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NEW FOREIGN SUPPLIER VERIFICATION PROGRAM & THIRD-PARTY AUDITOR RULES

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What Every Food Importer Needs to Know

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The Food and Drug Administration published July 29 two long-awaited proposed rules aimed at helping ensure that imported food meets the same safety standards as food produced in the U.S. These two regulations represent a significant increase in the responsibilities and liabilities of food importers.

Importers are therefore encouraged to become familiar with the provisions detailed in this white paper, consider how their operations could be affected – either negatively or positively – by the proposed rules, and then submit comments to the FDA by the Nov. 26 deadline. The FDA also plans to hold three public meetings on these proposals during the comment period to allow affected companies an additional opportunity to provide input.

SUMMARY OF PROPOSED RULES

The first rule – Foreign Supplier Verification Program or "FVSP" – would create foreign supplier verification programs that, for the first time, would give U.S. food importers a clearly defined responsibility to verify that their overseas suppliers are implementing modern, prevention-oriented food safety practices and achieving the same level of food safety as domestic growers and processors. In general, importers would be required to have a plan that provides for identifying the hazards associated with each imported food that are reasonably likely to occur and conducting activities that provide adequate assurances that such hazards are being adequately controlled. The proposed regulations vary based on the type of food product (e.g., processed foods, produce, and dietary supplements), the category of importer, the nature of the hazard in the food and who is to control the hazard.

The second rule – Third-Party Auditor Accreditation or "3-PAA" – aims to strengthen the quality, objectivity and transparency of the foreign food safety audits on which many food companies and importers rely to help manage the safety of their global food supply chains. Under this rule, the FDA would establish a program for the recognition (based on criteria including competency and impartiality) of bodies such as foreign government agencies or private companies that would accredit third-party auditors to audit and issue certifications for foreign food facilities and food under certain circumstances. Importers would not generally be required to obtain certifications, but the FDA could request and use such certifications to determine whether to admit certain imported food that poses a safety risk or in determining whether an importer is eligible to participate in a voluntary program now under development for expedited review and entry of food.

The FDA notes that these two proposals work in concert with two others previously released (in January) which concern safety and preventive controls in facilities that produce human food. (See "FDA Proposes Significant New Food Safety Rules for Foreign and Domestic Facilities," *Sandler, Travis & Rosenberg Trade Report*, January 9, 2013). Those proposed rules are currently open for comment until Sept. 16, but the FDA intends to extend that comment period through Nov. 15 to allow an opportunity to consider the interrelationships between all four proposed rules.

FOREIGN SUPPLIER VERIFICATION PROGRAM

The FSVP regulations would implement section 301 of the Food Safety Modernization Act.

- An importer of food would be the U.S. owner or consignee of the food at the time of entry or, if no such entity exists, the U.S. agent or representative of the foreign owner or consignee.
- All importers would be required to develop, maintain and follow an FSVP for each food it imports, which would generally need to include the following.

  Compliance Status Review: Importers would be required to review the compliance status of the food and the potential foreign supplier before importing the food and periodically thereafter. Such review would need to include any FDA warning letters, import alerts, and requirements for certification issued by the FDA under section 801(q) of the Federal Food, Drug, and Cosmetic Act.

  Hazard Analysis: Importers would be required to conduct an analysis that identifies the hazards that are reasonably likely to occur for each type of food imported and evaluates the severity of the illness or injury if such a hazard were to occur.

  Verification Activities: Importers would be required to conduct activities that provide adequate assurances that the hazards identified as reasonably likely to occur are adequately controlled; e.g., onsite auditing of foreign suppliers, periodic or lot-by-lot sampling and testing of food, and periodic review of foreign supplier food safety records. Verification activities applicable to all FSVPs, regardless of identified hazards, include maintaining a written list of foreign suppliers from which food is imported and establishing and following adequate written procedures for conducting verification activities.

  Corrective Actions: Importers would be required to review complaints they receive concerning the foods they import, investigate the cause or causes of adulteration or misbranding in some circumstances, take appropriate corrective actions, and revise their FSVPs when they appear to be inadequate.

Periodic Reassessment: Importers would be required to reassess their FSVPs within three years of establishing them or three years of the last assessment. However, importers would have to reassess the effectiveness of their FSVP sooner if they become aware of new information about potential hazards associated with the food; e.g., information on changes to the source of raw materials or to product formulation.

Importer Identification: Importers would be required to obtain a Dun and Bradstreet Data Universal Numbering System (DUNS) number for their company and to ensure that, for each food product offered for importation into the United States, their name and DUNS number are provided electronically when filing for entry with U.S. Customs and Border Protection.

Recordkeeping: Importers would be required to keep certain records, including those that document compliance status reviews, hazard analyses, foreign supplier verification activities, investigations and corrective actions, and FSVP reassessments.

- The requirements for supplier verification are primarily based on who is to control the hazards that are reasonably likely to occur with a particular food and the nature of the hazard.

  If the foreign supplier controls the hazard at its establishment and there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, the importer would be required to conduct or obtain documentation of onsite auditing of the foreign supplier. Onsite auditing would also be required for microbiological hazards in certain raw agricultural commodities. For other hazards that the foreign supplier controls, the importer would be required to conduct one or more of the verification activities mentioned above (onsite auditing, sampling and testing, review of the supplier's food safety records, or some other appropriate procedure) before using or distributing the food and periodically thereafter. In determining the appropriate verification activities, the importer would have to

consider the risk presented by the hazard and the food and foreign supplier's compliance status.

For all hazards that the foreign supplier will either control or verify that its supplier is controlling, importers would need to choose a verification procedure from among onsite auditing, sampling and testing, review of supplier food safety records, or some other appropriate procedure. In determining the appropriate verification activities and how frequently they should be conducted, the importer would need to consider 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.

If the importer, rather than the foreign supplier or its supplier, will be responsible for controlling a hazard that it has identified as reasonably likely to occur, the importer would have to document at least annually that it has established and is following procedures that adequately control the hazard. If the importer's customer will be controlling a hazard identified by the importer, the importer would need to obtain written assurance at least annually that its customer has established and is following procedures (identified in the written assurance) that adequately control the hazard.

The FDA intends to align the supplier verification provisions in the FSVP regulations with any supplier verification provisions included in the final rules on preventive controls for human and animal food to avoid imposing duplicative requirements on entities that would be subject to both regulations because they are both a food importer and a registered food facility.

- Modified FSVP requirements would apply in certain circumstances, including importation of a dietary supplement or dietary supplement component, importation of food by a very small importer or from a very small foreign supplier, and importation of food from a foreign supplier in good compliance standing with a food safety system that the FDA has officially recognized as comparable or determined to be equivalent to that of the United States.

- Imports of the following would be exempt from the FSVP requirements: juice and seafood from facilities that are in compliance with the Hazard Analysis & Critical Control Points regulations (which contain their own supplier verification provisions), food imported for research or evaluation purposes, food imported for personal consumption, alcoholic beverages, and food that is transshipped or imported for further processing and export.
- The FSVP regulations would become effective 60 days after a final rule is published in the Federal Register, and importers would generally not be required to come into compliance until 18 months after publication. However, because the FSVP rule is closely tied to the rules on preventive controls and produce safety, the compliance dates for importers in many cases would depend on the compliance dates for those rules. In general, the importer would be required to comply with the FSVP regulations six months after the foreign supplier of the food is required to comply with the new FSMA preventive controls regulations.
- The FDA plans to publish, at the time of the final rule, draft guidance to assist importers in developing and following FSVPs as well as complying with the other requirements of the FSVP rule.

THIRD-PARTY AUDITOR ACCREDITATION

This proposed rule would implement section 307 of the FSMA, which requires accredited third-party auditors to conduct food safety audits and issue certifications of foreign facilities and the human and animal foods they produce.

- ***Eligible Accrediting Bodies.*** An accreditation body could be a foreign government/agency or a private third-party and a third-party auditor could be a foreign government, foreign cooperative or other third party. Both accreditation bodies and third-party auditors would have to meet standards for legal authority, competency and capacity, impartiality/objectivity, quality assurance, and records procedures.

- ***Range of Assessments.*** Accreditation bodies would have to assess third-party auditors for accreditation; monitor the performance of the third-party auditors it accredits and notify the FDA of any change in, or denial of, accreditation; assess and correct any problems in its own performance; submit reports and other notifications to the FDA; protect against conflicts of interest; and maintain and provide the FDA access to records.
- ***Supervision of Audit Agents.*** The FDA would require accredited auditors to ensure their audit agents are competent and objective, conduct rigorous audits, submit reports of audits used for certification purposes (called regulatory audits) to the FDA, notify the FDA upon finding any condition posing a serious risk to the public health, assess and correct any problems in its own performance, protect against conflicts of interest, and maintain and provide the FDA access to records.
- ***Certifications and Voluntary Qualified Importer Program***. Accredited third-party auditors would audit and issue certifications for foreign facilities and food. To participate in the Voluntary Qualified Importer Program, which (once created) will provide for expedited review and entry of food, importers will have to import food from certified facilities. In addition, the FDA has authority to require certification as a condition of entry for certain foods that it has determined pose a food safety risk, and such certifications may be provided by an accredited third-party auditor.
- ***Accreditation Revocation.*** The FDA will closely monitor these systems and could revoke an accreditation body's recognition or withdraw an auditor's accreditation for good cause.
- ***Importer Reliance on Accredited Auditors.*** Although the FSVP proposal does not require the use of accredited third-party auditors, the FDA anticipates that once the accreditation system is in place importers may increasingly rely on audits by accredited third parties to meet their supplier verification requirements under FSVP.

- *Accreditation Standards.* Separate from this proposed rule, the FDA will issue draft model accreditation standards that specify what qualifications a certification body must have to qualify for accreditation, such as the minimum requirements for education and experience for third-party auditors and their audit agents. In developing model standards for the third-party auditor accreditation program, the FDA is required to look to standards already in place for guidance in order to avoid unnecessary duplication of efforts and costs. Examples include existing international voluntary consensus standards and current practices of accreditation bodies. Comments on the draft standards will be solicited and the standards will be finalized after the comments received are considered.
- *Time Frame for Accreditation.* The FDA intends to implement the third-party auditor accreditation program as soon as possible after publication of the final rule and the final model accreditation standards. Accreditation bodies could begin to apply for recognition when the program goes into effect, and third-party auditors could seek accreditation after one or more FDA-recognized accreditation bodies begin accepting applications.

IMPORTANT DATES AND DEADLINES

- **Nov. 15, 2013** – deadline for comments on produce safety and preventive controls proposed rules
- **Nov. 26, 2013** – deadline for comments on FSVP and third-party auditor proposed rules