

Questions and Answers Regarding Mandatory Food Recalls: Guidance for Industry and FDA Staff

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For questions or information regarding this guidance, contact the Office of Regulatory Affairs (ORA), Office of Strategic Planning and Operational Policy (OSPOP), Food and Drug Administration at ORAPolicyStaffs@fda.hhs.gov.

**U.S. Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
Center for Food Safety and Applied Nutrition
Center for Veterinary Medicine**

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Questions and Answers Regarding Mandatory Food Recalls: Guidance for Industry and FDA Staff¹

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on the FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

The purpose of this document is to provide guidance to industry and FDA staff on the implementation of the mandatory food recall provisions of section 423 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) [\[21 U.S.C. § 3501\]](#), which was added by section 206 of the FDA Food Safety Modernization Act of 2011 (FSMA). The guidance in this document is in the form of Questions and Answers and provides answers to common questions that might arise about these mandatory recall provisions and FDA's current thinking regarding their implementation.

The FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background

The 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 the FDA the authority to order a responsible party to recall an article of food where the 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).

¹ This guidance has been prepared by 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.

III. Questions and Answers

This list of Questions and Answers is intended to provide answers to common questions about the mandatory recall provisions in section 423 of the FD&C Act and the FDA's current thinking regarding their implementation.

1. Why is mandatory food recall authority important?

Before FSMA was enacted, the FDA relied on responsible parties to voluntarily recall violative food products (except infant formula recalls which are described under section 412 of the FD&C Act). The FDA continues to rely on responsible parties to voluntarily recall violative food products; however, FSMA's mandatory recall authority allows the 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. The FDA can use its mandatory recall authority when the FDA determines that there is a reasonable probability that an article of food is adulterated under section 402 of the FD&C Act and/or misbranded under section 403(w) of the FD&C Act and where there is a reasonable probability that the use of or exposure to such food would cause SAHCODHA.

2. What foods are subject to the FDA's mandatory food recall authority?

The articles of food that are subject to the 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. Infant formula is not covered under section 423 because it has its own recall requirements under section 412 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)]). The term "dietary supplement" refers, with certain exceptions, to a product that is labeled as a dietary supplement, is intended for ingestion, is intended to supplement the diet, and contains at least one dietary ingredient. Dietary ingredient(s) in these products include: vitamins, minerals, herbs or other botanicals, amino acids, and substances for use by man to supplement the diet by increasing total dietary intake. Dietary ingredients can also be extracts, metabolites, constituents, concentrates, or a combination of any of the above-mentioned dietary ingredients.

3. What is a responsible party under section 423 of the FD&C Act?

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The responsible party with respect to an article of food under section 423 of the FD&C Act is defined under section 417 of the FD&C Act. Section 417(a)(1) defines the term “responsible party” as a person who submits the registration under section 415(a) of the FD&C Act [21 U.S.C. § 350d(a)] for a food facility that is required to register under section 415(a), at which such article of food is manufactured, processed, packed, or held. “Person” is defined in section 201(e) of the FD&C Act [21 U.S.C. § 321(e)] as including individuals, partnerships, corporations and associations. As such, the owner, operator, or agent in charge of a facility who is responsible for submitting the registration is also responsible for implementing and assuring the recall is performed, if so ordered under section 423 of the FD&C Act.

4. What are the criteria for a mandatory recall?

Before the FDA can use its mandatory recall authority under section 423 of the FD&C Act, the FDA must make the determination 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 or misbranded under section 403(w) of the FD&C Act. The FDA must also make a determination that there is a reasonable probability that the use of or exposure to such food will cause SAHCODHA.

5. What process will FDA follow for a mandatory recall?

Once the FDA has determined that the criteria for a mandatory recall have been met, the 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. The FDA will notify the responsible party of this opportunity in writing using an expeditious method of delivery. If the responsible party refuses or does not voluntarily cease distribution and recall the article of food within the time and manner prescribed by the FDA, if so prescribed, the 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 to request an informal hearing² to be held not later than 2 days after the issuance of the order.

After these steps are completed, the FDA may order a recall under section 423(d) of the FD&C Act 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). If necessary, recall orders under section 423(d) shall be vacated by the Commissioner.

If the FDA orders a recall under section 423 of the FD&C Act, the FDA will generally follow the process for termination of the recall in accordance with 21 C.F.R. 7.55.

6. When is a food considered adulterated under section 402 of the FD&C Act?

² The informal hearing will be conducted in accordance with the procedures in 21 C.F.R. Part 16, Regulatory Hearing Before the Food and Drug Administration, to the extent that such procedures are not in conflict with section 423 of the FD&C Act.

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There are many reasons a food may be adulterated under section 402 of the FD&C Act including, but not limited to:

- If the food bears or contains any poisonous or deleterious substance which may render it injurious to health; consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food; or has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;
- If the food is a dietary supplement or contains a dietary ingredient that presents a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in labeling; is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury; or is a dietary supplement declared by the Secretary to pose an imminent hazard to public health or safety.

7. When is a food considered misbranded under section 403(w) of the FD&C Act?

Section 403(w) refers to product labeling required to be present if a food, other than a raw agricultural commodity, bears or contains a major food allergen. Major food allergens are defined at section 201(qq) of the FD&C Act [21 U.S.C. § 321(qq)] as milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, soybeans, and any food ingredients that contain a protein derived from these foods (with limited exceptions noted under section 201(qq)(2)). Under section 403(w), a food, other than a raw agricultural commodity, is misbranded if it bears or contains a major food allergen and the label for the food does not identify the name of the food source from which the major food allergen is derived, either through a “Contains” statement or in the ingredient list, as specified under section 403(w).

8. What evidence or circumstances might the FDA consider when deciding to move forward with a mandatory food recall under section 423?

The FDA will evaluate all applicable evidence, when determining whether there is a reasonable probability the article of food (other than infant formula) is adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act and that the use of or exposure to such article will cause SAHCODHA. These circumstances or evidence may include:

- Significant food safety observations made during establishment inspections;
- Results from sample analyses, which may include those for raw materials or finished food products, and certain sample swabs from the food facility manufacturing environment;
- Epidemiological data (e.g., food borne outbreak data directly related to the food product that suggest disease or injuries have already occurred from the consumption of/exposure to the product);

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- Vulnerability of the population that normally consumes or is exposed to the food product (the assessment of the hazard will take into account the segment of the population, e.g., infants, toddlers, the elderly, pregnant women, medically-compromised individuals, certain pets, young livestock);
- Nature of the food product (e.g., Ready-to-eat food³, raw, cooked);
- Reportable Food Registry data;
- Consumer and trade complaints; and
- Whether the responsible party has failed to initiate a voluntary recall.

9. What are some examples or situations when the FDA would deem a food product to represent a SAHCODHA risk?

Examples of situations generally representing a SAHCODHA risk include, but are not limited to, *Listeria monocytogenes (Lm)* or *Salmonella spp.* in Ready-to-eat foods, certain undeclared allergens in food products, *E. coli O157:H7* in leafy greens, and *botulinum toxin* found in food products. Some past Class I food recalls representing this risk have included:

- Peanut butter, alfalfa sprouts, and deli products found to be contaminated with *Salmonella spp.*;
- Under-processed canned chili that contained *Clostridium botulinum* toxin;
- Smoked salmon and pumpkin seeds found to be contaminated with *Lm.*;
- Products containing undeclared allergens (e.g., milk, peanuts, or eggs);
- Baby food that posed a choking hazard;
- Horse feed contaminated with elevated levels of monensin;
- Pet foods contaminated with elevated levels of melamine and cyanuric acid, or contaminated with *Salmonella spp.* or *Lm.*;
- Sheep feed containing elevated levels of copper.

10. How will the FDA publicize information about the mandatory recall?

In accordance with section 423(g) of the FD&C Act, the 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.

³ Per 21 C.F.R. 117.3, Ready-to-eat food (RTE food) means any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards.