FDA must provide Congress with a report on recommendations for establishing more effective product tracing, including consideration of costs and benefits, feasibility of technologies for different sectors, existing practices, and international efforts. Using the information gathered, FDA is directed to create, as appropriate, a product tracing system.

In addition, within one year, FDA is to develop and to publish a list of high-risk foods. Criteria for determining which foods are designated as high-risk includes: the known safety risk of a

particular food, likelihood of microbiological or chemical contamination, location in the manufacturing process, and likelihood that consuming the food will result in a foodborne illness.

Within two years, FDA must begin developing regulations for additional record-keeping requirements for high-risk food. The regulation must relate only to information that is reasonably available, consider cost and public health benefit, be scale-appropriate and similar across commodities, and should not prescribe specific technologies. It also may not require a full pedigree, may not require a record of the recipient of food beyond the immediate subsequent recipient, and may not require product tracking to the case level.

Who is impacted?

All registered facilities that manufacture, process, pack, distribute, receive, hold or import food will be required to comply with new recordkeeping requirement. Farms will be exempt from the new recordkeeping requirements for high risk food if the package maintains the integrity of the product and prevents subsequent contamination, and the food is labeled with the name, complete address, and business phone number of the farm. The legislation provides FDA authority to request that farms identify immediate recipients, other than consumers, during an active investigation or when deemed necessary to protect public health.

Section 206: Mandatory recall authority

What is new?

The new legislation gave 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 upon enactment. 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.

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.

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.

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.

Section 207: Administrative detention of food

What is new?

Within 180 days, FDA may utilize administrative detention for food where there is a "reason to believe" that the food is adulterated or misbranded. Currently, administrative detention can only be utilized when there is "credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals." The new legislation lowers the bar for FDA to use administrative detention. FDA will be able to take a more aggressive regulatory approach when importers fail to ensure the safety of the product they attempt to bring into the U.S.

Who is impacted?

This provision will impact anyone who manufactures, processes, hold, packs, distributes, or imports food into the U.S.

Section 211: Improving the reportable food registry

What is new?

Registered facilities will be required to submit consumer-oriented information regarding a reportable food, including a description of the food, affected product identification codes (UPC,

SKU, lot, or batch numbers) that are sufficient for the consumer to identify the article of foods and contact information for the responsible party.

The new law requires FDA to publish Reportable Food Registry notifications to their website in a format that can easily be printed by a grocery store for consumer notification. Grocery store chains (15 or more physical locations) will be required to print and post notifications for products carried, within 24 hours of notices posting to FDA's website, in a prominent location for 14 days. Within one year of enactment, FDA will develop and publish a list of acceptable locations for providing notifications.

Who is impacted?

This provision will impact registered facilities that are required to submit reports to the Reportable Food Registry.

Grocery stores will be responsible for monitoring the FDA website and posting alerts for consumer notification when they carry an affected product.

Section 301: Foreign supplier verification program

What is new?

Within two years, importers will be required to perform risk-based foreign supplier verification to ensure that all imported food is produced in a compliance with the preventive control requirements, the produce safety standards, and other U.S. laws and regulations.

FDA is required to issue guidance within one year to assist importers in developing verification programs and issue a regulation within one year that outlines the requirements for verification programs.

This provision shifts the burden to the importers to confirm that they are only offering food that is in compliance with U.S. laws and regulations. Importers will need to have to know and verify the food safety practices of their supply chain. Offering food for import without a verification program in place may result in injunction or criminal prosecution.

Without a verification program in place, importers will not be able to bring product into the United States. If importers wait to begin designing and implementing the foreign supplier verification program until FDA issues the regulation, it will be very difficult to be in compliance one year later when the rule takes effect.

Who is impacted?

This provision will directly impact the importer, defined as the U.S. owner or consignee of the article of food at the time of entry or the U.S. agent or representative of a foreign owner or consignee of the article of food.

The increased accountability on importers will result in importers putting increased pressure on foreign facilities and increased use of third party audits to ensure that food is produced in accordance with U.S. laws and regulations.

Section 302: Voluntary qualified importer program

What is new?

The development of a “green lane” for imports may be the silver lining in what otherwise is some significant new requirements for importers. The concept of the green lane is to provide those importers who are “doing things right” to have an expedited entry process for imported foods. Within one and a half years, FDA is required to establish a program that would provide expedited review of food from importers who participate in the voluntary program and import food from facilities that have been certified by a third party auditor. Specific requirements for participation will be outlined in a FDA guidance document. At this stage there are no details available but we believe this program will go beyond the basic compliance with the importer accountability requirements and possibly include components focused on best practices.

Importers who are eligible and volunteer to participate in the program will be able to expedite entry into the U.S. by gaining access to the “green lane.” To be eligible for expedited entry, importers will need to apply to the program and pay a fee to cover the administrative costs of participation. Importers can use third-party auditors to verify the facilities are producing food are in compliance with U.S. laws and regulations. At a minimum, the combination of a qualified importer and product from a certified facility will be necessary to expedite entry.

Importers should closely watch the development of the voluntary qualified importer program and the third party certification program to gain insight into the eligibility requirements for facilities to be certified for participation in the program. Watching the development of the programs and responding as specific requirements are known will put importers in the best position to ensure that they are eligible to participate in the program and will be able to immediately expedite product into the U.S.

Who is impacted?

This provision will directly impact importers. Foreign facilities and third-party auditors will also be impacted by the implementation of the voluntary qualified importer program.

Section 303: 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. Entry into the U.S. may be delayed until certification is obtained If it is determined that a food article or facility requires certification.

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.

Who is impacted?

Foreign registered facilities, including manufacturers, processors, packers, and holders and importers will be impacted by this provision.

Section 304: Prior notice of food shipments

What is new?

Within 180 days of enactment, importers will be required to disclose to FDA if the food offered for import was refused by any other country as part of the prior notice requirements.

Who is impacted?

Importers need to be aware of this new requirement.

Section 307: Accreditation of third-party auditors

What is new?

The legislation requires FDA to establish a program to recognize accreditation bodies and third-party auditors. Third-parties can be a foreign government or a private entity. Third-party audit certifications will be used to ensure that the product offered for import is in compliance with U.S. laws and regulations and to determine if a facility is eligible to offer food for import under the voluntary qualified importer program.

FDA will be looking for outside parties to assist in providing coverage of the food supply, particularly in the foreign arena. Importers will need to be familiar with the program FDA develops for third-party auditors and the standards to which they certify. Third-party auditors will be an essential resource for importers to both verify that their supply chain is in compliance with U.S. laws and regulations and to enable participation in the voluntary qualified importer program.

Who is impacted?

This provision will impact third-party auditors, registered facilities, and importers.