

Crisis Control Newsletter

Crisis Control Newsletter from RQA, Inc.—An XL Catlin Preferred Provider to Foodservice, Food Processing and Consumer Products Industries

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Guidance for Mandatory Recalls

FDA's mandatory food recall authority went into effect when FSMA was enacted on January 4, 2011. Section 423 of the FD&C Act, as added by Section 206 of FSMA, gives FDA the authority to order a responsible party to recall an article of food where FDA determines that there is a reasonable probability that the article of food (other than infant formula) is adulterated under section 402 of the FD&C Act [21 U.S.C. § 342] or misbranded under section 403(w) of the FD&C Act [21 U.S.C. § 343(w)] and that the use of or exposure to such article will cause serious adverse health consequences or death to humans or animals (SAHCODHA)

The articles of food that are subject to FDA's mandatory recall authority are all articles of food (other than infant formula) that are manufactured, processed, packed, or held at a food facility that is required to register under section 415(a) of the FD&C Act. The term "food" refers to (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article (section 201(f) of the FD&C Act [21 U.S.C. § 321(f)]). The term "food" includes dietary supplements, which are deemed to be food under the FD&C Act (section 201(ff) of the FD&C Act [21 U.S.C. § 321(ff)]).

Once FDA has determined that the criteria for a mandatory recall have been met, FDA must first provide the responsible party (as defined in section 417(a)(1) of the FD&C Act) with an opportunity to voluntarily cease distribution and recall the article of food. FDA will provide the opportunity to voluntarily cease distribution and recall to the responsible party in written form using an expeditious method. If the responsible party refuses or does not voluntarily cease distribution and recall the article of food within the time and manner prescribed by FDA, if so prescribed, FDA may order the responsible party to cease distributing the article of food, order the responsible party to give notice to certain other persons to cease distributing the article of food, and give the responsible party an opportunity for an informal hearing. After these steps are completed, FDA may order a recall under section if it is determined that the removal of the article from commerce is necessary. Only the FDA Commissioner has the authority to order a recall under section 423(d). Recall orders under Section 423(d) may, if necessary, be vacated by the Commissioner.

FDA will evaluate all applicable evidence, when determining whether there is a reasonable probability the article of food is adulterated or misbranded and that the use of or exposure to such article will cause SAHCODHA. Evidence may include:

- Observations made during inspections of the responsible party or other parties;
- Results from sample analyses;
- Epidemiological data;
- Reportable Food Registry data; and
- Consumer and trade complaints.

Mandatory Recalls (cont)

In accordance with Section 423(g) of the FD&C Act, FDA will ensure that a press release is published regarding the recall, as well as alerts and public notices, as appropriate, to provide notification to affected consumers and retailers. The publication will include, at a minimum, the name of the article of food subject to recall, a description of the risks associated with the food, and to the extent practical, information about similar articles of food that are not affected by the recall.

Section 743(a)(1)(B) of the FD&C Act authorizes the collection of fees from a responsible party for a domestic facility and an importer who does not comply with a food recall order under section 423 or under section 412(f) of the FD&C Act (infant formula recalls).

The fees would cover time spent by FDA conducting food recall activities, including technical assistance, follow-up effectiveness checks, and public notifications. Noncompliance may include the following:

1. Not initiating a recall as ordered by FDA;
2. Not conducting the recall in the manner specified by FDA in the recall order; or
3. Not providing FDA with requested information regarding the recall, as ordered by FDA.

FDA publishes a Federal Register notice of fees for noncompliance with a Recall Order no later than 60 days before the start of each fiscal year.

FSMA amended Section 303(f)(2)(A) of the FD&C Act [21 U.S.C. 333(f)(2)(A)] to permit FDA to assess civil money penalties to any person who does not comply with a recall order under Section 423.

Before FSMA was enacted, FDA relied on responsible parties to voluntarily recall violative food products. FDA continues to rely on responsible parties to voluntarily recall violative food products; however, FSMA's mandatory recall authority allows FDA to mandate a recall when a responsible party chooses not to conduct a voluntary recall when the criteria under section 423 of the FD&C Act are met.

Source: Office of Enforcement and Import Operations in the Office of Regulatory Affairs in cooperation with the Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine at the U.S. Food and Drug Administration

Food and Drug Administration Recalls (www.fda.gov)

Product: Potato Salad
Incident: Possible Health Risk–*Listeria monocytogenes*

A Milwaukee, WI firm is voluntarily recalling its potato salad, due to the possibility of *Listeria monocytogenes* contamination. The product was distributed at retail stores in the Chicago area and may have been sold at delicatessen counters between May 30 and June 9, 2015. The problem was identified through internal testing at the firm as part of its robust testing protocols. There have been no reported illnesses associate with the consumption of the recalled product. Consumers who have purchased these items are urged to dispose of the product immediately or return it to their local store for a full refund. Consumers with questions should contact the company.

Product: Smoked Salmon
Incident: Possible Health Risk– *Listeria monocytogenes*

A Santa Barbara, CA firm is voluntarily recalling all cold smoked salmon from March 1 through April 8, 2015 because it has the potential to be contaminated with *Listeria monocytogenes*. The cold smoked salmon was distributed nationwide through retail stores and a food wholesaler. No illnesses have been reported to date. The company is recommending as a precautionary measure to pull frozen product produced on or before April 8, 2015. Consumers who have purchased any of these products are urged not to consume them and should contact the company for a pick up. Consumers with questions should contact the company directly for more information.

United States Department of Agriculture Recalls (www.usda.gov)

Product: Beef Products
Incident: Possible Health Risk–*E. Coli* O157:H7

A Dakota City, NE establishment is recalling approximately 16,000 pounds of ground beef products that may be contaminated with *E. coli* O157:H7. The ground beef products were produced on May 16, 2015 and includes 5-lb. chubs of 80% lean ground beef. These products were shipped to one distribution location in New York. FSIS discovered the problem during a routine sampling program. There have not been any reports of illnesses associated with the consumption of this product. There is some concern that some product may have been sold and stored in consumers' freezers. Consumers and media with questions about the recall should contact the firm directly for more information.

Product: Poultry Product
Incident: Possible Health Risk–Undeclared Allergen

A Lake Charles, LA establishment is recalling approximately 93,006 pounds of both raw and cooked stuffed chicken product due to misbranding and an undeclared allergen. The product contains wheat, a known allergen which is not declared on the product label. The products were produced on various dates from June 9, 2013 through June 9, 2015. The products were shipped to retail outlets in LA, MD, PA, TX, AR, MO, NJ, AZ, FL and TN. The problem was discovered on June 8, 2015 when FSIS personnel observed that the chicken stuffing was formulated with an ingredient that contained wheat gluten. FSIS has received no reports of adverse reactions due to consumption of these products. Media and consumers with questions in regards to the recall should contact the company's consumer hotline.

Consumer Product Safety Commission Recalls (www.cpsc.gov)

Product: Wireless Speakers
Incident: Possible Risk-Fire Hazard

Culver City, CA and Cupertino, CA importers are recalling approximately 222,000 units of wireless speakers (11,000 units in Canada). The recall involves their plastic, capsule-shaped, portable, wireless speakers. The speakers come in five colors: black, white, pink, metallic sky and titanium. The battery can overheat, posing a fire hazard. The speakers were manufactured in China and sold at major retail stores nationwide and online from January 2014 through June 2015. The firm has received eight reports of incidents of the speakers overheating, including one with a burn to a consumer's finger and one with damage to a consumer's desk. Consumers should immediately stop using the recalled product and contact the company for store credit or electronic payment. Consumers with questions should contact the company directly or visit their website for more information.

Product: LED Replacement Lamps
Incident: Possible Risk-Burn Hazard

A Durham, NC importer and distributor is recalling approximately 700,000 units of LED lamps (11,500 units in Canada) manufactured in China. The recall involves LED lamps used indoors to replace traditional two pin fluorescent tubes. The white lamps have a cylindrical shape and measure 48 inches long. Electrical arcing may cause the lamp to overheat and melt, posing a burn hazard. The company has received four reports of the lamps overheating and melting. No injuries have been reported. The lamps were sold at a hardware retailer nationwide and to commercial lighting customers through electrical distributors from August 2014 through April 2015. Consumers should immediately stop using, disconnect or switch off the fixture, remove the recalled lamp, put it in a safe place and contact the firm for a full refund or replacement. Consumers with questions should contact the company directly for additional information.

Crisis Control is a newsletter jointly published by RQA, Inc. & XL Catlin.

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