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FDA ISSUES PROPOSED RULES ON FOREIGN SUPPLIER VERIFICATION AND ACCREDITATION OF THIRD-PARTY AUDITORS UNDER FSMA

On July 29, 2013, FDA published two proposed rules required by the Food Safety Modernization Act ("FSMA") on its foreign supplier verification program ("FSVP") and accreditation of third-party auditors. These are two of the five outstanding proposed rules that a court recently ordered FDA to publish by November 30, 2013.[1] The comment period on the proposed rules is open until November 26, 2013.[2]

FOREIGN SUPPLIER VERIFICATION PROGRAM

FDA's proposed rule on the FSVP would establish a risk-based framework in which importers of food analyze hazards reasonably likely to occur and then take measures to verify that these hazards are adequately controlled by the foreign supplier, the importer, or the importer's customer.[3] The rule would implement section 301 of the FSMA, which added section 805 to the Federal Food, Drug, and Cosmetic Act ("FDCA").

Scope of the Rule

The proposed rule would apply to an "importer," which it proposes to define as "the person in the United States who has purchased an article of food that is being offered for import into the United States." In most cases, the importer will be the consignee of the food at the time of entry. If the article of food has not been sold or consigned to a person in the United States at the time of U.S. entry, however, "the importer is the U.S. agent or representative of the foreign owner or consignee at the time of entry." In taking this approach, FDA reasoned that obligations under the rule should fall on the party who has a direct financial interest in the food and is most likely to have knowledge and control over the supply chain.

The proposed rule would apply to most types of imported food, but there are notable exceptions. Products subject to the seafood and juice hazard analysis and critical control point ("HACCP") regulations of 21 C.F.R. Part 120 and 123 would be required to comply with the supplier verification requirements of those regulations in lieu of the FSVP regulations. There are further exceptions for food imported (and labeled) for research, food for personal consumption, and alcoholic beverages. As described below, modified requirements apply to "very small businesses," imports of dietary supplement components and finished products, and imports from certain countries with comparable or equivalent food safety systems.

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[1] For additional information, see our client alert, Court Establishes Deadlines for FDA to Complete Rulemaking Required by FSMA (Jun. 25, 2013), available here.

[2] During a conference call announcing the proposed rules, FDA officials stated that the agency intends to extend (for a second time) the comment period of the proposed Current Good Manufacturing Practice and Hazard Analysis and Preventive Controls for Human Food and Produce Safety Rules to overlap with this period. Our client alerts for these proposed rules are available here and here.

[3] The proposed rule as published in the Federal Register is available here.

Implementing an FSVP

The key requirement of the proposed rule is that importers implement a written FSVP providing "adequate assurances" that foreign suppliers are producing food in compliance with the requirements of the FDCA, including, as applicable, the hazard analysis and prevent controls ("HA/PC") requirements of section 418 and the produce safety requirements of section 419.

The FSVP must be developed by a "qualified individual," defined as a "person who has the necessary education, training, and experience to perform the activities needed to meet the requirements" of the FSVP regulation. Similar to the HA/PC proposed rule, the qualified individual may, but need not, be an employee of the importer.

Hazard Analysis

The proposed rule would require that importers conduct a hazard analysis for most types of imported food to determine hazards reasonably likely to occur and the severity of the illness or injury from that hazard. The hazard analysis must consider biological, chemical, physical, and radiological hazards reasonably likely to occur with the imported food. The analysis must consider factors such as the food's ingredients, the condition of the foreign supplier's equipment, transportation practices, packaging, and intended use.

In lieu of conducting the analysis itself, an importer may elect to identify reasonably likely hazards by reviewing and evaluating a hazard analysis conducted by a foreign supplier. The importer would be required to document its hazards determination based on this review.

A hazard analysis would not be required for microbiological hazards in raw fruits and vegetables. FDA reasons that the proposed produce safety rule already identifies foreseeable microbiological hazards, and the additional hazard analysis would be duplicative. Importers would be required to conduct a hazard analysis for non-microbiological hazards associated with these foods (e.g., pesticide residue).

Verification Activities

The proposed rule would require that the importer conduct verification activities to ensure that foreign suppliers are in compliance with the FDCA's requirements.

As an initial activity, an importer would be required to review the "compliance status" of a food and a foreign supplier before importation. This review would include referencing FDA warning letters, import alerts, and any requirement for certification under section 801(q) of the FDCA—the FSMA's "mandatory certification" program for certain high-risk foods designated by FDA, which has not yet been established. The preamble also suggests that importers "might" review FDA Form 483s, Establishment Inspection Reports ("EIRS"), and documents relating to injunctions or seizures. Although FDA warning letters and import alerts are published on FDA's website, the latter category of documents likely would need to be requested from the foreign supplier or located through non-public databases.

Assuming the foreign supplier's compliance status is acceptable, the importer would need to conduct additional verification activities. These activities vary depending on the nature of the hazard and how it is controlled.

- In all cases, non-exempt importers must keep a written list of foreign suppliers.
- Where no hazard is identified (except for raw fruits and vegetables), no additional verification activity is required.

- Where a hazard is identified but controlled by the importer, the importer must document, at least annually, that it has adequate procedures to control the hazard.
- Where a hazard is identified but controlled by the importer's customer, the importer must obtain "written assurances," at least annually, that the customer is controlling the hazard.
- Where a hazard is identified but controlled by the supplier, the rule would require certain verification activities. FDA has proposed two options for this scenario.
  - In **Option 1**, the importer would be required to conduct an initial onsite audit and periodic (at least annual) audits thereafter for any hazard for which there is a reasonable probability that exposure will result in serious adverse health consequences or death to humans or animals (termed by FDA as a "SAHCODHA" hazard). To the extent the audits, alone, cannot provide adequate assurances that the hazard is controlled, additional verification activities would be necessary. For non-SAHCODHA hazards, importers would choose verification activities appropriate to the risk, which may include audits, lot-by-lot sampling and testing, review of food safety records, and "other appropriate procedures." Auditors may be employees of the importer or a third-party organization, but they must not have a financial interest in the foreign supplier. In lieu of conducting an audit, an importer could rely on an FDA or an "officially recognized or equivalent food safety authority" inspection if it occurred within the last year.
  - **Option 2** is less prescriptive and would provide flexibility to importers to choose appropriate verification activities for both SAHCODHA and non-SAHCODHA hazards. Like Option 1, potential verification activities would include audits, lot-by-lot sampling and testing, review of food safety records, and "other appropriate procedures." Option 2 would appear to provide more flexibility but less certainty that FDA would be satisfied with the rigor of the verification activities.
- For produce subject to the produce safety regulations of proposed Part 112, FDA again establishes two options, with the first requiring an onsite audit that examines the control of microbiological hazards, and the second providing discretion to the importer to choose an appropriate verification procedure.

Complaint Review, Corrective Actions, Reassessment, and Records

The proposed rule would require "prompt" review of "customer, consumer, or other complaint[s]" to determine whether the complaint relates to the FSVP. Notably, this aspect of the proposed FSVP rule diverges from the proposed HA/PC rule, which did not propose to require review of customer complaints for issues related to a manufacturer's food safety plan. Inclusion of this requirement in the proposed FSVP rule could signal that FDA intends to include a comparable provision in the final HA/PC rule.

In addition to complaint review, the rule would require investigations if an importer discovers that imported food is adulterated or fails to declare a major allergen. The importer would need to take corrective actions when it discovers that a supplier fails to produce food in compliance with applicable requirements.

Like a food safety plan under the proposed HA/PC rule, the FSVP would need to be reassessed every three years by a qualified individual. Reassessment would be required upon learning about "new information" about potential hazards. Records required by the rule generally would need to be maintained for a period of two years and be made accessible to FDA upon request.

Modified Requirements for Dietary Supplements, Very Small Businesses, and Food From Countries With Equivalent Food Safety Systems

Importers of dietary supplement components and finished dietary supplement products would be subject to modified requirements. The proposed rule would require importers of dietary supplement components and packaging material that comes into contact with dietary supplements to verify that the component or

material meets specifications established under 21 C.F.R. Part 111 or obtain written assurances annually that the importer's customer has verified that the components or materials meet specifications.

For importers of finished dietary supplements, a hazard analysis would not be required. These importers would be required to maintain a list of suppliers and verify that suppliers meet the requirements of FDA's dietary supplement cGMP regulations of 21 C.F.R. Part 111. Importers would choose appropriate verification activities, which may include auditing, lot-by-lot sampling, review of food safety records, and other appropriate procedures.

Very small importers—defined as importers (including their subsidiaries and affiliates) with average annual sales in the last three years of less than $500,000—would be required to maintain a list of suppliers, verify their FDA "compliance status," and obtain "written assurance" at least every two years that the supplier is producing food in compliance with the FDCA. The same requirements would apply to imports from "very small foreign suppliers," defined as suppliers (including their subsidiaries and affiliates) with average annual sales in the last three years of less than $500,000.

Imports of food from countries whose food safety system FDA has officially deemed comparable or equivalent to that of the United States would be subject to very limited requirements. If the food falls within the scope of such a determination, an importer would be required to verify that the supplier is in "good compliance standing" with that country's food safety authority, but the importer would not need to conduct a hazard analysis or institute verification activities for that import. So far, as the result of a pilot project, FDA has recognized the food safety system of New Zealand as comparable to the United States and signed a systems recognition agreement with that country. A second assessment pilot project is underway with Canada.

Effective Dates and Implementation

The preamble to the proposed rule explains that the "general" effective date will be 18 months after publication of the final rule. Exceptions to this general effective date will apply for food that is subject of the proposed HA/PC rule and animal food preventive controls rule that is under development. For food subject to these rules, FDA would require importation of food to comply with the FSVP rule six months after the HA/PC or animal food preventive controls rule has become effective for that supplier. FDA proposes a similar approach for produce covered by the produce safety rule.

FDA intends to issue a draft guidance concurrently with the final FSVP rule and a final FSVP guidance before the FSVP requirements become effective.

Potential Issues for Comment

Like the proposed HA/PC rule, the proposed FSVP regulations are complex, and their effect on a given importer may vary considerably according to its business model. Throughout the preamble, FDA requests comments on a variety of conceptual and technical issues. For example, FDA asks whether importers should be required to conduct foreign supplier verification when importing food from entities under the same corporate ownership structure—an issue that may be of interest to companies that own and import food from facilities in other countries. Stakeholders should review the preamble and consider commenting on issues of concern.

One of the broader issues that likely will elicit comment from stakeholders is the choice between the more prescriptive Option 1 and more flexible Option 2 for verification activities. As described above, Option 1 would require annual audits for suppliers of foods for which a SAHCODHA hazard is reasonably likely to occur. Option 2 would provide more discretion to importers to choose an appropriate activity, but it is possible that FDA would delineate the activities it expects through guidance documents or inspections.

ACCREDITATION OF THIRD-PARTY AUDITORS

To implement section 307 of FSMA, which adds section 808 to the FDCA, FDA proposes to amend its regulations to provide for accreditation of third-party auditors and certification bodies to conduct food safety audits of foreign food entities, including registered foreign food facilities, and to issue food and facility certifications.[4] Under this program, in which participation is voluntary, FDA will recognize accreditation bodies, which will in turn accredit third-party auditors to conduct food safety audits and issue certifications for foreign facilities and food under specified programs. Certification bodies and third-party auditors can be foreign governments, agents of foreign governments, or any other third party eligible to be considered for accreditation.

The proposed rule contains requirements and procedures for recognition and accreditation for both accreditation bodies seeking recognition by FDA and third-party auditors seeking accreditation. According to FDA, these requirements will help to ensure the "competence and independence" of participants. The rule also contains requirements on auditing and certification of foreign food facilities and food under the program. The proposed rule provides for "consultative audits," performed for internal purposes to determine whether an entity is meeting FDA requirements, and "regulatory audits," performed to determine eligibility for food certification with a report submitted to FDA. Importantly, the third-party auditors and certification bodies must immediately notify FDA of "any condition that could cause or contribute to a serious risk to the public health," regardless of whether the risk is discovered in a consultative or regulatory audit.

Apart from the proposed rule, FDA will issue draft Model Accreditation Standards that specify what qualifications a certification body must have to qualify for accreditation. As required by FSMA, FDA will look to standards already in place for guidance, such as existing international voluntary consensus standards and current practices of accreditation bodies. FDA will issue draft Model Accreditation Standards for comment before finalizing them.

FDA will use certifications issued by accredited third party auditors for two purposes under FSMA: under section 302, the Voluntary Qualified Importer Program (VQIP); and, under section 303, the authority to require certification under section 801(q) of the FDCA as a condition of entry for foods FDA has determined pose a food safety risk. In a call hosted by FDA to announce the proposed rules on July 26, 2013, FDA officials indicated that the certifications eventually may be used for other purposes as well.

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Covington & Burling LLP continues to monitor FDA's implementation of the FSMA and will keep its clients updated regarding developments and next steps.

If you have any questions concerning the material discussed in this client alert, please contact the attorneys listed below:

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[4] The proposed rule as published in the Federal Register is available here.