

THE ALMANAC

OF THE CANNING, FREEZING, PRESERVING INDUSTRIES

Section VIII

THE BIOTERRORISM ACT and THE FDA FOOD SAFETY MODERNIZATION ACT

Overview

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act)¹ and the FDA Food Safety Modernization Act of 2011² (FSMA) have significantly expanded the Food and Drug Administration's (FDA) enforcement authorities and imposed new requirements on the food industry.

The Bioterrorism Act was developed in the aftermath of the tragic events of September 11, 2001 and was intended primarily to defend the U.S. food supply from intentional contamination. The FSMA was enacted in response to several high-profile outbreaks of foodborne illness. However, in both cases, the expansion of FDA's food enforcement authorities had been advocated in Congress for many years prior to legislative action.

With the Bioterrorism Act, "food security" or "food defense" became a major new priority for FDA, one that is related to, but distinct from, food safety. These terms refer to protection of the food supply from bioterrorism and other acts of intentional contamination. However, despite its name, the Bioterrorism Act is not limited to bioterrorist incidents; its provisions apply to any threat to the food supply, intentional or unintentional.

Title III of the Bioterrorism Act contains the Act's food provisions. Four of these provisions (registration of food facilities, prior notice of food imports, administrative detention, and new recordkeeping and records access requirements) required FDA regulations to implement them, as discussed below.

The Food Institute also publishes a *Food Industry Users Guide to the Bioterrorism Act and Regulations*. The *Guide* provides a comprehensive explanation of the Bioterrorism Act, FDA's implementing regulations and guidances, and is designed to assist both U.S. and foreign food industry users. The *Guide* is available from The Food Institute at (201)-791-5570, ext. 12, or online at www.foodinstitute.com.

¹ Pub. L. No. 107-188.

² Pub. L. No. 111-353.

On January 4, 2011, President Obama signed into law the FDA Food Safety Modernization Act, which contained extensive amendments to the food safety provisions of the Federal Food, Drug, and Cosmetic Act (FFD&CA). The FSMA gives FDA mandatory recall authority and the authority to suspend a food facility's registration, thereby shutting it down. It also requires most registered food facilities to conduct a hazard analysis and implement a written preventive controls plan. Among numerous other changes, the new law amended the Bioterrorism Act requirements for registration of food facilities, prior notice of food imports, administrative detention of food, and food recordkeeping and records access.

A third piece of legislation, the FDA Amendments Act of 2007 (FDAAA), created a new reporting requirement. If a registered food facility determines there is a reasonable probability that a food it has manufactured, processed, packed, or held will cause serious adverse health consequences or death to humans or animals, it must submit an electronic report to FDA's Reportable Food Registry with 24 hours and investigate the cause of the problem.³

Scope

The provisions of the Bioterrorism Act and the FDA Food Safety Modernization Act apply to "food." The FFD&CA defines "food" as "(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."⁴ However, because the Bioterrorism Act and the FSMA provide that they shall not alter the division of jurisdiction between FDA and the U.S. Department of Agriculture (USDA), the Bioterrorism Act and FSMA do not apply to meat, poultry, and egg products that are *exclusively* regulated by USDA. Therefore, the Bioterrorism Act and FSMA apply to FDA-regulated foods, including the following:

- Raw agricultural commodities for use as food or components of food;
- Fruits and vegetables;
- Fish and seafood;
- Dairy products and shell eggs;
- Canned and frozen foods;
- Bakery goods, snack food, candy, and chewing gum;
- Beverages, including alcoholic beverages and bottled water;
- Infant formula;
- Food ingredients and food additives;
- Dietary supplements and dietary ingredients;
- Live food animals; and
- Animal feed, including pet food.

All foods, except meat, poultry, and processed egg products, fall under FDA's jurisdiction. Thus, FDA regulates approximately 80% of the U.S. food supply. The remainder is regulated by USDA.

Main Provisions

The following are the main provisions of the Bioterrorism Act, FSMA, and FDAAA relevant to the canning, freezing, and preserving industries.

Registration of Food Facilities

Section 415 of the FFD&CA⁵ requires all foreign and domestic facilities that manufacture, process, pack, or hold food intended for human or animal consumption in the United States to register with FDA, unless the facility qualifies for an exemption. Foreign facilities that are required to register must designate a "U.S. agent." The ambit of this requirement is vast, and includes the majority of facilities

³ FFD&CA § 417 (21 U.S.C. § 350f).

⁴ 21 U.S.C. § 321(f).

⁵ 21 U.S.C. § 350d. FDA implementing regulations appear at 21 C.F.R. Part 1, Subpart H.