

Washington Report



FDA's Recall Powers

The agency is taking its increased abilities under FSMA seriously, imposing significant consequences on those who refuse to follow its rules | BY TED AGRES

In May, the FDA published draft guidance for industry on how the agency plans to implement the mandatory food recall authority granted it under the Food Safety Modernization Act (FSMA). Although FDA has exercised this mandatory recall power twice since FSMA was enacted in 2011, the [draft guidance](#) outlines specific steps the agency will take and how food producers, distributors, and other “registered facilities” are expected to respond.

Prior to FSMA, FDA had to rely on food companies to voluntarily recall their products when requested. If a company refused, FDA was required to take often time-consuming legal steps, including obtaining a court order to seize and remove unsafe products from commerce.

Section 206 of FSMA gives FDA the authority to order a recall directly when the agency determines that there is a rea-

sonable probability that an article of food (other than infant formula, which is covered under a separate recall procedure) is adulterated or misbranded and that the use of or exposure to the food will cause serious adverse health consequences or death to humans or animals (known as SAHCOHDA).

This authority covers all articles of food that are manufactured, processed, packed, or held at any food facility that is required to register under section 415(a) of the FD&C Act. FSMA defines “articles of food” as those used for food or drink for humans or animals, chewing gum, and articles used as components of any such food. As such, “food” also includes dietary supplements such as vitamins, minerals, herbs or other botanicals, amino acids, and substances to supplement the diet by increasing total dietary intake. Dietary ingredients also include extracts, metab-

olites, constituents, or concentrates, the agency says.

A “responsible party” is the person who submits a food facility registration, and can be an individual, partnership, corporation, or association. The owner, operator, or agent in charge of a facility who is responsible for submitting the registration is also responsible for implementing and assuring that the recall is performed, the FDA says.

Two conditions must exist before FDA can exercise its mandatory recall authority. First, FDA has to determine that there is a “reasonable probability” that the product is adulterated (under Section 402 of the FD&C Act) or misbranded (under Section 403(w) of the FD&C Act). Second, the agency must determine that there is a “reasonable probability” that the use of or exposure to such food will cause SAHCOHDA.

According to the seven-page document, once FDA has determined that these criteria have been met, the agency must give the responsible party an opportunity to voluntarily stop distribution and recall the article of food. Notification will be given in written form “using an expeditious method.” If the responsible party still refuses or does not voluntarily cease distribution and issue the recall within the timeframe and manner specified by FDA, the agency may order the responsible party to cease distributing the food, order it to notify others to also stop distributing it, and provide an opportunity for an informal hearing. Only after all these steps are completed may FDA formally order a recall, and this authority is reserved only for the FDA commissioner.

Adulteration and Misbranding

According to the guidance document, food is considered adulterated when it 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 be rendered injurious to health.”

Adulteration for a dietary supplement occurs when an ingredient represents 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 [of Health and Human Services] to pose an imminent hazard to public health or safety.”

Products that contain a major food allergen (such as milk, egg, fish, shellfish, tree nuts, wheat, peanuts, or soybeans) are considered misbranded if the product label does not disclose allergen, either through a “Contains” statement or in the ingredient list. Some of the evidence FDA may consider in making determinations of adulteration or misbranding include observations made during inspections; results from sample analyses; epidemiological data; Reportable Food Registry data; and consumer and trade complaints.

FSMA allows FDA to collect user fees from companies that do not comply with a food recall order. These fees include the time spent by FDA in conducting food recall activities, including obtaining technical assistance, follow-up effectiveness checks, and public notifications. The agency can also assess civil monetary penalties. When finalized, the guidance document will reflect the agency’s “current thinking” on this topic, FDA said.

Prior Mandatory Recalls

The FDA has exercised its mandatory recall authority twice since FSMA was enacted in 2011. In 2013, the agency ordered a mandatory recall of *Salmonella*-tainted pet treats manufactured by Kasel Associated Industries Inc., Denver, Colo. Kasel had initially voluntarily recalled some but not all its affected products. After receiving the mandatory notice, it subsequently completed the recall.

Also in 2013, FDA ordered the recall of OxyElite Pro dietary supplements manufactured by USPLabs LLC, Dallas, Texas, that had been linked to dozens of cases of acute non-viral hepatitis. At least 47 peo-

ple were hospitalized, three received liver transplants, and one death was reported. The FDA warning letter said the products were adulterated because they contained aegeline, a new dietary ingredient for which USPLabs had not provided safety evidence, as required. After receiving the mandatory recall notice, the company voluntarily recalled the products.

This was not the company’s first run-in with FDA. A short time earlier USPLabs had destroyed different lots of OxyElite Pro after FDA issued an administrative detention order because of the presence of a stimulant in those products, DMAA (dimethylamylamine), which can cause high blood pressure and lead to heart attacks, seizures, psychiatric disorders, and death. The agency said it had received more than 100 reports of illness, including six deaths, among people who used the products. It was after this that USPLabs substituted aegeline for DMAA.

“Twice in a short period, this company has added new dietary ingredients to supplements without notifying the FDA and providing a reasonable expectation of safety, as required by law,” said Daniel Fabricant, PhD, director of FDA’s Division of Dietary Supplement Programs, at the time. “Losses to the company [estimated at \$22 million retail] should also serve as a reminder that FDA’s laws and regulations serve a purpose and must be followed.”

Preparing for a Recall

“It is a well-founded truism in the food industry that it is not a matter of *if* you will have a recall but *when*,” says Michael A. Walsh, a partner with the Strasburger & Price lawfirm in Dallas. The FDA is taking its expanded powers under FSMA seriously “and will impose significant costs on those who refuse to obey its edicts,” he says. “It is also a well-founded truism that lack of planning distinguishes a problem from a crisis. More than ever, having a recall response team and procedures in place before you need them should be the first order of business,” Walsh wrote in an [online blog posting](#).

Preparedness is essential in order to respond adequately to any recall-related issue agrees David Acheson, MD, founder and CEO of The Acheson Group and a former FDA associate commissioner for foods. “A recall can happen in a variety of ways,

including from a customer complaint, a call from a supplier who says there is a problem in what was shipped, or a call from the FDA,” Dr. Acheson says. “It may not be your fault. Bad things happen to good companies because biological systems are not predictable.”

Regardless of how a recall may be triggered, the time to figure how to respond is not when a regulator from FDA or USDA’s Food Safety and Inspection Service shows up at the door. Food companies must first have access to a network of knowledgeable people and be able to contact them quickly, Dr. Acheson says.

While very large companies typically have this expertise in-house or readily available, most small- to mid-size companies have not previously faced a food safety issue and are usually unprepared to deal with it. “Determining the scope of the problem is important,” Dr. Acheson tells *Food Quality & Safety* magazine. “Doing or saying something that gets you on the wrong side of the FDA or USDA is not a good place to be because you will find yourself digging out of a hole.”

After contacting the appropriate people in your organization or through a network provided by a consultancy or lawfirm, the next step is to assemble and review your records, including where the ingredients came from, where they were stored, when they were used and in what lots, and when and to whom they were shipped. A final step involves communication, both internally to your employees and stakeholders and externally to the public, including the media, when appropriate.

“A recall is not a simple matter,” Dr. Acheson says. “It’s not just pulling back a product. There are many moving parts and many things can get screwed up. It’s also an incredibly stressful time. For many companies, it’s the first time such a thing has happened.”

Dr. Acheson also suggests a company should conduct a mock recall exercise that spans its production chain from supplier traceability to shipment. “That’s a way to diminish stress and will help you come out in good shape,” Dr. Acheson says. “Of course, you can do it without experience and get all stressed out and do things that end up diminishing your brand.” ■

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