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Report to Congressional Requesters

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FOOD SAFETY

Actions Needed by USDA and FDA to Ensure That Companies Promptly Carry Out Recalls

GAO

Accountability * Integrity * Reliability

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Abbreviations

CDC	Centers for Disease Control and Prevention
CFSAN	Center for Food Safety and Applied Nutrition
FDA	Food and Drug Administration
HACCP	hazard analysis and critical control point
ORA	Office of Regulatory Affairs
USDA	U.S. Department of Agriculture

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Resources, Community, and
Economic Development Division

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August 17, 2000

The Honorable Tom Harkin
Ranking Minority Member
Committee on Agriculture, Nutrition, and Forestry
United States Senate

The Honorable Lynn Rivers
House of Representatives

The Centers for Disease Control and Prevention (CDC) estimates that approximately 76 million people suffer from foodborne illnesses and 5,000 die from these illnesses in the United States each year. While many foodborne illnesses may be caused by poor food handling and preparation, they may also be caused by eating contaminated or adulterated foods, or foods whose labels do not identify potential allergens. To reduce the number of foodborne illnesses from contaminated, adulterated, and mislabeled foods that may be on the market, manufacturers can recall food that poses a risk of illness or injury. Problems warranting a recall may be identified by the manufacturer, a state or local health department, the U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA), CDC, or consumers. The types of problems and risks associated with food recalls vary. For example, a food contaminated with bacteria, such as *E. Coli* 0157:H7, may cause serious illness, even death, while a food that contains more water than specified on its label would present no imminent health risk.

USDA has a program in place to assist, coordinate, and track recalls that involve USDA-regulated meat and poultry products, such as ground beef and chicken. FDA operates a program to assist, coordinate, and track recalls involving all other foods, such as fruit juices and alfalfa sprouts. USDA and FDA can request companies to voluntarily recall food that is contaminated, adulterated, or mislabeled. If the manufacturer does not voluntarily do so, USDA and FDA can seek a court order to seize the food. Although FDA has direct legislative authority to require recalls that involve infant formula, neither agency has authority under its food safety laws to require a company to conduct a recall of any other food.

To assist your consideration of legislative proposals that would give mandatory recall authority to USDA and FDA, you asked us for information

on several aspects of the current, voluntary recall programs. Specifically, this report provides information on (1) the number of food recalls documented by USDA and FDA since 1984, and of those, the number associated with outbreaks of foodborne illnesses; (2) for recalls associated with such outbreaks, the extent to which USDA and FDA identified the cause of the outbreak and how the product became contaminated; (3) the extent to which companies delayed or did not comply with USDA- or FDA-requested recalls; and, (4) the economic impact of recalls on affected companies, to the extent identifiable. As defined by CDC, an outbreak of foodborne illness occurs when two or more people come down with the same illness after consuming the same contaminated food.

To conduct this review, we analyzed data from USDA's electronic recall database, which contains information dating back to 1984, and summary data from multiple FDA electronic files dating back to 1986. We analyzed detailed case files on each of the recalls associated with outbreaks of foodborne illnesses. We also discussed the economic impact of recalls with major food industry associations and analyzed the coverage and limitations of insurance available for recalls. See appendix I for detailed information on our scope and methodology.

Results in Brief

USDA and FDA documented more than 3,700 food recalls from the mid-1980s through 1999. USDA, which generally maintains its data by calendar year, identified 515 recalls of fresh and processed meat and poultry from calendar year 1984 through 1999. FDA, which began compiling such data electronically in 1986, identified 3,248 recalls of other foods from fiscal year 1986 through fiscal year 1999. Neither agency has tracked whether recalls were associated with outbreaks of foodborne illnesses over those time periods. However, USDA, according to its electronic recall files since 1992 and its staff's recollections, identified 12 recalls from 1988 through 1999 that were associated with outbreaks of foodborne illnesses. Likewise, FDA, according to its staff's recollections and data on illness outbreaks that it has collected since fiscal year 1997, identified 49 recalls for 1997 through 1999 that were associated with outbreaks of foodborne illnesses.

USDA and FDA were able to identify a specific contaminant for each of the 61 recalls they considered to be associated with an outbreak; in total, the agencies believe strains of five bacteria and two viruses were responsible. However, the agencies generally were unable to determine how the food became contaminated. According to USDA and FDA officials, efforts to determine the cause of contamination are generally not successful because

so much time passes—up to several weeks or months—before an illness is linked to a specific food. Recently implemented systems by CDC to track foodborne illnesses could reduce that lag time and may improve the agencies' ability to determine points of contamination.

Both agencies believe that companies have generally initiated recalls without delays—either on their own initiative or in response to requests to voluntarily do so. USDA said there were no instances in which companies delayed or failed to initiate a recall. FDA identified nine cases out of several thousand where companies delayed or failed to initiate a recall. For both agencies, information on companies' recall efforts is based on the recollections of agency officials because neither agency systematically measures the full extent of companies' recall activities. Although both agencies selectively check with customers to determine whether recalls are implemented, neither can assure the public that companies are carrying out recalls in a timely manner. In addition, neither agency's written guidance to companies specifies time frames for initiating or carrying out recalls, even for recalls that involve potentially serious health risks.

Neither USDA nor FDA compiles information on the economic impact of recalls on affected companies. Similarly, the food industry associations we contacted do not collect this information. However, according to food industry officials, recalls can have a significant economic impact on affected companies through lost sales and food retrieval costs. The extent of this impact depends on such factors as the amount and value of the food recalled, its location in the distribution process, and the severity of the health risk. In addition, following a recall, consumers may stop buying a company's products or switch to another company's brand for future purchases.

We are making recommendations to USDA and FDA to strengthen their guidance to companies on recalls that involve serious health risks and to improve their agencies' ability to assess the timeliness of companies' recall actions.

Background

USDA and FDA share federal responsibility for ensuring the safety of the nation's food supply. USDA, under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act, is generally responsible for meat, poultry, and certain egg products. FDA, under the Federal Food, Drug, and Cosmetic Act, is responsible for all other foods, including certain canned, frozen, and otherwise packaged

foods containing meat, poultry, and eggs that are not regulated by USDA.[1, 2] FDA has regulatory jurisdiction only if the food or its ingredients have been offered into interstate commerce, whereas USDA has regulatory jurisdiction over meat and poultry products that may or may not be in interstate commerce. USDA's and FDA's respective recall programs track recalls involving the foods they regulate. Both agencies include multiple food items in a recall when multiple foods from the same manufacturer are linked to the same contamination. (For additional information on USDA's and FDA's regulatory responsibilities regarding food safety, see Related GAO Products listed at the end of this report.)

Companies initiate recalls on their own initiative or at the request of USDA, FDA, or states. Both USDA and FDA consider a recall to be a voluntary action by a company to remove or correct a food after it has left the possession and control of the company responsible for the food's becoming contaminated, adulterated, or mislabeled. Under their recall procedures, when the agencies determine that food may be contaminated and a recall warranted, they work informally with the company to encourage it to initiate a recall. If this informal approach does not work, USDA can detain the product for up to 20 days while it seeks a court order to seize the food,[3] whereas FDA can issue a written request that the company voluntarily conduct the recall. If the company does not initiate the recall following this formal request, FDA, which does not have detention authority for food under the Federal Food, Drug, and Cosmetic Act, can seek a court order to seize the food.

The recalling company is generally the manufacturer or an importer. A recall may involve a relatively small amount of food—such as a portion of a single day's production run of a single item—or a very large quantity—such as all the production of a plant over several days. Some or all of a recalled

[1]FDA is responsible for meats that are not explicitly named in the Federal Meat Inspection Act (such as venison and buffalo) and poultry not explicitly named in the Poultry Products Inspection Act (such as quail and pheasant). USDA is responsible for food containing 2 percent or more cooked, or 3 percent or more raw, USDA-regulated meat or poultry.

[2] FDA, under the Public Health Service Act, may have authority to issue mandatory recall regulations for foods that are "vectors of communicable diseases." FDA has never used this authority with regard to food recalls. It has used the Public Health Service Act authority to issue recall regulations for human tissue.

[3]USDA can also remove its inspectors from a plant, which would force the plant to close.

food may be retrieved—or its label corrected—before any of it reaches the consumer.

Both USDA and FDA classify recalls on the basis of their potential health threat and provide written guidance to their staff and the recalling firms for conducting recalls. Both agencies provide direct assistance and monitoring through their field office staff and maintain individual case files on recalls in field and headquarters offices. The agencies also maintain selected information on all recalls electronically at headquarters. In addition, USDA has delegated certain recall responsibilities to states that have implemented inspection programs equal to USDA's and have sought the responsibility. Appendix II provides additional information on USDA's and FDA's recall programs and procedures.

State and local public health and agriculture officers and inspectors, who generally carry out food safety inspections in retail stores, restaurants, warehouses, institutional settings (such as hospitals, nursing homes, and prisons), and at food processors, often discover problems that warrant recalls. The state and local public health departments are also often the first to identify outbreaks of foodborne illnesses and collect data to link the outbreak to a common food source. The state and local public health departments report outbreaks to CDC, which monitors and investigates outbreaks of foodborne and other illnesses nationwide. Neither companies nor the states are required by law or regulation to notify USDA or FDA of recalls.[4]

Agencies Have Documented Over 3,700 Food Recalls

Together, USDA and FDA have documented more than 3,700 food recalls from 1984 through 1999. However, neither agency has maintained information on the number of recalls associated with outbreaks of foodborne illnesses.

USDA, which generally maintains recall data by calendar year, identified 515 recalls of fresh and processed meat and poultry during calendar years 1984 through 1999.[5] FDA, which maintains recall data by fiscal year and began compiling such data electronically in 1986, identified 3,248 recalls of

[4] FDA's laws and regulations require companies to notify FDA when they conduct a recall regarding infant formula due to risk to human health.

[5] USDA can sort its recall data by fiscal year but numerically codes recalls by calendar year.

other foods during fiscal years 1986 through 1999. Neither agency has tracked whether these recalls were associated with outbreaks of foodborne illnesses over those time periods. However, USDA, relying on its electronic recall files since 1992 and its staff's recollections, identified 12 recalls associated with such outbreaks since 1988. FDA, which began tracking outbreaks for FDA-regulated foods in 1997, did not record whether these outbreaks resulted in a recall. From FDA's review of its outbreak data and the recollections of FDA staff, FDA identified 49 recalls associated with outbreaks of foodborne illness during fiscal years 1997 through 1999. Table 1 shows the number of recalls documented by USDA and FDA annually since 1984 and the number of recalls associated with outbreaks of foodborne illness that the agencies identified. As table 1 indicates, the number of recalls has varied considerably from year to year.

Table 1: USDA- and FDA-Documented Food Recalls Since 1984 and Recalls Associated With Outbreaks of Foodborne Illness Identified by the Agencies

	USDA-documented food recalls		FDA-documented food recalls	
Year[a]	Total	Associated with outbreaks of foodborne illness	Total	Associated with outbreaks of foodborne illness
1999	**62**	1	275	15
1998	**45**	4	219	6
1997	**27**	1	254	28
1996	**25**	0	235	[b]
1995	**36**	2	229	[b]
1994	**48**	1	227	[b]
1993	**38**	0	233	[b]
1992	**36**	0	222	[b]
1991	**37**	1	179	[b]
1990	**28**	1	197	[b]
1989	**26**	[b]	192	[b]
1988	**21**	1	169	[b]
1987	**43**	[b]	253	[b]
1986	**15**	[b]	364	[b]
1985	**18**	[b]	[c]	[b]
1984	**10**	[b]	[c]	[b]
Total	**515**	**12**	**3,248**	**49**

[a]Calendar year for USDA; fiscal year for FDA.

[b]The agencies did not have this information.

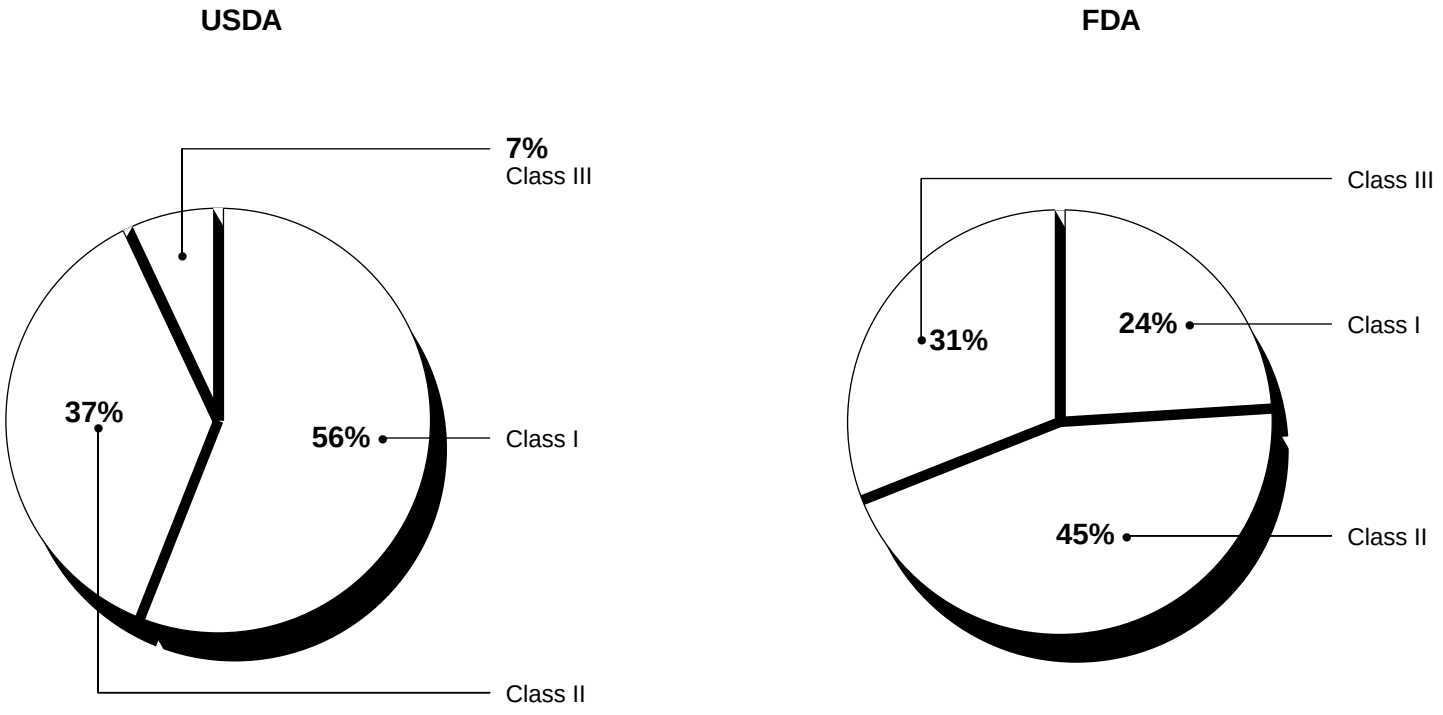
[c]FDA does not maintain electronic data for this year.

Source: USDA and FDA.

USDA and FDA classify recalled products by the potential health risk they may present. Both agencies define recalled products as Class I if eating the product poses a reasonable probability of causing serious adverse health consequences or death. USDA defines recalled products as Class II if they present a remote probability of adverse health consequences. FDA defines recalled products as Class II if they present a remote probability of serious adverse health consequences or if they may cause temporary or medically reversible adverse health consequences. USDA defines Class III products as those involving foods that will not cause adverse health consequences, while FDA defines Class III products as those that are not likely to cause adverse health consequences.

As figure 1 shows, USDA classified about 56 percent of the 515 recalls it documented since 1984 as Class I. Of this total, 187 involved foods with bacterial contamination. FDA classified 796 of its 3,248 recalls as Class I. These recalls included foods with bacterial contamination and ingredients not identified on the label, such as peanuts, that can be life-threatening to individuals sensitive to those products.

Figure 1: USDA's and FDA's Classification by Potential Risk Since 1984



Source: USDA and FDA.

Regarding the number of documented recalls since 1984, the 3,248 FDA-documented recalls do not include recalls when the food and all its ingredients were produced and distributed within a single state—that is, when the food and its ingredients were never part of interstate commerce; responsibility for recalls of such foods rests with the state. FDA has regulatory jurisdiction, under the Federal Food, Drug, and Cosmestic Act, only if the food has been offered into interstate commerce or contains an ingredient that has traveled in interstate commerce. The 515 USDA-documented recalls do not include recalls where the food and all its ingredients were produced and distributed within a single state if the state has a USDA-approved state inspection system and was responsible for inspecting the plant. It includes, however, intrastate recalls in states that do not have approved systems because USDA inspectors must monitor the recalls in these states. Twenty-three states have USDA-approved inspection systems for meat and poultry, and 2 others have approved state inspection

systems for meat only.[6] Unlike FDA, USDA has regulatory jurisdiction even when the food and its ingredients were never part of interstate commerce. In addition, because food safety laws do not require states or companies to report recalls (except those involving infant formula) to USDA or FDA, the agencies may not have been made aware of all recalls initiated by companies or states.

Agencies Identified the Contaminant but Generally Not the Cause of Contamination for Outbreak-Related Recalls

USDA and FDA identified a specific bacterial or viral contaminant for each of the 61 recalls they considered to be associated with outbreaks of foodborne illnesses. However, the agencies generally were unable to determine how the food became contaminated. Such information could assist companies' and food safety inspectors' efforts to prevent future problems. Making such determinations are difficult, however, given the considerable time lag—often several weeks or months—between individuals' becoming ill and the identification of the specific food that caused the illness.

The agencies believe strains of five bacterial and two viral contaminants were responsible in the recalls associated with outbreaks of foodborne illnesses. The particularly virulent bacteria—*E. Coli* O157:H7—was responsible in 7 of the 12 recalls of USDA-regulated foods associated with outbreaks of foodborne illness, while a virus common to shellfish—Norwalk or Norwalk-like virus—was responsible in 22 of the 49 recalls of FDA-regulated foods. Table 2 shows the contaminants responsible for the recalls associated with outbreaks of foodborne illnesses. In addition, appendix III provides information about bacterial and viral contaminants that can cause foodborne illnesses, including the length of time for the onset of illness after eating contaminated food, the symptoms of the illness, and examples of foods that have carried the contaminant.

[6]The following states have USDA-approved inspection systems for meat and poultry: Alabama, Arizona, Delaware, Illinois, Indiana, Iowa, Kansas, Louisiana, Minnesota, Mississippi, Montana, New Mexico, North Carolina, Ohio, Oklahoma, South Carolina, Texas, Utah, Vermont, Virginia, West Virginia, Wisconsin, and Wyoming. In addition, Georgia and South Dakota have USDA-approved inspection systems for meat.

Table 2: Contaminants Identified in the Recalls Associated With Foodborne Illness Outbreaks

	Number of recalls	
Bacterial contaminant	**FDA**	**USDA**
E.coli O157:H7	3	7
Staphyloccocus toxin	0	1
Vibrio parahaemolyticus	4	0
Listeria monocytogenes	0	1
Salmonella	14[a]	3
Viral contaminant		
Hepatitis A	6	0
Norwalk or Norwalk-like	22	0
Total	**49**	**12**

[a]One *salmonella* recall also involved *E. Coli* contamination.

Source: USDA and FDA data.

The outbreak-related recalls involved 10 foods. As table 3 shows, the highest number of recalls for USDA was associated with ground beef, and for FDA, the highest number was associated with raw oysters.

Table 3: Foods in Recalls Associated With Foodborne Illness Outbreaks

	Number of recalls	
Food	**FDA**	**USDA**
Raw oysters	26	
Ground beef		5
Sprouts/seeds	9	
Frozen strawberries and products with the strawberries	6	
Unpasteurized fruit juice/cider	4	
Cold cuts and hot dogs		6
Mamey (a tropical fruit)	2	
Chicken/pork dressing		1
Toasted oats cereal	1	
Chili rellenos	1	
Total	**49**	**12**

Source: USDA and FDA data.

For all but one of the outbreak-related recalls, USDA and FDA were not able to determine with certainty how the foods became contaminated. In the case in which USDA made a determination, it concluded that *salmonella* got into a chicken/pork dressing mix through a cracked seal in a pump that transferred the mix from the cooking vat to the packaging line.

According to USDA officials, their inspectors do not attempt to determine the cause of contamination for every recall. They believe this is the responsibility of the recalling company. Since January 2000, all plants that USDA inspects are required by regulation to have a hazard analysis critical control point (commonly called HACCP) plan for each process in the plant. According to USDA officials, when a company conducts a recall of a contaminated food, it must determine the cause of the contamination and take immediate corrective action to prevent a recurrence as part of its responsibilities under a HACCP plan. According to FDA officials, their inspectors attempt to determine the cause of contamination for every recall. In fact, FDA guidance to its inspectors says that the facility will be examined to determine how the food became contaminated.

This information is important to ensure that points of contamination are corrected. As CDC reports, an investigation that clarifies the nature and mechanism of contamination can provide critical information even if the outbreak is over; understanding the contamination event can lead to prevention measures that reduce the risk of similar outbreaks elsewhere.

According to USDA and FDA officials, tracing a foodborne illness to a specific food source is difficult and time-consuming. It can often take several weeks or longer from the time contaminated food is eaten until individuals become ill and food safety agencies can link the illnesses to a specific food. And even when a specific food source is initially isolated, the food itself may not be the problem. For example, a local health department may conclude that 12 people became ill with food poisoning after eating a certain brand of chili at a neighborhood party, but the chili may not have been contaminated. Rather, the bowl in which the chili was served may have been contaminated or the chili could have been left out too long. According to CDC, many foodborne illnesses are due to improper food handling or preparation.

We have recently begun to examine, at your request, the extent to which two 5-year old surveillance systems for foodborne illnesses facilitate food safety agencies' efforts to identify the cause of an outbreak of foodborne illness. The Foodborne Diseases Active Surveillance Network—known as

FoodNet—is a collaborative project of CDC, USDA, FDA, and nine states. It provides a network for responding to new and emerging foodborne diseases and for identifying the sources of specific foodborne diseases. CDC also operates PulseNet, a national network of public health laboratories to "fingerprint" bacteria cultures submitted by state health laboratories. These two tracking systems could reduce the lag time in linking foodborne illnesses to specific foods, which, in turn, may improve inspectors' ability to determine points of contamination for recalled foods.

USDA and FDA Believe Companies Conduct Timely Recalls, but the Agencies Do Not Maintain Data to Confirm This View

USDA and FDA believe companies typically cooperate and act without delay in initiating recalls, but the agencies do not systematically measure and maintain data on companies' performance. Moreover, USDA's and FDA's guidance to companies does not specify time frames for initiating and carrying out recalls without delays.

When asked for cases in which companies delayed initiating a recall following an informal request by the agency, USDA officials told us that USDA had not had any such instances, whereas FDA officials identified nine cases out of over 3,000 recalls. This information is based on the recollections of agency officials, because neither agency systematically measures or compiles data on companies' recall activities, such as the dates that problems warranting recalls were first discovered, the dates that companies initiated recalls,[7] the dates and methods companies used to notify their distributors and the public, and the dates companies completed their recalls. In addition, FDA does not track the dates it asked the companies to conduct a recall. However, both agencies selectively check with customers of the recalling companies to determine whether recalls have been implemented. The extent of this verification is determined on a case-by-case basis. Our review of case files in agency headquarters and district offices showed that these files contained some information on company recall activities, but such information is not being captured and analyzed systematically.

Of the nine recalls FDA officials identified as involving a delayed response by the companies to an informal request, six involved a subsequent formal written FDA request to conduct a voluntary recall. According to FDA, a formal written request is the last step before it takes regulatory action,

[7]Beginning in fiscal year 1999, FDA included in its recall database the recall initiation date.

such as seeking an injunction to prevent further manufacturing and distribution, or a court order to seize the food. For five of these six cases, the company recalled the products after receiving FDA's formal request. In the sixth case, the firm, claiming that there was no more product on the market, refused to make the recall. FDA issued a public warning that the product posed a serious risk to consumers' health because FDA believed that a number of consumers who had purchased the product might still have it in their homes. FDA said seizure was not a viable option because it was unlikely that FDA would find sufficient quantities of the product to seize. For two of the other recalls, although the companies did not recall the foods immediately in response to an informal FDA request, they did so before FDA had an opportunity to issue a written request. In the other case, the firm complied with FDA's informal request, but the firm's distributor refused to recall the product or provide distribution data to FDA. FDA issued a press release warning consumers not to eat the product but did not pursue court authority to seize the product because it did not know where the product had been distributed. Beginning in fiscal year 1999, FDA included information in its recall database indicating whether it had formally requested the recall. See appendix IV for more information on each of the nine cases.

USDA officials said there were no recalls involving a delayed response by the company to a recall request. However, two USDA Class I recalls have received considerable publicity regarding the timeliness of recall activities. In the first, USDA increased dramatically the amount of ground beef patties it requested the company to recall because of potential contamination with *E. Coli* 0157:H7—from 20,000 pounds initially, to 1.2 million pounds 3 days later, and finally, to 25 million pounds by the ninth day. In the second, USDA did not advise the company to initiate a recall of hot dogs and other packaged deli meats suspected of being contaminated with listeria monocytogenes, although it had epidemiological data[8] linking 40 illnesses and 4 deaths to the products. According to USDA officials, the agency did not believe that the epidemiological data conclusively implicated the products and it was unable to find contamination in unopened samples. The company on its own initiative decided to recall the products. More information on each of these cases is in appendix V.

[8]Epidemiological data are data showing the distributions and determinants of health-related conditions or events in specified populations.

In addition, while both agencies' guidance instructs companies to promptly implement recalls, neither agency provides specific time frames for initiating or carrying them out. For example, although both agencies' guidance instructs companies to notify their distributors promptly that the food is being recalled, neither instructs them to use the most expeditious means for Class I recalls. Thus, even for recalls involving life-threatening contaminants, companies may use mail to contact their distributors—instead of the telephone, E-mail, or facsimile—which could unnecessarily delay by several days the removal of contaminated food. Many of the recalls associated with outbreaks of foodborne illnesses, for example, involved perishable foods, such as fresh sprouts and raw oysters, that would have been sold and consumed within those few days.

Agencies differ in how they notify the public of the most serious recalls of contaminated food. Under its procedures for recalls prior to February 2000, USDA was required to issue press releases for all Class I recall products that could be identified by consumers. In February 2000, USDA began issuing press releases for all three classes of recalls, even if the product is not identifiable to consumers. We found that press releases for the outbreak-related recalls involving USDA-regulated foods (all were Class I) were generally issued on the same day the company decided to recall the product; in only one instance was the press release issued more than 24 hours later.

FDA believes that press releases are necessary for Class I and selected Class II recalls and prefers that the company, not FDA, issue the press release. According to FDA officials, if the company does not issue a press release promptly, FDA will issue a release. FDA stated that it would issue the press release if the company did not do so within 24 hours. It further noted that in some instances CDC and state and local agencies may issue their own press releases to alert the public about outbreaks associated with specific foods and/or recalls. If FDA considers these press releases adequate, it will not pursue additional press coverage. However, FDA has not issued written guidance to companies telling them that they are expected to issue press releases within 24 hours of initiating a recall. We were unable to obtain sufficient information from FDA case files to analyze the timeliness of press releases on the 49 recalls associated with outbreaks of foodborne illness.

According to USDA and FDA officials, press releases are intended to alert consumers about food they may have in their homes. Consumers are not routinely informed of the particular restaurants, caterers, or institutions,

such as hospitals or retirement homes, that may have served recalled foods, even when this information could mean the difference between life and death for high-risk individuals.[9] According to USDA and FDA officials, however, the agencies cannot divulge such information to the public because it is considered confidential business information.[10] According to CDC, listeria monocytogenes can cause illness anywhere from 2 to 8 weeks after consumption; while generally mild, the illness can be severe for a person with a weakened immune system, and an infection during pregnancy can lead to the loss of a fetus. If individuals at risk of serious illness were aware that they might have eaten listeria-contaminated food, they could seek medical attention.

USDA can more readily confirm than FDA that contaminated meat and poultry products are removed from distribution. Unlike FDA, USDA has access to companies' distribution records at all points in the distribution chain. In addition, USDA inspectors, store employees, and consumers can more readily identify recalled canned meat and poultry products because, under the federal meat and poultry products acts and implementing regulations, the canned products must be marked with a code, which allows production lots to be identified. FDA-regulated foods, with the exception of infant formula and low acid and acidified foods, are not required to have label encoding.

USDA officials told us that if a coding system were required for all USDA-regulated processed foods, everyone (for example, inspectors, grocery stores, and consumers) could more readily identify the recalled food. According to FDA officials, access to distribution data and product coding would facilitate FDA's recall efforts and help ensure that contaminated foods are removed from grocery shelves.

[9]Beginning in February 2000, USDA included in some of its press releases a statement to the public to check with any restaurants where they may have eaten the recalled food.

[10]According to USDA, it has a rulemaking in process to allow the disclosure of customer lists to other federal and state agencies. As part of the rulemaking, agencies would not be able to divulge the information to the public.

Information on the Economic Impact of Recalls Is Lacking, but a Number of Factors Are Cited as Contributing to Any Impact

Neither USDA nor FDA compiles information on the economic impact of recalls on affected companies. Similarly, the food industry associations we contacted do not collect this information. However, according to food industry officials, recalls can have a significant economic impact on affected companies through lost sales and food retrieval costs. The extent of this impact depends on such factors as the amount and value of the food recalled, its location in the distribution process, and the severity of the health risk. In addition, following a recall, consumers may stop buying a company's products or switch to another company's brand for future purchases.

Although comprehensive data on the economic impact of recalls are lacking, food industry officials noted that this impact may be substantial in terms of lost sales and retrieval costs. In some cases, this impact may lead to a company's going out of business, particularly if the company is marginally profitable or already experiencing other problems. For example, several food industry associations told us that Hudson Foods went out of business after recalling approximately 25 million pounds of ground beef patties. However, USDA officials noted that management problems, including poor record-keeping, had contributed to this company's failure. Specifically, poor record-keeping led to a larger recall than otherwise might have been necessary because the company was unable to determine the extent to which meat from various production batches may have been combined.

In general, the economic impact of a recall depends on the amount and value of the food recalled, its location in the distribution process at the time of recall, and the severity of the anticipated health risk. For example, the affected company loses expected revenues associated with the sale of the recalled product. It may also lose future sales revenues if consumers stop buying the company's products or switch to another brand. Regarding the distribution process, a company conducting a recall bears the cost of retrieving and replacing the food throughout its distribution chain. These costs increase if the product has already reached the market because the company must then notify consumers of the risk. The severity of the anticipated health risk is also an important factor. A recall involving contamination by harmful bacteria may result in the destruction of the affected food and the loss of sales revenue. However, if the recall is conducted because the food has been mislabeled, the affected company may redistribute the food into commerce after making the necessary label corrections.

Recalls may also have an economic impact on companies other than the one conducting the recall. For example, according to the Food Marketing Institute, retail supermarkets may experience a drop in sales if consumers avoid the recalled food and other products by the same manufacturer or even other brands of the recalled item. In addition, companies that use a recalled product as an ingredient can incur significant costs from a recall. For example, if a particular brand of pepperoni is recalled, a company using that brand in its frozen pizzas may have to recall the pizzas. Although the pizza manufacturer should be reimbursed for the lost revenues and replacement costs, it may also experience a drop in future sales if consumers have a negative impression of the pizza because of the recall.

Because the economic impact of a recall may be significant, some food companies carry recall insurance to cover lost revenues and retrieval costs. However, according to several food industry associations, many of their member companies consider recall insurance to be too expensive and thus have not purchased it. According to an insurance broker who works with the meat industry, a typical policy for a company with $1 billion in annual sales might have a $25 million limit, $250,000 deductible, and a $60,000 annual premium, while a smaller company with $20 million in annual sales might have a policy with a $3 million limit, $10,000 deductible, and a $13,300 annual premium.

Conclusions

While USDA and FDA believe companies conduct timely recalls, they do not have data to support this view. Although both agencies track information on their own recall activities, they do not systematically track companies' activities to ensure that recalls, particularly of foods that may cause serious adverse health consequences, are initiated and carried out without delay. Specifically, USDA does not track when companies initiate recalls, and neither agency tracks when or how companies notify their distribution chains of the recalls, when or how they notify the public, and when recalls are completed. Neither USDA nor FDA has provided guidance to companies on specific time frames for initiating and carrying out recalls.

Recommendations

To ensure that companies initiate and carry out recalls without delays, particularly of foods that may cause serious adverse health consequences, we recommend that the Secretaries of Agriculture and of Health and Human Services direct the Food Safety and Inspection Service and the Food and Drug Administration, respectively, to

- Provide specific guidance to companies on time frames for quickly initiating and carrying out food recalls that involve potentially serious adverse health risks, including procedures to expeditiously notify their distribution chains and alert the public.
- Modify existing recall databases, as necessary, to include information on the timeliness of companies' recall activities to determine whether companies delay in initiating and carrying out recalls. The information should, at a minimum, include the dates a company (1) finds out about the problem warranting a recall, (2) initiates the recall, (3) notifies the distribution chain, (4) notifies the public, and (5) completes the recall. In addition, the database should track the methods the company used to notify its distributors and the public, and the date(s) on which the agencies requested the company to initiate the recall.

Agency Comments

We provided USDA and FDA with a draft of this report for review and comment. USDA said that the recommendations are doable but does not believe that they will fundamentally help speed up or make the recall process more effective. While we agree that our recommendations, when implemented, will not by themselves speed up the recall process, we believe that their implementation will provide USDA with information on whether, and where in the process, delays are occurring. USDA also said that our draft report is somewhat unbalanced and mischaracterizes the Department's oversight of firms' recall activities. USDA contends that since January 2000, the responsibility for the food recall process has rested with food companies, which were required to implement HACCP systems that are designed to identify problems in meat and poultry production processes and prevent their recurrence. We have revised the report to more fully describe HACCP's role. The merits of HACCP notwithstanding, we believe that USDA, as part of its responsibility for ensuring the safety of meat and poultry, must have sufficient information on companies' recall actions to assure itself that consumers are adequately protected. USDA also contends that it needs mandatory recall authority and additional enforcement tools to improve food safety and has supported proposed legislation that would provide this assistance. USDA's comments and our detailed responses are presented in appendix VI.

FDA concurred, for the most part, with our recommendations and found the report to be an accurate reflection of the many administrative, regulatory, and legal challenges it faces in monitoring companies' recall activity. FDA stated that it already tracks the date companies initiate a recall and whether FDA had formally requested the recall. While our report

recognized this, we clarified our recommendation to reflect these actions. However, FDA also stated that it would have difficulty tracking some of the information we are recommending, such as the date the company finds out about the problem necessiating the recall and the date the company notifies the distribution chain. We disagree. Our recommendation would not preclude entering multiple dates for activities, such as the date companies notify distributors. FDA told us that it is in the process of revising its recall procedures and guidance to companies. This provides a good opportunity to clearly define terms and time frames for expediting recalls, especially recalls of foods that pose serious health risks. FDA's letter and our responses appear in appendix VII.

USDA and FDA both expressed the view that the title of our draft report was misleading because they both believe they know whether companies are initiating and carrying out recalls promptly. We disagree. While both agencies maintain certain information in detailed recall files about when recalls were initiated and how they were carried out, neither agency collects consistent information on all recalls or systematically compiles such information. As a result, we continue to believe that actions are needed by the agencies to ensure that companies promptly carry out recalls. However, we have changed our title to more clearly reflect the recommendations of the report regarding the need to maintain data on the timeliness of companies' recall actions and the need for specific guidance on time frames for initiating and carrying out recalls.

USDA and FDA also made technical clarifications, which we incorporated as appropriate.

As arranged with your offices, unless you announce its contents earlier, we plan no further distribution of this report until 30 days after the date of this letter. At that time, we will send copies of this report to congressional committees with jurisdiction over these matters. We will also send copies of this report to the Honorable Dan Glickman, Secretary of Agriculture; the Honorable Donna E. Shalala, Secretary of Health and Human Services; the Honorable Thomas J. Billy, Administrator, Food Safety and Inspection Service, USDA; the Honorable Jane Henney, M.D., Commissioner, Food and Drug Administration, Department of Health and Human Services; and the Honorable Jacob J. Lew, Director, Office of Management and Budget. We will also make copies available to others on request.

If you or your staff have any questions about this report, please contact me or Erin Lansburgh at (202) 512-5138. Key contributors to this report were Rosellen McCarthy and Jay L. Scott.

Lawrence J. Dyckman
Director, Food and Agriculture Issues

Scope and Methodology

To determine the number of food recalls documented by the U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA) since 1984, we analyzed data from USDA's electronic recall database and relied on FDA to provide similar data, which it extracted from its recall databases. USDA officials told us that all recalls since 1984 were contained in USDA's electronic database. FDA began electronically tracking food recalls in 1986 and thus provided data back to 1986, not 1984. We obtained the computerized file for these recalls and summarized the recalls and classification of recalls by year. For recalls associated with outbreaks of foodborne illnesses, we traced file information to the database and found no discrepancies. Additionally, we interviewed the USDA official responsible for maintaining the database to determine how recall information is added to it. On the basis of our review of the recalls for the outbreak cases and the simplicity of the database, we believe the information we used from the database is sufficiently accurate to identify the number of recalls.

To determine the number of recalls associated with outbreaks of foodborne illnesses, we relied on the agencies to provide such data. Although neither agency records whether a recall was associated with an outbreak of foodborne illness, USDA reviewed its recall files and relied on the recollections of its staff to identify specific cases. Although FDA began tracking outbreaks of foodborne illnesses for FDA-regulated foods in 1997, it did not record whether those outbreaks resulted in a recall. From FDA's review of its outbreak data and the recollections of FDA staff, FDA identified recalls associated with outbreaks of foodborne illness during fiscal years 1997 through 1999.

To determine the extent to which USDA and FDA identified the causes of the outbreaks of foodborne illnesses and how the recalled product became contaminated, we analyzed case files on each of the outbreak-related recalls and discussed the cases with USDA and FDA officials.

To determine the extent to which companies delayed or did not comply with USDA or FDA requests to recall products, we relied on USDA and FDA officials' recollections of such requests because the agencies' electronic databases do not identify if companies delayed action. We reviewed case file documents for seven of the nine FDA-identified recalls. (FDA could not find documentation on two of the cases.) Also, to gain an understanding of consumers' perspective on whether companies delayed or did not comply with USDA and FDA recall requests, we interviewed the

director for food safety of the Center for Science in the Public Interest and reviewed some of the Center's reports and testimony.

To determine the economic impact of recalls on companies, we discussed economic factors and costs with USDA's Economic Research Service and food industry associations, including the American Meat Institute, American Frozen Food Institute, Food Marketing Institute, National Food Processors Association, United Fresh Fruit and Vegetable Association, National Fisheries Institute, and the National Chicken Council. We also analyzed the coverage and limitations of a recall insurance policy and discussed coverage, cost, and limitations with associations and two recall insurance brokers. Furthermore, to gain perspective on recalls, we reviewed proposed legislation dealing with mandatory food recall authority for USDA.

We conducted our review from December 1999 through July 2000 in accordance with generally accepted government auditing standards.

Selected Information on USDA's and FDA's Recall Programs

This appendix discusses the phases of USDA's and FDA's food recall programs.

USDA's Recall Program

USDA defines a recall as a firm's voluntary removal of distributed meat or poultry products from commerce when there is reason to believe that such products are adulterated or misbranded under the provisions of the Federal Meat Inspection Act or the Poultry Products Inspection Act.

Determining the Need for a Recall

USDA can learn about the possibility of unsafe meat or poultry in several ways: (1) often, through test results of meat and poultry samples taken by USDA as part of its sampling program; (2) from information gathered or observations made by USDA field inspectors and compliance officers, in the course of their routine duties, that may lead to the discovery of unsafe or improperly labeled products in commerce; and (3) from consumer complaints, epidemiological data submitted by state and local public health departments, other USDA agencies, FDA, and the company that manufactured or distributed the product in question.

According to USDA, when it learns that unsafe meat or poultry may be in commerce, it conducts a preliminary investigation to help determine whether a recall of the product is warranted. The preliminary investigation may include collecting and verifying information about suspected products, documenting a chronology of events, contacting the manufacturer of the products for more information, holding discussions with USDA field inspection and compliance personnel, interviewing a consumer who allegedly became ill or injured from eating the product, collecting and analyzing product samples, and contacting state and local health departments.

If the preliminary investigation indicates that calling back an adulterated or misbranded product may be necessary to protect the public health or welfare, USDA convenes a meeting of its Recall Committee, usually by teleconference. Members of the committee include USDA scientists, technical experts, field inspection managers, and enforcement personnel. They evaluate the available information to determine whether a recall is necessary to protect consumers. As part of this evaluation, the committee may review laboratory reports, health department reports, and other documents, and consult with USDA field personnel who may be able to clarify conflicting or incomplete information.

On the basis of this evaluation, the committee assigns a classification to the recall, according to the relative health risk the product presents. In a Class I recall, USDA has determined that a strong likelihood exists that a product will cause serious adverse health consequences or death. For example, a meat product that is contaminated with pathogenic bacteria would be subject to a Class I recall. Examples of adulterants that would lead to Class I recalls are *listeria monocytogenes* in a ready-to-eat product; E. coli 0157:H7 in ground beef; and the inclusion of an allergen, such as eggs, as an ingredient in a processed meat product that is not listed on the product's label.

A Class II recall would be declared when a remote possibility exists of an adverse health consequence resulting from consuming the meat or poultry product. For example, a Class II recall would be warranted if pistachios, a Class II allergen, were an ingredient in a sausage product without listing pistachios on the label.

In a Class III recall, the consumption of the product will not cause adverse health consequences—for example, an improperly labeled processed meat product in which added water is not listed on the label, as required by federal regulations.

In addition to determining the class of the recall, the committee identifies and recommends the depth and scope of the recall. The depth of a recall is the lowest level of distribution that the recall is targeting, such as a recall to the "consumer level." This recall level targets household consumers and includes alerting consumers through the media as well as directly communicating with the recalling firm and its distributors. A recall to the "user level" is targeted to restaurants and other food service institutions when product is not in the hands of consumers. A recall to the "retail level" includes all types of retail sales; and the "wholesale level" extends only to wholesale distributors.

The scope of a recall concerns the amount and kind of product recalled. For example, if sampling by USDA indicates *Listeria monocytogenes* in a frankfurter, the Recall Committee evaluates relevant data to determine whether frankfurters made by the plant during other shifts or days need to be included in the recall and whether other ready-to-eat products made by the plant during those times also need to be recalled.

During the latter part of the committee meeting, a representative of the company that processed the product participates in a telephone

conference. The committee advises the company representative of its recommendation that the company conduct a Class I, II, or III recall and asks the company representative questions to add to or clarify the information it has obtained. If the company believes that the product should not be recalled or that the depth and scope of the recall should be modified, it is given the opportunity to supply data to support its position. The Recall Committee considers any new information before advising the company representative of its recommendation.

Notifying the Public

On February 1, 2000, USDA began issuing a press release for all recalls. The press release

- describes the product being recalled along with any identifying marks or codes, the reason for the recall, and an explanation of the risk involved in consuming the product;
- provides instructions to the public on what to do with the product if they can identify it and have it in their possession, and the name and telephone number of a company contact for consumers with any questions;
- explains, for products that are not in the public domain or for products that consumers cannot identify by labeling or packaging, that the product is being recalled before consumers can obtain it; and
- provides general information about a product's destination but does not identify the specific recipients of product (e.g., grocery store, restaurant, airline) unless the supplier chooses to release the information to the public.

Prior to February 2000, the Recall Committee evaluated how products were distributed and recommended whether USDA should issue a press release about a recall. A decision to issue a press release was based on the relative risk associated with the use of the product and whether the product being recalled was in the hands of consumers. The purpose of a press release was to advise consumers who had the product not to eat it but instead to return it to the place where they bought it.

A recall of a product sold only to food service establishments or to firms for further processing usually would not have warranted a press release. In such cases, USDA relied on recall effectiveness checks to verify that a firm conducting the recall provided appropriate notification to all holders of the recalled products. The notification would have included instructions to

stop serving or processing the products and to return or properly dispose of them.

In addition to press releases, USDA provides the public with details about all meat and poultry product recalls through recall notification reports that are posted on its recall Web site. Recall notification reports are also sent by facsimile and electronic mail to food safety and public health officials throughout the country at the federal, state, and local levels. This notification provides the public health community with important data to use in following up on illnesses, if any, and determining whether those illnesses may have been caused by the recalled product.

Effectiveness of Recalls

Both USDA and the recalling firms conduct effectiveness checks to determine that (1) the company provided adequate notice about the recall to all distributors and (2) distributors located and controlled the recalled products and followed the recalling firm's instructions for removing the product. In the event that USDA effectiveness checks disclose that distributors were not notified of the product recall or did not act as requested by the recalling firm, USDA can detain any products posing a health risk, notify the firm, take additional regulatory action, and/or issue another press release.

Extent of USDA Involvement in Recalls

USDA gets involved in all recalls made by all meat and poultry plants it inspects. This includes all plants that ship their products in interstate commerce and all plants in states that do not have USDA-approved state inspection systems for meat and poultry.

USDA is not involved in, and may not know about, recalls made by meat and poultry plants it does not inspect. These plants include those in the states that have USDA-approved state inspection systems for meat and poultry and only ship their products within the state. For meat and poultry, these are Alabama, Arizona, Delaware, Illinois, Indiana, Iowa, Kansas, Louisiana, Minnesota, Mississippi, Montana, New Mexico, North Carolina, Ohio, Oklahoma, South Carolina, Texas, Utah, Vermont, Virginia, West Virginia, Wisconsin, and Wyoming. In addition, Georgia and South Dakota have USDA-approved inspection systems for meat only.

USDA is not involved in, and may not know about, recalls made by state-inspected retail establishments.

FDA's Recall Program

FDA defines a recall as a firm's removal or correction of a marketed product that FDA considers to be in violation of the laws it administers and against which it would initiate legal action, such as a seizure[1]. According to FDA, a recall is a voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect public health and well-being from products that present a risk of injury or gross deception or are otherwise defective.

In situations where a product presents a significant risk of illness or injury and the firm does not voluntarily initiate a recall on the basis of discussions with FDA, FDA may request in writing that the firm conduct a recall. This FDA-requested recall is considered a voluntary action by the firm. Under the Federal Food, Drug, and Cosmetic Act, FDA has statutory authority to require recalls only for infant formula.[2]

FDA's jurisdiction over foods under the Federal Food, Drug, and Cosmetic Act is limited to those in domestic interstate commerce and those offered for import into the United States.

FDA's recall regulations request that a firm notify FDA when the firm removes or corrects a distributed product. The regulations describe how a firm should communicate the recall to its customers and request that the firm provide FDA with periodic recall status reports. FDA's procedures for its staff to use in handling recalls of FDA-regulated food products are described in the agency's *Regulatory Procedures Manual*.

Problems warranting a recall can be identified in several ways: (1) FDA's investigation of consumer complaint or FDA's sampling during an inspection of a firm; (2) companies' discovery of a violative product; (3) an outbreak of foodborne illness traced to an FDA-regulated product; and (4)

[1]FDA does not have independent seizure authority. FDA must initiate a seizure through the U.S. Attorney's Office, which employs U.S. marshals to effect the seizure. According to FDA, the process takes at least a couple of weeks, even on an emergency basis. While the paperwork is being prepared, the items in question may be moved, even sold, with no penalty because FDA does not have detention authority for foods under the Federal Food, Drug, and Cosmetic Act.

[2]FDA, under the Public Health Service Act, may have authority to issue mandatory recall regulations for foods that are "vectors of communicable diseases." FDA has never used this authority with regard to food recalls. It has used the authority to issue recall regulations for human tissue.

state agencies discovery of violations through inspections, surveillance sampling, follow-ups on complaints, or other activities.

FDA-, State-, and Firm-Initiated Food Recalls

Since fiscal year 1997, FDA has categorized food recalls as FDA-, state-, and firm-initiated. FDA-initiated recalls are those in which FDA contacts the firm, and a recall decision and action begin after the FDA contact. State-initiated recalls are those initiated by the regulated firm after having out-of-compliance situations brought to its attention. Firm-initiated recalls are those initiated by industry, regardless of the reason, without any FDA contact or input into the decision to take the recall action. Table 4 below identifies the number of FDA-, firm-, and state-initiated recalls in fiscal years 1997 through 1999.

Table 4: Category of FDA Recalls, Fiscal Years 1997 Through 1999

	FDA recalls			
Fiscal year	Total	FDA-initiated	Firm-initiated	State-initiated
1999	275	69	92	114
1998	219	66	93	60
1997	254	67	113	74
Total (percentage)	748 (100%)	202 (27%)	298 (40%)	248 (33%)

Source: FDA.

The Recall Process

FDA's district offices, Center for Food Safety and Applied Nutrition (CFSAN), and Office of Regulatory Affairs (ORA) are involved in the food recall process. Once the firm informs the district office that a recall has been or will be initiated, the district obtains preliminary information from the firm, including the name(s) and lot number(s) of the product(s) under recall and the reason for recalling the product. The district should provide CFSAN and ORA with this information within 24 hours in a document referred to as the "24-hour alert."

CFSAN reviews the alert and determines if the problem with the product is one that has been evaluated previously. If the problem is new or unique, CFSAN conducts a preliminary health hazard evaluation with its Health

Hazard Evaluation Board. The Board consists of a group of CFSAN scientists and health professionals.

The district office obtains additional information from the firm and prepares a document called a "recall recommendation." In addition to the information the district already provided in the 24-hour alert, the recall recommendation describes the volume of the recalled product in commerce, its distribution pattern, the firm's and FDA's strategy for handling the recall, the name of the firm's contact, and a recommendation about the classification (Class I, II, or III) of the recall. The district submits the recall recommendation to CFSAN, along with any additional supporting documents (e.g., copies of labels, copies of the firm's recall communication to its customers, test results, and copies of consumer complaints).

The district office may assist the firm in developing its recall strategy. The recall strategy includes things such as the manner in which a firm contacts and gives instructions to its customers on how to handle the recalled product and the method the firm will use to determine if the recall is effective. The amount of FDA assistance required usually depends on the firm involved in the recall. A small firm that has not conducted a recall in the past may require more assistance than a large corporation that has recall procedures in place. Firms are not required to consult with FDA or modify its recall strategy on the basis of FDA's recommendations.

CFSAN prepares a written health hazard evaluation when it receives all the necessary information from the district office. The evaluation discusses the problem(s) with the product(s) under recall, describes the hazard posed by the product(s), and assesses the severity of the hazard. The completed evaluation has the signed concurrence of at least two health hazard evaluation board members. CFSAN uses the conclusion in the evaluation to classify the recall. A recall may involve multiple products that pose different levels of hazard. For Class II and III recalls, CFSAN conveys the classification of each product directly to the district in a memorandum. The memorandum also assigns a recall number to each product under recall.

If one or more of the products involved in a recall pose a serious or life-threatening hazard, then either the CFSAN Deputy Director or the Associate Commissioner for Regulatory Affairs must approve the Class I designation before the classification memorandum can be sent to the district. The Deputy Director approves certain Class I recalls (i.e., recalls for ready-to-eat foods contaminated with *listeria monocytogenes* and foods with undeclared peanuts, sulfites, tree nuts, and eggs), and the Associate

Commissioner approves the other Class I recalls. CFSAN issues the classification memorandum for Class I recalls to the district with a copy to the ORA recall coordinator and the Office of Public Affairs. The district then prepares a letter to the firm (1) advising it of the classification of the recalled product(s) and recall number(s) assigned and (2) providing concurrence with or recommending changes to the firm's recall strategy.

FDA monitors the progress of a firm's recall by conducting audit checks and by reviewing the firm's status reports. FDA conducts audit checks by contacting a portion of the firm's customers to determine if the recalling firm informed them of the recall and if they followed the recalling firm's instructions. The district issues audit check assignments after consulting with CFSAN. If the recalled product was widely distributed, the audit check assignment may be issued to more than one FDA district office. The district issues audit check assignments for Class I recalls before the recall has been formally classified and after the formal classification for Class II recalls. FDA districts do not normally conduct audit checks for Class III recalls, since the product(s) are not likely to cause adverse health consequences. The results of the audit checks are reported back to the monitoring district. The district may request that firms submit periodic status reports detailing the progress of their recall, for example, detailing how many of the customers have been successfully contacted and how much of the product has been retrieved, disposed of, or corrected.

If it appears that the recall is not progressing in a timely manner or that customers are not aware of the recall, the district contacts the recalling firm and attempts to resolve the issue.

FDA considers a recall to be completed when a firm has made all reasonable efforts to remove or correct the product on the market. If the recalling firm retrieves the recalled product (as opposed to correcting or destroying the products at the business site of their customers), the district office continues monitoring to ensure that the recalled product is reconditioned or destroyed and not inadvertently redistributed. The district may request that the firm allow it to witness the reconditioning or destruction of the product. Once the reconditioning or destruction is completed, the FDA district moves to terminate the recall.

To terminate the recall, the district prepares a recall termination recommendation that summarizes the activities associated with a recall, including the amount of product recovered/corrected, disposition of the recalled product, results of audit and effectiveness checks, and action that

the firm is taking to prevent similar problems. After the recall termination recommendation is approved, the district advises the firm in a letter that its recall has been terminated.

Notifying the Public About a Recall

At the onset of a recall, FDA considers the need for a press release, taking into account the level of hazard posed by the product, the manner in which it was distributed, the type of customer who received the product, and the customer's ability to identify the product.

According to FDA, it encourages the recalling firm to issue a press release for Class I recalls and selected Class II recalls. FDA developed and issued model press releases providing standardized language for the types of Class I recalls that the agency most frequently encounters—situations involving *Clostridium botulinum, listeria monocytogenes*, all types of *salmonella, E. coli 157:H7*, and undeclared allergens.[3] To facilitate the use of the model press releases, FDA issued a guidance document to its district offices on how to assist recalling firms in preparing press releases for the problems covered in the models. FDA has given responsibilities to its district offices to work with recalling companies to issue a notice, discuss the press release with the firm, and provide it with the relevant model recall press release (also available on FDA's Web site). When a recall involves a problem that is not covered by a model press release, FDA works with the recalling firm to develop appropriate language for its press release. FDA advises the firm that FDA monitors the adequacy of the media coverage for a press release involving a Class I recall. If the press release does not receive adequate coverage, FDA will either ask the firm to reissue its press release or issue its own press release. FDA asks the firm to provide its draft press release for review prior to publication. FDA tells the firm that if it does not issue a press release within 24 hours of initiating a recall, FDA will issue its own press release informing the public about the firm's recall, including any appropriate warning about avoiding consumption of the firm's product. According to FDA, in some instances CDC and state and local agencies may issue their own press releases to alert the public about outbreaks associated with specific foods and/or recalls. If these press releases are adequate, FDA will not pursue additional press coverage.

[3]Undeclared allergens include peanuts and other tree nuts (chestnuts, brazil nuts, walnuts, hazelnuts, pecans, pine nuts, and cashews); eggs; and sulfites.

The district recall coordinators are expected to speak for FDA in telling a firm that a Class I food recall warrants the issuance of a press release by the firm on its own letterhead. According to FDA, firms should be told that publicizing their recall to consumers promptly is an important part of their overall recall strategy and demonstrates their concern for their customers.

FDA does not require public notification of a recall when the product is (1) not expected to be in the hands of consumers; (2) in bulk and the consumer is unable to distinguish the recalled product from the nonrecalled product; (3) an ingredient used by food manufacturers, and firms' distributors can be contacted in an expeditious manner; and (4) sold through mail order, and the firm can contact recipients in an expeditious manner. If the FDA district office believes that no press is needed on the basis of these criteria, the district should confirm the adequacy of its decision with CFSAN.

Within a week of the recall's classification, the Office of Public Affairs publishes information about the recall in the weekly *FDA Enforcement Report*. The report is posted on FDA's Web site and is available in hard copy via paid subscription. The enforcement report lists the recalled product and its sizes; product coding; the name of the manufacturer; the name of the recalling firm and how and when the recall was initiated (e.g., by letter and the date); the distribution of the product (e.g., names of the states); the quantity of product being recalled; the product's classification; and the reason for the recall.

FDA does not generally require companies to issue press releases for Class II and III recalls.

FDA's Recall Database

CFSAN and ORA maintain databases on recalls. CFSAN's database tracks food recalls only, whereas the ORA database tracks all FDA recalls, including those for food, devices, and drugs.

FDA's recall databases do not include recalls when the food and all its ingredients were produced and distributed within a single state. In such instances, the responsibility rests exclusively with the state.

Bacterial and Viral Contaminants Identified in Recalls Associated With Outbreaks of Foodborne Illnesses

Bacterial contaminant	Incubation period	Symptoms	Some foods that have contained the contaminant
E.coli 157:H7	1 to10 days; usually 3 to 4 days	Bloody diarrhea, abdominal cramps, little or no fever.	Ground beef, salami, lettuce, unpasteurized milk, and juice.
Listeria monocytogenes	2 to 8 weeks	Fever, muscle aches, and sometimes nausea and/or diarrhea.	Hot dogs and packaged meats; uncooked vegetables.
Salmonella	12 to 72 hours	Abdominal cramps, fever, and diarrhea, and sometimes nausea and vomiting.	Foods of animal origin such as beef, poultry, milk, or eggs.
Staphyloccocus toxin	30 minutes to 8 hours	Diarrhea, vomiting, nausea, abdominal cramps, and exhaustion lasting 24 to 48 hours.	Fermented sausage and salads.
Vibrio parahaemolyticus	24 hours	Diarrhea, often with abdominal cramps, nausea, vomiting, fever, and chills.	Raw oysters.
Viral contaminant			
Hepatitis A	15 to 50 days, with an average of 28 days	Some people may have no symptoms. If symptoms occur, they can include fever, fatigue, loss of appetite, nausea, abdominal cramps, dark urine, and jaundice.	Cold cuts and sandwiches, fruits and fruit juices, milk, vegetables, salads, shellfish, and iced drinks.
Norwalk or Norwalk-like	24 to 48 hours	Vomiting, abdominal cramps, diarrhea, nausea, and headache.	Shellfish and salad ingredients.

Cases in Which FDA Believed Companies Delayed Initiating a Recall

The following describes FDA's experiences with companies the agency believes delayed initiating a recall.

- **Nutritional supplements contaminated with *salmonella*.** This recall, which occurred in 1988, involved a company that had voluntarily recalled products contaminated with *salmonella*. After the recall, the firm moved its manufacturing operations to a new location. State inspectors found *salmonella* contamination in ingredients at the new facility. When FDA asked the company to extend the recall to include supplements manufactured at the new facility, it refused. The firm agreed to extend the recall after FDA sent a letter formally requesting one and issued a press release.
- **Dairy products contaminated with *salmonella*.** This recall occurred in 1993 and involved a company that dried and packaged products, such as powdered milk and ice cream mixes. The company did not respond to FDA's informal request to conduct a recall. The firm agreed to recall the products after FDA formally requested the recall and issued a press release.
- **Dietary supplements that contained ma huang (an amphetamine-like chemical that acts as a stimulant) and kola nut (a source of caffeine)**. The combination of these ingredients, according to FDA, posed a life-threatening hazard to the health of certain segments of the population. According to its label, the product was useful for weight loss and energy enhancement. FDA formally requested a recall in 1995. The firm replied to FDA that there was no justification for a recall and refused. Because the company failed to recall the product, FDA issued a public warning that the product posed a risk to consumers' health. FDA said seizure was not a viable option since it was unlikely that FDA would find sufficient quantities of product to seize.
- **Chop suey vegetables, bean sprouts, and Chinese mixed vegetables that were processed under conditions that FDA found could result in deadly botulism poisoning**. According to FDA, the firm said it would recall the products but did not. In 1995, FDA formally requested that the company conduct a recall. According to FDA, the company complied with the formal request.
- **Hummus dips and salad products contaminated with *listeria monocytogenes*.** In this 1997 case, FDA wanted the company to expand an ongoing recall. Although initially the company refused to do so, it expanded the recall after FDA made a formal request.

- **Cold smoked fish products contaminated with *listeria monocytogenes*.** This recall, which occurred in March 2000,[1] was a formal request to extend an earlier recall to include all lots/batches of cold smoked fish products—not just a limited amount as in the earlier recall. The request letter noted that the firm, during the prior 6 months, had demonstrated a clear pattern of producing cold smoked fish contaminated with listeria monocytogenes. The company extended its recall after receiving the formal request.
- **Sprouts associated with a 1998-99 outbreak of salmonellosis**. Although epidemiological data linked the *salmonella* illnesses to the consumption of sprouts, the company that grew and packaged the sprouts resisted initiating a recall. About a day or 2 after these data were available, while FDA was drafting a formal written request to the company to recall the product, the company agreed to conduct the recall.
- **Unpasteurized orange juice associated with a 1999 *salmonella* outbreak**. Epidemiological data indicated contaminated juice, but the company initially was reluctant to initiate a recall when FDA informally requested one. According to an FDA official, the company's sampling of the product indicated no contamination. However, the company reconsidered and decided to recall. Following the recall, a more refined sampling methodology found *salmonella* contamination, according to an FDA official.
- **Imported smoked salmon contaminated with *listeria monocytogenes*.** In this 1997 case, the importer initiated a recall of the product and ceased importing it; however, the sole distributor would not cooperate. When FDA informally requested a recall, the distributor refused to recall the salmon or to provide FDA with further distribution information. FDA issued a press release warning consumers not to eat the salmon but did not pursue court authority to seize the salmon because it did not know where it had been distributed.

[1]Because this recall occurred in 2000, it was not among the recalls enumerated earlier for the period 1984 through 1999.

Two Class I Recalls in Which USDA Appeared to be Slow and/or Indecisive

We identified two instances in which USDA did not appear to take prompt action or appeared to be indecisive about initiating a recall.

On August 12, 1997, at USDA's request, Hudson Foods voluntarily recalled 1 day's production linked to an outbreak of *E. Coli* 0157:H7—20,000 pounds of frozen ground beef patties. The following day, USDA dispatched one of its compliance officers to the plant to review production records. The records indicated 1.2 million pounds of patties should be subject to recall. On August 15, 1997, following USDA's advice, Hudson expanded the recall to include 1.2 million pounds of patties. On August 17, 1997, a USDA team arrived at the plant to investigate the discrepancy in the amount of product recalled. The team found that it was Hudson Foods' practice to use ground beef left over from one day's production for subsequent production, thus possibly contaminating all subsequent production. USDA found that Hudson Foods did not have adequate records to determine when the risk of potential contamination would have ended. On August 21, 1997, again following USDA's advice, Hudson Foods expanded the recall to include all Hudson Foods brand beef burgers and beef patties—an estimated 25 million pounds—distributed nationwide and closed the plant where the beef patties had been made.

On December 22, 1998, Bil Mar Foods voluntarily recalled an estimated 35 million pounds of hot dogs and other packaged deli meats that were epidemiologically linked to 40 illnesses and 4 deaths from a rare strain of *listeria monocytogenes*. In addition to the epidemiological data, *listeria monocytogenes* was found in an opened package of Bil Mar hot dogs. Throughout the month of December, as the evidence linking the outbreak to Bil Mar's products grew, Bil Mar sought advice from USDA about whether the company should conduct a recall, but USDA never recommended it. Although USDA can recommend a recall on the basis of epidemiological data, USDA officials did not believe the epidemiological evidence was sufficient to warrant a recall, and USDA inspectors had not found the bacteria in unopened packages from the suspect production lots.

Comments From the U.S. Department of Agriculture

Note: GAO's comments supplementing those in the report text appear at the end of this appendix.

United States Department of Agriculture | Food Safety and Inspection Service | Washington, D.C. 20250

AUG 14 2000

Mr. Lawrence J. Dyckman
Director, RCED Division
Food and Agriculture Issues
U.S. General Accounting Office
441 G Street, NW, Room 2T23
Washington, DC 20548

Dear Mr. Dyckman:

See comment 1.

Thank you for the opportunity to review and provide comments on the Draft Report RCED-00-195, "Food Safety: USDA and FDA Do Not Know Whether Companies Promptly Initiate and Carry Out Recalls." Generally, we consider the report somewhat unbalanced and mischaracterizes our oversight of firms' voluntary recall activities. We have provided you with both general and specific comments (see the Enclosure) in order to provide a more complete characterization of USDA-FSIS' current ability to oversee and monitor the effectiveness of voluntary recall activities at meat and poultry product establishments.

I. GENERAL COMMENTS

See comment 2.

1. The report has not adequately considered and integrated the USDA-FSIS application of the Pathogen Reduction/Hazard Analysis Critical Control Point (HACCP) rule and the roles and responsibilities of food establishments in the recall process. Since January 2000, all plants under USDA inspection are required by regulations to have a HACCP plan for each process in their plant. These regulations require plants to take immediate corrective action in response to a deviation or an unforeseen hazard. A noncompliance report (NR) will be issued to a plant when it has produced and/or shipped adulterated product. A plant that is recalling product will be issued a NR. Under 9 CFR 417.3, the plant is required to take immediate corrective action to determine the cause and take measures to prevent a recurrence. It is the establishment's responsibility to determine what happened, fix the problem and prevent it from happening again.

See comment 3.

2. It is important that the report reflect the fact that FSIS decides whether to request a recall based on whether an adulteration standard is being met, as opposed to whether there is an epidemiological link between a food and a group illness. If you believe, as your report seems to suggest, that confirming an epidemiological link between a food and an outbreak should be enough to trigger a recall, your report should suggest that the statutes for meat and poultry products be amended to allow FSIS to require that a recall be conducted based solely on such a confirmed association.

FSIS FORM 2630-9 (6/86) EQUAL OPPORTUNITY IN EMPLOYMENT AND SERVICES

See comment 4.

3. The recommendations in this report are doable, however, we do not believe that they will fundamentally help speed up or make the recall process more effective. A statutory adjustment that is tailored to the current and emerging recall situations that will be faced by industry and the government would be more effective.

   USDA has supported proposed legislation that would amend the Federal Meat Inspection Act and the Poultry Products Inspection Act to provide for improved public health and food safety through enhanced enforcement. USDA needs the additional enforcement tools contained in the proposed legislation – civil penalties, mandatory recall authority, mandatory notification, and withdrawal of inspection for willful or repeated violations of the Acts, when contaminated meat or poultry may enter the market.

   Currently, all meat and poultry recalls are done on a completely voluntary basis. For the most part, this voluntary system works. If, however, the system does not function smoothly, the mandatory notification and recall authority for the Secretary of Agriculture would provide an insurance policy guaranteeing that consumers will be protected from potentially dangerous meat or poultry without delay.

4. Finally, it should be understood that USDA's practice in conducting voluntary recalls is to initiate fact-finding, complete the request to recall and issue a press release the same day it is notified of an adulteration. This is especially true of Class I recalls where virtually all recalls are initiated and requested by the agency the same day. This practice applies during normal workdays as well as after official work hours and weekends. An electronic paging system has been established to notify key personnel of positive and negative results seven days a week including holidays. USDA initiated the practice of same-day recalls to provide increased public health protection.

We have enclosed a number of detailed comments to further help clarify FSIS' recall program. If you have any questions or need further assistance, please contact Vincent Fayne of my staff at (202) 720-5959.

Sincerely,

Ronald F. Hicks
Deputy Administrator
Office of Management

Enclosure

GAO's Comments

1. We disagree. The report presents a balanced and accurate picture of federal efforts regarding food recalls. It describes the information USDA maintains as well as the information it does not maintain. While USDA believes it has good information on companies' efforts to initiate and carry out recalls, it could not tell us, for example, the average length of a recall from start to finish or the specific length of time of each individual recall. We believe this information should be an integral part of USDA's food safety monitoring and oversight.

2. We added information about hazard analysis and critical control point (HACCP) systems to the report, including the fact that plants must take immediate corrective action to determine the cause and prevent recurrence of the problem that caused a recall. HACCP systems notwithstanding, we believe that USDA must have sufficient information on companies' recall actions to assure itself that consumers are adequately protected as part of its responsibilities for ensuring the safety of meat and poultry.

3. USDA has requested recalls solely on the basis of epidemiological data; in fact, the initial recall request to Hudson Foods was based on epidemiological data. This suggests that reliance on epidemiological data is already an administrative option for USDA. Nonetheless, if USDA believes that the current statute needs to be adjusted to allow the Food Safety and Inspection Service to request a recall solely on the basis of epidemiological data, and that this would be more protective of human health and food safety, it should seek such authority.

4. While we agree that our recommendations, when implemented, will not, by themselves, speed up the recall process, they will provide USDA with information on whether, and where in the process, delays are occurring. This should provide the impetus for taking action to further strengthen the federal food safety system.

Comments From the Department of Health and Human Services

Note: GAO's comments supplementing those in the report text appear at the end of this appendix.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Mr. Lawrence J. Dyckman
Director, Food and
Agriculture Issues
U.S. General Accounting Office
441 G Street N.W. Rm 2T23
Washington, D.C. 20548

Dear Mr. Dyckman:

Enclosed are the Food and Drug Administration's comments on the GAO draft report entitled, FOOD SAFETY: USDA and FDA Do Not Know Whether Companies Promptly Initiate and Carry Out Recalls. GAO/RCED-00-195

If we can be of further assistance, please call Ms. Lois Adams at (301) 827-0125.

Sincerely,

Melinda K. Plaisier
Associate Commissioner
for Legislation

Enclosure

FOOD AND DRUG ADMINISTRATION COMMENTS ON THE GENERAL ACCOUNTING OFFICE DRAFT REPORT ENTITLED, FOOD SAFETY: USDA and FDA Do Not Know Whether Companies Promptly Initiate and Carry Out Recalls, GAO/RCED-00-195

GENERAL COMMENTS

The Food and Drug Administration (FDA) welcomes the General Accounting Office's (GAO) draft report on food recalls and appreciates the opportunity to comment. The report reflects the many administrative, regulatory and legal challenges FDA confronts with monitoring firms' recall activities. The report should note, however, that FDA already has taken steps to assist firms in their recall operations by issuing guidances and by working with the firms to develop a strategy for ensuring that the recall is both timely and effective. FDA also monitors the effectiveness of all Class I recalls to ensure that the appropriate level of effectiveness is attained. FDA is currently updating its recall procedures, including providing both guidance and recall information on the internet. This work is in progress. Its completion is dependent upon the availability of the resources required to update the procedures and guidelines and to complete the internet website where the information will be made available to the general public as well as the regulated industry.

GAO RECOMMENDATION

To ensure that companies initiate and carry out recalls without delays, particularly of foods that may cause serious adverse health consequences, we recommend that the Secretaries of Agriculture and Health and Human Services direct the Food Safety and Inspection Service and the Food and Drug Administration, respectively, to

> Provide specific guidance to companies on time frames for quickly initiating and carrying out food recalls that involve potentially serious adverse health risks, including procedures to expeditiously notify their distribution chains and alert the public.

FDA COMMENT

We concur. FDA's goal is to see that firms quickly recall their products when necessary to protect the public health. FDA will develop additional guidance to help achieve that goal. It should be recognized, however, that such guidance is not legally binding on the companies, and not enforceable by FDA. It should also be recognized that many factors affect a company's ability to carry out a recall effectively within an established time frame. Among those factors are the number of products being recalled, the quantities of each that have entered the distribution chain, the adequacy of the firm's distribution and record keeping systems as well as the responsiveness of the distributors.

See comment 1.

FDA has already taken steps to assist firms in improving their recall operations. To assist companies in writing press releases when necessary, FDA currently posts a model press

release for Class I recalls on the internet. As stated above, FDA currently is updating the recall process, which will include establishing a new FDA recall website for posting real-time recall information. The redesigned website also will include a section for posting guidance to industry. FDA intends to develop a guidance document to cover various aspects of food recalls, including the notification process.

GAO RECOMMENDATION

Modify existing recall database to include information on the timeliness of companies' recall activities to determine whether companies delay in initiating and carrying out recalls. The information should, at a minimum, include the dates the company (1) finds out about the problem that warrants the recall, (2) initiates the recall, (3) notifies the distribution chain, (4) notifies the public, and (5) completes the recall. In addition, the database should track (1) the method used by the company to notify its distributors and the public; (2) for FDA recalls, if it was a FDA formally requested recall; and (3) the date the federal agency informally or formally requested the company to initiate a recall.

FDA COMMENT

The report recommends that FDA track the following:

1) The date the company finds out about the problem that warrants the recall.

See comment 2.

FDA does not agree that this information can be captured as a single date in the database. This is more appropriately documented as a narrative which describes when and what type of information a firm received regarding a product and what type of investigation the firm conducted to determine if a recall was necessary. FDA's Regulatory Procedures Manual (RPM) directs the district offices to collect this information and report it in the district's recall recommendation under "Reason for Recall Recommendation." Specifically, the RPM states, "If the firm advised FDA of the problem, report and explain firm's own analytical results and how firm learned of the need for recall."

2) The date the company initiates a recall.

See comment 3.

The date of recall initiation is currently a data field in the database.

3) The date the company notifies the distribution chain.

See comment 4.

FDA does not agree that this can be captured as a single date in the database. Firms may issue multiple recall notifications on different dates. This information is more appropriately documented in a narrative format. The current practice is that the districts' recall recommendations to the Center for Food Safety and Applied Nutrition (CFSAN) include this information under "Firm's Recall Strategy."

4) The date the company notifies the public.

FDA agrees to add this date to the database.

5) The date the company completes the recall.

FDA agrees to add this date to the database.

In addition, the report recommends that the database should track the following items.

1) The method used by the company to notify its distributors.

See comment 5.

FDA does not agree that this should be a database element. This is more appropriately documented as a narrative, as is currently done in the district's recall recommendation under "Firm's Recall Strategy." Firms may notify their consignees in different manners within the course of one recall.

2) For FDA recalls, if it was a FDA formally requested recall.

This is currently a field in the FDA database.

3) The date the federal agency informally or formally requested the company to initiate a recall.

FDA agrees to add to the database the date that FDA advised the firm of the problem for FDA-initiated recalls. For FDA-requested recalls, we agree to add to the database the date that the recall request was delivered to the firm.

GAO's Comments

1. Appendix II recognizes that FDA has issued guidance to companies and provided model press releases to companies, and that FDA works with companies in developing their recall strategies. However, FDA has not issued specific guidance to companies on time frames for quickly initiating and carrying out food recalls that involve potentially serious adverse health risks, including procedures to expeditiously notify their distribution chains and alert the public.

2. While we acknowledge that there may be several points in time that could be considered to be “the date the company finds out about the problem that warrants the recall,” we believe that FDA could define a meaningful point in time to record in its database for monitoring the company's recall performance.

3. As we stated in the draft and the final report, FDA, beginning in fiscal year 1999, included in its recall database the recall initiation date.

4. We recognize that a company may have to issue more than one notice to address a recall problem in its product. We believe that FDA could develop a system that captures multiple dates of notification.

5. We believe that this information can be readily identified in a data system by, for example, having a data field for each type of method of notification (e.g., telephone, facismile, E-mail, letter).

Related GAO Products

Food Safety: Improvements Needed in Overseeing the Safety of Dietary Supplements and "Functional Foods" (GAO/RCED-00-156, July 11, 2000).

Food Safety: U.S. Needs a Single Agency to Administer a Unified, Risk-Based Inspection System (GAO/T-RCED-99-256, Aug. 4, 1999).

Food Safety: U.S. Lacks a Consistent Farm-to-Table Approach to Egg Safety (GAO/RCED-99-184, July 1, 1999).

Food Safety: Experiences of Four Countries in Consolidating Their Food Safety Systems (GAO/RCED-99-80, Apr. 20, 1999).

Food Safety: Opportunities to Redirect Federal Resources and Funds Can Enhance Effectiveness (GAO/RCED-98-224, Aug. 6, 1998).

Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable (GAO/RCED-98-103, Apr. 30, 1998).

Food Safety: Agencies' Handling of a Dioxin Incident Caused Hardships for Some Producers and Processors (GAO/RCED-98-104, Apr. 10, 1998).

Food Safety: Information on Foodborne Illnesses (GAO/RCED-96-96, May 8, 1996).

Food Safety: Changes Needed to Minimize Unsafe Chemicals in Food (GAO/RCED-94-192, Sept. 26, 1994).

Food Safety: A Unified, Risk-Based Food Safety System Needed (GAO/T-RCED-94-223, May 25, 1994).

Food Safety: Risk-Based Inspections and Microbial Monitoring Needed for Meat and Poultry (GAO/RCED-94-110, May 19, 1994).

Food Safety and Quality: Uniform, Risk-Based Inspection System Needed to Ensure Safe Food Supply (GAO/RCED-92-152, June 26, 1992).

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