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CLIENT ALERT

FDA Proposes New Food Safety Rules Requiring Importers to Verify Compliance of Foreign Suppliers and Establishing Third-Party Accreditation Standards

Aug.08.2013

On July 26, 2013, the U.S. Food and Drug Administration (FDA), continuing the process of implementing the 2011 Food Safety Modernization Act (FSMA), published two new proposed rules: one on foreign supplier verification programs for food importers and one on accreditation of third-party food safety auditors. These proposed rules are the foreign counterparts to two proposals published earlier this year, which set standards for preventive controls and produce production at domestic food facilities. The FDA, which missed several statutory deadlines for promulgating new food safety regulations, is under increasing pressure from stakeholders and the courts to complete the FSMA rulemaking process. This latest move brings the agency significantly closer to achieving that goal.

Foreign Supplier Verification Programs

Under the proposed regulations, all food importers, with some exceptions, must develop, maintain, and follow a Foreign Supplier Verification Program (FSVP) for each food it imports. As part of the FSVP, importers will have to:

- **Maintain a list of their foreign suppliers and establish and follow written procedures for verifying that they are adequately controlling for identified hazards;**
- **Check whether food offered for import and the foreign suppliers of that food are compliant with food safety requirements both before and even periodically after importation;**
- **Analyze the hazards associated with each food they import, similar to the hazard analysis that would be required for domestic entities under the pending proposal for preventive controls; and**
- **Obtain a universal number and provide their name and number electronically when filing for entry with Customs and Border Protection each time they attempt to import food.**

FSVPs must also include procedures for handling complaints, ensuring that importers review and investigate complaints, take corrective actions as needed, and revise their FSVPs if they are inadequate. Independently, importers would have to reassess

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their FSVPs every three years or sooner if they learn of new information about potential hazards. Importers would be required to maintain records relating to their FSVPs for two years and provide them to FDA upon request.

For all hazards that are identified as reasonably likely to occur and that are within importers' control, importers must also document annually that they have established and are following procedures that adequately control the hazard. If a customer will be controlling a hazard identified by an importer, the importer must obtain written assurance annually that its customer has established and is following the identified procedures, and that such procedures adequately control the hazard.

FDA has proposed two alternative supplier verification options for hazards that are controlled by foreign suppliers. One would allow importers to choose the appropriate verification activities and how frequently they will be conducted, taking into consideration the risk presented by the hazard, the probability that exposure to the hazard will result in serious harm, and the food and foreign supplier's compliance status. Under the second option, the importer would only have that flexibility for hazards that do not have a reasonable probability of resulting in serious adverse health consequences or death to humans or animals. For more serious hazards (as well as microbiological hazards in certain raw agricultural commodities), the importer would be required to conduct or obtain documentation of onsite auditing of its foreign supplier. FDA will likely rely heavily on the comments it receives to decide which of the two options is codified in the final rule or whether a third option is appropriate.

In addition to determining which supplier verification option to utilize, FDA will likely revise other aspects of the proposed rule in response to comments. Also, to avoid duplicative requirements imposed by the pending rule on preventive controls, FDA says it will try to align the final FSVP rules with any supplier verification provisions included in other final FSMA rules.

Not all foods would be bound by this proposed rule: juice and seafood from facilities that comply with the Hazard Analysis & Critical Control Points (HACCP) regulations, food imported for research or evaluation purposes, food imported for personal consumption, alcoholic beverages, and food that is imported for further processing and export are all exempt from the FSVP requirements. Furthermore, modified requirements would apply to importers of dietary supplements, very small importers, importers from very small foreign suppliers, and importers from a foreign supplier in good standing with a food safety system comparable to that of the U.S.

Third-Party Accreditation

The other proposed rule establishes requirements for accreditation bodies and third-party auditors. Under the proposal, FDA would recognize entities that satisfied certain standards as accreditation bodies. Accreditation bodies recognized by FDA could accredit third-party auditors to audit and issue certifications for foreign facilities and food. Accredited third-party auditors would have to submit reports to FDA regarding any audits that foreign facilities use for certification purposes, notify FDA if they discover any condition posing a serious risk to the public health, and maintain and provide FDA access to their auditing records. FDA plans to publish model accreditation standards that would specify what qualifications a third-party auditor must have for accreditation. If an accreditation body or a third-party auditor fails to satisfy FDA's standards, the agency could revoke its recognition or accreditation, respectively.

Although importers will not generally be required to obtain certifications from an accredited auditor, FDA may require such a certification before allowing certain foods that FDA has determined poses a food safety risk to enter the U.S. or before allowing an importer to participate in the Voluntary Qualified Importer Program (VQIP), currently being developed, for

expedited review and entry of food into the U.S.. The criteria and procedures for VQIP will be published in the future. Additionally, audits conducted by an accredited third party could be used to satisfy the supplier verification requirements under FSVP. On the other hand, a foreign facility that uses a third-party auditor essentially grants FDA access to information about the foreign facility and documents collected by the auditor, without the agency necessarily having to seek consent from, or having to provide prior notice to, the foreign facility.

FDA is proposing that importers generally would have eighteen months after publication of the final FSVP rules to comply. Most importers, however, have foreign suppliers that will be subject to the new preventive controls rules, which will have varying compliance dates depending on the size of the supplier. Accordingly, FDA will not require importers with suppliers covered by the new preventive control rules to comply with the FSVP rules until six months after the foreign supplier of the food is required to comply with the preventive control regulations. The differing compliance dates for suppliers will cause the compliance dates for importers to vary as well. Importers who use suppliers that will be covered by the new produce safety rule will receive a similar delay in requiring compliance. The third-party accreditation rule would go into effect as early as possible after it is final. Comments on both proposed rules are due by November 26, 2013. The comment periods for the preventive controls and domestic produce production proposals were recently extended until November 15, 2013 to allow interested parties more time to consider the interrelationships among all four proposed rules. FDA will also be holding public meetings during the comment period to solicit additional input on the two new proposed rules.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

John Fuson
Partner – Washington, D.C.
Phone: +1 202.624.2910
Email: jfuson@crowell.com

John B. Brew
Partner – Washington, D.C.
Phone: +1 202.624.2720
Email: jbrew@crowell.com