



**Congressional
Research Service**

Informing the legislative debate since 1914

Food Recalls and Other FDA Administrative Enforcement Actions

Emily M. Lanza
Legislative Attorney

November 20, 2014

Congressional Research Service

7-5700

www.crs.gov

R43794

Summary

The U.S. Food and Drug Administration (FDA) ensures the safety of all food except for meat, poultry, and certain egg products over which the U.S. Department of Agriculture (USDA) has regulatory oversight. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), the FDA has the authority to regulate the manufacturing, processing, and labeling of food with the primary goal of promoting food safety.

Congress has granted the FDA the authority to take both administrative and judicial enforcement actions. The agency initiates and carries out administrative enforcement actions while judicial enforcement actions, including seizures and injunctions, require some type of involvement by the courts. Additionally, administrative enforcement actions, such as inspections and warning letters, tend to precede any judicial enforcement action. The Food Safety Modernization Act (FSMA) expanded the FDA's enforcement authority with new and broader measures. This report focuses on the statutory authority and legal issues relating to the following administrative enforcement actions: inspections, warning letters, recalls, suspension of registration, and administrative detention.

Inspections: The FDA conducts inspections of regulated facilities in order to oversee a firm's compliance with the FFDCA and corresponding regulations. The FFDCA grants the agency with the enforcement authority to inspect both facilities and records. However, the act narrowly tailors this authority in order to balance the protection of the facility owners' Fourth Amendment rights and the promotion of public health.

Warning Letters: Under the FFDCA, the FDA also has the ability to decline to institute formal enforcement proceedings for minor violations of the act if the agency believes that it could adequately serve public interest through written correspondence to violators. These warning letters give recipient firms an opportunity to take voluntary corrective actions before the FDA initiates a more formal enforcement action.

Recalls: The recall process permits the FDA to enforce the adulteration and misbranding provisions of the FFDCA by encouraging industry participants to remove the product and correct the violation. FDA regulations outline several steps that both the firm and agency must take when issuing either a voluntary or mandatory recall. FSMA granted the FDA the authority to issue a mandatory recall. FSMA also established the opportunity for an informal hearing, at which a firm may dispute these types of recalls, in order to protect the due process rights of the recalling firms.

Suspension of Registration: The FFDCA requires all food facilities to register with the FDA so that the agency may effectively oversee all areas of food production. If the FDA determines that a food manufactured, processed, packed, received, or held by a registered facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals, the agency may suspend the registration of a facility that created, caused, or was otherwise responsible. This enforcement authority is intended to permit the agency to determine the location and source of an outbreak of food-borne illness and thus notify facilities that may be affected quickly and efficiently.

Administrative Detention: Under the FFDCA, an FDA employee may order the detention of any article of food that is found during an FDA inspection if the employee has reason to believe that

such article is adulterated or misbranded. Under this administrative detention authority, the FDA may prevent illegal articles from being moved or consumed until the court grants a seizure order.

Contents

| | |
|---|----|
| FDA Enforcement Authority..... | 1 |
| Inspections | 1 |
| Facilities | 2 |
| Records..... | 3 |
| Targeting Inspection Resources..... | 3 |
| Fourth Amendment Constraints..... | 3 |
| Warning Letters..... | 4 |
| Recalls..... | 6 |
| Types of Recalls | 6 |
| Voluntary and Mandatory Recalls | 7 |
| Recall Process..... | 8 |
| Initiation of the Recall..... | 8 |
| Classification of the Recall | 8 |
| Notification and Public Warning | 9 |
| Monitoring and Auditing the Recall..... | 10 |
| Termination of the Recall..... | 10 |
| Due Process Protections Within Mandatory Recall Authority | 10 |
| Suspension of Registration | 11 |
| Administrative Detention..... | 12 |

Contacts

| | |
|---------------------------------|----|
| Author Contact Information..... | 13 |
|---------------------------------|----|

The U.S. Food and Drug Administration (FDA) ensures the safety of all food except for meat, poultry, and certain egg products over which the U.S. Department of Agriculture (USDA) has regulatory oversight.¹ Under the Federal Food, Drug, and Cosmetic Act (FFDCA), the FDA has the authority to regulate the manufacturing, processing, and labeling of food, with the primary goal of promoting food safety.²

Congress has granted the FDA with the authority to take both administrative and judicial enforcement actions. The agency initiates and carries out administrative enforcement actions while judicial enforcement actions, including seizures and injunctions, require some type of involvement by the courts.³ Additionally, administrative enforcement actions, such as inspections and warning letters, tend to precede any judicial enforcement action. The Food Safety Modernization Act (FSMA) expanded the FDA's enforcement authority with new and broader measures.⁴ The FDA's implementation of FSMA and related delays in the rulemaking process, in addition to general oversight of FSMA's new food safety provisions, are of continuing interest to Congress.⁵ This report focuses on the FDA's statutory authority to initiate the following administrative enforcement actions: inspections, warning letters, recalls, suspension of registration, administrative detention, and related legal issues.

FDA Enforcement Authority

Section 301 of the FFDCA prohibits the violation of any of the substantive provisions of the act and serves as the basis for the FDA's enforcement actions.⁶ Under Section 301, "causing" any of the prohibited acts as well as the act itself is prohibited. The specific enforcement mechanisms available to the agency to enforce the FFDCA are found throughout the act. Private citizens do not have the right to sue to enforce the FFDCA. Section 310(a) states that "all ... proceedings for the enforcement, or to restrain violations, of this [act] shall be by and in the name of the United States."⁷

Inspections

The FDA conducts inspections of regulated facilities in order to oversee a firm's compliance with the FFDCA and corresponding regulations.⁸ The FFDCA grants the agency with the enforcement authority to inspect both facilities and records. However, courts have generally held that

¹ Memorandum of Understanding with the Department of Agriculture and the Food and Drug Administration, 40 Fed. Reg. 25079 (June 12, 1975) (agreement concerning related objectives in carrying out the Federal Meat Inspection Act, Poultry Products Inspection Act, and the Federal Food, Drug, and Cosmetic Act.)

² 21 U.S.C. §301 et seq.

³ See FDA, FDA Compliance and Enforcement Information, available at <http://www.fda.gov/AboutFDA/Transparency/Transparencyinitiative/ucm254426.htm>.

⁴ Food Safety Modernization Act of 2010 (2011) (FSMA), P.L. 111-353, 124 Stat. 3885.

⁵ See CRS Report R42885, *Food Safety Issues for the 113th Congress*, by Renée Johnson, for a discussion on the current food safety issues of interest to Congress.

⁶ 21 U.S.C. §331.

⁷ 21 U.S.C. §337(a).

⁸ 21 U.S.C. §374.

inspections properly executed under the FFDCCA do not violate the Fourth Amendment rights against search and seizure of the facility owners.⁹

This section examines the inspection enforcement authority of both facilities and records. Because of FSMA's mandate to increase the number of inspections by the FDA, this section also discusses the tools and methods used by the agency to target inspection resources effectively and efficiently. The section concludes by analyzing the Fourth Amendment protections embedded within this particular enforcement authority.

Facilities

The FFDCCA authorizes designated FDA employees to enter “at reasonable times and within reasonable limits and in a reasonable manner” any factory, warehouse, or establishment in which food is manufactured, processed, packed, or held for introduction into interstate commerce.¹⁰ Generally, courts have interpreted “reasonableness” in this context by considering whether the inspection meets the statutory requirements outlined in Sections 703 and 704 of the FFDCCA.¹¹

This inspection authority covers all pertinent equipment, finished and unfinished materials, containers, and labeling at these locations. The FDA inspector must present the appropriate credentials and a written notice to the owner, operator, or agent in charge before entering the facility.¹² However, the act does not require the FDA to include the reasons for the inspection in this notice.¹³

After the inspection, the FDA employee presents the owner, operator, or agent in charge with a written report setting forth the conditions or practices observed. This report notes any food that contains filthy, putrid, or decomposed substances, or whether the food has been prepared, packed, or held under insanitary conditions, leading to contamination that may be injurious to a consumer's health.¹⁴ The FDA employee also provides the owner, operator, or agent in charge with a receipt for any samples obtained during the inspection.¹⁵ Refusal to permit an FDA inspector to duly enter and inspect a regulated facility violates the FFDCCA and may lead to the FDA seeking further judicial enforcement action, such as an inspection warrant issued by a district court.¹⁶

⁹ See, e.g., *U.S. v. Jamieson-McKames Pharmaceuticals, Inc.*, 651 F.2d 532, 536-41 (8th Cir. 1981); *U.S. v. Del Campo Baking Mfg. Co.*, 345 F.Supp. 1371, 1376-77 (D. Del. 1972) (discussion whether FDA's general inspection authority is consistent with the Fourth Amendment).

¹⁰ 21 U.S.C. §374(a)(1)(B).

¹¹ See *U.S. v. Gel Spice Co., Inc.*, 601 F.Supp. 1214, 1228-29 (E.D.N.Y. 1985).

¹² 21 U.S.C. §374(a)(1).

¹³ See FDA, Investigations Operations Manual 2014, Exhibit 5-1, Example of a Notice of Inspection, <http://www.fda.gov/downloads/ICECI/Inspections/IOM/ucm127428.pdf>.

¹⁴ 21 U.S.C. §374(b).

¹⁵ 21 U.S.C. §374(c).

¹⁶ 21 U.S.C. §331(f). See FDA, Investigations Operations Manual 2014, 5.2, <http://www.fda.gov/ICECI/Inspections/IOM/ucm122530.htm#5.2.5.1>.

Records

If the FDA reasonably believes that an article of food is likely to be adulterated and presents a threat of serious health consequences or death to humans and/or animals, then the FDA may inspect the records related to that food.¹⁷ According to the FDA, such determinations are fact specific, and thus are made on a case-by-case basis.¹⁸ The holder of the relevant records must make the records accessible to the FDA within 24 hours from the receipt of the official FDA request.¹⁹ The holders of these records include those who manufacture, process, pack, distribute, receive, hold, or import the food.²⁰ The FFDCAs generally exempt farms, restaurants, and some retail food establishments from these record requirements.²¹

Targeting Inspection Resources

FSMA directed the FDA to increase the frequency of inspections at all facilities.²² For domestic high-risk facilities, the FDA must inspect each facility at least once between January 4, 2011,²³ and January 4, 2016, and then once every three years after January 4, 2016. For domestic facilities that are not high risk, the FDA must inspect each facility once between January 4, 2011, and January 4, 2018, and then once every five years after January 4, 2018.

FSMA required the FDA to create “risk profiles” of certain foods susceptible to microbial contamination in order to assist the FDA with scheduling inspections and allocating resources to accommodate this increased frequency of food facility inspections.²⁴ A risk profile incorporates known safety risks of the food that is manufactured, processed, packed, or held at the facility.²⁵ The profile also addresses the compliance history of the facility, and the effectiveness of the facility’s hazard analysis and risk-based preventative controls.²⁶

Fourth Amendment Constraints

Generally, government inspections are a form of a search, and thus are constrained by the Fourth Amendment’s prohibition against “unreasonable searches and seizures.”²⁷ However, courts have held that the FDA is not required to obtain a search warrant to inspect a facility under Section 704 of the FFDCAs as long as the FDA conducts the inspection reasonably as to time, place, and method.²⁸

¹⁷ 21 U.S.C. §350c(a).

¹⁸ 79 Fed. Reg. 18799, 18801 (Apr. 4, 2014).

¹⁹ 21 C.F.R. §1.361.

²⁰ 21 U.S.C. §350c(a).

²¹ 21 C.F.R. §1.327.

²² FSMA, P.L. 111-353 (2011), §201.

²³ FSMA’s date of enactment.

²⁴ 21 U.S.C. §350j(a).

²⁵ *Id.*

²⁶ *Id.*

²⁷ U.S. CONST. amend. IV.

²⁸ *See, e.g.,* U.S. v. New England Grocers Supply Co., 488 F. Supp. 230, 238-39 (D. Mass. 1980).

In a case involving the inspection authority pursuant to the Gun Control Act of 1968,²⁹ the U.S. Supreme Court in *U.S. v. Biswell* stated that a warrantless inspection is reasonable under the Fourth Amendment when a statute provides the authority to conduct an inspection in a carefully limited manner.³⁰ The Court expanded on this principle in *New York v. Burger* by holding that an owner of commercial premises in a closely regulated industry has a reduced expectation of privacy regarding inspections by the government. Therefore, according to the Court in *Burger*, a warrantless inspection of the commercial premises by the government may be reasonable under the Fourth Amendment.³¹ The Court in this case outlined three criteria that would deem a warrantless government inspection as reasonable under what the Court referred to as the *Colannade-Biswell* doctrine.³² First, a substantial government interest must support the regulatory inspection scheme.³³ Second, the warrantless inspections must be “necessary to further [the] regulatory scheme.”³⁴ Finally, the regulatory statute must function as a warrant by limiting the discretion of the inspecting officers and by advising the owner of the commercial premises that the government may conduct a search within the properly defined scope of the law.³⁵

Applying the *Colannade-Biswell* doctrine to FDA inspections, lower courts have concluded that these inspections generally further a federal interest in food safety, and thus may proceed without a warrant despite the potential threat to privacy.³⁶ In *U.S. v. New England Grocers Supply Co.*, the court held that neither a warrant nor consent was required to inspect the defendant’s warehouse because the government’s interest in food safety underlies the FDA’s inspection regulations and the agency conducted the searches reasonably as to time, manner, and scope.³⁷ Although considering the search and seizure of veterinary drugs, the Ninth Circuit in *U.S. v. Argent Chemical Laboratories, Inc.* held that an FDA inspection pursuant to the relevant FFDCA provisions satisfied the *Colannade-Biswell* doctrine because a substantial government interest is present regarding the safety and effectiveness of the product; unannounced, warrantless inspections further the regulatory scheme by having a deterrent effect; and finally the FFDCA and accompanying regulations define the scope of the search and serve as a “[C]onstitutionally adequate substitute for a warrant.”³⁸

Warning Letters

Section 309 of the FFDCA permits the FDA to decline to institute formal enforcement proceedings for “minor violations of this [act] whenever [the agency] believes that the public interest [would] be adequately served by a suitable written notice or warning.”³⁹ These warning

²⁹ 18 U.S.C. §921 *et seq.*

³⁰ *U.S. v. Biswell*, 406 U.S. 311, 315-16 (1972).

³¹ *N.Y. v. Burger*, 482 U.S. 691, 701-02 (1987).

³² *Id.* at 702-03.

³³ *Id.* at 702.

³⁴ *Id.* (citing *Donovan v. Dewey*, 452 U.S. 594, 600 (1981)).

³⁵ *Burger*, 482 U.S. at 703.

³⁶ See *U.S. v. Bus. Builders, Inc.*, 354 F.Supp. 141, 143 (N.D. Okla. 1973); *U.S. v. Del Campo Baking Mfg. Co.*, 345 F.Supp. 1371, 1376 (D. Del. 1972).

³⁷ *New England Grocers Supply Co.*, 488 F.Supp. at 238-39.

³⁸ *U.S. v. Argent Chem. Labs., Inc.*, 93 F.3d 572, 576 (9th Cir. 1996).

³⁹ 21 U.S.C. §336.

letters give recipient firms an opportunity to take voluntary corrective actions before the FDA initiates more formal enforcement action.⁴⁰ A warning letter sent by the FDA also establishes prior notice and documents prior warning if adequate corrections are not made and further enforcement action is necessary.⁴¹

The FDA may consider issuing a warning letter if the agency has found evidence that a firm or product violates the FFDCFA and that failure to correct such a violation may lead to the agency's consideration of further formal enforcement action.⁴² The agency may favor a warning letter as a more efficient enforcement option if the agency reasonably expects that the responsible firm or persons would take prompt corrective action after receiving such a letter.⁴³

Warning letters include two types of correspondence: a regulatory letter and a report of investigation finding.⁴⁴ A regulatory letter warns the violator that formal enforcement is likely in the absence of voluntary compliance. A report of investigation finding (also referred to as an information letter) requests voluntary correction by the addressee. Both methods of communication are informal and advisory.⁴⁵ An FDA warning letter typically is labeled as such and includes the dates of the inspection during which the agency discovered the statutory violation(s).⁴⁶ The letter would also request the recipient to institute corrective action(s) and to return a written response to the agency's warning letter. The FDA generally includes a warning in the letter that failure to correct the violation promptly may result in additional enforcement action.⁴⁷

FDA warning letters are informal and advisory.⁴⁸ A warning letter may communicate the FDA's position on a certain issue but does not commit the agency to taking any further enforcement action. Thus, the FDA has concluded that a warning letter does not qualify as a final agency action subject to judicial review under the Administrative Procedure Act.⁴⁹

Courts generally agree with this interpretation of the legal status of warning letters. In *Holistic Candlers and Consumers Ass'n v. FDA*, the D.C. Circuit found that the agency's warning letters requesting that the addressee take prompt action to correct certain FFDCFA product violations did not qualify as final agency action, and thus could not serve as the basis for the addressee's legal claim against the agency.⁵⁰ The D.C. Circuit further articulated that in order for any agency action to be "final" the action must mark the beginning of the agency's decision-making process, and that the action must be one from which "legal consequences will flow."⁵¹ According to the court,

⁴⁰ FDA, Regulatory Procedures Manual, 4-1-1, available at <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm>. It is important to note that the Regulatory Procedures Manual serves as a reference for FDA employees and industry. The manual is not binding on industry or the agency.

⁴¹ *Id.*

⁴² Regulatory Procedures Manual, *supra* note 40, at 4-1-3.

⁴³ *Id.*

⁴⁴ Regulatory Procedures Manual, *supra* note 40, at 4-1-1.

⁴⁵ *Id.*

⁴⁶ Regulatory Procedures Manual, *supra* note 40, at 4-1-10.

⁴⁷ *Id.*

⁴⁸ Regulatory Procedures Manual, *supra* note 40, at 4-1-1.

⁴⁹ 21 C.F.R. §10.65(a).

⁵⁰ *Holistic Candlers and Consumers Ass'n v. FDA*, 664 F.3d 940, 946 (D.C. Cir. 2012).

⁵¹ *Id.* at 943.

an FDA warning letter is not final because it provides firms with an opportunity to take voluntary corrective action before the FDA decides to initiate any enforcement action.⁵² Additionally, the court concluded that “legal consequences” cannot arise from warning letters due to their informal and advisory nature.⁵³ Similarly, the Ninth Circuit in *Biotics Research Corp. v. Heckler* emphasized the point that FDA regulatory letters do not constitute final administrative determinations subject to judicial review due to the absence of any commitment on behalf of the FDA to follow the correspondence with additional enforcement actions.⁵⁴

Recalls

The recall process permits the FDA to enforce the adulteration and misbranding provisions of the FFDCFA by encouraging industry participants to remove the product and correct the violation. This section addresses this FDA recall enforcement authority by first analyzing the various triggers of the recall process and then by examining the FDA recall process itself. This section concludes with an analysis of the due process concerns related to the mandatory recall enforcement authority.

Types of Recalls

FDA regulations define a “recall” as a firm’s removal or correction of a marketed product that the FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action, such as a seizure.⁵⁵ Under these regulations, a “recall” is different from a “market withdrawal.” A market withdrawal is a firm’s removal or correction of a distributed product that involves a minor violation that would not be subject to legal action by the FDA.⁵⁶ A market withdrawal may not involve an FFDCFA violation at all. Normal stock rotation practices and routine equipment adjustments and repairs may prompt a market withdrawal.⁵⁷ The FDA may assist a firm issuing a market withdrawal when the cause for withdrawal may not be obvious or clearly understood, but the deficiency of the product is apparent (for example, when a consumer complains of adverse reactions to the product).⁵⁸

A common reason for a recall is an undeclared ingredient.⁵⁹ These recalls typically violate FFDCFA’s labeling provisions that require food labels to declare major food allergens.⁶⁰ A food label subject to such type of recall may not include a statement after the ingredient list disclosing that the food contains a major food allergen, or the label may list the major food allergen in the ingredients but not by the common or usual name. For example, Whole Foods Market recalled its

⁵² *Id.* at 944.

⁵³ *Id.*

⁵⁴ *Biotics Research Corp. v. Heckler*, 710 F.2d 1375, 1377-78 (9th Cir. 1983).

⁵⁵ 21 C.F.R. §7.3(g).

⁵⁶ 21 C.F.R. §7.3(j).

⁵⁷ *Id.*

⁵⁸ 21 C.F.R. §7.46(d).

⁵⁹ Common food allergens include milk, egg, fish, shellfish, tree nuts, wheat, and peanuts. See FDA, *2013 Recalls, Market Withdrawals & Safety Alerts*, available at <http://www.fda.gov/Safety/Recalls/ArchiveRecalls/2013/default.htm>.

⁶⁰ See 21 U.S.C. §343(w).

organic creamy spinach dip in December 11, 2013, because the label did not disclose that the dip contained eggs, a major food allergen.⁶¹

Another common trigger of a recall is the detection of microbiological contamination, such as *Salmonella enteritidis* and *Listeria monocytogenes*. For example, Flat Creek Farm & Dairy recalled 200 pounds of Heavenly Blue Cheese in November 26, 2013, due to potential contamination with *Salmonella enteritidis*.⁶² Recalls due to microbiological contamination often arise because of a firm's violation of the FDA's Current Good Manufacturing Practices (CGMPs).⁶³ CGMPs outline the methods, equipment, facilities, and controls to produce safe and wholesome food.

Voluntary and Mandatory Recalls

If the FDA determines that there is a reasonable probability that an article of food is adulterated⁶⁴ or misbranded⁶⁵ and the use or exposure to such article of food⁶⁶ will cause serious health consequences or death to humans or animals, the FDA then provides the responsible party with the opportunity to cease distribution and recall such article of food voluntarily.⁶⁷

While most recalls are “voluntary” or “requested by the FDA,” FSMA granted the FDA with the authority to issue mandatory recalls.⁶⁸ If the responsible party does not cease distribution or recall such an article of food within the time and manner prescribed by the FDA or refuses to act at all, the FDA may require the responsible party to immediately cease distribution of the violative product.⁶⁹ The FDA must provide the responsible party with the opportunity to initiate a voluntary recall before the agency issues the mandatory recall order.⁷⁰ After receiving the mandatory recall order, the responsible party then notifies the following people of the recall: those involved in manufacturing, processing, packing, transporting, distributing, receiving, holding, importing, or selling of the product.⁷¹ The responsible party must also provide third-party warehouses with sufficient information to identify the article of food covered by the recall.⁷²

⁶¹ Press Release, Whole Foods Market, Whole Foods Market Mid-Atlantic Region Recalls Spinach Dip Due to Undeclared Egg (Dec. 11, 2013), *available at* <http://www.fda.gov/Safety/Recalls/ucm378448.htm>.

⁶² Press Release, Flat Creek Farm & Dairy, Flat Creek Farm & Dairy Recalls Heavenly Blue Because of Possible Health Risk (Nov. 26, 2013), *available at* <http://www.fda.gov/Safety/Recalls/ucm376981.htm>.

⁶³ See 21 C.F.R. §110.3 et seq.

⁶⁴ 21 U.S.C. §342.

⁶⁵ 21 U.S.C. §343.

⁶⁶ The statute excludes infant formula from the articles of food that are subject to a voluntary recall under this provision. 21 U.S.C. §350l(a). Infant formula recalls follow the procedures outlined in 21 C.F.R. §107.200 et seq.

⁶⁷ 21 U.S.C. §350l(a).

⁶⁸ FSMA, P.L. 111-353 (2011), §206.

⁶⁹ 21 U.S.C. §350l(b)(1).

⁷⁰ FDA cannot issue a mandatory recall for alcoholic beverages under the mandatory recall statutory authority (21 U.S.C. §350l) until the Alcohol and Tobacco Tax and Trade Bureau has had a reasonable opportunity to cease distribution and recall such beverage. 21 U.S.C. §350l(e).

⁷¹ *Id.*

⁷² 21 U.S.C. §350l(b)(2).

Recall Process

FDA guidance outlines five broad phases as part of the recall process for both voluntary and mandatory recalls.⁷³ The five phases are as follows: initiation, classification, notification, monitoring, and termination.

Initiation of the Recall

The recalling firm and the FDA take different steps to initiate the recall depending on whether the recall is voluntary, requested by the FDA, or mandated by the FDA. When a company voluntarily initiates a recall, FDA regulations recommend that the recalling firm immediately contact the FDA.⁷⁴ At this phase, the recalling firm provides the FDA with the following information: identity of the product involved in the recall; reason for removal; an evaluation of the risk; total amount of such products produced and distributed; distribution information; and a proposed strategy for conducting the recall.⁷⁵

The FDA may request a recall if a product presents a risk of illness, injury, or gross consumer deception; the firm has not initiated a recall of the product; and agency action is necessary to protect public health and welfare.⁷⁶ If the FDA has requested the recall, the FDA notifies the firm that has the primary responsibility for the manufacture or marketing of the product of the need to recall the product immediately.⁷⁷ The firm then provides the agency with similar information to that described in the above paragraph.⁷⁸

If the FDA has issued a mandatory recall, the FDA then issues a written order to the firm to recall the product.⁷⁹ The order includes the provision of the act violated by the firm that prompted the recall,⁸⁰ the basis for FDA's authority to issue the recall,⁸¹ a description of the product, and a time frame for the firm to reply.⁸²

Classification of the Recall

After either the FDA or the firm initiates the recall, the FDA evaluates the health hazard presented by the product and looks at whether a precedent exists to guide strategy based on this specific health hazard.⁸³ Relying on the information from the evaluation, the FDA classifies the recall according to the health hazard presented by the recalled product.⁸⁴ A reasonable probability of

⁷³ See generally, FDA, Regulatory Procedures Manual, Chapter 7, available at <http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074312.pdf>.

⁷⁴ 21 C.F.R. §7.40(b).

⁷⁵ 21 C.F.R. §7.46(a).

⁷⁶ 21 C.F.R. §7.45(a)(1)-(3).

⁷⁷ 21 C.F.R. §7.45(b).

⁷⁸ 21 C.F.R. §7.45(c).

⁷⁹ Regulatory Procedures Manual, *supra* note 40, at 7-5-3.

⁸⁰ For example, the FDA will cite 21 U.S.C. §402 for adulterated food or 21 U.S.C §403(w) for misbranded food.

⁸¹ 21 U.S.C. §350l.

⁸² Regulatory Procedures Manual, *supra* note 40, at 7-5-3.

⁸³ Regulatory Procedures Manual, *supra* note 40, at 7-6-1.

⁸⁴ 21 C.F.R. §7.41

serious adverse health risks and/or death triggers a Class I recall.⁸⁵ A Class II recall covers products that may cause a temporary or medically reversible adverse health outcome.⁸⁶ A Class III recall includes violative products that are unlikely to cause an adverse health outcome.⁸⁷

When classifying a recall, an ad hoc committee of FDA scientists may take into account the following factors:

- “(1) Whether any disease or injuries have already occurred from the use of the product.
- (2) Whether any existing conditions could contribute to a clinical situation that could expose humans or animals to a health hazard....
- (3) Assessment of hazard to various segments of the population ... who are expected to be exposed to the product being considered, with particular attention paid to the hazard to those individuals who may be at greatest risk.
- (4) Assessment of the degree of seriousness of the health hazard to which the populations at risk would be exposed.
- (5) Assessment of the likelihood of occurrence of the hazard.
- (6) Assessment of the consequences (immediate or long-range) of occurrence of the hazard.”¹

In conjunction with the classification, the FDA reviews the recall strategy presented by the firm.⁸⁸ The strategy addresses the depth and scope of the recall, a communication plan to warn the public, and methods used to measure the effectiveness of the recall.⁸⁹

Notification and Public Warning

After classification, the firm must then notify affected parties. FDA regulations state that the format, content, and extent of the recall communication should reflect the hazard of the product being recalled as well as the strategy for that particular recall.⁹⁰ Recall communications should convey information that identifies the product in question and the reason for the recall and provide instructions regarding any specific actions that should be taken with the product.⁹¹ FDA guidance also outlines the scope of recipients. These recipients may include the wholesale distributor, retail vendor, or the consumer, depending on how far the violative product has been distributed in commerce.⁹²

⁸⁵ *Id.*

⁸⁶ *Id.*

⁸⁷ *Id.*

⁸⁸ Regulatory Procedures Manual, *supra* note 40, at 7-6-3.

⁸⁹ 21 C.F.R. §7.42(b).

⁹⁰ 21 C.F.R. §7.49(a).

⁹¹ 21 C.F.R. §7.49(a), (c).

⁹² See FDA, Guidance for Industry: Product Recalls, Including Removals and Corrections, Nov. 3, 2003, available at <http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm>.

In addition to recall communications issued by the firm, the FDA also notifies other federal agencies and state and local governments of the recall and relevant information.⁹³ Additionally, the FDA agency publicly discloses all recalls on its website, and may also notify consumers by issuing a press release for Class I recalls.⁹⁴ The FDA lists each recall and accompanying information in its weekly FDA Enforcement Report.⁹⁵ The agency does not include market withdrawals or stock recoveries in this report.⁹⁶

Monitoring and Auditing the Recall

The recalling firm has the legal responsibility to monitor the effectiveness of the recall.⁹⁷ As part of this monitoring, the firm must submit recall status reports to the appropriate FDA district office, generally every two to four weeks.⁹⁸ These reports update the agency on the number of individuals who were notified, the response to these notifications, and the number of products returned.⁹⁹ The FDA can provide assistance with monitoring the effectiveness of the recall if some substantial difficulty is present, such as when the product is widely dispersed on the consumer level.¹⁰⁰ The FDA may also audit the recall independently of this assistance to ensure that the recall action has been effective.¹⁰¹

Termination of the Recall

The FDA terminates a recall when the firm has completed all recall activity, as required by the previous phases.¹⁰² When the FDA makes such a final determination, the agency provides a written notification of the termination to the recalling firm. Generally, the agency officially terminates a successful recall within three months of the recalling firm's completion of the recall activities.

Due Process Protections Within Mandatory Recall Authority

Before Congress granted the FDA with the mandatory recall authority under FSMA, commentators speculating about the possibility of this method of enforcement raised concerns about due process. Commentators were particularly concerned with the protection of a firm's interests against a potentially arbitrary mandatory recall order.¹⁰³ FSMA's provision mandating

⁹³ Regulatory Procedures Manual, *supra* note 40, at 7-7-2.

⁹⁴ Regulatory Procedures Manual, *supra* note 40, at 7-7-3.

⁹⁵ 21 C.F.R. §7.50.

⁹⁶ *Id.*

⁹⁷ Regulatory Procedures Manual, *supra* note 40, at 7-8-1.

⁹⁸ 21 C.F.R. §7.53(a).

⁹⁹ 21 C.F.R. §7.53(b).

¹⁰⁰ Regulatory Procedures Manual, *supra* note 40, at 7-8-1.

¹⁰¹ Regulatory Procedures Manual, *supra* note 40, at 7-8-2.

¹⁰² Regulatory Procedures Manual, *supra* note 40, at 7-9.

¹⁰³ See, e.g., Julie Gallagher, "Recall Authority Would Allow for Due Process," SUPERMARKET NEWS BLOG, (Apr. 20, 2009), <http://supermarketnews.com/blog/recall-authority-would-allow-due-process>; Michael T. Roberts, *Mandatory Recall Authority: A Sensible and Minimalist Approach to Improving Food Safety*, 59 FOOD & DRUG L.J. 563, 579 (2004).

that the FDA shall provide the responsible party subject to a mandatory recall order with the opportunity for an informal hearing addresses these due process concerns.¹⁰⁴

This informal hearing must occur no later than two days after the mandatory recall order.¹⁰⁵ The hearing is designed to address the actions required by the order. The recalling firm also has the opportunity at the hearing to argue against the recall and to articulate reasons for its termination. After the hearing, the FDA may then amend the order to specify a timetable for the recall and to require periodic reports, submitted by the responsible party, updating the agency on the recall's progress;¹⁰⁶ or the agency may vacate the order if the agency determines at the hearing that adequate grounds do not exist for the recall.¹⁰⁷

Suspension of Registration

The FFDCA requires all food facilities to register with the FDA and to renew such registration biennially so that the agency may effectively oversee all areas of food production.¹⁰⁸ To register, facilities must submit the following information to the FDA: the name (including trade names), address, and phone number of the facility, and the food product categories associated with that facility.¹⁰⁹ All food facilities that manufacture, process, pack, or hold food for consumption in the United States must complete this registration process.¹¹⁰ However, FDA regulations exempt foreign facilities, where the food from such facility undergoes further manufacturing or processing by another facility outside the United States.¹¹¹ Farms, retail food establishments, restaurants, and meat and egg facilities that are regulated exclusively by the USDA are also exempted from these requirements.¹¹²

The FFDCA¹¹³ authorizes the FDA to suspend the registration of a food facility to enforce the public health and safety provisions of the act. If the FDA determines that a food manufactured, processed, packed, received, or held by a facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals, the agency may suspend the registration of a facility that created, caused, or was otherwise responsible.¹¹⁴ The agency may also order a registration suspension of a facility that knew of or had reason to know of such reasonable probability of harm and packed, received, or held such food.¹¹⁵ With its registration suspended, a facility cannot import or export food into the United States or introduce food into

¹⁰⁴ 21 U.S.C. §350l(c); FSMA, P.L. 111-353 (2011), §206.

¹⁰⁵ 21 U.S.C. §350l(c).

¹⁰⁶ 21 U.S.C. §350l(d).

¹⁰⁷ 21 U.S.C. §350l(d)(2).

¹⁰⁸ 21 U.S.C. §350d(a).

¹⁰⁹ *Id.*

¹¹⁰ 21 C.F.R. §1.225.

¹¹¹ 21 C.F.R. §1.226.

¹¹² *Id.*

¹¹³ FSMA, P.L. 111-353 (2011), §102 amended §415 of the FFDCA to provide the FDA with the authority to suspend a food facility's registration.

¹¹⁴ 21 U.S.C. §350d(b).

¹¹⁵ *Id.*

interstate or intrastate commerce in the United States.¹¹⁶ Any distribution of food products from such facility violates the FFDCFA and may lead to the FDA taking further enforcement action.¹¹⁷ Food facility registration and the suspension of such registration enable the agency to determine the location and source of an outbreak of food-borne illnesses and thus notify facilities that may be affected quickly and efficiently.¹¹⁸

Similar to other enforcement actions, the suspension provision in the FFDCFA offers due process protections for a facility subject to a registration suspension.¹¹⁹ The FDA must provide a registrant with the opportunity for an informal hearing no less than two business days after issuing a suspension order.¹²⁰ The hearing gives the registrant an opportunity to present reasons for reinstating the registration. If at the hearing, the FDA determines that a suspension is necessary, the registrant must then submit a corrective action plan to the agency.¹²¹ The FDA will reinstate a registration if the agency determines, based on the evidence presented at the hearing, that adequate grounds do not exist to continue the suspension of the registration.¹²² When the FDA determines that adequate grounds do not exist to continue the suspension, the FDA will then vacate the order suspending the facility's registration and reinstate the registration for that particular facility.¹²³

Administrative Detention

Under Section 304 of the FFDCFA,¹²⁴ a designated FDA employee may order the detention of any article of food that is found during an FDA inspection if the employee has reason to believe that such article is adulterated or misbranded.¹²⁵ Under this administrative detention authority, FDA may prevent holders of illegal articles from moving the food before a federal district court issues a warrant permitting the agency to seize the food.¹²⁶ This enforcement authority also permits the agency to prevent consumption of the illegal articles in an effort to ensure public safety. The FDA may detain the food under an administrative detention for a reasonable period, generally

¹¹⁶ 21 U.S.C. §350d(b)(4).

¹¹⁷ 21 U.S.C. §331(d).

¹¹⁸ FDA, Guidance for Industry: What You Need to Know About Registration of Food Facilities, *available at*, <http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm331957.htm>.

¹¹⁹ See The Network for Public Health Law, "Section 102: Registration of Food Facilities," FOOD SAFETY MODERNIZATION ACT (FSMA) PRIMER, *available at*, https://www.networkforphl.org/_asset/d0v8kb/Primer-for-Section-102-of-FSMA-FIN.pdf (briefly discusses the informal hearing opportunities in the context of due process protections).

¹²⁰ 21 U.S.C. §350d(b)(2).

¹²¹ 21 U.S.C. §350d(b)(3).

¹²² 21 U.S.C. §350d(b)(2).

¹²³ *Id.*

¹²⁴ FSMA, P.L. 111-353, §207 amended the FDA's administrative detention authority under §304 of the FFDCFA. Prior to FSMA, the FDA could order an administrative detention if the agency had credible evidence that the food presented a threat of serious adverse health consequences or death to humans or animals. See also FDA, FAQs on the Food Safety Modernization Act, *available at* <http://www.fda.gov/food/guidanceregulation/fsma/ucm247559.htm#registration>.

¹²⁵ 21 U.S.C. §334(h)(1).

¹²⁶ Regulatory Procedures Manual, *supra* note 40, at 5-3-2.

measured by the time necessary to institute a seizure action.¹²⁷ The FFDCFA states that such period cannot exceed 30 days.¹²⁸

Any person, who is entitled to claim the article, may file an appeal of the detention order.¹²⁹ The claimant must file the appeal within two calendar days upon receipt of the detention order for perishable food and within four calendar days upon receipt of the detention order for nonperishable food.¹³⁰ Upon such appeal, the FDA must then grant the claimant the opportunity for an informal hearing. At the informal hearing, the agency can either terminate or confirm the order, which serves as a final agency action.¹³¹ Generally, federal courts lack jurisdiction over agency actions committed under the agency's discretion as granted by law, including, for example, most of the statutory enforcement authorities discussed in this report.¹³² However, a federal court may exercise judicial review of an agency's activities, if such an activity is a final agency action; the party subject to the agency action has exhausted the procedures provided by the agency; and no other remedies at law are present.¹³³ Therefore, the agency's termination or confirmation of an administrative detention order may be subject to judicial review.

Author Contact Information

Emily M. Lanza
Legislative Attorney
elanza@crs.loc.gov, 7-6508

¹²⁷ 21 U.S.C. §334(h)(2).

¹²⁸ *Id.*

¹²⁹ 21 U.S.C. §334(h)(4).

¹³⁰ 21 C.F.R. §1.402.

¹³¹ 21 U.S.C. §334(h)(4).

¹³² *See* 5 U.S.C. §701(a).

¹³³ 5 U.S.C. §704.