

FDA Releases FSVP and Supply Chain Program Draft Guidances and Announces FSVP Enforcement Discretion

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Food, Beverage, and Dietary Supplements

Last week (January 24, 2018), FDA issued a series of guidance documents and an enforcement discretion policy intended to help the food industry comply with the requirements of the Food Safety Modernization Act (FSMA). The documents further FDA's goal to ensure that all food under its jurisdiction is produced under procedures that comply with its risk-based food safety standards, regardless of where it originates or who is manufacturing it.

Two of the four guidance documents cover FDA's foreign supplier verification program (FSVP) requirements and include a general [FSVP draft guidance](#) and an [FSVP small entity compliance guide](#). Alongside these FSVP guidance documents, FDA released its [policy](#) explaining that it intends to exercise enforcement discretion on FSVP requirements for certain importers of grain raw agricultural commodities (RACs). A third guidance document is [Chapter 15 Supply-Chain Program for Human Food Products](#) of FDA's preventive controls (PC) draft guidance for human food (FDA has already released Chapters 1 - 6). The fourth [draft guidance](#) covers FDA's framework for determining whether a process, procedure, or other action provides the "same level of public health protection" as used in FDA's FSVP and produce safety rules.

This alert provides a few high-level insights on FDA's FSVP draft guidance, its enforcement discretion for importers of grain RACs, and Chapter 15 covering supply chain programs. This alert concludes with some insight that affected stakeholders could consider in assessing whether to provide FDA with additional information to think through before finalizing the guidances.

FDA is requesting any feedback by May 25, 2018 so that it has enough time to consider the feedback before it completes final versions of the guidances.

FDA's FSVP draft guidance for importers of food for humans and animals

Under the FSVP rule, importers of food must implement FSVPs to ensure that the importer's foreign suppliers produce food in compliance with processes and procedures that provide the same level of public health protection as those required under the Federal Food, Drug and Cosmetic Act (FDCA).

The [FSVP draft guidance](#) provides a detailed step-by-step overview of how to develop and implement an FSVP and should be a good reference for companies to keep on hand to understand FDA's position on specific questions that might arise. The FSVP draft guidance clarifies certain key issues, such as the following:

- *Who is considered the FSVP importer?* After clarifying the definition of FSVP “importer,” FDA provides guidance regarding situations when multiple entities meet the “importer” definition. According to FDA, these entities must determine who will be responsible for meeting the FSVP requirements for the food. FDA expects U.S. owners and consignees to do so in their contractual agreements when they have a direct commercial relationship. When there are multiple unaffiliated U.S. owners or consignees for the same line of an entry of a food, FDA anticipates that each such entity will develop an FSVP for the food and foreign supplier. If, however, one of the entities is willing to serve as the FSVP importer for this food from this foreign supplier, FDA says this would be permissible.
- *When can an importer use an unapproved foreign supplier?* An FSVP importer may import food from an unapproved foreign supplier on a temporary basis if, for example, unexpected circumstances arise that make it impossible for the importer to obtain a particular food from an approved supplier. The draft guidance provides examples of such unexpected circumstances; recommends that the importer conduct at least a minimal review of the supplier, e.g., by reviewing FDA's website to see if the potential supplier has received a warning letter or is listed on an import alert; and emphasizes that the importer must subject the food to adequate verification activities before importing it.
- *What FSVP requirements apply to dietary supplement importers?* The FSVP draft guidance clarifies the difference between the FSVP requirements that apply to importers of finished dietary supplements and importers of dietary supplement components.

The draft guidance does not appear to address what an FSVP importer must provide during an FDA inspection to demonstrate under 21 CFR 1.502 that it is “deemed to be in compliance” with the FSVP requirements because it is in compliance with the PC requirements or supply chain programs under 21 CFR Parts 117 or 507.

FDA's enforcement discretion for importers of grain RACs and for food contact substances

In addition, FDA intends to exercise enforcement discretion for (1) importers of food contact substances and (2) importers of grain RACs that either (a) are solely engaged in the storage of grain intended for further distribution/processing or (b) do not take physical possession of the grain they import, but instead arrange for the delivery of the grain to others for storage, packing, or manufacturing/processing. Although such importers do not need to meet FSVP requirements, they nevertheless remain subject to the FDCA's prohibition against the introduction or delivery for introduction into interstate commerce of adulterated food.

To help importers of grain RACs understand whether and how FDA's enforcement discretion applies to them, FDA has provided its [policy](#) with details of its enforcement discretion. FDA's enforcement discretion is intended to better align the FSVP rule with its exemption for non-produce RACs under the PC rules.

FDA's FSVP Small Entity Compliance Guide

The other FSVP guidance, the [FSVP small entity compliance guide](#), primarily addresses issues that might apply to small entities, such as eligibility for modified FSVP requirements that apply to very small importers and those who import from small foreign suppliers.

Chapter 15 Supply-Chain Program for Human Food Products

[Chapter 15 Supply-Chain Program for Human Food Products](#) provides a significant level of detail reflecting FDA's expectations for supply chain programs under 21 CFR Part 117 subpart G. While FSMA and the supply chain program, under a risk-based approach, provide flexibility in determining the food safety measure that might be appropriate for a food and the facility, the draft guidance includes specific "recommendations," with a level of detail not reflected in FSMA or FDA's regulations.

For example, in its discussion of the regulatory requirement to conduct supplier verification activities, which may include sampling and testing, FDA states, "such sampling and testing can be on a periodic basis or on a lot-by-lot basis." FDA further recommends "that you establish the frequency of such testing by first conducting the sampling and testing on a relatively frequent basis (e.g., monthly) until the supplier establishes a good history of supplying an acceptable raw material or other ingredient, after which time you could sample and test less frequently, such as quarterly" (see section 15.7.2.2). Although the draft guidance generally provides a risk-based approach, it is unclear whether FDA would take the position that the amount of testing it recommends would be necessary in all situations in which a receiving facility uses sampling and testing as a verification activity.

Similarly, FDA explains that "the determination of supplier verification activities, and the frequency of conducting those activities, also should be risk-based – i.e., the greater the risk presented by the hazard, the more robust the verification activity, and the greater the frequency of the verification" (see section 15.7.4.1). Although this statement is in line with FSMA's risk-based approach, it leaves open for interpretation the level of activity that might be acceptable to FDA.

Considerations

By necessity, FSMA provides a level of flexibility that is intended to allow food facilities to implement food safety measures that are appropriate to the food and the facility. This flexibility, however, may lead to a variety of food safety approaches in seemingly similar situations. Thus, it will be of great interest to observe how FDA views these approaches in practice, i.e., during facility inspections, while retaining the flexibility inherent in and essential to FSMA, given that there might be different interpretations of the requirements by food facilities and FDA.

Affected stakeholders may wish to review the draft guidance documents, particularly the information provided by FDA as "recommendations," to assess whether the recommendations retain the flexibility of FSMA or whether the recommendations might apply too narrowly. Stakeholders may wish to provide FDA with additional insight regarding FDA's recommendations and whether they are applicable broadly across industry or may result in unintended inflexibility.

Food, Beverage, and Dietary Supplements

Finally, the draft guidances do not address a significant issue facing some facilities required to establish FSVPs or PC-based supply chain programs -- how to encourage a supplier to provide sufficient food safety information (e.g., a hazard analysis for the food), to enable the facility to assess its own FSMA obligations for the food. The guidances presume that suppliers are willing to share such information and that the market will adjust accordingly. Affected stakeholders may wish to provide feedback to FDA and share approaches that may facilitate this necessary information-sharing so that FDA can include such examples in its final guidances or request that FDA include examples of effective approaches that it has observed since implementation of FSMA.

Covington & Burling LLP has extensive experience advising companies and trade associations on FDA's FSMA requirements and other food-related requirements. Please feel free to contact any of the following attorneys if you have any questions about FDA's recently released FSVP guidance documents and policy or any FSMA-related questions:

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