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ALERTS

FDA Issues Proposed Rule On Accreditation Of Third-Party Auditors For Food Safety

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As regular readers of these Alerts know, when the Food Safety Modernization Act (FSMA) was passed in January 2011, it required the FDA to adopt several sets of regulations, including one on the accreditation of third-party auditors of compliance with food safety regulations. The statute set an 18-month deadline for the regulations, which the FDA missed. Consumer groups have sued FDA to force it to issue the regulations, and a federal district court in San Francisco recently ordered the FDA to complete the regulations by June 2015. Last Friday, the FDA issued proposed regulations for both the accreditation of third party auditors and the foreign supplier verification program (FSVP). With these proposals, the FDA has now issued proposed rules for four of the seven required subjects.

According to the highlights section of the FDA's announcement, the proposed rule for third-party auditors sets eligibility requirements for recognition as an accreditation body. An accreditation body can be a foreign government/agency or a private third-party. It must also meet standards for legal authority, competency and capacity, impartiality/objectivity, quality assurance, and records procedures.

The proposed rule would require accreditation bodies to:

- assess third-party auditors for accreditation;
- monitor 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.

The proposed rule also sets eligibility requirements for accreditation as a third-party auditor. A third-party auditor can be a foreign government, foreign cooperative, or other third-party. It must also meet standards for legal authority, competency and capacity, impartiality/objectivity, quality assurance, and records procedures.

Accredited third-party auditors would audit and issue certifications for foreign facilities and food. The FDA would require accredited auditors to:

- ensure their audit agents are competent and objective;
- conduct rigorous audits;

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- 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.

The FDA would closely monitor these systems and could revoke an accreditation body's recognition or withdraw an auditor's accreditation for good cause.

The FDA will use certifications issued by accredited third-party auditors for two purposes under FSMA. First, section 302 of FSMA authorizes the FDA to create the Voluntary Qualified Importer Program (VQIP), which provides for expedited review and entry of food into the United States. To participate in VQIP, importers must import food from certified facilities.

Second, section 303 of FSMA gives the FDA authority to require certification under section 801(q) of the Food, Drug, and Cosmetic Act as a condition of entry for certain foods that FDA has determined pose a food safety risk. Such certifications may be provided by an accredited third-party auditor.

Although the Foreign Supplier Verification Programs (FSVP) proposal does not require the use of accredited third-party auditors, the FDA anticipates that once the FDA accreditation system is in place, importers may increasingly rely on audits by accredited third parties to meet their supplier verification requirements under FSVP.

Separate from this proposed rule, the FDA will issue draft model accreditation standards that would 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. The FDA will issue the Model Accreditation Standards in draft and open a docket to accept comments.

The FDA intends to implement the accreditation and third-party auditor programs 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.

A copy of the proposed regulation can be found here.

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