Quick Start: Creating the Perfect Foreign Supplier Verification Plan

October 10, 2017 | Shawn K. Stevens, Food Safety Consultant and Lawyer

Questions/Answers

Q: If you are purchasing ingredients from a supplier who is importing materials from overseas are we required to have a supplier verification program for importing product?

A: The answer depends upon whether you fall within the definition of importer. Under the rule, an importer is defined as the U.S. owner or consignee of an article of food that is being offered for import into the United States. In turn, the owner or consignee is defined as the person in the United States who, at the time of U.S. entry, either owns the food, has purchased the food, or has agreed in writing to purchase the food. Thus, if you have already agreed in writing to purchase the food at the time of entry, you could be the importer. If your supplier owns the food at the time of entry, however, your supplier might also fall within the definition of importer. Thus, under these circumstances, you should talk to your supplier and decide which of you is most appropriate to assume the role of importer.

Q: Does the categorization of the product matter (e.g. dietary ingredient vs. food) if the product is to be used within a dietary supplement? If it is categories as food do we need to perform a hazard analysis at that point or would we still treat it as a dietary ingredient that would not require a hazard analysis?

A: According to FDA, the exemption does not apply to the manufacturing, processing, packing, or holding of dietary ingredients. Dietary ingredients are subject to the requirements of the rule, including the current good manufacturing practice (CGMP) requirements of 21 CFR part 117, subpart B; the hazard analysis and risk based preventive controls requirements of 21 CFR part 117, subpart C; the supply chain program requirements of 21 CFR part 117, subpart G; and the recordkeeping requirements of 21 CFR part 117, subpart F. Thus, the purchase of dietary ingredients would require a hazard analysis.

Q: What are the roles and responsibilities for Brokers, Distributors, and Importers that needs to be educated to be compliance with FSVP?

A: I would recommend taking the Foods Safety Preventive Controls Alliance courses for Preventive Controls for Human Food and Foreign Supplier Verification Plans.

Q: We are a food packaging producer that isn't required to be registered with the FDA and purchases through domestic brokers and not directly from foreign suppliers. Are we required to have a FSVP?

A: Yes, an FSVP may be required. Although the compliance dates for these categories have been extended by FDA until May 2019.

Q: If as a company we determined that we are not to be listed as FSVP. What's the best way to verify that no one is using our DUNs #?
A: If you are confident you do not fall within the definition of an FSVP importer, make sure to document your conclusion. That way, regardless of whom might use your DUNs #, you'll be covered if FDA arrives. Also, if you have suspicions about a company improperly using your information, be sure to contact FDA. I letter to your importers reminding them of their FSVP obligations and warning them not to use your DUNs # may do the trick as well.

Q: For Canadian suppliers, is reviewing a GFSI audit sufficient to meet the modified requirements?
A: Yes, in most cases this should be sufficient. With that said, I would request a statement confirming they are in good standing with CFIA.

Q: Are Canadian suppliers that export to USA obliged to write a Foreign Supplier Verification Plan? Or does this only apply to US importers? We have a lot of the required programs in place (with SQF audit and HACCP plan) but it's not in the form of a plan.
A: Importers of food products legally manufactured in Canada are not required to prepare an FSVP for those products. With that said, you should obtain a statement from your Canadian supplier confirming that the supplier is in good standing with CFIA.

Q: If a supplier has signed a letter that they are satisfying the PC rules is that sufficient?
A: No.

Q: Are we required to write comments of a review in addition to a simple check that an element was reviewed?
A: Depends upon the circumstance. If the documents reviewed clearly establish on their face that the required elements are satisfied, and you maintain those documents for FDA review, then a check should be sufficient. If less than clear, than a more detailed justification should be provided.

Q: What are the requirements for food packaging producers? My understanding is that for the purposes of FSVP direct food contact packaging is considered food and thus requires an FSVP. Would you envision this FSVP following the Form A format?
A: Yes, an FSVP may be required. Although the compliance dates for these categories have been extended by FDA until May 2019. The form used would depend upon the sufficiency of the supplier's hazard analysis and food safety programs.

Q: Are verification activities supposed to be scheduled for all shipments received from that foreign supplier or is it up to the FSVP importer to determine the frequency of these activities based on risk (i.e. once a year)?
A: Depending upon the product and risk, you may determine that some level of verification activities is appropriate for each shipment (i.e., a Certificate of Analysis showing negative pathogen results for

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finished product testing on a high-risk product). With that said, determining appropriate verification activities, and frequency of those activities, is reserved to the FSVP importer based upon risk.

Q: We have a foreign supplier that imports product to a US warehouse then sells to us out of that warehouse. Are they a foreign supplier?
A: This depends upon the circumstances. I would ask the foreign supplier if it owns and registers the U.S. warehouse with FDA. If so, it might also be deemed the U.S. FSVP importer.

Q: How do you deal with a Supplier that gets his materials as raw materials or products from 5 different manufacturers?
A: The hazard analysis will have to account for all raw materials and all related risk, ensure that all hazards are identified, and that all appropriate controls are put into place.

Q: Regarding verification activities can a GFSI 3rd party audit qualify as an "onsite audit" or do we the importer need to do a direct onsite audit?
A: A GFSI audit will qualify as an audit.

Q: Also, regarding verification activities: Sampling and Testing... Do we the importer need to perform the test via a 3rd party, or can we accept the supplier's COA testing from their inhouse or 3rd party overseas lab?
A: You can accept the supplier's COA. If you have reason to suspect the merits of any such COAs, however, you may elect to conduct your own sampling and testing using your own third-party lab.

Q: If we are strictly procuring ingredients from domestic vendors, how can we make sure they are compliant with FSVP for the materials they procure from overseas?
A: As a US manufacturer, you are required to implement a risk-based supply chain program as part of your written food safety plan if you hazard analysis identifies a hazard that (1) requires a preventive control and (2) the control will be applied in before the product reaches you. The steps you select for supplier approval and verification should be designed to address any concerns.

Q: Some companies are in the FDA's green list for import. Does it count as a verification activity?
A: Yes, ensuring a supplier is in the green list could qualify as a supplier evaluation activity and as one element of ongoing verification, when combined with other appropriate verification activities.

Q: If we import various commodities, what would you suggest the QI to use to know what hazards are associated with that commodities?
A: Common sense, reason, research of food product recalls, and PCQI training and course materials.

Q: Does a foreign supplier who obtains a GFSI, accomplish many of the responsibilities an importer has?

A: It is not possible to approve a supplier without conducting a hazard analysis with respect to each imported food and/or reviewing your supplier's hazard analysis. Thus, merely reviewing a GFSI audit will not be sufficient. With that said, a GFSI audit may be a useful tool for ongoing verification once the hazard analysis is complete, you have evaluated the food product and supplier, and the supplier is approved.

Q: If the foreign supplier has a HACCP, we don't need the FSVP?
A: No. You need a FSVP. Why you are permitted to rely upon your supplier's HACCP plan, you are still required, as part of your FSVP, to review the HACCP plan and determine that all hazards are identified and appropriate controls are put in place. This review must be documented in your FSVP.

Q: Does this need to be a separate plan or can it be combined with your Food Safety Plan (compliant with GFSI and the PC Rule)?
A: It could be a stand-alone plan or an element of your Food Safety plan (i.e., part of your supply chain program).

Q: Can you use the same approach under the Supply chain controls required for manufacturing facilities already subject to PC rule?
A: According to FDA, you can be deemed in compliance with most of the FSVP requirements for foods you import if you implement preventive controls for the hazards in the food in accordance with applicable requirements, or if you comply with the PC supply-chain program requirements. With that said, you will still need to provide certain identification information when importing the food, such as a unique facility identifier for each line entry of food offered for importation into the United States.

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