On Nov. 27, 2015, the U.S. Food and Drug Administration (FDA) published the Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals rule in the Code of Federal Regulations under the Food Safety Modernization Act (FSMA). The final rule requires that importers perform risk-based activities to verify that all foods imported into the United States have been produced in a manner that provides the same level of public health protection as domestically produced food.

The goals are to ensure that:
- Each food is produced in a manner that provides the same level of public health protections as the produce safety rule and the preventive controls rule (where applicable)
- Food is not adulterated (i.e., safe)
- Allergen labeling is correct.

WHO IS IMPACTED
For the Florida citrus industry, this rule has the potential to impact importers of fresh fruit, though juice processors who import juice and already fall under the Juice Hazard Analysis and Critical Control Point (HACCP) final rule are not covered by FSVP. The first compliance date for FSVP was on May 30, 2017.

Under the FSVP rule, an FSVP importer is defined as the U.S. owner or consignee of a food offered for import into the United States. If there is no U.S. owner or consignee, the U.S. agency or representative of the foreign owner or consignee must consent in writing before being designated as the FSVP importer at the time of entry. If the importer is an operation subject to the preventive controls rule, no FSVP program is necessary, except to designate a U.S.-based FSVP importer at entry. In this case, any hazards in the imported foods would be identified and managed under that operation’s supply-chain, preventive controls, food-safety plan. The FSVP compliance date for foods subject to the preventive controls or produce safety rules is six months after the foreign supplier is required to comply with that regulation.

The FSVP rule also applies to food contact substances. Food contact substances are defined by the rule as any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting or holding food if the substance is not intended to have any technical effect on the food. Further guidance on the application of the FSVP to these substances and the compliance date for food contact substances are pending.

IMPORTER REQUIREMENTS
The FSVP rule requires that an importer provide its name, electronic mail address, address and unique facility identifier (UFI) for each line entry of food product offered for import into the United States. The Data Universal Numbering System (DUNS) numbers...
are recognized by FDA as acceptable UFIs for the FSVP. DUNS numbers are available at www.FDAdunslookup.com free of charge to importers. Importers who fall under FSVP are required to develop, maintain and follow FSVP for each food brought into the United States and the supplier of that food. If the importer imports the same food from different suppliers, a separate FSVP would be required for each of those suppliers. Similarly, if the importer obtains many different foods from a single supplier, a separate FSVP would be required for each food. The FSVP requires importers to:

- Determine known or reasonably foreseeable hazards in each imported food
- Evaluate the risk posed by a food, based on a hazard analysis, and the foreign supplier’s performance
- Use that evaluation to approve suppliers and determine appropriate supplier verification activities
- Conduct supplier verification activities
- Conduct corrective actions

The FSVP must be reevaluated at least every three years, or when new information comes to light about a potential hazard or the foreign supplier’s performance. The hazard analysis performed by an importer will need to evaluate biological, chemical (including radiological) and physical hazards that are reasonably likely to cause illness or injury in the absence of control. The analysis also will need to include hazards that are naturally occurring, unintentionally introduced or intentionally introduced for purposes of economic gain. The importer can rely on another entity (including the foreign supplier) to conduct the hazard analysis, so long as the importer reviews and assesses the relevant documentation.

An evaluation of the food risk and supplier performance must be performed, including the hazard analysis, and the entity that is significantly
minimizing or preventing the hazards (such as the foreign supplier; in the case of citrus, the primary producer/grower is the supplier). Other evaluations need to include the foreign suppliers’ procedures, processes and practices related to food safety; the applicability of and compliance with FDA food safety regulations; the firm’s food safety history including the responsiveness of the foreign supplier in correcting past problems; and other factors including storage and transportation practices. As with the hazard analysis, another entity (but not the foreign supplier) can be relied upon to perform the evaluation of risk, so long as the importer reviews and assesses the relevant documentation.

Supplier verification activities are flexible and should be based upon the evaluation of risk. Options include:

- Annual on-site audits of the supplier’s facility
- Sampling and testing
- A review of the supplier’s relevant food-safety records.

Similar to the hazard analysis, another entity (but not the foreign supplier) can be relied upon to perform the evaluation of risk, so long as the importer reviews and assesses the relevant documentation. If something goes wrong, importers must promptly take corrective actions. These will depend on the circumstance, but may include discontinuing use of the foreign supplier until the issue has been adequately addressed.

**RULE MODIFICATIONS**

Modified requirements exist for very small importers and certain small suppliers. The definition of a very small importer is consistent with the definition of a very small business in the preventive controls rule (i.e., less than $1 million in human food sales) combined with the U.S. market value of the food that is imported, manufactured, processed, packaged or held without sale. Examples of these suppliers from which the Florida citrus industry might import product include:

- Facilities subject to modified

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- Restoring growth to the European fruit juice market

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requirement under the prevention controls rules because they are qualified facilities
• Farms that are not covered under the produce safety rule because they average $25,000 or less in annual produce sales or meet the produce safety rule requirements for a qualified exemption

There are also modified requirements for foods from foreign suppliers in countries where food-safety systems have been determined to be equivalent to the United States. Currently, these countries include Australia, Canada and New Zealand. Any product imported from these countries would be subject to modified requirements. An example of the modified requirements would be that the importer would not have to conduct a hazard analysis, and could verify the foreign supplier by obtaining written assurances from that supplier.

MORE INFORMATION

There is no requirement to attend a training program following a standardized curriculum recognized as adequate by FDA. However, the Food Safety Preventive Controls Alliance (www.ifsh.iit.edu/fs pca), which developed the preventive controls for both human and animal food training, has designed a two-day curriculum to help importers understand how the FSVP requirements can be met.

Visit www.fda.gov/fsma for more information and the full FSVP final rule.

Go to www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm to contact FDA about FSMA and find the new online form for submitting questions directly to FDA.

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