## Food

### Imports

Information available related to Imports under the FDA Food Safety Modernization Act (FSMA).


- Making Certain Imported Foods Meet U.S. Standards under FDA Food Safety Modernization Act
- Frequently Asked Questions
- Sections of the Law Relating to Imports
- Listen to FDA Expert Talk about Imports
- Public Meeting
- Speeches and Statements
- Guidance and Rules


#### Making Certain Imported Foods Meet U.S. Standards under FDA Food Safety Modernization Act

About 48 million people (1 in 6 Americans) get sick, 128,000 are hospitalized, and 3,000 die each year from foodborne diseases, according to recent data from the Centers for Disease Control and Prevention. This is a significant public health burden that is largely preventable.

The FDA Food Safety Modernization Act (FSMA), signed into law by President Obama on Jan. 4, enables FDA to better protect public health by strengthening the food safety system. It gives FDA new tools and authorities to make certain imported foods meet the same safety standards as foods produced in the U.S.

Building a new food safety system based on prevention will take time, and FDA is creating a process for getting this work done. Congress has established specific implementation dates in the legislation. The funding the Agency gets each year, which affects staffing and vital operations, will affect how quickly FDA can put this legislation into effect. FDA is committed to implementing the requirements through an open process with opportunity for input from all stakeholders.

The following are among FDA's key new import authorities and mandates. Specific implementation dates specified in the law are noted in parentheses:

- Importer accountability: For the first time, importers have an explicit responsibility to verify that their foreign suppliers have adequate preventive controls in place to ensure that the food they produce is safe. (Final regulation and guidance due 1 year following enactment)
- Third Party Certification: The FSMA establishes a program through which qualified third parties can certify that foreign food facilities comply with U.S. food safety standards. This certification may be used to facilitate the entry of imports. (Establishment of a system for FDA to recognize accreditation bodies is due 2 years after enactment)
- Certification for high risk foods: FDA has the authority to require that high-risk imported foods be accompanied by a credible third party certification or other assurance of compliance as a condition of entry into the U.S.
- Voluntary qualified importer program: FDA must establish a voluntary program for importers that provides for expedited review and entry of foods from participating importers. Eligibility is limited to, among other things, importers offering food from certified facilities. (Implementation due 18 months after enactment)
- Authority to deny entry: FDA can refuse entry into the U.S. of food from a foreign facility if FDA is denied access by the facility or the country in which the facility is located.

#### Frequently Asked Questions on Imports

**General Information on Imports**

**I.1.1 What are the key areas that the importer will notice that will be different under FSMA?**

For the first time, importers will be specifically required to have a program to verify that the food products they are bringing into this country are safe. Among other things, importers will need to verify that their suppliers are in compliance with reasonably appropriate risk-based preventive controls that provide the same level of public health protection as those required under FSMA.

**I.1.2 If a foreign facility is already registered in the U. S. will it need to renew its registration?**

Yes. All food facilities that are required to register with FDA under section 415 of the FD&C Act, including foreign facilities (as defined in 21 CFR 1.227(b)(2)), must renew their registrations with FDA, as required by section 102 of FSMA. Registrants are required to submit registrations to FDA containing the information described in section 415(a)(2) of the FD&C Act, including the new information added by section 102 of FSMA.

**Foreign Supplier Verification Program**

**I.2.1 What is the Foreign Supplier Verification Program (FSVP) and how will it work?**

The FSVP requires importers to conduct risk-based foreign supplier verification activities to verify that imported food is not, among other things, adulterated and that it was produced in compliance with FDA's preventive controls requirements and

produce safety standards, where applicable.

**Foreign Supplier Verification Program**

**I.2.2 Who is subject to the foreign supplier verification program?**
When the foreign supplier verification program's requirements take effect, they will apply to all importers, unless there's an exemption. The law defines "importer" as: (A) the United States owner or consignee of the article of food at the time of entry of such article into the United States; or (B) in the case when there is no United States owner or consignee as described in subparagraph (A), the United States agent or representative of a foreign owner or consignee of the article of food at the time of entry of such article into the United States.

**I.2.3 What food does the program's requirements apply to?**
The requirements of the foreign supplier verification program will apply to all food imported by the importer or agent of the importer, unless there's an exemption.

**I.2.4 Are any companies exempt from this requirement?**
The requirements do not apply to a facility if the owner, operator, or agent in charge is subject to, and in compliance with FDA's seafood, juice, or low-acid canned food products requirements. The exemption relating to low-acid canned food applies only with respect to microbiological hazards. The statute also directs FDA to exempt, by notice in the Federal Register, food imported into the United States in small quantities for research and evaluation purposes or for personal consumption. The statute further directs FDA to issue implementing regulations and guidance on FSVPs.

**I.2.5 Is there an exemption for small research quantities?**
The law contains an exemption for food imported in small quantities for research and evaluations purposes, provided the food is not intended for retail sale and not sold or distributed to the public.

**Certification**

**I.3.1 What is the relationship between the certification program and the foreign supplier verification program?**
"Certification" differs from the "foreign supplier verification program." Foreign supplier verification is a general requirement applicable to all food importers, unless there's an exemption. In contrast, certification is only required in those situations where FDA requires certification. FDA must base its decision to require certification on the risk of the food, including taking into account certain factors specified in the law.

**Audits**

**I.4.1 How will the third-party auditor accreditation program work?**
Section 307 directs FDA to establish a system for the recognition of accreditation bodies that accredit third-party auditors to, among other things, issue certifications for purposes of the import certification for food. The statute directs FDA to issue implementing regulations, including provisions on conflicts of interest, financial ties, and unannounced audits, as well as model accreditation standards, including requirements for regulatory audit reports.

**I.4.2 Is the accredited auditor required to notify the FDA if a condition of concern is found during a consultative audit?** The law requires that during an audit, an accredited third-party auditor or audit agent of such auditors must immediately notify FDA if they discover a condition that could cause or contribute to a serious risk to the public health.

**I.4.3 Will auditors have to submit their audit reports to FDA?**
An accredited third-party auditor or audit agent of such auditor will need to prepare an audit report for each audit conducted. In the case of a regulatory audit, which the law distinguishes from consultative audits, it must submit the report to FDA. The law also has a provision whereby FDA may require the submission of certain reports from a regulatory audit and can access the results of a consultative audit in accordance with its records access authority under another provision of the Federal Food, Drug, and Cosmetic Act.

**I.4.4 Can a foreign government serve as a third-party auditor?**
Foreign cooperatives and governments agencies are eligible for accreditation as third-party auditors.

**I.4.5 What is the voluntary Qualified Importer Program (VQIP) and won't this force FDA to rely heavily on inspections by foreign governments?**
Section 302 of the statute requires FDA to establish a voluntary, user-fee funded voluntary qualified importer program (VQIP) to expedite entry into the United States of imported food from eligible, qualified importers. To be eligible to participate in VQIP, an importer must offer food for importation from a facility that has a certification by an accredited third party. FDA will qualify eligible importers to participate in VQIP based on risk considerations. The new law directs FDA to issue guidance on participation in and compliance with VQIP.

**I.4.6 There are ISO standards for inspection and accreditation bodies. Will FDA allow countries that adhere to these standards automatic recognition under the accreditation and certification provisions?**
In developing the model standards under the third party auditory accreditation program, there is explicit language in the law that FDA must look to standards in place on the date of the enactment of this section for guidance, to avoid unnecessary duplication of efforts and costs. FDA will continue to consider international standards and leverage with accreditation bodies in developing these standards.

**I.4.7 Will there be import certification required for high-risk foods?**
FDA is now working on determining how to define and identify high-risk foods.

**I.4.8 Does FDA have new compliance tools for imports?**
Yes. First, we will increase the number of foreign inspections we do. FDA can deny entry to an import if a foreign facility refuses an FDA inspection it can require certification for high-risk foods; and prior notice submissions will need to include, as an additional element, any country to which the food has been refused entry.

**I.4.9 Has FDA considered using the GFSI (Global Food Safety Initiative) program as the (or one of a few) third party accreditation? NEW**

As a general matter, we cannot answer this or any other question that relates to predecisional, internal agency deliberative processes. Moreover, the question is unclear as worded. What we can state publicly that FDA is currently developing regulations and model accreditation standards directed by FSMA section 307 on third-party accreditation. FSMA directs the agency to look to existing standards to avoid unnecessary duplication of costs and efforts. To the extent that the questioner is asking whether FDA will rely on GFSI benchmarked standards, we cannot answer the question at this time. To the extent that the question is asking whether GFSI will have a role in the third-party program, we can say that after the third-party rulemaking is final, the program will go into effect and accreditation bodies can begin to seek FDA recognition and likewise, third-party auditors (also known as certification bodies) can begin to seek accreditation from an accreditation body recognized by FDA. Direct accreditation of certification bodies may take place only under certain conditions and after the program has been in effect for two years.

**I.4.10 Will third party auditors have the same authorities and tools of FDA when qualifying imported food companies for entry into the US? NEW**
No. Accredited third-party certification bodies will not be commissioned by FDA nor will they otherwise be in the role of regulatory authority, acting on FDA's behalf. This is true regardless of whether the accredited certification body is, itself, government (i.e., public) entity.

**Accreditation**

**I.5.1 Will in-house laboratories (set up by a company for the testing of its own foods) be eligible for laboratory accreditation per FSMA?**
Valid analytical results are essential to make informed decisions that impact public health. At its heart, laboratory accreditation is about laboratories' consistently producing valid results by focusing on assuring 1) management requirements for the operation and effectiveness of the quality management system within the laboratory and 2) technical requirements that address the correctness and reliability of the tests and calibrations performed in laboratory. FDA supports laboratories' interests in pursuing accreditation but FDA has not yet fully developed its thinking or rulemaking with regard to FSMA implementation so any interpretations of requirements are premature at this time.

**Smuggled Food**

**I.6.1 Will FDA be targeting all smuggled food, including those foods transported in luggage for personal use?**
Section 309 of FSMA defines smuggled food as "any food that a person introduces into the United States through fraudulent means or with the intent to defraud or mislead." While this could be interpreted to apply to a single undeclared low risk food item carried in personal luggage, FDA and DHS will focus resources on imported food that poses the greatest risk to public health.

**I.6.2 How will FDA notify the public of potentially dangerous smuggled food?**
FSMA provides for public notifications of harmful and dangerous smuggled food "reasonably believe[d] to [have] entered domestic commerce" and "likely to be consumed". FDA intends to issue a press release and use other appropriate emergency communications or recall networks in order to warn consumers, distributors, and vendors about the threat.

**I.6.3 How will FDA evaluate the impact of this strategy?**
FDA and CBP will measure the number of food import examinations targeted to alert for smuggled food against the number of shipments where food smuggling is actually discovered and acted upon. Outcomes will be measured according to metrics developed under the strategy at regular intervals and any adjustments to strategy will be made after consideration of these results.

### Listen to FDA Expert Talk about Imports

http://www.fda.gov/Food/guidanceregulation/FSMA/ucm249243.htm#imports[1]

### Full Text of the Law Related to Imports

- Section 202. Laboratory accreditation for analyses of food[2]
- Section 301. Foreign supplier verification program[3]
- Section 302. Voluntary qualified importer program[4]
- Section 303. Authority to require import certifications for food[5]
- Section 304. Prior notice of imported food shipments[6]
- Section 305. Building capacity of foreign governments with respect to food safety[7]
- Section 306. Inspection of foreign food facilities[8]
- Section 307. Accreditation of third-party auditors[9]
- Section 308. Foreign offices of the Food and Drug Administration[10]
- Section 309. Smuggled food[11]

### Public Meeting

FDA hosted an all-day public meeting entitled FDA Food Safety Modernization Act: A New Paradigm for Importers[12] to discuss the implementation of the import safety provisions of the FDA Food Safety Modernization Act (FSMA).

**Speeches and Statements**

The FDA Food Safety Modernization Act: A New Paradigm for Importers[13]
Global Food Safety Conference, London, England
February 17, 2011

**Guidance and Rules**

- Enforcement Policy Concerning Certain Prior Notice Requirements[14]
  Guidance for Industry
- Information Required in Prior Notice of Imported Food[15]
  Final Rule
  See also *Constituent Update: FDA Issues Final Rule, Information Required in Prior Notice of Imported Food*[16]

Page Last Updated: 06/20/2013
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.



U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA



**Links on this page:**

1. /Food/GuidanceRegulation/FSMA/ucm249243.htm#imports
2. ssLINK/ucm247548.htm#SEC202
3. ssLINK/ucm247548.htm#SEC301
4. ssLINK/ucm247548.htm#SEC302
5. ssLINK/ucm247548.htm#SEC303
6. ssLINK/ucm247548.htm#SEC304
7. ssLINK/ucm247548.htm#SEC305
8. ssLINK/ucm247548.htm#SEC306
9. ssLINK/ucm247548.htm#SEC307
10. ssLINK/ucm247548.htm#SEC308
11. ssLINK/ucm247548.htm#SEC309
12. /Food/GuidanceRegulation/FSMA/ucm249257.htm
13. /AboutFDA/CentersOffices/OfficeofFoods/ucm243591.htm
14. /Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm261080.htm
15. https://www.federalregister.gov/articles/2013/05/30/2013-12833/information-required-in-prior-notice-of-imported-food
16. /Food/NewsEvents/ConstituentUpdates/ucm354209.htm