

FSVP Webinar Questions – Included here are answers to some of the questions posed during the May 19 Understanding FDAs Food Supplier Verification Program Webinar. Additional questions and answers will be included as they become available.

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Q: How do we handle trade shows for foreign importers that don't have US representation?

A: The FDA final rule is clear that samples for trade shows are subject to the FSVP. Therefore, the foreign owner or consignee would need to appoint a U.S. agent, as confirmed by the written consent of the agent, to be the FSVP importer. There are consulting firms that assist with food supplier verification activities and who may agree to be the U.S. agent as part of their service.

Q: Do we need to supply the FSVP importer's FDA registration number?

A: No -- the FSVP importer may not necessarily be a "food facility" that is required to register, so registration numbers are not required.

Q: Must small importers "register" somehow with FDA?

A: No, not under the FSVP, though they may be required to register as a food facility under the Bioterrorism Act if the small importer is a facility engaged in manufacturing/processing, packing or holding of food products.

Q: I know you touched on this a few times during the webinar, but will you touch again exactly on what the broker's obligations are for FSVP compliance and what FDA will look to the broker to provide and have on file to be in compliance with FSVP?

A: A customs broker is only required to enter in ACE the name, address, DUNS number and email address of the FSVP importer, as provided to you by the Importer of Record. While the FSVP rule does not include any further requirements, the FSVP could become an issue for a customs broker during an FDA Filer Review, particularly if the FSVP name or contact information entered turns out to be incorrect when the FDA inspects the FSVP importer. In such cases, the FDA can be expected to follow the trail up the supply chain to see why incorrect information was entered into ACE. Therefore, brokers will want some type of record to document that the information was provided to you by your customer and appears to be accurate. For example, if a U.S. agent has been listed as the FSVP importer, you may want the foreign importer to provide a copy of the agent's written consent. Or, if the FSVP information appears to be incorrect on its face (for example, if it is the name of an intermediary instead of an owner or purchaser), you will want to follow-up with your client.

Q: Can a law firm act as an FSVP Importer for a Foreign Importer?

A: Yes, a law firm can agree in writing to be the U.S. Agent for the Foreign owner/consignee and take responsibility for FSVP compliance.

Q: What qualifies as a qualified individual? Can the shipping clerk at the shipper constitute a qualified individual?

A: The FDA defines a "qualified individual" as a person with the education, training or experience (or a combination thereof) necessary to perform an FSVP activity. The FDA plans to elaborate through guidance documents what appropriate education, training and experience a Qualified Individual must have. Unfortunately, that guidance is not likely until later in the year. Unless he or she has a background and specific training in food safety, a shipping clerk for a shipper probably would not have the education, training and experience to conduct hazard evaluations and evaluate food safety records or similar FSVP activities.

Q: Does the foreign supplier need a DUNS number?

A: No, only the FSVP importer (who must be a U.S. party) needs a DUNS number.

Q: FSVP is not required on products applicable to Prior Notice? Is that correct, seems off?

A: No that is not correct.

Q: If a company has a delayed implementation date, are customs brokers still required to transmit the FSVP party information for their imports?

A: No, the customs broker can enter "FSX" on the entry instead of the FSVP party information for an import subject to a delayed implementation date.

Q: How will shipments for trade shows be handled? Is there any exceptions for these types of shipments?

A: Shipments for trade shows are subject to FSVP. There is not an exception.

Q: Can you please confirm that if an IOR is claiming a modified requirement that they are still required to provide the FSVP data elements and that using a modified requirement does not exempt the FSVP IOR from providing the necessary data.

A. Yes that is correct.

B.

Q: How are Food Contact Substances handled under FSVP?

A: The compliance date for Food Contact Substances has been delayed until May 28, 2019. We will provide details at a later date.

Q: As a customs broker we are required to transmit the FSVP data, but what requirement do we have to make sure the FSVP is doing their job and verifying the suppliers?

A: There is no requirement for the customs broker to oversee the FSVP importer or to verify that he is doing his job.

Q: Why does a foreign manufacturer need a DUNS number?

A: For purposes of the FSVP, the only DUNS number required is for the FSVP importer in the U.S.

Q: For foreign importers, do you use their DUNS number?

A: No, the FSVP importer must be a party in the U.S.