Understanding the Foreign Supplier Verification Programs rule

By Travis K. Chapin, Keith R. Schneider, Renée Goodrich Schneider and Michelle D. Danyluk

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 revaluated 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.

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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

requirements under the preventive 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/fspca), which developed the preventive controls for both human and animal food training, has designed a two-day curricula 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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HLB Research Beyond CRDF: Florida's Goal Achieved

By Harold Browning

As 2017 draws to a close, the Citrus Research and Development Foundation (CRDF) is working to redefine the primary directions for its research and delivery programs. Federal funding programs that have emerged over the past four years are covering much of the discovery and knowledge-building research, and are assisting with field implementation of candidate solutions that can be integrated into citrus management systems here in Florida, as well as in Texas, California and other citrus states. A significant portion of these projects that now have federal funding began with CRDF project funding, allowing those early results to guide next-phase priorities. While this has not translated into immediate results for the industry in all cases, it illustrates the value of aggressive pursuit of HLB tools that the Florida industry began investing in more than eight years ago.

The California citrus community has become more attuned to the needs associated with managing HLB, as more dooryard citrus trees in Southern California are confirmed HLB positive. In response, the California Citrus Research Board is expanding its HLB research efforts and has encouraged cooperation with CRDF in areas of common interest, including evaluation of plant germplasm for HLB resistance.

CRDF has forestalled issuing a new call for proposals in light of other funding availability and the ongoing deep evaluation of what has been accomplished to date across the 400 projects that represent the Florida industry research portfolio. In addition, results of the comprehensive external review of research coordinated by CRDF in the United States by the National Academy of Sciences-National Research Council will be available in the first quarter of 2018. These results will be incorporated into CRDF planning, allowing for a call for proposals during spring 2018.

Important progress is being made in attracting interested scientists from across the country to participate in finding solutions to HLB, reinforcing the depth of work on this disease conducted in Florida by the University of Florida, U.S Department of Agriculture (USDA)-Agricultural Research Service and other institutions. CRDF's next steps will focus most clearly on delivering and validating short-term tools to assist Florida growers while advancements in plant resistance are made. We anticipate that CRDF committee and board meetings in January 2018 and beyond will refine priorities and determine how best to meet industry needs. Concurrently, federal and other state programs will be planning next-stage research in accordance with their funding cycles.

Florida organized to find solutions to HLB in 2009–10, committing significant resources to developing a management system. Many growers and researchers alike envisioned a larger, nationally coordinated effort that involved other citrus states and the federal government. That system is now well developed. The combined forces of CRDF, the farm bill citrus program, the USDA HLB Multiagency Coordination Group and other citrus state research programs are sharing the responsibilities for continued discovery, testing, delivery and adoption of tools to assist Florida and other U.S. citrus growers. Florida growers have achieved the goal of building a strong system to find HLB solutions, and the fight continues.

Visit citrusrdf.org for more information on CRDF.

Harold Browning is Chief Operations Officer of CRDF. The foundation is charged with funding citrus research and getting the results of that research to use in the grove.

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