



FDA Food Safety Modernization Act of 2010 *Likely Impact on the Produce Industry* January 2011

Background

On December 21, 2010 Congress passed S.510 (renamed as H.R. 2751) the FDA Food Safety Modernization Act of 2010. The President signed the bill into law on January 4, 2011 [[P.L. 111-353](#)]. This legislation represents the first comprehensive reform of U.S. food safety laws since the Federal Food, Drug and Cosmetic Act was enacted in 1938. Implementing this law will require over a dozen separate rulemakings and at least 10 guidance documents. The implementation of the legislation will take more than three years.

In general, the Food Safety Modernization Act of 2010 is designed to shift food safety regulation to prevention, rather than control or investigation after a problem is found. Companies will be required to develop preventive food safety controls, and share these plans with the FDA. In addition, the law overall supports a risk-based approach to regulation, encouraging FDA to focus on those areas of greatest risk.

This White Paper provides a brief summary of the legislation and how the law will likely impact the produce supply chain, including grower-shippers, processors and wholesalers, importers, retail and foodservice operations. For any questions, please contact Robert Guenther, senior vice president for public policy, at rguenther@unitedfresh.org.

Impact on Produce Grower-Shippers

Produce Safety Standards

Within a year of the bill's enactment, FDA, in consultation with USDA, state departments of agriculture, and the Secretary of Homeland Security, is required to publish a proposed rule establishing "minimum science-based standards for those types of fruits and vegetables, including specific mixes or categories of fruits or vegetables, that are raw agricultural commodities, based on known safety risks, which may include a history of foodborne illness outbreaks." FDA is instructed to prioritize regulations for fruits and vegetables that have been associated with foodborne illness outbreaks.

The wording of this section of the law is intended to direct FDA attention to specific commodities based on risk. This was a major goal of United Fresh efforts in Congress, and now FDA must be held to this Congressional intent rather than applying broad-brush one-size-fits-all regulations. In addition, any produce regulations are directed to provide sufficient flexibility and be appropriate to the scale and diversity of the production and harvesting of such commodities.

When necessary under the terms above, the law requires produce standards to address growing, harvesting, sorting, packing and storage operations, through the development of science-based minimum standards related to soil amendments, hygiene, packaging, temperature controls, animals in the growing area, and water.

Within a year of the bill's enactment – January 2012 – FDA must publish a new Guidance Document for Good Agricultural Practices, another indication of Congressional intent that regulations are not intended for all fruit and vegetable commodities in the same way as guidance. FDA is required to hold at least three public meetings to conduct education and outreach regarding the guidance.

FDA must also permit states and foreign governments to seek variances from the requirements if they can demonstrate equivalency of food safety protection, another provision actively supported by United Fresh because of differences in growing regions and state regulatory initiatives. Finally, FDA must provide for coordination of education and enforcement activities with USDA, states and local governments, thus providing greater on-farm expertise and awareness of produce growers' needs and practices.

During the proposed rulemaking comment period, FDA will be required to conduct at least three public meetings in diverse geographical areas. A final rule must be published within a year after the closing of the comment period on the proposal.

Flexibility for Small Farms

The effective date for small businesses and very small businesses will be 1 year and 2 years, respectively, from the date of completion of this regulation.

FDA has the authority to modify the requirements or exempt small and very small businesses, if the agency determines that their production constitutes low risk fruits and vegetables.

FDA is required give flexibility to different types of entities including farms that sell directly to consumers, as well as consider conservation practices and organic production requirements.

For very small farms, there would be a limited exemption from produce safety standards. United Fresh strongly opposed this provision, known as the "Tester Amendment," as food safety risk is not related to size or geography. While a clearly egregious principle, the exemption is narrow:

- The limited size is for annual sales (3 year average) of less than \$500,000.
- The limited scope of distribution is either intrastate or within a 275 mile radius (includes Canadian or Mexican imports).
- A majority of the distribution must be directly to qualified end-users – directly to consumers or directly to restaurants or retail food establishments (i.e., not through distributors).
- The product label (if it has one) must include the name/place of business, or if no label, this information must be provided in a written placard at retail sale or some other suitable means.
- The exemption can be withdrawn by FDA, on a facility basis, if the agency has reason to believe food from such a producer may be contaminated.

Impact on Processors, Wholesalers, and Distributors

Registration of Facilities

Starting 180 days after enactment, food facilities, both domestic and foreign, are required to register with FDA every two years. There will be an “abbreviated registration renewal” for those facilities reporting no changes. FDA has the authority to adjust food registration categories. FDA also has the authority to require registration in electronic format, but not before five years after enactment of the bill.

Preventive Controls/Food Safety Plans

Within 18 months, FDA must promulgate regulations establishing minimum standards for the effective implementation of preventive control requirements, sometimes known as food safety plans, for each registered facility. FDA must review existing domestic and international standards to ensure consistency with such standards, as appropriate.

Under the new regulation, each registered facility would be required to conduct a hazard evaluation to identify known or reasonably foreseeable hazards,” including “biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, decomposition, parasites, and unapproved food and color additives,” and “hazards that occur naturally or may be unintentionally introduced” as well as hazards that “may be intentionally introduced, including by acts of terrorism” and implement preventive controls (including at critical control points, if any) to provide assurances that the identified hazards would be significantly minimized or prevented. Preventive controls expressly include the following controls:

- Sanitation
- Training
- Environmental controls
- Allergen controls
- Recall contingency plan
- Good Manufacturing Practices (GMPs)
- Supplier verification activities

Each facility will be required to monitor the controls; establish corrective actions; and maintain records of monitoring, instances of nonconformance, and corrective actions taken. Also, such plans must have action steps to ensure that if the controls are not properly implemented or are found to be ineffective, that all affected food is evaluated and prevented from entering commerce if it cannot be ensured that it is not adulterated. Finally, there must be verification steps that the plan is working, including the use of environmental and product testing programs.

A written hazard evaluation and identification of preventive controls must be made available to FDA during an inspection, along with documentation that the plan is being implemented. A hazard re-evaluation is required at least every three years or when a significant change is made in the activities conducted at a facility. The re-evaluation must be completed before the change in activities begins.

Within nine months, FDA is required to issue a proposed rule clarifying the on-farm activities that would require facility registration (such as potentially a packing shed handling multiple growers’ products). FDA is directed to conduct a science-based risk analysis of such activities and exempt certain small facilities engaged in low-risk activities from the preventive controls requirements and inspection frequency. FDA is required to issue a final rule within nine months of the close of the comment period for the proposed rule.

Flexibility for Small Business

The regulations must provide sufficient flexibility to small businesses, comply with the Paperwork Reduction Act, and not require any facility to hire a 3rd party to identify, implement, or audit preventive controls. FDA is required to issue a Small Entity Compliance Guide (SECG) within 180 days of enactment.

FDA must define, by regulation, "small business" and "very small business" after conducting a study. The effective date for small businesses and very small businesses would be six months and 18 months, respectively, from the date of completion of this regulation. The section excludes the following "facilities"

- Warehouses that store raw agricultural commodities other than fruits and vegetables intended for further processing or distribution, and pet food manufacturers, at FDA's discretion;
- Those facilities subject to the Produce Standards section on the safety of fruits and vegetables;
- Those facilities subject to other FDA HACCP or analogous regulatory programs, such as seafood, juice and low acid canned foods;
- Dietary supplements;
- Alcohol related facilities.

For very small businesses that manufacture, process, pack or hold food, the bill would exempt qualifying very small businesses from the preventive controls requirements, based on limited size and limited scope of distribution. This is also based on provisions of the Tester Amendment, which United Fresh strongly opposed. While equally egregious as the produce exemption, the exemption for food facilities is also narrow:

- The facility is still subject to the registration requirement.
- The limited size is for annual sales (three-year average) of less than \$500,000.
- The limited scope of distribution is either intrastate or within a 275 mile radius (includes Canadian or Mexican imports).
- A majority of the distribution must be directly to consumers or directly to restaurants or retail food establishments (i.e., not through distributors).
- The product label (if it has one) must include the name/place of business, or if no label, this information must be provided in a written placard at retail sale or some other suitable means.
- To qualify, the facility must submit to FDA either: (a) documentation that it is applying preventive controls; or (b) documentation that it is in compliance with state, local or other non-Federal requirements.
- The exemption can be withdrawn by FDA, on a facility basis, if the agency has reason to believe food from such a producer may be contaminated.

Inspection Frequency

FDA is required to adopt a risk-based approach to inspections of facilities taking into account the known safety risks of the food, the history of recalls at the facility, the rigor of the facility's preventive controls plan, whether the food may be subject to intentional adulteration. High risk facilities would be subject to inspection once in the first five years after enactment and then at least once every three years. Low risk facilities would be subject to inspection at least once in the first seven years after enactment and then at least once every five years. To meet this requirement, FDA could rely on inspections conducted by other Federal, state or local agencies.

Record Keeping and Records Access

Effective immediately without additional regulation, if FDA has a reasonable belief that an article of food presents a threat of serious adverse health consequences or death, FDA now has access to and authority to copy all records relating to such article of food and any "other article of food" that "the Secretary reasonably believes is likely to be affected in a similar manner." This provision extends FDA's authority for records access from only a potentially contaminated food product to most likely include all food produced on the same manufacturing line or potentially in the same facility.

Suspension of Registration

FDA has the authority to suspend the registration of any facility if FDA determines that food manufactured, processed, packed or held by that facility "has a reasonable probability of causing serious adverse health consequences or death" and the facility was responsible for the adulteration or, in the case of facilities that merely pack, receive or hold food, the facility knew or had reason to know that the food presented a reasonable probability of causing serious adverse health consequences or death." This, in effect, provides FDA authority to shut down a facility.

Informal hearings to challenge a suspension determination would be permitted. The power to suspend registration, and authority to hold an informal hearing, are assigned strictly to the FDA Commissioner and could not be further delegated. Following such hearings, the Commissioner could either vacate the order or require the submission of a corrective action plan before lifting the suspension. Any facility with a suspended registration would be prohibited from introducing food into interstate commerce.

FDA is required to promulgate regulations describing the standards used in deciding to suspend a registration.

Impact on Fruit and Vegetable Importers

Foreign Supplier Safety Assurance Program

Each importer of food (defined as the owner of the food at the time of entry into the United States) will be required to have in place a program to verify that its imported food is produced in accordance with U.S. requirements (including the new preventive controls and produce standards), is not adulterated and does not contain an undeclared allergen. The importation of food without a foreign supplier safety assurance program is prohibited.

FDA will be required to issue guidance on the development of foreign supplier verification programs and promulgate regulations regarding the content of these programs. Regulations will establish the process for verification by a U.S. importer for each relevant foreign supplier. Related records will be required to be maintained for two years and made available upon request. An exemption is provided for importers of seafood, juice, and low-acid canned foods required to comply with existing HACCP based regulations, which already include specific requirements for importers. FDA is required to publish a notice in the Federal Register exempting research samples and food for personal consumption.

Expedited Entry

FDA is required to establish, in consultation with the Department of Homeland Security, a program for expedited review and importation of products from importers voluntarily participating in a qualified importer program. Importers that wish to participate will be required to provide notice and an application to FDA. Eligibility for the program will require consideration of the nature of the food, third-party certification, risk of intentional adulteration of the food, compliance history of the foreign supplier, exporting country's capability for ensuring compliance with U.S. standards, compliance with the foreign supplier verification program, and recordkeeping, testing, facility inspections and audits, traceability, temperature controls, and sourcing practices of the importer. FDA will be required to reevaluate importers qualified under this program every three years. FDA will establish a user fee for this program.

Third Party Certification

FDA is authorized to use third-party certification of imported foods, based upon its determination of risks associated with the type of food or its place of origin, or a finding by FDA that the food safety system of the country of origin is inadequate. If FDA does determine that the food safety system of a foreign region, country or territory is inadequate, FDA would be required to identify the inadequacies and establish a process for the foreign government to inform the agency of improvements to its program.

These certifications or assurances could be provided in the form of shipment-specific certificates, a listing of certified entities, or in other form specified by FDA. FDA could require that certifications be renewed as deemed appropriate and refuse to accept certifications it deems no longer valid. The requirement for such certification would not prevent the FDA from conducting random checks of the covered imports.

FDA is authorized to implement a system whereby (a) it would recognize accrediting bodies that operate in accordance with established standards, rather than carrying out that function itself (however, if FDA hasn't recognized an accreditation body in two years, FDA would be able to directly accredit third-party auditors); (b) the accreditation bodies would then evaluate and accredit third-party auditors; and, (c) the third-party auditors would certify that foreign facilities meet the requirements of the Act. This program can apply to imported foods only.

As a condition of accreditation, an auditor would be required to agree to issue a written and electronic certification to accompany each food shipment made for import from a facility certified. Such certificates would be considered by FDA when targeting inspection resources. Certification would be required to participate in the Voluntary Qualified Importer Program.

FDA would be authorized to monitor auditors, conduct its own inspections, and review inspection reports generated by auditors. The agency would also publish a public list of accreditation bodies and accredited third-party auditors.

FDA would be required to issue regulations regarding conflicts of interest, including a requirement that audits be unannounced. In addition, false statements to auditors would be considered a criminal act. Auditors would be required to immediately notify FDA upon discovering "a condition that could cause or contribute to a serious risk to the public health."

FDA could withdraw accreditation from an auditor if food from a facility it certifies is linked to an illness outbreak, if the auditor no longer meets requirements, or following a refusal to allow U.S. officials to conduct necessary audits.

Foreign Inspectors & Capacity Building

FDA is authorized to enter into agreements with foreign countries to facilitate the inspection of registered foreign facilities and require that inspection resources be directed to those facilities that present the highest risk. By October 1, 2011, FDA must submit a report to Congress describing the process and progress in establishing offices in foreign countries.

Within two years of enactment, FDA is required to develop a plan to expand the technical, scientific, and regulatory capacity of foreign countries exporting food to the United States. Reflecting consultation with other government agencies, the plan would include recommendations for bilateral or multilateral agreements, provisions for electronic data sharing, provisions for mutual recognition of inspection reports, training of foreign governments and producers, recommendations for harmonization with Code Alimentarius, and provisions for multilateral acceptance of laboratory methods and detection techniques.

During 2011, the first year after enactment, FDA is required to inspect at least 600 foreign facilities. Thereafter, FDA is required to double the number of inspections of foreign facilities every year for five years.

Impact on Retail and Food Service

Notice Posted in Retail Stores of Reportable Foods

When companies report cases of contaminated food to the FDA Reportable Food Registry, even without a recall or other action required, the Agency is now authorized to require that companies submit a description of the food, the affected product identification codes, and contact information for the responsible party. FDA is required to publish this information in a standardized one-page summary on the FDA website. If a 15-store or greater grocery chain sold such food, then the store would be required to prominently display the summary within 24 hours for 14 days.

FDA is required to develop a list of acceptable locations in which grocery stores can provide the notification. These would include posting near the register, the location of the reportable food, or through providing targeted recall information to consumers at purchase. The knowing and willful failure to comply with this requirement is prohibited.

Impact on Food Transporters

Sanitary Transportation of Food

Within 18 months of enactment, FDA is required to promulgate regulations regarding the sanitary transportation of food. FDA is also directed to study the transportation of food, including an examination of the unique needs of rural areas.

General Provisions of the Law Applicable to All Sectors

Mandatory Recall Authority

FDA is immediately granted mandatory recall authority if a company refuses to voluntarily recall a product for which “there is a reasonable probability” that the food is adulterated or contains an undeclared food allergen and consumption of the food will cause “serious adverse health consequences or death.” Procedures will be established for informal hearings on mandatory recall orders. Only the FDA Commissioner has direct authority to issue a mandatory recall order.

FDA is directed to consult USDA policies in determining whether to publish a public list of retail consignees involved in a Class I recall.

FDA is required to publish on the web a picture of a recalled food. The agency is required to establish a web-search engine to allow consumer access to search information regarding foods that are subject to a recall.

FDA is required to establish an incident command operation that would operate within 24 hours of the initiation of a class I recall, regardless of whether the recall was mandated or conducted voluntarily. Additionally, FDA is required to provide an annual report to Congress identifying when the agency used the mandatory recall authority and the circumstances by which the agency concluded that the situation warranted use of such authority.

Failure to comply with a recall order would trigger a civil money penalty, and would constitute a prohibited act for which criminal penalties are provided under existing law.

The Government Accounting Office (GAO) is directed to provide a report to Congress within 90 days of enactment reviewing state and federal mandatory recall authority and the mechanisms available to compensate parties for wrongfully ordered recalls. Within 90 days of the report, USDA would be directed to conduct a study on the ability to implement a farmer restitution program, in the event of a wrongful food recall that harms farmers.

Traceability Provisions

Within nine months of enactment, FDA is required to conduct pilot projects, in cooperation with the applicable food sector, to explore methods to improve the tracking and tracing of food. FDA must conduct one or more separate pilot projects for: (a) packaged food; and (b) fruits and vegetables that are raw agricultural commodities.

FDA is required to conduct additional data gathering to assess the cost and benefits associated with adoption of product tracing technologies, the feasibility of such technologies for different food sectors, and whether such technologies are compatible with the statutory requirements for this section. FDA is also required to evaluate domestic and international product tracing practices in commercial use, consider international efforts, and consult with a diverse and broad range of experts and stakeholders.

Within one year of enactment, the GAO is required to submit a report to Congress evaluating the benefits and risks of limiting product tracing requirements to high-risk foods, and of limiting the participation of restaurants.

Within 18 months of enactment, FDA must report to Congress on the findings of the pilot projects together with recommendations for improving the tracking and tracing of food. At that time, FDA is authorized to “establish within the Agency a product tracing system to

receive information that improves the capacity to effectively and rapidly track and trace food that is in the United States or offered for import into the United States.

Within two years of enactment – January 2013 – FDA is required to issue a notice of proposed rulemaking to “rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak,” specifically applicable only to high-risk foods as defined by the Agency. In determining whether a food is high-risk for these purposes, FDA is directed to evaluate the history of outbreaks attributed to the food, likelihood of contamination, and steps taken during manufacturing to reduce the likelihood of contamination. FDA is directed to determine within one year of enactment what are determined to be “high-risk” foods under this provision.

Additional requirements for “high-risk” foods are defined by statute. Such proposed requirements would (1) be required to be science based; (2) ensure that the public health benefits outweigh the costs of compliance; (3) not require use of specific technologies; (4) not require the full pedigree, or record of previous distribution history of a food; (5) not require records of recipients of food beyond the immediate subsequent recipient; (6) not require product tracking to the case level; (7) be scale appropriate; (8) maintain records at a central location, available to FDA within 24 hours; (9) be commensurate with known safety risks of the food; (10) take into account international trade obligations; (11) minimize the number of different requirements for facilities that handle more than one type of food; and (12) ensure that FDA has procedures in place to protect trade secret or other confidential information.

During an active investigation of a foodborne illness outbreak, FDA is authorized to direct that a farm identify potential immediate recipients of the food that is the subject of the investigation.

Foodborne Illness Surveillance Systems

The Centers for Disease Control and Prevention is directed to enhance foodborne illness surveillance systems to improve the collection, analysis, reporting, and usefulness of data on foodborne illnesses by— (A) coordinating Federal, State and local foodborne illness surveillance systems; (B) facilitating sharing of surveillance information on a more timely basis among governmental agencies; (C) developing improved epidemiological tools for obtaining quality exposure data and microbiological methods for classifying cases; (D) augmenting such systems to improve attribution of a foodborne illness outbreak to a specific food; and other such methods.

CDC and FDA are also directed to support and maintain a diverse working group of experts and stakeholders from Federal, State, and local food safety and health agencies, the food and food testing industries, consumer organizations, and academia. Such working group shall provide the Secretary advice and recommendations on an ongoing basis regarding the improvement of foodborne illness surveillance, opportunities to improve coordination among Federal, State, and local levels of government; and improvement in the timeliness and depth of access by regulatory and health agencies, the food industry, academic researchers, and consumers to foodborne illness aggregated, de-identified surveillance data.

Education and Training

FDA is required to set standards and administer training and education programs for state and local food safety officials. FDA is authorized to use such employees to conduct inspections and investigations.

Within 180 days of enactment, FDA is required to enter into a memorandum of understanding with USDA to establish a competitive grant program to provide food safety training, education, extension, outreach, and technical assistance to owners and operators of farms; small food processors; and small fruit and vegetable merchant wholesalers. FDA also is authorized to make grants to states and localities, as well as nonprofit food safety training entities that partner with an institution of higher education, to undertake training.

Protection Against Intentional Contamination

Within 18 months after enactment, FDA is required to promulgate specific additional regulations to protect food against intentional adulteration, although preventive controls and produce standards must also address intentional contamination. These additional regulations would apply only to food in bulk or batch form, prior to being packaged for the final consumer, for which FDA has identified clear vulnerabilities that there is a high risk that intentional adulteration could cause serious adverse health consequences or death. To make these determinations, FDA will be required to conduct vulnerability assessments of the food system taking into consideration risk assessments by the Department of Homeland Security (DHS), consider risks and costs, and determine the types of science-based strategies necessary for protection. Within a year of enactment, FDA is required to issue guidance documents related to protection against intentional adulteration of food. FDA and DHS can determine the time, manner and form in which the guidance documents are made public.

Laboratory Testing

FDA is required to provide for the recognition of accreditation bodies that accredit laboratories – including independent private laboratories and laboratories operated by a Federal agency -- and to establish a publicly available registry of recognized accreditation bodies and accredited labs. As a condition of inclusion in this registry, accreditation bodies would have to require laboratories meet certain model standards developed by FDA. Foreign laboratories that meet these standards are also eligible for accreditation. FDA is required to reevaluate all recognized accreditation bodies every five years and to revoke recognition if warranted. FDA is directed to work to increase the number of accredited labs.

Within 30 months of enactment – July 2014 – either federal labs or labs accredited by an accreditation body on FDA's registry would be required to be used for all food testing in support of admission of an imported food, as required by specific regulations (but only when used to address an identified or suspected food safety problem), as required by an Import Alert, or as otherwise deemed appropriate by FDA (also to meet an identified or suspected food safety problem). Test results must be provided directly to FDA, although the Agency could, by regulation, exempt certain test results from the requirement that they be submitted directly to the Agency. Also, FDA can waive the required use of an accredited lab if new methodologies have been developed and validated and are necessary to protect the public health during a foodborne illness outbreak, but a laboratory has not yet been accredited to use such methodologies. If the testing of food by a state-run lab results in a state recall of a particular food, FDA is required to review the sampling and testing results to determine the need for a national recall.

Reference Chart
Food Safety Modernization Act
Summary of key changes impacting produce industry



Produce Industry Sector	What is new?	What will be different?	What does this mean?	Implementation Timeline
Grower-Shippers	<ul style="list-style-type: none"> Mandatory Produce Safety Standards. (Sec. 105) 	For the first time, FDA will develop mandatory standards for produce	Once regulations are adopted by FDA, farms who grow fruits and vegetables subject to produce standards, would be in violation of law if they did not adhere to the FDA standards.	1 year after enactment for proposed rule. 1 year after close of comment period
Fresh-cut Processors, Wholesalers, Distributors	<ul style="list-style-type: none"> Registration of facility every two years. (Sec. 102) Requires food facilities to develop and implement preventive control standards. (Sec. 103) Creates a risk-based inspection frequency program for food facilities. (Sec. 201) FDA would have access to records associated a food that may be part of an outbreak investigation or 	<p>Current law requires and initial registration of facilities and requires updates on any changes to facility</p> <p>This provision will require food facilities subject to this section to have a written food safety plan. This plan will be subject to inspection by FDA. The plan will need to be analyze and rewritten (if necessary) every 3 years.</p> <p>Current law gives FDA the authority to inspect facilities but the frequency of inspections is not established.</p> <p>Prior to the new legislation, FDA could only access records relating to articles of food believed to be</p>	<p>Fresh-cut processors and wholesalers must reregister with FDA every two years.</p> <p>It will require facilities to evaluate hazards, implement and monitor preventive controls, maintain records of monitoring and take corrective actions for any nonconformance.</p> <p>The law requires federal inspection of high-risk facilities once in the first five years of enactment and then once every three years. For low-risk facilities, an inspection must be conducted within seven years of enactment and then once every 5 years. FDA could use other federal, state, or local agencies to comply with this requirement.</p> <p>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</p>	<p>Up to 180 days after enactment</p> <p>18 months after enactment</p> <p>Upon enactment</p> <p>Upon enactment</p>

Produce Industry Sector	What is new?	What will be different?	What does this mean?	Implementation Timeline
	<p>any other article of food that is likely to be affected in a similar manner. (Sec.101)</p> <ul style="list-style-type: none"> FDA could suspend the registration of any facility there was reasonable probability that food from the facility could cause serious adverse health consequences to humans or animals. (Sec. 102) 	<p>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.</p> <p>New authority for FDA that is similar to USDA authority for meat and poultry. Allows for FDA to suspend a facility from shipping food products if FDA suspends registration.</p>	<p>of food will cause a serious adverse health event or death, and exactly how that is subsequently defined will be important.</p> <p>Basically allows a tool to quickly shut down a facility that is seen as having unsafe or unsanitary conditions. By suspending the registration, the facility would not be allowed to ship food products. Allows for informal hearing with FDA for facility owner.</p>	<p>Up to 180 days after enactment</p>
<p>Fruit and Vegetable Importers</p>	<ul style="list-style-type: none"> Requires importers to perform risk-based foreign supplier verification to verify that imported food is produced in compliance with applicable U.S. laws and is not adulterated or misbranded. (Sec. 301) Requires FDA to establish a voluntary qualified importer program. (Sec. 107) Authorizes FDA to require imported food to have a certification of compliance with applicable requirements. (Sec. 303) 	<p>There are currently no specific requirements for importers of food to establish a verification plan. However, food brought into this country must comply with all U.S. food safety standards.</p> <p>This would be a new program established by FDA that would allow for expedited entry of foods by importers.</p> <p>Certification may be required, based on consideration's, including risk associated the type of food or its place of origin, or</p>	<p>Importers will need to develop a program that verifies its imported food meets all U.S. food safety standards and is not adulterated.</p> <p>Importers who wished to participate in this program would be required to apply for participation with FDA. To be eligible would require third-party certification, consideration of a number of factors related to food safety programs of the foreign supplier, the country that the food originates from, the risk of intentional contamination.</p> <p>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</p>	<p>Guidance and regulation 1 year after enactment. Final rule is effective 2 years after enactment.</p> <p>Guidance 1 year after enactment. Final program 18 months after enactment.</p> <p>Upon enactment</p>

Produce Industry Sector	What is new?	What will be different?	What does this mean?	Implementation Timeline
		a finding by FDA that the food safety system of the country of origin is inadequate.	likely include those foods with a history of problems or countries that have consistently had problems controlling the safety of exported foods.	
Retailers and Food Service	<ul style="list-style-type: none"> The new law requires additional information to be submitted to the reportable food registry that impacts retailers. (Sec. 211) 	Will require responsible party to include additional information to reportable food registry including a description of the food, the affected product identification codes, and contact information for the responsible party. FDA would be required to publish this information and retail stores that sold such food (and have more than 15 stores in the chain) would need to prominently display this summary in their stores for 14 days.	FDA will be required to now create documents that retail food stores can download and display in their stores based on information on the reportable food registry. Where this information is posted and how it impacts perishable food such as fruits and vegetables will be determined in rulemaking.	Final regulation within 18 months of enactment.
Food Transporters	<ul style="list-style-type: none"> FDA is required to develop new regulations for the safe transportation of food. (Sec. 111) 	This is a date specific requirement that FDA must issue new regulations on the transportation of food.	In 2005 Congress passed the Safe Food Transportation Act. In April of 2010, FDA issued an ANPRM regarding regulations for this act. This new law requires these regulations to be implemented within 18 months.	Final regulation within 18 months of enactment.
General Provisions	<ul style="list-style-type: none"> 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. (Sec. 206) 	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.	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	Upon Enactment

Produce Industry Sector	What is new?	What will be different?	What does this mean?	Implementation Timeline
	<ul style="list-style-type: none"> <li data-bbox="468 321 858 521">Requires FDA to pilot tracing systems, consider establishing a product tracing program, and expand record keeping requirements for high-risk foods. (Sec. 204) <li data-bbox="468 699 858 813">Requires FDA to develop guidance and regulation to protect against intentional contamination. (Sec. 106) 	<p data-bbox="879 321 1230 493">This would establish a new requirement under food safety law that would allow FDA to mandate tracking and tracing programs for particular food products.</p> <p data-bbox="879 699 1230 899">This will change current law to require FDA working with DHS to conduct a threat risk-assessment to identify vulnerabilities for intentional contamination in the food supply.</p>	<p data-bbox="1251 261 1583 289">than the current approach.</p> <p data-bbox="1251 321 1661 548">For fresh produce, we can expect that certain fruits and vegetables to be identified as high-risk and therefore fall under these requirements. PTI would likely be in compliance with any mandatory standards that would be required.</p> <p data-bbox="1251 699 1661 922">Once the threat assessment if completed, guidance and then regulation will be developed that will require some level of attention through the distribution chain, including at retail level, to address and mollify intentional contamination threats.</p>	<p data-bbox="1692 321 2024 662">Pilot programs 180 days after enactment; Publishing of high-risk foods 1 year after enactment; Notice for proposed rulemaking for additional record keeping requirements 2 years after enactment; and FDA establishment of product tracing system no specific deadline.</p> <p data-bbox="1692 699 2024 781">Guidance 1 year after enactment. Regulation 18 months after enactment.</p>

Reference Chart
Food Safety Modernization Act
Timeline for Regulatory Implementation



Section	Upon Enactment	180 Days	270 Days	1 Year	1.5 Years	2 Years	2.5 Years	Other
Sec. 101. Inspection of Records: Expands FDA access, up request to all records relating to an article of food and all records relating to any food that is likely to be affected in a similar manner, when there is a probability that the use or exposure to the food will cause serious adverse health consequences or death to humans or animals.	X							
Sec. 102. Registration of Food Facilities: Requires biennial facility registration renewal on even number years, give secretary the authority to suspend registration if there is a reasonable probability of serious health consequences or death.	X							
<ul style="list-style-type: none"> Food Facilities subject to new requirements 		X						Or upon FDA Issuance of regulation, if before 180 day
<ul style="list-style-type: none"> FDA may require electronic submission 								5 Years
Sec. 103. Hazard analysis and risk-based preventive controls: Requires registered facilities to evaluate hazards, implement preventive controls, monitor the performance and effectiveness of preventive controls, and maintain records, including a written plan, on hazards and preventive controls								
<ul style="list-style-type: none"> In general, requirements for Section 103 take effect 					X			Small + 6 months from effective date of regulation Very small + 18 months from effective date of regulation
<ul style="list-style-type: none"> FDA to establish science-based standards for conducting a hazard analysis, implementing preventive controls, and documenting implementation of preventive controls and to define "small" and "very small" businesses 					X			
<ul style="list-style-type: none"> FDA to publish a Notice for Proposed Rulemaking (NPRM) on activities that constitute on-farm packing, holding, 			X					

Section	Upon Enactment	180 Days	270 Days	1 Year	1.5 Years	2 Years	2.5 Years	Other
• FDA publish guidance				X				
• FDA publish regulation				X				
• Effective Date						X		
Sec. 302. Voluntary qualified importer program: Establishes a program for expedited review of food offered by importers who have agreed to voluntarily participate in program								
• FDA publish guidance				X				
• FDA establish program					X			
Sec. 303. Authority to require import certification for food: Authorizes the Secretary to require imported food to have a certificate of compliance with applicable requirements	X							
Sec. 306. Inspection of foreign facilities: Authorizes the Secretary enter into arrangements with foreign governments to facilitate inspection of foreign registered facilities and refuse admission of food from facilities refusing inspection	X							