FDA issues final food defense regulation

Regulation marks the seventh and final major rule under FDA Food Safety Modernization Act

May 26, 2016

Release

The U.S. Food and Drug Administration today finalized a new food safety rule under the landmark, bipartisan FDA Food Safety Modernization Act (FSMA) that will help to prevent wide-scale public health harm by requiring companies in the United States and abroad to take steps to prevent intentional adulteration of the food supply. While such acts are unlikely to occur, the new rule advances mitigation strategies to further protect the food supply.

Under the new rule, both domestic and foreign food facilities, for the first time, are required to complete and maintain a written food defense plan that assesses their potential vulnerabilities to deliberate contamination where the intent is to cause wide-scale public health harm. Facilities now have to identify and implement mitigation strategies to address these vulnerabilities, establish food defense monitoring procedures and corrective actions, verify that the system is working, ensure that personnel assigned to these areas receive appropriate training and maintain certain records.

“Today’s final rule on intentional adulteration will further strengthen the safety of an increasingly global and complex food supply,” said Stephen Ostroff, M.D., incoming deputy commissioner for foods and veterinary medicine, FDA. “The rule will work in concert with other components of FSMA by preventing food safety problems before they occur.”

The rule was proposed in December 2013 and takes into consideration more than 200 comments submitted by the food industry, government regulatory partners, consumer advocates and others.

The FDA is committed to working with both industry and its state, local and tribal partners to ensure effective implementation of this new rule. Implementation of the Intentional Adulteration rule and all FSMA final rules will require partnership, education, and training. The FDA and others will provide industry with valuable tools to make compliance with the final rules easier, such as guidances, training courses and a technical assistance center.

Food manufacturers are required to comply with the new regulation within three to five years after publication of the final rule, depending on the size of the business.

The FDA has now finalized all seven major rules that implement the core of FSMA. The Intentional Adulteration final rule builds on the Preventive Controls rules for human food and animal food, the Produce Safety rule, Foreign Supplier Verification Program rule, Accreditation of Third-Party Certification rule and the rule on Sanitary Transportation of Human and Animal Food. These seven rules will work together to systemically strengthen the food safety system and better protect public health.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency is also responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

For Immediate Release

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