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IN FOCUS

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FDA Oversight of Food Safety and Foodborne Illness Outbreaks

Background

The Centers for Disease Control and Prevention (CDC) estimate that foodborne pathogens account for 48 million illnesses, 128,000 hospitalizations, and 3,000 deaths per year. In 2024, the Food and Drug Administration (FDA) investigated more than 20 foodborne illness outbreaks responsible for causing at least 1,364 illnesses, 357 hospitalizations, and 7 deaths. FDA regulates 77% of the U.S. food supply, covering more than 220,000 facilities, including farms, food manufacturing facilities, distributors, and other entities in the food supply chain. About 40% of these facilities are located domestically.

FDA-regulated foods include produce, seafood, shell eggs, infant formula, packaged foods, and others. The U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service regulates the rest of the U.S. food supply, including most meat and poultry and some egg products. Several federal, state, and local public health agencies play a role in food safety and foodborne illness response.

The FDA Human Foods Program coordinates all FDA activities related to food safety and nutrition. This In Focus summarizes FDA's role in preventing and responding to foodborne illnesses.

Food Safety Risks

Many pathogens that cause foodborne illnesses, including *E. coli*, *Listeria*, *Salmonella*, and *Clostridium botulinum*, reside throughout the environment. Given the appropriate conditions, these pathogens can multiply quickly and contaminate foods during production. Food safety procedures work to limit the risks of contamination that ingestion causes illness. Some measures, such as using heat (e.g., pasteurization, cooking), pressure, or pH control, directly reduce the number of active pathogens. Such methods are not useful for some foods that are not fully cooked or otherwise processed before consumption, such as fresh produce or eggs. Additionally, some foodborne illnesses, notably botulism, are caused by bacteria making a toxin that is not eliminated by cooking.

Food Safety Laws and Regulations

The Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§301 et seq.) is a major federal law on food safety. The act authorizes FDA to regulate certain foods and prohibits the introduction of *adulterated* foods into interstate commerce. Examples of how food is deemed adulterated include "if it bears or contains any poisonous or deleterious substance which may render it injurious to health" or "if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth" (21 U.S.C. §342(a)-(c)). Adulterated foods include those with pathogens or their toxins.

Congress has provided FDA with additional authorities and has influenced the level and direction of food safety oversight. Congress directed FDA to establish manufacturing and nutritional standards for infant formula and provided mandatory recall authority in 1986 (P.L. 99-570). In 2011, the Food Safety Modernization Act (FSMA; P.L. 111-353) amended FDA's existing structure and authorities to require comprehensive preventive controls across the food supply to minimize contamination risk. FSMA directed FDA to regulate foods and operations that previously lacked detailed requirements. FSMA also provided FDA with additional inspection authorities and mandatory recall authority if the agency deemed or suspected regulated foods to be adulterated.

FDA often bases its food safety regulations on a risk assessment framework to control or prevent hazards, prioritizing those that have a high risk or likelihood of contaminating food. In 1969, FDA established current good manufacturing practices (cGMP, 21 C.F.R. Part 110) to ensure food manufacturers were maintaining clean facilities and ensuring food safety. FDA has since updated cGMP regulations by adding preventive, monitoring, and recordkeeping requirements. Some foods are considered high-risk for being more often associated with foodborne illnesses than others due to pathogen growth conditions and consumption habits. FDA issued specific regulations to address unique safety issues in products such as low-acid canned foods, acidified foods, and shell eggs, with a focus on certain pathogens. Other food-specific regulations, such as those for juice and seafood, are based on systems that analyze and control specific hazards at critical control points (HACCP). Following FSMA enactment, FDA issued other regulations (e.g., Preventive Controls for Human Foods Rule; Produce Safety Rule; and Food Traceability Rule) to reduce foodborne illnesses by preventing food contamination, keeping necessary records to monitor control methods for efficacy and removing potentially contaminated food from the market.

Outbreak Response

When preventive approaches fail, reactive approaches to food safety, such as food recalls, can be implemented with the appropriate traceback information. In 2011, FDA established the Coordinated Outbreak Response and Evaluation Network (CORE) to be responsible for surveillance, response, and post-response activities associated with illness outbreaks caused by food, dietary supplements, and cosmetics. CORE works with CDC, FDA field offices, and state agencies to monitor emerging

outbreaks and disease trends. CORE publishes and updates active foodborne illness investigations. FDA issues public health advisories for investigations that have resulted in specific, actionable steps for consumers to take to protect themselves. FDA investigations that prompted public health advisories in 2024 include *E. coli* in carrots, raw cheddar cheese, onions, and walnuts; *Salmonella* in cucumbers, basil, and eggs; and *Listeria* in soft cheeses.

In 2022, FDA issued the final Food Traceability Rule designed to aid in faster identification and removal of potentially contaminated food from the market. It requires certain subject entities (e.g., farms, processing facilities, retail food establishments) that manufacture, process, pack, or hold defined high-risk foods to maintain additional records.

Inspection Activities

FDA Food Compliance Programs provide instructions to inspectors to evaluate industry compliance with food safety laws and regulations. FSMA authorized FDA to rely on inspections of other federal, state, and local agencies in meeting its increased domestic facility inspection mandate. FDA has cooperative agreements with some states and territories for inspections of certain foods, such as produce, shell eggs, and manufactured foods. Some seafood inspections are conducted in coordination with the Secretary of Commerce (74 *Federal Register* 58027).

FSMA authorized the establishment of foreign FDA offices to provide direct risk-based inspection support to foreign government entities to ensure imported food safety. FDA-regulated products must be safe regardless of their origin or inspection jurisdiction.

Inspectors perform three types of inspections: surveillance, compliance follow-up, and for-cause. *Surveillance inspections* can be routine or targeted and can assess an operation's compliance with a regulation or focus on an emerging food safety issue. Routine inspections vary in frequency and are prioritized based on risk. High-risk food (e.g., ready-to-eat, consumed raw, or minimally processed) facilities are inspected more frequently. Infant formula manufacturers are required to have annual inspections. FSMA required non-high-risk food facilities to be inspected every five years. Targeted inspections are based on specific food safety risks that may include novel outbreak information, contamination risk factors, regional environmental impacts, and compliance history. *Compliance follow-up inspections* verify regulatory adherence and corrective actions after observing violations or official agency action. *For-cause inspections* are a type of compliance follow-up to evaluate an operation's actions after a specific issue, such as involvement in foodborne illnesses or recall. Inspections result in one of three final outcomes: no action indicated, voluntary action indicated, or official action indicated.

Enforcement Actions

FDA takes official enforcement actions when a product violation is deemed a threat to public health. FDA usually issues a warning letter, a type of advisory action, to allow the responsible operation to promptly and voluntarily correct the violation before the agency initiates other enforcement actions. Recalls (the removal of a product from the market) may be used as a way to correct a violation. Since 2011, FDA has used its mandatory recall authority for human foods once, in 2018, due to *Salmonella*, after the producer refused to initiate a voluntary recall.

Other enforcement actions include import alerts, registration suspension, and civil money penalties. An import alert allows FDA to have products detained at the border pending further examination. Products determined to be in violation may be exported or destroyed by Customs and Border Protection. FDA may suspend the registration of facilities deemed to pose a serious threat to public health. FDA may also impose civil money penalties. FDA relies on support from the Department of Justice for some of its civil enforcement actions, such as seizures and injunctions, and criminal investigations. FDA maintains a list of individuals and operations debarred from importing food.

Funding

The Further Consolidated Appropriations Act, 2024 (P.L. 118-47), provided $1.186 billion to FDA's Center for Food Safety and Applied Nutrition and related field activities. (In 2024, FDA reorganized the activities as part of the Human Foods Program.) Congress specified that no less than $15 million of the amount be used for inspections of foreign seafood manufacturers and field examinations of imported seafood. FDA reports spending approximately $800 million annually on field-related foods program activities.

Issues for Congress

FDA's foods program has been under scrutiny by Congress due to concerns about continuing foodborne illness outbreaks, food contaminants, and the safety of infant formula. FDA has reported difficulties with disclosure laws preempting information sharing across jurisdictions during multistate traceback investigations and has requested additional authorities to disclose this information. The 118th Congress considered, but did not enact, legislation that would have allowed information sharing (H.R. 9443) to address these concerns. Other legislation would have decreased recordkeeping requirements for some operations while requiring FDA to evaluate low-cost food tracing technologies (H.R. 7563). Some retailer groups favor such changes, citing an increased recordkeeping burden under FSMA. Other stakeholders assert such recordkeeping is essential during traceback investigations. FDA also requested authority to require pre-market testing of baby food (a proposed new categorization of high-risk food) for pathogens, with a requirement to report within 24 hours if any pathogens are found. The 118th Congress considered bills related to the infant formula and baby foods industries that would have required testing for pathogens in the food manufacturing environment (H.R. 6770, H.R. 5316, H.R. 9105/S. 4728, H.R. 8385/S. 4303) for these products.

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