FSVP: What Do Importers Need to Know?

A Conversation with Sharon Mayl

The first major compliance date for importers covered by the Foreign Supplier Verification Programs (FSVP) rule arrives on May 30, 2017. FSVP is mandated by the FDA Food Safety Modernization Act (FSMA). A central tenet of that law is that the same preventive food safety standards apply to food consumed in the U.S., regardless of where the food is produced.

FSVP requires importers to verify that their foreign suppliers of food for human and animal consumption meet applicable FDA safety standards. More specifically, FSVP requires that importers verify that their suppliers are producing food using processes and procedures that offer the same level of public health protection as the preventive controls (PC) requirements in the preventive controls and current good manufacturing practices rules for human food and animal food and produce safety FSMA rules, and that the food is not adulterated and properly labeled with respect to allergens.

Sharon Mayl, Senior Advisor for Policy in the Office of Foods and Veterinary Medicine at FDA, explains what importers need to know when facing this May compliance date and what lies ahead for FSVP implementation.

Q: When are the compliance dates for the FSVP rule?

It is important to note the compliance dates for FSVP **are not based on the size of the importer**. Instead, the **compliance dates (/Food/GuidanceRegulation/FSMA/ucm503822.htm)** are staggered based on the size of the foreign supplier and the regulations that apply to the foreign supplier. The first compliance date is eighteen months after the FSVP final rule was published in the **Federal Register (https://www.federalregister.gov/documents/2015/11/27/2015-28158/foreign-supplier-verification-programs-for-importers-of-food-for-humans-and-animals)**. This date gives importers sufficient time to understand the rule and develop their FSVPs. After that, importers generally have to comply six months after their foreign supplier has to be in compliance with the PC or produce safety rules. We linked the FSVP compliance dates to the other FSMA rules because we wanted to minimize the likelihood that an importer would be required to comply with the FSVP regulation before its supplier is required to comply with other FSMA food safety regulations.

Q: Who must be in compliance with the FSVP requirements by May 30, 2017?

U.S. importers subject to this first compliance date have foreign suppliers that fall into one of three categories:

- Foreign suppliers that will *not* be covered by the PC or **produce safety rules (/Food/GuidanceRegulation/FSMA/ucm334114.htm)**;
- Foreign suppliers subject to the **PC for Human Food rule (/Food/GuidanceRegulation/FSMA/ucm334115.htm)** and are not "small businesses," "qualified facilities" (certain very small businesses) or subject to the Pasteurized Milk Ordinance; or
- Foreign suppliers subject to the current good manufacturing practices (CGMP) requirements in the **PC for Animal Food rule (/Food/GuidanceRegulation/FSMA/ucm366510.htm)**, and are not "small businesses" or "qualified facilities".

For ease of viewing, we have a chart on fda.gov titled ***"Am I Subject to FSVP?" (/downloads/Food/GuidanceRegulation/FSMA/UCM480038.pdf)***that importers can refer to if they are unsure if the rule applies to them.

Q: What do importers have to verify on May 30, 2017?

Importers covered by the FSVP rule will have to verify that their suppliers meet applicable FDA food safety requirements, including that the food is not adulterated or misbranded with respect to allergens.

The largest foreign suppliers subject to the PC for Human Food rule had to be in compliance in September 2016 with both the PC provisions and the CGMP requirements of that rule, but the largest suppliers subject to the PC for Animal Food rule only had to be in compliance with the CGMP requirements by that date. Therefore, importers of foods from those facilities will only need to consider those provisions of the PC rules that their suppliers have had to come in compliance with by May 30, as well as verify that the food is not adulterated or misbranded with respect to allergens.

And I want to clarify that importers have some flexibility with respect to the PC and produce safety rules. Importers will need to have a program that allows them to demonstrate that their foreign suppliers are producing food in a manner that provides the same level of public health protection as the PC or produce rules.

As noted above, importers will have additional time to develop and implement FSVPs for foods from smaller suppliers that are considered qualified facilities or small businesses under the PC rules, as well for food subject to the produce safety rule.

Q: When the first compliance dates arrived in September 2016 for the preventive controls rules, FDA indicated that it would focus on education, training, and technical assistance. Is that also true for this FSVP compliance date?

Yes, we have done a lot of outreach already to help importers understand the regulations and what they have to do. However, we understand that this is new to a lot of importers, so our approach will be to educate while we regulate to create a culture of compliance. Importers can expect interactive FDA inspections with opportunities to explain how their programs meet our requirements and how they will take corrective actions if we observe deficiencies. Good communication is key. Our initial enforcement priorities will be, as they are now, on food safety problems that pose an imminent public health risk. But the FDA's mandate is to protect public health and, when appropriate, the agency will act swiftly.

Q: Will FSVP change the admission process?

All foods regulated by the FDA **will see changes to the entry process as of May 30, 2017**. When food is offered for entry into the United States, the Customs and Border Patrol (CBP) Automated Commercial Environment (ACE) system will require the filer to enter at least one additional code as part of the required data elements. An FSVP importer subject to the May 30 compliance date should use the entity role code "FSV," indicating the entry is subject to the FSVP regulation. This will then prompt the ACE system to ask for the importer's name, email address, and unique facility identifier (UFI) recognized as acceptable by FDA. We recently issued guidance formally recognizing the **Data Universal Numbering System (DUNS) number as an acceptable UFI for FSVP (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm549623.htm)**.

Conversely, if the food entry line is exempt from the requirements of FSVP, or not yet subject to the rule because it has a later compliance date, the filer should use one of two Affirmation of Compliance codes, either "FSX" (designating that the food is exempt from FSVP or that compliance with FSVP is not yet required) or "RNE" (designating, more specifically, that the food is exempt from FSVP because it will be used for research or evaluation in accordance with 21 CFR 1.501(c) of the FSVP regulation). If one of these codes is not transmitted for an imported food product under FDA jurisdiction, the entry line will be rejected.

We have heard that there is some concern within the importing community that not everyone will be able to obtain a DUNS number in time for the first compliance date on May 30. While we expect all FSVP importers to provide their UFI starting on the applicable compliance date, because this is a new rule, we have provided a temporary solution. For a limited time, importers can submit the value "UNK" (to represent "unknown") in the entry data field where the DUNS number would have been provided for the FSVP importer. This will give importers extra time to obtain their DUNS numbers and will provide us with a list of FSVP importers whom we can contact to ensure they understand and are taking the necessary steps to meet the FSVP requirements. But, remember, the submission of the "UNK" option is temporary. Therefore, FSVP importers should work now to ensure they have accurate and complete entry data (including their DUNS numbers) and understand the process for filing to avoid any future delays in the entry of their products.

It is important to note that while importers will be required to provide their importer identificati**(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**on information through the ACE system, we will not be enforcing overall compliance with this rule on a shipment-by-shipment basis at the port of entry. Rather, our general approach to enforcing compliance will be to inspect U.S. importers and review their records to make sure they are in compliance.

Q: What can importers expect when an investigator reviews their FSVPs?

Remember that, unlike traditional facility inspections, FSVP inspections are based on the review of records, rather than observations of food production. While most of the FSVP inspections will be at the importer's place of business, we are also going to request that some importers provide FSVP records to FDA electronically, or through other means that delivers the records promptly, as part of a pilot program. In either case, the investigator will ask to view the importer's FSVP records to determine if there are deficiencies. In most cases, if any deficiencies are found, the importer will be provided an opportunity to correct them. Our focus right now is on supporting compliance, except for problems that pose a danger to health or reflect intentional disregard for legal responsibilities.

I also want to emphasize that we are investing significant resources in training FDA personnel on how to conduct these inspections. Importers can expect an approach that is interactive, and by that I mean that our investigators will be asking questions about what they see and there will be the opportunity for a real dialogue. We encourage importers to keep the lines of communication open with FDA if problems are found. If a corrective action is needed, the importer should communicate clearly what actions will be taken and by what date the corrections will be completed. If problems arise in meeting deadlines, the importer should let us know.

Q: I already audit my supplier. Can I use that audit as a verification activity?

There are many different types of verification activities that can be used to meet the requirements in the rule. The rule mentions review of the supplier's relevant food safety records, sampling and testing, and onsite auditing as examples of verification activities that may be appropriate, either individually or in combination. Which activity importers choose should be based on their evaluation of the risk of the food and their supplier's performance.

If importers determine that an audit is the appropriate verification activity, they must make sure the audit meets the requirements in the rule, namely that the audit considers the FDA food safety requirements that apply, and that the auditor is qualified to perform the audit (e.g., education, training, experience). These requirements are designed to be flexible and there are a variety of audits currently being used within the industry that may meet our requirements.

We are aware of several organizations, such as the USDA's Agricultural Marketing Service (AMS) and the Global Food Safety Initiative (GFSI), that are working to ensure their audits meet our requirements. We have stated our intention to build on current private and public audit activity and we applaud the efforts of external organizations to align their standards and practices with FDA food safety requirements.

That said, the agency would encourage all importers to ensure the scope of the audits they currently use consider all applicable FDA food safety regulations, including the PC and produce safety rules if they apply to their supplier. In addition, they should ensure that the auditors performing the audits are qualified auditors in accordance with the FSVP rule.

Q: For importers whose compliance date hasn't arrived yet, what should they be doing to prepare for FSVP compliance?

I mentioned earlier that all importers subject to the FSVP rule should obtain a DUNS number. I would urge importers subject to the rule to obtain a DUNS number prior to their compliance date if they do not already have one.

Of course, they should also be working to ensure that they know the requirements of the FSVP rule, beginning to put together their FSVPs, and, if appropriate, conducting verification activities prior to their compliance dates. There is a lot of information on our website that can help importers comply,

including fact sheets and other materials. Questions about how the rule may apply to you can also be submitted to our **Technical Assistance Network (/Food/GuidanceRegulation/FSMA/ucm459719.htm)** (TAN) for a response by experts here at FDA. They can find information about the network online, and I would encourage them to be very specific about their circumstances when they submit questions to help the FDA experts give them the best advice on how the rule applies to them.

There is also training for importers available through the **Food Safety Preventive Controls Alliance (FSPCA) (https://www.ifsh.iit.edu/fspca)** designed to provide the knowledge required to meet the FSVP requirements. The training is also available to others who have an interest in ensuring that FSVP requirements are met, such as brokers, foreign suppliers, and representatives of foreign governments.

Q: We've talked a lot about what importers need to know to be in compliance, but what about the big picture: How does FSVP protect our food supply?

FSVP is a significant new tool in our import toolkit. We have many tools that help protect consumers from unsafe imported products. Some of those tools have been around for a while, like examinations and sampling at ports of entry and foreign inspections, but the volume of food imports and the logistics and cost of foreign inspections require something more to ensure the safety of imported food. FSVP allows us to hold importers accountable for ensuring the products they bring into the United States are held to the same safety standards as domestically produced food. That's a significant change to the way we currently do business, and complements our other import tools. FSVP provides us a way to get information about foreign suppliers to help ensure that they are meeting U.S. safety requirements and, thus, keeping food safe for U.S. consumers.

More in Food Safety Modernization Act (FSMA) (/Food/GuidanceRegulation/FSMA/default.htm)

- The Law, Rules & Guidance (/Food/GuidanceRegulation/FSMA/ucm359436.htm)
- Fact Sheets & Presentations (/Food/GuidanceRegulation/FSMA/ucm247546.htm)
- Frequently Asked Questions on FSMA (/Food/GuidanceRegulation/FSMA/ucm247559.htm)
- FDA Actions and Meetings (/Food/GuidanceRegulation/FSMA/ucm359450.htm)
- FSMA Training (/Food/GuidanceRegulation/FSMA/ucm461513.htm)
- FSMA Technical Assistance Network (TAN) (/Food/GuidanceRegulation/FSMA/ucm459719.htm)