Food Fight: FSMA and the FDA's New Era of Enforcement

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Panelists:

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Food Safety Modernization Act

President Obama signed the Food Safety Modernization Act of 2011 (FSMA) into law on January 4, 2011. The FSMA constitutes the most comprehensive overhaul of the food safety laws of the United States in more than 70 years. Although touted as a significant paradigm shift toward preventing contamination rather than simply responding to it, that characterization is not entirely accurate. The general Current Good Manufacturing Practices regulations (CGMPs) require systems that assure proper design, monitoring, and control of manufacturing processes and facilities. In addition, the Hazard Analysis and Critical Control Points (HACCP) regulations involve a systematic preventive approach to food safety from biological, chemical, and physical hazards in the production process. Finally, there are many other regulations that have existed for decades that are intended to make the food supply safer.

Compliance Deadlines:

The FSMA consists of seven foundational rules for implementation. The deadline for compliance depends on the size of the business.

Foundational Rule	Compliance Deadline(s)
Preventive Controls for human food	General: 9/19/16
	Small business (< 500 employees): 9/18/17
	Very Small business (average sales of food plus market value of food held without sale of <$1M annually): 9/17/18 (records to support status as very small business required by 1/1/16)
	Business subject to the Pasteurized Milk Ordinance: 9/17/18
	Compliance dates for supply chain requirements extended depending upon size of business and whether supplier is subject to human preventive controls rule or the product safety rule (81 Fed. Reg. 57784 (Aug. 24, 2016)
Preventive Controls for animal feed	
(a) Current Good Manufacturing Practices	General: 9/19/16
	Small Business (<500 employees): 9/18/17
	Very Small Business (average sales of animal feed plus market value of food held without sale of <$2.5M annually): 9/17/18
(b) Compliance with Preventative Controls	General: 9/19/17
	Small Business (<500 employees): 9/18/18
	Very Small Business: 1/1/17

	Compliance dates for supply chain requirements extended depending upon size of business and whether supplier is subject to CGMP or preventive controls (81 Fed. Reg. 57784 (Aug. 24, 2016)
Produce Safety	General: Two years plus 60 days
	Small Business (>$250k but no more than $500k in average annual produce sales during the three previous years): Three years plus 60 days
	Very Small Business (>$25k but no more than $250k in average annual produce sales during the three previous years): Four years plus 60 days
	Compliance dates extended by two years for each of the above. (81 Fed. Reg. 57784) (Aug. 24, 2016)
Foreign Supplier Verification	Deadlines vary for importers according to a number of considerations: the size of the foreign supplier, the nature of the importer, and whether the foreign supplier must meet the requirements of the rules (1)-(3) above.
	Compliance dates extended. 81 Fed. Reg. 57784 (Aug. 24, 2016)
Third Party Accreditation and Certification	Plan to implement "as soon as possible" after publication of (a) final Model Accreditation Standards guidance, and (b) the final user fee rule.
	FDA published these documents in December 2016, and fees for fiscal year 2017 have been set.
Sanitary Transportation	General: One year
	Small Business: (Business that is not also a shipper or receiver employing <500 persons and a motor carrier having less than $27.5M in annual receipts): Two years
	Several exemptions, including shippers, receivers, or carriers engaged in food transportation operations with <$500,000 in average annual revenue)
Food Defense	General: Three years plus 60 days
	Small Business: (Business with <500 employees): 4 years plus 60 days
	Very Small Business: (various criteria including averaging less than $10M in human food sales per year, during past three year period preceding): 5 years plus 60 days

Enforcement:

Before the FSMA became law, the FDA had the following tools available to force compliance with food safety rules:

(a) Voluntary correction onsite during course of inspection
(b) Adverse publicity
(c) Untitled letter
(d) Warning letter
(e) Voluntary recall (Class I, II, or II)
    (i) District
    (ii) Firm-initiated
    (iii) FDA-requested
(f) Import detention/refusal of entry
(g) Administrative detention (Bioterrorism Act; credible evidence or information of threat of serious adverse health consequences or death)
(h) Seizure
(i) Injunction
(j) Prosecution under the Federal Food, Drug, and Cosmetic Act
    (i) Misdemeanor, *United States v. Park*, 421 U.S. 658 (1975); *United Sates v. Dotterweich*, 320 U.S. 277 (1943)
    (ii) Felony, "intent to defraud or mislead"

The FSMA adds the following new enforcement tools for compliance with food safety rules:

(a) Administrative correction via deficiency letter issued by District in consultation with Center for Food Safety and Applied Nutrition (CFSAN))(food) or Center for Veterinary Medicine (CVM) (animal food)
(b) Administrative detention (broader than the Bioterrorism Act; reason to believe adulterated or misbranded)
(c) Mandatory recall
(d) Suspension of registration

The right to force a mandatory recall of product is considered a significant change in the enforcement powers of the FDA, along with the ability to suspend the food manufacturer's registration.

FDA Inspection:

The FDA is given extensive powers to investigate any risk to the nation's food supply. This may be through voluntary inspections or through search and seizure warrants obtained *ex parte* from a judge. Pursuant to 21 U.S.C. §§ 373-374, the FDA may have access to and copy all records showing the movement of food through interstate commerce. The FDA may conduct random or targeted inspections as a result of this authority. In a routine inspection, the FDA can examine the operations related to food production and distribution. The FDA may also conduct a targeted inspection that focuses on a particular product or process generally in response to a complaint or concern related to that product. These inspections involve examination of the products, storage

facilities, manufacturing and shipping processes, as well as interviews of employees at the facility. The purpose of the inspection is to determine whether there is any violation of the Food Drug and Cosmetic Act or the regulations implementing the FDCA. As such, it is important to recognize that the inspection is an adversarial action, and the involvement of an attorney representing the company is important.

The following information generally falls within the broad investigatory powers of the FDA, and thus can be accessed during an inspection:

- Labels, advertising, catalogs, brochures, or other promotional materials used to sell the products;
- Samples of ingredients and finished products;
- Sources of ingredients and certificates of analysis for those ingredients;
- Adverse event reporting files and company responses to adverse event reporting
- Access to locations in the plant where products are manufactured, ingredients are stored, and shipped for distribution
- Standard operating procedures, corrective actions, lab results, purchase orders, shipping records, etc.

Because some of this information qualifies as a trade secret, and it can be obtained through a FOIA request by other parties, it is important to remember that the company has the right to label the documents "confidential" to prevent the release of the information to the public.

483 Letters and Responding to 483 Letters:

The inspection ends with the presentation of Form FDA 483. This contains a list of significant objectionable conditions and practices that violate statutes or regulations enforced by the FDA. The Form 483 is not intended to be an all-inclusive list of issues found at the site. The purpose of the form is to notify the food manufacturer of any significant, perceived violations. The interview to discuss the Form 483 is intended to provide an opportunity for the food manufacturer to clarify any issues identified, and any deficiencies corrected during the inspection. The Form 483 is subject to release through a FOIA request.

The food manufacturer is entitled to respond to the Form 483 within 15 business days after receipt. If the food manufacturer does not respond within the 15 day window, the agency will not consider the response in determining whether to take subsequent action. The response should acknowledge the significance of the observations noted, and describe the corrective actions taken or to be taken by the food manufacturer, along with reasonable time frames for accomplishment of the corrective actions. The response should also assure the FDA that the quality of the products previously distributed are not a risk to public safety, and provide information to support this assurance.

The FDA prepares an inspection report, which identifies the issues found at the site, and determines the corrective action that should be taken. The inspection report may classify the inspection as NAI (No Action Indicated); VAI (Voluntary Action Indicated); and OAI (Office Action Indicated). The inspection may result in a Warning Letter to the food manufacturer, which is published immediately and is available to the public through a FOIA request. The purpose of the Warning

Letter is to obtain voluntary compliance with FDA statutes and regulations by the food manufacturer. It identifies significant violations, and may lead to enforcement actions if not promptly and adequately addressed. Failure to correct the significant violations may lead to recall, seizure of product, injunction on food manufacturers' ability to operate, monetary fines, suspension or revocation of licenses, or even prosecution.

Recalls:

A recall occurs when product is removed from the market due to the risk that it is unsafe, adulterated, or mislabeled. Food recalls are classified according to the risk to the consumer of that food.

Type of Recall	Standards	Examples
Class I	There is a "reasonable probability" that consuming the food will cause serious, adverse health consequences or death.	L. Monocytogenes, E. coli; salmonella; food with an undeclared allergen
Class II	There is a "remote possibility" that consuming the food will cause adverse health consequences.	Product containing a foreign material
Class III	Eating the food will not cause adverse health consequences.	Minor label discrepancy or undeclared ingredients that are not allergens, etc.

Recalls often began with a report submitted by the manufacturer to the Reportable Food Registry (RFR), an electronic portal for notifying the FDA of "reportable foods." The manufacturer is required to submit a report to the RFR when there is a reasonable probability that the use of, or exposure to, an article of food will cause *serious adverse health consequences or death to humans or animals*. Upon receipt of this report, the FDA reviews it to determine an appropriate response. This might include an alert or notification, or a voluntary or mandatory recall. The standard used to determine the appropriate action is whether it is necessary to protect the public's health. The recall process is overseen by the FDA.

The three critical components of a recall include (a) Notice of the Recall; (b) Removal of the Affected Product from the food supply; and (c) Control of the Recalled Products. The FDA reviews these components to evaluate the effectiveness of the recall, and this in turn may determine the impact on the food manufacturer's ability to continue doing business.

A food manufacturer must be diligent in providing the Notice of the Recall, and tracking the response of the recipients of the Notice of Recall. This requires appropriate and timely notice of the recall to the relevant entities, identifying the affected product (including company name, brand name, lot codes, product dates, etc.) with specific instructions as to the action to be taken, and acknowledgement of the notice and a report of the actions taken by the recipients of the notice. The instructions must include directions to notify any entities that received the product through the distribution process after leaving the control of the food manufacturer. The FDA also takes steps to provide notice to consumers through press releases, as well as notices posted on the FDA website.

The responses from the entities receiving the recalled product must be collected and reported to the FDA for the FDA to evaluate the effectiveness of the recall. The responses should include data related to the amount of affected product in inventory through the distribution process, which enables the FDA to determine the amount of affected product that has reached the ultimate consumer. It is the responsibility of the manufacturer to provide specific instructions related to the destruction and disposal of the product in a safe manner that will prevent consumption by a human, and the entity that destroys and disposes of the product must provide verification of the destruction and disposal of the affected products.

See www.fda.gov/Food/FoodSafety/FSMA/ucm247548.htm for information related to the FDA's regulatory authority related to food recalls.

Additional Resources:

Enforcement:
"Operational Strategy for Implementing the FDA Food Safety Modernization Act (FSMA)," https://www.fda.gov/food/guidanceregulation/fsma/ucm395105.htm

Compliance dates:
Human food preventive controls:
https://www.fda.gov/food/guidanceregulation/fsma/ucm334115.htm

Animal feed preventive controls:
https://www.fda.gov/food/guidanceregulation/fsma/ucm366510.htm

Produce safety:
https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm#dates

Foreign supplier verification program:
https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm503822.htm

Third party accreditation and certification:
https://www.fda.gov/food/guidanceregulation/fsma/ucm361903.htm

Sanitary transportation:
https://www.fda.gov/food/guidanceregulation/fsma/ucm383763.htm

Food defense:
https://www.fda.gov/food/guidanceregulation/fsma/ucm378628.htm#compliance_dates
https://www.gpo.gov/fdsys/pkg/FR-2016-08-24/pdf/2016-20176.pdf