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INSIGHT

Food and Drug Administration (FDA) Response to a Raw Dairy Toxic *E. coli* Outbreak

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Introduction

On March 15, 2026, the U.S. Department of Health and Human Services' (HHS's) Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA) and certain state public health officials announced an investigation into a multistate outbreak of toxic *E. coli* O157:H7 infections linked to raw (unpasteurized) cheese and milk sold by RAW FARM, LLC (Raw Farm). The investigation confirmed nine *E. coli* cases in three states between September 2025 and February 2026, with the majority of illnesses occurring in children under five.

On April 2, 2026, after initially refusing, Raw Farm voluntarily recalled certain raw cheddar cheese products and stated it "disputes being the cause of this outbreak." Raw Farm, the largest raw milk farm in the country, reported that this recall impacted approximately $1.5 million of its product. The farm was identified by CDC and FDA as the likely source of a similar 2024 *E. coli* outbreak. According to CDC, children under five, adults 65 and older, and people with compromised immune systems are at a higher risk of becoming ill with a toxic *E. coli* infection, which can cause serious health conditions. Raw dairy products, compared with pasteurized products, generally are associated with a higher risk of foodborne illness, including *E. coli* infection.

Food Recalls

Foods may be recalled from the market for various reasons, including labeling errors, possible microbial contamination, or the presence of health hazards that could result in serious impacts or death. If a potentially unsafe food is identified during a foodborne illness investigation, the food producer may recall it voluntarily. Voluntary recalls may be initiated at any time by the producer or at FDA's request (under certain conditions). If the producer does not voluntarily recall the product (a rare occurrence), FDA has statutory authority to order a recall when deemed necessary to protect public health. Congress gave FDA mandatory recall authority for foods (excluding infant formula) in the FDA Food Safety Modernization

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Act (FSMA; P.L. 111-353), enacted in 2011, if certain conditions are met (see **textbox**). FDA has used its FSMA mandatory recall authority once, in 2018—in dietary supplements, considered food in this context (21 U.S.C. §321(ff)), containing contaminated kratom.

FSMA Mandatory Recall Authority—Selected Provisions (21 U.S.C. §350l)

- If the HHS Secretary determines that there is a reasonable probability that a food (except infant formula) is adulterated or misbranded *and* exposure to the food will cause serious adverse health consequences or death, "the Secretary shall provide the responsible party with an opportunity to" perform a voluntary food recall (21 U.S.C. §350l(a)).
- "If the responsible party refuses to or does not voluntarily cease distribution or recall" the food within the time frame and manner set by the Secretary, FDA may order the party to immediately cease distribution and give notice and sufficient information to any other entities within the supply chain that may be holding, processing, or distributing the food (21 U.S.C. §350l(b)).
- After the mandatory recall order is issued, an informal hearing is required as soon as possible, but no later than two days after the order, for the Secretary to provide mandatory recall instructions and allow the responsible party to make a case for why the food should not be recalled (21 U.S.C. §350l(c)).
- After the hearing, if necessary, the Secretary shall continue the mandatory recall order and provide further instruction (e.g., specify time frame, require periodic updates) (21 U.S.C. §350l(d)(1)). If the Secretary determines that adequate grounds for continuing the recall do not exist, the Secretary is to vacate or modify the order (21 U.S.C. §350l(d)(2)).
- The Secretary is to ensure public notification of the mandatory recall, including a press release, alerts, and public notices, as appropriate. The notification is to include the food name, a description of the risk associated with the food, and "information for consumers about similar articles of food" not part of the recall (21 U.S.C. §350l(g)(1)).
- The Secretary is to coordinate communications via an "incident command operation" within HHS that is to be active "not later than 24 hours" from the start of the order and ensure clear communication within and from HHS with other agencies, organizations, and the public (providing a single point of contact for public inquiries) (21 U.S.C. §350l(j)).
- The Secretary shall work in coordination with federal, state, local, and tribal authorities, as appropriate (21 U.S.C. §350l(f) and §(j)(2)(D)).
- The Secretary is to end the order when deemed appropriate (21 U.S.C. §350l(j)(2)(E)).

FDA must submit an annual report to Congress under FSMA (21 U.S.C. §350l-1) on its use of mandatory recall authority. FDA has separate mandatory recall authority for infant formula under the Infant Formula Act of 1980 (P.L. 96-359).

Foodborne Illness Outbreak Investigations

Many federal and state agencies collaborate to regulate food safety and monitor for foodborne illness outbreaks. Foodborne illness outbreak investigations are not linear—multiple investigation activities can occur simultaneously across agencies. Various factors may impact the success of outbreak investigations, including illness onset time, food shelf-life, patient memory, and genetic relatedness of the pathogen that caused the illness. Investigative activities may include patient interviews, testing of suspected food products (e.g., in stores, patient homes, or production facilities), and inspections and testing of food facilities along the supply chain. The absence of a positive pathogen result in product testing does not necessarily mean the food is not associated with an outbreak. Likewise, a positive result does not necessarily mean there is food safety noncompliance but may highlight inherent risks in food production. All information gathered during investigations may inform next steps for regulatory and public health officials, actions of impacted food producers or retailers, and preventive practices for producers and consumers.

Considerations for Congress

Some House Members of the Congressional Food Safety Caucus urged FDA and Raw Farm to remove the outbreak-linked products from the market and indicated openness to strengthening FDA's mandatory

recall authority, if needed. Policy issues of potential interest to Congress include timelines for voluntary recall compliance, the sufficiency of FDA's recall procedures, and oversight of FDA's use of mandatory recall authority.

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