

# FDA Publishes Final Rule on Foreign Supplier Verification Program

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Food & Drug

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On November 13, 2015, the Food and Drug Administration (FDA) issued its final food safety rule establishing foreign supplier verification program (FSVP) requirements for importers of both human and animal food.<sup>1</sup> This final rule reflects the statutory requirements set forth in the Food Safety Modernization Act (FSMA) and is intended to provide a flexible, risk-based approach to foreign supplier verification that aligns with the hazard analysis and risk-based preventive controls requirements for food facilities that were established in FDA's preventive control final rules for human food and animal food released earlier this year.<sup>2</sup> Notably, as discussed in more detail below, FDA clarified that it will not be necessary for an importer that is also a registered food facility and is controlling hazards under the preventive controls regulations to comply with the majority of the provisions of this rule.<sup>3</sup>

This alert provides a high-level summary of the final rule, highlights key differences between the proposed rules and final rule, and discusses major points of interest to industry stakeholders. FDA has provided additional information about the final rule on its FSMA website.<sup>4</sup>

## Core Requirements of the Final Rule

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Under the final rule, importers of food for humans and animals must implement FSVPs in order to ensure that the importer's foreign suppliers produce food in compliance with processes and procedures, including risk-based preventive controls, that provide the same level of public health protection as those required under the Federal Food, Drug, and Cosmetic Act (FDCA). In particular, importers must verify that their foreign suppliers are compliant with sections 418 (hazard analysis and preventive controls), 419 (produce safety), 402 (food adulteration provisions), and 403(w) (food allergen labeling provisions) of the FDCA.

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<sup>1</sup> The FSVP Final Rule is scheduled to be published in the Federal Register on November 27, 2015. It is currently available [online](#) in a pre-publication PDF.

<sup>2</sup> See our prior client alerts on the [Final Rules for Preventive Controls for Human Food](#) (September 17, 2015) and [Animal Food](#) (September 18, 2015).

<sup>3</sup> See, e.g., Final Rule, at p. 130.

<sup>4</sup> See FSMA Final Rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals on [FDA's website](#).

In general, an importer must, for each food that it imports, implement an FSVP for each foreign supplier before importing a food into the United States as necessary to provide assurance that hazards in food requiring a control are significantly minimized or prevented. The FSVP must include a written hazard analysis, an evaluation of the risks posed by a food and the foreign supplier's performance, supplier verification activities to allow the importer to approve the foreign supplier, and corrective action procedures. The FSVP must be developed and implemented by a qualified individual who has the education, training, or experience needed to perform the necessary activities, and any required audits must be conducted by a qualified auditor.

### **Key Definitions: “Importer,” “Foreign Supplier,” and “U.S. Owner or Consignee”**

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The FSVP requirements apply to entities that meet the definitions of “importer” and “foreign supplier.” The final rule includes a revised definition of “importer” in which FDA has attempted to clarify to which of the potentially many entities in a supply and distribution chain the final rule will apply. “Importer” is now defined as the U.S. owner or consignee of an article of food that is being offered for import into the United States.<sup>5</sup> If there is no U.S. owner or consignee, then the importer will be the U.S. agent or representative of the foreign owner or consignee, as confirmed in a signed statement of consent. “Owner or consignee” replaces the provision in the proposed rule that made the importer the purchaser of the food, or if there is no purchaser, the U.S. consignee.

To further clarify this definition of importer, FDA has added a new definition for “U.S. owner or consignee,” which is the “person in the U.S. who, at the time of entry, owns the food, has purchased the food, or has agreed in writing to purchase the food.”<sup>6</sup> Doing so will prevent a warehouse to which food is merely delivered, and has little connection to the article of food, from being the importer. Absent other ownership or purchase in those circumstances, the importer would be the U.S. agent or representative of the foreign owner. FDA stated that this change would better ensure that the importer is the person that has a financial interest in the food and has knowledge and control over the food's supply chain. FDA also clarifies in the preamble that “time of entry” refers to the time of submission of entry documents, or when an import entry is submitted to Customs and Border Protection in electronic or paper form.<sup>7</sup>

The final rule defines “foreign supplier” as the establishment that manufactures/processes the food, raises the animal, or grows the food exported to the United States without further processing, except if the manufacturing or processing consists solely of the addition of labeling or other similar de minimis activity.<sup>8</sup> This definition does not include firms that merely pack or hold food with no or de minimis further processing, which is consistent with the proposed rule. The new definition replaces “harvesting” in the definition in the proposed rule with “growing.”

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<sup>5</sup> 21 C.F.R. 1.500.

<sup>6</sup> 21 C.F.R. 1.500.

<sup>7</sup> Final Rule, at p. 56.

<sup>8</sup> 21 C.F.R. 1.500.

FDA made this change to accommodate for different business models, which were acknowledged in the revised definition of “farm” in 21 C.F.R. 1.227, in which growing and harvesting may be conducted by different entities. In the proposed rule FDA had assumed that growing and harvesting would be conducted by the same entity, but for the final rule the agency determined that it is most appropriate for the grower to be the foreign supplier.

## The Scope of the Final Rule and Key Exemptions and Modified Requirements

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The final rule requires a FSVP for most types of imported food and most foreign suppliers. However, there are a few notable exemptions from the FSVP requirements that are mainly required by FSMA and do not deviate significantly from what FDA proposed. Juice, fish, and fishery products from foreign suppliers who are required to comply with, and are in compliance with, the seafood and juice hazard analysis and critical control point (“HACCP”) regulations of 21 C.F.R. Part 120 and 123 are exempt from FSVP requirements. FDA clarified that this exemption applies not only to finished products, but also to raw materials or other ingredients for use in the manufacturing or processing of juice, fish, or fishery products subject to Part 120 or 123. Importers of these products are still responsible for supplier verification, but must conduct verification activities under the relevant HACCP regulations instead of under the FSVP requirements.

The final rule also provides exemptions for: food imported (and labeled) for research or evaluation that is not sold or distributed to the public; food for personal consumption with a non-commercial purpose that is not sold or distributed to the public; alcoholic beverages (including raw materials and other ingredients that are imported for use in the manufacturing/processing, packing, or holding of alcoholic beverages); food that is transshipped through the U.S. or imported for processing and future export; food that was manufactured/processed, raised, or grown in the U.S., exported, and returned to the U.S. without further manufacturing/processing; and meat, poultry, and egg products that are subject to specific USDA requirements at the time of inspection.<sup>9</sup>

In addition, the final rule also establishes certain modified requirements, many of which mirror similar modified requirements in the preventive controls final rules, for a number of circumstances:

- *Compliance with Preventive Controls:* If an importer is a receiving facility that, in accordance with the preventive controls requirements for human or animal food, has implemented preventive controls for hazards in the food, or is not required to implement preventive controls, or has established and implemented a risk-based supply-chain program, then FDA deems that importer to be in compliance with all FSVP requirements, except for the requirement to identify the importer at the time of entry in 21 C.F.R. 1.509.<sup>10</sup>

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<sup>9</sup> 21 C.F.R. 1.501(c)-(h).

<sup>10</sup> 21 C.F.R. 1.502(c).

- *Low-Acid Canned Food*: With respect to microbiological hazards that are controlled by the low-acid canned food (LACF) regulation in 21 C.F.R. Part 113, importers would only be required to verify and document that the food was produced in accordance with the LACF regulation. However, for all other hazards not controlled by Part 113, importers must comply with FSVP requirements. These modified requirements apply to the importation of finished LACF products and also to the importation of raw materials and other ingredients by U.S. facilities for use in manufacturing or processing LACF.<sup>11</sup>
- *Dietary Supplements*: If an importer is subject to and in compliance with certain dietary supplement current good manufacturing practice (CGMP) requirements in 21 C.F.R. Part 111, then for that food the importer must only comply with the importer identification requirements in 21 C.F.R. 1.509. If an importer is importing from a foreign supplier that is subject to and in compliance with certain dietary supplement CGMP requirements, and obtains written assurance to that effect, then for that food and that foreign supplier the importer must only comply with the importer identification and recordkeeping requirements in 21 C.F.R. 1.509 and 1.510. Other importers of dietary supplements are subject to modified FSVP requirements set forth in 21 C.F.R. 1.511(c).
- *Hazards Controlled Before Consumption or After Importation*: If an importer identifies a hazard requiring a control in a food and determines and documents that the type of food cannot be consumed without application of an appropriate control (e.g., cocoa beans) or that the hazard will be controlled downstream in the distribution chain, then the importer is not required to perform FSVP supplier approval and verification activities required in 21 C.F.R. 1.505 and 1.506.<sup>12</sup>
- *Very Small Importers/Food from Small Foreign Suppliers*: If an importer is a “very small importer”<sup>13</sup> or imports food from “certain small foreign suppliers” (a “qualified facility” under the preventive controls requirements for human or animal food, a farm that is not covered by the produce requirements in 21 C.F.R. Part 112, or a shell egg producer that is exempt from the requirements of 21 C.F.R. Part 118), then that importer must perform modified foreign supplier verification activities, which primarily involve obtaining a written assurance from each foreign supplier that the supplier is producing food in compliance with all relevant food safety requirements.<sup>14</sup>
- *Officially Recognized or Equivalent Food Safety System*: If an importer is importing food from a foreign supplier that is in, and under the regulatory oversight of, a country whose food safety system FDA has officially recognized as comparable or equivalent to that of the U.S., and the supplier is in good compliance standing with the food safety authority of that country, then the importer must only comply with the importer identification requirements in 21 C.F.R. 1.509 and then recordkeeping requirements in 21 C.F.R.

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<sup>11</sup> 21 C.F.R. 1.502(b).

<sup>12</sup> 21 C.F.R. 1.507.

<sup>13</sup> The final rule defines “very small importer” with respect to human food as an importer with less than \$1 million in average sales of human food over the previous three years, and with respect to animal food as an importer with less than \$2.5 million in average sales of animal food over the previous three years. 21 C.F.R. 1.500.

<sup>14</sup> 21 C.F.R. 1.512.

1.510.<sup>15</sup> This exemption only applies to food that is not intended for further manufacturing/processing after import.

- *“Covered produce”*: If an importer is importing a raw agricultural commodity that is a fruit or vegetable that is “covered produce” under 21 C.F.R. 112.3, then the importer’s hazard analysis of that food must not include an analysis of biological hazards, because those hazards are covered by the requirements of Part 112 (the produce rule). However, the importer still must determine whether there are any other types of hazards requiring a control in such food.<sup>16</sup>

## Implementing an FSVP

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### Hazard Analysis

The final rule requires importers to conduct a hazard analysis for most types of imported food to identify and evaluate known or reasonably foreseeable hazards in order to determine whether there are any hazards requiring a control. One noteworthy change from the proposed rule is the revised definition of “significant hazard,” which FDA has replaced, throughout the rule, with the term “hazard requiring a control.” FDA defines this term as a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis, establish one or more controls or measures to significantly minimize or prevent the hazard.<sup>17</sup> The final rule clarifies the definition of “hazard” to reflect that this is a broad term referring to any biological, chemical, radiological and physical agent that could cause illness or injury, but not necessarily an agent that requires a control.

Moreover, FDA has expressly incorporated risk assessment into the final definition of “hazard requiring a control” by: (1) ensuring that it includes an assessment of the severity of the illness or injury if the hazard were to occur and the probability that will occur in the absence of a control or measure; and (2) limiting the management components--e.g., monitoring, corrections, corrective actions, verification and records--to those that are appropriate to the food, the facility, and the nature of the control or measure and its role in the food safety system. This parallels the hazard analysis framework in the preventive controls final rules.

The hazard analysis must consider any known or reasonably foreseeable hazards for each imported food, including biological, chemical, physical, and radiological hazards, that may be present in the food because the hazard is naturally occurring, because it may be unintentionally introduced, or because it may be intentionally introduced for purposes of economic gain. The analysis must consider factors such as the food’s ingredients, the condition of the foreign supplier’s equipment, transportation practices, packaging, and intended use.

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<sup>15</sup> 21 C.F.R. 1.513.

<sup>16</sup> 21 C.F.R. 1.504(e).

<sup>17</sup> 21 C.F.R. 1.500.

## **Evaluation and Verification Activities**

Once the importer has performed a hazard analysis for each food, the importer must evaluate the risk posed by the food and the foreign supplier's performance. For example, the importer must evaluate the entity that will be significantly minimizing or preventing the hazards, such as the foreign supplier or the supplier's raw material or ingredient supplier, the foreign supplier's procedures, processes and practices related to the safety of food, all applicable FDA food safety requirements and information regarding the foreign supplier's compliance history, and the foreign supplier's food safety history, including the responsiveness of the foreign supplier in correcting past problems.<sup>18</sup> The importer can rely on another entity (other than the foreign supplier) to perform the evaluation of risk, so long as the importer reviews and assesses the relevant documentation.

Based upon this evaluation, the importer must establish and follow written procedures to ensure, in most instances, that it only imports from approved foreign suppliers, and must conduct appropriate supplier verification activities. The final rule provides flexibility in the types of verification activities, rather than prescribing precise requirements, depending on unique food risks and supplier characteristics, so long as the verification provides adequate assurances that the foreign supplier is producing food in accordance with relevant FDA requirements.<sup>19</sup> Verification activities could include: annual on-site audits of the supplier's facility (which would generally be necessary when there is a reasonable probability that exposure to a hazard controlled by the foreign supplier will result in serious adverse health consequences or death to humans or animals); sampling and testing; and a review of the supplier's relevant food safety records. An importer can rely on another entity (other than the foreign supplier) to determine and perform appropriate supplier verification activities, so long as the importer reviews and assesses the relevant documentation.

## **Corrective Actions, Reassessment, Records**

Importers must promptly take appropriate corrective actions if they determine that a foreign supplier has not used processes and procedures that provide the same level of public health protection as required under relevant FDCA provisions and FDA regulations. The risk posed by the imported food and the supplier's performance must be reevaluated at least every three years, or when new information comes to light about a potential hazard or the foreign supplier's performance. The final rule also imposes a number of recordkeeping requirements.

## **Compliance Dates**

The date by which importers must comply with the FSVP regulations is the latest of the following dates:

- 18 months after publication of the final rule (late May 2017);
- For the importation of food from a supplier that is subject to the preventive controls or produce safety rules, six months after the foreign supplier is required to meet the relevant regulations;

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<sup>18</sup> 21 C.F.R. 1.505(a).

<sup>19</sup> 21 C.F.R. 1.506.

- For an importer that is itself a manufacturer or processor subject to the supply-chain program provisions in the preventive controls rules, the date by which it has to comply with those provisions. A range of compliance dates were established in the preventive controls rules for the supply-chain program provisions, which vary based on the size of the receiving facility and when the receiving facility's supplier is required to comply with the new FSMA regulations.

Covington & Burling LLP continues to monitor FDA's implementation of FSMA and to advise clients on relevant developments. If you have any questions concerning FSMA or other food regulatory matters, please contact any of the following attorneys of our Food & Drug Practice Group or visit our food and beverage practice website:

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