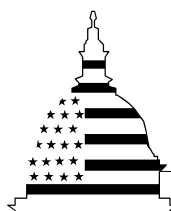


October 2004

FOOD SAFETY

USDA and FDA Need to Better Ensure Prompt and Complete Recalls of Potentially Unsafe Food



G A O

Accountability * Integrity * Reliability



Highlights of [GAO-05-51](#), a report to congressional requesters

Why GAO Did This Study

Two large food recalls completed in 2003 were associated with 8 deaths and nearly 100 serious illnesses in at least 16 states. Manufacturers voluntarily recall potentially unsafe food by notifying their customers to return or destroy it. The U.S. Department of Agriculture (USDA), for meat, poultry, and egg products, and the Food and Drug Administration (FDA), for other food, have programs to monitor voluntary food recalls, verify that companies contact their customers, and maintain recall data. GAO (1) examined the recall programs and procedures USDA and FDA use to protect consumers from unsafe foods and (2) compared their food recall authority with the authority of agencies to recall other consumer products.

What GAO Recommends

GAO proposes that Congress consider legislation requiring a company to notify USDA or FDA if it discovers it has distributed unsafe food and giving agencies authority to order food recalls, and recommends that the agencies take actions to ensure prompt, complete recalls and better recall monitoring. USDA said the report was generally accurate and its May 2004 directive will address weaknesses GAO found. FDA did not believe its system lengthened recalls or its processes reduced recovery. FDA disagreed with some recommendations. GAO continues to believe its recommended actions are needed to protect consumers.

www.gao.gov/cgi-bin/getrpt?GAO-05-51.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Lawrence J. Dyckman at (202) 512-3841 or dyckmanl@gao.gov.

FOOD SAFETY

USDA and FDA Need to Better Ensure Prompt and Complete Recalls of Potentially Unsafe Food

What GAO Found

Weaknesses in USDA's and FDA's food recall programs heighten the risk that unsafe food will remain in the food supply and ultimately be consumed. Specifically, USDA and FDA do not know how promptly and completely the recalling companies and their distributors and other customers are carrying out recalls, and neither agency is using its data systems to effectively track and manage its recall programs. For these and other reasons, most recalled food is not recovered and therefore may be consumed. GAO's analysis of recalls in 2003 showed that about 38 percent and 36 percent of recalled food was ultimately recovered in recalls overseen by USDA and FDA, respectively. These agencies also told GAO of instances in which companies were slow to reveal where they had distributed the food or provided inaccurate customer lists. That distribution information is critical because USDA's and FDA's primary role in recalls is to monitor the effectiveness of a company's recall actions. To do so, the agencies contact a sample of the distribution chain from these lists to verify that customers in the food distribution chain received notice of the recall, and that they located the food and removed it from the marketplace. However, the methodology that the agencies use for selecting the customers to check can result in entire segments of complex distribution chains being overlooked. Moreover, GAO found that the agencies did not complete verification checks for some recalls before the shelf life of the food expired. In addition, consumer groups and others question the usefulness of USDA's and FDA's efforts to communicate with the public, suggesting alternatives such as posting notices in grocery stores and direct notification of consumers.

Agencies responsible for the safety of products, such as toys, heart pacemakers, and automobiles, have specific recall authority not available to USDA and FDA for food. This includes the authority to (1) require a company to notify the agency when it has distributed a potentially unsafe product, (2) order a recall, (3) establish recall requirements, and (4) impose monetary penalties if a company violates recall requirements. For example, by law, companies must promptly notify the Consumer Product Safety Commission after learning that a product may pose an unreasonable risk of serious injury or death, or face penalties of up to \$1.65 million. Likewise, FDA has recall authority for unsafe biological products, medical devices, radiation emitting electronic products, and infant formula. Moreover, in contrast to its inability to penalize a company that is slow to conduct a food recall, FDA can impose penalties of up to \$100,000 per day for a company that fails to recall a defective biological product, such as a vaccine.

Contents

Letter

Results in Brief	1
Background	4
Weaknesses in USDA's and FDA's Recall Programs Heighten the Risk That Unsafe Food Will Reach Consumers	7
Other Government Agencies Have Recall Authority Not Available to USDA and FDA for Food That May Better Protect Consumers	13
Conclusions	25
Matters for Congressional Consideration	30
Recommendations for Executive Action	31
Agency Comments and Our Evaluation	31
	32

Appendixes

Appendix I: Objectives, Scope, and Methodology	36
Appendix II: Federal Actions Associated with the Discovery of an Animal in the United States Infected with BSE	39
Beef Recall Was Triggered by a BSE-Positive Sample from One Cow	39
Recall Begun in December 2003 Was Completed in March 2004	39
Recall Was Complicated by Inaccurate Distribution Lists and Mixing of Potentially Contaminated and Noncontaminated Beef	40
FDA's Role in USDA's Recall	44
USDA and FDA Worked Together on the Recall	45
Appendix III: Information on a 2002 Recall of Ground Beef by a ConAgra Plant in Greeley, Colorado	48
Appendix IV: USDA and FDA Actions on the Recommendations We Made in 2000	50
Appendix V: Information on the 20 Food Recalls We Examined for 2003	52
Appendix VI: Recall Authority of Selected Government Agencies	54
USDA's Food Safety and Inspection Service	54
FDA's Center for Food Safety and Applied Nutrition	55
FDA's Center for Biologics Evaluation and Research	56
FDA's Center for Devices and Radiological Health	57
FDA's Center for Drug Evaluation and Research	59
FDA's Center for Veterinary Medicine	60
Consumer Product Safety Commission	60
Department of Transportation's National Highway Traffic Safety Administration	61

	Canadian Food Inspection Agency	62
Appendix VII: Comments from the U.S. Department of Agriculture		64
	GAO Comments	67
Appendix VIII: Comments from the Food and Drug Administration		70
	GAO Comments	74
Appendix IX: GAO Contacts and Staff Acknowledgments		76
	GAO Contacts	76
	Staff Acknowledgments	76

Tables

Table 1: USDA and FDA Verification Rates for 20 Selected Class I Recalls in 2003	21
Table 2: Recall Authority of Selected Government Agencies	27
Table 3: Detailed Timeline of USDA, FDA, and Company Actions Related to the Discovery of an Animal Infected with BSE	45
Table 4: USDA and FDA Actions on GAO's Recommendations to Modify Recall Data Systems	50
Table 5: Selected Information on the 20 Class I Food Recalls We Examined	52

Figures

Figure 1: USDA and FDA Recalls by Risk Classification, 2003	8
Figure 2: Downstream Distribution Chain May Include Multiple Levels of Distributors, Processors, and Retailers before the Food Reaches Consumers	10
Figure 3: Number of Days after Production When Recall Occurred and Expected Shelf Lives for Four Recalls	17
Figure 4: USDA's Recall Verification Checks by Location and Customer Type for Meat Associated with the Animal Infected with BSE	43

Abbreviations

BSE	bovine spongiform encephalopathy
CFIA	Canadian Food Inspection Agency
CPSC	Consumer Product Safety Commission
FDA	Food and Drug Administration
FSIS	Food Safety and Inspection Service
NHTSA	National Highway Traffic Safety Administration
USDA	U.S. Department of Agriculture

This is a work of the U.S. government and is not subject to copyright protection in the United States. It may be reproduced and distributed in its entirety without further permission from GAO. However, because this work may contain copyrighted images or other material, permission from the copyright holder may be necessary if you wish to reproduce this material separately.



United States Government Accountability Office
Washington, D.C. 20548

October 6, 2004

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

The Honorable Marcy Kaptur
Ranking Minority Member
Subcommittee on Agriculture, Rural Development,
Food and Drug Administration, and Related Agencies
Committee on Appropriations
House of Representatives

When food companies discover that they may have distributed food that is contaminated with disease-causing bacteria or that contains allergens that can cause serious illness or death, they will usually conduct a voluntary recall. That is, they will contact their customers and instruct them to contact the wholesalers, retailers, and others in the food's distribution chain and ask them to return or destroy the potentially unsafe food. Recalls may not always prevent serious health problems. In fact, two large recalls completed in 2003 were associated with foodborne illness outbreaks involving nearly 100 hospitalizations or serious illnesses, 8 deaths, and 3 miscarriages in at least 16 states, according to the U.S. Department of Agriculture (USDA).

In recent years, the volume of food that companies recalled in the United States increased substantially; for meat and poultry alone, the amount recalled increased from nearly 6 million pounds in 1988 to about 36 million pounds in 2003. Concerns that contaminated food could reach consumers have also intensified because of the potential susceptibility of food to deliberate contamination. In January 2004, the President identified the U.S. food system as vulnerable to intentional acts of terrorism.¹

Food recalls are voluntary and federal agencies responsible for food safety have no authority to compel companies to carry out recalls—with the exception of the Food and Drug Administration's (FDA) authority to require a recall for infant formula. USDA provides guidance to companies

¹Homeland Security Presidential Directive/HSPD-9, *Defense of United States Agriculture and Food* (Jan. 30, 2004).

for carrying out voluntary recalls of meat, poultry, and egg products and monitors those recalls. FDA provides guidance to companies for carrying out voluntary recalls of other foods and monitors those recalls.

In August 2000, we reported that while USDA and FDA believed companies carried out timely recalls, the two agencies did not have data to support their views.² We recommended that, among other things, USDA and FDA provide specific guidance to companies, including time frames for quickly initiating and carrying out recalls, and that the agencies maintain key dates—such as when the recall started, when customers in the distribution chain were notified, and when the recalls were completed—in their recall data systems to allow the agencies to assess whether companies do indeed carry out timely recalls.

As part of their recall programs, both USDA and FDA classify recalls on the basis of their severity, with Class I recalls presenting the greatest risk to human health. Class I recalls may involve food contaminated with disease-causing bacteria, such as *Listeria monocytogenes* (listeria) and *Escherichia coli* (*E. coli*), or food containing ingredients not identified on the label (e.g., nuts or eggs) that could cause severe illness or death to someone allergic to that ingredient. Class II and Class III recalls involve foods that present little or no risk of adverse health consequences. For example, in FDA's case, these foods may cause medically reversible adverse consequences, such as seasoned popcorn containing a color additive not listed on the label that can cause mild allergic reactions.

In their guidance to companies for voluntary recalls, both USDA and FDA have procedures for companies to notify their downstream customers—such as processors, wholesalers, distributors, institutions, and retailers in the distribution chain—as well as procedures for returning or disposing of the food (referred to as “recovery”).

Both USDA and FDA also have guidance for their respective field staff with procedures for monitoring the progress of the recall, ensuring that the public is notified through press releases and Web postings, carrying out verification checks to confirm that the company has notified its downstream customers, and documenting certain agency and company

²GAO, *Food Safety: Actions Needed by USDA and FDA to Ensure That Companies Promptly Carry Out Recalls*, [GAO/RCED-00-195](#) (Washington, D.C.: Aug. 17, 2000).

recall activities in their respective recall databases—Recall Web for USDA, and Recall Enterprise System for FDA.

In contrast to the voluntary food recall programs at USDA and FDA, other agencies have authority to issue mandatory recall orders: the National Highway Traffic Safety Administration’s recall authority for motor vehicles; the Consumer Product Safety Commission’s recall authority for many consumer goods; and FDA’s recall authority for infant formula, biological products, medical devices, and radiation-emitting electronic products. At the time of our previous study, legislation had been introduced that would have given mandatory authority to USDA and FDA for food recalls. Similar legislation was introduced in the current Congress.³

As you requested, this report (1) examines the recall programs and procedures USDA and FDA use to protect consumers from unsafe foods and (2) compares USDA’s and FDA’s authority for food recalls with the recall authority of agencies responsible for the safety of other consumer products, such as toys, medical devices, and automobiles. In addition, information you requested on USDA’s and FDA’s efforts to identify and recall food from a cow slaughtered in Washington State that had bovine spongiform encephalopathy (BSE), otherwise known as mad cow disease, is presented in appendix II. You also requested information on a 2002 recall of ground beef by a ConAgra plant in Greeley, Colorado, which is presented in appendix III.

For the purpose of this report, the term “food” refers to food intended for human consumption, the term “customer” refers to any company in the downstream distribution chain of the company conducting the recall, and, with respect to recall authority, the term “order” includes the authority to order or to require a recall. To examine the recall programs and procedures USDA and FDA use to protect consumers from unsafe foods, we analyzed in depth 20 Class I recalls that were ongoing in fiscal year 2003—10 from USDA and 10 from FDA. We discussed these recalls with officials from the recalling companies and with the agencies’ district offices that monitored the recalls. These recalls represented a range of foods, contaminants, and geographical locations. In addition, we examined the reliability of

³See, for example, the SAFER Meat, Poultry, and Food Act (H.R. 3547) and the Consumer Food Safety Act of 2003 (H.R. 1496). In addition, legislation was introduced to provide USDA with authority to order recalls for food served in the school meals programs (S. 506/H.R. 1551).

information from USDA and FDA recall data systems for that year. We also obtained views on USDA's and FDA's recall programs from representatives of trade and consumer organizations, such as the American Meat Institute, the Center for Science in the Public Interest, and the Consumer Federation of America. To compare USDA's and FDA's authority for food recalls with recall authority available to federal agencies responsible for the safety of other consumer products, we compared statutes and regulations and discussed these recall programs with agency officials. This report also provides information on, but does not evaluate, the Canadian Food Inspection Agency's recall program. The Canadian agency has the authority to order food recalls. Appendix I discusses our objectives, scope, and methodology in detail. We conducted our review between May 2003 and August 2004 in accordance with generally accepted government auditing standards.

Results in Brief

Even in the context of their limited recall authority, USDA and FDA can do a better job in carrying out their food recall programs. Weaknesses in these agencies' systems for monitoring food recalls heighten the risk that unsafe food will remain in the food supply and ultimately be consumed.

Specifically:

- USDA and FDA do not know how promptly and completely companies are carrying out recalls. Neither agency's guidance provides time frames for companies on how quickly to initiate and carry out recalls. Consequently, companies may have less impetus to notify downstream customers and remove potentially unsafe food from the marketplace. Moreover, USDA and FDA are not using their data systems to effectively monitor and manage their recall programs. They do not track important dates to calculate how long companies take to carry out recalls and the percentage of food that is recovered. Furthermore, managers do not receive routine reports on the progress of ongoing recalls to target program resources. Finally, we found that FDA's food recall program staff maintain a recall data system that is separate from FDA's official recall data system. FDA uses information from this other data system to report to Congress because, according to program staff, the system maintained by the program staff contains the most accurate data. Moreover, the two systems do not contain consistent information, which brings into question the validity and reliability of FDA's official system.
- USDA and FDA do not promptly verify that recalls have reached all segments of the distribution chain, yet monitoring the effectiveness of a

company's recall actions is the agencies' primary role in a food recall. For the 10 USDA recalls we examined in depth that occurred in 2003, USDA staff averaged 38 days to complete verification checks, and for the 10 FDA recalls we examined in depth, FDA staff averaged 31 days. These time frames exceeded the expected shelf life for some perishable foods that were recalled, such as fresh ground beef and fresh-cut bagged lettuce. Moreover, the agencies' procedures for selecting the sample of companies to check do not ensure that all segments of a food distribution chain are included. In May 2004, USDA issued new procedures to its staff with time frames for completing verification checks—within 13 days for Class I recalls—and with a methodology designed to reach all segments of the distribution chain. If implemented, these procedures should provide reasonable assurance that recalls are effective.

- The procedures USDA and FDA use to alert consumers to a recall—press releases and Web postings—may not be effective. According to consumer groups and others, relatively few consumers may see that information. They identified additional methods to notify the public, such as posting recall notices in grocery stores and directly notifying consumers using “shoppers’ club” information.

In contrast to the limited, or lack of, authority that federal food safety agencies have to order food recalls, agencies responsible for the safety of certain other consumer products have more specific recall authority that may help them better protect consumers. This includes the authority to (1) require a company to notify the agency when it has distributed a potentially unsafe product, (2) order a recall, (3) establish recall requirements, and (4) impose monetary penalties if a company does not cooperate. For example, manufacturers of many consumer goods are generally required to notify the Consumer Product Safety Commission within 24 hours of obtaining information that suggests a product could create a substantial risk of injury. The commission has the authority to impose monetary penalties of up to \$1.65 million if a company does not inform the commission promptly about an unsafe product. Likewise, FDA has authority to order recalls of unsafe biological products and medical devices—and it has used this authority in the past. Furthermore, the National Highway Traffic Safety Administration has used its authority to establish recall requirements to require companies to directly notify the purchasers of vehicles with defects and to remedy the defects. Finally, FDA can impose penalties of up to \$100,000 per day on companies that do not recall unsafe biological products, such as vaccines.

We are proposing that Congress consider legislation that would require companies to alert USDA or FDA when they discover they have distributed potentially unsafe food and that would give both agencies mandatory food recall authority. We are also recommending that USDA and FDA better track and manage food recalls, achieve more prompt and complete recalls, and determine if additional ways are needed to alert consumers about recalled food that they may have in their homes.

In commenting on a draft of this report, USDA said the report was generally factually accurate, and the department believes that the procedures it adopted in late May 2004 will address most of the weaknesses we observed in its recall program. However, USDA disagreed with our recommendations regarding additional data collection and report generation. USDA believes that those recommendations may be a burden to the agency and industry. We do not believe it would be burdensome to USDA because the department already generally collects these data in its inspection paperwork but does not systematically capture them in its Recall Web database, which should be able to generate the management reports we recommend. With regard to industry, companies are already required by law to maintain food distribution information. Appendix VII contains USDA's written comments and our detailed response. In its comments, FDA said we did not demonstrate that FDA recalls were lengthy because of system inefficiencies or that weaknesses in FDA's recall process resulted in little recovery of food. FDA agreed with our recommendations regarding using the Recall Enterprise System to generate routine management reports and eliminating the duplicative recall database, but it disagreed with our recommendations regarding the need for specific time frames for companies' actions and for recording the dates of company and agency actions in the Recall Enterprise System. We continue to believe that time frames are critical to reinforce the urgency for companies to act promptly to protect consumers and that tracking these dates is essential for FDA to effectively monitor ongoing recalls and assess actions to improve the timeliness of recalls. Appendix VIII contains FDA's written comments and our detailed response.

Background

Food companies, USDA, and FDA may discover that unsafe food has been distributed from customer complaints, routine facility investigations, product testing by the company or a federal or state government agency, or an outbreak of a foodborne illness. Depending on the food, USDA (for meat, poultry, and egg products) or FDA (for all other food), would generally monitor the recall.⁴

USDA and FDA classify recalls by the potential health risk that the food poses, as follows:

- *Class I:* Recalls of food that poses a reasonable probability of causing serious, adverse health consequences or death, such as foods that contain listeria, salmonella, or *E. coli* O157:H7, or undeclared allergens such as peanuts and eggs.⁵
- *Class II:* For USDA, recalls of food that poses a remote probability of adverse health consequences, and, for FDA, recalls of food that presents a remote probability of serious adverse health consequences or may cause temporary or medically reversible adverse health consequences.
- *Class III:* For USDA, recalls of food that will not cause adverse health consequences. (For example, meat or poultry that contains added water not disclosed on the label, which USDA regulation prohibits.) For FDA, recalls of food not likely to cause adverse health consequences. (For example, food that contains mold or insects, which FDA regards as unfit, although the food is unlikely to pose adverse health consequences.)

The number of food recalls has generally increased over the past decade, with a record high of more than 500 in 2002.⁶ In addition, for fiscal year 2003, most recalls were Class I—for food that poses the greatest risk of illness or death. As figure 1 shows, Class I recalls accounted for 51 (66

⁴The Department of Defense may also coordinate recall responsibilities with respect to foods purchased to feed military personnel and their families.

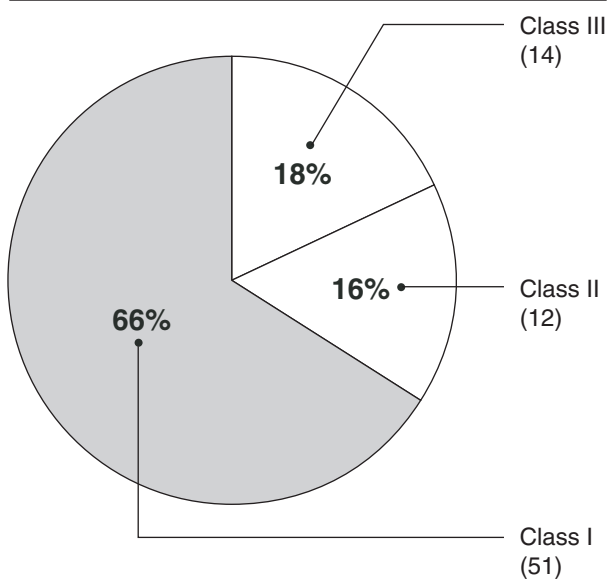
⁵USDA classifications are in the Food Safety and Inspection Service Directive 8080.1, Revision 4. FDA recall classifications are provided in 21 C.F.R. § 7.3(m)(2004).

⁶The number of food recalls each year has ranged from 260 to 519 over the past decade, with an average of 335 recalls a year for that period.

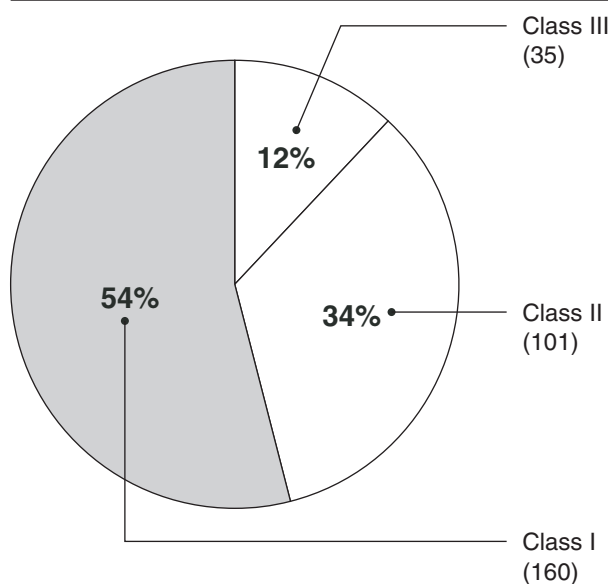
percent) of the 77 food recalls for USDA in 2003 and 160 (54 percent) of the 296 recalls for FDA in that year.

Figure 1: USDA and FDA Recalls by Risk Classification, 2003

USDA (77 recalls)



FDA (296 recalls)



- Food that will not cause serious adverse health consequences or that may cause temporary or medically reversible adverse health consequences
- Food that poses a reasonable probability of causing serious illness or death

Source: GAO analysis based on USDA and FDA recall data.

USDA and FDA generally monitor a food recall when the recalling company alerts the agency or when the agency learns about a problem from, for example, routine facility inspections or product tests. Typically, recalls are monitored by the agencies' district office responsible for the geographic area where the recalling company is located. District office inspectors obtain preliminary information from the company, such as the reason for the recall, the amount of food to be recalled, and the food's labeling and packaging. For USDA, a recall committee comprised of headquarters and district recall staff assign the risk classification, and, for FDA, the districts assign a preliminary risk classification.

Both USDA and FDA rely on press releases and Web site postings to alert consumers about recalls, although there is no law requiring them to provide such notification. USDA's Food Safety and Inspection Service will generally issue press releases for Class I and Class II recalls and post information on its recall Web site:

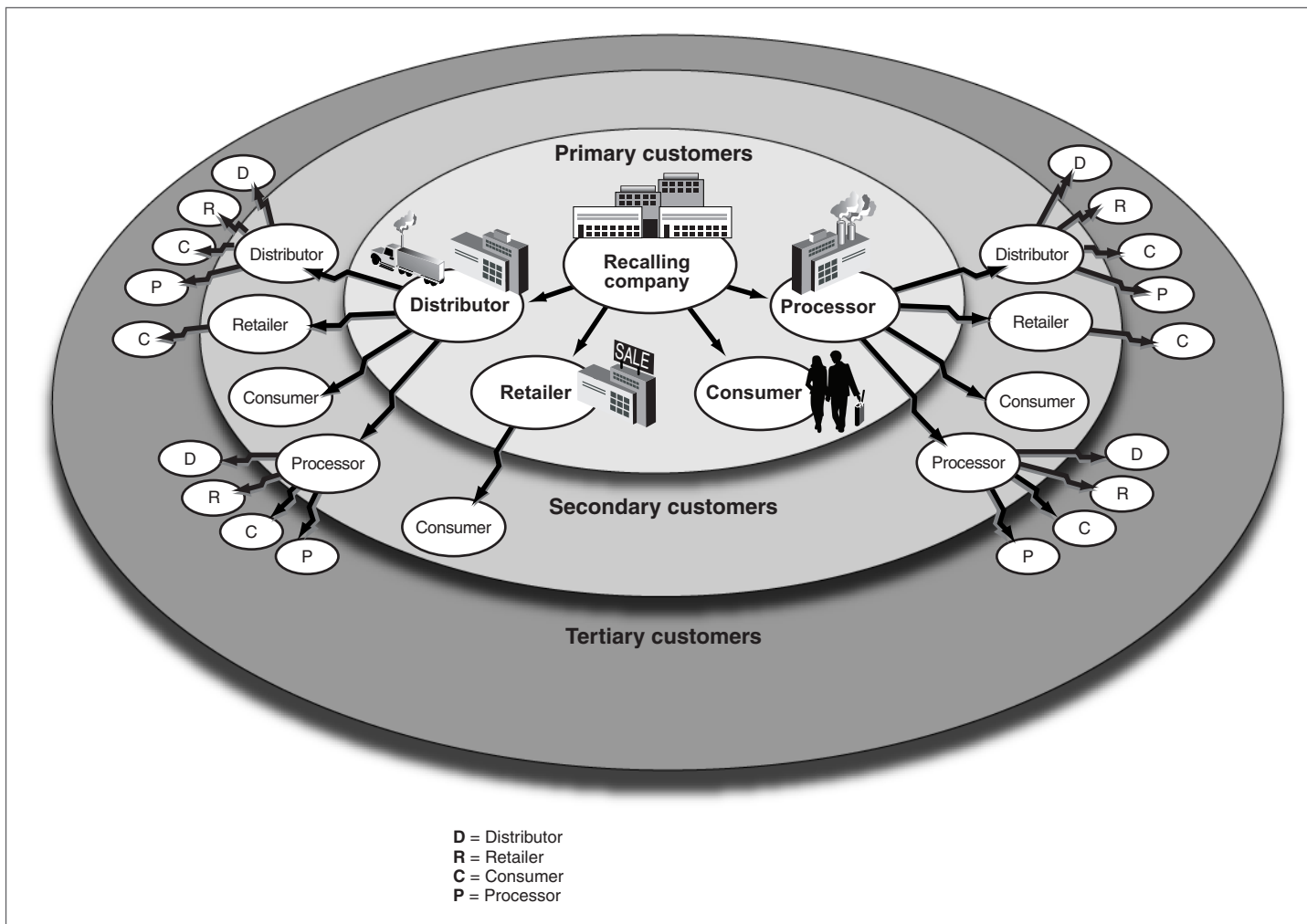
http://www.fsis.usda.gov/fsis_recalls/index.asp. USDA's press releases describe the product, including any identifying marks or codes; the reason for the recall; and the risk involved with consuming the product. The press releases also instruct consumers on what to do with any product in their possession and provide a name and telephone number of a company contact for questions.

For FDA recalls, the recalling company generally issues a press release for Class I recalls. FDA guidance recommends that the press release be issued promptly, and if the company fails to issue the press release, FDA may do so. FDA posts these press releases on its recalls Web site:

<http://www.fda.gov/opacom/7alerts.html>, along with recalls for the other products that it regulates. FDA provides companies with model language for press releases for several different causes of Class I recalls (e.g., allergens, *E. coli* O157:H7, or salmonella), which covers, in general, the same information found in USDA's press releases. In addition, USDA and FDA food recalls are also posted on a governmentwide recall Web site: <http://www.recalls.gov>, which is managed by the Consumer Product Safety Commission.

In addition, under both USDA and FDA guidelines, a recalling company is to alert its customers to the recall and provide them with instructions for recovery—return or disposal—of the food. This first level of customers—referred to as primary—can be any number and combination of processors, distributors, retailers, or other customers and may also include direct-to-consumer sales. For example, some frozen food companies distribute their products by direct delivery to individual homes. The recalling company is to ask its primary customers to pass the alert to subsequent customers in the distribution chain (referred to as secondary and tertiary), when they have further distributed or sold the food. As figure 2 shows, the entire distribution chain can include multiple levels of downstream processors, distributors, and retailers before the food reaches consumers.

Figure 2: Downstream Distribution Chain May Include Multiple Levels of Distributors, Processors, and Retailers before the Food Reaches Consumers



Source: GAO.

USDA's and FDA's primary role is to monitor the effectiveness of a company's recall actions by verifying that customers in the food distribution chain receive notice of the recall, and that the food is located and removed from the marketplace. To carry out their verification checks, USDA and FDA contact a percentage of the company's customers to determine whether the recall was carried out—specifically, that the customers were provided with recall information, and that they followed instructions for returning or destroying the food.⁷ In addition, several states have agreements with USDA and FDA to coordinate verification responsibilities for companies in their states. States are to report the results of the verification checks to the monitoring agency. USDA and FDA may also request that recalling companies periodically submit status reports on their progress, including the number of customers contacted and the amount of the food recovered or otherwise accounted for. USDA and FDA inspectors should be consulted prior to the destruction of the food, and they may request that the company allow them to witness the final disposition of the food.⁸

Both USDA and FDA consider a recall completed when their district officials finish verification checks and determine that the company has made all reasonable efforts to recall the food. The agencies are to notify recalling companies in writing that no further action is necessary. At this point, the agencies put summary information into their respective data systems.

The report we issued in August 2000 provided information on several aspects of USDA's and FDA's voluntary recall programs. It was intended to assist congressional consideration of then-pending legislative proposals to give mandatory recall authority to USDA and FDA. Although such legislation has not been enacted, USDA and FDA do have authority to detain, seize through the courts, and condemn foods as part of their overall responsibility for food safety. Specifically:

- The Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act give USDA authority to detain

⁷USDA refers to its verification checks as “effectiveness checks,” whereas FDA refers to them as “audit checks.”

⁸Disposition of a recalled product may include actions such as relabeling, reworking (e.g., further cooking to sell as food or rendering to sell as fertilizer or animal feed), or destroying the food (e.g., disposing of food in a landfill).

meat, poultry, and egg products for up to 20 days when it has reason to believe the food is adulterated or misbranded. These acts give USDA authority, through the courts, to seize, condemn, and destroy unsafe food. USDA also may withdraw meat and poultry inspectors from slaughtering and processing facilities or withhold or remove the USDA “inspected and passed” label—both measures that require the production line to be shut down—if the sanitary conditions at the company’s facility cause food to become unsafe.

- The Federal Food, Drug, and Cosmetic Act gives FDA authority, through the courts, to seize, condemn, and destroy adulterated or misbranded food not exclusively regulated by USDA. The act also gives FDA authority to disseminate information about foods that are believed to present a danger to public health. In addition, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002⁹ (commonly referred to as the Bioterrorism Act), authorizes FDA to detain food for up to 30 days without a court order, if the agency has evidence indicating that the food presents a threat of serious adverse health consequences or death to humans or animals. FDA issued its final rule for administrative detention on June 4, 2004.¹⁰

⁹Pub. L. No. 107-188, 116 Stat. 594(2002).

¹⁰Administrative Detention of Food, 69 Fed. Reg. 31660 (June 4, 2004)(to be codified at 21 C.F.R. §§ 1.377 *et seq.*).

The Bioterrorism Act also authorizes FDA to establish record-keeping requirements for companies involved in the food industry (except farms and restaurants) so that FDA will be better able to identify companies involved in the food distribution chain—that is, the immediate previous sources and subsequent recipients of food. In this way, the act attempts to address, if necessary, “credible threats of serious adverse health consequences or death to humans or animals.”¹¹ As of August 2004, FDA had not issued final regulations to implement these record-keeping requirements, and the agency told us it has not determined the applicability of the act to food recalls.¹²

Weaknesses in USDA’s and FDA’s Recall Programs Heighten the Risk That Unsafe Food Will Reach Consumers

Even recognizing the limitations in their recall authority, federal agencies could still better protect consumers from unsafe foods if they addressed weaknesses we identified in their monitoring of companies’ recalls. Specifically, USDA and FDA have not set time frames to encourage companies to act promptly, and, because the agencies do not track important dates and recovery rates in their recall data systems, they do not know how promptly and completely companies are carrying out recalls. Furthermore, the agencies’ procedures for conducting verification checks do not ensure that agency staff promptly verify that recalls have reached all segments of the distribution chain. Finally, consumer groups have raised questions about the effectiveness of the agencies’ public notification efforts.

USDA and FDA Do Not Know How Promptly and Completely Companies Carry Out Recalls

In November 2003, FDA issued new recall guidance to companies, and, in May 2004, USDA also issued new guidance. However, neither agency included time frames for companies to initiate and carry out recalls of food that involve potentially serious adverse health risks, nor procedures for the

¹¹21 U.S.C. § 350c(b).

¹²In the preamble of the proposed regulations, FDA stated that it intends to make this process as simple as possible for both domestic and foreign facilities. FDA has proposed that covered entities would be required to maintain specific information in their files, but the form or type of records maintenance system would not be specified. The proposed regulations would, if finalized, require companies to provide FDA with information within specified time frames about the immediate previous source and subsequent recipient of all food. *See* Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 25188 (proposed May 9, 2003)(to be codified at 21 C.F.R. §§ 1.326 *et seq.*).

companies to notify their distribution chains and alert the public. Without specific guidance on time frames, companies may have less impetus to promptly notify downstream customers and retrieve potentially unsafe food from the marketplace. Of particular concern are perishable foods that are sold and consumed within a few days. In our 2000 report, we recommended that the agencies include time frames to ensure that companies would initiate and carry out recalls without delay. Appendix IV provides information on the actions USDA and FDA have taken on the other recommendations we made to them in 2000.

Moreover, we found that, although USDA and FDA have developed new data systems since our 2000 report, the agencies are not using the systems to effectively monitor and manage their recall programs. The agencies do not track some critical data for assessing the timeliness and effectiveness of recalls. For example, USDA does not track when a company learns that it needs to initiate a recall or when it provides complete distribution lists. In addition, neither USDA nor FDA tracks when the company begins and finishes notifying its customers or when the agency begins and finishes its verification checks. Without tracking these data, the agencies do not have the information they need to assess how quickly the company and the agency have acted. Even when the agencies collect data, they do not use the information to generate routine reports that would help their managers track the progress of recalls that are ongoing or assess the effectiveness of their recall programs' activities. Such reports are a key prerequisite to effective management of resources, as emphasized in the Government Performance and Results Act of 1993.¹³

¹³Pub. L. No. 103-62, 107 Stat. 285(1993).

We found, for example, that while both agencies record the information for calculating the recovery rate, they do not calculate the recovery rate for recalls. As a result, they did not know how much food was actually recovered, although both agencies told us recovery was an important indicator of a successful recall. Using the information in USDA's Recall Web database, we calculated that the total recovery rate has generally declined since 1988 for recalls monitored by USDA.¹⁴ We could not similarly analyze recovery rates for FDA-monitored recalls for multiple years because the agency has not recorded recovery information in its database in a way that allowed us to do the calculation. That is, FDA uses inconsistent units, such as cases, cans, boxes, or bags of food, which prevented us from calculating annual recall volume. However, we calculated the average recovery rate for about one-half of FDA recalls in 2003 for which the agency used the same unit for both "quantity distributed" and "quantity recovered."¹⁵ We found that companies' recovery rates for FDA-regulated food was about 36 percent. In a similar analysis of USDA recalls, about 38 percent of food was recovered.

USDA has a low expectation of recovering much food with a short shelf life, such as fresh meat, which moves quickly through the distribution chain. USDA said that the drop in its recovery rates may also be due, in part, to the significant number of recalls related to its *E. coli* O157:H7 testing programs, which started around 1994.¹⁶ Test results take several days. That is, because of the delay in getting the test results, meat that tested positive for *E. coli* O157:H7 may have already been distributed, sold, and consumed—thus reducing the amount that may be recovered. Some companies told us that, to avoid recalls related to positive *E. coli* O157:H7 tests taken by USDA, they have begun holding meat from distribution until test results are back. Another reason for low recovery rates is that USDA is

¹⁴We calculated the total recovery rate by dividing the total pounds recovered by the total pounds recalled in each year. The first complete year that USDA recorded pounds recovered was 1988.

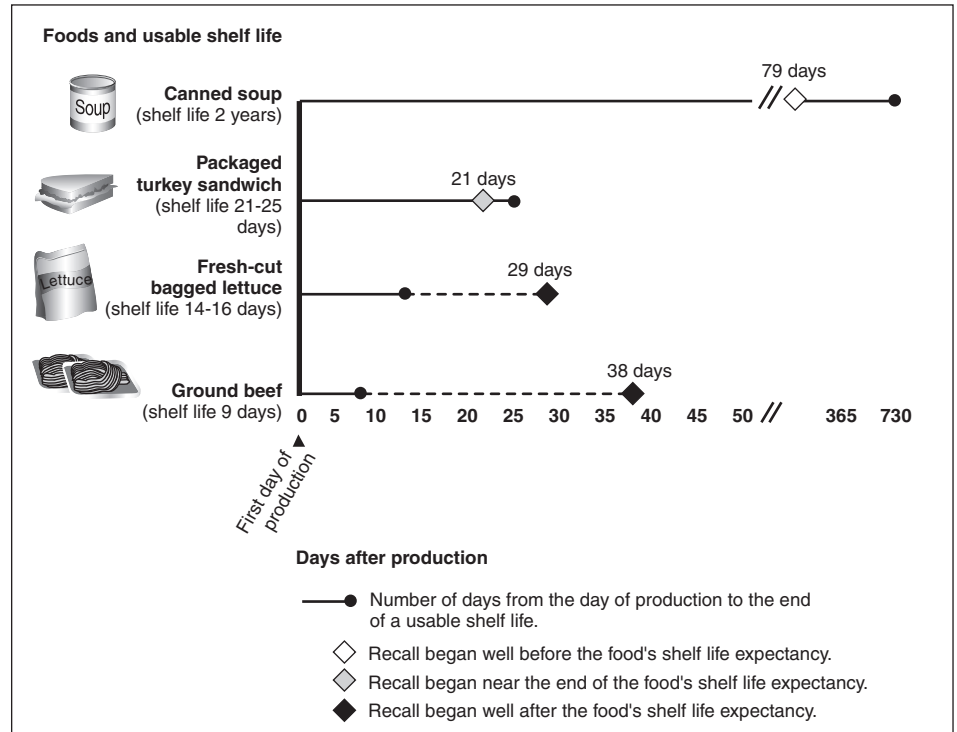
¹⁵To calculate the average fiscal year 2003 recovery rate, we averaged rates for individual recalls. For FDA, we included in our analysis 86 of the 153 recalls started in 2003 that had been completed by the end of February 2004 and for which FDA recorded the same unit in the fields for "quantity distributed" and the "quantity recovered/number of units corrected." For the remaining recalls, FDA was missing data in one or both fields, or the fields had different units. For USDA, we were able to include in our analysis 75 of the 77 fiscal year 2003 recalls, because USDA recorded both the quantity distributed and the quantity recovered in pounds.

¹⁶*E. coli* O157:H7 is a virulent strain of *E. coli* bacteria.

using epidemiological evidence, such as outbreaks of foodborne illnesses that are traced back to the food, as a basis for requesting that companies conduct a recall. Because traceback can be slow, recalls linked to illness outbreaks may have low recovery rates.

Recovering perishable foods is particularly challenging because they may be subject to recall after the product's shelf life has passed. As USDA pointed out, it is unlikely that much food will be recovered in these recalls. Figure 3 illustrates the timeline for 4 of the 20 recalls that we examined in depth. Of these 4 recalls, the recall for canned soup began well before the end of the food's shelf life, the recall for packaged turkey sandwiches near the end, and the recalls for fresh-cut bagged lettuce and ground beef well after the recommended shelf life of the product. USDA recall officials pointed out that consumers could have frozen the meat or poultry, so that some of those products could still have been in consumers' homes. FDA also pointed out that the fresh-cut bagged lettuce may have deteriorated in quality, but may still have been edible after its shelf life expired.

Figure 3: Number of Days after Production When Recall Occurred and Expected Shelf Lives for Four Recalls



Source: GAO analysis based on USDA and FDA data.

Note: The recall of canned soup began during the soup's shelf life. The recall of ground beef began after the shelf life because of the time it took to identify the source of the contamination following an illness outbreak. The recall of packaged turkey sandwiches began near the end of the sandwiches' shelf life because the turkey used in the sandwiches was part of an expanded recall conducted by another company. The recall of fresh-cut bagged lettuce began after the shelf life of the lettuce because the food tested positive for listeria after it already had reached store shelves, and the test results were slow to reach the agency and the company.

We relied primarily on the agencies' documents for our analysis. We cannot say with confidence that FDA's Recall Enterprise System accurately depicts actions taken. At the end of our review, we learned that FDA's Center for Food Safety and Applied Nutrition continues to maintain a separate food recall data system and uses that system—not the official Recall Enterprise System—to report recall information to Congress. According to center program staff, FDA uses information from this unofficial data system to report to Congress because the center's system contains the most accurate data. FDA invested more than \$3 million to implement the Recall Enterprise System, which was designed to be a valid and reliable

automated system for capturing information about recalls across FDA's five centers. The system is accessible to FDA staff in both headquarters and district offices. In addition to this substantial investment and the duplication of effort for maintaining two separate data systems, the existence of a second recall data system raises several other concerns:

- The unofficial database reflects a substantial difference in the number of recalls over the period we examined. For example, the unofficial database included 296 food recalls for 2003, while the Recall Enterprise System shows only 207. Some of the difference can be explained because recall counts from the unofficial system are based on the year that FDA assigns a risk classification—typically at the end of the recall—whereas our analysis of Recall Enterprise System data used the year the recall began. FDA was not able to provide us with enough information on the recalls to resolve the differences.
- Data in the two systems were not consistent for individual recalls. For example, the start date and classification date for some recalls did not agree.
- Some fields, such as the date the company completed its recall actions, are in both the Recall Enterprise System and the unofficial system. This is one of the critical dates we recommended in our 2000 report that the agency should track. However, we found that this date was not entered into the Recall Enterprise System for a significant number of recalls—about 20 percent of recalls in 2003.

These problems raise significant questions about the validity and reliability of the official Recall Enterprise System.

USDA and FDA Do Not Promptly Verify That Recalls Reach All Segments of the Distribution Chain

Neither USDA nor FDA acted promptly to carry out verification checks or used a sound methodology for selecting the sample of a company's downstream distribution chain for verification. As a result, the agencies could overlook entire segments of a food's distribution chain, as they did in many of the recalls we examined in detail.

For the 10 USDA recalls from 2003 that we examined in detail, USDA did not have guidance in place with time frames for when agency staff should finish verifying that a company had completed its recall. In addition, USDA does not collect in its data system information on when agency staff begin and finish verification checks. Therefore, we could not calculate how long

USDA took to verify all recalls for the period we reviewed. However, for the USDA recalls, we calculated that district staff took an average of 38 days to verify whether the recalling company's customers were aware of the recall. That length of time exceeds the shelf life of fresh meat and poultry. Furthermore, it delays the agencies' ability to identify problems with the recall and request corrective actions before consumers eat the recalled food.

USDA revised its guidance to its staff in May 2004 and included a risk-based goal for verification activities that considers the class of the recall.¹⁷ Specifically:

- For Class I recalls, district offices should begin verification to determine whether a company carried out the recall within 3 days of the start of the recall and should substantially complete the verification within 10 days thereafter.¹⁸
- For Class II recalls, verification should begin within 5 days and be completed within 12 days.
- For Class III recalls, verification should begin within 10 days and be completed within 17 days.

In contrast, FDA had guidance for beginning and finishing its verification checks during the recalls we reviewed. The total process is to take 20 days: that is, checks are to begin within 10 days of the company's starting a recall and be completed no more than 10 days after checks begin.¹⁹ Because FDA, like USDA, does not collect information on when agency staff begin and finish verification checks in its Recall Enterprise System, we could not assess the extent to which FDA met its time frame for all recalls in 2003. However, we were able to make that determination for the 10 recalls we examined in depth. We found that FDA did not conduct verification checks

¹⁷USDA Food Safety and Inspection Service Directive 8080.1, Revision 4, Attachment 3, May 24, 2004.

¹⁸Had the goal for the Class I recalls been in place during 2003, USDA would have met it for 1 of the 10 recalls that we examined for which USDA conducted checks.

¹⁹FDA's guidance to its staff is provided in chapter 7 of its Regulatory Procedures Manual, March 2004 edition, effective May 6, 2004 (http://www.fda.gov/ora/compliance_ref/rpm/default.htm). Additional industry guidance is also provided in regulation (21 C.F.R. §§ 7.40-7.59).

for 4 of those recalls. For the remaining 6 recalls, we calculated that district staff took an average of 31 days to complete the checks—with 3 recalls taking more than the targeted number of days.

In conducting their verification checks, USDA and FDA told us that they can be hindered in their efforts to initiate verification checks when companies delay in providing their distribution lists or provide imprecise lists. According to FDA, if every customer in a distribution chain takes 2 days to provide its list, even with a short distribution chain, this could add 2 weeks to the verification process. In a May 2003 proposed rulemaking under the Bioterrorism Act, FDA stated that the amount of time it would take FDA to determine where a food is located “may be increased if the [distribution] records are incomplete and FDA has to wait for missing records to be retrieved. This possible delay would be a substantial concern if FDA were attempting to remove [unsafe] food that presents a threat of serious adverse health consequences or death....”²⁰

We also found that the agencies have not been using sound methodologies for selecting the sample of companies in the distribution chain for verification. As part of their recall activities, USDA and FDA decided on what percentage of the recalling company’s primary and secondary customers they would contact to determine whether the customers were aware of the recall and had removed the food from the marketplace according to the recalling company’s instructions. If the downstream customers they checked were aware and had removed the food, USDA and FDA generally considered the food recall effective.

Both USDA’s and FDA’s recall procedures include methodologies for conducting verification checks. Although USDA revised its procedures in May 2004, the practice that was in effect during the recalls we reviewed was for district staff to contact at least 20 percent of primary customers and 10 percent of secondary customers. We found that the districts’ understanding, and therefore implementation, of that practice varied, with some districts saying that, for example, they were to check 10 percent of primary customers and others saying they were to check 20 percent. As table 1 shows, for the 10 Class I recalls we examined, USDA checked between 14 and 100 percent of primary customers.

²⁰68 Fed. Reg. 25188, see footnote 12.

The procedures that FDA used are based on regulations that specify five different verification levels—0, 2, 10, between 10 and 100, or 100 percent.²¹ However, the regulations and FDA's procedures do not specify when to use different levels of verification. FDA officials told us that district staff would generally not do any checks when they believe the food is no longer on store shelves or when the company can demonstrate that it is doing the verification checks. Agency recall officials said that they select a level depending on the size of the distribution chain and the risk associated with the recalled product. As table 1 shows, for the 10 FDA Class I recalls we examined in detail, FDA checked from 0 to 100 percent of primary customers. In 4 recalls, FDA determined that no verification checks were needed. Appendix V provides USDA's and FDA's recall identification numbers for the 20 recalls we examined.

Table 1: USDA and FDA Verification Rates for 20 Selected Class I Recalls in 2003

Agency	Food	Reason for recall	Primary customers		
			Number checked	Total number	Percentage of total
USDA	Fresh ground beef	<i>E. coli</i>	7	15	47
	Chicken frankfurters	Listeria	9	24	38
	Ground beef	<i>E. coli</i>	4	12	33
	Fully cooked frozen chicken	Hard piece of plastic ^a	8	14	57
	Fresh and frozen ground beef	<i>E. coli</i>	51	84	61
	Fresh and frozen ground beef	<i>E. coli</i>	18	30	60
	Frozen ground beef	<i>E. coli</i>	41	129	32
	Fresh and frozen ready-to-eat turkey and chicken	Listeria	103	757	14
	Fresh and frozen ready-to-eat turkey and chicken	Listeria	47	144	33
	Canned soup	Cheese ^b	1	1	100

²¹21 C.F.R. § 7.42(b)(3)(i)-(v)(2004).

(Continued From Previous Page)

Agency	Food	Reason for recall	Primary customers		
			Number checked	Total number	Percentage of total
FDA	Crab cakes	Milk ^b	22	34	65
	Ice cream	Peanuts ^b	1	1	100
	Salted herring	Botulinum spores	2	8	25
	Oregano	Salmonella	0	11	0 ^c
	Fresh-cut bagged lettuce	Listeria	0	79	0 ^d
	Packaged turkey sandwiches	Listeria	0	2,700	0 ^e
	Alfalfa sprouts	Salmonella	14	25	56
	Smoked salmon	Listeria	12	107	11
	Packaged breakfast pastry	Egg ^b	0	341	0 ^f
	Chocolate milk	Excessive amounts of vitamins A and D	4	53	8

Source: GAO summary of USDA and FDA data and documents.

^aThe hard piece of plastic was considered to be foreign material.

^bThe presence of a potential allergen (cheese, milk, peanuts, or eggs) was not declared on the food's ingredient label.

^cFDA did not conduct checks because the recalling company recovered 100 percent of the distributed oregano.

^dFDA did not conduct checks because the bagged salad was 2 weeks past its expiration date, and it concluded that the salad was not likely to be available on store shelves.

^eFDA did not conduct checks because the recalling company documented that it visited each of its customers and recovered sandwiches.

^fFDA did not conduct checks because the recalling company used a third-party vendor to contact 100 percent of the primary customers, and the company faxed timely status reports to update the agency.

USDA and FDA were limited in their ability to reasonably ensure that recalls were effective because their methodologies did not take into account the complexities of downstream distribution chains. In the recalls we examined, USDA and FDA generally obtained the recalling company's primary distribution lists and then checked a percentage of the customers on those lists. The agencies then obtained customer lists only from the primary customers that they checked, which enabled them to identify secondary customers associated with the primary customers that they checked. Because the agencies did not usually check all primary customers, they were not aware of all secondary customers. As a result, the agencies may have overlooked whole segments of a distribution chain with their verification checks. That is, even when the agencies conducted the recommended percentage of verification checks, they may not have conducted enough checks across the distribution chain to be able to determine whether the recall was effective.

Moreover, USDA's Office of Inspector General issued a report in June 2004 that was critical of USDA's verification process.²² That report recommended that USDA's Food Safety and Inspection Service document its recall effectiveness determinations, implement controls to ensure the data are valid, and conduct future effectiveness checks in a timely and methodologically sound manner.

In the future, however, USDA's verification checks may help the agency better ascertain whether a recall was effective because USDA adopted new verification guidance in May 2004. If properly implemented, this guidance will provide greater assurance that downstream customers are aware of a recall and have followed the recalling company's instructions for removing the food from the marketplace. USDA's new guidance provides a statistical, risk-based method that considers the class of recall, any illnesses associated with the food, and the number of customers in the distribution chain. Specifically, the guidance sets standards for the (1) number of checks to conduct, (2) method for sampling which customers to check, (3) method for conducting the checks (e.g., on-site visits or telephone calls), and (4) critical number of verification checks, finding that customers were not aware of the recall, beyond which USDA determines that the recall process was inadequate and warrants further action by the recalling company. In addition, the guidance provides time frames for completing these checks.

For example, for a Class I recall with associated illnesses and a distribution chain that included 1,000 customers, USDA would select 200 customers by checking every fifth customer and consider the recall ineffective if it found any customers that were not notified of the recall or that still had food that could reach consumers. USDA also would begin checks within 3 days of the recall's start and finish checks within 10 days thereafter. USDA's new approach is similar to the one that the Canadian Food Inspection Agency has used since 2001.

FDA's verification approach also does not ensure that a reasonable number of downstream customers are aware of a recall and have taken the appropriate action. While FDA's policy is to determine the percentage of downstream customers to contact on the basis of the size and the risk

²²U.S. Department of Agriculture, Office of Inspector General, *Food Safety and Inspection Service: Effectiveness Checks for the 2002 Pilgrim's Pride Recall*, Report No. 24601-03-Hy (June 2004).

associated with the recall, we found that the agency lacks methods for consistently determining which level of checks—the percentage of the downstream customers—to use in verifying a given recall. FDA’s verification approach also lacks other features of a risk-based methodology, such as considering whether illnesses have resulted from the unsafe food or criteria for whether to consider the recall ineffective.

Agencies and Consumer Groups Differ in Their Views on the Effectiveness of Public Notification

More than 200 Class I food recalls occurred in 2003, but the procedures USDA and FDA use to alert consumers to a recall—press releases and Web postings—may not be effective. Both USDA and FDA rely on press releases as their main tool to alert consumers to the dangers of recalled foods. Both agencies also make recall press releases available on their Web sites as a service to consumers; the media; and other interested parties, such as state and local health officials.

Views on the usefulness of the agencies’ efforts to communicate with the public differ, according to the officials and organizations we interviewed. For example, a California State health official expressed concerns that the frequency of recall press releases can overwhelm the public. Nevertheless, the official thought that press releases from a government entity are given more weight by consumers and the media than press releases issued by individual food companies; hence, that USDA-issued press releases may have greater impact than company-issued press releases (for FDA-regulated foods).

Public interest groups presented a different view. According to the Center for Science in the Public Interest and the Consumer Federation of America, most press releases are not useful to consumers because the releases lack the specificity, such as store locations, that consumers need to help them determine whether they purchased the food that is being recalled. According to these officials, if industry and government want consumers to avoid eating a recalled food, information about the recall should be prominently displayed in the grocery stores that sold the food. We identified some stores that voluntarily provide additional information to help consumers, including a membership warehouse that uses member information from its “shoppers’ club” to directly contact its customers who purchased a recalled food.

According to USDA and FDA officials, the agencies generally do not have the authority to publicly name the retail stores that are selling a recalled food because the information is considered confidential business information. For example, USDA provided a distribution list of the recalled beef products to the California Department of Health Services during the December 2003 recall of beef potentially contaminated with BSE.²³ Although California could use the list to help its inspectors ensure that the meat was removed from store shelves, the state had to agree not to publicly identify the stores and restaurants where the recalled beef was sold. USDA and FDA officials told us that they plan to look into additional options to help consumers identify recalled foods in their homes.

Even if the agencies could disclose store locations, consumers may still not be able to identify the recalled food. As USDA pointed out, consumers may have difficulty identifying a recalled food because packaging may change at different points in the distribution chain, especially for such foods as ground beef, which may be mixed with other meat or further processed into prepared foods such as frozen lasagna, canned ravioli, or ready-to-eat sandwiches. In such instances, recalling companies may not know how their downstream customers have processed or distributed these foods.

Other Government Agencies Have Recall Authority Not Available to USDA and FDA for Food That May Better Protect Consumers

Government agencies that regulate the safety of other products, such as toys and automobile tires, have recall authority not available to USDA and FDA for food and have had to use their authority to ensure that recalls were conducted when companies did not cooperate. These recall authorities may facilitate faster recalls and better protect consumers.

Agencies that have recall authority for other products include the following:

²³According to USDA, distribution lists obtained from a firm recalling a meat or poultry product are considered proprietary information protected from public disclosure. However, a USDA regulation authorizes limited disclosure, under certain conditions, to states and other federal government agencies to verify removal of a recalled food. 9 C.F.R. § 390.9(2004).

-
- FDA, for infant formula, human biological products, medical devices and radiation-emitting electronic products, human drugs, animal drugs, and medicated animal feeds;²⁴
 - the Consumer Product Safety Commission, for many consumer goods; and
 - the Department of Transportation's National Highway Traffic Safety Administration, for motor vehicles, motor vehicle equipment, child safety seats, and tires.

In addition, the Canadian Food Inspection Agency has recall authority for foods sold in Canada.²⁵

Table 2 compares USDA's and FDA's food recall authority with the authority of agencies responsible for recall programs of other products we examined, and appendix VI provides additional information for the programs we examined.

²⁴Some human biological products are approved for use through "new drug" applications and are treated as human drugs for recall purposes. Likewise, some human drugs are licensed under the same procedures as human biological products and are treated as human biological products for recall purposes.

²⁵In April 1997, regulatory responsibility for food safety in Canada was consolidated into a single agency, the Canadian Food Inspection Agency.

Table 2: Recall Authority of Selected Government Agencies

Agency	Products covered	Requirement to notify the agency when a company identifies a potentially unsafe product	Authority to issue a mandatory recall order ^a	Authority to establish recall requirements or approve recall plans	Authority to impose monetary penalties or seek fines or imprisonment
USDA					
	Meat, poultry, egg products	No	No	No	^b
FDA					
	Foods not exclusively regulated by USDA	No	No	No	^b
	Infant formula	Yes	Yes	Yes	Yes
	Human biological products	Yes	Yes	Yes ^c	Yes
	Medical devices, radiation-emitting electronic products	Yes	Yes	Yes	Yes ^d
	Human drugs	Yes	No	No	Yes
	Animal feed	No	No	No	^b
	Animal drugs, medicated feeds	Yes	No	No	Yes
Consumer Product Safety Commission	Consumer goods ^e	Yes	Yes	Yes ^f	Yes
National Highway Traffic Safety Administration	Motor vehicles, motor vehicle equipment, child safety seats, tires	Yes	Yes	Yes ^g	Yes
Canadian Food Inspection Agency	Food	No	Yes	Yes ^h	Yes

Source: GAO analysis of applicable laws and regulations.

^aFor the purposes of this report, we define a “mandatory recall order” to include the requirement to remove, repair, replace, or refund the cost of a defective or unsafe product.

^bNot applicable because no recall requirements exist.

^cFDA’s recall authority for licensed biological products is found in section 351(d) of the Public Health Service Act (42 U.S.C. § 262(d)) and has not been elaborated on in implementing regulations.

^dFDA’s authority to assess civil monetary penalties depends on the nature of the device violation. For example, penalties are authorized only for significant or intentional failures to file required reports. 21 U.S.C. § 333(g)(1).

^eThe Consumer Product Safety Commission’s jurisdiction does not cover tobacco, motor vehicles and related equipment, pesticides, firearms, aircraft, boats, food, drugs, medical devices, or cosmetics. 15 U.S.C. § 2052(a)(1) (definition of “consumer product”).

^fWhile the manufacturer, retailer, or distributor may choose to repair, replace, or refund the cost of the defective product, the Consumer Product Safety Commission may require submission of a plan “satisfactory to the Commission, for taking action...” 15 U.S.C. § 2064(d).

^gWhile the manufacturer may repair, replace, or refund the cost of defective products, the National Highway Traffic Safety Administration may order a manufacturer to take a specific action if the manufacturer’s remedy is determined to be inadequate. 49 U.S.C. § 30120(e).

^hThe applicable Canadian statute is general and there are no implementing regulations. This information is largely based on our discussions with Canadian officials.

As table 2 shows, in contrast to USDA and FDA, the other agencies we examined, and FDA with regard to some products, have authority to order recalls and to be notified about unsafe products. Specifically, they have authority to (1) require a company to notify the agency when it has distributed a potentially unsafe product; (2) order a recall; (3) establish recall requirements; and (4) impose monetary penalties, or seek fines or imprisonment, if a company violates the recall requirements. These authorities are discussed below:

- *Requirement that a company notify the agency when the company identifies a potentially unsafe product.* Companies manufacturing or selling products regulated by some of the agencies we reviewed are subject to stringent notification requirements. For example, companies that manufacture consumer products, such as toys or appliances, must notify the Consumer Product Safety Commission immediately, generally within 24 hours of obtaining information that reasonably supports the conclusion that a product could create an unreasonable risk of serious injury or death, such as a toy that poses a choking danger to children. Also, if a manufacturer of infant formula has information indicating that the formula it processed does not contain the required nutrients or is otherwise adulterated, the manufacturer must promptly notify FDA.

-
- *Authority to order a company to conduct a recall if the company refuses to do so voluntarily.* Several agencies can order a company to conduct a recall if the company refuses to do so voluntarily. For example, the Canadian Food Inspection Agency, after determining that there are reasonable grounds to believe that a product poses a risk to public health, can order anyone selling, marketing, or distributing the food to conduct a recall. The Canadian agency rarely has had to use its recall authority. Agency officials told us that, as of April 2004, the agency had used its mandatory authority for eight recalls since 1997. For the period of 1997 through 2003, the agency reported that Canadian companies had conducted 1,890 recalls.²⁶ Likewise, FDA has authority to order recalls of unsafe biological products and medical devices and has used this authority in the past.
 - *Authority to establish recall requirements or approve recall plans, including direct notification to consumers.* Some agencies we reviewed have authority to establish recall requirements, such as requiring direct notification to consumers or prescribing a recall plan if voluntary efforts are insufficient. For example, the National Highway Traffic Safety Administration may require companies to speed up a recall or renotify owners, purchasers, and dealers in a manner prescribed in regulation if it determines that the initial notice was not effective. FDA has authority to review the terms of a company's recall plan for recalls of medical devices to ensure that the way the company proposes to fix the problem sufficiently addresses the risk. If FDA determines that the company's recall plan is insufficient, FDA can prescribe a recall plan that may include repairing the device, replacing it, or refunding its cost. Also, if FDA determines that a device recall is warranted, it must specify a timetable for the recall and require periodic reports. In addition, for infant formula, a recalling firm must submit to FDA in writing an evaluation of the hazard, a recall strategy, and all recall communications.
 - *Authority to impose monetary penalties or seek fines or imprisonment if a company violates recall requirements.* Most agencies we examined have the authority to impose civil monetary penalties or seek fines or imprisonment when companies either refuse to conduct recalls or fail to follow recall requirements. For example,

²⁶These recall counts are for the Canadian fiscal years 1997-98 through 2002-03. The Canadian fiscal year runs from April 1 through March 31.

failure to obey an FDA order to recall a biological product that poses an imminent hazard to public health could result in monetary penalties of \$100,000 or more. Similarly, the Consumer Product Safety Commission can impose monetary penalties of \$7,000 for each product violation, up to \$1.65 million for related violations, if a company fails to notify the commission promptly, in accordance with the applicable law and regulations.

Officials in FDA, the Consumer Product Safety Commission, and the National Highway Traffic Safety Administration, as well as Canadian officials, told us that companies generally cooperate in recalls. Nonetheless, the agencies have had to use the additional authority in some instances to ensure that recalls are conducted promptly and completely.

USDA and FDA officials told us that while they believe companies generally cooperate with food recalls, they recognize that in some instances, recalls can be particularly challenging. For example, when the food company has gone out of business or when the company is located overseas.

Conclusions

USDA and FDA are responsible for ensuring the safety of the food supply. While we recognize that they have limited recall authority, we believe the agencies can do better in carrying out their food recall programs. Consumers may be vulnerable to serious illness, hospitalization, and even death, in part, because of weaknesses in USDA's and FDA's programs for monitoring companies' recalls of unsafe food. Although no single weakness may be directly linked to serious health consequences in the recalls we examined, these weaknesses may have contributed to the lengthy recall of unsafe food and, consequently, to relatively little recovery of the food.

USDA and FDA could address these weaknesses—lack of time frames for company actions, ineffective use of their data systems to monitor and manage recalls, a verification system that does not ensure the timeliness and completeness of a recall, and potentially ineffective consumer notification—by modifying their existing programs. Indeed, with its new risk-based, scientific verification procedures, USDA has taken positive steps to improve its verification processes—the agencies' primary method for ensuring an effective recall. FDA continues to rely on a flawed process.

We are also concerned about the quality of data in FDA's Recall Enterprise System—its official recall data system. FDA continues to maintain

information about food recalls in its unofficial data system. The two systems do not contain the same information, which raises questions about the validity and reliability of the official system and reports FDA issued to Congress. Moreover, FDA's investment in developing the Recall Enterprise System will not be entirely realized until the agency fully implements it as the sole system for collecting and managing recall data.

We believe that addressing the problems we have identified could raise the likelihood that recalled food will be removed from the marketplace more promptly and completely. However, these corrective steps, while necessary, will still leave fundamental vulnerabilities because the agencies lack specific recall authority available to other agencies with consumer safety responsibilities. Although we did not identify any instances in which companies refused to carry out a food recall, such refusal is possible, as Canada's experience has indicated. As in Canada, USDA and FDA may not need this authority for most recalls, but if enacted, it would be available when needed.

Matters for Congressional Consideration

To ensure that USDA and FDA have information and authority so they can act quickly to remove potentially unsafe food from the marketplace and can better protect consumers, we propose that Congress consider legislation that would

- require a company to notify the responsible agency when it becomes aware that a food it has distributed is unsafe and
- give USDA and FDA authority to (1) issue a mandatory recall order, (2) establish recall requirements, and (3) impose monetary penalties or seek fines or imprisonment for failing to follow food recall requirements.

Recommendations for Executive Action

To ensure that companies promptly and effectively recall foods that may cause serious illness or death, we are making the following five recommendations to the Secretary of Agriculture and the Commissioner of FDA:

- revise agency guidance to recalling companies to include specific time frames for notifying their customers, removing recalled food from the

marketplace, and providing the agencies with the names and locations of customers that received the food;

- use agency data systems to routinely generate reports for recall program managers so that they may monitor ongoing recalls and oversee recall timeliness and effectiveness;
- track in their recall data systems the dates that companies (1) start and finish notifying their customers, (2) provide the agency with the lists of customers that received the food, and (3) start and finish recovering the recalled food;
- track in their data systems the dates that the agencies start and finish verification checks; and
- work jointly to determine what, if any, additional approaches are needed for alerting consumers about recalls.

We also make the following four recommendations to the Commissioner of FDA:

- revise guidance to agency staff to include risk-based time frames for completing verification checks promptly;
- develop a sound methodology for district staff to verify that companies have quickly and effectively carried out recalls;
- when tracking the amount of food recalled and recovered for individual recalls, use the same units of measure to facilitate calculations of the recovery rate; and
- direct the recall staff to use FDA's Recall Enterprise System as the sole data system to capture recall information, manage food recalls, and generate reports to Congress.

Agency Comments and Our Evaluation

We provided USDA and FDA with a draft of this report for review and comment. We also provided segments of the draft describing their respective recall authority and rules to the Consumer Product Safety Commission, the National Highway Traffic Safety Administration, and the Canadian Food Inspection Agency.

USDA stated that the report was generally factually correct. However, it characterized as “alarmist” the report’s statement that “Consumers may be vulnerable to serious illness, hospitalization, and even death because of weaknesses in USDA’s and FDA’s programs for monitoring companies’ recalls of unsafe food.” We recognize that the cause of the illnesses, hospitalizations, and deaths was contaminated food not the agencies’ programs. However, because the public is relying on USDA and FDA to protect consumers from potentially unsafe food, it is important that the agencies’ recall programs be as effective as possible. As our report points out, two large recalls in 2003 were associated with nearly 100 hospitalizations or serious illnesses and 8 deaths. Both of those recalls, monitored by USDA, were expanded to more and more customers and, therefore, it took some time to locate and recover the food. USDA’s Inspector General reported that during one of the two recalls, USDA’s field staff took longer than 4 months to complete their verification checks. The Inspector General’s report concluded that the department did not identify and correct problems with the recall to maximize recovery and take enforcement actions—potentially exposing consumers to unsafe meat. USDA further said that it believes the new procedures adopted on May 24, 2004, will address most of the observed weaknesses we found in its food recall program. As our report discusses, the new procedures do provide a statistical, risk-based method that will provide greater assurance that downstream customers are aware of recalls and that they have followed instructions for removing food from the marketplace, and the procedures include time frames for USDA to complete its verification checks. While the new procedures should improve USDA’s verification of recalls, it is premature to tell whether they will address any other weaknesses we found in USDA’s recall program. Thus we continue to believe that our recommendations—for (1) time frames for recalling companies’ actions—to encourage prompt recalls—and companies’ disclosure of the locations where they sent the food, (2) using routinely generated management reports from the official recall data system, (3) tracking critical dates, or (4) working with FDA on how best to alert consumers about recalls of food that can cause serious illnesses—are needed to further strengthen the safety of the food supply by providing for a more effective food recall system. Finally, USDA said the report implies that the Consumer Product Safety Commission’s and the National Highway Traffic Safety Administration’s recall authorities and procedures offer better protection to consumers but does not discuss how long those agencies work with companies before they announce recalls. We did not independently evaluate the effectiveness of the other agencies’ recall programs nor did we imply that they were faster or better. Our point in discussing those

programs is to show that they (1) have additional recall authority not available to USDA and FDA for food and (2) have had to use their recall authority. We also note that USDA has supported, as recently as late 2000, proposed legislation that would have given the department the additional recall authority that those other agencies have at their disposal, if and when they need it.

FDA stated that our report did not demonstrate that FDA recalls were lengthy because of system inefficiencies or that weaknesses in FDA's recall process resulted in little recovery of food. We believe our report accurately presents the current recall system's performance. The report describes significant inefficiencies and weaknesses in FDA's verification process that resulted in delays in identifying and correcting problems in the recalls we examined. For example, in 3 of the 10 recalls we examined, FDA took longer than its 20-day target for completion of verification checks. In addition, FDA noted that, "companies are encouraged to initiate action as soon as possible and strongly encouraged to issue press releases within 24 hours of deciding to recall a product." FDA further stated that its expectation of a recalling firm is immediate notification, timely removal, and timely disposal. While such statements are appropriate, we did not find that they were effective. Furthermore, FDA asserts that we did not present evidence to support our point that information in its unofficial recall database is inaccurate. Our concern is twofold. First, maintaining two separate recall databases is an inefficient use of resources, especially when FDA cited resource limitations as a factor for not yet incorporating routine management reports in its Recall Enterprise System. Second, since we identified inconsistencies in the information in the two systems, the validity and reliability of the official system is in question. FDA agreed with our recommendations regarding using the Recall Enterprise System to generate routine management reports and eliminating the duplicative recall database. However, it disagreed with our recommendation regarding the need for specific time frames for companies' actions and noted that it would be difficult to specify such time frames. We believe time frames are critical to reinforce the urgency with which companies need to act, particularly for Class I recalls where even 1 day's delay can result in additional serious health consequences. Also, FDA sees limited utility in our recommendations for recording the dates of company and agency actions in its Recall Enterprise System. We continue to maintain that these dates are essential for FDA to effectively monitor ongoing recalls and assess actions to improve the timeliness of recalls.

USDA's written comments and our more detailed responses to them are in appendix VII. FDA's written comments and our responses are in appendix VIII. In addition, USDA, FDA, the Consumer Product Safety Commission, the National Highway Traffic Safety Administration, and the Canadian Food Inspection Agency provided technical comments, which we incorporated into the report as appropriate.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from its issuance. At that time, we will send copies of this report to interested congressional committees, the Secretary of Agriculture, the Commissioner of Food and Drugs, and other interested parties. We will make copies available to others upon request. In addition, the report will be available at no charge on GAO's Web site at <http://www.gao.gov>.

If you or your staff have any questions about this report, please call me at (202) 512-3841. Key contributors to this report are listed in appendix IX.



Lawrence J. Dyckman
Director, Natural Resources and Environment

Objectives, Scope, and Methodology

This report (1) examines the extent to which the U.S. Department of Agriculture's (USDA) and the Food and Drug Administration's (FDA) recall programs protect consumers from unsafe foods and (2) compares USDA's and FDA's authority to conduct food recalls with the recall authority of agencies responsible for the safety of other consumer products, such as toys, medical devices, and automobiles. This report also provides information on USDA's and FDA's efforts to identify and recall foods associated with the December 2003 cow infected with bovine spongiform encephalopathy (BSE), otherwise known as mad cow disease, found in Washington State (see app. II) and information on a 2002 recall of ground beef by a ConAgra plant in Greeley, Colorado (see app. III).

To determine the extent to which USDA and FDA recall programs have adequately protected consumers from unsafe foods, we studied the agencies' recall procedures and analyzed in depth agency actions during 20 recent recalls—10 from USDA and 10 from FDA. The 20 we selected were ongoing in fiscal year 2003 and were Class I recalls—that is, those with the potential to cause serious illness or death. We systematically selected recalls in order to cover (1) a wide range of food products, (2) different types of contaminants, and (3) geographical locations. Priority was given to large recalls of foods that were widely distributed. However, recalls were not randomly selected and therefore are not statistically representative of all food recalls conducted in fiscal year 2003. In reviewing these 20 recalls, we examined USDA and FDA documents, including verification records, and interviewed company and agency officials responsible for monitoring them. In addition, we obtained USDA and FDA aggregate recall data for 2003 and examined the reliability of information in those systems. We also analyzed data from USDA's recall database and relied on FDA to extract similar data from its recall data systems. We obtained the computerized files for these recalls and summarized the Class I recalls by year. Additionally, we interviewed USDA and FDA district and headquarters officials responsible for maintaining their recall data systems to determine how they collect recall information and add it to their data systems.

To understand whether consumers are adequately informed of food recalls and to get perspectives on measures that could affect the timeliness and effectiveness of recalls, we interviewed representatives from the food industry; trade associations; and consumer advocacy groups, including Costco, the American Meat Institute, the Center for Science in the Public Interest, and the Consumer Federation of America. To determine the amount of product recovered per year for USDA, we relied on agency data to compare the pounds of product distributed with the pounds of product

recovered. To calculate the amount of product recovered for FDA in 2003, we compared the database fields for “product distributed” and “product recovered” for those recalls with identical units in the database fields.

To compare USDA’s and FDA’s authority to conduct food recalls with the recall authority of agencies responsible for the safety of other consumer products, such as toys, medical devices, and automobiles, we reviewed and compared FDA’s and other agencies’ statutes and regulations. We identified the agencies that have mandatory recall authority by conducting literature and Internet searches and by asking officials at USDA and FDA. We also reviewed the transcript of proceedings from the December 12, 2002, USDA public meeting “Food Safety and Inspection Service Public Meeting—Improving the Recall Process.” We selected the following agencies and products, which account for a substantial share of major consumer goods:

- FDA, for infant formula, human biological products, medical devices and radiation-emitting electronic devices, human drugs, animal feed, animal drugs, and medicated feeds;
- Consumer Product Safety Commission, for many consumer goods; and
- Department of Transportation’s National Highway Traffic Safety Administration, for motor vehicles, motor vehicle equipment, child safety seats, and tires.

In addition, we included the Canadian Food Inspection Agency, which has regulatory responsibility, including mandatory recall authority, for food sold in Canada. We did not include the following agencies because they have a narrower scope: the U.S. Coast Guard, for boats, boating equipment, and floatation devices; the Environmental Protection Agency, for pesticides and emission control devices; and the Department of Housing and Urban Development, for manufactured housing.

To conduct our comparison, we first focused on USDA’s and FDA’s authority to detain and seize unsafe food and then reviewed laws authorizing other agencies to require companies to take specific recall actions. We also examined the laws requiring manufacturers and other companies to notify the appropriate agency when they become aware of unsafe products. To gain insight on how different authorities are applied in practice, we interviewed agency officials, using a standard set of questions, from USDA’s Food Safety Inspection Service; FDA’s Centers for Food Safety and Applied Nutrition, Biologics Evaluation and Research, Devices

and Radiological Health, Drug Evaluation and Research, and Veterinary Medicine; the Consumer Product Safety Commission; the National Highway Traffic Safety Administration; and the Canadian Food Inspection Agency. We compared the results of the legal review and interviews to identify authority and related legal requirements of other agencies helpful in the administration of recalls that are not available to USDA and FDA for food recalls.

To examine the voluntary recall of beef products associated with the December 2003 discovery of an animal infected with BSE, we analyzed the distribution lists USDA collected from companies and the verification checks it conducted to develop a diagram illustrating the location and volume of recalled beef that reached different levels of the distribution chain. We compared the distribution lists and verification checks to identify how many customers listed on the distribution lists did not receive the recalled beef and the number of customers not listed on distribution lists that received the recalled beef. We interviewed USDA and FDA staff involved with the recall to understand the timing of recall actions and the challenges encountered during the recall.

To develop information on the 2002 recall of ground beef by a ConAgra plant in Greeley, Colorado, we reviewed USDA's recall file and other documents on the recall. We also met with the department's Office of Inspector General and reviewed the Inspector General's September 2003 report.¹

We conducted our review from May 2003 through August 2004 in accordance with generally accepted government auditing standards.

¹U.S. Department of Agriculture, Office of Inspector General, Great Plains Region Audit Report: *Food Safety and Inspection Service: Oversight of Production Process and Recall at ConAgra Plant (Establishment 969)*, Report No. 24601-2-KC (September 2003).

Federal Actions Associated with the Discovery of an Animal in the United States Infected with BSE

On December 23, 2003, USDA announced that a cow in the state of Washington had tested positive for BSE—commonly referred to as mad cow disease. This appendix describes the actions USDA took to recall the meat and the actions FDA took with respect to FDA-regulated products, such as animal feed and cosmetics, made from rendered parts of the animal.

Beef Recall Was Triggered by a BSE-Positive Sample from One Cow

On December 9, 2003, the recalling company slaughtered 23 cows. USDA, in accordance with its BSE surveillance policy at the time, took a sample of 1 cow that was unable to walk, although the condition of the tested cow is now disputed. USDA did not process the sample in its Ames, Iowa National Veterinary Services Laboratory in an expedited manner because the cow did not show symptoms of neurological disorder. USDA test results indicated a presumptive positive for BSE on December 23, 2003.

Recall Begun in December 2003 Was Completed in March 2004

On December 23, 2003, after learning about the positive BSE test, USDA headquarters notified the Boulder District Office, which is the field office with jurisdiction over the recalling firm. The Boulder District began gathering information about the recalling company's product distribution. Field staff telephoned the recalling company and were on-site at 7:00 p.m. The Boulder District initially thought 3 days of the recalling company's production would have to be recalled, but further examination of facility cleanup and shipping records revealed that it was only necessary to recall 1 day of production. USDA recall staff convened at 9:15 p.m. and discussed the science related to BSE and whether the recalling company's cleanup practices were sufficient to limit the recall to 1 day of production. Following USDA's determination to conduct a Class II recall—that is, the beef posed a remote possibility of adverse health consequences—USDA contacted the recalling company to discuss recall details and the press release. The press release and Recall Notification Report were released that evening.

On December 24, 2003, USDA's Food Safety and Inspection Service (FSIS) sent inspectors to the recalling company's primary customers to obtain secondary customer distribution lists and product shipping records. USDA conducted 100 percent verification checks for this recall—it contacted every customer that received the recalled meat. This level of verification checks is well above the percentage of checks conducted by USDA district offices for the Class I recalls we reviewed.

On December 26, 2003, USDA began checking the primary and secondary customers of the recalling company that it was aware of, although the entire product distribution chain was unknown. During the checks, USDA tried to determine if the product was further distributed, and it used verification checks to acquire distribution lists for secondary and tertiary customers of the recalling company.

Verification checks continued until February 25, 2004. Three USDA districts conducted these verification checks. The Boulder District coordinated the checks and assigned checks to the Minneapolis District Office for customers in Montana and to the Alameda District Office for customers in California. USDA required that 100 percent of the primary checks, 50 percent of the secondary checks, and 20 percent of the tertiary checks be conducted on-site. According to USDA, more than 50 percent of the secondary checks were actually conducted on-site. FDA officials helped conduct verification checks. According to USDA, the recall took a long time to complete because USDA contacted each customer at least twice. USDA first contacted each customer to conduct the check and again to verify product disposition.

On February 25, 2004, the Boulder District concluded that the recall was conducted in an effective manner. On March 1, 2004, USDA's Recall Management Division recommended that the agency terminate the recall, and USDA sent a letter to the recalling company to document that USDA considered the recall to be complete.

**Recall Was
Complicated by
Inaccurate Distribution
Lists and Mixing of
Potentially
Contaminated and
Noncontaminated Beef**

USDA used distribution lists and shipping records to piece together where the recalled product was distributed. According to USDA, one of the recalling company's three primary customers was slow in providing its customer list. USDA could not begin verification activities for that primary customer without this list. Furthermore, some customers of the recalling company provided USDA with imprecise lists that did not specify which customers received the recalled product. As a consequence, USDA could not quickly determine the scope of product distribution and had to take time conducting extra research using shipping invoices to determine which specific customers received the product.

Even when USDA determined the amount and location of beef, the agency still had trouble tracking the beef in certain types of establishments, such as grocery store distributors. USDA could not easily track the individual stores where those distributors sent the beef because of product mixing

Appendix II
Federal Actions Associated with the
Discovery of an Animal in the United States
Infected with BSE

and the distributors' record-keeping practices. Generally, distributors purchase beef from multiple sources, mix it in their inventory, and lose track of the source of the beef they send to the stores that they supply. To deal with this problem, USDA first identified the dates when recalled beef was shipped to the distributors and then asked for a list of the stores that were shipped any beef after those dates. Consequently, some stores were included in the recall that may never have received recalled beef.

The recall was also complicated by repeated mixing of recalled beef with nonrecalled beef, thereby increasing the amount of meat involved in the recall. The recalling company slaughtered 23 cows on December 9, 2003, and shipped those and 20 other carcasses to a primary customer on December 10, 2003. The recalling company's carcasses were tagged to identify the slaughter date and the individual cow. The primary customer removed the identification tags and mixed the 23 recalled carcasses with the 20 nonrecalled carcasses. Because the carcasses could not be distinguished, the recall included all 43 carcasses at the primary customer. After one round of processing at the primary customer, the meat from the carcasses was shipped to two other processing facilities. Both establishments further mixed the recalled meat from the 43 carcasses with meat from other sources. In all, the mixing of beef from 1 BSE-positive cow resulted in over 500 customers receiving potentially contaminated beef.

Imprecise distribution lists and the mixing of recalled beef combined to complicate USDA's identification of where the product went. Specifically, on December 23, 2003, USDA's initial press release stated that the recalling company was located in Washington State. Three days later, on December 26, 2003, USDA announced that the recalled beef was distributed within Washington and Oregon. On December 27, 2003, USDA determined that one of the primary customers of the recalling firm distributed beef to facilities in California and Nevada, in addition to Washington and Oregon, for a total of four states. On December 28, 2003, USDA announced that some of the secondary customers of the recalling company may also have distributed the product to Alaska, Montana, Hawaii, Idaho, and Guam, for a total of eight states and one territory.

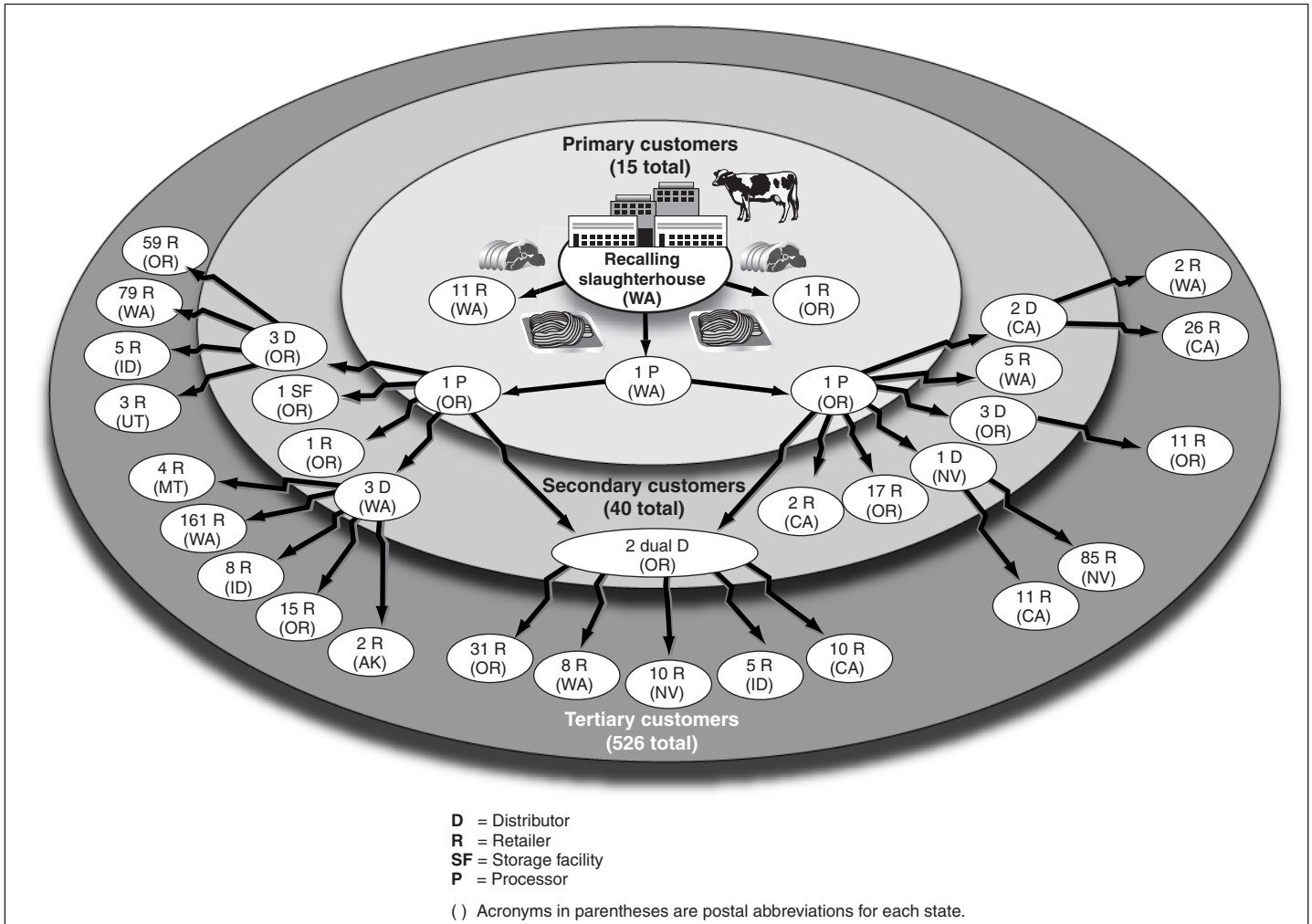
On January 6, 2004, over 2 weeks from recall initiation, USDA determined that the beef went to only six states—Washington, Oregon, California, Nevada, Idaho, and Montana—and that no beef went to Alaska, Hawaii, or Guam. To reach that conclusion, USDA used the distribution lists, shipping records, and sales invoices that it received from companies to piece together exactly where the recalled beef may have been sent. The lists

Appendix II
Federal Actions Associated with the
Discovery of an Animal in the United States
Infected with BSE

showed that 713 customers may have received the recalled beef; 6 of those may have received beef from more than one source. USDA determined that 176 customers on the lists did not actually receive recalled beef, including the customers in Guam and Hawaii. USDA's review also indicated that recalled beef was probably not shipped to Alaska or Utah, and USDA checked 2 retailers in Alaska and 3 retailers in Utah to confirm that was the case. In total, USDA conducted verification checks on 537 of the 713 customers on the lists. USDA's initial checks identified an additional 45 customers that may have received the recalled beef that were not included on the distribution lists, for a total of 582 verification checks. Figure 4 summarizes USDA's verification efforts during the recall.

Appendix II
Federal Actions Associated with the
Discovery of an Animal in the United States
Infected with BSE

Figure 4: USDA's Recall Verification Checks by Location and Customer Type for Meat Associated with the Animal Infected with BSE



Source: GAO analysis of USDA verification check documents.

Note: USDA checked 15 primary, 40 secondary, and 526 tertiary customers plus the recalling company, for a total of 582 verification checks.

USDA's press release stated that the recall involved 10,410 pounds of beef products, and the USDA recall coordinator for this recall told us that downstream processors mixed the recalled beef with nonrecalled beef, for a total of more than 38,000 pounds of beef that was distributed at the secondary customer level. According to USDA officials involved with the

recall, the precise amount of meat that was sold at the retail level is unknown because retailers at the tertiary level further mixed nonrecalled meat with potentially contaminated meat. USDA told us that more than 64,000 pounds of beef was ultimately returned or destroyed by customers, and that, because of the mixing, it was not able to determine how much of the original 10,410 pounds of recalled beef was contained in the 64,000 pounds that were recovered.

FDA's Role in USDA's Recall

Parts of the BSE-infected animal slaughtered on December 9, 2003, were not used for food, but they were sent to renderers to be separated into raw materials, such as proteins and blood. Rendered materials are used for many purposes, including cosmetics and vaccines. FDA has jurisdiction over renderers.

When USDA learned of the BSE-infected cow on December 23, 2003, the agency immediately notified FDA. On December 24, 2003, FDA sent an inspection team to a renderer that handled materials from the BSE cow. Inspectors confirmed that the parts of the slaughtered BSE positive cow were on the premises. FDA later identified a second company that potentially rendered material from the slaughtered BSE cow. Both renderers agreed to voluntarily hold all product processed from the diseased cow and dispose of the product as directed by FDA and local authorities.

On January 7, 2004, 15 containers of potentially contaminated, rendered material (meat and bone meal) were inadvertently loaded on a ship, and on January 8, 2004, the ship left Seattle, Washington, for Asia. The renderer initiated steps to recover the shipped material, so it could be disposed of as directed by FDA and local authorities. The ship carrying the material returned to the United States on February 24, 2004, and the material was disposed of in a landfill on March 2, 2004.

On January 12, 2004, FDA asked both renderers to expand their voluntary holds to rendered materials processed from December 23, 2003, through January 9, 2004, because they may have rendered some recalled meat or trim that was recovered from retail establishments. Both renderers agreed to the expanded product hold. In total, FDA requested that renderers voluntarily hold approximately 2,000 tons of rendered material. FDA confirmed that none of the potentially contaminated, rendered material entered commerce, because FDA accounted for all rendered material. FDA

**Appendix II
Federal Actions Associated with the
Discovery of an Animal in the United States
Infected with BSE**

reported that no recall was necessary because no product was distributed commercially by the rendering companies.

**USDA and FDA
Worked Together on
the Recall**

USDA and FDA worked together in two ways. First, both agencies notified each other if their investigations yielded any information about products within the jurisdiction of the other agency. For instance, when conducting the second round of verification checks, USDA tracked the disposition of the product to renderers and landfills and notified FDA when the product went to renderers. Second, FDA officials helped conduct verification checks. FDA conducted 32 of the 582 verification checks (approximately 5 percent) for the USDA recall. Officials from both agencies indicated they regularly interacted and shared information. Table 3 outlines the agencies' actions.

Table 3: Detailed Timeline of USDA, FDA, and Company Actions Related to the Discovery of an Animal Infected with BSE

Date	USDA recall actions	FDA actions	Company actions
12/9/03	<ul style="list-style-type: none"> • USDA samples cow for BSE. 		<ul style="list-style-type: none"> • BSE cow is slaughtered.
12/11/03	<ul style="list-style-type: none"> • Sample is sent to Ames, Iowa, for BSE testing. 		<ul style="list-style-type: none"> • Recalling company sends carcasses to primary customer for processing.
12/12/03			<ul style="list-style-type: none"> • Primary customer sends meat products to two other primary customers for further processing.
12/12 - 12/23/03			<ul style="list-style-type: none"> • Other primary customers distribute recalled product to secondary customers. • Secondary customers distribute recalled product to tertiary customers.
12/23/03	<ul style="list-style-type: none"> • BSE test results are presumptively positive. • Recall meeting. • Initiation of voluntary recall. • Press release. 	<ul style="list-style-type: none"> • FDA notified of BSE test results. • FDA dispatches investigation teams. 	
12/24/03		<ul style="list-style-type: none"> • FDA inspects Renderer 1. • FDA determines some rendered material from Renderer 1 is intended for Indonesia. • FDA discovers some material may have been sent to Renderer 2. • Renderer 1 agrees to hold remaining rendered material. 	<ul style="list-style-type: none"> • Recalling company contacts primary customers. • Primary customers contact their customers.

**Appendix II
Federal Actions Associated with the
Discovery of an Animal in the United States
Infected with BSE**

(Continued From Previous Page)

Date	USDA recall actions	FDA actions	Company actions
12/25/03	<ul style="list-style-type: none"> • USDA receives confirmation from reference lab in England that cow in question is BSE positive. 		
12/26/03	<ul style="list-style-type: none"> • Verification checks begin • USDA announces recalled product in Washington State and Oregon. 	<ul style="list-style-type: none"> • FDA begins process of comparing records to ensure all products from Renderers 1 and 2 are accounted for. • Renderer 2 agrees to hold all material that may have been derived from BSE cow. None of the rendered material has been distributed. 	
12/27/03	<ul style="list-style-type: none"> • USDA announces recalled product was distributed in Washington State, Oregon, California, and Nevada. 	<ul style="list-style-type: none"> • FDA issues statement confirming that the rendering plants that processed all of the nonedible material from the BSE cow have placed a voluntary hold on all of the potentially infectious product, none of which had left the control of the companies and entered commercial distribution. 	
12/28/03	<ul style="list-style-type: none"> • USDA announces recalled product was distributed in Washington State, Oregon, California, Nevada, Montana, Idaho, Alaska, Hawaii, and Guam. 		
12/29/03	<ul style="list-style-type: none"> • Food Safety and Inspection Service determines that the recalled meat products were distributed to 42 locations, with 80 percent of the products distributed to stores in Oregon and Washington State. 		
12/31/03		<ul style="list-style-type: none"> • FDA offers assistance to USDA to complete recall verification checks. 	
1/6/04	<ul style="list-style-type: none"> • USDA determines recalled product was only distributed in Washington State, Oregon, California, Nevada, Montana, and Idaho. 		
1/8/04		<ul style="list-style-type: none"> • FDA is notified by the renderer that some of the rendered material on hold from Renderer 1 was inadvertently shipped to Asia. Renderer 1 commits to isolate and return the rendered material. 	<ul style="list-style-type: none"> • Rendering company notifies FDA of shipment of product on hold.

Appendix II
Federal Actions Associated with the
Discovery of an Animal in the United States
Infected with BSE

(Continued From Previous Page)

Date	USDA recall actions	FDA actions	Company actions
1/12/04		<ul style="list-style-type: none"> • FDA advises Renderers 1 and 2 that they may have rendered meat or trim subject to recall from retail stores. • FDA requests Renderers 1 and 2 to place all rendered material from December 23 to January 9 on hold. • FDA determines neither renderer had shipped rendered material manufactured after December 23, 2003. 	
2/9/04		<ul style="list-style-type: none"> • All rendered material was disposed of in landfill, except material shipped to Asia. 	
2/24/04		<ul style="list-style-type: none"> • Ship carrying rendered material returns to U.S. port. 	
2/25/04	<ul style="list-style-type: none"> • Verification checks complete. • USDA Boulder District Office concludes recall is effective. 		
3/1/04	<ul style="list-style-type: none"> • Recall is closed. 		
3/2/04		<ul style="list-style-type: none"> • FDA observes disposal in landfill of remaining rendered material. 	

Source: GAO analysis of USDA and FDA information.

Information on a 2002 Recall of Ground Beef by a ConAgra Plant in Greeley, Colorado

This appendix provides general information about the recall of 18 million pounds of ground beef and beef products because of possible contamination with *E. coli* O157:H7 by the ConAgra Beef Company (ConAgra) plant in Greeley, Colorado, beginning in June 2002. USDA's Office of Inspector General evaluated the effectiveness of the department's management and oversight of the recall, issuing a report in September 2003.¹ As a result, we did not independently analyze the department's actions during this recall.

Beginning in June 2002, at least 46 people in 16 states became ill from contaminated meat. An epidemiological investigation by the Colorado Department of Public Health and Environment and the Centers for Disease Control and Prevention, confirmed that about 23 of those illnesses around Colorado were from the same genetic strain of *E. coli*, which linked the illnesses to the same source of contamination. Later testing confirmed that beef from the ConAgra plant was the source of that contamination.

On June 30, 2002, ConAgra officials agreed to a voluntary recall of 354,200 pounds of ground beef that the company identified as having been produced on May 31, 2002. FSIS's subsequent review of ConAgra records showed that beef from the plant had been testing positive for *E. coli* O157:H7 from April 12 through July 11, 2002. On July 18, the company decided to expand the recall to include about 18 million pounds of ground beef and beef trim. The expanded recall—one of the largest in U.S. history—included fresh and frozen ground beef products produced from April 12 through June 29, 2002, and beef trimmings produced from April 12 through July 11, 2002. The Centers for Disease Control and Prevention reported that the extent to which the recalled meat was repackaged and distributed under other labels was unclear, potentially making it difficult to identify the affected lots of beef by looking at the package. According to USDA, about 3 million pounds (17 percent) of the recalled beef was recovered.

USDA's Inspector General noted the following in 2003:

- USDA had imposed no specific requirements that plants keep production or distribution records, which increased the difficulty USDA had in tracking the distribution of the ground meat.

¹U.S. Department of Agriculture, Office of Inspector General, *Food Safety and Inspection Service*.

Appendix III
Information on a 2002 Recall of Ground Beef
by a ConAgra Plant in Greeley, Colorado

- USDA did not review verification checks in time to maximize the amount of recalled food that could be recovered, and the problems found during those checks received limited management attention.
- Of the 490 verification checks that USDA conducted, 67 indicated that companies in the downstream distribution chain had not been notified of the recall. Although USDA confirmed that ConAgra notified its primary customers of the recall, the agency took no action in the 67 cases where it found that those customers had not notified others in the distribution chain. These checks notwithstanding, USDA district office managers determined that the recall was a success because to their knowledge, no one consuming unrecovered product became ill.
- USDA conducted verification checks between July and November, 2002, months after the recall began, with about 31 percent of checks in July, 42 percent in August, 20 percent in September, and 7 percent in October. Two checks were performed in November.

USDA and FDA Actions on the Recommendations We Made in 2000

As previously discussed in this report, our 2000 report¹ on USDA's and FDA's food recall programs recommended that USDA and FDA provide guidance to companies with 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.

Our 2000 report also recommended that both USDA and FDA modify existing recall data systems to include information on the timeliness of companies' recall activities so that the agencies could determine whether companies delay initiating and carrying out recalls. Both agencies acted on our recommendations by implementing new recall data systems to help track information about the recalls they monitor. USDA began using its new system—Recall Web—in January 2001, and FDA began using its new system—Recall Enterprise System—in November 2002. FDA's Recall Enterprise System captures information on recalls of all FDA-regulated products, including food and other products such as medical devices and drugs. As table 4 shows, FDA implemented more of our recommendations than did USDA.

Table 4: USDA and FDA Actions on GAO's Recommendations to Modify Recall Data Systems

Agency	Modify data systems to track the following dates and methods							
	Dates						Methods	
	Company found out about problem	Agency requested company to initiate recall	Company initiated recall	Company notified customers	Company notified public	Company completed recall	Company used to notify customers	Company used to notify public
USDA	No	No	Yes	No	No	No	Yes	^a
FDA	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No ^b

Source: GAO analysis of the USDA Recall Web and the FDA Recall Enterprise System.

^aRegardless of the public notification action taken by the recalling company, FSIS will generally issue a press release for Class I and Class II recalls. The agency also will post them on the FSIS Web site.

^bAlthough FDA does not track this information in its data system, companies generally use a press release to notify the public, and FDA posts recall information on its Web site.

¹GAO, *Food Safety: Actions Needed by USDA and FDA to Ensure That Companies Promptly Carry Out Recalls*, [GAO/RCED-00-195](#) (Washington, D.C.: Aug. 17, 2000).

Appendix IV
USDA and FDA Actions on the
Recommendations We Made in 2000

As table 4 shows, USDA did not add fields in its new data system for most of the fields that we recommended, but its system does record the date the company initiated a recall and the methods it used to notify its customers. According to USDA recall staff, its system was designed to create the letters they use to officially begin and end recalls. The system does not track the agency's or company's actions. In contrast, FDA added all but one of the fields we recommended.

Information on the 20 Food Recalls We Examined for 2003

We analyzed 20 recent recalls—10 from USDA and 10 from FDA. The 20 we selected occurred in fiscal year 2003 and were among those with the greatest potential to cause serious illness or death—Class I recalls. Table 5 presents selected information on those recalls.

Table 5: Selected Information on the 20 Class I Food Recalls We Examined

Agency	Agency-assigned recall number	Location of facility	Lead district office	Recalled food	Reason for recall	Approximate amount recalled
USDA	107-2002	Ashville, NY	Albany	Fresh ground beef	<i>E. coli</i>	320,000 pounds
	001-2003	Bronx, NY	Albany	Chicken frankfurters	Listeria	26,400 pounds
	102-2002	Augusta, GA	Atlanta	Ground beef	<i>E. coli</i>	54,000 pounds
	112-2002	Elberton, GA	Atlanta	Fully cooked frozen chicken	Hard piece of plastic ^a	36,000 pounds
	086-2002	Milwaukee, WI	Madison	Fresh and frozen ground beef	<i>E. coli</i>	2,800,000 pounds ^b
	091-2002	Milwaukee, WI	Madison	Fresh and frozen ground beef	<i>E. coli</i>	568,000 pounds
	073-2002	Minneapolis, MN	Minneapolis	Frozen ground beef	<i>E. coli</i>	717,000 pounds
	090-2002	Franconia, PA	Philadelphia	Fresh and frozen ready-to-eat turkey and chicken	Listeria	27,400,000 pounds ^b
	098-2002	Camden, NJ	Philadelphia	Fresh and frozen ready-to-eat turkey and chicken	Listeria	4,200,000 pounds ^b
	008-2003	Napoleon, OH	Chicago	Canned soup	Cheese ^c	56,000 pounds
FDA	F-474/479-3	Trainer, PA	Philadelphia	Crab cakes	Milk ^c	40,000 pounds
	F-433-3	Conestoga, PA	Philadelphia	Ice cream	Peanuts ^c	14,916 units
	F-502-3	Brooklyn, NY	New York Downstate	Salted herring	Botulinum spores	2,025 pounds
	F-398-3	Farmingdale, NY	New York Downstate	Oregano	Salmonella	2,180 pounds
	F-463-3	Salinas, CA	San Francisco	Fresh-cut bagged lettuce	Listeria	5,622 cases
	F-207/218-3	Mukilteo, WA	Seattle	Packaged turkey sandwiches	Listeria	285,700 sandwiches
	F-381/383-3	Auburn, WA	Seattle	Alfalfa sprouts	Salmonella	32,000 pounds
	F-425-3	Clackamas, OR	Seattle	Smoked salmon	Listeria	434 pounds

**Appendix V
Information on the 20 Food Recalls We
Examined for 2003**

(Continued From Previous Page)

Agency	Agency- assigned recall number	Location of facility	Lead district office	Recalled food	Reason for recall	Approximate amount recalled
	F-185-3	Battle Creek, MI	Detroit	Packaged breakfast pastry	Egg ^c	730,000 packages
	F-482-3	Barberton, OH	Cincinnati	Chocolate milk	Excessive amounts of vitamins A and D	490 ½-gallon containers

Source: GAO analysis of USDA and FDA data and documents.

^aThe hard piece of plastic was considered to be foreign material.

^bThis recall was expanded beyond the initial amount. The amount listed is the final amount of recalled food.

^cThis item is a potential allergen that was not declared on the food's ingredient label.

Recall Authority of Selected Government Agencies

This appendix provides additional explanation of the information previously provided in table 2. It describes the requirements that manufacturers and other companies must follow to notify agencies of unsafe products and the authority of government agencies to recall products. The regulatory functions and products under the jurisdiction of each agency are discussed, followed by a description of the authority each agency has to recall products, including required notification of unsafe products.

USDA's Food Safety and Inspection Service

USDA's FSIS is responsible for protecting the public from foodborne illness by administering and enforcing the Federal Meat Inspection Act, Poultry Products Inspection Act, and Egg Products Inspection Act. FSIS's jurisdiction covers beef; pork; lamb; poultry; processed eggs; and other products that contain meat or poultry, such as sausage, soups, stews, and frozen pizzas or dinners. FSIS inspects individual products as well as processing plants, tests for various types of food contamination, establishes facility sanitation requirements, maintains a system of import inspections and controls, prescribes labeling requirements, and develops consumer education programs to keep the public informed on how to properly prepare and store food. FSIS also monitors the effectiveness of voluntary recalls to remove unsafe meat, poultry, and egg products from interstate commerce.

FSIS does not have authority to issue a mandatory recall order or require a company to follow certain recall procedures during a voluntary recall. Nor are companies required to notify the agency when they identify a potentially unsafe product. However, if a company refuses to recall a product believed to be hazardous to the public health, FSIS may rely on its authority to detain and seize it. If necessary, FSIS may detain meat, poultry, or egg products for up to 20 days when there is reason to believe they are adulterated or misbranded and may be used as human food. After this period, a U.S. district court may be petitioned to authorize USDA to seize and condemn the product. To encourage cooperation with a voluntary recall, FSIS can withdraw inspectors or withhold the USDA "inspected and passed" label, effectively shutting down a manufacturer, according to the Secretary of Agriculture.¹

¹Testimony before the House Agriculture Committee, January 21, 2004.

FDA's Center for Food Safety and Applied Nutrition

FDA's Center for Food Safety and Applied Nutrition, is responsible for the safety of food not exclusively regulated by USDA.² This includes food such as fruits and vegetables, and infant formula. FDA shares jurisdiction with USDA on foods such as eggs, (FDA is responsible for shell eggs while USDA is responsible for egg products), sandwiches (depending on whether they are open-faced or close-faced) and soups (depending on the quantity of meat they contain). To ensure the safety of food under its jurisdiction, center activities include regulation of certain food production facilities and food labeling and the approval of food additives. The center also conducts facility inspections, collects and tests food samples to detect unsafe food, conducts research on emerging food safety issues, and educates the public on proper food handling. If an unsafe food under its jurisdiction enters the market, FDA may request a voluntary food recall and issue a press release about the unsafe food.

With the exception of infant formula, FDA does not have explicit authority to order food recalls. Instead, FDA relies on its authority to detain and seize adulterated or misbranded foods. While adulterated or misbranded products are subject to seizure through the courts with the assistance of the U.S. Department of Justice, FDA may detain food for up to 30 days if it has credible evidence or information that indicates the food presents a threat of serious adverse health consequences or death to humans or animals. FDA may also issue publicity about foods that present a danger to public health. According to agency officials, companies usually conduct voluntary recalls to avoid such adverse publicity.

For infant formula, however, FDA can require a manufacturer to conduct a recall if FDA determines that the formula processed by the manufacturer presents a risk to human health. An infant formula may present a risk to human health if it does not provide the required nutrients or is otherwise adulterated or misbranded. Manufacturers that have knowledge that reasonably supports the conclusion that their formula may not contain the required nutrients, or otherwise may be adulterated or misbranded, must promptly report this information to FDA, which then will determine whether the infant formula presents a risk to human health. Reports are also required if there is a reasonable possibility of a causal relationship between the consumption of the company's infant formula and infant

²FDA's Center for Food Safety and Applied Nutrition also has regulatory responsibility for cosmetics, medical foods, and dietary supplements.

death. When a company conducts a recall, it must provide information to FDA by telephone about the infant formula within 24 hours. Within 14 days after the recall has begun, the manufacturer must provide a written report to FDA and at least every 14 days thereafter until the recall is terminated. The manufacturer also must request each retail establishment at which such formula is sold or is available for sale to post a notice of the recall. Failure to comply with the notification, reporting, or posting-request requirements are prohibited acts punishable by imprisonment, a fine, or both.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 includes a number of provisions that establish new requirements for those engaged in the food business and gives new authority to FDA to take action to protect the nation's food supply. These new requirements and powers include registration of food facilities, administrative detention of food believed to be unsafe, maintenance of and access to certain records, and notification of food imports prior to arrival.³

FDA's Center for Biologics Evaluation and Research

FDA's Center for Biologics Evaluation and Research is responsible for ensuring the safety and effectiveness of biological products, such as blood and vaccines. The center also regulates human tissue intended for transplant to prevent the transmission of communicable disease.⁴ To achieve its goals, the center reviews and approves biologics for licensing, inspects the conditions of facilities manufacturing biological products, regulates biological product quality, and conducts research to support these programs.

³Pub. L. No. 107-188, 116 Stat. 594, §§ 303, 305-07(2002).

⁴FDA has issued regulations that apply to human tissue establishments or persons engaged in the recovery, screening, testing, processing, storage, or distribution of human tissue. Human tissue determined to be in violation of these regulations may be recalled. 21 C.F.R. § 1270.43(2004).

Reports of adverse events associated with biological products can help identify whether a recall may be necessary. Manufacturers must report to FDA if they become aware of adverse experiences associated with their products. Such information may come from a number of sources, including commercial marketing experience, postmarketing clinical investigations, and scientific literature. Vaccine manufacturers and health care providers are also required to report certain reactions associated with the administration of routinely recommended childhood vaccines.⁵

The Public Health Service Act authorizes FDA to issue an order to recall a licensed biological product after determining that it presents “an imminent or substantial hazard to the public health...”⁶ Recalls must be carried out in a manner consistent with the FDA order and pertinent regulations. Violation of the recall requirements could result in monetary penalties of \$100,000 or more per day of violation, fines, and imprisonment.

FDA’s Center for Devices and Radiological Health

FDA’s Center for Devices and Radiological Health is responsible for ensuring the safety and effectiveness of medical devices and preventing unnecessary human exposure to radiation from electronic products. The center has regulatory jurisdiction over medical devices, such as heart pacemakers and electronic thermometers, as well as radiation-emitting electronic products, such as microwave ovens, infrared alarm systems, ultraviolet tanning lamps, and lasers. The center evaluates and approves certain devices for clinical trials and marketing, regulates manufacturing practices, sets performance standards, conducts postmarket surveillance of product performance, provides technical assistance to small manufacturers, and educates the public.

Medical device manufacturers and importers must report device-related deaths or serious injuries, as well as certain product corrections and market removals to FDA, and importers must report these events to the manufacturer(s). User facilities must report deaths that may have been caused by the use of a medical device to FDA and the manufacturer, if

⁵FDA has proposed to require adverse event reporting for human tissue products. *See* Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement, 66 Fed. Reg. 1508 (proposed Jan. 8, 2001)(to be codified at 21 C.F.R. pt. 1271). The agency is working on the final rule.

⁶42 U.S.C. § 262(d)(1).

known. Device-related serious injuries must be reported to the manufacturer or to FDA if the manufacturer is unknown.

FDA is authorized to order two types of recalls for medical devices: a “repair, replacement, or refund” order and a recall order.⁷ The first type may be initiated if (1) a device presents an unreasonable risk of substantial harm to the public health, (2) there are reasonable grounds to believe that the device was not properly designed or manufactured, (3) there are reasonable grounds to believe that the risk is not due to improper use or care, and (4) notification of the risk would not be sufficient to eliminate it.

If a device meets these criteria, FDA may order the manufacturer, importer, or distributor, or any combination of the three, to submit a plan to repair or replace the device or to refund the purchase price. The plan may not include a charge to anyone seeking a remedy, except manufacturers, importers, distributors, or retailers, where there are reasonable grounds to believe that the person or entity in question is eligible for a remedy. It must also provide for reimbursement of the reasonable and foreseeable expenses associated with obtaining repair, replacement, or refund. If a plan is unsatisfactory, FDA may prescribe a plan.

If there is a reasonable probability that a device would cause serious adverse health consequences or death, FDA must issue an order requiring the appropriate parties to immediately (1) cease distribution and (2) notify health professionals and device user facilities of the order and instruct them to stop using the device. After providing an opportunity for an informal hearing, FDA may amend the order to require a recall of the device specifying a time table for completion and periodic reporting. Such recall orders do not include recall of devices from individuals, although individuals subject to the risks associated with the recalled devices are required to be notified.

FDA is authorized to require manufacturers to adopt a method of device tracking for certain medical devices. According to FDA, this authority may be used to facilitate recalls. Tracking orders may be issued for devices (1) that if they failed, would be reasonably likely to cause serious adverse

⁷Electronic products are treated separately and subject to repair, replacement, or refund if they have a safety defect relating to the emission of electronic product radiation or fail to comply with certain performance standards. Failure to comply with the applicable requirements may result in penalties as large as \$300,000.

health consequences, (2) that are intended to be implanted in the body for more than a year, or (3) that are life-sustaining or life-supporting and used outside a device user facility.

Failure to comply with requirements or orders could result in penalties up to \$15,000 per violation, not to exceed \$1 million for all violations in a single proceeding; fines; and imprisonment.

FDA's Center for Drug Evaluation and Research

FDA's Center for Drug Evaluation and Research is responsible for ensuring the availability of safe and effective prescription and over-the-counter drugs for the American people. To ensure that drugs are safe and effective before they reach the market, the center reviews new drug applications and establishes manufacturing, product quality, and labeling standards. The center also conducts postmarket drug safety surveillance, collects samples of and analyzes drugs to help make sure they are safe and effective, administers a postmarket adverse drug experience program in an effort to identify potentially unsafe drugs, and provides consumers with the information they need to use drugs appropriately and safely.

Unlike foods, drugs must go through premarket approval and must be determined to be safe and effective before they can be marketed. Even after they are marketed, questions may arise regarding their safety or effectiveness. FDA may become aware of such concerns through adverse event reporting. Generally, manufacturers and others are required to report serious and unexpected adverse drug events to FDA within a certain time frame. FDA may use this information to determine whether particular drugs should continue to be marketed. Those who fail to make the required adverse event reports are subject to fines and imprisonment.

While FDA does not have the authority to issue a recall order for drugs determined to be unsafe or ineffective,⁸ it may immediately suspend and propose to withdraw the New Drug Application approval for such drugs if they are found to constitute an "imminent hazard."

⁸For human drugs regulated using a biologics license application, FDA has express statutory recall authority. However, FDA has not developed implementing regulations.

FDA's Center for Veterinary Medicine

FDA's Center for Veterinary Medicine regulates the approval, manufacture, and sale of animal drugs and feeds containing animal drugs. FDA may become aware of information concerning the safety and effectiveness of animal drugs and medicated feeds through the reporting of adverse reactions associated with them. Manufacturers of animal drugs are required to report serious and unexpected adverse drug events to FDA within a certain time frame whether administered directly or through feed. Those who fail to make the required reports may be subject to fines and imprisonment.

FDA's Center for Veterinary Medicine does not have authority to issue a recall order if any of these products are found to be unsafe or ineffective. However, the center may propose to withdraw marketing approval for such drugs or propose to revoke the license of the medicated feed manufacturer if certain conditions are not met. If the drug or medicated feed poses an imminent hazard to human health or the animals for which it is intended, the Secretary of Health and Human Services may immediately suspend the drug's marketing approval or the feed manufacturing license.

Consumer Product Safety Commission

The Consumer Product Safety Commission (CPSC) is charged with protecting the public from unreasonable risks of serious injury or death from over 15,000 types of consumer goods. Consumer goods generally fall under the regulatory jurisdiction of CPSC, with the exceptions of motor vehicles and motor vehicle equipment, food, human and animal drugs, aircraft, boats, tobacco, firearms, cosmetics, pesticides, and medical devices. To help protect consumers from unsafe products, CPSC develops and enforces product safety standards; administers recalls—which may include repair, replacement, or refund—of certain hazardous products; evaluates the safety of products; bans unsafe products; conducts research on the safety of products; and educates consumers.

Companies are required to notify CPSC immediately (generally within 24 hours) after obtaining information that reasonably supports the conclusion that a product violates a product safety ban or standard, the product contains a defect that could create a substantial product hazard or creates an unreasonable risk of serious injury or death. The staff verifies the defect or hazard and assists the company in developing a remedy. According to CPSC officials, virtually all recalls are conducted voluntarily without the need for litigation. If the commission determines that notification of the public about a product defect or failure is necessary, and the company does

not cooperate, the law provides for a hearing. After a hearing, CPSC may order the affected companies to give such notice publicly and through the mail to manufacturers, distributors, retailers, or individual consumers. Manufacturers also must notify CPSC if a product is the subject of three or more settled civil actions or adjudicated civil actions, in favor of the plaintiff, alleging death or grievous bodily injury—over a 2-year period. The company must report to CPSC within 30 days of final settlement or judgment in the third case.

Companies selling goods that a CPSC technical review finds to present “substantial product hazards” may be ordered to conduct a recall or develop a plan that provides for repair, replacement, or refund for the product in question. CPSC is authorized to review and approve any plan. Products that a U.S. district court determines to be imminently hazardous are subject to injunction and seizure. In such cases, relief may include notification of the risk to purchasers, public notice, recall, repair, replacement, refund, or condemnation. If someone knowingly fails to comply with the reporting, or a notification or recall order, CPSC may assess civil monetary penalties of \$7,000 per violation up to \$1.65 million for a related series of violations.⁹

Department of Transportation’s National Highway Traffic Safety Administration

The National Highway Traffic Safety Administration (NHTSA), an agency within the Department of Transportation, is charged with a number of responsibilities, including reducing deaths and injuries resulting from motor vehicle traffic accidents, establishing motor vehicle safety standards, administering motor vehicle and highway safety grant programs, securing and analyzing data to learn about safety trends, and monitoring the recall of defective products. Its jurisdiction covers motor vehicles and equipment, including tires and child safety seats.

⁹Maximum civil monetary penalties were last revised for inflation in 1999 and are required to be revised again later in 2004. *See* Notice of Adjusted Maximum Civil Penalty Amounts, 64 Fed. Reg. 51963(1999); 15 U.S.C. § 2069(a)(3).

NHTSA may become aware of problem products either through its own research or testing, or by notification from manufacturers or consumers. Manufacturers of motor vehicles or replacement equipment must notify NHTSA within 5 working days if the manufacturer decides that its products contain a defect related to motor vehicle safety or violate a motor vehicle safety standard.¹⁰ Owners, purchasers, and dealers must also be notified within a reasonable time and are entitled to remedies—which may include repairs, replacement, or refunds of the defective or noncompliant product—without charge. If there is insufficient customer response after the initial notification, NHTSA may order the manufacturer to send out a second notification in a manner prescribed by regulation. The manufacturer’s program to remedy the defect or noncompliance must be filed with NHTSA, which then makes it available to the public. If NHTSA decides that a manufacturer has not reasonably met the remedy requirements, it may order specific action. Failure to provide notification or a proper remedy may result in a civil monetary penalty of up to \$5,000 for each violation, up to \$15 million in total for a related series of violations.

Canadian Food Inspection Agency

The Canadian Food Inspection Agency (CFIA), created in April 1997, is Canada’s science-based regulator for food safety, animal health, and plant protection. Its responsibilities include activities that had been divided among four Canadian government departments. It is responsible for the administration and enforcement of 13 Canadian laws and their respective regulations. Through the delivery of inspection and other related services, which include inspection of food-processing facilities, analysis of food samples for impurities, inspection of international food products and animals, and evaluation of the safety of animal feeds and vaccines, the agency verifies compliance with these laws. Critical to the effective delivery of the CFIA’s responsibilities is the ongoing design and development of inspection-related tools and processes, which include the continual review of regulations and policies and the implementation of new science-based inspection methodologies.

The CFIA also coordinates food recalls across Canada and posts publications of food recalls on its government Web site. According to

¹⁰Manufacturers of motor vehicles or motor vehicle equipment must notify NHTSA within 5 working days after determining to conduct a safety recall or other safety campaign in a foreign country on vehicles or equipment that are identical or substantially similar to ones sold in the United States. 49 U.S.C. § 30166(l).

agency officials, although companies are not required by statute to notify the CFIA when they identify potentially unsafe products, the CFIA encourages and assists companies in the coordination of food emergency responses on a 24-hour basis. The CFIA Web site also has manuals and checklists for companies to structure food safety emergency response policies.

CFIA officials told us that although companies generally cooperate in recalls, the CFIA has mandatory recall authority that it may use in cases where cooperation is not forthcoming and a recall must be done promptly and completely. Section 19 of the *Canadian Food Inspection Agency Act* provides that the Minister of Agriculture and Agri-Food may order a recall of a particular product where there are reasonable grounds to believe that the product poses a risk to public, animal, or plant health. A recall order under this section applies to anyone who sells, markets, or distributes the product, and violation of a recall order may result in a fine of up to \$50,000 and imprisonment.¹¹

¹¹The applicable Canadian statute is general and there are no implementing regulations. This information is largely based on our discussions with Canadian officials.

Comments from the U.S. Department of Agriculture

Note: GAO 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

Mr. Lawrence J. Dyckman
Director, Food and Agricultural Issues
Natural Resources and Environment Team
United States Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Dyckman:

In your letter dated August 11, 2004, you requested the U.S. Department of Agriculture (USDA) written comments on the Draft report GAO-04-693 "FOOD SAFETY: USDA and FDA Need to Better Ensure Prompt and Complete Recalls of Potentially Unsafe Food." Thank you for the opportunity to provide comments on the draft report.

We find the draft report generally factually accurate but would like to offer some general comments on the report as well as the attached specific comments. On May 24, 2004, the Food Safety and Inspection Service (FSIS) issued FSIS Directive 8080.1, Revision 4, "Recall of Meat and Poultry Products" to revise the terminology, responsibilities and public notification procedures regarding the voluntary recall of FSIS-inspected meat and poultry products. FSIS is following the new procedures outlined in the new Directive, and believes that most of the perceived weaknesses in the Agency's recall efforts have been addressed by these new procedures.

FSIS Directive 8080.1, Revision 4, includes the general procedures involved in determining the need for a recall, and actions FSIS expects a firm to take to ensure that the maximum amount of product is recovered in the shortest amount of time. The directive includes effectiveness check procedures by which FSIS inspection program personnel verify that the recalling firm has been diligent and successful in notifying and advising consignees of the need to retrieve and control recalled product, and that the consignees have responded appropriately. Effectiveness check procedures are risk-based and dependent on the class of the recall as well as the number of consignees. The directive also includes closure procedures.

The FSIS recall process in place now is risk-based and cost effective. Recalls with higher risk to public health receive more agency verification resources than lower risk recalls. Additional data collection requirements can be costly to both FSIS and industry. Because recalls are voluntary, FSIS does not have the authority to mandate data collection requirements for industry. FSIS believes some of the report recommendations proposing that FSIS gather additional recall data and generate reports to aid recall management may be a burden to the Agency and overly prescriptive given the variety of recalls. Recalls can vary greatly in risk to public health, amount of product, and geographic scope.

See comment 1.

See comment 2.

District Recall Officers will be able to manage and monitor FSIS recall activities with the information provided in Directive 8080.1, Revision 4.

See comment 3.

The report should point out more prominently how quickly FSIS does respond when it receives information, either generated from within or outside of the Agency, that product that there is reason to believe is adulterated or misbranded has entered commerce. FSIS typically responds and has notified the public of recalls within hours of receiving the information.

General Comments:

See comment 4.

1. **Page 14, 2nd Paragraph, 2nd Sentence.** The draft report states, “As a result, they [FDA and USDA] did not know how much food is actually recovered, which the agencies indicate is the purpose of a recall.” FSIS suggests that this statement be clarified. The purpose of a recall is to remove product that there is reason to believe is adulterated or harmful from commerce and to alert consumers to potential problems if a particular product is consumed. The product may be thrown out by a consumer or destroyed by a consignee, either of which accomplishes the purpose of a recall by removing product from commerce and protecting the consumer, but these products would not count as “recovered.” The rate of recovery for perishable meat and poultry products is not the measure of a recall’s effectiveness. The key measure is the percentage of consignees notified. If consignees are notified, they can act to ensure the proper disposition of the product.

See comment 5.

2. **Page 29, 3rd Sentence, Last Paragraph.** The draft report states, “Consumers may be vulnerable to serious illness, hospitalization, or even death because of weaknesses in USDA’s and FDA’s programs for monitoring companies’ recalls of unsafe food.” FSIS suggests that this statement be removed altogether from the report. This is an alarmist statement. It is a poor assumption, unsubstantiated with any factual evidence that monitoring of a recall is related to consumer vulnerabilities.

See comment 6.

3. **Page 25, 2nd Sentence 1st Full Paragraph.** The draft report states “These recall authorities may facilitate faster recalls and better protect consumers.”
 - The report implies that the Consumer Product Safety Commission’s (CPSC) and the National Highway Traffic Safety Administration’s (NHTSB) authorities and procedures offer better protection to the consumer. The report assumes that if the Agency had those authorities it would better serve the public. The report should fully discuss how long the NHTSB and CPSC work with companies before they or the company announces a recall.
 - The report should include a substantive comparison between effectiveness of recalls conducted by USDA and recalls conducted by these other agencies.
 - The report accurately describes the Agency’s power to detain and seize product, however the report does not elaborate on how mandatory recall authority would better protect consumers than the authority FSIS currently has to detain product believed to be adulterated if a firm refuses to recall.

See comment 7.

- The report should examine the possibility that if USDA had mandatory recall authority, this may include some form of administrative procedure or appeal process which could conceivably slow the recall process. The report states that GAO did not identify any instance where companies refused to carry out recalls.

4. **Page 24, 1st Sentence 3rd Paragraph.** The draft report states “According to USDA and FDA officials, the agencies do not have the authority to publicly name the retail stores that are selling a recalled food, because the information is considered confidential business information.” GAO should include a statement that FSIS is currently considering our options in this regard.

Please find enclosed additional specific USDA comments on the draft report.

Sincerely,



Ronald F. Hicks
Assistant Administrator
Office of Program Evaluation, Enforcement and Review

Enclosure

The following are GAO's comments on the U.S. Department of Agriculture letter received August 31, 2004.

GAO Comments

1. USDA believes the new recall directive adopted May 24, 2004, will address most of the observed weaknesses we found in its food recall program. As the report already noted, the new directive does provide a statistical, risk-based method that will give greater assurance that downstream customers are aware of recalls and that they have followed instructions for removing food from the marketplace, and the directive includes time frames for USDA to complete its verification checks. However, although the directive includes general procedures to, among other things, determine the need for a recall and the actions the agency expects the company to take to ensure maximum recovery in the shortest amount of time, the procedures do not provide specific time frames as guidance to the companies. In particular, the new directive does not address our recommendations that USDA (1) set time frames for recalling companies' actions—to encourage prompt recalls—including time frames for companies to disclose the locations where they sent the food, (2) use routinely generated management reports from the official recall data system, (3) track critical dates, and (4) work with FDA on how best to alert consumers about recalls of food that can cause serious illnesses. While the new directive should improve USDA's verification of recalls, we believe it is premature to say whether it will address any other weaknesses we found in USDA's recall program.
2. USDA believes that our recommendations regarding additional data collection and report generation may be a burden to the agency, overly prescriptive, and costly to industry and USDA. We continue to believe that our recommendation is sound. Our review of specific recalls disclosed that inspectors generally are already capturing the additional data, such as the dates that the company started and completed the recall, in their paperwork. Our recommendations would have USDA systematically capture this information and other critical information in its Recall Web database to help the department better manage its recall program. With respect to routine management reports, both headquarters and district offices need routine reports to carry out their oversight responsibilities. Now that recalls are run and coordinated directly from the district offices, under the May 2004 procedures, it is particularly important for headquarters to be able to monitor the recall activities of USDA's 17 different district offices to ensure the new

procedures are uniformly implemented. Finally, with respect to the cost to industry, companies are already legally required to maintain distribution information. Our recommendation speaks to instances where USDA district staff told us they received broad customer lists instead of the specific locations where the recalled food was sent.

3. We recognize that USDA uses press releases and Web postings to notify the public after it learns about a recall. Our recommendation that USDA and FDA work jointly to determine what, if any, additional approaches are needed for alerting consumers addresses the situation in which consumers may not see the press release or Web posting and therefore may consume recalled food that is in their home.
4. We agree that the purpose of a recall is to remove potentially harmful food from commerce and alert consumers to potential risks of consumption. Consequently, the report defines “recovery” to include food that is returned or disposed of by firms in the distribution chain. That is, food that is removed from commerce. We revised the report to reflect that the recovery rate is an important indicator of a successful recall, rather than the purpose of a recall. As we note in the report, we remain concerned about how effectively the agencies are alerting consumers to potentially harmful foods that may be in their homes.
5. We recognize that the cause of the illnesses, hospitalizations, and deaths was contaminated food, not the agencies’ programs. However, because the public is relying on USDA and FDA to protect consumers from unsafe food, it is important that the agencies’ recall programs be as effective as they can. As appendix III discusses, USDA’s Inspector General reported that during one of the two recalls we mentioned that involved illnesses and deaths, USDA’s field staff took longer than 4 months to complete their verification checks. The Inspector General’s report concluded that the department did not identify and correct problems with the recall to maximize recovery and take enforcement actions—thereby potentially exposing consumers to the unsafe meat. Therefore, we believe our report’s presentation is fair and consistent with the facts.
6. With respect to the recall authority of other agencies, we sought to show that other agencies have recall authority and have had to use that authority. We did not evaluate those recall programs nor did we imply that they were faster or better. For example, FDA currently has explicit recall authority for infant formula and certain other products that the

agency regulates and has had to use that authority. In comments on our August 2000 report on USDA's and FDA's recall programs, USDA told us that it has supported proposed recall legislation that specifically included "civil penalties, mandatory recall authority, mandatory notification...when contaminated meat or poultry may enter the market." USDA noted that, for the most part, the voluntary system works but that mandatory authority would provide "an insurance policy guaranteeing that consumers will be protected from potentially dangerous meat or poultry without delay." Moreover, because the President has identified the food supply as at risk for intentional contamination, such authority is important. Finally, USDA's suggestion that mandatory recall authority could conceivably slow the recall process was not raised as an issue by any of the agencies we cite. Rather, they saw their recall authority as a useful tool—not a replacement for voluntary recalls—when companies are slow or uncooperative and consumers are at risk.

7. We revised the report to include a statement that USDA is considering additional options to help consumers identify recalled foods in their homes.

Comments from the Food and Drug Administration

Note: GAO 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

August 27, 2004

Lawrence J. Dyckman
Director, Food and Agricultural Issues
Natural Resources and Environment Team
United States Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Dyckman:

Please find the enclosed comments from the Food and Drug Administration on the GAO draft report entitled, *FOOD SAFETY: USDA and FDA Need to Better Ensure Prompt and Complete Recalls of Potentially Unsafe Food*, (GAO-04-693). The Agency provided technical comments directly to your staff.

We appreciate the opportunity to review and comment on this draft report before its publication as well as the opportunity to work with your staff in developing this report.

Sincerely,

A handwritten signature in black ink, appearing to read "Lester M. Crawford".

Lester M. Crawford, D.V.M., Ph.D.
Acting Commissioner of Food and Drugs

Enclosure

General Comments by the Department of Health and Human Services' Food and Drug Administration on the Government Accountability Office's Draft Report, *FOOD SAFETY: USDA and FDA Need to Better Ensure Prompt and Complete Recalls of Potentially Unsafe Food, (GAO-04-693)*

The Food and Drug Administration (FDA) appreciates the opportunity to review and comment on the Government Accountability Office's (GAO) draft report.

See comment 1.

In FDA's opinion, by its study and draft report, the GAO has not demonstrated that Class I recall actions were lengthy due to system inefficiency, or that weaknesses in the FDA food recall process have resulted in little recovery of food. The GAO has demonstrated only that FDA did not have data fields in its database to record time for completion of recall verification (audit) checks by the Agency.

The most significant stage of a recall is the initial action taken by the recalling firm to notify its consignees and the public of the product recall and have the product removed from the marketplace. FDA investigators and/or district office recall coordinators routinely work directly with management of food companies conducting recalls of potentially hazardous foods (particularly Class I recalls). They review and comment on recall notifications, recall strategy, and firm press releases. They know when and how firms are conducting their recall notifications. This information is recorded in and transmitted to FDA headquarters via the Recall Enterprise System (RES) and additionally via email and telecommunications as warranted by the situation. Companies are encouraged to initiate actions as soon as possible and strongly encouraged to issue press releases within 24 hours of deciding to recall a product, often with the understanding that if the firm does not issue timely press, FDA will. It is true that the FDA recall guidelines do not provide time frames for companies on recall initiation and termination; it is also true that FDA expectations of a recalling firm are immediate notification, timely removal, and timely disposal. For Class I recall situations, recall notification and product removal or correction has for the most part been timely.

See comment 2.

The recall completion date, according to GAO's statement, was found missing on only 20 percent of the recall records reviewed. The date of completion is tracked, but that field may not have been filled in with the completion date in all recall records. The failure to include such a date in the database is not necessarily an indication that the recall wasn't monitored appropriately. This date is a reflection of the time that the firm has taken to complete all action related to the recall effort, including the physical recovery or disposition of all recalled product. The time varies considerably depending on such factors as the type of product, disposition requested by the recalling firm, and distribution and recovery channels.

See comment 3.

GAO's draft report makes reference to FDA's official database and a separate database maintained by the Center for Food Safety and Applied Nutrition (CFSAN). FDA's centers have for many years each maintained their own recall databases. They are categorized by fiscal year and recalls "classified" during the fiscal year have historically been the counts of recalls, which have been reported to Congress and the public. There is no evidence to support that information recorded in the CFSAN database is inaccurate. The Agency recently developed, and on November 15, 2002, implemented, an agency-wide database referred to as the Recall Enterprise System (RES). In order to have the database as complete as possible including historical data, FDA directed the contract designer of RES to develop an application to migrate information from a pilot database which was the forerunner of RES. The pilot system did not contain all the data fields that were built into RES, not all FDA centers worked in the pilot

database and the data migrated was not identical, but clear to FDA staff working with it. The RES did not have a "reports" capability built in at the time of the GAO request for data. GAO requested and was provided a copy of the complete database, including the pilot database data.

It was our understanding that GAO had some difficulty interpreting the mixed data in RES and the means to extract it. When it was brought to FDA's attention that GAO was having difficulty resolving numbers from RES, we recommended that GAO use numbers from CFSAN's Access database. A review of RES data, using the identical parameters of the CFSAN Access database, finds the information and numbers equivalent.

RECOMMENDATIONS FOR EXECUTIVE ACTION

To ensure that companies promptly and effectively recall foods that may cause serious illness or death, we are making the following five recommendations to the Secretary of Agriculture and the Commissioner of FDA:

- 1) Revise agency guidance to recalling companies to include specific time frames for notifying their customers, removing recalled food from the marketplace, and providing the agencies with the names and locations of customers that received the food.**

FDA Comment

Specifying workable timeframes for these actions are difficult because of the vast differences in the types of food processors and products, in the sizes of the companies, and in the distribution practices and patterns. Such timeframes, because they would not be mandatory, and may serve no better purpose than the current procedure, which is to have recall notifications and press (for Class I recalls) issued as soon as possible, usually within 24-48 hours of learning of the problem and the need for recall. Firms are also advised via a Notification of Classification Letter that "... it is equally important to assure that all returned merchandise is promptly inventoried, handled, and stored in such a manner as to assure its separation from acceptable materials so it will not inadvertently be used or shipped." The letter also states, "We...urge you to immediately begin making plans to destroy or recondition it to bring it into compliance with the law."

The establishment of artificial time frames for firms conducting voluntary recalls would not necessarily provide any quicker action.

- 2) Use agency data systems to routinely generate reports for recall program managers to monitor ongoing recalls and oversee recall timeliness and effectiveness.**

FDA Comment

FDA agrees that data systems should be used to routinely generate reports for recall program managers. Such reports for district and headquarters managers are expected to be available by the end of fiscal year 2004. However, it should also be noted that it is primarily the FDA district recall coordinators who manage recalls and who use both (RES) and recall folders containing pertinent documents, such as copies of recall notices, letters, press releases, analytical data, and verification reports daily in the processing, tracking, and monitoring of each recall.

See comment 4.

3) Track in their recall data systems the dates that companies (1) start and finish notifying their customers, (2) provide the agency the lists of customers that received the food, and (3) start and finish recovering the recalled food.

4) Track in their data systems the dates that the agencies start and finish verification checks.

See comment 5.

FDA Comment

FDA does not see the added consumer safety value in establishing additional fields in RES to record when a firm completes notification to its customers, the date that the district office receives the distribution information, or information documenting when audit checks are assigned and completed. Typically, recall notifications regarding food are handled promptly, at the initiation of the recall, and that date is recorded in RES. Additional date recording provides little more than a reporting statistic that the agency believes is of limited utility in protecting public health, while providing additional recordkeeping burdens. If such information is needed, the information can typically be found in the recall file.

5) Work jointly to determine what, if any, approaches are needed for alerting consumers about recalls.

FDA Comment

FDA and FSIS continue to work together on an ongoing basis at both the national and district levels to coordinate recall efforts to assure that American consumers have one of the safest food supplies in the world.

We also make the following four recommendations to the Commissioner of FDA:

- 1) Revise guidance to agency staff to include risk-based time frames for completing verification checks promptly.**
- 2) Develop a sound methodology for district staff to verify that companies have quickly and effectively carried out recalls.**
- 3) When tracking the amount of food recalled and recovered for individual recalls, use the same units of measure to facilitate calculations of the recovery rate.**
- 4) Direct the recall staff to use FDA's Recall Enterprise System as the sole data system to capture recall information, manage food recalls, and generate reports to Congress.**

See comment 6.

FDA Comment

FDA is planning a review of recall operations and application of quality systems principles and controls. Guidance can be provided to FDA field personnel to request comparable unit information regarding recovered products. However, often multiple products in multiple size containers and multiple size shipping cases are a part of the same recall. Data available at recovery sites for industry may not have individual product or case breakdown. FDA is moving forward as rapidly as possible to complete all aspects of the RES so that it can eliminate duplicative recall data entry and can provide sole source reports for the agency management of recalls, reporting of recall statistics, and reporting to Congress.

The following are GAO's comments on the Food and Drug Administration letter dated August 27, 2004.

GAO Comments

1. FDA believes that Class I recall actions were not lengthy because of system inefficiency, and that the relatively small percentage of recalled food that is recovered is not a result of weaknesses in FDA food recall processes. While we do not believe that these are the sole reasons why FDA's recalls may be slow or result in low recovery, we do believe that its system and processes are contributing factors. As FDA pointed out, the most significant stage of a recall is the initial action the recalling company takes to notify the public and its customers to have the food removed from the marketplace, with the assistance of FDA investigators and/or district recall coordinators. However, FDA staff from several district offices told us that companies sometimes conduct recalls without contacting FDA and therefore without the benefit of FDA assistance. Our report does note that FDA encourages companies to initiate promptly when deciding to recall a product and that companies usually agree to carry out recalls. That notwithstanding, FDA staff told us that, in some instances, they had to place considerable pressure on companies before they "voluntarily" conducted the recall. In addition, as our report points out, FDA's verification process serves a critical function in recalls—to identify and correct problems with recall notification and product removal—a process that does not consistently meet FDA's timeliness guidelines.
2. As FDA states, the recall completion date reflects the amount of time that the recalling company took to complete all actions related to the recall effort. We agree that this time can vary significantly depending on the particular circumstances of the recall. However, we continue to believe, as we stated in our 2000 report, that it is important to document the completion date as an important indicator for FDA's recall managers to assess the overall promptness of company actions to protect consumers from unsafe food in the marketplace.
3. We did not assess the reliability or validity of the unofficial database maintained by FDA's Center for Food Safety and Applied Nutrition. However, we are concerned that the information in FDA's official database—the Recall Enterprise System—was not the same as information in the center's database. FDA comments state that the differences we found are the result of information in the pilot database that preceded the Recall Enterprise System. We did not compare

information in the pilot database. Rather, we compared information in the Recall Enterprise System and the center's database for such dates as when the recalls started and when they were classified by risk. We continue to believe that these differences reflect potential weaknesses in the reliability and validity of FDA's official recall database.

4. FDA believes that it would be difficult to specify workable time frames to companies, and that such time frames may serve no better purpose than current procedure to have recall notifications and press releases issued as soon as possible. We continue to believe that more specific time frames are needed as guidance to industry. This is particularly important for Class I recalls, which pose serious health risks, where even a day's delay may have adverse health consequences. FDA also states that firms are advised about time frames via a letter. However, for the 10 recalls we examined in detail, FDA sent this letter between 26 and 213 days after the company initiated the recall. According to FDA officials, it is commonly FDA's practice to send the letter at the end of the recall. Therefore, we do not believe the letter serves as a timely means of instructing the recalling company to act quickly.
5. We agree that data should only be captured if they provide useful information to recall program managers. As FDA states, "the most significant stage of a recall is the initial action taken by the recalling [company] to notify its [customers]...of the product recall and have the product removed from the marketplace." We therefore believe that the Recall Enterprise System should capture those critical dates so field staff can monitor ongoing recalls and headquarters recall managers can determine how much time elapses between critical steps of the recall process and take steps to reduce time frames, to the extent possible.
6. FDA believes that data available on recalled food may not include individual product or case breakdown. While capturing details about the amount recalled and amount recovered may not always be possible, we believe that FDA field staff should be instructed to take care that, when such information is available, it be captured in the Recall Enterprise System using comparable units.

GAO Contacts and Staff Acknowledgments

GAO Contacts

Lawrence J. Dyckman, (202) 512-3841
J. Erin Lansburgh, (202) 512-3017

Staff Acknowledgments

In addition to those named above, Terrance N. Horner, Jr.; Julian Klazkin; Lynn Musser; Jennifer Popovic; Julia A. Roberts; Carol Herrnstadt Shulman; Joseph Thompson; and Jonathan Weiss made key contributions to this report.

GAO's Mission

The Government Accountability Office, the audit, evaluation and investigative arm of Congress, exists to support Congress in meeting its constitutional responsibilities and to help improve the performance and accountability of the federal government for the American people. GAO examines the use of public funds; evaluates federal programs and policies; and provides analyses, recommendations, and other assistance to help Congress make informed oversight, policy, and funding decisions. GAO's commitment to good government is reflected in its core values of accountability, integrity, and reliability.

Obtaining Copies of GAO Reports and Testimony

The fastest and easiest way to obtain copies of GAO documents at no cost is through GAO's Web site (www.gao.gov). Each weekday, GAO posts newly released reports, testimony, and correspondence on its Web site. To have GAO e-mail you a list of newly posted products every afternoon, go to www.gao.gov and select "Subscribe to Updates."

Order by Mail or Phone

The first copy of each printed report is free. Additional copies are \$2 each. A check or money order should be made out to the Superintendent of Documents. GAO also accepts VISA and Mastercard. Orders for 100 or more copies mailed to a single address are discounted 25 percent. Orders should be sent to:

U.S. Government Accountability Office
441 G Street NW, Room LM
Washington, D.C. 20548

To order by Phone: Voice: (202) 512-6000
TDD: (202) 512-2537
Fax: (202) 512-6061

To Report Fraud, Waste, and Abuse in Federal Programs

Contact:

Web site: www.gao.gov/fraudnet/fraudnet.htm

E-mail: fraudnet@gao.gov

Automated answering system: (800) 424-5454 or (202) 512-7470

Congressional Relations

Gloria Jarmon, Managing Director, JarmonG@gao.gov (202) 512-4400
U.S. Government Accountability Office, 441 G Street NW, Room 7125
Washington, D.C. 20548

Public Affairs

Jeff Nelligan, Managing Director, NelliganJ@gao.gov (202) 512-4800
U.S. Government Accountability Office, 441 G Street NW, Room 7149
Washington, D.C. 20548

**United States
Government Accountability Office
Washington, D.C. 20548-0001**

**Official Business
Penalty for Private Use \$300**

Address Service Requested

**Presorted Standard
Postage & Fees Paid
GAO
Permit No. GI00**

