

FDA Food Safety Modernization Act (FSMA): A Foreign Suppliers Guide

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The FDA Food Safety Modernization Act (FSMA) represents the most sweeping reform of the food safety laws in the United States in over 70 years. FSMA was signed into law by President Obama on January 4, 2011, and it gives FDA new tools to address food safety from both a preventive and a responsive approach. FSMA has broad implications, and its requirements will have an impact on those who grow, process, transport, import, export and store food on a global scale. The requirements will affect finished food producers, as well as ingredient and raw material suppliers. Some requirements will even affect the producers and suppliers of food-contact substances, such as packaging materials.

Among the key food safety enhancements included in FSMA are:

- **Preventive controls:** FDA will now require comprehensive, risk-based preventive controls at facilities across the food supply chain.
- **Inspection and Compliance:** FDA has enhanced inspection targets and broader record access, in recognition of the important role that on-site inspections play in promoting accountability for safety.
- **Imported Food Safety:** The legislation provides significant enhancements to FDA's ability to achieve greater oversight of imported foods. It also imposes a new supplier verification-based framework for the import market.
- **Response:** FDA now has mandatory recall authority over all food products.
- **Enhanced Partnerships:** The legislation recognizes the importance of strengthening existing collaborations among international, regional, and local food safety agencies to achieve public health goals.

FSMA implementation is well underway, and FDA has finalized rules to implement the following key provisions of the law:

- Good Manufacturing Practice & Hazard Analysis and Risk-Based Preventive Controls for Human Food;
- Good Manufacturing Practice & Hazard Analysis and Risk-Based Preventive Controls for Food for Animals;
- Produce Safety Standards; and
- Foreign Supplier Verification Program (FSVP).

Below, we provide a brief synopsis of each final rule, as well as links to the full text of the final rules and links to Keller and Heckman's summaries of the requirements and implications of each rule.

- **Human Food GMP/HARPC Rule**

- The final GMP/HARPC rule for human food modernizes and recodifies existing Current Good Manufacturing Practices (CGMPs); requires food facilities to establish and implement a food safety plan that includes a hazard analysis and risk-based preventive controls (HARPC); and clarifies the definition of a "farm," which is central to the determination of whether certain entities must register as food facilities (thus generally becoming subject to the HARPC requirements). Companies generally have 1 year from the date of publication to comply with the final rule (including both the revised CGMPs and the new HARPC requirements), i.e., September 19, 2016.
- Text of the final rule: Final Rule for Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, 80 Fed. Reg. 55908 (Sept. 17, 2015) is available [here](#).
- Keller and Heckman's summary of the requirements and implications of the final rule is available [here](#).

- **Animal Food GMP/HARPC Rule**

- The final GMP/HARPC rule for animal food establishes for the first time CGMPs for food for animals, which are akin to the CGMPs that have long applied to human food. The rule also requires animal food facilities to develop a written food safety plan that includes a hazard analysis and risk-based preventive controls, also similar in key respects to the human food HARPC requirements. For the GMP requirements, food facilities generally have 1 year from publication of the final rule (September 19, 2016) to comply. For the HARPC requirements, the general compliance date is 2 years from publication of the final rule (September 18, 2017).
- Text of the final rule: Final Rule for Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals, 80 Fed. Reg. 56170 (Sept. 17, 2015) is available [here](#).

- Summary of the requirements and implications of the final rule is available [here](#).

- **Produce Safety Standards**

- The produce safety standards apply to farms engaged in the growing, harvesting, packing, or holding of raw agricultural commodities (e.g., fruits, vegetables) for human consumption. The final rule sets standards related to agricultural water; biological soil amendments; sprouts; domesticated and wild animals; worker training and health and hygiene; and equipment, tools and buildings, among other things. The final rule became effective January 26, 2016, but companies generally have 2 years from the effective date to comply, i.e., January 26, 2018. Covered farms have an additional 2 years to comply with certain agricultural water requirements, and compliance dates for covered activities related to sprouts are sooner (generally, 1 year from the effective date, i.e., January 26, 2017).
- Text of the final rule: Final Rule for Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 80 Fed. Reg. 74354 (Nov. 27, 2015) is available [here](#).
- Summary of the requirements and implications of the final rule is available [here](#).

- **Foreign Supplier Verification Program (FSVP)**

- The FSVP rule generally requires importers to conduct a range of activities to ensure that food from foreign suppliers is produced in compliance with applicable food safety provisions, e.g., HARPC requirements or produce safety standards. Companies generally have 18 months from the date of publication to comply, i.e., May 28, 2017.
- Text of the final rule: Final Rule for Foreign Supplier Verification Programs for Importers of Food for Humans and Animals, 80 Fed. Reg. 74226 (Nov. 27, 2015) is available [here](#).
- Summary of the requirements and implications of the final rule is available [here](#).

We will continue to monitor and update you on the latest developments related to FSMA. In the meantime, we hope you can join us for our complimentary webinar on April 27.

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