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FDA 2018 Year in Review: Food

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Developments in 2018

The Food Safety Modernization Act (FSMA) of 2011 amended the FDCA to require persons who import food to the United States to perform risk-based foreign supplier verification activities. The activities are for the purpose of verifying that:

- Food is produced in compliance with hazard analysis and risk-based preventive control requirements, or in compliance with standards for the safe production and harvesting of certain fruits and vegetables that are raw agricultural commodities.
- Food is not adulterated.
- Food is not misbranded.

The FSMA amendments also directed FDA to issue regulations on the content of foreign supplier verification programs (FSVP). These regulations were finalized in November 2015 (see 21 CFR §§ 1.500 and 1.514). In January 2018, FDA published a number of guidance documents related to the FSVP, including:

- Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs: Guidance for Industry: states FDA's intent to exercise enforcement discretion with respect to the preventive controls requirements (and, in some cases, the cGMP requirements) of 21 CFR Parts 117 and 507 for certain facilities until completion of future rulemaking related to farm activities

- Draft Guidance for Industry: Foreign Supplier Verification Programs for Importers of Food for Humans and Animals: covers a range of topics, including the requirements of an FSVP and qualifications of individuals who develop an FSVP, hazard analyses and evaluation for foreign supplier approval, foreign supplier verification activities and hazard controls

- Draft Guidance for Industry: Considerations for Determining Whether a Measure Provides the Same Level of Public Health Protection as the Corresponding Requirement in 21 CFR part 112 or the Preventive Controls Requirements in part 117 or 507: includes considerations for determining whether a measure or procedure used in lieu of an FDA requirement in 21 CFR Parts 112, 117 or 507 provides the same level of public health protection as the corresponding FDA requirement

- Guidance for Industry: Foreign Supplier Verification Programs for Importers of Food for Humans and Animals: What You Need to Know About the FDA Regulation; Small Entity Compliance Guide: contains modified procedures for a “very small importer” as well as importers of food from certain small foreign suppliers

- Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry, Chapter 15: Supply-Chain Program for Human Food contains supply-chain program requirements, including the role of a corporate parent in establishing and implementing a supply-chain program.

Read more on FDA 2018 Year in Review.

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