FSVP Case Studies

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SCENARIO 1

Perpetual French

• Very Small Importer (VSI)
• Imports French inspired foods (i.e., chocolates, liquors, beef jerky) from supplier, Bleu Chateau
• Packaged individually in cellophane bags & 5-10 randomly selected foods are placed in boxes prior to importation to VSI for distribution to paying subscribers
• Contents of subscription boxes vary each month; same products are not consistently imported; small amounts imported
• Average annual sales: $1.3 million

Very Small Importer

• May choose to comply w/ modified FSVP requirements under 21 CFR 1.512 if importer meets definition of VSI
• Importer averaging <$1 million/yr., adjusted for inflation, during the 3-yr period preceding the applicable calendar yr., in sales of human food + the U.S. market value of human food imported, manufactured, processed, packed, or held w/o sale.

Question: Does Perpetual French meet the definition of a very small importer? Why or why not?
SCENARIO 1

• Answer: No, Perpetual French does not meet the definition of a very small importer.

• Sales calculations to determine eligibility to importer as a very small importer must include all human foods, including:
  – Foods that are imported, manufactured, processed, packed, or held by all subsidiaries and affiliates regardless of what U.S. food safety regulations the food is subject to (i.e., Preventive Controls and Produce Safety regulations).
  – Alcoholic beverages, dietary supplements, fish and fishery products, juice.
  – Raw agricultural commodities, grains, milk, raw milk, shell eggs.
  – Foods under USDA jurisdiction (i.e., certain meat and egg products).

• Very small importers of human foods will not include animal foods or other products that are not human food in the sales calculation.
**Integral Imports**

- Buys many products from many suppliers around the world.
- Dutiful Distributors, based in Germany, supplies, from various manufacturers, a handful of products to Integral.
- Dutiful Distributors collects all the needed food safety documentation.
- Some items require temperature control and are stored at Dutiful’s warehouse.
- Dutiful Distributors collects and reviews the required food safety information and has temperature control records for all products with that issue. Dutiful Distributors informs the importer to list it as the foreign supplier on all products it provides.

**Question 1:** Does Dutiful Distributors meet the definition of a foreign supplier for any, some or all of the products?

**Question 2:** What documentation does the FSVP importer need and from which entity(ies)?

**Question 3:** What problems might the FSVP importer encounter in terms of document collection?
SCENARIO 2

Answer 1: No. Dutiful Distributors does not meet the definition of a foreign supplier because it is not the establishment that manufactures/processes the food, raises the animal or grows the food that is exported to the United States without further manufacturing/processing by another establishment.

Answer 2: The FSVP importer needs the same documentation it would collect as if it was importing directly from the foreign supplier. In short, it needs all information related to the preventive control plan and the verification steps it calls for. Integral still needs to review and assess all information it receives from this and any other entity.

Answer 3: The FSVP importer needs to educate Dutiful Distributors about the definition of foreign supplier. To protect its relationship with its suppliers and keep Integral and others from buying direct, Dutiful might not want to share the food safety documentation. It’s among the tough conversations it’ll take for Integral to properly handle its FSVP requirements. Assuming Dutiful agrees, it’s in the best position to (continue to) collect the food safety documentation.
SCENARIO 3

Yum Yum Teas, Taiwan

- Headquarters based in Taiwan; allows for U.S. entities to purchase franchise
- Maintains >100 franchises; indicates each responsible for complying w/FSVP
- Average annual sales: $2.2 million

Yum Yum Teas, USA (Franchise)

- Yum Yum Teas USA claims to meet the definition of VSI based on sales for previous 3 years
- Provided tax records and supplier written assurances, but no eligibility records
- Average annual sales: $765,000

Question 1: Was the investigator correct in conducting the inspection against the standard FSVP requirements? Why or why not?

Question 2: Can a franchisee meet the definition of “very small importer” even if the franchisor company is not a very small importer?
SCENARIO 3

- Very small importers must consider their sales as well as sales of any subsidiaries and affiliates to determine eligibility.
- If franchisor is neither same business entity as franchisee, affiliate or subsidiary, the franchisee would not consider franchisor’s sales when calculating average sales during applicable 3-yr period.
- Thus, it is possible that a franchisee can be a very small importer even if the franchisor is not a very small importer.
- If franchisee and franchisor are the same business entity, affiliate, or subsidiary, the franchisee would include franchisor operations in sales calculation.
- Answer 1: No, the importer chose to comply with section 1.512 and meets the definition of a very small importer.
- Answer 2: Yes, in this scenario, the franchisee and franchisor are separate entities, so the franchisee meets the definition of a very small importer.
SCENARIO 4

Roundabout Imports

• Mega Manufacturer, with offices and facilities in the U.S., also has production facilities in other countries.
• Double Distribution doesn’t buy directly from Mega.
• Roundabout Imports buys Mega’s product from Double Distribution.
• Roundabout is the FSVP importer.

Question 1: How can Roundabout meet its FSVP responsibilities?
Question 2: What problems might the FSVP importer encounter in terms of document collection?
Question 3: Any advice to Mega on how to avoid this scenario?
**SCENARIO 4**

**Answer 1:** It’s unlikely Roundabout will be able to comply; in order to do so, it will need Mega’s food safety information.

**Answer 2:** To comply with the FSVP regulation, Roundabout would need Double Distribution to get all of the needed information from Mega Manufacturer – or get it directly from Mega. That’s unlikely to happen because there’s almost no change Mega will provide that.

**Answer 3:** Mega has to educate anyone it sells to about the FSVP requirements and put everything in writing in contracts, etc. The regulation might actually help Mega tighten its distribution by eliminating these resellers.
Animal Pet Favorite Treats, LLC

- Imports dog and cat treats (i.e., biscuits, semi-moist morsels, dried beef, lamb, & chicken jerky)
- Suppliers located in Canada or Australia
- Some treats are imported in bulk for repacking in U.S.; some are imported in final packaging for retail sale at pet stores in U.S.
- Average annual sales: $5 million
- FSVPI claims to meet modified requirements under section 1.513 because foods are included in systems recognized agreements w/ Canada and Australia
- No FSVP for jerky treats; USDA jurisdiction

Question 1: Does this animal food FSVPI, Animal Pet Favorite Treats, LLC, fall under the system recognized agreement? Why or why not?

Question 2: Does the jerky fall under USDA jurisdiction? Why or why not?

Question 3: Is there anything else that you must consider when looking at animal food products going for further processing?

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SCENARIO 5

Answer 1: No, imported products are animal food, which do not have any system recognized agreements. FSVPI must develop, maintain, and follow an FSVP to provide adequate assurances that the foreign supplier is producing a food in compliance with processes and procedures w/applicable food safety regulations. Products not undergoing further processing are subject to the FSVP.

Answer 2: No, although some products are dried meat treats, they are not exempt from FSVP. These animal foods are not under the jurisdiction of the USDA and should be included in the FSVP.

Answer 3: Yes, the FSVPI receives some products that will be further processed (repackaged) at a receiving facility and would be deemed in compliance with FSVP if they meet one of the following:

- Implemented preventive controls for the hazards in the food in accordance with preventive control requirements (507.34)
- Followed the customer provisions in 507.36 or
- Established and implemented a risked-based supply chain program as a supply-chain-applied control has been identified by the facility (21 CFR 507 Subpart E).
SCENARIO 6

**International Imports**

- International Imports, an FSVP importer, buys many products from many suppliers around the world.
- One of its suppliers says its products are FDA-certified.
- One of its customers says it will accept only FDA-certified products.

**Question 1:** What’s the likelihood of the supplier’s products being FDA-certified?

**Question 2:** Is it likely the customer will get FDA-certified product?

**Question 3:** How is all this going to be worked out?
SCENARIO 6

**Answer 1:** Almost nil. It’s very likely a case of the supplier thinking that because its facility is registered with FDA that it’s FDA-certified.

**Answer 2:** No. In this case, it’s likely the customer has heard about but doesn’t really understand the Voluntary Qualified Importer Program, so it thinks FDA-certified product is something an importer can easily arrange.

**Answer 3:** Communication! In order to do FSVP compliance correctly, FSVP importers have to have educate all other entities in their supply chain about the requirements and they often have to correct misinterpretations by those entities. The FSVP importer must be proactive; doing so will reduce the chance of any misunderstandings – which often lead to delays and/or added costs.
SCENARIO 7

Tasty Imports

• Tasty Imports buys many products from several suppliers around the world.
• It hears about the FSPCA FSVP training.
• It also receives something from a vendor that says “The FSMA-FSVP Certification program consists of three levels: Level 2 (Basic), Level 2 (Enhanced), and Level 2 (Advanced).”
• Tasty Imports’ owner decides to have its traffic manager/quality control person take the FSPCA course.
• After receiving the certificate for completing the course, the attendee asks the instructor about the levels listed above.

Question 1: Individual reaches out to FSPCA instructor and says, “I’m certified but at what level?” What’s the reply?

Question 2: How might this question be avoided?
SCENARIO 7

Answer 1: Almost nil. It’s very likely a case of the supplier thinking that because its facility is registered with FDA that it’s FDA-certified.

Answer 2: Since certification questions and misunderstandings are somewhat prevalent, instructors might need to spend a little more time explaining certifications – and the lack thereof.