The Food Safety Modernization Act: Impact on Food Importation

On July 26, 2013, the federal Food and Drug Administration (FDA) released two proposed rules governing the importation of foreign foods into the United States pursuant to the Food Safety Modernization Act (the "Act"): the proposed rule on Foreign Supplier Verification Programs, also known as FSVPs, and the proposed rule on the Accreditation of Third-Party Auditors.

Under the proposed rules, "importers" will be required to develop and implement rigid foreign supplier verification programs to ensure that imported food is compliant with FDA regulations. The broad proposed definition of "importer" may encompass not only suppliers who manufacture, import, broker and sell food to grocery stores, but also the retailers themselves.

These new rules shift the burden of verifying food safety from the foreign supplier to the domestic "importer," who, under the proposed rules, would face significant consequences for noncompliance. Importing, or even offering for import, a food without having a compliant verification program is a prohibited act subject to injunction and criminal prosecution.

Furthermore, an article of food is subject to refusal of admission if it appears that an importer failed to follow a verification program.

The comment period for both proposed rules ended on Jan. 27, 2014. The FDA is considering the comments submitted and will adopt a final rule, set to be published in the Federal Register as a binding regulation on Oct. 31, 2015.

The FDA is proposing a compliance date of as early as six months after the publication of the final rules, leaving little time for importers to develop and begin implementing verification programs.

Background

Passed by Congress in 2011, the Act gives the FDA broad regulatory authority over food safety. As part of this authority, the Act directs the FDA to enact new regulations aimed towards strengthening the oversight of foods imported for U.S. consumers, with a focus on foreign suppliers and U.S. importers.

Ryan Pierse/Getty Images News/ Thinkstock

Given the fact that approximately 15 percent of U.S. food is imported, the proposed rules establish requirements to ensure that foreign suppliers are implementing the modern, prevention-oriented food safety practices mandated by the Act.

Proposed Rule for Foreign Supplier Verification Programs Overview

Under the proposed rule for foreign supplier verification programs, importers are required to perform certain risk-based activities to verify that food imported into the United States has been produced in a manner that provides the same level of public health protection as that required of domestic food producers.

"Importers" are required to ensure that imported food is compliant with FDA regulations and conduct activities and procedures to verify that compliance. For purposes of the proposed rule, an "importer" is

Continued on p. 26

Continued from p. 25

defined as the U.S. owner or buyer of the food at the time of entry, or, if there is no U.S. owner or buyer, the U.S. agent or representative of the foreign owner.

This definition of "importer" includes food brokers and suppliers, but is broad enough to also include grocers themselves in certain circumstances.

As currently drafted, the proposed rule will require importers to develop, maintain and follow a verification program for each food imported which includes the following elements:

a. review of the compliance status of food before importation,
b. hazard analysis,
c. verification activities which could include periodic auditing and sampling of food,
d. review of complaints received for the food imported,
e. recordkeeping requirements,
f. importer identification, and
g. reassessment of verification programs within three years of establishing the programs.

The key element of such a program is the verification activities. Under the proposed rule, the FDA presented two options for determining what constitutes appropriate verification activities.

The key difference between the options is that Option 1 requires an on-site audit for hazards that have a reasonable probability of causing serious adverse health consequences or death to humans or animals, whereas Option 2 allows importers to choose between an on-site audit, periodic sampling or testing of imported food, or other appropriate practices.

The FDA's goal is that verification programs will strengthen the oversight of foods imported for U.S. consumers.

In an attempt to alleviate some of the burdens imposed by the proposed rule, the FDA exempts certain food products from coverage and provides alternative procedures to avoid duplication of efforts where safety regulations are already in place or for administrative expediency when the safety risk is reduced.

For example, imports of juice, fish and fish products, which are already regulated under the FDA's Hazard Analysis and Critical Control Points procedures; food for personal consumption; alcoholic beverages; food that is not transshipped; food for re-export; and food for research or evaluation are exempt from the rule. Dietary supplements, low-acid canned food and small food importers would also be governed by modified procedures.

Proposed Rule on Accreditation of Third-Party Auditors Overview

Concurrently with the proposed rule for foreign supplier verification programs, the FDA proposed a rule that would establish a program for the accreditation of third-party auditors for foreign food facilities.

Under this program, the FDA would recognize accreditation bodies, which would in turn accredit third-party auditors to, among other things, conduct food safety audits, and issue certifications for foreign facilities and food under specified programs.

The accredited third-party auditors would be used to conduct food safety audits as part of the verification programs and in connection with the planned Voluntary Qualified Importer Program, which would allow for expedited review and entry of food into the United States.

The proposal sets forth the requirements for accreditation bodies (e.g. foreign government/agency or private third party) and third-party auditors/certification bodies (e.g., foreign government, foreign cooperative, or other third party) including how accreditation bodies are recognized by FDA and how third-party auditors/certification bodies are accredited by the accreditation body.

The accreditation bodies would be required to monitor performance of the third-party auditors, assess third-party auditors for accreditation, submit reports to the FDA, and maintain and provide the FDA access to records. The third-party auditors would audit and issue certifications for foreign facilities and food. The third-party auditors would be responsible for conducting audits, submitting reports of the audits for certifications purposes, and notifying the FDA upon findings that could affect public health.

Legal Effects of the Proposed Rules

Unless a retailer is a direct importer, the burdens of complying with the proposed rule for foreign supplier verification programs will likely fall to importing suppliers. However, grocers who rely on brokers to import food may still meet the definition of "importer" under the proposed rules and be required to comply with the mandates of the rules when finalized.

Moreover, even grocers and retailers who do not fit the definition of "importers" under the proposed rule need to be aware of the new regulatory requirements facing their importing suppliers, in the context of the proposed rules for both verification programs and third-party auditors.

Grocers should carefully draft their agreements with importing suppliers in a way that represents and warrants that the suppliers are complying with verification program requirements, including the use of accredited third-party auditors, and all of the components of the Act and its implementing regulations. ■

Ashley Porter is an Associate in the Environmental Law and Food & Agriculture Practices at Downey Brand, LLP in Sacramento, California. Ashley focuses in the areas of environmental litigation and regulatory compliance.

Harveen Gill is an Associate in the firm's Food & Agriculture Practice. Harveen's practice focuses on general litigation issues for food producers, processors and retailers.

Christopher Burton is an Associate in the firm's Litigation and Food & Agriculture Practices, with a focus on commercial litigation.