

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**THE FOOD AND DRUG
ADMINISTRATION'S
FOOD-RECALL PROCESS
DID NOT ALWAYS ENSURE
THE SAFETY OF THE
NATION'S FOOD SUPPLY**

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Office of Inspector General

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Report in Brief

Date: December 2017

Report No. A-01-16-01502

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL



Why OIG Did This Review

Prior OIG reviews focused on U.S. Food and Drug Administration (FDA) oversight of food recalls. Food recalls are the most effective means of protecting public health when a widely consumed food product is either defective or potentially harmful. At the time of those OIG reviews, FDA did not have statutory authority to require food manufacturers to initiate recalls of most foods.

After those reviews, enactment of the FDA Food Safety Modernization Act gave FDA new authority to order a mandatory recall and require firms to recall certain harmful foods. We conducted this review to determine whether FDA is fulfilling its responsibility in safeguarding the Nation's food supply now that it has mandatory recall authority.

Our objective was to determine whether FDA had an efficient and effective food-recall process that ensured the safety of the Nation's food supply. Specifically, we focused on FDA's (1) oversight of firms' initiation of food recalls, (2) monitoring of firm-initiated recalls, and (3) maintenance of food-recall data in the electronic recall data system.

How OIG Did This Review

We reviewed documentation for 30 voluntary food recalls judgmentally selected from the 1,557 food recalls reported to FDA between October 1, 2012, and May 4, 2015.

The Food and Drug Administration's Food-Recall Process Did Not Always Ensure the Safety of the Nation's Food Supply

What OIG Found

FDA did not always have an efficient and effective food-recall process that ensured the safety of the Nation's food supply. We identified deficiencies in FDA's oversight of recall initiation, monitoring of recalls, and the recall information captured and maintained in FDA's electronic recall data system, the Recall Enterprise System (RES). Specifically, we found that FDA could not always ensure that firms initiated recalls promptly and that FDA did not always (1) evaluate health hazards in a timely manner, (2) issue audit check assignments at the appropriate level, (3) complete audit checks in accordance with its procedures, (4) collect timely and complete status reports from firms that have issued recalls, (5) track key recall data in the RES, and (6) maintain accurate recall data in the RES.

Recalls were not always initiated promptly because FDA does not have adequate procedures to ensure that firms take prompt and effective action in initiating voluntary food recalls. FDA's monitoring of recalls was not always adequate because FDA staff had insufficient oversight to ensure that the assignment was at the appropriate level and FDA obtained incomplete or inaccurate consignee information from firms initiating recalls. Additionally, FDA lacked adequate procedures to collect timely and complete status reports from these firms because the procedures did not require staff to request status reports at the time the recall was initiated. Lastly, the RES contained deficient recall information because it did not track all information necessary for FDA to effectively monitor recall activities and assess the timeliness of recalls; the RES also contained inaccurate data.

What OIG Recommends and FDA Comments

We recommend that FDA use its Strategic Coordinated Oversight of Recall Execution (SCORE) initiative to establish set timeframes, expedite decision-making and move recall cases forward, and improve electronic recall data. We also made other procedural recommendations, which are listed in the report.

FDA agreed with our conclusion that it needs to help ensure that recalls are initiated promptly in all circumstances and said that it will consider the results of our review as it "continues to operate the SCORE team." FDA also described other actions it has taken in response to our early alert, issued June 8, 2016, and draft report including initiating a new quality system audit process and a plan to provide early notice to the public and more guidance to staff.

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INTRODUCTION

WHY WE DID THIS REVIEW

Prior Office of Inspector General (OIG) reviews focused on U.S. Food and Drug Administration (FDA) oversight of food recalls.¹ Food recalls are the most effective means of protecting public health when a widely consumed food product is either defective or potentially harmful. At the time of those OIG reviews, FDA did not have statutory authority to require food manufacturers to initiate recalls of most foods. We found that (1) FDA's procedures were not always adequate for monitoring recalls, (2) FDA's guidance for developing and implementing recalls was not adequate to ensure the safety of the Nation's food supply, and (3) FDA did not always follow its own procedures for ensuring that the recall process operated efficiently and effectively. After those reviews, enactment of the FDA Food Safety Modernization Act (FSMA) gave FDA new authority to order a mandatory recall and require firms to recall certain harmful foods. We conducted this review to determine whether FDA is fulfilling its responsibility in safeguarding the Nation's food supply now that it has authority to order a mandatory recall.

OBJECTIVE

Our objective was to determine whether FDA had an efficient and effective food-recall process that ensured the safety of the Nation's food supply. Specifically, we focused on FDA's (1) oversight of firms' initiation of food recalls, (2) monitoring of firm-initiated recalls, and (3) maintenance of food-recall data in the electronic recall data system.

BACKGROUND

Food and Drug Administration's Oversight of Food Recalls

The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires FDA to safeguard the Nation's food supply, including dietary supplements, and ensure that all ingredients are safe. Within FDA, the Center for Food Safety and Applied Nutrition (CFSAN) and the Office of Regulatory Affairs (ORA) collaborate in the oversight of food recalls. The ORA district office responsible for overseeing the region where a recalling firm is located is designated as the lead district and is responsible for providing guidance to the recalling firm and for monitoring day-to-day recall activities. This report refers to the lead district as the "FDA monitoring district office." Generally, each FDA monitoring district office has a district director and recall coordinators responsible for managing day-to-day activities associated with FDA's recall oversight.

¹ *Review of the Food and Drug Administration's Monitoring of Pet Food Recalls* (A-01-07-01503, August 2009). Available online at <https://oig.hhs.gov/oas/reports/region1/10701503.pdf>. *Review of the Food and Drug Administration's Monitoring of Imported Food Recalls* (A-01-09-01500, June 2011). Available online at <https://oig.hhs.gov/oas/reports/region10/10901500.pdf>.

FDA generally relies on firms to protect public health by voluntarily recalling food products that present a risk of injury or gross deception or are otherwise defective.² FDA monitors and assesses the adequacy of a firm's recall efforts. According to FDA, recalls should be evaluated on a case-by-case basis because some recalls are more challenging or complex than others.

In 2011, the FSMA added section 423 to the FD&C Act to give FDA new authority to order a firm to recall certain articles of food.³ As of August 2016, FDA twice initiated the process to use its mandatory recall authority under FSMA.⁴

Overview of FDA's Food-Recall Oversight Process

A recall is a firm's removal or correction of a marketed product that FDA considers to be in violation of the FD&C Act and against which FDA would initiate a legal action (e.g., seizure).⁵ When FDA learns about a potentially hazardous product, FDA may inform the firm that the product violates the law and discuss the possibility of a recall with the firm without specifically requesting a recall. If the firm decides to recall the product, the firm's action is considered a voluntary recall.

FDA will complete a health hazard evaluation (HHE) for each recall, which it uses to classify the recall and assess the firm's recall strategy. A recall may be classified as Class I, II, or III, with Class I indicating the greatest health hazard.⁶ The FDA monitoring district office then sends a notification letter to the firm with the recall's classification, FDA's assessment of the firm's recall strategy, and any suggested strategy revisions.

If the firm fails to voluntarily recall the violative product or FDA determines that the recall is ineffective, FDA may take appropriate regulatory action. One action that FDA may consider is a

² 21 CFR § 7.40.

³ Section 206 of the FSMA, P.L. No. 111-353 (enacted January 4, 2011).

⁴ In September 2012, FDA became aware of pet food distributed by Kasel Associates Industries, Inc., that was adulterated with *Salmonella*, a pathogenic organism, and initiated the process to use its mandatory recall authority for the first time in February 2013. In September 2013, FDA became aware of dietary supplements distributed by USPlabs, LLC, that were adulterated with aegeline (a new dietary ingredient for which there was inadequate information to provide reasonable assurance that it would not present a significant or unreasonable risk of injury or illness) and initiated the mandatory recall process for the second time in November 2013.

⁵ 21 CFR § 7.3.

⁶ 21 CFR § 7.41. In Class I recalls, there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death. In Class II recalls, the use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or the probability of serious adverse health consequences or death is remote. In Class III recalls, the use of or exposure to a violative product is not likely to cause adverse health consequences (21 CFR § 7.3).

mandatory recall.⁷ To use its mandatory recall authority, FDA must determine that there is a reasonable probability that the food is adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act and that it will cause serious adverse health consequences or death to humans or animals (serious adverse health consequences or death). FDA must then issue to a firm a “423(a) letter” and give the firm the opportunity to voluntarily stop distribution and recall the product. Specifically, a 423(a) letter states that FDA may, by order, require the firm to immediately cease distribution of the product if the firm does not do so voluntarily. If a firm refuses or fails to complete the recall, FDA may order the firm to stop distribution of the product and to notify others to also stop its distribution. If, after a firm is given an opportunity for an informal hearing, FDA determines that it is necessary to recall the product, FDA may amend the order and require the firm to recall the product and specify a recall timetable.

If a firm voluntarily initiates a recall, the FDA monitoring district office oversees the effectiveness of the recall through various methods that may include conducting audit checks and reviewing the firm’s periodic status reports.⁸ An audit check is a visit, telephone call, or letter (or a combination of them) to a consignee (primarily distributors and retailers of the product) to verify that the consignee has been notified of the recall and has taken appropriate action. In certain cases, State agencies (e.g., the California Department of Public Health) and third-party contractors can conduct audit checks. Further, the FDA monitoring district office may request that the recalling firm submit periodic status reports so that it can assess the progress of the recall. Recall personnel at the FDA monitoring district office are responsible for day-to-day management of a recall, including ensuring that FDA receives and reviews the firm’s status reports in a timely manner.

Throughout the recall, FDA recall personnel use the Recall Enterprise System (RES), which is an electronic data system, to document the submission, updates, classification, and termination of recalls. (Appendix A contains the details of FDA’s food-recall process.)

Recall Regulations and Procedures

Recall Regulations

FDA regulations provide guidance to FDA and firms in planning and implementing a recall (21 CFR part 7). This report refers to these regulations as “Recall Regulations.”

⁷ FD&C Act § 423.

⁸ FDA cannot require firms to provide status reports. It can only request periodic status reports from the recalling firm. The frequency of such status reports will be determined by the relative urgency of the recall and will be specified by FDA in each recall case; generally, the reporting interval will be between 2 and 4 weeks (21 CFR § 7.53).

FDA Recall Procedures

FDA's recall procedures generally include classifying, publicizing, and monitoring firm recalls and assessing their effectiveness. FDA's *Regulatory Procedures Manual* (RPM) and *Investigations Operations Manual* (IOM) detail these procedures. In addition, FDA's *Mandatory Food Recalls* (document #ORA-OEIO.005, version #1.1, dated December 27, 2012), *Interim Mandatory Recall Procedures*, details interim procedures for how and when FDA should exercise its mandatory recall authority and outlines the related roles and responsibilities of FDA staff.⁹

Office of Inspector General Early Alert Memorandum

In June 2016, OIG issued an Early Alert memorandum to FDA, raising concerns that FDA did not have adequate policies and procedures to ensure that firms take prompt and effective action in initiating voluntary recalls. According to FDA, our Early Alert memorandum and this review were catalysts to major changes in FDA's oversight of the process. Specifically, FDA expedited changes to improve voluntary recall oversight and strengthen its enforcement strategies, including its ability to use its mandatory recall authority. (See Appendix B for the Early Alert memorandum.)

HOW WE CONDUCTED THIS REVIEW

Our audit covered 30 voluntary food recalls (23 Class I and 7 Class II) judgmentally selected from the 1,557 food recalls reported to FDA between October 1, 2012, and May 4, 2015. We selected recalls based on risk factors related to the timing of the recall and other risk factors. Timing-related risk factors included how long it took to initiate the recall, when the firm began notifying its distribution chain of the recall, when the firm issued a press release, how long it took to classify the recall, how long it took to complete the recall, and how long it took to terminate the completed recall. Other risk factors included the level of FDA's involvement in the initiation of the recall (i.e., firm-initiated, State-initiated, or FDA-initiated), the scope of the recall (i.e., depth of recall, number of consignees, number of days the product was manufactured, and number of days the product was distributed), the reason for the recall, the classification of the recall, and media coverage. This resulted in the selection of 30 recalls overseen by FDA.¹⁰ FDA considers all 30 selected recalls to be among its most complex.

We reviewed recall files and interviewed FDA recall staff to compare practices with FDA guidance and related internal policies and procedures. We limited our review of FDA's internal controls to those related to our audit objective.

⁹ FDA continually updates its policies and procedures and had most recently revised the IOM in 2017. According to FDA, it will update the RPM and finalize the Mandatory Recall Procedures by the end of fiscal year 2017. We used FDA's policies and procedures that were in effect during the scope of our audit.

¹⁰ Because we selected a judgmental sample, the sample results are informative about deficiencies in FDA's food-recall oversight process but are not applicable to the full population of FDA recalls.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objective. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

Appendix C contains the details of our audit scope and methodology.

FINDINGS

FDA did not always have an efficient and effective food-recall process that ensured the safety of the Nation's food supply. We identified deficiencies in FDA's oversight of recall initiation as well as its recall monitoring and the recall information captured and maintained in the RES. Specifically, we found that FDA could not always ensure that firms initiated recalls promptly (initiation). We also found that FDA did not always:

- evaluate health hazards in a timely manner (initiation),
- issue audit check assignments at the appropriate level (monitoring),
- complete audit checks in accordance with its procedures (monitoring),
- collect timely and complete status reports from recalling firms (monitoring),
- track key recall data in the RES (data system), and
- maintain accurate recall data in the RES (data system).

FDA could not always ensure that firms initiated recalls promptly; therefore, some consumers became ill and others were at risk of illness or, in some cases, death. FDA relies primarily on voluntary recalls, which makes the timeliness of the recalls largely dependent on the firm's willingness to take action.

Recalls were not always initiated promptly because FDA does not have adequate procedures to ensure that firms take prompt and effective action in initiating voluntary food recalls. In addition, FDA had not established risk-based internal timeframes for reaching certain milestones, such as when to instruct recall staff to request that firms voluntarily recall their products, which delayed FDA from taking further action in some recalls. We also found that FDA did not always evaluate health hazards in a timely manner, which would limit FDA's ability to use its mandatory recall authority in certain Class I recalls. FDA explained that delays in evaluating health hazards were due to, among other reasons, difficulties in obtaining the information necessary to make decisions about the seriousness of the health hazard presented by the product.

FDA's monitoring of recalls was not always effective because FDA staff did not always follow procedures or those procedures were inadequate. As a result, FDA could not consistently ensure that the recalling firms' consignees appropriately removed harmful products from retail stores and other points in the distribution chain.

FDA relies on data from the RES to facilitate effective monitoring of recalls and report the length of time it took a firm to initiate a recall. FDA did not maintain all necessary information in the RES because the system was not designed to capture some information and because key terms related to data fields were not well defined.

FDA COULD NOT ALWAYS ENSURE THAT FIRMS INITIATED RECALLS PROMPTLY

FDA Recall Regulations and Procedures

FDA may inform a firm that a product violates the law and discuss the possibility of a recall without specifically requesting a recall. If the firm decides to recall the product, the firm's action is a "firm-initiated recall" (21 CFR § 7.46). FDA should document this conversation in internal meeting minutes or notes (RPM, chapter 7-5-1).

FDA may take appropriate regulatory action or other measures if the firm refuses or fails to recall a violative product in a timely fashion or if the recall action is ineffective (RPM, chapter 7-3).

Recall Initiation

The 30 voluntary recalls that we reviewed had a median of 29 days to initiate, with an average of 57 days. Initiation of these recalls ranged from 9 days before to 303 days after FDA learned that the product was potentially hazardous (Figure 1 on the next page).^{11, 12} (Appendix D contains details of each recall.)

The timeliness of recalls depended primarily on how quickly firms chose to act on information they received from FDA or other sources indicating that their products were potentially hazardous. When firms acted promptly by voluntarily initiating a recall, FDA did not need to take further action to recall the product. For example, in a Class I recall of smoked salmon

¹¹ We considered the date that "FDA learned that the product was potentially hazardous" as the time that FDA first became aware of or was notified that a product is a potential health hazard. At this point, FDA might not always have had all of the information necessary to determine whether all relevant products were violative or to determine the appropriate scope of the recall.

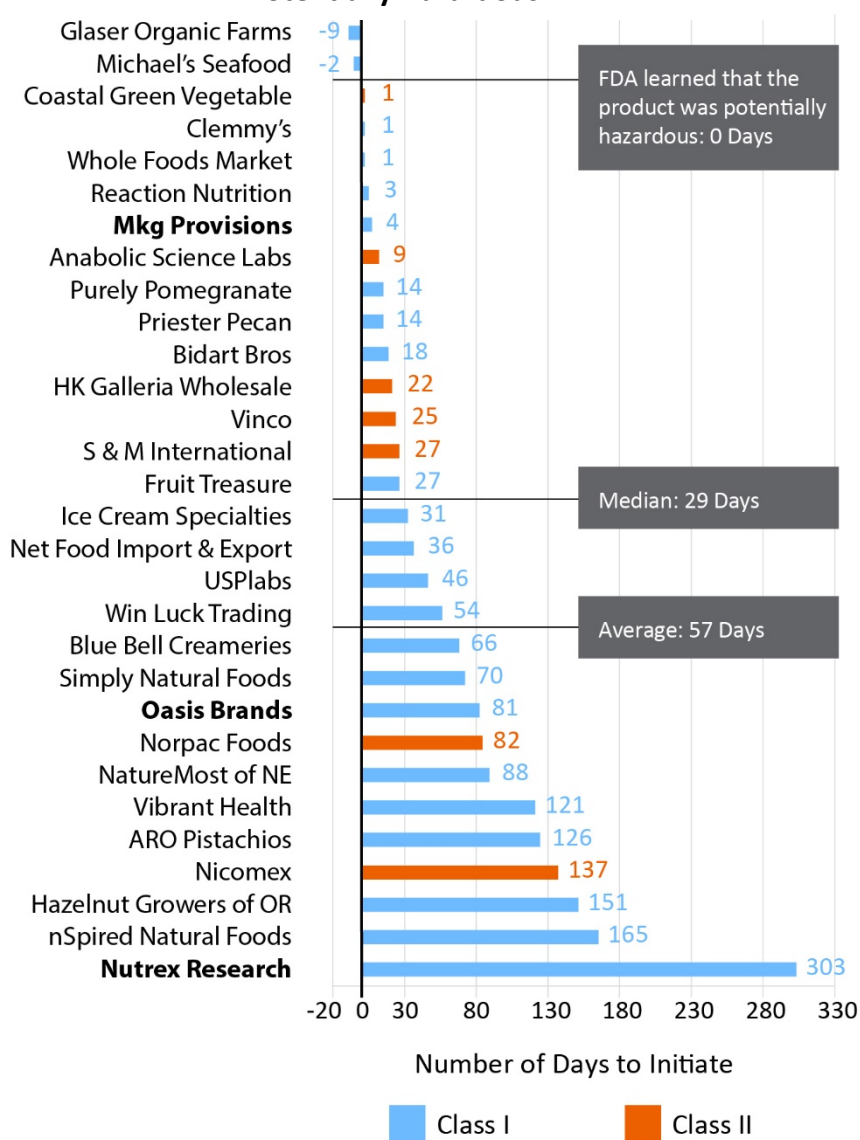
¹² A negative number of days means that a firm initiated the recall voluntarily before FDA became aware of a potentially hazardous product. This occurred in 2 of the 30 recalls we reviewed.

contaminated with *Listeria monocytogenes*, the firm voluntarily initiated a recall 4 days after FDA informed it of positive sample results (Mkg Provisions, Inc.; Class I recall).

In contrast, when FDA and a firm disputed the lawfulness of a product or when firms were reluctant to initiate timely recalls, FDA’s food-recall initiation process could not always ensure that the Nation’s food supply was protected from hazardous products. For example, in a Class I recall of an adulterated dietary supplement, FDA and the firm disagreed over whether the product was lawful, and the firm did not recall the product until 303 days after receiving a warning letter from FDA.^{13, 14} The letter stated that the product was adulterated because the product contained a new dietary ingredient that the firm did not notify FDA about (Nutrex Research, Inc.; Class I). In addition, the firm distributed free samples of the adulterated product for more than 8 months after receiving the warning letter.

In another example, which involved a series of recalls of various cheese

Figure 1: Days It Took Firms To Initiate Recall After FDA First Learned a Product Was Potentially Hazardous



¹³ Nutrex labeled and promoted several products as dietary supplements that contained the ingredient methylhexanamine (DMAA). A “new dietary ingredient” is one that was not marketed in the United States before October 15, 1994 (FD&C Act § 413(d)).

¹⁴ In addition to the warning letter sent to Nutrex, FDA issued several other warning letters in April 2012 to other firms marketing products containing DMAA. FDA also issued a public announcement that said that while FDA worked to remove these products from the market, consumers should not buy or use any product marketed as a dietary supplement containing DMAA (see <https://www.fda.gov/food/dietarysupplements/productsingredients/ucm346576.htm>; accessed on May 16, 2017).

products contaminated with *Listeria monocytogenes*, 81 days passed from the date FDA became aware of the adulterated product and the date the firm had voluntarily recalled all affected products (Oasis Brands, Inc.; Class I). During that time, the firm's owner agreed with FDA to suspend manufacturing and temporarily halt its distribution of cheese. However, the owner, despite knowing that the product had tested positive for *Listeria monocytogenes*, then had multiple trays of cheese, which had been held in processing, packaged and distributed.¹⁵

Recalls were not always initiated promptly because FDA did not have adequate procedures to ensure that firms take prompt and effective action in initiating voluntary food recalls. FDA had not established risk-based internal timeframes for reaching certain milestones, which delayed it from taking further action in some recalls. Therefore, in situations in which firms acted promptly and voluntarily initiated a recall, FDA did not need to take further action to recall the product. However, when firms were reluctant to initiate timely recalls, FDA's food-recall initiation process could not ensure the efficiency and effectiveness of food recalls to protect the Nation's food supply from hazardous products.

FDA DID NOT ALWAYS EVALUATE HEALTH HAZARDS IN A TIMELY MANNER

FDA Recall Regulations and Procedures

After learning of a planned or in-progress food recall, the FDA monitoring district office should submit a recall alert through the RES to notify CFSAN's Center Recall Unit (CRU) of the recall as soon as possible, but preferably within 24 hours of learning of a planned or in-progress recall (RPM, chapter 7-5-1.1). Within 5 working days of the recall alert, or as soon as possible, the FDA monitoring district office must submit a recall recommendation through the RES to the CRU. The FDA monitoring district office must also submit other information, including information about the product, the reason for the recall recommendation, and the firm's recall strategy (RPM, chapter 7-5-1.2).

A committee of FDA scientists reviews this information and completes the HHE within 2 working days of receiving the recall recommendation unless additional information is required or the product is no longer in distribution (21 CFR § 7.41 and RPM, chapter 7-6-1). A precedent HHE will be used if the product is identical or similar to one in a previously classified recall action. If a precedent HHE does not exist, the committee will submit an approved HHE to the CRU (RPM, chapter 7-6-1). The CRU will normally classify the recall within 2 days of receiving the HHE (RPM, chapter 7-6-2).

¹⁵ In September 2016, the owner of Oasis Brands was sentenced to 15 months in prison after pleading guilty to a felony and misdemeanor. The owner pleaded guilty to a felony for delivering an adulterated food into interstate commerce with the intent to defraud and mislead the Government and to a misdemeanor as the corporate official responsible for ensuring that adulterated foods are not introduced into interstate commerce (see <https://www.justice.gov/usao-sdfl/pr/miami-dade-resident-sentenced-fifteen-months-prison-distributing-contaminated-cheese>; accessed on May 16, 2017).

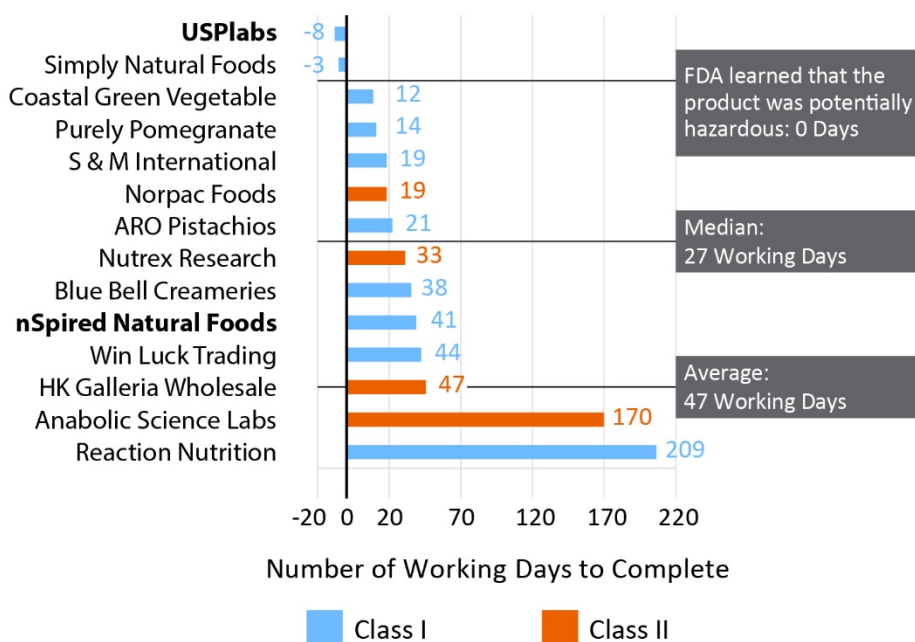
After receiving the classification, the FDA monitoring district office will promptly send a notification letter to the firm with essential recall information, including the recall classification and FDA’s assessment of the firm’s recall strategy (i.e., type of notification, depth of recall, and level-of-effectiveness check) (RPM, chapter 7-7-1.3).

FDA’s interim mandatory recall procedures state that FDA can also begin an HHE after learning of “the need to consider exercising its authority” to mandate a recall. At this point, FDA will also begin determining whether the recall meets the requirements established by section 423 of the FD&C Act. Only after FDA has completed the HHE may it begin initiating the process to exercise its mandatory recall authority (Interim Mandatory Recall Procedures, section 6.1).

Health Hazard Evaluations

For 14 of the 30 recalls for which FDA did not rely on a precedent HHE,¹⁶ the median working days¹⁷ to complete the HHE after learning of a planned or in-progress recall was 27 working days, with an average of 47 working days. Completion of the HHE ranged from 8 working days before learning of a planned or in-progress recall to 209 working days after learning of a planned or in-progress recall (Figure 2).¹⁸ (Appendix E contains details of each recall.)

Figure 2: Days Taken for FDA To Complete a Health Hazard Evaluation After Learning of a Planned or In-Progress Recall



¹⁶ For the remaining 16 recalls, FDA assigned a precedent HHE and did not track the assignment date. Therefore, we could not calculate the number of days it took FDA to evaluate the hazard of these food products.

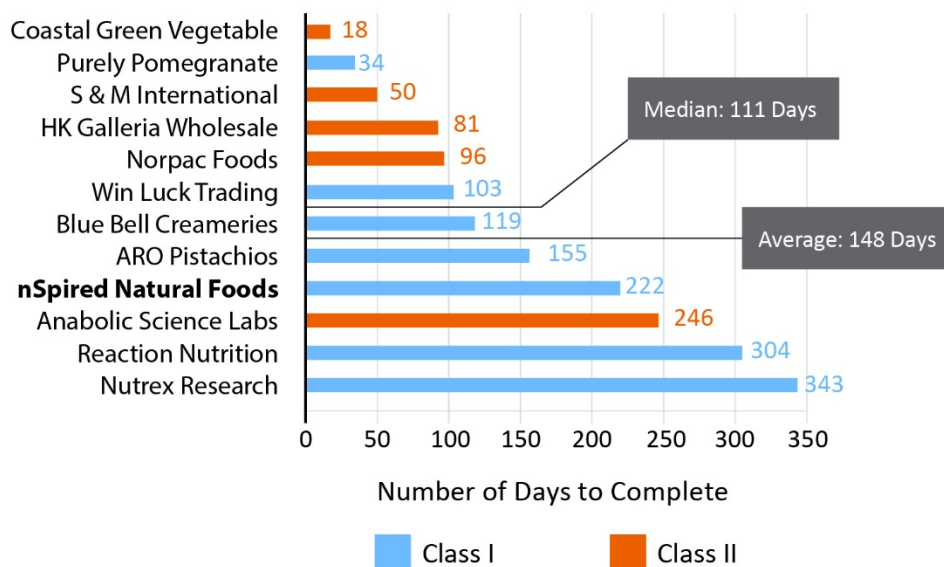
¹⁷ We define “working days” as business days.

¹⁸ A negative number of days means that FDA completed the HHE before learning of a planned or in-progress recall. This occurred in 2 of the 14 recalls we reviewed.

For 12 of the 14 recalls, FDA did not complete the HHE prior to the firm initiating a voluntarily recall. For those 12, the median days for FDA to complete the HHE after learning that the product was potentially hazardous was 111 days, with an average of 148 days and a range of 18 to 343 days. Without a timely HHE, FDA could not establish that there was a reasonable probability that the food would cause serious adverse health consequences or death and, therefore, was not always in a position to determine whether to exercise its mandatory recall authority. (Appendix F contains details of each recall.)

For example, in a Class I recall involving aegeline (a new dietary ingredient for which there was inadequate information to provide reasonable assurance that it would not present a significant or unreasonable risk of injury or illness) in a dietary supplement, the HHE was signed and completed 8 days before the firm voluntarily agreed to recall its product (USPlabs, LLC; Class I). FDA issued the 423(a) letter, and the firm initiated the recall 3 days after receiving the letter.¹⁹

Figure 3: Days Taken for FDA To Complete a Health Hazard Evaluation After Learning a Product Was Potentially Hazardous



In contrast, when firms were reluctant to provide FDA with information necessary to complete the HHE, FDA could not complete it in a timely manner. For example, in a Class I recall involving various nut butter products contaminated with *Salmonella*, FDA had been aware of the contamination for 161 days before the firm agreed to recall its products. FDA then took an additional 41 working days to complete the HHE. It took FDA 222 days to complete the HHE after learning that the product was potentially hazardous (Figure 3) (nSpired Natural Foods, Inc.; Class I). At least 14 people became ill from the *Salmonella* contamination.

We found that FDA officials did not complete some HHEs in a timely manner for three reasons:

1. FDA did not always follow the 24-hour timeframe in its procedures for submitting the recall alert to the RES after learning of a firm’s decision to recall. Specifically, for all 30 recalls, FDA submitted the recall alert an average of 34 days after learning of a planned

¹⁹ On November 17, 2015, an 11-count indictment was unsealed against several USPlabs executives. The indictments alleged that USPlabs engaged in a conspiracy to import ingredients from China using false certificates of analysis and false labeling and then lied about the source and the nature of those ingredients after it put them in its products. See <https://www.justice.gov/usao-ndtx/pr/usplabs-and-corporate-officers-indicted>.

or in-progress recall. The recall alert triggers the HHE process because it notifies CFSAN of the recall.

2. FDA officials explained that they sometimes had difficulties obtaining the information necessary to make decisions about the seriousness of the health hazard presented by the product. Specifically, firms were not always responsive to FDA's requests for information or had difficulties compiling the information for FDA in a timely manner. Additionally, according to FDA, when a firm is initially hesitant or unwilling to recall, the burden on FDA to gather strong evidence to support the seriousness of the health hazard is greater than if the firm promptly agrees to recall voluntarily.
3. FDA's interim mandatory recall procedures did not include factors to consider when determining the existence of a reasonable probability that a food would cause serious adverse health consequences or death. FDA's interim mandatory recall procedures state that FDA will begin completing an HHE upon learning of "the need to consider exercising its authority." They also state that an HHE must be completed before FDA can draft and issue to a firm an order to cease distribution. We found in our interviews with FDA staff that there was an inconsistent understanding of the factors to consider when determining whether a reasonable probability that a food would cause serious adverse health consequences or death exists. Some staff believed that "water tight" and "absolute" evidence that a food would cause serious adverse health consequences or death would meet the "reasonable probability" standard; however, other staff believed that a lesser level of evidence would meet that standard. For more than 4 years (beginning in December 2012), FDA has relied on interim mandatory recall procedures that do not list the factors staff should consider when determining whether there is a reasonable probability that a food will cause serious adverse health consequence or death.

Without a timely HHE, FDA could not send out timely notification letters to firms with FDA's formal written assessment of the firms' recall strategy and any suggested strategy revisions or request periodic status reports. However, FDA stated that it provided firms with assessments of their recall strategies by phone and email that discussed suggested strategy revisions and requested periodic status reports. For 12 of the 14 recalls, FDA sent the notification letter to the recalling firm an average of 96 days after the recall was initiated, which was after all of the firms had already notified their consignees. For the remaining two recalls, FDA did not send a notification letter to the firm.

FDA DID NOT ALWAYS ISSUE AUDIT CHECK ASSIGNMENTS CONSISTENT WITH THE LEVEL IN THE PROPOSED AUDIT PROGRAM

FDA Procedures

The FDA monitoring district office should provide CFSAN with a proposed audit program for monitoring a recall to verify the recall's effectiveness. The audit program should include a

timetable for reviewing the recall status and the level and type of audit checks (IOM, chapter 7.2.9.9).

A recall “audit check” is a visit, telephone call, or letter (or a combination of them) from FDA staff to a consignee to verify that the consignee has been notified of the recall and has taken appropriate action (IOM, chapter 7.3.2.1). FDA’s procedures state that “Level A” audit checks indicate that FDA should contact 100 percent of consignees. “Level B” audit checks indicate that FDA should contact more than 10 percent but less than 100 percent of consignees. “Level C” audit checks indicate that FDA should contact 10 percent of consignees. “Level D” audit checks indicate that FDA should contact 2 percent of consignees. “Level E” audit checks indicate that FDA does not conduct audit checks (IOM, chapter 7.3.2.2). The FDA monitoring district office should issue the number of audit checks consistent with the level proposed in the audit program (RPM, chapter 7-8-3).

Audit Check Assignments

For 19 of the 27 recalls,²⁰ the FDA monitoring district office issued audit check assignments at the level in the proposed audit program. For example, in a Class I recall involving *Listeria monocytogenes* in apples, the FDA monitoring district office proposed “Level A” (100 percent) audit checks (Bidart Bros., Class I). The firm reported distributing the potentially contaminated products to 79 domestic consignees, and the FDA monitoring district office issued audit checks to all 79 domestic consignees (100 percent).

In contrast, for the remaining eight recalls, the FDA monitoring district office issued fewer audit check assignments than what was required for the level in the proposed audit program. For example, in a Class I recall involving high levels of an undeclared allergen in dark chocolate, the FDA monitoring district office proposed “Level A” (100 percent) audit checks (Simply Natural Foods LLC, Class I). The firm reported distributing mislabeled products to 19 domestic consignees; however, the FDA monitoring district office issued audit checks at only 12 domestic consignees (63 percent). (Appendix G contains details of each recall.)

In addition, FDA relies on the distribution list provided by the firms so that the FDA recall coordinator can identify the consignees for audit checks. However, the recall coordinator does not always perform a reconciliation against shipping records to verify the list’s completeness and accuracy. For example, in the Class I recall mentioned above, at least five consignees did not report receiving any of the contaminated product; therefore, audit checks of them were unnecessary.

²⁰ For 3 of the 30 recalls, FDA determined that it was not necessary to assign audit checks for various reasons, such as the products were distributed internationally or the recalled products would have expired by the time the recall went into effect.

FDA monitoring district offices did not always issue audit check assignments consistent with assigned recall levels or based on complete and accurate distribution lists because recall coordinators (1) had insufficient oversight to ensure that the assignment was at the appropriate level or (2) obtained incomplete or inaccurate consignee information from recalling firms.

Without assigning audit checks at the appropriate level, FDA could not adequately ensure that consignees were notified of the recall and followed recall instructions. For these reasons, FDA's audit check assignment process was not always effective and efficient to ensure that the Nation's food supply was protected from hazardous products.

FDA DID NOT ALWAYS COMPLETE AUDIT CHECKS IN ACCORDANCE WITH PROCEDURES

FDA Recall Regulations and Procedures

Firms are responsible for promptly notifying their consignees about a recall through recall communications (21 CFR § 7.49).

The RPM, chapter 7-8-2, states:

Normally within 10 days of issuance of the firm's recall communication, the monitoring district will issue audit check assignments at the level in the FDA audit program. . . . The district office receiving audit check assignments should consider them high priority and should accomplish them as soon as possible. Submit copies of audit check reports to the monitoring district. If possible, complete assignments within 10 working days from receipt of assignment. For Class I recalls, provide audit check reports to monitoring district at least once a week or more often if so directed. . . . It is the responsibility of the receiving district to notify the issuing district of circumstances which will adversely delay the completion of the assignment.

Audit Check Completion

FDA did not always complete audit checks within the timeframes set out in its procedures. FDA conducted audit checks at 25 of the 30 firms with recalls in our sample.²¹ For 4 of the 25 recalls, FDA completed the last audit check within 20 days of issuance of the firm's recall communication. For example, in a Class I recall involving pomegranate seeds contaminated with hepatitis A, FDA completed the last audit check 5 working days from when the firm issued its recall communication (Purely Pomegranate, Inc., Class I). For this recall, FDA conducted

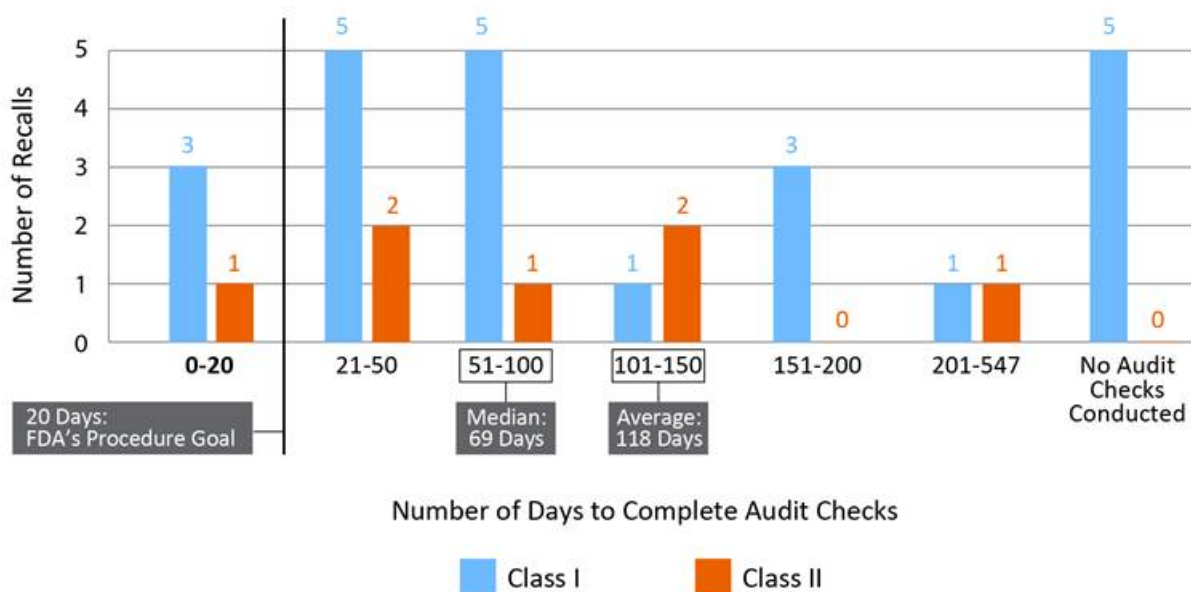
²¹ For 5 of the 30 recalls, FDA did not conduct audit checks for various reasons. Specifically, for two recalls, FDA determined that it was not necessary to assign audit checks because either the products were distributed internationally or the recalled products would have expired by the time the recall went into effect. For the remaining three recalls, audit checks were not conducted because of limited resources or because the products were distributed as "free samples."

three audit checks 1 to 5 days after the firm issued its recall communication with what FDA called an abundance of caution because of public concerns about the hepatitis A virus.

In contrast, for the remaining 21 recalls, FDA did not complete the last audit check within 20 days of the issuance of the firm’s recall communication.²² For these 21 recalls, the median days for FDA to finish conducting all audit checks after the firm issued its recall communication was 69 days (with an average of 118 days and a range of 22 to 547 days) (Figure 4). (Appendix H contains details of each recall.)

For example, in a Class I recall involving undeclared allergens in a dietary supplement, FDA did not complete the last audit check until 547 days after the firm issued its recall communication (Reaction Nutrition LLC, Class I). Of the 18 audit checks that FDA conducted for this recall, 3 were conducted 302 to 306 days after the firm issued the recall communication revealing that the mislabeled product was still available for sale to customers at 3 retail stores.

Figure 4: Days Taken for FDA To Complete the Last Audit Check After Firms Issued Their Recall Communications



In addition, we noted for all 21 recalls that did not have the last audit check completed within 20 days of the issuance of the firm’s recall communication, FDA did not retain a third-party contractor to assist with its audit checks despite having limited staff resources. We also found that the FDA staff conducting audit checks did not always provide regular updates to the recall

²² We used the 20-day threshold (10 days to issue audit check assignments and 10 working days to complete the assignments) to match FDA’s policies and procedures. When calculating days to complete last audit check, we used calendar days to determine how long it took to assign audit checks and working (business) days to determine how long it took to complete the last audit check.

coordinator and that recall coordinators did not always follow up with district offices to ensure that audit checks were completed in a timely manner. In addition, none of FDA's systems, including the RES, could be used to assist staff with tracking the results of audit checks.

Because it did not always complete audit checks within 20 days, FDA did not always adequately protect the public by ensuring that consignees took timely, appropriate action and that harmful products were removed from retail stores and other points in the distribution chain.

FDA DID NOT ALWAYS COLLECT TIMELY AND COMPLETE STATUS REPORTS FROM RECALLING FIRMS

FDA Recall Regulations and Procedures

The FDA monitoring district office's notification letter should request that the recalling firm submit periodic recall status reports to the FDA monitoring district office so that it may assess the progress of the recall (21 CFR § 7.53 and RPM, chapter 7-7-1).

The recall coordinator and appropriate district director are responsible for the day-to-day management of a recall, including ensuring that FDA receives and reviews the firm's status reports in a timely manner (RPM, chapter 7-8-2). Status reports should contain specific information, including the number and results of the firm's effectiveness checks (21 CFR § 7.53). The firm has an obligation to conduct effectiveness checks, which help verify that all known, affected consignees have received notification about a recall and have taken appropriate action (RPM, chapter 7-8-1).

Status Reports

FDA did not always collect timely status reports. For 11 of the 30 recalls, FDA either did not request or did not collect status reports.²³ For the remaining 19 recalls, the median days for FDA to collect the first status report was 122 days (with an average of 143 days and a range of 14 to 605 days) after the recalls were initiated. (Appendix I contains details of each recall.)

In addition, FDA did not always collect complete status reports. Of the 19 recalls in which at least 1 status report was provided, we found that 5 did not contain complete effectiveness check information.

For example, in a Class I recall involving a product containing undeclared egg, an allergen, FDA collected the firm's first status report 605 days after the recall was initiated (Win Luck Trading, Inc., Class I). In addition, the status report did not contain information about the number and

²³ For 7 of the 11 recalls, FDA requested status reports through its notification letter, but the firms did not provide status reports. For 3 of the 11 recalls, FDA sent a combined recall classification/termination letter; therefore, it did not request status reports. For the one remaining recall, there was no evidence that FDA sent a notification letter requesting status reports.

results of the firm’s effectiveness checks. FDA did not officially request status reports through its notification letter to the firm until 57 days after the recall was initiated, and there was no evidence that FDA followed up with the firm about status reports during the remaining 548 days.

FDA’s procedure to collect timely and complete status reports from recalling firms was inadequate because the procedures did not require staff to request status reports at the time the recall was initiated. Instead, FDA officially requested status reports only after it had sent the recall notification letter to the firm. In addition, FDA did not always include the request for status reports in the recall notification letter or follow up with firms when the status reports were not provided, were provided late, or were incomplete. Without obtaining timely and complete status reports from the firm, FDA could not adequately monitor the progress and effectiveness of a recall and assess whether additional action was necessary to protect the public.

FDA DID NOT TRACK KEY RECALL DATA IN THE ELECTRONIC RECALL ENTERPRISE SYSTEM

Federal Internal Control Standards

Management should establish internal controls through policies and procedures to achieve objectives and respond to risk in the internal control system, which includes the entity’s information system. Management should design control activities to achieve objectives and respond to risk by taking the following steps:

- Conduct top-level reviews of actual performance. Management should track major entity achievements and compare these to the plans, goals, and objectives set by the entity.
- Review activity level. Management should compare actual performance to planned or expected results throughout the organization and analyze significant differences.
- Establish and review performance measures and indicators. Management should establish activities to monitor performance measures and indicators. These activities might include assessing comparisons of different sets of data so that analyses of the relationships can be made and appropriate action taken.²⁴

FDA Procedures

The RES is an electronic data system used by FDA recall personnel to submit, update, classify, and terminate recalls (RPM, chapter 7-4). The information that FDA staff enter in the RES is gathered from various sources, including the field, the firm, ORA, and the CRU.

²⁴ Government Accountability Office, *Standards for Internal Control in the Federal Government*, “Control Activities,” pp. 44–47, September 2014.

In addition to being used to manage a recall, the RES also provides a central, searchable database so FDA can more efficiently track information, generate reports of recall activities, and disseminate those reports (RPM, chapter 7-4).

Lack of Performance Measures and Key Recall Data in the Recall Enterprise System

FDA did not have established performance measures and indicators to track key milestones of the food-recall process, such as the amount of time between the date that FDA learned that the product was potentially hazardous and the date a firm initiated a voluntary recall. In addition, FDA's RES did not track all information necessary for FDA to effectively monitor recall activities and assess the timeliness of recalls. Specifically, the RES did not track the date that FDA learned a product was potentially hazardous.

For example, in a Class I recall involving hazelnuts contaminated with *Salmonella*, FDA learned that the hazelnuts were potentially hazardous on December 2, 2012, when it was notified of positive test results from the Canadian Food Inspection Agency (Hazelnut Growers of Oregon, Class I). The firm initiated the recall on May 2, 2013. However, because the RES did not have a field for the date that FDA first learned the product was potentially hazardous (December 2, 2012), FDA could not use the RES to calculate that it took 151 days to initiate the recall.

FDA staff documented the date that FDA learned a product was potentially hazardous only in the recall files. FDA stated that tracking this date for all recalls would be time consuming and difficult as the date may be located in different FDA systems or obtained from sources outside of FDA. Without tracking this date in the RES, FDA could not effectively identify and respond to those firms that fail to voluntarily recall food products that present a risk to public health.

FDA DID NOT ALWAYS MAINTAIN ACCURATE RECALL DATA IN THE RECALL ENTERPRISE SYSTEM

Federal Internal Control Standards

Effective information and communication are vital for an entity to achieve its objectives. Management should use quality information to achieve the entity's objectives.²⁵

FDA Procedures

FDA's procedures state that in addition to being used to manage a recall, the RES also provides a central, searchable database so FDA can more efficiently track information, generate reports of recall activities, and disseminate those reports (RPM, chapter 7-4).

²⁵ Government Accountability Office, *Standards for Internal Control in the Federal Government*, "Control Activities," p. 46, Sept. 2014.

The RES User Manual defines the recall initiation date as the “date that the recall action was initiated by a company” (*RES User Manual for the Mission Accomplishment and Regulatory Compliance Services (MARCS) Integrator Contract (MIC)*, Release 1.0, April 16, 2012).

Inaccurate Data in the Recall Enterprise System

FDA did not always enter accurate recall initiation dates in the RES. For 11 of the 30 recalls (37 percent) we sampled, the RES contained an inaccurate recall initiation date, which was off by a median of 4 days and an average of 16 days. The inaccurate recall initiation dates ranged from 1 day before the initiation date inputted into the RES to 89 days after. For example, in a Class I recall involving undeclared allergens in a dietary supplement, June 5, 2013, was entered as the recall initiation date. However, based on a review of the recall file, we determined that recall was not initiated until September 2, 2013, when the firm began notifying its consignees of the recall. As a result, the date in the RES was incorrect by approximately 3 months (89 days) (NatureMost of New England, Class I).

FDA’s RES User Manual did not clearly define the term “recall initiation” date and, therefore, FDA staff input other dates into the RES. For example, in the Class I recall discussed above, the recall coordinator explained that she entered the date the firm started discussing a possible recall as the recall initiation date.²⁶ In addition, FDA did not have a data quality assurance process to help ensure that data inputted into the RES was both accurate and complete.

Without an accurate recall initiation date documented in the RES, FDA could not use the RES to determine the length of time it took a firm to initiate a recall. As a result, FDA did not have assurance that the data in the RES were accurate and that the RES was reporting correct information.

FDA RESPONSE TO THE OIG EARLY ALERT MEMORANDUM

We issued an Early Alert memorandum to FDA raising concerns that FDA did not have adequate policies and procedures to ensure that firms take prompt and effective action in initiating voluntary recalls. In response to our Early Alert memorandum, FDA told us that it made the following changes:

- In April 2016, FDA established Strategic Coordinated Oversight of Recall Execution (SCORE), a team of senior leaders that makes decisions during the most challenging high-risk food recall cases. SCORE examines cases that present a significant hazard to human health, whether or not there are reports that people have fallen ill. SCORE will expedite decision-making and move cases forward when senior leadership needs to

²⁶ In 2015, FDA revised the RES data dictionary and defined “recall initiation” as “the date that the firm first began notifying the public or their consignees of the recall.”

articulate policy, where expert support is needed, or when expected response timelines have not been met.

- In September 2016, with support from senior leadership, ORA designed and implemented a plan to audit ORA’s recall program across all regulated product areas. ORA described the program as a “quality system recall audit plan” that provides for both “traditional auditing and continuous monitoring of the recall program.” The plan includes aspects of the recall program that are important to the effective and efficient removal of products that pose a public health risk from the marketplace.
- In December 2016, ORA completed a project charter that implemented a recall strategic plan to identify strategic priorities that optimize FDA’s policies and procedures regarding recall of FDA regulated products that pose a public health risk. The project charter outlines the priorities and lists a set of deliverables to be completed by October 2017.

RECOMMENDATIONS

We recommend that FDA:

- establish set timeframes, through its SCORE initiative, for (1) FDA to discuss the possibility of a voluntary recall with a firm and (2) FDA to initiate use of its mandatory recall authority after it has made the determination that the legal standard for use of that authority has been met and a firm is not willing to voluntarily conduct a recall;
- include in its recall audit plan a step to monitor when the recall alert was submitted to the RES in accordance with current FDA alert submission procedures and, if appropriate, take steps to encourage the recall staff’s submission of the recall audit plan to the RES as soon as possible and preferably within 24 hours after learning of a firm-initiated recall;
- finalize its interim mandatory recall procedures and consider issuing guidance for FDA staff on those factors that staff should consider when determining whether there is a reasonable probability that a food could cause serious adverse health consequence or death;
- ensure, through its recall audit plan, that audit checks are issued at the level specified in the FDA audit program;
- develop procedures to determine whether a reconciliation of distribution lists to shipping records is necessary to ensure that FDA uses complete and accurate distribution lists when assigning audit checks;
- increase the use of third-party audit checks through its recall strategic plan;

- ensure, through its recall audit plan, that FDA district offices conducting audit checks follow procedures by completing audit check status updates and providing audit check reports, as directed by the recall coordinators;
- improve audit check tracking and monitoring using the RES or another FDA system;
- implement procedures to request status reports at the initiation of the recall and, through its recall audit plan, ensure FDA monitoring district offices follow up with firms that do not provide timely or complete status reports;
- develop a policy for defining and a procedure for identifying retrospectively the date that FDA learns of a potentially hazardous product and consider adding a field for the date to the RES or another FDA system so that FDA staff involved in managing a recall have access to this information;
- establish performance measures for the amount of time between the date FDA learns of a potentially hazardous product and the date a firm initiates a voluntary recall, monitor performance, and refine operating procedures, as needed;
- clarify the definition of “recall initiation date” in its policies and procedures and ensure a consistent understanding of “recall initiation date” among recall personnel;
- develop and implement a data quality assurance process, through its recall audit plan, to ensure that the RES contains accurate information; and
- consider the results of our review when implementing its recent SCORE initiative.

FOOD AND DRUG ADMINISTRATION COMMENTS

In written comments on our draft report, FDA said it agrees with our conclusion that it needs to help ensure recalls are initiated quickly to prevent the public’s exposure to potentially unsafe food, even when there are complex facts or other complicating factors. To address situations such as those described in our Early Alert and this review, FDA said it established SCORE, a team of FDA senior leaders that leads “all of the components involved in resolving potentially hazardous food issues, including the components charged with compliance, inspections, communication, outbreak investigation, and legal and policy review.” FDA said it also initiated a new quality system audit process and a plan to provide early notice to the public and more guidance to staff. FDA said that it will consider the results of our review and recommendations as it continues “to operate the SCORE team.”

FDA pointed out that it considers the 30 recalls in our judgmental sample to be extreme outliers and that it oversaw more than 1,500 food recalls during the period of our review. It also said:

FDA's data for all food recalls during the period covered in the OIG report indicate that, in cases in which FDA found out about a product problem that eventually resulted in a recall, the recall initiation took place, on average, in less than four days. In the highest risk recalls, when there was a reasonable probability that the use of or exposure to a product would cause serious adverse health consequences or death, recall initiation took place, on average, in less than three days.

FDA also provided us written technical comments that we addressed, as appropriate. FDA's comments, excluding its technical comments, are included as Appendix J.

OFFICE OF INSPECTOR GENERAL RESPONSE

We appreciate the efforts FDA has taken and plans to take in response to the findings and recommendations in our Early Alert and this review. We maintain that our findings and recommendations are valid, and we have concerns about FDA's comments regarding our sample items and the FDA's calculation of the average number of days it took for all food recalls to be initiated.

FDA commented that it oversaw more than 1,500 recalls during the period covered by our audit, and it considers all 30 judgmentally selected food recalls in our review to be "extreme outliers."

We disagree that all our sample items were "extreme outliers." To gather information about deficiencies in FDA's food-recall process, we selected recalls based on risk factors. How long it took a firm to initiate a recall was only one of several risk factors that we considered. For example, in one-third of our sample items, recalls were initiated in 2 days or less, according to FDA's tracking system.

FDA also stated that recall initiations took place, on average, in less than 4 days, and, for its highest risk recalls, in less than 3 days. It was beyond the scope of our review to determine whether FDA's calculations for the average length of time it took for all food recalls to be initiated were correct. However, we have concerns about FDA's assertion that recalls took an average of 4 days or less because we did not find evidence that FDA had a reliable system for capturing the recall initiation date or the date FDA became aware of potentially hazardous food products.

Specifically, over a third of the sample items (11 of the 30) we selected contained inaccurate recall initiation dates. For these 11, the recall initiation dates were off by an average of 16 days. Additionally, FDA's system did not contain the date when FDA first became aware of the potential hazard. The dates in FDA's system showed an average time of 33 days between the FDA district awareness date and the recall initiation date for the 30 recalls in our review. However, we recalculated the length of time using information from the recall files and

determined that for these recalls the average time was 57 days between the date FDA became aware of a potential hazard and the recall initiation date.

APPENDIX A: FDA’S FOOD-RECALL PROCESS

RECALL INITIATION

FDA first hears about potentially hazardous products in several ways, including:

- a company discovers a problem and contacts FDA,
- FDA inspects a manufacturing facility and determines the potential for a recall,
- FDA receives reports of health problems through various reporting systems, and
- the Centers for Disease Control and Prevention (CDC) contacts FDA.²⁷

FDA’s recall policies and procedures state that FDA may inform a firm that a product violates the law and discuss the possibility of a recall with the firm without specifically requesting a recall. Under these circumstances, the firm may decide to recall a product, and FDA considers the firm’s action a “firm-initiated recall.” FDA should document its conversation with the firm in internal meeting minutes or notes, in accordance with FDA’s procedures (RPM, chapter 7-5-1).

FDA may take appropriate regulatory action or other measures when the firm fails to recall a violative product or when a recall action fails. Specifically, regulatory actions will be taken when:

- the firm refuses to recall a product after being requested or ordered to do so by the FDA,
- the firm fails to complete a recall in a timely fashion, or
- FDA has reason to believe that the firm’s recall strategy is not effective (RPM, chapter 7-3).

Health Hazard Evaluation

FDA may learn of the need to consider exercising its mandatory recall authority from information developed internally or from outside sources, such as States or other agencies. FDA may exercise its mandatory recall authority when it has determined that there is a “reasonable probability” that an article of food is adulterated or misbranded and that it will cause serious adverse health consequences or death (FD&C Act § 423). Before moving forward

²⁷ FDA 101: Product Recalls (August 28, 2015). Available at <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm049070.htm>; accessed on June 12, 2017.

with a mandatory recall, FDA must complete an HHE (FDA, *Mandatory Food Recalls*, Document #ORA-OEIO.005, December 27, 2012).

FDA's Recall Regulations specifies that FDA should conduct an HHE to assess the seriousness of the health hazard presented by a product being recalled or considered for recall and assign a recall classification. The evaluation will be conducted by a committee of FDA scientists, which will take into account a number of factors (21 CFR § 7.41).

The FDA monitoring district office, as soon as possible but preferably within 24 hours (1 working day) after learning of a recall either planned or in progress, should notify the appropriate CRU and the Recall Operations Staff. (This notification is referred to as the "recall alert.") The FDA monitoring district office should submit this recall alert through the RES by inputting certain information (RPM, chapter 7-5-1.1). The FDA monitoring district office must submit a complete recall recommendation (RR) through the RES within 5 working days after submitting the recall alert or as soon as the recalling firm has provided the information necessary for the RR (RPM, chapter 7-5-1.2). Upon receipt of each RR or other information from any source that indicates a recall may be necessary, the CRU determines whether an up-to-date precedent HHE currently exists that covers the situation. A precedent HHE is one that has already been written that will be used when the product is identical or similar and has basically the same defect or violation as a recalled product that was previously classified. If a precedent does not exist, the CRU forwards the appropriate information to the Center Health Hazard Evaluation Committee (HHE Committee) for review. The HHE Committee will complete, endorse, and forward the HHE form to the center recall unit within 2 working days after receiving the RR unless the HHE Committee requires additional information (RPM, chapter 7-6-1).

The FDA monitoring district office, upon receiving the HHE, will promptly send a notification letter to the firm with essential recall information, including FDA's assessment of the firm's recall strategy (i.e., type of notification, depth of recall, and level of effectiveness check) and the recall classification (RPM, chapter 7-7-1.3).

Audit Checks

According to FDA's IOM, the FDA monitoring district office should provide the CRU with a proposed program for monitoring the recall. The audit program should include a timetable for reviewing the recall status and the level and type of audit checks, which are performed to verify the recall's effectiveness (IOM, chapter 7.2.9.9).

FDA defines a recall "audit check" as a visit, telephone call, or letter (or a combination of them) from FDA staff to a consignee to verify that the consignee has been notified of the recall and has taken appropriate action (IOM, chapter 7.3.2.1). FDA's procedures state that "Level A" audit checks indicate that FDA should contact 100 percent of the consignees. "Level B" audit checks indicate that FDA should contact more than 10 percent but less than 100 percent of the consignees. "Level C" audit checks indicate that FDA should contact 10 percent of consignees.

“Level D” audit checks indicate that FDA should contact 2 percent of the consignees. “Level E” audit checks indicate that FDA does not conduct audit checks (IOM, chapter 7.3.2.2). The FDA monitoring district office should issue audit check assignments at the level in the monitoring program (RPM, chapter 7-8-2.3).

The RPM, chapter 7-8-2.3, states, “Normally within 10 days from the issuance of the firm’s recall communication, the monitoring district will issue audit check assignments at the level in the FDA audit program.” Exceptions to the 10-day timeframe would be made for Class I situations in which the recall is to the consumer/user level and it is critical that the FDA monitoring district office be certain that the products are off the market or that consumer/users have been notified of the recall action (RPM, chapter 7-8-2.3). In addition, the FDA district office that receives audit check assignments should consider them high priority and, if possible, complete the assignments within 10 working days (RPM, chapter 7-8-2.4).

Status Reports

FDA should request, through its district notification letter, that the recalling firm submit periodic recall status reports to the FDA monitoring district office so that it may assess the progress of the recall (21 CFR § 7.53 and RPM, chapter 7-7-1). The recall coordinator and appropriate supervisors are responsible for the day-to-day management of a recall, including ensuring that FDA receives and reviews the firm’s status reports in a timely manner (RPM, chapter 7-8-2).

Status reports should contain specific information, including the number and results of the recalling firm’s effectiveness checks (21 CFR § 7.53). The firm has an obligation to conduct effectiveness checks, which help verify that all known, affected consignees have received notification about a recall and have taken appropriate action (RPM, chapter 7-8-1).

Recall Enterprise System

According to FDA’s RPM, the RES is an electronic data system used by FDA recall personnel to submit, update, classify, and terminate recalls. The information entered in the RES is gathered from various sources, including the field, the firm involved in the recall, ORA, and the CRU (RPM, chapter 7-4). The RES User Manual contains detailed information needed to use the RES. The RES User Manual defines the recall initiation date as the “date that the recall action was initiated by a company” (p. 28).

In addition to being used to manage a recall, the RES also provides a central, searchable database to more efficiently track information and then generate and disseminate reports of recall activities (RPM, chapter 7-4).

APPENDIX B: EARLY ALERT MEMORANDUM



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



June 8, 2016

TO: Robert M. Califf, M.D.
Commissioner of Food and Drugs
Food and Drug Administration

FROM: /Daniel R. Levinson/
Inspector General

SUBJECT: Early Alert: The Food and Drug Administration Does Not Have an Efficient and Effective Food Recall Initiation Process (A-01-15-01500)

The purpose of this memorandum is to alert you to a preliminary finding from our ongoing audit of the Food and Drug Administration (FDA) food recall program. One of the objectives of our audit is to determine whether FDA has an efficient and effective food recall initiation process that helps ensure the safety of the Nation's food supply.

We found that FDA did not have an efficient and effective food recall initiation process that helps ensure the safety of the Nation's food supply. Specifically, FDA did not have policies and procedures to ensure that firms¹ or responsible parties² (collectively referred to in this document as "firms") initiated voluntary food recalls promptly. This issue is a significant matter and requires FDA's immediate attention.

We suggest that FDA update its policies and procedures to instruct its recall staff to establish set timeframes for (1) FDA to request that firms voluntarily recall their products and (2) firms to initiate voluntary food recalls.

Our audit is a followup of our June 2011 report, *Review of the Food and Drug Administration's Monitoring of Imported Food Recalls* (A-01-09-01500). In that audit, we found FDA's food recall program was inadequate because FDA did not have the authority to require firms to recall certain foods and FDA did not always follow its own procedures. To help ensure the safety of the Nation's food supply, we recommended that FDA consider our findings when implementing the FDA Food Safety Modernization Act (FSMA) and follow its own procedures for monitoring recalls. FDA agreed with our recommendations.

¹ See 21 CFR part 7, subpart C.

² Under section 423 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), a "responsible party" means a person who submits the registration under section 415(a) of the FD&C Act for a food facility that is required to register under section 415(a) of the FD&C Act.

BACKGROUND

FDA generally relies on firms to voluntarily recall harmful articles of food.³ Before 2011, FDA did not have the authority to require a firm to recall certain articles of food. However, the FSMA added section 423 to the FD&C Act,⁴ which gives FDA the authority to order a firm to recall certain articles of food after FDA determines that there is a reasonable probability that the food is adulterated or misbranded and that it will cause serious adverse health consequences or death to humans or animals (this is commonly referred to as SAHCOHHA). FDA has used its authority under FSMA twice.⁵

Before issuing a mandatory recall order, FDA must provide the firm with an opportunity to voluntarily recall the product. FDA may require that the firm complete the recall in a prescribed timeframe. If the firm refuses or fails to complete the recall, FDA may order the firm to cease its distribution. After the firm is given an opportunity for an informal hearing, FDA may order the product's recall and specify a recall timetable.

We selected a judgmental sample of 30 imported and domestic voluntary human food recalls reported to FDA between October 1, 2012, and May 4, 2015.⁶ We performed site visits at 7 of the 11 FDA district offices responsible for monitoring the 30 recalls to conduct interviews and review recall files. We obtained recall files electronically from the remaining four district offices.

PRELIMINARY AUDIT RESULTS

We found that FDA did not have an efficient and effective food recall initiation process that helps ensure the safety of the Nation's food supply. Specifically, we found that FDA's policies and procedures did not instruct its recall staff to prescribe to the firms a time and a manner in which to initiate the voluntary recall. We also found that FDA did not have policies and procedures to ensure that firms initiated voluntary food recalls promptly.

For all 30 voluntary recalls in our sample, after FDA first became aware that an adulterated or misbranded product could be in the food supply chain, it did not prescribe a timeline for each firm to initiate a recall. For two recalls, the firms did not initiate the recall of all potentially harmful products until 165 days and 81 days after FDA became aware of the potential

³ See 21 CFR part 7, subpart C.

⁴ Section 206 of the FSMA, P.L. No. 111-353 (enacted January 4, 2011).

⁵ In September 2012, FDA became aware of pet food distributed by Kasel Associates Industries, Inc., that was adulterated with *Salmonella*, a pathogenic organism, and initiated its mandatory recall authority for the first time in February 2013. In September 2013, FDA became aware of dietary supplements distributed by USP Labs that were adulterated with aegeline (a new ingredient for which there was inadequate information to provide reasonable assurance that it would not present a significant or unreasonable risk of injury or illness) and initiated its mandatory recall authority for the second time in November 2013.

⁶ We selected recalls by considering certain risk factors, including but not limited to the recall classification, length of time for the firm to initiate a recall, and length of time for the FDA to classify a recall.

contaminations. The delays in the firms' recalls may have occurred because FDA did not have policies and procedures that instruct its recall staff to establish set timeframes for (1) FDA to request that firms voluntarily recall their products and (2) firms to initiate voluntary food recalls. As a result, consumers remained at risk of illness or death for several weeks after FDA knew of potentially hazardous food.

For example:

- In a recall involving nut butter,⁷ at least 14 people became ill with a strain of *Salmonella*⁸ indistinguishable from or linked to the strain found at the firm's manufacturing facility. 165 days passed from the date FDA identified the potentially adulterated product and the date the firm initiated a voluntary food recall. See Attachment A for a timeline of events for this recall.
- In a series of recalls involving various cheese products,⁹ at least nine people became ill from *Listeria monocytogenes*,¹⁰ including one infant who died. According to FDA records, the Centers for Disease Control and Prevention (CDC) also linked two fetal losses to these illnesses. 81 days passed from the date FDA became aware of the adulterated product and the date the firm had voluntarily recalled all affected products. See Attachment B for a timeline of events for this recall.

CONCLUSION

FDA does not have adequate policies and procedures to ensure that firms take prompt and effective action in initiating voluntary food recalls. As a result, consumers remained at risk of illness or death for several weeks after FDA was aware of a potentially hazardous food in the supply chain.

We suggest that FDA revise its policies and procedures to instruct recall staff to establish set timeframes for (1) FDA to request that firms voluntarily recall their products and (2) firms to initiate voluntary food recalls.

⁷ The firm that voluntarily conducted the recall was nSpired Natural Foods, Inc.

⁸ *Salmonella* is a pathogenic organism that can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems. Healthy individuals may suffer short-term symptoms such as severe diarrhea, bloody diarrhea, fever, chills, abdominal discomfort, and occasionally vomiting.

⁹ The firm that voluntarily conducted the recall was Oasis Brands, Inc.

¹⁰ *Listeria monocytogenes* is an organism that can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems. Healthy individuals may suffer only short-term symptoms such as a high fever, severe headache, stiffness, nausea, abdominal pain, and diarrhea. *Listeria* infection can cause miscarriages and stillbirths among pregnant women.

Page 4 – Robert M. Califf, M.D.

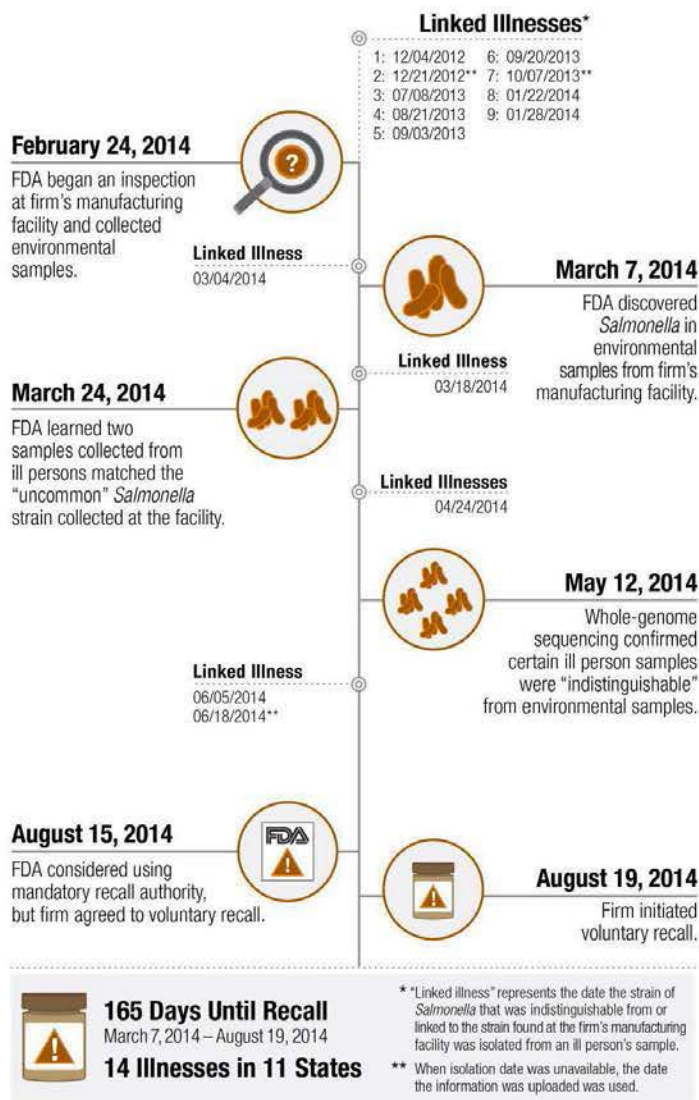
The information in this early alert is preliminary, and the audit is continuing. We will issue a draft report at the conclusion of the audit and include comments and actions taken in response to this early alert.

If you have any comments or questions about this memorandum, please do not hesitate to call me, or your staff may contact Amy J. Frontz, Assistant Inspector General for Audit Services, at (202) 619-1157 or through email at Amy.Frontz@oig.hhs.gov.

Attachments

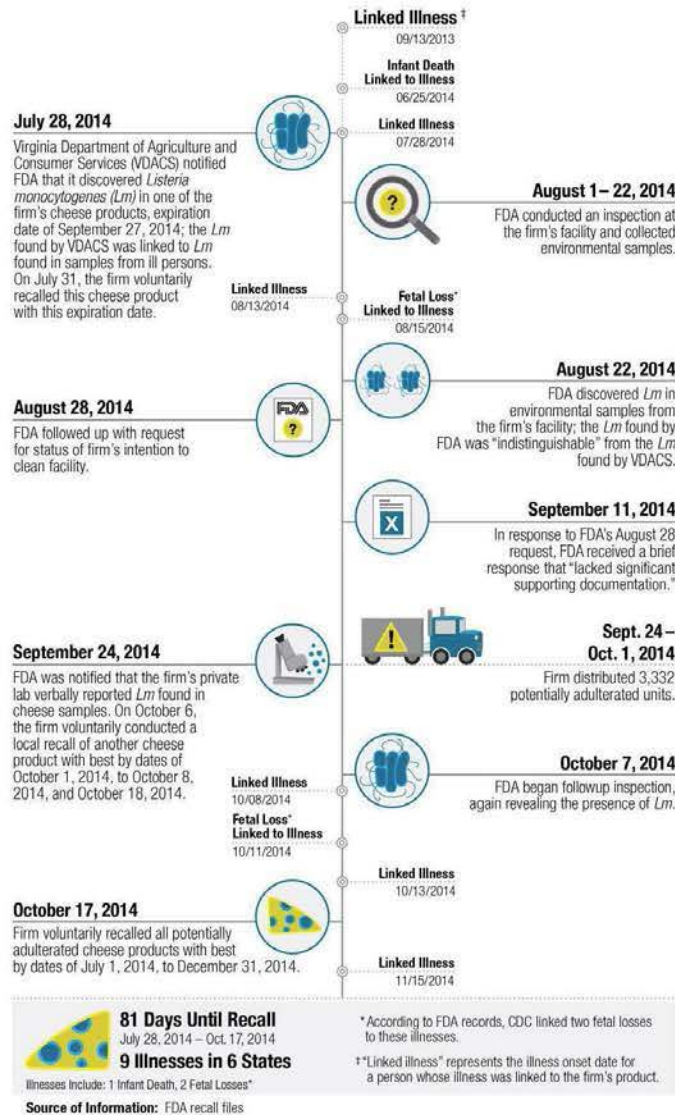
ATTACHMENT A

In a recall involving nut butter, at least 14 people became ill with a strain of *Salmonella* indistinguishable from or linked to the strain found at the firm’s manufacturing facility. 165 days passed from the date FDA identified the potentially adulterated product and the date the firm initiated a voluntary food recall.



ATTACHMENT B

In a series of recalls involving various cheese products, at least nine people became ill from *Listeria monocytogenes*, including one infant who died. According to FDA records, the CDC also linked two fetal losses to these illnesses. 81 days passed from the date FDA became aware of the adulterated product and the date the firm had voluntarily recalled all affected products.



APPENDIX C: AUDIT SCOPE AND METHODOLOGY

SCOPE

We selected a judgmental sample of 30 voluntary food recalls (23 Class I and 7 Class II) from the 1,557 food recalls reported to FDA between October 1, 2012, and May 4, 2015. We selected recalls based on the timing of the recall and other risk factors. Timing-related risk factors included how long it took to initiate the recall, when the firm began notifying its distribution chain of the recall, when the firm issued its press release, how long it took to classify, how long it took to complete the recall, and how long it took to terminate the recall after it was completed. Other risk factors included the level of FDA's involvement in the initiation of the recall (i.e. firm-initiated, State-initiated, or FDA-initiated), the scope of the recall (i.e., depth of recall, number of consignees, number of days the product was manufactured, number of days the product was distributed), the reason for the recall, the classification of the recall, and media coverage. This resulted in the selection of some recalls that FDA considered to be among its most complex.

We performed site visits at FDA offices in Silver Spring, Maryland, as well as at 7 of the 11 FDA monitoring district offices responsible for monitoring the 30 recalls. We obtained recall files electronically from the remaining four FDA monitoring district offices. We conducted our field work from April 2015 through April 2017.

METHODOLOGY

To accomplish our objective, we:

- reviewed Federal laws, regulations, policies, and procedures related to food recalls;
- performed tests on RES data, such as a reconciliation of RES data to an internal recall tracking database maintained by CFSAN and a comparison of certain fields in hardcopy reports generated by the RES to information in the RES, to determine whether RES data were complete and accurate;
- identified from FDA's recall database 1,557 recalls of imported and domestic food products and judgmentally selected 30 recalls for review, considering a combination of the following risk factors in making our selection:
 - length of time to initiate the recall (to determine how long after FDA became aware of the contaminated product did the firm initiate the recall);
 - length of time for the firm to begin notifying the firm's distribution chain of the recall (to determine how long after FDA became aware of the contaminated product did the firm take to notify its consignees of the recall);

- length of time to issue a press release (to determine how long after FDA became aware of the contaminated product did the firm take to issue a press release);
 - length of time to classify a recall (to determine how long after FDA became aware of the contaminated product did FDA take to classify the recall);
 - length of time to complete the recall (to determine how long after FDA became aware of the contaminated product did the firm take to complete the recall);
 - length of time to terminate the recall after recall completion (to determine how long after recall completion did it take FDA to terminate the recall);
 - recalls in which FDA was involved in the initiation (to identify recalls that were firm-initiated, State-initiated, or FDA-initiated);
 - scope of recall (to identify the recall depth, number of consignees that received the product, number of days the product was manufactured, and number of days the product was distributed) and the reason for the recall; and
 - classification and media coverage;
- interviewed FDA officials and staff from CFSAN and ORA involved in food recalls;
 - interviewed FDA recall staff from the FDA monitoring district offices responsible for monitoring the 30 recalls for review;
 - reviewed recall files, compliance files, and firm inspection files maintained at FDA monitoring district offices;
 - assessed the timeliness of the recalls and FDA's evaluation of the health hazard posed by the recalled products;
 - compared FDA's proposed audit check level in the RES to the actual level at which FDA issued audit checks and calculated the total number of days to complete all the audit checks;
 - assessed whether FDA engaged in collecting timely and complete status reports from firms;
 - evaluated the availability and accuracy of the RES information related to our objective; and
 - discussed the results of our review with FDA officials.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

**APPENDIX D: DAYS IT TOOK FIRMS TO INITIATE RECALL AFTER FDA FIRST LEARNED A
PRODUCT WAS POTENTIALLY HAZARDOUS**

Recalling Firm	Product	Class	Recall Reason	Days To Initiate
Nutrex Research, Inc.	Dietary supplements	1	New Dietary Ingredient (Methylhexanamine (DMAA))	303
nSpired Natural Foods	Nut butters	1	<i>Salmonella</i>	165
Hazelnut Growers of Oregon	Hazelnuts	1	<i>Salmonella</i>	151
Nicomex, Inc.	Dried whole shrimp	2	Labeling/Undeclared sulfites	137
ARO Pistachios, Inc.	Pistachios	1	<i>Salmonella</i>	126
Vibrant Health	Dietary supplements	1	<i>Salmonella</i>	121
NatureMost of New England	Dietary supplements	1	Labeling/Undeclared allergen	88
Norpac Foods, Inc.	Frozen spinach	2	Cadmium	82
Oasis Brands, Inc.	Fresh curd	1	<i>Listeria monocytogenes</i>	81
Simply Natural Foods, LLC	Dark chocolate	1	Labeling/Undeclared allergen	70
Blue Bell Creameries, L.P.	Ice cream	1	<i>Listeria monocytogenes</i>	66
Win Luck Trading, Inc.	Seafood	1	Labeling/Undeclared allergen	54
USPlabs, LLC	Dietary supplements	1	New Dietary Ingredient (Aegeline)	46
Net Food Import and Export	Dried apricots	1	Labeling/Undeclared sulfites	36
Ice Cream Specialties	Ice cream	1	Labeling/Undeclared allergen	31
Fruit Treasure, Inc.	Chili peppers	1	<i>Salmonella</i>	27
S&M International, Inc.	Cooked salted duck eggs	2	<i>Clostridium botulinum</i>	27
Vinco, Inc.	Dietary supplements	2	<i>Salmonella</i>	25
HK Galleria Wholesale, L.P.	Rice porridge	2	<i>Clostridium botulinum</i>	22

Recalling Firm	Product	Class	Recall Reason	Days To Initiate
Bidart Bros.	Apples	1	<i>Listeria monocytogenes</i>	18
Purely Pomegranate, Inc.	Pomegranate seeds	1	Hepatitis A	14
Priester Pecan Company, Inc.	Nuts	1	<i>Salmonella</i>	14
Anabolic Science Labs, LLC	Dietary supplements	2	Methylated anabolic steroid	9
Mkg Provisions, Inc.	Smoked salmon	1	<i>Listeria monocytogenes</i>	4
Reaction Nutrition, LLC	Dietary supplements	1	Labeling/Undeclared allergen	3
Whole Foods Market	Cheese	1	<i>Listeria monocytogenes</i>	1
Clemmy's, LLC	Ice cream	1	<i>Salmonella</i>	1
Coastal Green Vegetable Co., LLC	Frozen Spinach	2	<i>Listeria monocytogenes</i>	1
Michael's Seafood, Inc.	Smoked salmon	1	<i>Listeria monocytogenes</i>	-2
Glaser Organic Farms	Carob products	1	<i>Salmonella</i>	-9

**APPENDIX E: DAYS TAKEN FOR FDA TO COMPLETE A HEALTH HAZARD EVALUATION AFTER
LEARNING OF A PLANNED OR IN-PROGRESS RECALL**

Recalling Firm	Product	Class	Recall Reason	Working Days From District Awareness Date
Reaction Nutrition, LLC	Dietary supplements	1	Labeling/Undeclared allergen	209
Anabolic Science Labs, LLC	Dietary supplements	2	Methylated anabolic steroid	170
HK Galleria Wholesale, L.P.	Rice porridge	2	<i>Clostridium botulinum</i>	47
Win Luck Trading, Inc.	Seafood	1	Labeling/Undeclared allergen	44
nSpired Natural Foods	Nut butters	1	<i>Salmonella</i>	41
Blue Bell Creameries, L.P.	Ice cream	1	<i>Listeria monocytogenes</i>	38
Nutrex Research, Inc.	Dietary supplements	1	New Dietary Ingredient (Methylhexanamine (DMAA))	33
ARO Pistachios, Inc.	Pistachios	1	<i>Salmonella</i>	21
Norpac Foods, Inc.	Frozen spinach	2	Cadmium	19
S&M International, Inc.	Cooked salted duck eggs	2	<i>Clostridium botulinum</i>	19
Purely Pomegranate, Inc.	Pomegranate seeds	1	Hepatitis A	14
Coastal Green Vegetable Co., LLC	Frozen spinach	2	<i>Listeria monocytogenes</i>	12
Simply Natural Foods, LLC	Dark chocolate	1	Labeling/Undeclared allergen	-3
USPlabs, LLC	Dietary supplements	1	New Dietary Ingredient (Aegeline)	-8

**APPENDIX F: DAYS TAKEN FOR FDA TO COMPLETE A HEALTH HAZARD EVALUATION AFTER
LEARNING A PRODUCT WAS POTENTIALLY HAZARDOUS**

Recalling Firm	Product	Class	Recall Reason	Days From FDA Awareness of Contamination
Nutrex Research, Inc.	Dietary supplements	1	New Dietary Ingredient (Methylhexanamine (DMAA))	343
Reaction Nutrition, LLC	Dietary supplements	1	Labeling/Undeclared allergen	304
Anabolic Science Labs, LLC	Dietary supplements	2	Methylated anabolic steroid	246
nSpired Natural Foods	Nut butters	1	<i>Salmonella</i>	222
ARO Pistachios, Inc.	Pistachios	1	<i>Salmonella</i>	155
Blue Bell Creameries, L.P.	Ice cream	1	<i>Listeria monocytogenes</i>	119
Win Luck Trading, Inc.	Seafood	1	Labeling/Undeclared allergen	103
Norpac Foods, Inc.	Frozen spinach	2	Cadmium	96
HK Galleria Wholesale, L.P.	Rice porridge	2	<i>Clostridium botulinum</i>	81
S&M International, Inc.	Cooked salted duck eggs	2	<i>Clostridium botulinum</i>	50
Purely Pomegranate, Inc.	Pomegranate seeds	1	Hepatitis A	34
Coastal Green Vegetable Co., LLC	Frozen spinach	2	<i>Listeria monocytogenes</i>	18

APPENDIX G: FDA MONITORING DISTRICT OFFICE ISSUED FEWER AUDIT CHECK ASSIGNMENTS THAN WHAT WAS REQUIRED

Recalling Firm	Product	Class	Recall Reason	No. of Domestic Consignees	Approved Level of Audit Checks		Level Assigned of Audit Checks		
					%	No.	Level	No.	No. Not Completed
Anabolic Science Labs, LLC	Dietary supplements	2	Methylated anabolic steroid	255	75%	192	15%	38	154
Clemmy's, LLC	Ice cream	1	<i>Salmonella</i>	19	50%	10	26%	5	5
Ice Cream Specialties	Ice cream	1	Labeling/ Undeclared allergen	124	10%	13	0%	0	13
Norpac Foods, Inc.	Frozen spinach	2	Cadmium	4	100%	4	50%	2	2
Nutrex Research, Inc.	Dietary supplements	1	New Dietary Ingredient (Methylhexanamine (DMAA))	22	2%	1	0%	0	1
Oasis Brands, Inc.	Fresh curd	1	<i>Listeria monocytogenes</i>	126	50%	63	2%	2	61
Simply Natural Foods, LLC	Dark chocolate	1	Labeling/Undeclared allergen	19	100%	19	63%	12	7
USPlabs, LLC	Dietary supplements	1	New Dietary Ingredient (Aegeline)	1598	10%	160	1%	16	144

APPENDIX H: DAYS TAKEN FOR FDA TO COMPLETE THE LAST AUDIT CHECK AFTER FIRMS ISSUED THEIR RECALL COMMUNICATIONS

Recalling Firm	Product	Class	Recall Reason	Days To Complete Final Audit Check
Reaction Nutrition, LLC	Dietary supplements	1	Labeling/Undeclared allergen	547
Vinco, Inc.	Dietary supplements	2	<i>Salmonella</i>	386
Vibrant Health	Dietary supplements	1	<i>Salmonella</i>	197
Bidart Bros.	Apples	1	<i>Listeria monocytogenes</i>	171
USPlabs, LLC	Dietary supplements	1	New Dietary Ingredient (Aegeline)	167
Nicomex, Inc.	Dried whole shrimp	2	Labeling/Undeclared sulfites	120
Anabolic Science Labs, LLC	Dietary supplements	2	Methylated anabolic steroid	110
Whole Foods Market	Cheese	1	<i>Listeria monocytogenes</i>	107
Simply Natural Foods, LLC	Dark chocolate	1	Labeling/Undeclared allergen	85
nSpired Natural Foods	Nut butters	1	<i>Salmonella</i>	77
NatureMost of New England	Dietary supplements	1	Labeling/Undeclared allergen	69
Glaser Organic Farms	Carob products	1	<i>Salmonella</i>	67
HK Galleria Wholesale, L.P.	Rice porridge	2	<i>Clostridium botulinum</i>	62
Net Food Import and Export	Dried apricots	1	Labeling/Undeclared sulfites	60
Oasis Brands, Inc.	Fresh curd	1	<i>Listeria monocytogenes</i>	50
Blue Bell Creameries, L.P.	Ice cream	1	<i>Listeria monocytogenes</i>	44
Michael's Seafood, Inc.	Smoked salmon	1	<i>Listeria monocytogenes</i>	38
Priester Pecan Company, Inc.	Nuts	1	<i>Salmonella</i>	34
Fruit Treasure, Inc.	Chili peppers	1	<i>Salmonella</i>	31

Recalling Firm	Product	Class	Recall Reason	Days To Complete Final Audit Check
S&M International, Inc.	Cooked salted duck eggs	2	<i>Clostridium botulinum</i>	31
Norpac Foods, Inc.	Frozen spinach	2	Cadmium	22
ARO Pistachios, Inc.	Pistachios	1	<i>Salmonella</i>	19
Clemmy's, LLC	Ice cream	1	<i>Salmonella</i>	17
Coastal Green Vegetable Co., LLC	Frozen spinach	2	<i>Listeria monocytogenes</i>	15
Purely Pomegranate, Inc.	Pomegranate seeds	1	Hepatitis A	3
Ice Cream Specialties	Ice cream	1	Labeling/Undeclared allergen	No audit checks conducted
Mkg Provisions, Inc.	Smoked salmon	1	<i>Listeria monocytogenes</i>	No audit checks conducted
Nutrex Research, Inc.	Dietary supplements	1	New Dietary Ingredient (Methylhexanamine (DMAA))	No audit checks conducted
Win Luck Trading, Inc.	Seafood	1	Labeling/Undeclared allergen	No audit checks conducted
Hazelnut Growers of Oregon	Hazelnuts	1	<i>Salmonella</i>	No audit checks conducted

APPENDIX I: DAYS TO COLLECT STATUS REPORTS FOR 19 OF 30 SELECTED FOOD RECALLS

Recalling Firm	Product	Class	Recall Reason	Days To Provide First Status Report From Initiation
Win Luck Trading, Inc.	Seafood	1	Labeling/Undeclared allergen	605
Reaction Nutrition, LLC	Dietary supplements	1	Labeling/Undeclared allergen	326
USPlabs, LLC	Dietary supplements	1	New Dietary Ingredient (Aegeline)	212
Anabolic Science Labs, LLC	Dietary supplements	2	Methylated anabolic steroid	196
Vinco, Inc.	Dietary supplements	2	<i>Salmonella</i>	173
NatureMost of New England	Dietary supplements	1	Labeling/Undeclared allergen	158
HK Galleria Wholesale, L.P.	Rice porridge	2	<i>Clostridium botulinum</i>	133
Vibrant Health	Dietary supplements	1	<i>Salmonella</i>	131
nSpired Natural Foods	Nut butters	1	<i>Salmonella</i>	126
Simply Natural Foods, LLC	Dark chocolate	1	Labeling/Undeclared allergen	122
Nutrex Research, Inc.	Dietary supplements	1	New Dietary Ingredient (Methylhexanamine (DMAA))	106
Blue Bell Creameries, L.P.	Ice cream	1	<i>Listeria monocytogenes</i>	102
Bidart Bros.	Apples	1	<i>Listeria monocytogenes</i>	97
Hazelnut Growers of Oregon	Hazelnuts	1	<i>Salmonella</i>	57
Coastal Green Vegetable Co., LLC	Frozen spinach	2	<i>Listeria monocytogenes</i>	45
S&M International, Inc.	Cooked salted duck eggs	2	<i>Clostridium botulinum</i>	43

Recalling Firm	Product	Class	Recall Reason	Days To Provide First Status Report From Initiation
Norpac Foods, Inc.	Frozen spinach	2	Cadmium	33
Ice Cream Specialties	Ice cream	1	Labeling/Undeclared allergen	31
ARO Pistachios, Inc.	Pistachios	1	<i>Salmonella</i>	14

APPENDIX J: FDA COMMENTS



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

DATE: October 6, 2017
TO: Inspector General
FROM: Deputy Associate Commissioner for Public Health Strategy and Analysis
SUBJECT: FDA's Comments to OIG Draft Report, *The Food and Drug Administration's Food-Recall Process Did Not Always Ensure the Safety of the Nation's Food Supply* (A-01-16-01502)

FDA is providing the attached comments to the OIG Draft Report, *The Food and Drug Administration's Food-Recall Process Did Not Always Ensure the Safety of the Nation's Food Supply* (A-01-16-01502).

We appreciate the opportunity to review and comment on this draft report before it is published.

A handwritten signature in black ink, appearing to read "Lisa Rovin", written over a horizontal line.

Lisa Rovin
Deputy Associate Commissioner for Public Health
Strategy and Analysis

Attachment

The Food and Drug Administration's General Comments to the Office of the Inspector General's Draft Report entitled, *The Food and Drug Administration's Food-Recall Process Did Not Always Ensure the Safety of the Nation's Food Supply (A-01-16-1502)*

The Food and Drug Administration (FDA or the Agency) appreciates the opportunity to comment on the Office of Inspector General's (OIG) draft report. FDA is committed to ensuring that firms take prompt and effective action in initiating food recalls when appropriate, and that FDA's recall process operates efficiently and effectively to protect consumers from unsafe food. Additionally, FDA is committed to using its authority under the Food Safety Modernization Act (FSMA) to mandate that firms recall certain food products when appropriate, provided that the necessary legal and evidentiary standards are met.

FDA takes the observations in the report seriously, and as described below, has implemented substantial changes to address complex and challenging recalls, which are the focus of this OIG report. To better address such situations, in April 2016 FDA established a team of senior leaders in the most challenging food recall cases. The team is called SCORE, which stands for Strategic Coordinated Oversight of Recall Execution. The members of SCORE lead all of the components involved in resolving potentially hazardous food issues, including the components charged with compliance, inspection, communication, outbreak investigation, and legal and policy review. SCORE has reviewed and directed a large number of operations in the most difficult cases that FDA has faced over the last eighteen months, and has made a difference in ensuring that FDA acts quickly to investigate and reduce consumer exposure to potentially harmful foods on the market.

FDA also has recently initiated a new quality systems audit process and a plan to provide earlier notice to the public and more guidance to staff. Moreover, FDA has begun the implementation of the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (PCHF) rule. For food with a hazard requiring a preventive control, this rule requires a covered facility to establish a written recall plan that includes procedures to effectively carry out a recall. During the period covered in the report, firms generally had no regulatory requirement to establish such a recall plan.

Ensuring Appropriate Recall Initiation in Challenging Recalls

FDA oversees a large number of recalls, and the vast majority of these recalls are initiated promptly. During the thirty-month period covered in this OIG report, FDA oversaw more than 7,300 recalls, more than 1,500 of which involved food. This OIG report examined thirty food recall events, which constitute of a very small fraction (0.2 percent) of all the recalls FDA monitored during this period. OIG acknowledges in its report that "[b]ecause [OIG] selected a judgmental sample, the sample results are informative about deficiencies in FDA's food-recall oversight process but are not applicable to the full population of FDA recalls."

FDA's data for all food recalls during the period covered in the OIG report indicate that, in cases in which FDA found out about a product problem that eventually resulted in a recall, the recall initiation took place, on average, in less than four days. In the highest risk recalls, when there was a reasonable probability that the use of or exposure to a product would cause serious adverse health consequences or death, recall initiation took place, on average, in less than three days.

The Agency's information indicates that the thirty recalls at issue in the OIG report generally took significantly more time to initiate than other recalls of FDA-regulated products. They often involved complicating factors that made the recalls more difficult, such as criminal conduct that involved misleading FDA,¹ complex legal issues contested in lengthy dispute, or the first use of a new technology (whole genome sequencing) to link clinical data and environmental monitoring. In other cases, identifying the source of a violative product involved matching information gathered from different data sources with environmental sampling, or expanding the recalls multiple times because of additional facts gathered during firm or FDA investigation.

Although FDA considers these recall cases to be extreme outliers, FDA is concerned about any significant period of delay in initiating a recall, and this OIG report provides an important service to the Agency in examining such delays. When a potentially unsafe food is on the market, time is of the essence to keep people from becoming ill. Where the industry does not act quickly to initiate a recall in such cases, FDA must act quickly within its available authorities to take appropriate actions to address the problem.

Ensuring that the Recall Process is Effective

The report notes delays in the thirty recalls related to the issuance and completion of audit check assignments and status reports. Among other tools, FDA uses audit checks and status reports to ensure that recalls are effective. Because recall audit assignments can fall behind inspections and other Agency priorities, FDA has recently expanded the use of a third-party audit contracts and established a quality systems audit process that identifies critical points in the recall process to ensure such actions.

Further, as noted above, FDA's ongoing implementation of the FSMA PCHF rule provides a substantial change in recall process. It is important to understand that, at the time of this OIG audit, food firms generally did not have a legal obligation to have a plan for executing recalls.

¹ See U.S. Department of Justice, *Miami-Dade Resident Sentenced to Fifteen Months in Prison for Distributing Contaminated Cheese* (November 15, 2016) [Press release] (noting that the defendant "had, in violation of his agreement with the FDA, finished packaging multiple trays of cheese then held in-processing and had gone on to ship and distribute these items.") (available at <https://www.justice.gov/usao-sdfl/pr/miami-dade-resident-sentenced-fifteen-months-prison-distributing-contaminated-cheese>).

For the vast majority of firms, there was no requirement to have a recall plan in place, to assess hazards that would need to be addressed in a recall plan, or to have written procedures to help ensure any such recall is effective. The PCHF rule changes this approach, ensuring, among other things, that wherever a firm identifies a hazard requiring a preventive control, the firm must have a plan in place to notify consignees, conduct effectiveness checks, and appropriately dispose of recalled product. In accordance with FSMA's overall approach, the rule helps to ensure that preventive steps are taken *before* consumer exposure to a potentially hazardous food occurs.

FDA agrees with the OIG's conclusion that to prevent the public's exposure to potentially unsafe food, the Agency needs to help ensure that recalls are initiated quickly, even when there are complex facts or other complicating factors. FDA is committed to continuously improving its procedures, practices, and Agency guidance to help ensure that recalls are initiated, overseen, and completed promptly and effectively to best protect consumers from unsafe food. As OIG recommends, FDA will consider the results of OIG's review as well as OIG's procedural recommendations as the Agency continues to operate its SCORE team.