



## **An Agricultural Law Research Article**

# **Anatomy of the Government's Role in The Recall of Unsafe Food Products**

by

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# Anatomy of the Government's Role in The Recall of Unsafe Food Products

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### Introduction

The government does not have the authority to mandate a recall of unsafe food.<sup>1</sup> Recalls of unsafe food products are voluntarily conducted by food companies and are monitored by either the Food and Drug Administration (FDA) or the United States Department of Agriculture (USDA) through its branch agency, the Food Safety and Inspection Service (FSIS).<sup>2</sup> In a typical food recall, the recalling company and the government agency work together to evaluate the product and risk and to recover that product.<sup>3</sup>

This article describes the government's role in this voluntary food recall system. This article first explains the need for an effective recall system to protect consumers from foodborne illnesses. Next, this article describes the unique dual-government agency responsibility for food recall, the basis for the "voluntary" food recall, and the government's specific responsibilities and roles in the voluntary food recall system.

### Need for an Effective Food Recall System

While the United States is generally regarded as having the safest food supply in the world,<sup>4</sup> foodborne illness caused by consuming contaminated foods or beverages is a compelling public health problem: the Centers for Disease Control and Prevention estimates that foodborne diseases cause approximately 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths annually.<sup>5</sup> Compounding the problem is the constantly changing nature of foodborne illness.<sup>6</sup> While

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<sup>1</sup> A reoccurring and divisive issue in the debate over food safety in the United States is whether the government should have the authority to order companies to recall unsafe food from commerce. For example, on December 12, 2002, the United States Department of Agriculture Food Safety and Inspection Service held a public meeting on the topic of "Improving the Recall Process." The meeting included a lively discussion on the implications of mandatory recall authority. Food Safety and Inspection Service (FSIS), Transcript of Proceedings: *Improving the Recall Process*, Wash. D.C. (Dec. 12, 2002).

<sup>2</sup> See GENERAL ACCOUNTING OFFICE, GAO/RCED-00-195, FOOD SAFETY: ACTIONS NEEDED BY USDA AND FDA TO ENSURE THAT COMPANIES PROMPTLY CARRY OUT RECALLS (2000), at 3.

<sup>3</sup> See National Meat Association, Comments Before the Senate Agriculture Committee, Oct. 8, 1997, available at <http://www.nmaonline.org/files/pr10-8.htm>.

<sup>4</sup> See ECONOMIC RESEARCH SERVICE, USDA BRIEFING ROOM, GOVERNMENT FOOD SAFETY POLICIES, available at <http://www.ers.usda.gov/Briefing/FoodSafetyPolicy/>.

<sup>5</sup> See Paul S. Mead, et al., *Food-Related Illness and Death in the United States*, 5 EMERGING INFECTIOUS DISEASES 607 (1999), available at <http://www.cdc.gov/ncidod/eid/vol5no5/mead.htm>.

<sup>6</sup> See CENTERS FOR DISEASE CONTROL, *FOODBORNE ILLNESS*, at

improvements in food safety, such as pasteurization and proper canning, have all but eliminated some diseases,<sup>7</sup> new foodborne infections have emerged. Today there are more than 250 different foodborne diseases, most of which are infections, caused by a variety of bacteria, viruses, and parasites.<sup>8</sup> The most commonly recognized foodborne infections are those caused by the bacteria *E. coli* 0157:H7,<sup>9</sup> *Salmonella*,<sup>10</sup> *Listeria*,<sup>11</sup> and *Campylobacter*,<sup>12</sup> and by a group called *calicivirus*, also known as the Norwalk viruses.<sup>13</sup>

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[http://www.cdc.gov/ncidod/dbmd/diseaseinfo/foodborneinfections\\_g.htm](http://www.cdc.gov/ncidod/dbmd/diseaseinfo/foodborneinfections_g.htm).

<sup>7</sup> See *id.*

<sup>8</sup> See *id.* The other type of foodborne diseases is poisonings, caused by harmful toxins or chemicals that have contaminated the food. See *id.*

<sup>9</sup> An estimated 73,000 cases of infection and 61 deaths occur in the United States each year from *Escherichia coli* 0157:H7. The organism lives in the intestines of healthy cattle. It was first recognized as a cause of illness in 1982 during an outbreak of severe bloody diarrhea that was traced to contaminated hamburgers. Human illness from *E. coli* 0157:H7 follows consumption of food or water that has been contaminated with cow feces. Most infections occur from eating undercooked ground beef. The illness it causes is often a severe and bloody diarrhea and painful abdominal cramps. It can cause temporary anemia, profuse bleeding, and kidney failure. See *id.* See also CENTERS FOR DISEASE CONTROL, *ESCHERICHIA COLI 0157:H7*, , at [http://www.cdc.gov/ncidod/dbmd/diseaseinfo/escherichiacoli\\_g.htm#What%20is%20Escherichia%20coli%200157:H7](http://www.cdc.gov/ncidod/dbmd/diseaseinfo/escherichiacoli_g.htm#What%20is%20Escherichia%20coli%200157:H7).

<sup>10</sup> Each year 40,000 cases of *Salmonella* are reported in the United States. Because many milder cases are not diagnosed or reported, the actual number of infections may be much higher. *Salmonella* is a bacterium that is widespread in the intestines of birds, reptiles, and mammals. It can spread to humans from a variety of different foods of animal origin. It causes salmonellosis, which includes fever, diarrhea, and abdominal cramps. With persons most vulnerable, such as the elderly, infants, and those with impaired immune systems, it can be life-threatening. It is estimated that 600 people die each year with acute *Salmonella*. See Mead, *supra*, note 15. See also CENTERS FOR DISEASE CONTROL, *SALMONELLOSIS*, at [http://www.cdc.gov/ncidod/dbmd/diseaseinfo/salmonellaosis\\_g.htm#What%20is%20salmonellaosis](http://www.cdc.gov/ncidod/dbmd/diseaseinfo/salmonellaosis_g.htm#What%20is%20salmonellaosis). In November of 2003, the USDA announced that the rate of *Salmonella* in raw meat and poultry dropped by sixty-six percent (66%) over the past six years and by sixteen percent (16%) in 2003 compared with 2002. USDA attributed the drop in reported *Salmonella* to strong, science-based enforcement of food safety rules. See USDA Press Release, Tests Show Salmonella in Meat and Poultry Products Declines 66 Percent, available at <http://www.usda.gov/news/releases/2003/11/0396.htm>.

<sup>11</sup> An estimated 2,500 persons become seriously ill with *listeriosis* each year, and of this number, 500 persons die. *Listeria monocytogenes* is found in soil and water. Uncooked vegetables, meats, processed foods, and unpasteurized dairy products may contain the bacterium. *Listeria* may be killed by cooking; however, in certain ready-to-eat foods such as hot dogs and deli meats, contamination may occur after cooking but before packaging. *Listeria* primarily affects pregnant women, newborns, and adults with weakened immune systems. *Listeria* causes fever, muscle aches, and sometimes-gastrointestinal symptoms such as nausea or diarrhea. See CENTERS FOR DISEASE CONTROL, *LISTERIA*, at [http://www.cdc.gov/ncidod/dbmd/diseaseinfo/listeriosis\\_g.htm#symptoms](http://www.cdc.gov/ncidod/dbmd/diseaseinfo/listeriosis_g.htm#symptoms). In October of 2003, USDA announced a one-year, twenty-five percent (25%) drop in positive *Listeria monocytogenes* samples and a seventy percent (70%) decline compared with years prior to the implementation of the Hazard Analysis and Critical Control Points (HACCP) system. See FSIS News Release, *Listeria* in FSIS Ready-to-Eat Products Shows Significant Decline, available at <http://www.fsis.usda.gov/OA/news/2003/rtdedata.htm>.

<sup>12</sup> *Campylobacter* is estimated to affect over one million people in the United States every year, or 0.5% of the population. Most cases go undiagnosed or unreported. It is estimated that 100 persons with *Campylobacter* infections will die each year. *Campylobacter* is a bacterial pathogen that causes fever, diarrhea, and abdominal cramps. It is the most commonly identified bacterial cause of diarrheal illness in the world. These bacteria live in the intestines of healthy birds, and most raw poultry meat has *Campylobacter* on it. Eating undercooked chicken or other food that has been contaminated with juices dripping from raw chicken is the most frequent source of this infection. See Mead, *supra* note 5. See also CENTERS FOR DISEASE CONTROL, *CAMPYLOBACTER*

Foodborne illness outbreaks are also becoming increasingly widespread and complicated. The classic outbreak of foodborne illness was confined to a local community, generally caused by a catered meal or a potluck dinner.<sup>14</sup> Changes in the way food is prepared and consumed today<sup>15</sup> cause foodborne illness outbreaks to affect many persons in many different places, spread out over long periods of time.<sup>16</sup>

To protect consumers from these foodborne illnesses, unsafe food products must be removed quickly and efficiently from commerce.<sup>17</sup> Food safety is, of course, ideally achieved by ensuring that recalls need not occur in the first place;<sup>18</sup> however, once unsafe food enters commerce, recalls are a critical tool for protecting the health and lives of consumers.<sup>19</sup>

## Overview of the Current Food Recall System

The current food recall system is marked by a unique food safety regulatory approach that allocates responsibilities to two government agencies that in turn develop oversight procedures and protocol for voluntary food recalls conducted by private companies.

### A. Dual Agency Responsibility for Food Recall

The two government agencies charged with food recall responsibility are the United States Department of Agriculture (USDA) and the Food and Drug Administration (FDA).<sup>20</sup> USDA derives its regulatory authority from the Meat Inspection Act<sup>21</sup> and the Poultry Products

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*INFECTIONS, at*

[http://www.cdc.gov/ncidod/dbmd/diseaseinfo/campylobacter\\_g.htm#What%20is%20campylobacteriosis](http://www.cdc.gov/ncidod/dbmd/diseaseinfo/campylobacter_g.htm#What%20is%20campylobacteriosis).

<sup>13</sup> *Norwalk-like virus* is an extremely common form of foodborne illness, though rarely diagnosed. It causes an acute gastrointestinal illness, usually with more vomiting than diarrhea that resolves itself after a few days. Unlike many foodborne pathogens that have animal reservoirs, *Norwalk-like viruses* spread primarily from one infected person to another, such as kitchen workers who contaminate a salad or sandwich as they prepare it. See Mead, *supra* note 5.

<sup>14</sup> See *id.*

<sup>15</sup> These changes include first, the increasing consumption of a greater variety of foods, particularly seafood, fresh fruits, and vegetables that are eaten raw; second, the dramatic increase in the variety of foods imported from all over the world; and, third, the increasingly number of people eating more of their meals away from home. See Joseph A. Levitt, *FDA's Foods Program*, 56 FOOD DRUG L.J. 255, 255-256 (2001).

<sup>16</sup> See *id.*

<sup>17</sup> See UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE, REPORT OF THE RECALL WORKING GROUP (Aug. 10, 1998), *available at* <http://www.fsis.usda.gov/OA/programs/recallwg.htm>.

<sup>18</sup> See FSIS Public Meeting, *supra* note 1, at 10.

<sup>19</sup> See *id.*

<sup>20</sup> GENERAL ACCOUNTING OFFICE, *supra* note 2, at 5.

<sup>21</sup> 21 U.S.C. § 601(1999).

Inspection Act,<sup>22</sup> giving it responsibility for the regulation of meat, poultry, and certain egg products. USDA administers a food safety and inspection program over these products through its branch agency, the Food Safety and Inspection Service (FSIS).<sup>23</sup> FDA derives its regulatory power from various laws including the Federal Food, Drug, and Cosmetic Act,<sup>24</sup> giving it responsibility for the regulation of all other food products, including whole (or shell) eggs, sea food, milk, grain products, fruits and vegetables, and certain canned, frozen, and otherwise packaged foods containing meat, poultry, and eggs that are not regulated by USDA.<sup>25</sup>

This food safety regulatory regime for USDA and FDA prohibits the adulteration and misbranding of food.<sup>26</sup> Implementing regulations and policy statements define adulteration and misbranding, and USDA and FDA enforce these provisions when violations are encountered.<sup>27</sup> An important tool used by USDA and FDA in the enforcement of these provisions is the recall of food.<sup>28</sup>

## **B. Basis for Voluntary Food Recall: the Implicit Threat**

Despite the importance of recall as an enforcement tool, neither USDA nor FDA has statutory authority to mandate a recall.<sup>29</sup> Recalls administered by USDA and FDA is strictly voluntary.<sup>30</sup> What

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<sup>22</sup> See *id.* at §§ 451-469 (1999).

<sup>23</sup> See 7 C.F.R. § 2.53 (2004) (describing various FSIS responsibilities).

<sup>24</sup> 21 U.S.C. § 392(a) (1999).

<sup>25</sup> The distinctions between food products regulated by USDA and FDA are often confusing. For example, FDA regulates the safety of egg shells, while USDA regulates processed egg products, except for certain processed egg products. See 21 U.S.C. §§ 1033(f), 1034(a), 1052(c) (1999); 7 C.F.R. § 55.2 (2004) (definition of “egg product”). See generally Michael R. Taylor, *Preparing America’s Food Safety System for the Twenty-First Century—Who Is Responsible for What When It Comes to Meeting the Food Safety Challenges of the Consumer-Driven Global Economy?* 52 FOOD DRUG L.J. 13, 18-19 (1997) (addressing the fragmented federal food safety system).

<sup>26</sup> See 21 U.S.C. §§ 402, 453(g)(3), and 601(m)(3) (1999).

<sup>27</sup> The basic legal standard for what constitutes adulterated food is the same under the Federal Food, Drug, and Cosmetic Act, the Federal Meat Inspection Act, and the Poultry Products Inspection Act. Generally speaking, the regulatory statutes establish four adulteration provisions: 1) a food is considered adulterated if it contains a harmful substance that may pose a safety risk; 2) a food is adulterated if it contains an added harmful substance that is acquired during production or cannot be reasonably avoided, and it exceeds applicable tolerance levels; 3) a food is adulterated if it contains a substance that has been intentionally added to the food but that has not been approved or otherwise sanctioned for use by a regulatory agency or one of the food safety statutes; and, 4) a food is adulterated if it has been handled under unsanitary conditions, creating a risk of contamination with a substance that may pose a safety threat. See THE FOOD INSTITUTE, HACCP & U.S. FOOD SAFETY GUIDE (2d ed.), at sec. 2, at p. 6.

<sup>28</sup> See Dr. Garry L. McKee, Food Safety & Inspection Service OIG Audit Report on ConAgra, Washington, D.C. (Oct. 2, 2003).

then triggers a voluntary recall? What leverage does the USDA or FDA have to motivate companies to voluntarily recall their food product?<sup>31</sup> The answer is simple: it is the implicit threat of regulatory action, liability, and adverse publicity.<sup>32</sup>

The threat of regulatory action involves an array of regulatory enforcement tools available to USDA and FDA in varying degree and scope: warning letters,<sup>33</sup> adverse publicity,<sup>34</sup> injunction,<sup>35</sup> retention,<sup>36</sup> seizure,<sup>37</sup> and criminal prosecution.<sup>38</sup> These sanctions are not mutually exclusive and

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<sup>29</sup> FSIS plainly states that “[a] food recall is a voluntary action by a manufacturer or distributor to protect the public from products that may cause health problems or possible death.” FOOD SAFETY AND INSPECTION SERVICE, BACKGROUNDER/KEY FACTS, FSIS FOOD RECALLS (2002), *available at* <http://www.fsis.usda.gov/Oabackground/bkrecalls.htm>. See also CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, U.S. FOOD AND DRUG ADMINISTRATION, INDUSTRY AFFAIRS STAFF BROCHURE, FDA RECALL POLICIES (June 2002), *available at* <http://vm.cfsan.fda.gov/~lrd/recall2.html>.

<sup>30</sup> GENERAL ACCOUNTING OFFICE, *supra* note 2, at 3.

<sup>31</sup> Headlines in the news indicate that it is commonly misperceived that food products are subject to mandatory recall by the government. Examples include “FDA Orders Peanut Butter Recall,” and “FDA Orders 6,500 Cases of Red-Dyed Mints Recalled.” The headlines are, of course, wrong in indicating that the Agency can order these recalls. See CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, *supra* note 29, *available at* <http://vm.cfsan.fda.gov/~lrd/recall2.html>.

<sup>32</sup> See FSIS Public Meeting, *supra* note 1, at 20-21.

<sup>33</sup> A warning letter from the FDA is a written communication to a company asserting that there has been a violation of the FDCA or implementing regulations. The letter will typically request that the company inform the agency about the action the company will take to correct the alleged violation. The warning letter will generally caution the company that enforcement action may be initiated “without further notice.” If a company does not correct the violation, further sanctions may be imposed. In contrast to FDA’s practice, USDA warning letters are sent after the department has decided not to take further regulatory action. In other words, the warning letter closes the file. See THE FOOD INSTITUTE, *supra* note 27, at Sec. 2, p.13.

<sup>34</sup> Adverse publicity consists of the dissemination of information that the company is not cooperating with enforcement officials. See 21 U.S.C. § 705 (1999).

<sup>35</sup> If FDA or USDA seeks an injunction, they must go to the U.S. Attorney where the company is located. If the prosecutor agrees to take the case, he or she will file a request for an injunction with the U.S. District Court. See THE FOOD INSTITUTE, *supra* note 27, at sec. 2, p.17.

<sup>36</sup> USDA retains product when an in-plant inspector places a “tag” on product located at a federally inspected facility that he or she believes to be adulterated or misbranded. Once tagged, a product cannot be removed from the facility without USDA approval. In most instances, a product is either reconditioned or destroyed within a few days. See *id.* at 15.

<sup>37</sup> In a seizure proceeding, the government initially seeks a court order authorizing the United States Marshall to “seize” the product. A seizure action seeks the destruction of a product, not merely a prohibition against its shipment. Once seized, the product cannot be moved without the court’s permission. The government will also file a complaint requesting that the product be “condemned” and destroyed. See *id.* at 16.

<sup>38</sup> The Food, Drug, and Cosmetic Act (FDCA), the Poultry Products Inspection Act (PPIA), and the Federal Meat Inspection Act (FMIA) have strong criminal provisions that are essentially strict liability statutes: to obtain a conviction, the government need not establish intent to violate the law. Two types of criminal violations exist: misdemeanors and felonies. Under FDCA, most food violations are misdemeanors; however, FDA can request a felony conviction if the government can prove intent to defraud or mislead or if there has been a prior conviction. Under PPIA and FMIA, any violation involving the distribution or attempted distribution of an adulterated food is a felony. See *id.* at 18.

may build upon one another.<sup>39</sup> Given these regulatory threats, a recall may be the only practical option for a company experiencing a food safety problem.<sup>40</sup>

Companies also recall food products to minimize and avoid liability.<sup>41</sup> A failure to recall unsafe food significantly increases a company's liability exposure and the risk of class actions and punitive damages.<sup>42</sup> Companies also risk adverse publicity that could destroy their brand image.<sup>43</sup> Consequently, some observers deem the term "voluntary" recall a misnomer since it is compelled by regulatory, legal, and marketing pressures.<sup>44</sup>

### C. Regulatory Oversight of Food Recall

USDA and FDA oversee, monitor, and coordinate food recall activities.<sup>45</sup> USDA procedures for recalls of defective meat are found in an FSIS Directive;<sup>46</sup> FDA procedures for recalls are published in the Code of Federal Regulations.<sup>47</sup> These procedures have been developed into recall programs that USDA, through FSIS, and FDA employ for the foods they regulate.<sup>48</sup> Notwithstanding these recall programs and the presence of the implicit threat, the essence of food recall activity is still voluntary: companies are not required by law to recall unsafe food,<sup>49</sup> and even if companies elect to voluntarily recall unsafe food, they are not required by law or regulation to notify USDA or FDA of their recall.<sup>50</sup>

#### 1. FSIS Food Recall Program

When FSIS learns that adulterated or misbranded meat or poultry may be in commerce,<sup>51</sup> it conducts a preliminary investigation to determine whether a recall of the food product is warranted.<sup>52</sup>

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<sup>39</sup> See *id.* at 12.

<sup>40</sup> See FSIS Public Meeting, *supra* note 1, at 17-21.

<sup>41</sup> See generally John M. Packman, *Civil and Criminal Liability Associated with Food Recalls*, 53 FOOD & DRUG L.J. 437 (1998).

<sup>42</sup> See *id.*

<sup>43</sup> See FSIS Public Meeting, *supra* note 1, at 181.

<sup>44</sup> See National Meat Association, *supra* note 3, available at <http://www.nmaonline.org/files/pr10-8.htm>.

<sup>45</sup> See GENERAL ACCOUNTING OFFICE, *supra* note 2, at 5.

<sup>46</sup> See UNITED STATES DEPARTMENT OF AGRICULTURE, FSIS INFORMATION CENTER, FSIS DIRECTIVE 8080.1, REV. 3, RECALL OF MEAT AND POULTRY PRODUCTS, available at [http://www.fsis.usda.gov/OA/recalls/rec\\_intr.htm](http://www.fsis.usda.gov/OA/recalls/rec_intr.htm); UNITED STATES DEPARTMENT OF AGRICULTURE, FSIS DIRECTIVE, RECALL OF MEAT AND POULTRY PRODUCTS (Jan. 19, 2000), available at <http://www.fsis.usda.gov/OPPDE/frdad/FSISDirectives/8080.1Rev3.htm>.

<sup>47</sup> See 21 C.F.R. §§ 7.40-.59 (2003).

<sup>48</sup> See GENERAL ACCOUNTING OFFICE, *supra* note 2, at 6.

<sup>49</sup> See *id.*

<sup>50</sup> See *id.* at 7, 11.

<sup>51</sup> FSIS can learn about the possibility of unsafe meat from several sources: the company that manufactured or

If FSIS determines that a recall is necessary, it convenes a meeting of its Recall Committee that is comprised of FSIS scientists, technical experts, field inspection managers, enforcement personnel, and communication specialists.<sup>53</sup> The Recall Committee evaluates available information and, based on the health risk of the food product, categorizes the recall into one of three classes: a Class I recall where a strong likelihood exists that a product will cause serious adverse health consequences or death,<sup>54</sup> a Class II recall where a remote possibility exists of an adverse health consequence resulting from consuming the meat or poultry product,<sup>55</sup> or a Class III recall where the consumption of the product will not cause adverse health consequences.<sup>56</sup> The Recall Committee also recommends the depth and scope of the recall.<sup>57</sup> FSIS and the recalling company conduct effectiveness checks to determine the adequacy of notice about the recall and the success in removing the product.<sup>58</sup> FSIS notifies the public of recalls in two ways: a press release<sup>59</sup> and a recall notification report.<sup>60</sup> FSIS also

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distributed the meat, test results received by FSIS as part of its sampling program, FSIS field inspectors and compliance officers, consumer complaints, epidemiological data submitted by state or local public health departments, and government agencies. See FSIS, REPORT OF THE RECALL WORKING GROUP, *supra* note 27, available at <http://www.fsis.usda.gov/Oabackground/bkrecalls.htm>.

<sup>52</sup> The preliminary investigation includes some or all of the following steps: collecting and verifying information about the inspected food; documenting a chronology of events; contacting the manufacturer of the food for more information; discussions with FSIS field inspection and compliance personnel; interviewing a consumer who allegedly became ill or injured from eating the food; collecting and analyzing food samples; and, contacting state and local health departments. See *id.*

<sup>53</sup> See FSIS DIRECTIVE, *supra* note 56, available at <http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/8080.1Rev3.htm>.

<sup>54</sup> An example of a Class I recall would be meat that is contaminated with pathogenic bacteria, such as *Listeria monocytogenes* in a ready-to-eat product or *Escherichia coli* 0157:H7 in raw ground beef. Another example includes the adding of Class I allergens, such as peanuts or eggs, as an ingredient in processed meat without listing them on the label. See FSIS, REPORT OF THE WORKING RECALL GROUP, *supra* note 17, available at <http://www.fsis.usda.gov/OA/programs/recallwg.htm>.

<sup>55</sup> An example of a Class II recall would be the presence of dry milk as an ingredient in sausage without mention of the dry milk on the label. Another example is the presence of undeclared allergens such as milk or soy products. See *id.* The well-publicized Class II recall announced on December 23, 2003, involving the BSE incident was designated a Class II by the FDA due to an extremely low likelihood that the products contained the infectious agent that causes BSE. The infected tissues including the brain, spinal cord, and distal ileum, were all removed from the carcass on the day of slaughter, meaning that the meat produced were cuts that would not be expected to be infected or have an adverse public health impact. See FSIS UPDATE OF RECALL ACTIVITIES (Feb. 9, 2004), available at <http://www.fsis.usda.gov/oa/recalls/prelease/update067-2003.html>.

<sup>56</sup> An example of Class III recall would be improperly labeled processed meat in which added water is not listed on the label as required by the federal regulations. See *id.*

<sup>57</sup> See OFFICE OF THE INSPECTOR GENERAL, UNITED STATES DEPARTMENT OF AGRICULTURE, GREAT PLAINS REGIONAL AUDIT REPORT 24601-2-KC, FOOD SAFETY AND INSPECTION SERVICE OVERSIGHT OF PRODUCTION PROCESS AND RECALL AT CONAGRA PLANT (ESTABLISHMENT 969) (2003), at 3.

<sup>58</sup> See GENERAL ACCOUNTING OFFICE, *supra* note 2, at 2.

<sup>59</sup> In February 2000, USDA began issuing press releases for all three classes of recalls, even if the product is not identifiable to consumers. See *id.* at 16, 28. The press release is issued to media outlets in the area where the product was distributed and to an email list-serv. See FSIS BACKGROUNDER, *supra* note 29. The public can request to receive FSIS press releases and other FSIS materials by subscribing to the *FSIS Constituent Update* at [www.fsis.usda.gov/oa/update/subscribe.asp](http://www.fsis.usda.gov/oa/update/subscribe.asp). The news release is posted on the FSIS Recall Web site at [www.fsis.usda.gov/OA/recalls/rec\\_intr.htm](http://www.fsis.usda.gov/OA/recalls/rec_intr.htm).

posts recall notification reports on its Web site and sends these reports to food safety and public health officials throughout the country.<sup>61</sup>

## 2. FDA Food Recall Program

When FDA learns that a recall needs to be, will be, or has been initiated,<sup>62</sup> the FDA's district office<sup>63</sup> obtains preliminary information about the recall and product and provides this information to FDA's Center for Food Safety and Applied Nutrition (CFSAN)<sup>64</sup> and FDA's Office of Regulatory Affairs (ORA)<sup>65</sup> within 24 hours.<sup>66</sup> The district office may assist the company in developing a recall strategy, although companies are not required to consult with FDA or modify its recall strategy on the basis of FDA's recommendations.<sup>67</sup> CFSAN prepares a written health hazard evaluation that is used to classify the recall into one of three classes:<sup>68</sup> a Class I recall for dangerous or defective products that predictably could cause serious health problems or death,<sup>69</sup> a Class II recall for products that might cause a temporary health problem or pose only a slight threat of a serious nature,<sup>70</sup> and a Class III recall for situations where eating the food will not cause adverse consequences.<sup>71</sup> FDA monitors the progress of a company's recall through its termination.<sup>72</sup> FDA encourages the recalling company to issue a press release for Class I and selected Class II recalls.<sup>73</sup> When FDA believes that the public

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<sup>60</sup> Recall Notification Reports (RNR) provide the public with detailed information about meat and poultry recalls. RNRs are sent by facsimile and electronic mail to food safety and public health officials throughout the country. *See id.*

<sup>61</sup> The RNR are posted on the FSIS Recall Web site at [www.fsis.usda.gov/OA/recalls/rec\\_intr.htm](http://www.fsis.usda.gov/OA/recalls/rec_intr.htm).

<sup>62</sup> FDA's recall regulations request that a company notify FDA when a company removes or corrects a distributed product. *See* CENTER FOR FOOD SAFETY AND APPLIED NUTRITION INDUSTRY, *supra* note 39, *available at* <http://vm.cfsan.fda.gov/~lrd/recall2.html>.

<sup>63</sup> For a description of the responsibilities of district offices in a food product recall, see Sandra Nowlin Whetstone, *ORA's Role at FDA Headquarters and in the Field for Product Recalls*, 53 FOOD & DRUG L. J. 513 (1998).

<sup>64</sup> *See id.* (describing CFSAN).

<sup>65</sup> *See id.* (describing ORA).

<sup>66</sup> FDA's *Regulatory Procedures Manual* describes procedures for FDA staff to use in handling recalls of FDA-regulated food products. *See* GENERAL ACCOUNTING OFFICE, *supra* note 2, at 31.

<sup>67</sup> *See id.* at 32.

<sup>68</sup> *See id.* at 32-33.

<sup>69</sup> Examples of Class I recall are a food found to contain botulinal toxin and food with undeclared allergens. CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, *supra* note 29, *available at* <http://vm.cfsan.fda.gov/~lrd/recall2.html>.

<sup>70</sup> *See id.*

<sup>71</sup> Examples of Class III recall are a container defect, off-taste color, leaks in a bottle, and a lack of English labeling in a retail food. *See id.*

<sup>72</sup> *See* GENERAL ACCOUNTING OFFICE, *supra* note 2, at 33.

<sup>73</sup> *See id.* at 34.

needs to be alerted about a serious hazard, FDA will issue its own press release.<sup>74</sup> FDA also posts an Enforcement Report on its Web site, listing all food recalls by the agency.<sup>75</sup>

### 3. *Market Withdrawal and Stock Recovery*

In addition to recalls, other actions may be taken by a food company to remove a product from commerce, including market withdrawal and stock recovery.<sup>76</sup> Market withdrawal is the removal of a distributed product that involves a minor violation that would not be subject to legal action by the FDA or FSIS, or when the company wishes to remove a product from distribution for other reasons, such as when a product does not meet the company's internal specifications.<sup>77</sup> Stock recovery is the removal of a product that has not been placed in retail distribution channels but is still under the direct control of the food company.<sup>78</sup>

## **Conclusion**

The removal of unsafe food product from commerce is conducted voluntarily by food companies in concert with the government's monitoring and oversight of the recall activity. The "implicit threat" of government enforcement, adverse publicity, and liability exposure, helps motivate food companies to engage with the government in the "voluntary" recall of unsafe food product. The extent of involvement by the FSIS and FDA in the recall of unsafe food product is defined by well-established procedures and processes.

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<sup>74</sup> *See id.*

<sup>75</sup> This is found through FDA Enforcement Reports, a weekly publication, available at <http://www.fda.gov/opacom/7alerts.html>.

<sup>76</sup> *See* NATIONAL FOOD PROCESSORS ASSOCIATION, FACT SHEET ON FOOD AND BEVERAGE PRODUCT RECALL, *available at* <http://www.nfpa-food.org/members/science/recallqa.html>.

<sup>77</sup> 21 C.F.R. § 7.3(j) (1996) (2003); *see also* FOOD PROCESSORS, *supra* note 76.

<sup>78</sup> 21 C.F.R. § 7.3(k) (1996) (2003); *see also* FOOD PROCESSORS, *supra* note 76.