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Food Safety Issues: FDA Judicial Enforcement Actions

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Summary

The U.S. Food and Drug Administration (FDA) has a statutory mission to ensure 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 vested 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 federal courts. While the FDA gathers information to recommend a judicial enforcement action, the Department of Justice represents the FDA before a federal court. This report focuses on the statutory authority for both the FDA and federal courts to initiate the following judicial enforcement actions: injunctions, seizures, and criminal prosecution. For more information about FDA's administrative enforcement actions, see CRS Report R43794, *Food Recalls and Other FDA Administrative Enforcement Actions*, by Emily M. Lanza.

Injunctions: An injunction is a civil judicial order initiated against an industry participant to stop or prevent a violation of the FFDCA and to halt the flow of violative products in interstate commerce. An injunction also provides an opportunity for the industry participant to correct the conditions that triggered the violation before the FDA takes additional enforcement action. The FFDCA grants federal district courts with the jurisdiction to issue such an order. Unlike the legal standard for injunctions for private litigants, the government does not need to prove irreparable harm for a court to grant an injunction.

Seizure: The government may seize an article of food that is adulterated or misbranded in interstate commerce. A seizure is a civil action used by the federal government when the removal of adulterated or misbranded goods from interstate commerce is necessary to reduce consumer accessibility to those goods. The government proceeds by filing a Complaint for Forfeiture and obtaining a warrant for the arrest directing the U.S. Marshal to seize the article of food.

Criminal Prosecution: The FDA's Office of Criminal Investigations conducts and coordinates criminal investigations and prosecutions for violations of the FFDCA. Potential defendants of a criminal prosecution are strictly liable for violations of the act. The government grants potential defendants notice and a hearing before proceeding with any criminal investigations. The government may prosecute both corporations and corporate officials for violations of the FFDCA under the *Park* doctrine, which grants the government the ability to prosecute both corporations and corporate officials. The FFDCA also outlines various penalties for persons and/or companies found guilty of violations of the act.

Food safety and oversight, including enforcement actions such as those described above, are of a continual interest to Congress. H.R. 609 and S. 287, introduced in the 114th Congress, propose restructuring federal oversight of food safety and would impact the federal government's enforcement of various food safety issues.

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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.⁴ 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. 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."⁵ Thus, private citizens do not have the right to sue to enforce the FFDCA. While the FDA may initiate these enforcement actions, the Department of Justice represents the FDA and the federal government in judicial enforcement proceedings.

Injunctions

An injunction is a civil judicial order initiated against an industry participant to stop or prevent a violation of the FFDCA and to halt the flow of violative products in interstate commerce.⁶ An injunction also provides an opportunity for the involved parties to correct the conditions that triggered the violation before the FDA takes additional enforcement action. The FFDCA grants federal district courts with the jurisdiction to issue such an order.⁷

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 21 U.S.C. §331.

⁵ 21 U.S.C. §337(a).

⁶ 21 U.S.C. §332(a).

⁷ *Id.*

This section of the report first discusses types of injunctions available to the FDA and then describes the process for filing an injunction by the FDA. The section concludes by examining the legal standard considered by courts for initiating an injunction.

Types of Injunctions

The FDA can initiate three types of injunctions: a temporary restraining order, a preliminary injunction, and a permanent injunction. The FDA uses a temporary restraining order (TRO) to respond to an emergency situation where immediate, temporary relief is needed, such as responding to the presence of a public health threat, which the FDA must immediately control.⁸ A TRO generally lasts for 10 days, with a possible additional 10-day extension before the FDA must seek additional enforcement action if necessary. A request for a TRO filed in court by the FDA may be subject to an *ex parte* hearing (where the defendant is not present). Upon gathering evidence in support of a TRO, the FDA should file the request for a TRO within 60 days.⁹ As a general rule of practice, a court considers evidence older than 60 days to be “untimely” and insufficient to support a TRO request.¹⁰

A preliminary injunction is a court order that temporarily requires the industry participant to stop the allegedly violative behavior prior to the final determination of the merits of a legal claim. A preliminary injunction filed by the FDA may be subject to a full hearing where the parties present evidence by affidavit or by the testimony of witnesses.¹¹

A permanent injunction is a final order of the court requiring the industry participant to stop the violative behavior.¹² A federal district court generally issues a permanent injunction following a hearing where the court found that the industry participant violated provisions of the FFDCAs and there is a likelihood that the violations would continue without judicial intervention.¹³ Defendants in an injunction proceeding and the government may also agree to a “Consent Decree of Permanent Injunction” as the result of a negotiated settlement.¹⁴ Under the consent decree, the industry participant and the government agree to terms relating to the resolution of the past violative conduct by the industry participant.

Process for Filing an Injunction

The FDA, in partnership with the Department of Justice, first files a complaint for an injunction after the FDA has presented “timely evidence” of an FFDCAs violation.¹⁵ Timely evidence includes the agency’s identification of a health hazard or a gross consumer deception that requires immediate action to stop the violative practice. The agency may also seek an injunction if

⁸ FDA, Regulatory Procedures manual, 6-2-3, 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.

⁹ *Id.* at 6-2-6.

¹⁰ *Id.*

¹¹ *Id.* at 6-2-3.

¹² *Id.*

¹³ *Id.*

¹⁴ Florence R. Parker, FDA ADMINISTRATIVE ENFORCEMENT MANUAL 115 (2005).

¹⁵ Regulatory Procedures Manual, *supra* note 9, at 6-2-2, 6-2-11.

significant amounts of violative products owned by the same industry participant have entered interstate commerce or if an industry participant has refused a voluntary recall or has issued an inadequate recall.¹⁶ The agency may also choose to file for an injunction if a seizure is impractical or uneconomical. However, filing for an injunction does not preclude further enforcement action by the FDA such as a recall or criminal prosecution.

The FDA can strengthen its request for an injunction action in the complaint by demonstrating that the agency provided the defendants with adequate notice of the alleged violation(s) and an opportunity to correct the alleged violation(s).¹⁷ While prior notice is not legally required, such information can demonstrate the defendant's resistance to FFDCa compliance to a court, and thus support the agency's request for judicial involvement with an injunction.¹⁸ Types of notice may include letters, meetings, and telephone calls. Notice is adequate if it is given to individuals with authority to prevent or correct violations and includes sufficient information to show that the proper action to correct these violations has not yet been taken.¹⁹

Courts have found that corporate officers as well as the corporate entity itself may be subject to FDA enforcement actions, including an injunction.²⁰ The Supreme Court has stated that "the public interest in the purity of its food is so great as to warrant the imposition of the highest standard of care on distributors."²¹ Because corporate agents and corporate entities both have the ability to inform themselves of the conditions of their facilities, the FDA has the authority to seek relief against executives as well as legal corporate entities.²² Thus, in order to successfully state a claim against individual defendants for the purposes of an injunction, the government must allege that the individuals had responsible relationships related to the furtherance of the transactions that ultimately violated the FFDCa.²³ Pursuing enforcement action against an agent or corporation does not preclude additional enforcement action against the other. The court in *U.S. v. Blue Ribbon Smoked Fish, Inc.* found that the injunction against the corporate entity did not preclude an injunction against the agents of that entity due to the agents' supervisory and managerial roles over the food processing and the corresponding responsibility for the sanitation of the plant.²⁴

Legal Standard

The FFDCa expressly authorizes federal district courts to grant injunctive relief to enforce its provisions.²⁵ After the FDA and the DOJ have filed a complaint requesting an injunction, the court will determine whether the government's complaint meets the legal standard for an injunction. The standard for a statutory injunction initiated by the government, however, differs from the injunction standard for private litigants. A private litigant must establish that he or she is

¹⁶ Regulatory Procedures Manual, *supra* note 9, at 6-2-4.

¹⁷ Regulatory Procedures Manual, *supra* note 9, at 6-2-5.

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ *See, e.g.*, *U.S. v. Park*, 421 U.S. 658, 671 (1975); *U.S. v. Blue Ribbon Smoked Fish, Inc.*, 179 F.Supp.2d 30, 41 (E.D.N.Y. 2001).

²¹ *Park*, 421 U.S. at 671 (internal citations omitted).

²² *Blue Ribbon*, 179 F.Supp.2d at 40-41.

²³ *Id.* at 41.

²⁴ *Id.*

²⁵ 21 U.S.C. §332(a).

likely to succeed on the merits; that he or she is likely to suffer irreparable harm in the absence of preliminary relief; that the balance of equities weighs in favor of the party seeking the injunction; and that the injunction is in the public interest.²⁶ The government, however, does not need to prove irreparable harm, as courts presume harm is present when a statutory violation has occurred.²⁷ In order for the court to make such a presumption, the purpose of the statute at issue must focus on protecting public interest, such as food safety.²⁸ The elevated standard of care that food processors must meet that is inherent in the FFDCFA justifies this difference in legal standards.²⁹

In order for the court to issue an injunction, the government must show that the defendant has violated the FFDCFA and “some cognizable danger of recurrent violation” of the statute is present.³⁰ When evaluating the risk of recurrent violations, courts may infer a likelihood of future violations from past unlawful conduct.³¹ More specifically, courts may consider “the bona fides of the expressed intent to comply, the effectiveness of the discontinuance and, in some cases, the character of past violations” to determine whether the defendant would continue to violate the FFDCFA.³² For example, the court in *U.S. v. Chung’s Products* found a danger of recurrent violations when the defendant refused to provide information about the conditions and records of a facility, impeded entry of FDA investigators, and repeatedly failed to put in place the FFDCFA required controls for *C. botulinum*.³³ This record of noncompliance, according to the court, showed a “cognizable danger of future violations necessitating a permanent injunction.”³⁴

The scope of the injunction depends on the specific legal violations.³⁵ A court may adjust the scope of the injunction depending on the likelihood that future violations may occur and whether the injunction can prevent these recurring violations.³⁶ The court in *U.S. v. N.Y. Fish, Inc.* found multiple FFDCFA violations by the defendants and the absence of any credible actions by the defendants to remedy even the most serious of the violations.³⁷ While the court acknowledged that an injunction where the defendant has already taken remedial measures is overbroad and unnecessary, the court found that a broad injunction was appropriate in this case because of the inaction by the defendants and the likelihood that alleged violations would continue.³⁸

²⁶ *Winter v. Natural Res. Def. Council*, 555 U.S. 7, 20 (2008)(internal citations omitted).

²⁷ See *U.S. v. Diapulse Corp. of America*, 457 F.2d 25, 27-28 (2d Cir. 1972).

²⁸ Congress has shifted the burden of proof away from the federal government because of the public interest in the enforcement of the statute. See *U.S. v. Dotterweich*, 320 U.S. 277, 285 (1943)(“Balancing relative hardships, Congress has preferred to place it upon those who have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless”).

²⁹ See *Park*, 421 U.S. at 671 (“The public interest in the purity of its food is so great as to warrant the imposition of the highest standard of care on distributors” (quoting *Smith v. CA*, 361 U.S. 147, 152 (1959))).

³⁰ *U.S. v. Chung’s Prod. LP*, 941 F.Supp.2d 770, 794 (S.D. Tex. 2013) (quoting *U.S. v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953)).

³¹ *U.S. v. N.Y. Fish, Inc.*, 10 F.Supp.3d 355, 370 (E.D.N.Y. 2014).

³² *Grant*, 345 U.S. at 633.

³³ *Chung*, 941 F.Supp.2d at 801.

³⁴ *Id.* at 806.

³⁵ *N.Y. Fish*, 10 F.Supp.3d at 380.

³⁶ *Id.*

³⁷ *Id.* at 381.

³⁸ *Id.*

Courts generally find the possibility that an injunction may put a party out of business as irrelevant with regards to determining the necessity and scope of an injunction. In *U.S. v. Blue Ribbon Smoked Fish*, the defendant-corporate agents opposed the substance of the government’s proposed permanent injunction, arguing that the injunction would force the company out of business.³⁹ The court, however, disagreed, stating that the injunction would not require the defendant company, Blue Ribbon, to stop processing food altogether, but to stop processing food “that is or has become adulterated.”⁴⁰

After the court has issued the order for an injunction, the FDA monitors the injunction throughout the entire term of such injunction. The agency may seek civil or criminal contempt of court or other regulatory action if the industry participant violates the injunction.⁴¹

Seizure

Under Section 304(a)(1) of the FFDCA, the government may seize an article of food in interstate commerce that is adulterated or misbranded.⁴² A seizure is a civil action used by the federal government when the removal of adulterated⁴³ or misbranded⁴⁴ goods from interstate commerce is necessary to reduce consumer accessibility to those goods in order to protect public health.

The seizure must occur when the goods are in interstate commerce or held for sale after shipment in interstate commerce.⁴⁵ The FFDCA broadly defines interstate commerce as “commerce between any State or Territory and any place outside thereof.”⁴⁶ Goods destined for sale in a state other than the place from which they are shipped qualify as goods in “interstate commerce,” even though they may not have yet physically crossed a boundary.⁴⁷ In this context, courts have also interpreted “interstate commerce” to mean imported foods held at a port of entry into the United States.⁴⁸

Generally, a seizure includes two steps: the U.S. government’s physical seizure of the adulterated or misbranded articles of food followed by the judicial condemnation proceeding. The U.S. district court where the article is found has jurisdiction over the seizure proceeding.⁴⁹ After a hearing on a seizure action, a district court may decree the “condemnation” of seized articles of food and order the destruction, sale, reconditioning, or export of such food.

³⁹ *Blue Ribbon*, 179 F.Supp.2d at 50.

⁴⁰ *Id.*

⁴¹ Regulatory Procedures Manual, *supra* note 9, at 6-2-2.

⁴² 21 U.S.C. §334(a)(1).

⁴³ 21 U.S.C. §342 defines when a food is deemed to be adulterated.

⁴⁴ 21 U.S.C. §343 defines when a food is deemed to be misbranded.

⁴⁵ *Id.*

⁴⁶ 21 U.S.C. §321(b).

⁴⁷ *See Merch. Fast Motor Lines, Inc. v. Interstate Commerce Comm’n*, 528 F.2d 1042, 1044 (5th Cir. 1976).

⁴⁸ *U.S. v. Food*, 2998 Cases, 64 F.3d 984, 993 (5th Cir. 1995); *U.S. v. Eight Unlabeled Cases, More or Less, of An Article of Food*, 909 F.Supp. 129, 131-32 (E.D.N.Y. 1995) (court held that food imported from a foreign port (Hong Kong) and refused admission into the United States met the “in interstate commerce” requirement of 21 U.S.C. §334(a)).

⁴⁹ 21 U.S.C. §334(a)(1).

The FFDCA prohibits multiple proceedings, including seizure actions, against an article of food based upon the same alleged misbranding, except when the FDA has probable cause to believe that the misbranded article is dangerous to health, exhibits fraudulent labeling, or is materially misleading causing injury to the consumer or purchaser.⁵⁰ Section 304 does not prohibit multiple seizures of adulterated articles of food.

This section of the report first describes the types of seizures conducted by the federal government and the condemnation proceedings the federal government must follow when conducting a seizure. The section then examines the legal standard for condemning seized goods. The section concludes by analyzing the due process issues related to seizure proceedings.

Types of Seizures

The FDA classifies seizures according to various types to facilitate its administration of this enforcement action by tracking seizures by size.⁵¹ These classifications do not carry a specific legal status. A “lot seizure” affects one lot of an adulterated or misbranded product that can be found in a single location.⁵² “Multiple seizures” involve more than one action to seize goods located in different jurisdictions.⁵³ Multiple seizures seek to prevent industry participants from shipping adulterated or misbranded products from different facilities. “Mass seizures” affect a warehouse full of adulterated or misbranded products found at one location.⁵⁴

A seizure extends to the article of food and the product labeling as well.⁵⁵ However, a seizure does not include the promotional materials for an illegal product unless they “accompany”⁵⁶ the product in interstate commerce.⁵⁷ In this context, these accompanying materials qualify as labeling and may be seized.⁵⁸

Seizure and Condemnation Proceedings

An administrative detention may precede a seizure action.⁵⁹ The FDA may order the detention of any article of food found during an inspection, examination, or investigation, that the agency has

⁵⁰ *Id.*

⁵¹ Regulatory Procedures Manual, *supra* note 9, at 6-1-3.

⁵² Florence R. Parker, FDA ADMINISTRATIVE ENFORCEMENT MANUAL 76 (2005).

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ See *U.S. v. 8 Cartons, Containing “Plantation ‘The Original’ etc. Molasses,”* 103 F.Supp. 626, 627-28 (W.D.N.Y. 1951).

⁵⁶ The meaning of “accompany” is broad and is not restricted to labels that are on or in the article of food as packaged and transported. See *Kordel v. U.S.*, 335 U.S. 345, 349 (1948).

⁵⁷ See *U.S. v. Vitasafe Corp.*, 345 F.2d 864, 867-68 (3d Cir. 1965).

⁵⁸ 21 U.S.C. §321(m).

⁵⁹ For information on FDA’s administrative detention authority, see CRS Report R43794, *Food Recalls and Other FDA Administrative Enforcement Actions*, by Emily M. Lanza.

reason to believe is adulterated or misbranded.⁶⁰ Such an order may be necessary before a court can issue a seizure action.⁶¹

The FDA initiates the seizure by filing a Complaint for Forfeiture in federal district court.⁶² The complaint names the United States as the plaintiff and the goods as the defendant. The federal district court then issues a warrant for the arrest (seizure) of the article of food through *in rem* jurisdiction.⁶³ Pursuant to the arrest warrant, a U.S. Marshal then seizes the violative goods and takes them into custody. The U.S. Marshall may physically remove the goods from the industry participant's warehouse or may sequester the goods from inventory in such a way to ensure that the goods subject to the seizure are separated from the rest of the inventory.⁶⁴ Neither the industry participant nor the courts are involved in the seizure process until the FDA files a complaint for forfeiture. The industry participant/owner may then intervene as a party in the case.

Following a seizure by the government, the owner/potential claimant has three options: (1) do not claim the seized articles; (2) file a claim to the articles and enter into a Consent Decree with the government, admitting the violation and agreeing to pay costs and to destroy or rehabilitate the articles of food; or (3) file a claim to the articles and contest the action by filing an answer to the complaint.⁶⁵

At the hearing, the court decides whether the government has proven the allegations in the complaint. If the court finds that the government has successfully met the legal standard, the court orders the condemnation of the food. If the court finds that the government has not met the legal standard, the court will release the goods from seizure. The government must prove by the preponderance of the evidence that the articles seized were food⁶⁶ that travelled in interstate commerce⁶⁷ and that this food was adulterated or misbranded when introduced into, while in, or while held for sale after shipment in interstate commerce.⁶⁸ The government may use warning letters sent to the owner, expert testimony, and samples collected during inspections as evidence.⁶⁹ If the owner chooses to argue against the seizure, the owner of the seized articles must show that the articles were improperly subject to seizure because the product is not adulterated or misbranded as defined by the FFDCA.⁷⁰ If an owner has not claimed the goods, the court will issue condemnation by default.

If there are two or more seizure proceedings involving the same claimant on the same issues of adulteration or misbranding outstanding at the same time, the claimant may apply to the court to

⁶⁰ 21 C.F.R. §1.378.

⁶¹ 21 C.F.R. §1.379.

⁶² 21 U.S.C. §334; Regulatory Procedures Manual, *supra* note 9, at 6-1-1.

⁶³ In condemnation proceedings, federal district courts have *in rem* jurisdiction (over the articles seized) as opposed to *in personam* jurisdiction (over the article's owner).

⁶⁴ Florence R. Parker, FDA ADMINISTRATIVE ENFORCEMENT MANUAL 76 (2005).

⁶⁵ Regulatory Procedures Manual, *supra* note 9, at 6-1-9.

⁶⁶ 21 U.S.C. §321(f) defines food as "articles used for food or drink for man or other animals."

⁶⁷ 21 U.S.C. §321(b) defines interstate commerce as "commerce between any state or territory and any place outside thereof."

⁶⁸ 21 U.S.C. §334. *See* U.S. v. 449 Cases, Containing "Tomato Paste," 212 F.2d 567, 572 (2d Cir. 1954)(government's burden of proof in a seizure proceeding is "by a preponderance of the evidence").

⁶⁹ Florence R. Parker, FDA ADMINISTRATIVE ENFORCEMENT MANUAL 76 (2005).

⁷⁰ *Id.*

consolidate the proceedings in a district court selected by the claimant where one such proceeding is pending or in a district court agreed upon between the parties.⁷¹ A claimant may also follow the procedures outlined in FFDCAs Section 304(b) to consolidate the proceedings in “a district of reasonable proximity to the claimant’s principal place of business.”⁷²

Disposition of the Goods

After the appropriate proceedings, the court will enter a decree that determines the disposition of the goods. If the owner/claimant did not appear before the court, the government then moves for condemnation under a default decree. Such an order directs the U.S. Marshall to dispose of the article of food in the following manner: constructive destruction, sale, conversion, or destruction.⁷³ Constructive destruction involves using the article for another purpose, such as donating misbranded food to a charity. The U.S. Marshall may sell the goods, if legally permissible, to recover the costs of the seizure, or may convert the goods to another use, such as for animal food. The government may also destroy the article of food by burning, burial, or dumping, in accordance with other relevant laws, such as the National Environmental Policy Act.⁷⁴

If the owner⁷⁵ filed a claim to the article of food, the owner may then agree to the entry of a Consent Decree, which would provide for the sale, destruction, or reconditioning of the article, as dictated by the court and agreed to by the federal government. A consent decree generally includes a statement of the condemnation of the article, provision for payment of storage and handling costs accrued by the U.S. Marshal,⁷⁶ and a provision that the claimant will bring the article into compliance with the FFDCAs under the supervision and to the satisfaction of the FDA.⁷⁷ Under the decree, the owner who claims the goods is required to post a penal bond to the court at twice the retail value of the goods seized.⁷⁸ The penal bond ensures that the owner complies with the conditions of the decree, as the owner must forfeit the penal bond if the terms and conditions of the decree are not kept. The owner must then destroy, recondition, or sell the article as dictated by the terms of the decree. Available methods of destruction include those followed by the U.S. Marshall as described in the previous paragraph. Reconditioning (such as through reprocessing or relabeling) must bring the article of food into compliance with FFDCAs provisions, under FDA supervision.⁷⁹ Courts generally defer to the FDA’s discretion regarding the supervision of reconditioning plans.⁸⁰ The owner bears the cost of bringing such article in

⁷¹ 21 U.S.C. §334(b).

⁷² *Id.*

⁷³ Regulatory Procedures Manual, *supra* note 9, at 6-1-9.

⁷⁴ 42 U.S.C. §§4321 *et seq.* The National Environmental Policy Act (NEPA) requires federal agencies to consider significant aspects of the environmental impact of an action before proceeding with it.

⁷⁵ The owner in this context is the person obtaining the release under 21 U.S.C. §334(d)(1).

⁷⁶ 21 U.S.C. §334(e).

⁷⁷ Regulatory Procedures Manual, *supra* note 9, at 6-1-9.

⁷⁸ Florence R. Parker, FDA ADMINISTRATIVE ENFORCEMENT MANUAL 77 (2005).

⁷⁹ 21 U.S.C. §334(d)(1).

⁸⁰ *See, e.g.* U.S. v. 1,638 Cases of Adulterated Alcoholic Beverages and Other Articles of Food, 624 F.2d 900, 902-03 (9th Cir. 1980)(court found that the FDA did not abuse its discretion by imposing a reconditioning plan on the owner, despite the economic hardship on the owner); U.S. v. 1,322 Cans, More or Less, of Black Raspberry Puree, 68 F.Supp. 881, 881 (N.D. Ohio 1946).

compliance. When the court orders the sale of the goods, the owner must pay all money collected during a sale (less legal fees, costs, and charges) into the U.S. Treasury.⁸¹

If the article was imported into the United States, the owner may export the article in lieu of destruction. To obtain a consent decree permitting export, the owner must show that the adulteration, misbranding, or FFDCa violation did not occur after the article was imported into the United States, and that he or she had no cause to believe that it was adulterated, misbranded, or in violation before it was released from customs custody.⁸² The owner must also meet the export provisions of the FFDCa and show that the product is within the specifications of the foreign country purchaser and must label the shipping package of the goods “FOR EXPORT ONLY.”⁸³ The owner cannot sell these products domestically. Exportation is not available for articles of food condemned for being poisonous or a deleterious substance injurious to health.⁸⁴

Expedited Procedures

The FDA may initiate expedited seizure procedures for perishable food. The FDA regulations define “perishable food” to include food that is not heat-treated, not frozen, and not otherwise preserved in a manner so as to prevent the quality of the food from being adversely affected if held longer than seven calendar days under normal shipping and storage conditions.⁸⁵ Under such expedited procedures, the FDA must send the seizure recommendation to the Department of Justice within four calendar days after the agency has issued the detention order.⁸⁶ The government generally then follows similar procedures to those described in the previous sections.

Due Process Constraints

Throughout the condemnation proceedings, the FDA must act within Due Process restrictions.⁸⁷ Under this constitutional provision, the federal government must provide an industry participant with “fair procedures” before depriving the participant of “life, liberty, or property.”⁸⁸ Courts generally view due process restrictions narrowly in this context due to the public health and safety goal of FDA enforcement.⁸⁹ A hearing immediately following the seizure generally has been found to preserve the claimant’s due process rights, as long as the owner has an opportunity to present his views before the final order has been issued.⁹⁰ At least one court has held that courts do not need to provide the owner with notice and a hearing prior to the seizure of his or her property.⁹¹

⁸¹ 21 U.S.C. §334(d)(1).

⁸² 21 U.S.C. §334(d)(1)(B).

⁸³ 21 C.F.R. §1.101(b)(3).

⁸⁴ 21 U.S.C. §342(a)(1), (2), (6).

⁸⁵ 21 C.F.R. §1.377.

⁸⁶ 21 C.F.R. §1.383.

⁸⁷ U.S. Const. amend. V (“no person shall ... be deprived of life, liberty, or property, without due process of law”).

⁸⁸ *See id.*

⁸⁹ *See id.*

⁹⁰ *See Ewing v. Mytinger & Casselberry*, 339 U.S. 594, 597 (1950).

⁹¹ *U.S. v. An Article of Device Theramatic*, 715 F.3d 1339, 1342 (9th Cir. 1983).

Criminal Prosecution

The FDA's Office of Criminal Investigations conducts and coordinates criminal investigations and prosecutions against individuals and corporations for violations of the FFDCA.⁹² Potential defendants of a criminal prosecution are strictly liable for these violations.⁹³ Ignorance of the violation, a lack of intent to commit the violative act, or the absence of personal involvement are not defenses against FFDCA violations under the strict liability standard.⁹⁴

This section of the report highlights two aspects of the criminal investigation process of particular relevance to FDA enforcement and food safety. The section first examines the FFDCA's Section 305 hearings, a prerequisite to any criminal proceeding. The section then analyzes the Supreme Court's *Park* doctrine, which grants the government the ability to prosecute both corporations and corporate officials. The section concludes with a brief discussion on statutory penalties.

Section 305 Hearing

Before the government institutes a criminal proceeding against a person, Section 305 of the FFDCA requires the government to provide that person with notice and an opportunity for a hearing.⁹⁵ At the hearing, he or she may present his or her reasons why the FDA should not recommend criminal prosecution to the Department of Justice.⁹⁶ The FDA does not need to provide notice and a hearing if the agency believes that such notice would result in the alteration or destruction of evidence or the flight of the prospective defendant to avoid prosecution.⁹⁷ A person who has received such notice of a hearing is not legally obligated to appear or answer in any manner.⁹⁸

Park Doctrine

The FDA may criminally prosecute corporations as well as corporate officials for FFDCA violations. When prosecuting an FFDCA violation, the government does not need to prove awareness of the wrongdoing—the conventional requirement for criminal conduct.⁹⁹ In the 1975 case *U.S. v. Park*, the Supreme Court found that a district court's jury instructions appropriately focused on the issue of the defendant's authority over the unsanitary conditions that led to the alleged violations.¹⁰⁰ The defendant, Park, was the chief executive officer (CEO) of Acme Markets Inc.¹⁰¹ The government charged both the corporation and the defendant with violating the

⁹² FDA, Office of Criminal Investigations, available at <http://www.fda.gov/ICECI/CriminalInvestigations/>.

⁹³ Strict liability is the imposition of liability on an individual without finding fault. See Black's Law Dictionary, 2d (ed).

⁹⁴ Neal D. Fortin, FOOD REGULATION: LAW SCIENCE, POLICY, AND PRACTICE 525 (2009).

⁹⁵ 21 U.S.C. §335.

⁹⁶ 21 C.F.R. §7.84(a).

⁹⁷ 21 C.F.R. §7.84(a)(2).

⁹⁸ 21 C.F.R. §7.84(f).

⁹⁹ Dotterweich, 320 U.S. at 281.

¹⁰⁰ *U.S. v. Park*, 421 U.S. 658, 676 (1975).

¹⁰¹ *Park*, 421 U.S. at 660.

FFDCA. While the corporation pled guilty to the allegations of violating FFDCA’s adulteration provisions, the defendant, Park, pleaded not guilty.¹⁰² The district court instructed the jury that in order to find the defendant guilty, he must have had “a responsible relationship to the issue.”¹⁰³ The Court of Appeals reversed the district court’s conviction, finding that the court’s instructions may have left the jury with the erroneous impression that the defendant could be found guilty in the absence of “wrongful action” on his part.¹⁰⁴ The Supreme Court reversed the Court of Appeals’ decision, finding that the FFDCA imposes upon persons with supervisory authority the responsibility to seek out and remedy violations and to prevent such violations.¹⁰⁵ According to the Court, the government does not need to show that the official had awareness of the criminal conduct due to the public safety context of the FFDCA.¹⁰⁶ The Court justified this interpretation by emphasizing that the corporate official has the ability and opportunity to correct and prevent such violations while the public may not.¹⁰⁷

Thus, under the *Park* doctrine, a responsible corporate official can be held liable for a first-time misdemeanor under the FFDCA without proof that the corporate official acted with intent or even negligence.¹⁰⁸ Such corporate official does not need to have any actual knowledge of, or participation in, the specific offense to be held liable under this doctrine. The FDA claims that this doctrine has a strong deterrent effect for defendants and other regulated entities.¹⁰⁹ When considering whether to pursue a *Park* doctrine prosecution against a corporate official, the FDA examines the individual’s position in the company and his or her relationship to the violation.¹¹⁰ The FDA also considers whether the corporate official had the authority to prevent the violation.¹¹¹ The Court in *Park* found that the failure to fulfill this duty imposed by the FFDCA and the position of authority provides a “sufficient causal link” for criminal prosecution and culpability.¹¹²

Statutory Penalties

Section 303 of the FFDCA outlines various penalties to which a person may be subject for FFDCA violations. If a person commits a prohibited act listed under Section 301,¹¹³ then the

¹⁰² *Id.* at 661.

¹⁰³ *Id.* at 658.

¹⁰⁴ *U.S. v. Park*, 499 F.2d 839, 843 (4th Cir. 1974).

¹⁰⁵ *Park*, 421 U.S. at 670-72.

¹⁰⁶ *Park*, 421 U.S. at 668. Prior to *Park*, lower courts had been relying on the principle that those in managerial positions may be deemed responsible for wrongdoing. Cases under the Federal Food and Drugs Act of 1906 had found that the government did not need to prove knowledge or intent for prosecutions under the act’s criminal provisions. *See, e.g. U.S. v. Mayfield*, 177 F. 765, 768-69 (N.D. Ala. 1910).

¹⁰⁷ *See Dotterweich*, 320 U.S. at 285 (“Balancing relative hardships, Congress has preferred to place it upon those who have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless”). The Supreme Court in *Park* referenced its reasoning in *Dotterweich*. *Park*, 421 U.S. at 668.

¹⁰⁸ *Park*, 421 U.S. at 671-72.

¹⁰⁹ Regulatory Procedures Manual, *supra* note 9, at 6-5-3.

¹¹⁰ *Park*, 421 U.S. at 674; Regulatory Procedures Manual, *supra* note 9, at 6-5-3.

¹¹¹ *Park*, 421 U.S. at 674.

¹¹² *Id.*

¹¹³ Prohibited acts listed under 21 U.S.C. §331 include the introduction or delivery for introduction of adulterated or misbranded food in interstate commerce.

person will be subject to a penalty of imprisonment for one year or less or fined \$1,000 or less or both.¹¹⁴ If a person commits a violation of Section 301 with the intent to defraud or mislead, then the penalty is raised to imprisonment for three years or less or fine of \$10,000 or less or both.¹¹⁵ However, these statutory penalties do not preclude other fines or payments imposed as a result of a settlement or consent decree.¹¹⁶

According to the FFDCA, a person shall not be subject to these penalties in certain cases of good faith.¹¹⁷ The FFDCA also states that a person shall not be subject to these penalties if the violation involved the misbranding of food due to its advertising.¹¹⁸

Related Legislation in the 114th Congress

Food safety and oversight, including enforcement actions such as those described above, are of a continual interest to Congress. Two bills (H.R. 609 and S. 287) introduced in the 114th Congress proposing the restructuring of federal oversight of food would impact the federal government's enforcement of various food safety issues.

H.R. 609/S. 287, known as the Safe Food Act of 2015, would create a single agency that administers and enforces food safety laws and oversees the implementation of federal food safety inspections, labeling requirements, enforcement, and research efforts.¹¹⁹ Under the proposed bills, related food safety agencies, currently within the jurisdiction of the Department of Agriculture, Department of Commerce, and the FDA, would transfer certain responsibilities to this proposed agency.¹²⁰ The bills would also grant the new food safety agency several enforcement authorities, including mandatory recall authority.¹²¹ Under the proposed food safety framework, the administrator of the food safety agency would have the authority to impose both civil and criminal penalties of not more than \$10,000 for both civil and criminal provisions and not more than a year of prison for criminal violations.¹²² However, the administrator would have the discretion to increase the penalty for severe criminal violations. The bills would permit a person, who has been assessed a civil penalty, to petition for judicial review of the order.

¹¹⁴ 21 U.S.C. §333(a)(1).

¹¹⁵ 21 U.S.C. §333(a)(2).

¹¹⁶ Neal D. Fortin, *FOOD REGULATION: LAW SCIENCE, POLICY, AND PRACTICE*, 532 (2009).

¹¹⁷ 21 U.S.C. §333(c).

¹¹⁸ 21 U.S.C. §333(d).

¹¹⁹ H.R. 609, S. 287, §101.

¹²⁰ *Id.* at §102.

¹²¹ *Id.* at §402. This authority is discussed in CRS Report R43794, *Food Recalls and Other FDA Administrative Enforcement Actions*, by Emily M. Lanza.

¹²² *Id.* at §404.

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