



### FSVP: What You Should Verify, Whether You're the Importer or Not

January 10, 2017 | Hilary Thesmar, PhD, RD, CFS, VP Food Safety Programs, FMI Questions/Answers

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Q: We have a broker/importer in the US (his office is in the US) that doesn't have a facility. He stores in various warehouses, and owns the product as it comes in (even if there is already a customer for it). Why is he not the FSVP Importer? I didn't think they need to have a facility.

A: A facility is not required, but the FSVP importer is required to be a US entity.

Q: Does a downstream customer have a responsibility in the regulation to ensure the Importer of record has performed their duties as required under FSVP?

A: No - just the FSVP Importer, but FDA will follow the paper trail if documents are missing.

Q: How would you go about the unique facility number/DUNS number if you are a broker that does not have a facility in the US?

A: You need to be a US entity to be the FSVP importer. To obtain a DUNS number go to <a href="http://www.dnb.com/duns-number/what-is-duns.htm">http://www.dnb.com/duns-number/what-is-duns.htm</a>

Q: Is the manufacturer of a product that has an imported ingredient in it ever considered the importer? Being a US manufacturer, wouldn't you still want to approve a supplier of a foreign ingredient even if they aren't the importer that initially receives the ingredient? Or do you just get a written verification from the importer that this foreign supplier meets the FSVP requirements?

A: Keep in mind, this webinar covered the FSVP regulation and how to comply. Your question addresses something that is important to do for food safety and as a best practice. Yes, going above and beyond the regulatory requirement is a very good idea.

Q: Best way to document you are not the FSVP importer?

A: That is outside the scope of the webinar and the regulation. I suggest consulting with a food lawyer.

Q: If a company is not listed as the importer on the CBP paperwork, but is listed as the consignee, is the company required to have a FSVP?

A: The CBP forms will require the FSVP importer to be identified once compliance begins. The FSVP Importer is responsible for FSVP compliance.

Q: Various opinions that FSMA and thus FSVP will apply to packaging. Has there been an official decision to include food contact packaging and/or their raw materials.

A: Those provision have been delayed until May 28, 2019 per the August 24, 2016 Federal Register Notice <a href="https://www.federalregister.gov/documents/2016/08/24/2016-20176/the-food-and-drug-administration-food-safety-modernization-act-extension-and-clarification-of">https://www.federalregister.gov/documents/2016/08/24/2016-20176/the-food-and-drug-administration-food-safety-modernization-act-extension-and-clarification-of</a>

#### Q: Can a third party manage FSVP for an importer? What is required to do this?

A: The FSVP Importer is responsible for FSVP compliance. If a third party manages the program, all elements of the regulation apply and the FSVP importer is responsible for compliance.

### Q: Are these categories covered by or exempt from FSVP: frozen vegetables, frozen meals, deal wine and sparkling wine? Thank you

A: rozen vegetables and frozen meals are covered under FSVP. Wine and sparkling wine are exempt as long as the conditions under §1.501 (e) are met.

### Q: A QI who has been FSMA trained PCQI - will that suffice as a QI for FSVP or do they have to train in FSVP class to be qualified as QI for FSVP?

A: Training is not required for the FSVP rule, however the FSVP Qualified Individual must be able to perform the assigned duties. In most cases, a PCQI would be qualified to do so.

# Q: We are in Canada and ship finished goods into the US to warehouses for further distribution. We are the owner at time of import, so I think we are the FSVP. My question is who would be responsible for the documentation and records? Would our US sales agent be able to do this?

A: The FSVP importer needs to be a US entity. So it can be your company if you have an office in the US or it would need to be an agent.

#### Q: What are the additional requirements above GSFI certs?

A: Compliance with FSVP which is to have the same level of public health protection as the preventive control rule or the produce safety rule.

#### Q: So, if we are a food manufacturer, we just need to identify the named FSMA importer?

A: Correct

#### Q: If a foreign supplier is registered with FDA, do they still need the Unique ID number?

A: The FSVP Importer needs a Unique Identifier. The foreign supplier just has to register with the FDA.

#### Q: FSPCA will have a training course for FSVP and helpful resources via FSPCA TAN.

A: Absolutely! For training resources see <a href="https://www.ifsh.iit.edu/fspca">https://www.ifsh.iit.edu/fspca</a>

#### Q: Do you know [sic] what the status is [sic] for FDA standard for audits?

A: As specified in §1.501 (e) (i) the onsite audit must be performed by a qualified auditor and must consider the appropriate FDA regulations, a review of the supplier's written food safety plan and implementation for the hazard being controlled

### Q: If a retailer is the owner of the product, they have final say in who they want to run fsvp program, right?

A: If the retailer is the owner at the time of import, then the retailer is the FSVP importer.

## Q: Please explain importing from Canada a little more. Since Canada already has similar FS programs, is it still the importer's responsibility to review the Canada manufacturer is following its country's regs.

A: §1.503 address importing from countries with recognized or equivalent food safety systems. If certain conditions are met, most of the FSVP provisions are waived including the hazard analysis, supplier evaluation, verification activities, corrective actions, re-evaluation. In order to comply with the modified requirements, you must identify the importer at entry and maintain records. You must document the supplier is under the regulatory oversight of a FDA recognized food safety system and document that they are in good standing. Additional details are in the regulation.

#### Q: Do these rules apply to Food Contact Packaging as well?

A: Those provision have been delayed until May 28, 2019 per the August 24, 2016 Federal Register Notice <a href="https://www.federalregister.gov/documents/2016/08/24/2016-20176/the-food-and-drug-administration-food-safety-modernization-act-extension-and-clarification-of">https://www.federalregister.gov/documents/2016/08/24/2016-20176/the-food-and-drug-administration-food-safety-modernization-act-extension-and-clarification-of</a>

## Q: We send food in primary packaging to China. It is packed into decorative containers and shipped back. Does this count as imported food or tran-shipped?

A: Food intended for consumption in the US is required to comply with the FSVP Regulation. Sounds like this is shipped to China for repackaging and back to the US for consumption, so the FSVP program would apply at the time of import back from China.

#### Q: Is the "qualified individual" a new training certification or would being a PCQI be sufficient?

A: Training is not required for the FSVP rule, however the FSVP Qualified Individual must be able to perform the assigned duties. In most cases, a PCQI would be qualified to do so.

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