

FOOD SAFETY FREQUENTLY ASKED QUESTIONS

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What is the Food Safety Act in general?

The Food and Drug Administration Food Safety Modernization Act (FSMA), also known as the Food Safety Act or S. 510, was signed into law on January 4, 2011. The Act amends the Federal Food, Drug, and Cosmetic Act with respect to safety of the food supply. The Act is aimed at helping the Food and Drug Administration (FDA) prevent food safety problems and it gives FDA new enforcement authorities and new tools for managing imported foods. In addition, it requires food facilities to identify potential food safety hazards and to develop and implement preventive control plans.

Among other things, the Act directs FDA to:

- Issue guidance for risk reduction;
- Establish fruit and vegetable harvesting standards;
- Collect fees related to re-inspections and recalls; and
- Develop food allergy guidelines for schools.

To enable faster detection and response to food safety problems, the Act requires FDA to:

- Inspect facilities and imported foods more frequently;
- Establish a product tracing system; and
- Alongside the Centers for Disease Control (CDC), improve data on food borne illnesses.

FDA is also charged with improving the safety of imported foods by requiring importers to verify that food is produced in compliance with hazard analysis and product safety standards, and is not adulterated or misbranded. The Act authorizes FDA to require certification showing that an article of food imported or offered for import complies with food safety requirements, and FDA is instructed to enter into arrangements with foreign governments to facilitate the inspection of foreign facilities.

In addition, the Act authorizes appropriations for the Center for Food Safety and Applied Nutrition, the Center for Veterinary Medicine, and related field activities in the Office of Regulatory Affairs of FDA for Fiscal Years 2011 through 2015.

The Act also establishes whistleblower protections for employees of entities involved in the manufacturing, processing, packing, transporting, distribution, reception, holding, or importation of food that provide information related to food safety violations.

The FDA has started the process of writing the regulations required by the Act, which will dictate how the agency will implement the law's provisions. See the section on page 8 of this document that explains when new regulations will take effect and how to help shape them.

What are the roles of the FDA and the U.S Department of Agriculture (USDA) when it comes to food safety?

The FDA is part of the Department of Health and Human Services (HHS), and is responsible for the safety of roughly 80% of food in the United States, including fresh and fresh-cut produce. The

Food Safety and Inspection Service (FSIS), part of USDA, is responsible for protecting the United States' commercial supply of meat (excluding game), poultry, and egg products against contamination. The FSMA focuses primarily on FDA and its role in preventing food safety problems, detecting and responding to potential problems, and improving the safety of imported foods. It thus does not impact the regulation of meat, poultry, or egg products. It does impact most everything else, including grains, oilseeds, dairy, and produce, though it has a particular focus on produce.

How does the Food Safety Act affect small and midsize family farms?

The Act addresses small and midsize family farms through a variety of provisions, including:

- The FDA is given the authority to either exempt small farms engaged in low or no risk processing or co-mingling activities from new regulatory requirements, or FDA can modify particular regulatory requirements for such farming operations.
- FDA is instructed to provide sufficient regulatory flexibility for all sizes and types of facilities, including small businesses such as small food processing facilities co-located on farms.
- FDA is prohibited from requiring any farm to keep records beyond the first point of sale when the product leaves the farm, except in the case of farms that co-mingle products from multiple farms, in which case those farms must also keep records one step back (to their suppliers) as well as one step forward (to their buyers).
- Certain small and midsize family farms that primarily direct market to consumers may not have to register with FDA as food facilities. The Act mandates that, others, including very small farms and processors, and larger farms who primarily direct market to consumers, restaurants, or grocery stores in their region, will qualify for alternatives to the Hazards Analysis and Risk-Based Preventive Controls (HARPC) that other facilities will be required to develop and implement, and may also qualify for alternatives to the produce standards. Specific qualifications for these alternatives can be seen below in the FAQ.
- USDA is authorized to run a food safety training, education, and outreach competitive grants program with an emphasis on small and mid-scale farms and small wholesalers and processors.

What is a Hazard Analysis & Risk-Based Preventive Control (HARPC) plan?

The Act requires food facilities to develop and implement HARPC plans. According to the FDA a HARPC plan is similar to the Hazard Analysis and Critical Control Points (HACCP) plan. According to FDA, HACCP is a management system that was created to ensure that food safety hazards are controlled to prevent unsafe food from reaching the consumer. HACCP plans address food safety through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement, and handling to manufacturing, distribution, and consumption of the finished products¹. HACCP is designed for use in all segments of the food industry. Every segment is responsible for providing the conditions necessary to protect food while it is under that segment's control. This has traditionally been accomplished through the application of current Good Manufacturing Practices. These conditions and practices are now considered to be prerequisites to the development and implementation of effective HACCP plans.

¹ <http://www.fda.gov/Food/FoodSafety/HazardAnalysisCriticalControlPointsHACCP/default.htm>

Farms that are not food facilities do not have to develop and implement HARPC plans to be in compliance with the regulations of the Act.

What is a food facility?

A food facility includes any factory, warehouse, or establishment that manufactures, processes, packs, or holds food. Manufacturing/processing activities include making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food crops or ingredients.

On farm washing, trimming of outer leaves of, and cooling produce are considered part of harvesting and would not require classification as a facility².

Which farms are required to register as food facilities with the FDA?

Farms must register as food facilities with the FDA if they:

- Manufacture, process, pack, or hold food beyond what is considered harvesting, and
- Direct market less than 50% of their product.

In this instance, direct marketing means direct farmer-to-consumer sales and does not apply – like in other direct marketing specifications in the Act – to stores and restaurants.

Manufacturing/processing activities include making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food crops or ingredients. Examples of manufacturing/processing include:

- Cutting
- Washing
- Rendering
- Freezing
- Homogenizing
- Bottling
- Extracting juices
- Packing
- Peeling
- Waxing
- Cooking
- Cooling
- Mixing
- Milling
- Distilling
- Trimming
- Eviscerating
- Baking
- Pasteurizing
- Formulating
- Grinding
- Labeling

On farm washing, trimming of outer leaves of, and cooling produce are considered part of harvesting and would not require classification as a facility³.

What is the FDA directed to do to determine whether those farms that must register as food facilities must do a HARPC plan?

For farms that must register with the FDA as food facilities, the FDA must either:

² The Bioterrorism Act, 68 Fed. Reg. 58894; October 10, 2003; codified at 21 CFR Part 1, Subpart H: <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodDefenseandEmergencyResponse/ucm121288.htm>

³ The Bioterrorism Act, 68 Fed. Reg. 58894; October 10, 2003; codified at 21 CFR Part 1, Subpart H: <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodDefenseandEmergencyResponse/ucm121288.htm>

- Exempt farms engaged in low or no risk on-farm processing or co-mingling activities from the requirement to do HARPC plans, or
- Modify HARPC requirements to make them appropriate for such farming operations.

Farms that are not food facilities do not have to develop and implement HARPC plans to be in compliance with the regulations of the Act. Please refer to the previous question for the definition of a food facility.

Which farmers qualify for less costly alternatives to the HARPC plans and what are the alternatives?

Farms that are also food facilities qualify for less costly alternatives if they:

- Direct market more than 50% of their products directly to consumers, stores, or restaurants that are in the same state or within 275 miles of the farm;
- Have gross sales (direct and non-direct combined) of less than \$500,000; and
- Display or otherwise provide their business name and address at the point of sale (e.g., on an invoice to a store or restaurant, on a label, on a sign posted at a farmers market table, etc.)

If a farm that is also a food facility meets these requirements, then there are two alternatives to developing and implementing a HARPC plan:

1. The farmer must provide documentation that his or her farm is in compliance with state regulations—including providing licenses, inspection reports, or other evidence.
2. If there are no state regulations or if the farmer prefers option two for whatever reason, he or she must provide the FDA with documentation showing that he or she has identified potential hazards, has implemented preventive controls, and is monitoring those controls for their effectiveness. FDA will further detail the exact nature of this option, sometimes referred to as HARPC-Lite, in its rulemaking.

Farms that are not food facilities do not have to develop and implement HARPC plans to be in compliance with the regulations of the Act.

What provision in the Act is specific to produce farms?

To be in compliance with the Act, produce farmers will have to meet production and harvesting standards. The Act requires the establishment of science-based minimum standards for the safe production and harvesting of fruits and vegetables, including specific mixes or categories of fruits and vegetables that are raw agricultural commodities. The FDA will develop these standards through rulemaking that will begin no later than one year after the date of the Act's enactment.

The Act requires the produce standards to:

- Be scale appropriate;
- Include standards related to soil amendments, hygiene, packaging, temperature controls, animals in the growing area, and water;
- Consider natural, unintentional, and intentional hazards;
- In the case of certified organic, not conflict or duplicate the requirements of the National Organic Program Regulations;
- Take into consideration conservation and environmental practice standards established by federal conservation and environmental agencies;
- Define the terms 'small business' and 'very small business'; and
- Prioritize the implementation for specific fruits and vegetables based on known risks.

Are any farms exempt from the produce standards?

There are alternatives to the produce standards for farms that:

- Direct market more than 50% of their products directly to consumers, stores or restaurants;
- Have gross sales (direct and non-direct combined) of less than \$500,000; and
- Sell to consumers, stores, or restaurants that are in-state or within 275 miles.

Farms that meet these requirements must prominently and conspicuously display the name and address of the farm on its label, or prominently and conspicuously display (on a label, poster, sign, placard, or documents delivered contemporaneously with the food in the normal course of business) at the point of purchase, the name and business address of the farm where the produce was grown. In the case of internet sales, this information must be available in an electronic notice.

Does the Food Safety Act restrict organic farming in any way?

The Act requires the FDA to consult with USDA's National Organic Program to ensure that food safety standards do not conflict with or duplicate organic certification standards.

How does the Act address the issue of food safety rules conflicting with farm conservation and environmental management?

The Act requires the FDA to take federal conservation and environmental standards and goals into account prior to issuing food safety regulations. FDA must apply sound science to any requirements that might impact wildlife and wildlife habitat on farms. FDA must take into account, consistent with ensuring enforceable public health protection, conservation and environmental practice standards and policies established by Federal natural resource conservation, wildlife conservation, and environmental agencies.

Do the alternatives for small farmers and processors pose a threat to food safety?

The alternatives do not inherently pose any additional threats to food safety. The Act requires the frequency of inspections by the FDA to be based on risk, and prioritizes implementation of regulation based on known risks. The Act aims to develop and implement strategies to enhance food safety and defense capacities at the State and local levels. FDA has the authority to withdraw any exemption small farmers and processors have received if FDA is concerned about a food borne illness outbreak.

Can the FDA issue a mandatory recall?

The new law gives the FDA the authority to recall a product if there is a reasonable probability that it is adulterated or misbranded and is capable of causing a serious adverse health consequence. Once advised of a recall, the responsible party has an opportunity to voluntarily recall the product. If that does not occur, FDA can order the immediate cease of distribution. After such action, an informal hearing will occur within two days. If the recall is still deemed necessary, FDA will establish a timeframe and require reports. Failure to comply with FDA could result in civil penalties. If the recall is determined unnecessary, FDA will withdraw it.

Will farmers be subject to new fees?

In most cases, farmers will not be subject to new fees. A controversial fee (tax) provision was included in the Administration's proposal and incorporated into the House version of the Act, but was rejected by the Senate and not included in the final Act. There are fees in the final Act, but only for:

- Re-inspection costs,
- Food recall activities,
- Administrative costs of the voluntary qualified importer program,
- Costs associated with issuing food export certification, and
- Costs to establish and administer the third party accreditation program for imported foods.

There is no fee for an initial inspection. Food facilities will not be required to pay a registration fee to register with the FDA. FDA will publish fee requirements each August with the methodology the agency used to arrive at those fees for the activities that are subject to fees.

What about other compliance costs?

Several new provisions are intended to decrease costs and burdens for small and midsize farms, by providing alternatives to expensive traceability and recordkeeping requirements and to HARPC requirements. In addition, the Food and Drug Administration is prohibited from requiring farms and other food facilities to hire outside consultants to write HARPC plans.

Will the FDA inspect farms?

The FDA has long had the authority to inspect manufacturers or processors of FDA-regulated products to verify that they comply with relevant regulations. FDA inspects food-processing facilities, dairy farms, and animal feed processors. A farm will be inspected only if, in addition to being a farm, it is also considered a food facility. A facility includes any factory, warehouse, or establishment that manufactures, processes, packs, or holds food. On farm washing, trimming of outer leaves of, and cooling produce are considered part of harvesting and would not require classification as a facility⁴. The term 'facility' does not inherently include farms, restaurants, or other retail food establishments. The new Food Safety Act directs FDA to either exempt farms engaged in low or no risk on-farm processing or co-mingling activities from new regulatory requirements, or to modify regulatory requirements to make them appropriate for such farming operations.

The Act requires an increase in the inspection of facilities. It states that high-risk facilities should be inspected at least once within five years of the Act's enactment, and no less than once every three years after that. Non-high-risk facilities should be inspected within seven years of the Act's enactment, no less than once every five years thereafter.

Are farmers subject to new record-keeping requirements?

The FDA has been instructed to minimize the number of different standards that apply to separate crops and foods and make requirements scale appropriate.

Farmers who qualify for the less costly alternative to HARPC must still provide documentation that their farm is in compliance with state regulations.

Farmers who are exempt from specific produce standards and preventive control standards must still display the name and address of the farm on their products and for foods without a label then

⁴ The Bioterrorism Act, 68 Fed. Reg. 58894; October 10, 2003; codified at 21 CFR Part 1, Subpart H: <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodDefenseandEmergencyResponse/ucm121288.htm>

by poster, sign, or placard, at the point of purchase or, in the case of internet sales, in an electronic notice, or in the case of sales to stores and restaurants, on the invoice.

Farmers who sell directly to consumers or to grocery stores, and whose labels preserve the identity of the farm through to the final consumer, may be exempt from extensive/expensive traceability and recordkeeping requirements.

FDA is prohibited from requiring any farm to keep records beyond the first point of sale when the product leaves the farm, except in the case of farms that co-mingle products from multiple farms, in which case they must also keep records one step back (to their suppliers) as well as one step forward (to the buyers).

What training is available to farmers to comply with food safety regulations?

The FDA and USDA will establish a competitive grant program within the National Institute of Food and Agriculture (NIFA). The grant program will 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, with a priority on small and midsize farms, to be delivered by non-governmental organizations (NGOs), extension, producer groups, etc. The budget for this grant program is to be determined by appropriations.

Do food safety regulations apply to home gardens?

Food safety regulations do not apply to home gardens that are not in the business of selling food to customers.

Does this law change state and local food safety guidelines?

Not directly, but the Act suggests increased communication with state and local governments. The FDA is still likely to rely on state and local agencies to do much of the implementation and enforcement of the new law. Also, given the provision which allows compliance with state regulation rather than federal for very small farms and processors and for direct market farms, it would not be surprising to see more attention given to any potential gaps in the state and local rules and procedures.

Will farmers' markets need to take on any new responsibilities because of this law?

No. However, it is strongly recommended that farmers markets require producers to adhere to all relevant state and local regulations. Market managers may want to remind producers of their obligation to clearly post their business name and address at their stands.

Does the Food Safety Act regulate food safety risks such as genetically modified organisms (GMOs), pesticide use, and antibiotic use in animal agriculture?

The Food Safety Act does not regulate GMOs, pesticide use, or antibiotic use in animal agriculture. The Act and the law that it amends are primarily only interested in pathogen contamination, not any other food safety or public health risks.

When will the food safety regulations take effect?

The food safety regulations will go into effect at various times. The FDA is attempting to have a set of proposed rules for preventive control plans and for produce standards out for public comment before the end of the 2011 calendar year.

The Act mandates each specific regulation to take effect no later than a time that is individualized for that regulation. The agency has already said publicly that there are many deadlines contained in the Act that it will not be possible to meet.

Timeline extracted from [Registrar Corp](#) website:

On or before July 3, 2011:

- FDA may suspend registration (effectively closing) of any facility that:
 - Created, caused, or was responsible for food having a reasonable probability of having adverse health consequences for humans or animals, or
 - Knew or had reason to know of such reasonable probability, and packed, received, or held such food.
- FDA will issue a small entity compliance guide within 180 days of issuing the interim regulations concerning facility registration.
- FDA and the USDA will establish a competitive grant program within NIFA to provide food safety training, education, extension, outreach, and technical assistance.

On or before October 4, 2011:

- FDA will publish a notice of proposed rulemaking in the Federal Register to promulgate regulations that further define farms and exemptions applicable to farms. Specifically, the regulations will address:
 - Activities that constitute on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership, and
 - Activities that constitute on-farm manufacturing or processing of food that is not consumed on that farm or on another farm under common ownership.

On or before January 4, 2012:

- FDA will begin to issue new rules for produce standards and safety. The rules will be staggered to give priority to specific fruits and vegetables based on known risks and history of incidents.

On or before July 4, 2012:

- FDA will issue HARPC regulations for all products except seafood and juice (which are already subject to HACCP regulations).
- FDA will report to Congress on the results of a study of the food-processing sector mandated by the statute. The study is to determine:
 - The distribution of food production by size and type of operation, including the monetary values of food sold;
 - The proportion of food produced by each type and size of operation;
 - The number and types of food facilities co-located on farms, segregated by commodity and by manufacturing or processing activity; and
 - The incidence of food borne illness originating from each size and type of operation, and assessments of risk of food borne illness associated with commingling, processing, transporting, and storing food and raw agricultural commodities.

- The results of the study shall include information necessary to enable the Secretary to define the terms ‘small business’ and ‘very small business.’
- FDA will issue regulations to protect against intentional adulteration of food. Farms will be exempt, except those that produce milk.

For a more detailed timeline go to:

<http://fda-news.registrarcorp.com/2011/01/important-dates-for-the-fda-food-safety-modernization-act/>

How can I be involved in helping to shape food safety regulations?

For an updated list of public hearings and opportunities for you to provide comments on the Food Safety Act, go to:

<http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm>

Check out [The National Sustainable Agriculture Coalition](#) to find out when grassroots action is needed to ensure effective implementation of the Act.

Sign up for the [Organic Farmers Action Network \(OFAN\)](#) to stay informed about the Food Safety Act, and other federal policy issues that directly affect organic farmers, and to learn how to effectively get involved.

For more information on the Act:

"Food Safety Act Amendments Explained." National Sustainable Agriculture Coalition, Dec 2010.

<http://sustainableagriculture.net/wp-content/uploads/2010/12/Food-Safety-Amendments-Explained.pdf>.

United States Food and Drug Administration. Background on the FDA Food Safety Modernization Act. Washington, DC. Web. 14 Mar 2011.

<http://www.fda.gov/Food/FoodSafety/FSMA/ucm239907.htm>.

To read the Act itself:

United States. FDA Food Modernization Act. Washington, DC: 2011. Web. 14 Mar

2011. <http://www.gpo.gov/fdsys/pkg/PLAW-111publ353/pdf/PLAW-111publ353.pdf>.

Appendix I – Summary of Food Safety Modernization titles

Title I: Contains most of the sections relevant to domestic producers and local and regional food systems. It focuses on food processing facilities and increases the authority of the FDA to inspect records, set safety practice standards, and require processors to have a prevention plan in place for any identified risks. The language repeatedly emphasizes that the FDA should direct the most scrutiny to high-risk foods and processing facilities. In order to avoid placing an undue burden on small and low-risk producers, the bill provides exemptions for these entities. Find out more about these exemptions in OFRF's FAQ.

- 101: Increases authority for inspecting producers' records.
- 102: Requires registration for food processing facilities. Exemptions for small producers.

- 103: Requires producers and processors to assess food safety risks and implement a prevention plan. Emphasizes most scrutiny on highest-risk producers.
- 104: FDA will issue written guidance every two years based on the latest science.
- 105: Authorizes FDA to set commodity-specific produce safety practice standards, again emphasizing the highest-risk foods.
- 106: Protect against intentional adulteration of the food supply by terrorists.
- 107: Assessing fees for compliance.
- 108: FDA must implement a food defense strategy.
- 109: Food defense coordinating council including private sector members.
- 110: Research and reports on food defense security.
- 111: Sanitary food transportation.
- 112: Food allergy management.
- 113: Must submit reports to DEA on new dietary ingredients that may contain steroids.
- 114: Oyster food safety practices.
- 115: Port safety.
- 116: Alcohol facility exemptions.

Title II: Creates provisions for identifying and dealing with food safety problems. It directs the FDA to recognize accredited laboratories, enhance food-tracking systems and increase surveillance of food-borne illness outbreaks. It also gives the FDA the authority to detain any suspect food and issue mandatory recalls.

- 201: Targeting inspections at highest-risk facilities and processes.
- 202: Directs FDA to recognize and create a directory of accredited labs for food safety testing.
- 203: Integrate lab networks for faster info sharing.
- 204: Pilot projects to test new methods of enhanced food tracking.
- 205: Food borne illness surveillance systems.
- 206: Authority to mandate recall of foods if producer does not.
- 207: Administrative detention of potentially contaminated foods.
- 208: Decontamination and disposal standards.
- 209: Training for state, local, and tribal food safety officers.
- 210: Grants for increasing food safety.
- 211: Improve reportable food registry.

Title III: Deals with foreign food producers and the standards for assuring that food imported into the US are properly inspected and processed in a trusted facility.

- 301: Food safety verification for imported foods.
- 302: Voluntary program for expedited importing for those who go above minimum standards of safety/inspection.
- 303: Requiring import certification of safety assurance.
- 304: Importers must give notice of countries that have already refused entry to this food.
- 305: Help expand food safety capacity of foreign governments.
- 306: Inspecting foreign food facilities.
- 307: Allowing third-party inspection of facilities.
- 308: Establish foreign offices for better coordination of the above tasks.
- 309: Identify smuggled food and prevent entry.

Title IV: Increasing in funding for field staff, whistleblower protection for reporting food safety incidents, and legal language specifying this bill doesn't change any treaties, trade agreements, or agency jurisdiction.

- 401: Increasing funding and increasing number of field staff.
- 402: Whistleblower protections.
- 403: Doesn't change any jurisdiction of agencies mentioned in the bill.
- 404: Doesn't change any treaties or trade agreements through provisions of this bill.