

# **FDA releases groundbreaking food safety rules for produce farms and imported food to modernize and strengthen food safety system**

The U.S. Food and Drug Administration today took major steps to prevent foodborne illness by finalizing rules implementing the bipartisan Food Safety Modernization Act that, for the first time, establish enforceable safety standards for produce farms and make importers accountable for verifying that imported food meets U.S. safety standards. The Agency also issued a rule establishing a program for the accreditation of third-party certification bodies, also known as auditors, to conduct food safety audits of foreign food facilities. These final rules will help produce farmers and food importers take steps to prevent problems before they occur.

An estimated 48 million people (1 in 6 Americans) get sick each year from foodborne diseases, according to recent data from the U.S. Centers for Disease Control and Prevention. Approximately 128,000 are hospitalized, and 3,000 die each year. Over the past few years, high-profile outbreaks related to various foods, from spinach to peanut products, have underscored the need to make continuous improvements in food safety.

The new rules released today – referred to as the Produce Safety rule, the Foreign Supplier Verification Programs rule, and the Accredited Third-Party Certification rule – are key elements of the comprehensive food safety overhaul envisioned in the 2011 bipartisan FDA Food Safety Modernization Act (FSMA). FSMA directs the FDA and food producers to prevent problems across the entire food system, rather than waiting to act until illness occurs. The new rules formalize industry accountability and best practices for food importers and the produce community.

“The recent multistate outbreak of Salmonella in imported cucumbers that has killed four Americans, hospitalized 157 and sickened hundreds more, is exactly the kind of outbreak these rules can help prevent,” said Michael R. Taylor, FDA deputy commissioner for foods and veterinary medicine. “The FDA is working with partners across the government and

industry to prevent foodborne outbreaks. The rules will help better protect consumers from foodborne illness and strengthen their confidence that modern preventive practices are in place, no matter where in the world the food is produced.”

The [Produce Safety rule](#) establishes science-based standards for growing, harvesting, packing, and holding produce that are designed to work effectively for food safety across the wide diversity of produce farms. The standards in the final rule include requirements for water quality, employee health and hygiene, wild and domesticated animals, biological soil amendments of animal origin (such as compost and manure), and equipment, tools, and buildings. When followed, the standards are designed to help minimize the risk of serious illness or death from consumption of contaminated produce. Public comments and input received during hundreds of farm visits, meetings and listening sessions have shaped the rule into one that will reduce the risk of harmful contamination while also allowing appropriate flexibility for farmers and producers.

The [Foreign Supplier Verification Programs rule](#) requires food importers to verify that foreign suppliers are producing food in a manner that meets U.S. safety standards and that they are achieving the same level of food safety as domestic farms and food facilities. In 2013, USDA estimated that imported food accounted for about 19 percent of the U.S. food supply, including about 52 percent of the fresh fruits and 22 percent of the fresh vegetables consumed by Americans. The final rule ensures that importers conduct verification activities (such as audits of a supplier’s facility, sampling and testing of food, or a review of the supplier’s relevant food safety records) based on risks linked to the imported food and the performance of the foreign supplier.

The FDA has also finalized a [rule on Accredited Third-Party Certification](#), which is part of FSMA’s new food import safety system. This rule establishes a program for the accreditation of third-party certification bodies (auditors) to conduct food safety audits and to certify that foreign food facilities and food produced by such facilities meet applicable FDA food safety requirements. To prevent potentially harmful food from reaching U.S. consumers, the FDA can require in specific circumstances that a food offered for import be accompanied by a certification from an accredited third-party certification body.

“The ultimate success of FSMA depends on full funding of the President’s FY 2016 budget request,” Taylor said. “This will help us train FDA and state food safety staff on

the new system, fund our state partners to work with farmers on produce safety, provide technical assistance to small farms and food businesses, and successfully implement the new import system that U.S. consumers deserve and Congress envisioned.”

The FDA has finalized five of the seven major rules that implement the core of FSMA. Today’s historic rules build on the preventive controls rules the FDA finalized in September 2015, which mandate modern preventive practices in food processing and storage facilities. These rules work together to systematically 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 ensuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is 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.