Food

Inspection & Compliance

Information available related to Inspection and Compliance under the FDA Food Safety Modernization Act (FSMA).

New Inspection and Compliance Mandates 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 recognizes that preventive control standards improve food safety only to the extent that producers and processors comply with them. Therefore, it will be necessary for FDA to provide oversight, ensure compliance with requirements and respond effectively when problems emerge.

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.

FSMA provides FDA with important new tools for inspection and compliance. Specific implementation dates specified in the law are noted in parentheses:

- Mandated inspection frequency: The FSMA establishes a mandated inspection frequency, based on risk, for food facilities and requires the frequency of inspection to increase immediately. All high-risk domestic facilities must be inspected within five years of enactment and no less than every three years thereafter. Within one year of enactment, the law directs FDA to inspect at least 600 foreign facilities and double those inspections every year for the next five years.
- Records access: FDA will have access to records, including industry food safety plans and the records firms will be required to keep documenting implementation of their plans.
- Testing by accredited laboratories: The FSMA requires certain food testing to be carried out by accredited laboratories and directs FDA to establish a program for laboratory accreditation to ensure that U.S. food testing laboratories meet high- quality standards. (Establishment of accreditation program due 2 years after enactment)

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Frequently Asked Questions on Inspection and Compliance

Records and Records Access

IC.1.1 FSMA has several provisions on inspections and compliance. What will be new?

For the first time, FDA has been given an inspection mandate. The legislation requires inspections to be based on risk, and the frequency of inspections to increase. It calls for all high-risk domestic food facilities to be inspected within five years of the bill's signing and then at least once every three years after that.

Further, all other domestic food facilities are to be inspected within seven years of the bill's signing and then at least once every five years thereafter.

IC.1.2 What about inspections of foreign facilities?
Within one year of the bill's signing, FDA is to increase inspections of foreign facilities, and then increase that number every year for five years.

IC.1.3 For how long are records required under the new law's "Hazard Analysis and Risk-Based Preventive Controls" provision (FSMA §103/FDCA §418) required to be kept?
This section of the new law contains a provision (FDCA §418(g)) requiring

In February 2012, FDA issued an interim final rule (IFR) amending FDA's existing regulation on the record availability requirements as part of its implementation of the amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act) made by the FDA Food Safety Modernization Act (FSMA), which was signed into law by President Obama in January, 2011.

This particular FSMA amendment expands

that certain records established under that section be kept for at least 2 years.

IC.1.4 Who will conduct the foreign inspections? Are there fees associated?
It is not possible at this time to answer the question about who will conduct foreign inspections. Under FSMA, FDA has the authority to assess and collect fees for some types of costs, such as re-inspection-related costs when an initial inspection has identified certain food safety problems. Under the law, there is no fee for the initial FDA inspection. FDA's ability to collect fees is subject to sufficient appropriations for food safety activities in a given fiscal year.

IC.1.5 What records do I have to provide to FDA based on the FSMA amendments?
The manner in which you respond to a FDA records request remains unchanged. Similarly, the type of documents that you may have to provide to FDA in response to a records request remains unchanged. The FSMA amendment simply expands FDA's former records access beyond records related to the specific suspect article of food for which FDA reasonably believes is adulterated and presents a threat of serious adverse health consequences or death to humans or animals to now include records relating to any article of food that is reasonably likely to be affected in a similar manner.

In addition, the FSMA amendment permits FDA to access records related to articles of food for which FDA believes that there is a reasonable probability that the use of or exposure to the article of food, and any other article of food is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animal.
Once either of the above mentioned circumstances are met, FDA may request all existing records needed to assist the agency in determining whether the circumstances, which gave rise to the records request, exist.

FDA's records access authority beyond records related to the specific suspect article of food to records relating to any article of food for which there is a reasonable belief that it will be affected in a similar manner. In addition, the amendment also permits FDA to access records relating to articles of food for which the Secretary believes that there is a reasonable probability that the use of or exposure to the article of food, and any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals.

- Interim Final Rule: Establishment, Maintenance, and Availability of Records: Amendment to Record[3]
- Draft Guidance: FDA Records Access Authority Under Sections 414 and 704 of the Federal Food, Drug, & Cosmetic Act[4]
- Questions and Answers Regarding Establishment and Maintenance of Records By Persons Who Manufacture, Process, Pack, Transport, Distribute, Receive, Hold, or Import Food (Edition 5)[5]

IC.1.6 What constitutes a "reasonable belief" that food is affected in a similar manner in the context of FDA records access?
Decisions regarding whether FDA "reasonably believes" a food is affected in similar manner so as to either be adulterated and present a threat of serious adverse health consequences or death to humans or animals or to pose a reasonable probability that the use of or exposure to such food will cause serious adverse health consequences or death to humans or animals will be made on a case-by-case basis because such decisions are fact-specific.

IC.1.7 How does FDA identify a high-risk (HR) facility?
See FSMA Domestic Facility Risk Categorization (FY 2012)[6].

IC.1.8 Does the FSMA Domestic Facility Risk Categorization approach apply to all registered facilities, i.e., food and animal feed facilities?
To date, FDA has only categorized facilities manufacturing food for human consumption as high-risk and non-high-risk under the framework established by FSMA. FDA has existing risk models that are used to prioritize work within each program operated at by the Center for Veterinary Medicine. The Agency is currently working to update these models based on the framework established by FSMA.

Recalls

IC.2.1 Under FSMA, FDA now has authority to order a mandatory recall. How will that work?
FDA anticipates that mandatory recall authority will be used in rare instances. Companies will be provided with an opportunity for an informal hearing before an order to require recall is made.

IC.2.2 Would a voluntary recall preclude an FDA mandated recall under FSMA §206/FDCA §423? Under FDCA §423(a), FDA is required to first give a responsible party the opportunity to cease distribution and conduct a voluntary recall of an article of food. If the responsible party refuses to or does not voluntarily cease distribution or recall such food within the time and in the manner prescribed by FDA, FDA may proceed under the mandatory recall authority as set forth in FDCA §423.

IC.2.3 What is the standard and process for a mandatory recall?
FDA's mandatory recall authority became effective when President Obama signed the FSMA into law on January 4, 2011. Section 206 of FSMA sets forth the standard for mandatory recall and procedures FDA will follow when it exercises its mandatory recall authority.

Registration

(see the Registration[8] topic page)

Administrative Detention

IC.4.1 For administrative detention, what is the process to detain food and what if the food is perishable and can spoil?
FSMA enhances FDA's administrative detention authority by authorizing FDA to administratively detain articles of food that FDA has a reason to believe may be adulterated or misbranded. FDA intends to revise its administrative

More Questions & Answers Concerning Administrative Detention

Guidance for Industry: What You Need to Know About Administrative Detention of Foods; Small Entity Compliance Guide[7]

This guidance document, updated March 2013, provides updated information

detention regulations and other relevant documents to reflect this new standard.

IC.4.2 Is compensation available for those whose products are determined to have been recalled or detained without cause?
There is nothing in FSMA that changes existing rules regarding such matters, such as, for example, the Federal Tort Claims Act.

IC.4.3 What changes did FSMA make to FDA's administrative detention authority?
The changes made by FSMA to the criteria for administrative detention in the FD&C Act further strengthened FDA's ability to prevent potentially unsafe food from entering commerce. Under the new criteria, FDA can order an administrative detention if the agency has reason to believe that an article of food is adulterated or misbranded. Prior to FSMA, FDA could order an administrative detention if it had credible evidence or information that the food presented a threat of serious adverse health consequences or death to humans or animals.

pertaining to the FDA's authority to order the administrative detention of human or animal food under section 304(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. 334(h)]. Congress originally established this authority in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and amended it in January 2011 as part of the FDA Food Safety Modernization Act (FSMA).

IC.4.4 Has FDA used its expanded administrative detention authority since the IFR published in July 2011?
FDA has effectively implemented this expanded authority three times since the IFR became effective. One of these administrative detentions led to a request to recondition the goods under FDA supervision, while another resulted in a seizure, and another terminated when the owner voluntarily destroyed the suspect food.

Product Tracing

(See the Product Tracing[9] topic page)
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Full Text of the Law Relating to Inspection and Compliance

- SEC 101. Inspections and Records.[10]
- SEC 102. Registration of Food Facilities.[11]
- SEC 115. Port Shopping.[12]
- SEC 201. Targeting on inspection resources for domestic facilities, foreign facilities and ports of entry; annual report.[13]
- SEC 204. Enhancing tracking and tracing of food and recordkeeping.[14]
- SEC 206. Mandatory recall authority.[15]
- SEC 207. Administrative detention of food.[16]
- SEC 211. Improving the reportable food registry.[17]

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Listen to FDA Expert Talk about Inspections and Compliance

http://www.fda.gov/Food/guidanceregulation/FSMA/ucm249243.htm#inspections[18]

Public Meeting on Inspection and Compliance

A public meeting, FDA Food Safety Modernization Act: Focus on Inspections and Compliance Provisions[19], was held on June 6, 2011. The purpose of this public meeting is to provide interested persons an opportunity to discuss implementation of the inspections and compliance provisions of the recently enacted FDA Food Safety Modernization Act (FSMA).

Guidance and Rules

- What You Need to Know About Administrative Detention of Foods; Small Entity Compliance Guide[20] (November 2004; Revised October 2011 and March 2013)
  Guidance for Industry
  Docket Number: FDA-2011-D-0643[21]
- Criteria Used to Order Administrative Detention of Food for Human or Animal Consumption[22]
  Final Rule
  Docket Number: FDA-2011-N-0197[23]
- Establishment, Maintenance, and Availability of Records: Amendment to Record Availability Requirements[24]
  Interim Final Rule
  Docket Number: FDA-2002-N-0153[25]
- FDA Records Access Authority Under Sections 414 and 704 of the Federal Food, Drug, & Cosmetic Act[26]
  Draft Guidance for Industry
  Docket Number: FDA-2011-D-0674[27]
- Questions and Answers Regarding Establishment and Maintenance of Records By Persons Who Manufacture, Process, Pack, Transport, Distribute, Receive, Hold, or Import Food (Edition 5)[28]

Guidance for Industry
Docket Number: FDA-2011-D-0598[29]

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Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

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Links on this page:

1. /Food/GuidanceRegulation/FSMA/ucm270851.htm
2. /Food/GuidanceRegulation/FSMA/ucm314178.htm
3. http://www.gpo.gov/fdsys/pkg/FR-2012-02-23/html/2012-4165.htm
4. /Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm292745.htm
5. /Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm292746.htm
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15. ssLINK/ucm247548.htm#SEC206
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17. ssLINK/ucm247548.htm#SEC211
18. /Food/GuidanceRegulation/FSMA/ucm249243.htm#inspections
19. /Food/GuidanceRegulation/FSMA/ucm255954.htm
20. /Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm342588.htm
21. http://www.regulations.gov/#!documentDetail;D=FDA-2011-D-0643-0001
22. https://www.federalregister.gov/articles/2013/02/05/2013-02497/criteria-used-to-order-administrative-detention-of-food-for-human-or-animal-consumption
23. http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0197-0001
24. http://www.gpo.gov/fdsys/pkg/FR-2012-02-23/html/2012-4165.htm
25. http://www.regulations.gov/#!documentDetail;D=FDA-2002-N-0153-0125

26. /Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm292745.htm
27. http://www.regulations.gov/#!documentDetail;D=FDA-2011-D-0674-0001
28. /Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm292746.htm
29. http://www.regulations.gov/#!documentDetail;D=FDA-2011-D-0598-0001