Order Code RL34167

# CRS Report for Congress

## The FDA's Authority to Recall Products

**Updated September 16, 2008**

Vanessa K. Burrows
Legislative Attorney
American Law Division


Prepared for Members and
Committees of Congress

# The FDA's Authority to Recall Products

## Summary

The Food and Drug Administration (FDA) has fielded increasing numbers of questions regarding recalls of unsafe imports, including jalapeño peppers, pet food, the blood thinner heparin, and toothpaste. Additionally, several domestic food products, from peanut butter contaminated with *Salmonella* to spinach linked to *E. coli 0157:H7* to canned meat products such as chili sauce spoiled by *Clostridium botulinum* (botulism), have been voluntarily recalled by businesses in the last year. Recalls may decrease consumer confidence in the recalling company, food imports, or food safety agencies such as the FDA; products later subject to a recall may have sickened or killed people or pets. While the FDA only has the authority to order recalls of infant formula, medical devices, and human tissue products, the agency may request that a company recall other products, such as food, drugs, and cosmetics. This report provides an overview of the FDA's statutory authority with regard to the three types of products that it can recall, as well as FDA regulations for designating the particular class of recall, publicizing and monitoring the effectiveness of recalls, and carrying out recalls. Additionally, this report reviews the recall provisions in legislation proposed in the 110th Congress, which would give the FDA authority to require recalls of additional products.

The 110th Congress has shown significant interest in the issue of food safety. Congress passed H.R. 3580, P.L. 110-85, the FDA Amendments Act of 2007 (FDAAA), which contains provisions addressing communications and information postings during a food recall similar to those the Senate previously approved, by a vote of 94-0, in Senator Durbin's amendment to the FDA Revitalization Act (S. 1082/H.R. 2900). Several bills would grant the FDA the ability to order recalls of food and other products. The Food and Drug Import Safety Act of 2007, H.R. 3610, would grant the Secretary of Health and Human Services (HHS) the authority to require food recalls. Representative Dingell's draft of the Food and Drug Administration Globalization Act of 2008 — posted for comment on the House Energy and Commerce Committee website — would also grant the Secretary the authority to require food recalls and, in addition, would grant the Secretary the same authority for recalling drugs as the Secretary has for recalling devices. The Family Smoking Prevention and Tobacco Control Act, S. 625/H.R. 1108, would provide the Secretary with the authority to require recalls of tobacco products. Other bills that would provide the FDA with recall authority include the FDA Food Safety Modernization Act, S. 3385; the Human and Pet Food Safety Act of 2007, S. 1274/H.R. 2108; the Safe Food Act of 2007, S. 654/H.R. 1148; the Protect Consumers Act of 2007, H.R. 2099; the Safe And Fair Enforcement and Recall for (SAFER) Meat, Poultry, and Food Act of 2007, H.R. 3484; the Food and Product Responsibility Act of 2007, S. 2081; the Consumer Food Safety Act of 2007, H.R. 3624; and the Food Import Safety Act of 2007, H.R. 3937.

## Contents

# The FDA's Authority to Recall Products

## Background

The Food and Drug Administration (FDA) has fielded increasing numbers of questions regarding recalls of unsafe imports, including jalapeño peppers, pet food, the blood thinner heparin, and toothpaste. Additionally, several domestic food products, from peanut butter contaminated with *Salmonella* to spinach linked to *E. coli 0157:H7* to canned meat products such as chili sauce spoiled by *Clostridium botulinum* (botulism), have been recalled in the last year. A recall is "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, e.g., seizure."[1]

Recalls may decrease consumer confidence in the recalling company, food imports, or food safety agencies such as the FDA; products later subject to a recall may have sickened or killed people or pets.[2] Recalls of tainted or defective products can be costly to the recalling company in terms of the costs of the recall, injury to reputation, and exposure to liability via class action lawsuits and punitive damages.[3] For example, pet owners filed suit against Menu Foods seeking "compensation for veterinary care, medical monitoring and other expenses, damages for negligence and breach of express and implied warranty and attorney fees and costs," which

---

[1] 21 C.F.R. § 7.3(g). The definition of a recall "does not include a market withdrawal or a stock recovery." *Id.* A market withdrawal is "a firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the [FDA] or which involves no violation, e.g., normal stock rotation practices, routine equipment adjustments and repairs." 21 C.F.R. § 7.3(j). A stock recovery is "a firm's removal or correction of a product that has not been marketed or that has not left the direct control of the firm, i.e., the product is located on premises owned by, or under the control of, the firm and no portion of the lot has been released for sale or use." 21 C.F.R. § 7.3(k).

[2] More than 1,250 people were sickened in an outbreak linked to jalapeño peppers; 246 deaths of patients receiving heparin were reported to the FDA (though "[i]n the majority of reports with a death outcome, there was not enough clinical information to assess the relationship between death and use of heparin"); and reportedly about "1,950 cats and 2,200 dogs died from kidney failure from eating melamine-contaminated pet food." Annys Shin, *Salmonella-Tainted Jalapeño Found in Texas*, WASH. POST, July 22, 2008, at A1; FDA, Information on Adverse Event Reports and Heparin, [http://www.fda.gov/cder/drug/infopage/heparin/adverse_events.htm]; John Pacenti, *Animal Owners Seek Class Action Status in Suit Over Pet Food Additives*, Law.com, June 10, 2008.

[3] Michael T. Roberts, *Mandatory Recall Authority: A Sensible and Minimalist Approach to Improving Food Safety*, 59:4 FOOD & DRUG L. J. 563, 568 (2004).

reportedly may settle for $24 million.[4] The company began testing its pet food on animals at the end of February 2007, "one week after it began hearing from owners who said the food had made their pets ill."[5] However, the company did not contact the FDA or begin a recall of more than 60 million containers of pet food until March 2007.[6]

While the FDA only has the authority to order recalls of infant formula, medical devices, and human tissue products, the agency may request that a company voluntarily recall other products, such as food, drugs, and cosmetics. Companies typically recall tainted products voluntarily but this may not always be the case.[7] For this reason and others discussed below, supporters of stronger food safety laws have argued that the FDA should be given statutory authority to mandate recalls of food and other products.

This report provides an overview of the FDA's statutory authority with regard to the three types of products for which the agency can require recalls, as well as FDA regulations for designating the particular class of recall, publicizing and monitoring the effectiveness of recalls, and carrying out recalls. Additionally, this report reviews the recall provisions in legislation proposed in the 110th Congress, which would give the FDA authority to require recalls of additional products.

## Mandatory Recall Authority: Supporting and Opposing Views

Representative Rosa DeLauro and others have reportedly asserted that the current food safety system, which "relies on voluntary recalls[,] implicitly protects industry before it protects public health."[8] As a result, some argue that the discovery

---

[4] Lisa Brennan, *Judge Seethes Over Direct Contact of Represented Parties in Pet Food Case*, N.J. Law Journal, June 4, 2007; Geoff Mulvihill, *Recalled Pet Food Settlement Gets Initial Approval*, Law.com, June 2, 2008.

[5] Katie Zezima, *Tests by Pet Food Maker Killed 7 Animals Before Recall*, N.Y. TIMES, March 20, 2007, at A12.

[6] Chuck Neubauer, *FDA Officials Will Face Senate Inquiry on Pet Food*, LA TIMES, April 8, 2007, at A18; *Hearing on Pet Food Safety Before the Senate Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies*, 110th Cong. 6 (April 12, 2007) (statement of Duane Ekedahl, President, Pet Food Institute), [http://appropriations.senate.gov/hearings.cfm].

[7] Center for Science in the Public Interest, *Support H.R. 1612 and S. 908 — The Consumer Food Safety Act of 1999*, [http://www.cspinet.org/foodsafety/hr1612.html]. According to this advocacy organization, "[i]n August 1997, FDA tried to recall Royal Line smoked salmon contaminated with Listeria, a bacteria that causes serious illnesses and deaths. The salmon, sold in plastic packages, was imported from Denmark. However, the salmon's U.S. distributor refused to cooperate in the recall, leaving American consumers at risk of food poisoning from the product." *Id.*

[8] *Veggie Booty Recall Grows, Prompting Criticism of Weak FDA*, Inside Health Policy, July 6, 2007.

of the source of contaminated products may not immediately be identified.[9] The FDA has also been accused of failing to aggressively pursue investigations of products that were later recalled.[10] For example, lawsuits have been brought against ConAgra Foods, Inc. by individuals who allegedly became sick, sometimes more than once, because they ate peanut butter tainted with *Salmonella*. According to the plaintiffs, ConAgra did not recall contaminated peanut butter from one plant until February 2007, though the FDA "suspected that peanut butter manufactured by ConAgra Foods under different brand names might have been contaminated with salmonella" as early as 2005.[11]

Consumer rights groups seek new statutory authority that would allow the FDA to mandate recalls of food and other products.[12] However, the FDA's Center for Food Safety and Applied Nutrition has argued that "cooperation between FDA and its regulated industries has proven over the years to be the quickest and most reliable method to remove potentially dangerous products from the market."[13] According to the agency, both the FDA and industry share an interest in removing unsafe and/or defective products from the marketplace.[14] An industry representative involved in the pet food recall has also argued against additional regulation, saying that industry "could have been a more valuable partner" in the recall process if it received access to the same information as the FDA.[15] According to the head of the Pet Food Institute, which represents U.S. pet food manufacturers, the communication of such information would have allowed the organization to "cross-reference . . . lot numbers, shipping information, and other data."[16]

Some have argued that in situations where the manufacturer of a product cannot be determined — such as the case of tainted toothpaste found in discount stores, prisons, hospitals, and luxury hotels — granting the FDA the ability to recall such

---

[9] *See id.*

[10] "A similar lack of aggressiveness on the part of FDA may have contributed to the peanut butter contamination deaths and illnesses." *Diminished Capacity: Can the FDA Assure the Safety and Security of the Nation's Food Supply — Part 2: Hearing Before the H. Comm. on Energy and Commerce, Subcomm. on Oversight and Investigations*, 110th Cong. (July 17, 2007) (Staff Statement at p. 16), [http://energycommerce.house.gov/cmte_mtgs/110-oi-hrg.071707.Staff-testimony.pdf], (hereinafter "Subcommittee Staff Statement").

[11] Marian Burros, *Who's Watching What We Eat?*, N.Y. Times, May 16, 2007, at D1; R. Robin McDonald, *ConAgra Faces 39 Suits Over Bad Peanut Butter*, Fulton County Daily Report, August 13, 2007. A Centers for Disease Control and Prevention network that monitors food-borne diseases observed a "slowly rising increase" in cases of a certain type of *Salmonella* that were connected to one peanut butter plant. *Id.*

[12] *See* Caroline Smith DeWaal, Director of Food Safety, Center for Science in the Public Interest, Statement at the National Food Policy Conference (May 9, 2003), [http://www.cspinet.org/foodsafety/new_bioact.html].

[13] FDA, Center for Food Safety and Applied Nutrition, Industry Affairs Staff Brochure, *FDA Recall Policies* (June 2002), [http://vm.cfsan.fda.gov/~lrd/recall2.html]. The FDA's recall policies are described in detail in this document.

[14] *Id.*

[15] Ekedahl, *supra* note 6, at 8-9.

[16] *Id.* at 9.

products would expedite the process of removing adulterated articles from store shelves.[17] Such authority would enable the agency to take actions beyond issuing a warning about a particular product.[18] A 2004 Government Accountability Office (GAO) report found that:

> FDA do[es] not know how promptly and completely the recalling companies and their distributors and other customers are carrying out recalls, and neither [the FDA nor the U.S. Department of Agriculture (USDA)] is using its data systems to effectively track and manage its recall programs. For these and other reasons, most recalled food is not recovered and therefore may be consumed.[19]

According to GAO, the FDA may not be using the regulations on voluntary recalls that the agency currently has in place to their maximum effectiveness.[20] The staff of the House Energy and Commerce Committee's Subcommittee on Oversight and Investigations has also remarked that the "FDA's current regulatory approach, which relies upon voluntary guidelines for most domestic and imported foods, appears inadequate in responding to the changing food industry."[21]

In addition, advocates for a single food safety agency argue that a single contact point could save time and lives in the event of a food recall.[22] As demonstrated by the chili products recall due to the potential for botulism, more than one agency may have jurisdiction over adulterated or contaminated food.[23] In that situation, the FDA website listed all the recalled product numbers but only included photos of the labels for chili products that did not contain meat and pet food products involved in the same recall. (The FDA has jurisdiction over pet food.) Consumers were directed to the USDA Meat and Poultry Hotline website for products containing meat, over

---

[17] Press Release, Senator Charles Schumer, Schumer Reveals: Chinese Product Dangers Go Far Beyond Tires, Seafood and Toothpaste (July 1, 2007), [http://schumer.senate.gov/SchumerWebsite/pressroom/record.cfm?id=278328]; *see also* FDA, Imported Toothpaste, [http://www.fda.gov/oc/opacom/hottopics/toothpaste.html].

[18] *See Veggie Booty*, *supra* note 8.

[19] GAO, Food Safety: USDA and FDA Need to Better Ensure Prompt and Complete Recalls of Potentially Unsafe Food (October 2004), [http://www.gao.gov/new.items/d0551.pdf].

[20] *See id.* at 13-16, 21-22.

[21] Subcommittee Staff Statement, *supra* note 10, at 2.

[22] The U.S. Government does have a single website dedicated to product recalls, [http://www.recalls.gov]. However, this website apparently does not address the concerns of supporters of a single food safety agency, such as two agencies — FDA and USDA — maintaining jurisdiction over eggs in shell, processed, and liquid forms.

[23] In 2004, the FDA found contaminated animal feed but did not report the contamination to the USDA, which inspects livestock that consume such feed, or the state involved, which has authority to prevent such meat from entering the market. The state seized and destroyed the animals before the FDA even sent a warning letter to the feed mill. Government Accountability Office (GAO), Mad Cow Disease: FDA's Management of the Feed Ban Has Improved, but Oversight Weaknesses Continue to Limit Program Effectiveness, 24 (February 2005), [http://www.gao.gov/new.items/d05101.pdf].

which the USDA has jurisdiction.[24] The linked USDA webpage provides general information, but does not provide information about the meat products recalled due to being potentially contaminated with botulism.[25] Some have argued that the lack of complete information regarding the recall, as well as links to webpages not specifically associated with the chili product recall, could result in consumers overlooking relevant information and potentially consuming tainted products. The Food Marketing Institute — a nonprofit association of retailers and wholesalers that account for the majority of U.S. grocery store sales — and others have contended that the creation of a single food safety agency would help in a food crisis, because the "public is faced with a lengthy delay while overlapping bureaucracies creak into some attempt at a coordinated response. While the search for who knew what and when goes on, the crisis worsens and public confidence erodes."[26]

Those opposed to the idea of combining FDA and USDA into a single food safety agency assert that such a measure would distract the agencies involved from their mission while the reorganization process occurs.[27] They argue that "food security would be compromised" and that overlap between agencies "is not as significant [an issue] as many assume."[28] Furthermore, critics of a single food safety agency point out that coordination between federal, state, and local government agencies would still be required to address threats to the food supply.[29]

## Current Statutory Authority for Mandatory Recalls

The FDA possesses mandatory recall authority only with regard to three products: infant formula,[30] medical devices,[31] and biologic products.[32] This section provides an overview of the statutory authorities that exist for recalling these three

---

[24] FDA, Chili Products (Botulism) Recall (Includes Canned Chili, Stew, Hash, BBQ, Gravy, and Pet Food Products), [http://www.fda.gov/oc/opacom/hottopics/castleberry.html#meat].

[25] USDA, Food Safety Education, USDA Meat & Poultry Hotline, [http://www.fsis.usda.gov/Food_Safety_Education/USDA_Meat_&_Poultry_Hotline/index.asp]. A press release found after clicking on several links in the USDA website details the chili products with meat that were recalled. Press Release, USDA, Georgia Firm Expands Recall of Canned Meat Products that may Contain *Clostridium botulinum*, [http://www.fsis.usda.gov/News_&_Events/Recall_033_2007_expanded/index.asp].

[26] Timothy M. Hammonds, *It is Time to Designate a Single Food Safety Agency*, 59:3 FOOD & DRUG L. J. 427, 428 (2004); *see, e.g.*, Richard J. Durbin, *Food Safety Oversight for the 21st Century: The Creation of a Single, Independent Federal Food Safety Agency*, 59:3 FOOD & DRUG L. J. 383 (2004); Sandra B. Eskin, *Putting All Your Eggs in One Basket: Egg Safety and the Case for a Single Food-Safety Agency*, 59:3 FOOD & DRUG L. J. 441 (2004).

[27] Stuart M. Pape, Paul D. Rubin, & Heili Kim, *Food Security Would be Compromised by Combining the Food and Drug Administration and the U.S. Department of Agriculture Into a Single Food Agency*, 59:3 FOOD & DRUG L. J. 405, 406 (2004).

[28] *Id.* at 405-06.

[29] *Id.* at 406.

[30] Federal Food, Drug, and Cosmetic Act (FFDCA) § 412(f).

[31] FFDCA § 518(e).

[32] Public Health Service Act § 351; 42 U.S.C. § 262.

products. The FDA is one of several agencies that comprise HHS. Therefore, the Federal Food, Drug, and Cosmetic Act (FFDCA) provisions refer to the Secretary of HHS, who, in turn, delegates authority to the FDA.

**Infant Formula.** The HHS Secretary has prescribed regulations for recalls of infant formula "begun by a manufacturer,"[33] which address the mandatory scope and extent of infant formula recalls "necessary and appropriate for the degree of risks to human health presented by the formula subject to the recall."[34] The regulations for infant formula recalls are available at 21 C.F.R. Part 107, Subpart E, Infant Formula Recalls, and state, in part, the following:

> When the Food and Drug Administration determines that an adulterated or misbranded infant formula presents a risk to human health, a manufacturer shall immediately take all actions necessary to recall that formula, extending to and including the retail level, consistent with the requirements of [21 C.F.R. Part 107, Subpart E].[35]

The FFDCA states that the regulations must require manufacturers that begin an infant formula recall "because of a risk to human health to request each retail establishment at which such formula is sold or available for sale to post at the point of purchase . . . a notice of such recall at such establishment for such time that the Secretary determines necessary to inform the public of such recall."[36] The FFDCA also requires manufacturers of infant formula to create and keep "records respecting the distribution of infant formula through any establishment owned or operated by such manufacturer as may be necessary to effect and monitor recalls."[37] The manufacturer must retain such records for "at least one year after the expiration of the shelf life of the infant formula,"[38] and the Secretary may promulgate regulations regarding recordkeeping if the Secretary determines that the required records "are not being made or maintained."[39]

**Medical Devices.** The FFDCA's medical device recall authority provisions place requirements on device manufacturers, importers, distributors, retailers, and other "appropriate persons." If the HHS Secretary "finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death," then the Secretary must issue an order requiring "the appropriate person" to (1) immediately stop distributing the device, (2) immediately notify health professionals and device user facilities of the Secretary's order, and

---

[33] FFDCA § 412(f)(1).

[34] FFDCA § 412(f)(2).

[35] 21 C.F.R. § 107.200.

[36] FFDCA § 412(f)(3); *see* 21 C.F.R. § 107.230(d); *see also* 21 C.F.R. § 107.250.

[37] FFDCA § 412(g)(1).

[38] *Id.*

[39] FFDCA § 412(g)(2).

(3) instruct health professionals and device user facilities to stop use of the device.[40] Thus, the first step of the statute does not require a mandatory recall of a device for which the Secretary makes the above determination.

However, the order may be amended to mandate a recall of such device. The Secretary's order must "provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require a recall."[41] If the Secretary determines, after the informal hearing, that the order should be amended as such, the Secretary must amend the order to require the recall, set a timetable for the recall, and require periodic reports describing the recall's progress.[42] The Secretary's amended order must not include a recall of the device from individuals and must not include a recall from device user facilities "if the Secretary determines that the risk of recalling such device from the facilities presents a greater health risk than the health risk of not recalling the device from use."[43]

Additionally, the Secretary's amended order must provide "notice to individuals subject to the risks associated with the use of such device."[44] To notify individuals regarding the device, the statute provides that "the Secretary may use the assistance of health professionals who prescribed or used such a device."[45] However, if "a significant number" of individuals cannot be identified, the Secretary must notify them via FFDCA § 705(b). That provision gives the Secretary the broad authority to "cause to be disseminated information . . . in situations involving, in the opinion of the Secretary, imminent danger to health, or gross deception of the consumer."[46] Recalling a device is only one of the methods that the Secretary may use to address the risk it presents to the public health. The Secretary may also notify health professionals who prescribe or use the device; order the manufacturer, importer, or any distributor to submit a plan for repairing or replacing the device, or refunding all or part of the purchase cost of the device; and may require the manufacturer, importer, distributor, or retailer to reimburse, for expenses incurred in carrying out the Secretary's order, "any other person who is a manufacturer, importer, distributor, or retailer."[47]

**Biological Products.** For biological products such as blood, blood components, and human tissue, the Secretary must issue an order immediately requiring a recall of "a batch, lot, or other quantity of a product licensed under [42

---

[40] FFDCA § 518(e)(1).

[41] *Id.*

[42] FFDCA § 518(e)(2)(A).

[43] FFDCA § 518(e)(2)(B)(i).

[44] FFDCA § 518(e)(2)(B)(ii).

[45] FFDCA § 518(e)(2)(B).

[46] FFDCA § 705(b).

[47] FFDCA § 518(a), (b), (c), (e)(3).

U.S.C. § 262, Regulation of Biological Products]" once a determination is made that that quantity "presents an imminent or substantial hazard to the public health."[48] The Secretary's order must be issued in accordance with 5 U.S.C. § 554, which addresses formal adjudications after an opportunity for an agency hearing. Violators of these provisions may face inflation-adjustable civil penalties of up to $100,000 per day of violation.[49]

## Current FDA Regulations Regarding Voluntary Recalls

Part 7, Subpart C, of Title 21, Code of Federal Regulations gives "guidance for manufacturers and distributors to follow with respect to their voluntary removal or correction" of a FDA-regulated product on the market that violates the FFDCA or other law that the FDA administers.[50] Chapter Seven of the FDA's Regulatory Procedures Manual also serves as a reference for FDA employees and industry as to recall procedures; the manual is not law and does not bind the FDA or industry.[51] As a result, only FDA regulatory authorities and not the manual are discussed in this report.

The FDA views voluntary, industry-initiated recalls as an alternative to FDA legal actions to remove or correct products that violate laws.[52] For example, the FDA has the power to seize adulterated and misbranded products under the FFDCA.[53] However, the agency states that a company recall "is generally more appropriate and affords better protection for consumers than seizure, when many lots of the product have been widely distributed."[54] The FDA may turn to seizure as a remedy if "the agency has reason to believe that a recall would not be effective, determines that a recall is ineffective, or discovers that a violation is continuing."[55]

**Industry-Initiated Recalls.** The FDA recommends that companies undertake certain practices that may prepare them for a recall or assist them during a recall. These include (1) creating a contingency plan, (2) using codes on FDA-regulated products that will make it possible to identify and recall the defective products, and (3) keeping records — even beyond the shelf or expected use life of a product — that

---

[48] 42 U.S.C. § 262(d)(1); FDA, FDA 101: Biological Products, [http://www.fda.gov/consumer/updates/biologics062608.html].

[49] 42 U.S.C. § 262(d)(2). The statute provides a formula for adjusting the maximum amount of the civil penalty for violations of the recall statute. *Id.*

[50] 21 C.F.R. §§ 7.1, 7.40.

[51] FDA, FDA REGULATORY PROCEDURES MANUAL, [http://www.fda.gov/ora/compliance_ref/rpm].

[52] *See* 21 C.F.R. § 7.40(a).

[53] 21 U.S.C. § 334; FFDCA § 304.

[54] 21 C.F.R. § 7.40(c).

[55] *Id.*

can be used to find the tainted products.[56] If a company initiates a recall, the FDA regulations suggest that the firm immediately notify the closest FDA district office. If the product being recalled would be subject to a court action, such as seizure for being misbranded or adulterated, then the FDA deems the company's action to be a recall and will ask the business to provide the agency with information on the amount and identity of the product, as well as communications about the recall and other data.[57]

FDA regulations also provide for instances in which a company decides to recall a product after being informed by the agency that "the product in question violates the law, but the agency has not specifically requested a recall."[58] In this case, the company's decision to recall the product is treated as an industry-initiated recall. Furthermore, agency regulations provide procedures if a company begins to remove or correct a product in a way that the company believes would constitute a market withdrawal. A market withdrawal is "a firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the [FDA] or which involves no violation, e.g., normal stock rotation practices."[59] If the business is conducting a market withdrawal, but the reason for the need to remove the product is not clear, the FDA is willing to help the company ascertain the cause of the problem. For example, consumers may have experienced adverse reactions to the product, but the source of the problem may not be "obvious or clearly understood."[60]

**FDA-Requested Recalls.** The FDA can request a business to voluntarily recall a FDA-regulated product; however, such requests are "reserved for urgent situations."[61] The FDA would make such a request to the company with "primary responsibility for the manufacture and marketing" of the defective product.[62] The FDA Commissioner can request a company to conduct a recall after these three determinations have been made:

---

[56] 21 C.F.R. § 7.59.

[57] 21 C.F.R. § 7.46.

[58] *Id.* One example of this may be Menu Foods's expansion of its pet food recall to include cat food varieties. The FDA "had confirmed test results it received from a laboratory . . . [that] found that canned cat food which had not been included in Menu Foods' earlier recalls tested positive for melamine, a chemical used as a fertilizer and in the manufacture of cutlery and kitchenware." The FDA informed Menu Foods, Inc., and the company acted to expand the recall. It is unclear whether the FDA requested the expanded recall or simply informed Menu Foods that the cat food varieties violated the FFDCA. Press Release, FDA, FDA Warns Consumers that Retailers May Still Have Recalled Pet Food on Shelves (April 12, 2007), [http://www.fda.gov/bbs/topics/NEWS/2007/NEW01605.html].

[59] 21 C.F.R. § 7.3(j); *see supra* note 1.

[60] 21 C.F.R. § 7.46(d).

[61] 21 C.F.R. § 7.40(b).

[62] *Id.* The FDA's Associate Commissioner for Regulatory Affairs, who leads the FDA's Office of Regulatory Affairs, "has direct responsibility for approval of all recalls requested by FDA and Class I recalls." Sandra Nowlin Whetstone, *ORA's Role at FDA Headquarters and in the Field for Product Recalls*, 53:3 FOOD & DRUG L. J. 513, 513 (1998).

(1) That a product that has been distributed presents a risk of illness or injury or gross consumer deception.
(2) That the firm has not initiated a recall of the product.
(3) That an agency action is necessary to protect public health and welfare.[63]

If the company refuses to recall its products after the FDA makes its request, the agency may then turn to seizures or other court actions to protect the public health.[64] According to its regulations, if the FDA requests a recall, the agency should take into account the factors listed in its recall strategy, such as "the degree to which the product remains unused in the marketplace" and the "ease in identifying the product."[65]

**Classification of Recalls.** The FDA categorizes recalls in three classes. Class I recalls involve "situation[s] in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death."[66] According to the FDA, over 100 Class I recalls of food products occurred in FY2006 and the average number of Class I food recalls for the last five fiscal years is 188.[67] Class II recalls involve "situation[s] in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote," while Class III recalls involve "situation[s] in which use of, or exposure to, a violative product is not likely to cause adverse health consequences."[68] The FDA posts information regarding all three classes of recalls on its website in the agency's weekly FDA Enforcement Report.[69] Additionally, the FDA's webpage devoted to "Recalls, Market Withdrawals, and Safety Alerts" contains press releases and information for mostly Class I recalls.[70]

In order to determine what classification to assign a recall, an ad hoc committee of FDA scientists, perhaps at the closest FDA district office, will first examine the factors below.

(1) Whether any disease or injuries have already occurred from the use of the product.

---

[63] 21 C.F.R. § 7.45. When making its request, the FDA notice of the above determinations will state the violation of the FDA-administered laws, the classification of the recall, the recall strategy, and any agency instructions on carrying out the recall. *Id.*

[64] 21 C.F.R. § 7.40(c).

[65] 21 C.F.R. § 7.42(a).

[66] 21 C.F.R. § 7.3(m)(1).

[67] FDA, FDA's Pilot Program to Better Educate Consumers about Recalled Food Products, [http://www.fda.gov/oc/po/firmrecalls/pilot.html].

[68] 21 C.F.R. § 7.3(m)(2) and (3).

[69] FDA, FDA Enforcement Report Index, [http://www.fda.gov/opacom/Enforce.html].

[70] FDA, Recalls, Market Withdrawals and Safety Alerts, [http://www.fda.gov/opacom/7alerts.html].

> (2) Whether any existing conditions could contribute to a clinical situation that could expose humans or animals to a health hazard. Any conclusion shall be supported as completely as possible by scientific documentation and/or statements that the conclusion is the opinion of the individual(s) making the health hazard determination.
> (3) Assessment of hazard to various segments of the population, e.g., children, surgical patients, pets, livestock, etc., 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.[71]

The committee is not limited to evaluating the health hazard posed by a product based on these factors alone however.[72] The FDA is to then use the committee's health hazard evaluation as the basis for assigning a classification.[73]

**Communication Regarding a Recall.** The company that recalls a product "is responsible for promptly notifying each of its affected direct accounts about the recall."[74] The FDA regulations set out what information should be specified in the notification, such as the identity of the product, the need to stop distributing the product, that the notified person should in turn notify its customers, and what other steps to take with the recalled product. The agency also provides instructions about the contents — or lack thereof, in the case of including promotional materials that could distract from the recall information — and appearance of the communication that will inform a customer of the recall. Those who purchased, received, or used the product being recalled who are notified via a recall communication should also promptly notify their customers or the individuals who may have received or used the product.[75] As mentioned above, the FDA will place information regarding recalls in its weekly FDA Enforcement Report, with two exceptions: (1) product removals or corrections that the FDA finds are market withdrawals or stock recoveries[76] and (2) "intentionally delay[ed] public notification of recalls of certain drugs and devices where the agency determines that public notification may cause unnecessary and

---

[71] 21 C.F.R. § 7.41(a).

[72] 21 C.F.R. § 7.41.

[73] *Id.* The FDA's Office of Regulatory Affairs' Associate Commissioner "may, and has, delegated designation of certain Class I recalls to the agency's Center directors," such as the Center for Food Safety and Applied Nutrition (CFSAN). Whetstone, *supra* note 62, at 513. "CFSAN's director has been delegated authority for certain routine Class I food recalls, e.g., listeria and undeclared allergen Class I recalls." *Id.*

[74] 21 C.F.R. § 7.49.

[75] 21 C.F.R. § 7.49.

[76] *See supra* note 1.

harmful anxiety in patients and that initial consultation between patients and their physicians is essential."[77]

**Monitoring and Termination of a Recall.** The FDA regulations request that companies recalling products to send progress reports on the recall to the appropriate FDA district or field office. The FDA is to inform the firm, based on the urgency of the recall, of how often it should submit recall status reports.[78] The recalling company should continue to send recall progress reports until the FDA terminates the recall, and such reports should include information on the numbers of individuals who were notified, who responded, or who failed to respond to the company's recall communication. The reports should also state the number of products returned and accounted for, how many verification checks were conducted to determine if the recall was effective and the results of such checks, and the firm's estimate of the time until the recall is completed.[79] The FDA field office "is responsible for determining whether the recall was effective and that disposition of the product was completed properly."[80]

Once the FDA "determines that all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy, and when it is reasonable to assume that the product subject to the recall has been removed" and either disposed of or corrected, the agency is to issue a written notice that the recall is terminated.[81] The FDA's determination may depend on the degree of public health hazard associated with product being recalled.[82] For Class I recalls, the FDA district office is to prepare a recommendation for the appropriate FDA center, such as the Center for Food Safety and Applied Nutrition, that the Class I recall be terminated. However, Class II and III recalls do not need approval from an FDA Center.[83] Alternately, the recalling company can request, in writing, that the FDA terminate the recall. This request should include a statement in writing that the recall is effective, in line with the type of determination that the FDA would make when terminating a recall.[84] The FDA's Regulatory Procedures Manual states that the time from when a company considers its recall complete to the time when the agency terminates the recall should generally not exceed three months.[85]

---

[77] 21 C.F.R. § 7.50.

[78] 21 C.F.R. § 7.53. The regulations state that "generally the reporting interval will be between 2 and 4 weeks." *Id.*

[79] 21 C.F.R. § 7.53. For example, in the Menu Foods pet food recall, the FDA conducted approximately 400 effectiveness checks in retail stores. *See* Press Release, *supra* note 58.

[80] Whetstone, *supra* note 62, at 514.

[81] 21 C.F.R. § 7.55(a).

[82] *Id.*

[83] Whetstone, *supra* note 62, at 514.

[84] 21 C.F.R. § 7.55(b).

[85] FDA, REGULATORY PROCEDURES MANUAL ch. 7, at 7-25, [http://www.fda.gov/ora/compliance_ref/rpm/pdf/ch7.pdf].

## The FDA's Pilot Program

From mid-February 2007 until August 12, 2007, the FDA ran a six-month pilot program "to educate and assist consumers in identifying recalled food products that may pose a significant health risk."[86] The program concentrated on posting photos of Class I food product recalls, in the hope that pictures of the main label or display panel would help consumers recognize and avoid using recalled products. Press releases with these photos also contained other identifying information for the food product, such as a lot number or flavor of a product, if only one flavor was affected.[87] The FDA accepted comments from consumers and industry on the program, and the agency's website stated that the program would be "continuing for a short time after the end date while it is being evaluated."[88]

## Food and Drug Administration Amendments Act of 2007 (FDAAA)

Public Law 110-85 contains provisions addressing communications and information postings during a food recall.[89] To enhance communication during a recall, the law requires the Secretary to post information regarding recalled human or pet food products on the FDA website; work with industry, professional organizations, and others to gather information relevant to the recall; and communicate with the public.[90] The law mandates that the HHS Secretary, by September 27, 2008, "establish an early warning and surveillance system to identify adulteration of the pet food supply and outbreaks of illness associated with pet food."[91] The law also requires the Secretary to work with notification networks during a pet food recall "to inform veterinarians and relevant stakeholders."[92]

## Legislative Proposals to Grant the FDA Recall Authority

The 110th Congress has shown significant interest in the issue of food safety. Several bills would grant the FDA the ability to order recalls of food products, drugs, and tobacco products. The following summaries of proposed legislation address the mandatory recall provisions in such legislation. S. 2418, the Ending Agricultural Threats: Safeguarding America's Food for Everyone (EAT SAFE) Act of 2007 also

---

[86] FDA, FDA's Pilot Program to Better Educate Consumers about Recalled Food Products, [http://www.fda.gov/oc/po/firmrecalls/pilot.html].

[87] *Id.*

[88] *Id.* As of July 18, 2007, the FDA received 188 comments. The website states that "[t]he majority of consumers who commented on the pilot find the program beneficial." *Id.*

[89] These provisions were similar to those the Senate approved, by a vote of 94-0, in Senator Durbin's amendment to the FDA Revitalization Act (S. 1082).

[90] P.L. 110-85, § 1003.

[91] P.L. 110-85, § 1002.

[92] P.L. 110-85, § 1002.

contains provisions regarding product recalls; however, it does not provide the FDA with mandatory recall authority.

**Human and Pet Food Safety Act of 2007.** S. 1274 and H.R. 2108 propose to amend the FFDCA to allow the HHS Secretary to handle recalls in a voluntary manner at first. The bills would give the Secretary statutory authority for both voluntary and mandatory recalls. If the Secretary determines that food in interstate commerce violates the FFDCA and "that there is a reasonable probability that the food, if consumed, would present a threat to public health," the bills then require the Secretary to "give the appropriate persons (including the manufacturers, importers, distributors, or retailers of the food) an opportunity to" cease distributing the food; notify individuals such as distributors, processors, handlers, consumers, and state and local public health officials; and recall the food.[93] The bills also provide civil penalties of up to $10,000 per violation per day.[94]

If a person, such as a manufacturer, refuses to or fails to adequately carry out the above described actions "within the time period and in the manner prescribed by the Secretary," the bills would grant the Secretary the authority to "control and possess the food, including ordering the shipment of the food from a food establishment . . . to the Secretary" at either the establishment's expense or, in an emergency, at the Secretary's expense.[95] The Secretary would be required to issue an order mandating importers, retailers, or others to stop distributing the food and notify those involved with the food product's handling, transportation, sale, and other activities. Furthermore, the Secretary must notify "consumers to whom the food was, or may have been distributed," as well as state and local public health officials.[96] Persons such as distributors, processors, handlers, and sellers notified by either the Secretary or an "appropriate person," as described above, must also stop distributing the food product and make available records regarding others who processed, distributed, and sold the food.[97] After an informal hearing, the Secretary would also be able to require a recall, set a timetable for the recall, mandate progress reports on the recall, and give notice of the recall to consumers.[98]

The bills also contain provisions similar to those incorporated in FDAAA. To enhance communication during a recall, the bills would require the Secretary to post information regarding recalled human or pet food products on the FDA website; work with industry, professional organizations, and others to gather information relevant to the recall; and communicate with the public.[99] Finally, the HHS Secretary

---

[93] S. 1274, § 2; H.R. 2108, § 2 (proposed FFDCA § 417(b)).

[94] S. 1274, § 2; H.R. 2108, § 2 (proposed FFDCA § 417(c)).

[95] S. 1274, § 2; H.R. 2108, § 2 (proposed FFDCA § 418(a)(1)).

[96] S. 1274, § 2; H.R. 2108, § 2 (proposed FFDCA § 418(b)).

[97] S. 1274, § 2; H.R. 2108, § 2 (proposed FFDCA § 418(c) and (d)).

[98] S. 1274, § 2; H.R. 2108, § 2 (proposed FFDCA § 418(f)(1)).

[99] S. 1274, § 3; H.R. 2108, § 3.

would have to work with notification networks during a pet food recall "to inform veterinarians and relevant stakeholders."[100]

**Food and Drug Administration Revitalization Act.** Senator Durbin's amendment to S. 1082, which passed 94-0, contains the same communication and notification requirements during recalls as the Human and Pet Food Safety Act of 2007 (see above), which were similar to those incorporated in FDAAA. The amendment would expand the FDA's authority in other areas as well.

**Safe Food Act of 2007.** S. 654 and H.R. 1148 would create an independent single food agency, headed by an Administrator of Food Safety. The bills' voluntary and mandatory recall provisions, in Section 403, are basically the same as those in the Human and Pet Food Safety Act of 2007, except that the Administrator replaces the Secretary of HHS; the term "food establishment" is defined in these bills;[101] and S. 654 and H.R. 1148 prohibit violations of food safety laws in general — from the Egg Products Inspection Act to the Sanitary Food Transportation Act of 1990, as amended — rather than solely the FFDCA.

The bills would institute additional recall provisions as well. Section 204 of the bills would give the Administrator the power to order recalls from food establishments if the Administrator determines that an establishment fails to meet a performance standard for contaminants in food and does not take corrective actions determined by the Administrator. These standards would be promulgated by the Administrator. The frequency with which a food establishment conducts recalls of its products would be taken into account in the bills' provisions classifying food establishments and how often the new agency would inspect such establishments.[102] The bills also specify that any protections that the Administrator develops "to prevent the unauthorized disclosure of any trade secret or confidential information obtained by the Administrator" would not "limit the public disclosure of distribution records or other records related to a food subject to a voluntary or mandatory recall."[103] Section 207 of the bills states that the new agency's Administrator must support state and local recall authorities. Like the current FFDCA, the bills create a section of prohibited acts, one of which would be failing to comply with a recall or other order.[104] Additionally, the bills provide civil and criminal penalties.[105]

---

[100] S. 1274, § 4; H.R. 2108, § 4.

[101] The bills define "food establishment" as "a slaughterhouse, factory, warehouse, or facility owned or operated by a person located in any State that processes food or a facility that holds, stores, or transports food or food ingredients." The terms "does not include a farm, restaurant, other retail food establishment, nonprofit food establishment in which food is prepared for or served directly to the consumer, or fishing vessel." S. 654, § 3(13); H.R. 1148, § 3(13).

[102] S. 654, § 205(d); H.R. 1148, § 205(d).

[103] S. 654, § 205(i); H.R. 1148, § 205(i).

[104] S. 654, § 401(11); H.R. 1148, § 401(11).

[105] S. 654, § 405; H.R. 1148, § 405.

**FDA Food Safety Modernization Act.** Under S. 3385, the Secretary must first provide the responsible party with an opportunity to voluntarily cease distribution and recall the article of food if the Secretary makes a determination based on information gathered through the FFDCA reportable food registry or through any other means. The Secretary may determine that there is a reasonable probability that an article of food is adulterated or misbranded, and the use of or exposure to such article will cause serious adverse health consequences or death to humans or animals. If a person refuses to comply or does not voluntarily comply with a request by the Secretary to cease distribution or sale of, or to recall, an article of food, the Secretary would be authorized to issue an order to cease distribution and to immediately notify others to stop distribution of the article of food. After an opportunity for an informal hearing, the Secretary could amend the order to cease distribution to include a mandatory recall of the food involved, set a timetable for the recall, require reports on its progress from the responsible party, and provide notice to consumers to whom the food may have been distributed.

The Secretary would be required to work with state and local public health officials, as appropriate, to carry out the recall provisions of the bill. In conducting a recall, the Secretary would be required to issue a press release, and other notices as appropriate, to provide consumers and retailers with information about the affected articles of food, and the risks posed. The Secretary's authority to issue or vacate recall orders would not be able to be delegated to anyone other than the FDA Commissioner, and the bill's recall provisions would not affect the authority of the Secretary to request or participate in a voluntary recall. Failure to comply with an order by the Secretary would be a prohibited act under the FFDCA, and the person who does not comply with such an order would be subject to a civil monetary penalty.

**Protect Consumers Act of 2007.** H.R. 2099 would enable the HHS Secretary to institute a mandatory recall of an FDA-regulated product. Under the bill, if the Secretary makes a determination that a mandatory recall is necessary, the Secretary must issue an order requiring distribution, manufacture, and sales of the product to cease; giving "notice to individuals subject to the risks associated with the use of such product"; and recalling the product immediately.[106] The bill would provide for an opportunity for an informal hearing after the order is issued. Depending on whether the Secretary determines that there are adequate grounds to support the order, the order could be vacated or could remain in effect until a future decision by the Secretary. Noncompliance with an order would be treated as a violation of the FFDCA. Section 3 of the bill would also provide for a study on procedures for instituting voluntary and mandatory recalls and making them more effective. The Secretary would also be required to promulgate regulations as a result of the study on new recall procedures.

**Food and Drug Import Safety Act of 2007.** Section 10 of H.R. 3610 would grant the FDA mandatory authority to order manufacturers, importers, distributors, retailers, and others to stop distributing food products if "the Secretary finds that a food may cause serious, adverse health consequences or death." After an

---

[106] H.R. 2099, § 2.

opportunity for an informal hearing, the HHS Secretary could amend the order to cease distribution to include a mandatory recall of the food involved, except from individuals. The Secretary would also set a timetable for the recall and require reports on its progress. This proposal has been endorsed by the consumer group Food & Water Watch, which believes that "giving FDA such authority will speed up the removal of adulterated food from commerce."[107]

**Food and Product Responsibility Act of 2007.** S. 2081 would grant the FDA authority, after the Secretary has provided an opportunity for an informal hearing, to require a recall of an article of food if "the Secretary determines that there is a reasonable probability that human consumption of the article . . . presents a threat to public health." After an opportunity for an informal hearing, the HHS Secretary may also set a timetable for the recall, require reports on its progress, and "provide notice of the recall to consumers to which the article was, or may have been, distributed." The bill would also require manufacturers of food, drugs, devices, cosmetics, biologics, meat and poultry and their products, consumer products, eggs and egg products, and certain replacement equipment to obtain a recall responsibility certificate from U.S. Customs and Border Protection that indicates

> a manufacturer possess[es] sufficient means (through insurance or otherwise) for the 5-year period beginning on the date the manufacturer begins to distribute in commerce [such a] product, to cover — (A) the entire cost of a recall of that product . . . ; and (B) compensatory damages and costs (including reasonable attorneys fees) of any product liability or other lawsuit filed for claims arising out of, relating to, or resulting from any defect in that product.

**SAFER Meat, Poultry, and Food Act of 2007.** H.R. 3484 would grant the FDA authority to mandate a recall of an article of food if the Secretary finds that it is "adulterated or misbranded in a manner that, if consumed, may result in illness or injury." The Secretary must first provide an opportunity for a person to take voluntary actions such as recalling the article of food or stopping distribution of the article. Then, if the person "does not carry out the actions . . . within the time period and in the manner prescribed by the Secretary," the Secretary must require the immediate ceasing of distribution of the article of food, including the immediate notification of others to stop distribution of the article of food. The Secretary may also "take control or possession of the article," which would be in addition to the Secretary's existing seizure authority under FFDCA § 304, and notify consumers and state and local health officials. The Secretary must provide an opportunity for a hearing on an order issued by the Secretary, and, after such hearing, may amend the order to require a recall of an article of food or other action, set a timetable for the recall, require reports on the recall's progress, and "provide notice of the recall to consumers to which the article was, or may have been, distributed," if the Secretary determines that the article "is adulterated or misbranded in a manner that, if consumed, may result in illness or injury."

---

[107] Letter from Wenonah Hauter, Executive Director, Food & Water Watch, to Representative John Dingell, Chairman, House Committee on Energy and Commerce, at 3 (August 17, 2007).

The bill would also make it a prohibited act under the FFDCA to fail to comply with certain orders or an amended order issued by the Secretary, such as those that would require a person to cease distribution of an article of food or would require a recall of the article of food. H.R. 3484 would also increase civil penalties for those who commit prohibited acts "with respect to an article of food" and make "[e]ach prohibited act and each day during which the act continues . . . a separate offense."

**Consumer Food Safety Act of 2007.** H.R. 3624 contains provisions similar to H.R. 3484. H.R. 3624 would grant the FDA authority to mandate a recall of an article of food if the Secretary finds that it is "adulterated or misbranded" and "there is a reasonable probability that such article, if consumed, would present a threat to public health." The Secretary must first provide an opportunity for a person to take voluntary actions such as recalling the article of food or stopping distribution of the article. Then, if the person "refuses to or does not voluntarily cease distribution, make notification, recall such article, or provide notice to consumers, as applicable, within the time and in the manner prescribed by the Secretary," the Secretary must require the immediate ceasing of distribution of the article of food, or the immediate notification of others, such as those who process and transport the article of food, or both actions. The Secretary also "shall, as the Secretary deems necessary, provide notice to consumers to whom such article was, or may have been distributed." The Secretary must provide an opportunity for a hearing on an order issued by the Secretary, and after such hearing, may amend the order to require a recall of an article of food or other action, set a timetable for the recall, require reports on the recall's progress, and "provide notice of the recall to consumers to which the article was, or may have been, distributed," if the Secretary determines that "there is a reasonable probability that the article . . . if consumed, presents a threat to public health."

The bill would make the failure to comply with certain orders or an amended order issued by the Secretary, such as those that would require a person to cease distribution of an article of food or would require a recall of the article of food, a prohibited act under the FFDCA. H.R. 3624 would add civil penalties for those who commit a violation of the FFDCA or the Consumer Food Safety Act of 2007 with respect to food. H.R. 3624 would also enable any person to sue for a violation of a recall order or "other action of the Secretary to ensure the safety of food products."

**Food Import Safety Act of 2007.** Under H.R. 3937, the Secretary must first provide an opportunity for a person to take voluntary actions such as recalling the article of food or stopping distribution of the article, if the Secretary has determined that the food violates the FFDCA and "that there is a reasonable probability that the food, if consumed, would present a threat to public health." Then, if the person "refuses to or does not adequately carry out the action described . . . within the time period and in the manner prescribed by the Secretary," H.R. 3937 would grant the FDA authority to "control and possess the food, including ordering the shipment of the food from a food establishment," or to require a person to immediately cease distribution of the food and notify others with regard to the immediate ceasing of distribution of the food. The Secretary also "shall, as the Secretary deems necessary, provide notice . . . to consumers to whom the food was, or may have been, distributed" and to state and local public health officials. The Secretary must provide an opportunity for an informal hearing on an order issued by the Secretary, and after

such hearing, may amend the order to require a recall of an article of food or other action, set a timetable for the recall, require reports on the recall's progress, and "provide notice of the recall to consumers to which the article was, or may have been, distributed," if the Secretary determines that "there is a reasonable probability that the food . . . if consumed, would present a threat to public health."

The bill would also add civil penalties for those who violate its notification and recall standards. Each violative act and each day a violation continues would be considered a separate offense, and the bill provides for a good faith exception to the civil penalties.

**Draft of the Food and Drug Administration Globalization Act of 2008.** On the website of the House Energy and Commerce Committee, Representative Dingell has posted a discussion draft of a bill that would be entitled the Food and Drug Administration Globalization Act of 2008.[108] The bill would grant the Secretary the authority to require food recalls and would grant the Secretary the same authority for recalling drugs as the Secretary has for recalling devices.

**Family Smoking Prevention and Tobacco Control Act.** S. 625 and H.R. 1108 would provide the HHS Secretary with the authority to require recalls of tobacco products in a manner substantially similar to the Secretary's authority to recall medical devices. "If the Secretary finds that there is a reasonable probability that a tobacco product contains a manufacturing or other defect not ordinarily contained in tobacco products on the market that would cause serious, adverse health consequences or death," then the Secretary must issue an order requiring distribution of such tobacco products to cease.[109] The Secretary's order would affect manufacturers, importers, distributors, and/or retailers.[110] Thus, similar to the Secretary's authority to recall medical devices, the first step of the statute does not require a mandatory recall of the tobacco product for which the Secretary makes the above determination.

As with medical devices, after providing an opportunity for an informal hearing within 10 days of the date the order was issued, the Secretary would be able to amend the order to require recalls of such tobacco products. The Secretary must set a timeline "in which the tobacco product recall will occur."[111] The bills also specify that the Secretary must require reports "describing the progress of the recall," but does not state from whom such reports would be required.[112] Defective tobacco products could not be recalled from individuals, however, an amended order from the

---

[108] [http://energycommerce.house.gov/FDAGlobalAct-08/Dingel_60AXML.pdf].

[109] S. 625, § 908(c); H.R. 1108, § 908(c).

[110] The medical device recall provisions in the FFDCA call for notification "to health professionals who prescribe or use the device and to any other person (including manufacturers, importers, distributors, retailers, and device users) who should properly receive such notification in order to eliminate such risk." FFDCA § 518(a); 21 U.S.C. § 360h(a).

[111] S. 625, § 908(c)(2)(A); H.R. 1108, § 908(c)(2)(A).

[112] S. 625, § 908(c)(2)(A); H.R. 1108, § 908(c)(2)(A).

Secretary requiring a recall must give notice of the risks associated with using a defective tobacco product. The Secretary could ask retailers and other distributors to notify individuals about the defective tobacco products, which is arguably comparable to the Secretary's ability to use "the assistance of health professionals who prescribed or used" a medical device subjected to a recall.[113]

Again, similar to the Secretary's authority for recalling medical devices, if a significant number of retailers and/or distributors of the defective products cannot be identified,[114] the Secretary must notify these persons by publicizing information under FFDCA § 705(b).[115] Unlike the medical device recall provisions, S. 625 and H.R. 1108 do not provide for replacements, reimbursements, or refunds, however, the bills specify that the value of remedies (potentially, a reimbursement of a retailer's costs associated with replacing the defective products) must be taken into account in an award of damages for economic loss.[116]

---

[113] FFDCA § 518(e)(2)(B).

[114] S. 625, § 908(c)(2)(B); H.R. 1108, § 908(c)(2)(B).

[115] However, S. 625 and H.R. 1108 do not amend FFDCA § 705(b) to include tobacco products. Section 705(b) currently states that "The Secretary may also cause to be disseminated information regarding *food, drugs, devices, or cosmetics* in situations involving, in the opinion of the Secretary, imminent danger to health or gross deception of the consumer. . . ." (emphasis added).

[116] S. 625, § 908(b); H.R. 1108(b).