



Food Importers Beware: FDA Begins New Phase of Foreign Supplier Verification Program Enforcement

With little fanfare, the Food and Drug Administration (FDA) entered a new phase for enforcing the Foreign Supplier Verification Program (FSVP). In May, FDA issued an import alert listing against two importers whose food appears to have had no previous safety issues. This import alert listing is essentially an import ban where the importers cannot import the food until they implement an appropriate FSVP to FDA's satisfaction. With these import alert listings and an increase of FSVP Warning Letters, importers must take caution that FDA is stepping up FSVP enforcement with stronger consequences for non-compliance.

WHAT IS FSVP?

The Food Safety Modernization Act (FSMA) created a new requirement for food importers—the Foreign Supplier Verification Program (FSVP). FSVP requires a food importer to create a due diligence program to review and approve its foreign suppliers. Then the importer must take action to verify that the food was produced in a manner that provides at least the same level of protection as the U.S. requirements, is not otherwise adulterated and does not contain an undeclared major food allergen. This supplier approval program seeks to prevent food safety problems; however, an importer can violate this requirement even without any indication that the food is unsafe.

If an importer fails to comply with FSVP, then FDA can issue an administrative import refusal against the food it imports.

HOW DOES FDA INSPECT AND ENFORCE FSVP?

FDA will inspect an importer to verify compliance with FSVP—FDA does not preapprove an importer's FSVP. If FDA finds the program inadequate, the Agency will usually issue a Form 483, which is the investigator's observations of potential non-compliance. After FDA issues a Form 483, the importer can make changes and submit supporting documentation to FDA for review to avoid possible compliance issues. If an importer fails to respond or FDA finds its response inadequate, FDA may issue a Warning Letter.

A Warning Letter is a notice used by FDA that seeks to obtain voluntary compliance through the threat of an enforcement action and public shaming (FDA posts Warning Letters on its [website](#), which can then trigger lawsuits). In the warning, FDA explains the violation(s) and provides the importer an opportunity to voluntarily fix the problem. If it fails to do so

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adequately, FDA may take further action to obtain compliance. For FSVP, that further action will normally be to place the importer and the applicable food on [Import Alert 99-41](#).

An import alert is an internal directive indicating that future shipments of a listing product can be stopped by FDA and possibly refused importation. Unlike other import alerts, FDA is not likely to consider product testing as persuasive evidence to seek an import release; rather, every shipment is likely to be refused. Like Warning Letters, FDA makes its import alert listings public so that others are aware when a company is placed on the alert.

WHAT'S NEW?

FDA is now placing importers on Import Alert 99-41 even without any indication that the importer's food was unsafe. In October 2019, FDA placed the first importer on import alert after an inspection found it non-compliant with the FSVP requirement. FDA inspected the importer after its food was associated with foodborne illnesses by potentially containing *Salmonella*. The new importers placed on import alert appear to have no history of food safety issues, thereby indicating FDA is willing to place any importer on import alert now.

HOW CAN A COMPANY RESOLVE AN IMPORT ALERT LISTING?

The importer must create and implement a compliant FSVP program, which is then submitted to FDA for review. If FDA finds the changes sufficient, then it will ultimately remove the importer from Import Alert 99-41. If FDA finds the changes insufficient, then the importer must make further changes and resubmit. Note that while this is occurring, the importer is effectively banned from importing the food until the issue is resolved to FDA's satisfaction.

HOW CAN A COMPANY AVOID AN IMPORT ALERT LISTING?

Create and implement a compliant FSVP program. However, if a firm received an FDA Form 483 (investigator's observations of non-compliance) after an inspection or an FDA Warning Letter, it must take them seriously and

respond accordingly by voluntarily getting into compliance with the FSVP regulations. The importer must also effectively communicate these changes to FDA because the Agency will not assume that an importer has made the appropriate changes. Rather, FDA will assume that the importer has done nothing and may take further action against the importer.

Importers that previously failed an FDA inspection should take extra care as they are more likely to experience additional FDA scrutiny and run a greater risk of being placed on import alert.

Those that previously "passed" an FDA inspection must remain diligent to verify that their program has remained sustained and appropriately implemented through self-audits or external audits.

Those that rely on others to import foods they need for their businesses should audit their suppliers to ensure they remain in compliance to avoid possible disruptions or other consequences.

Author [John Johnson III](#) is Of Counsel at Shook, Hardy and Bacon and practices FDA regulatory law. In his practice, he works with importers to develop and implement practical FSVP compliance programs. Additionally, he works with importers to prepare for and successfully manage FDA FSVP inspections and, as needed, respond to FDA actions, such as import detentions, FDA Form 483 and Warning Letters.