

FDA Publishes Final Rule on Voluntary Third-Party Auditor Program

November 17, 2015

Food & Drug

On November 13, 2015, the Food and Drug Administration (FDA) issued a final rule, under the Food Safety Modernization Act (FSMA), establishing a voluntary program for the accreditation of third-party certification bodies (i.e., third-party auditors) to conduct food safety audits of foreign food facilities and issue food (human and animal) and facility certifications (third-party auditor final rule).¹

This alert provides a high-level summary of the final rule and highlights key differences between the proposed and final rules. FDA has provided additional information about the final rule on its FSMA website.²

Highlights of the Final Rule

The final rule implements section 808 of the Federal Food, Drug, and Cosmetic Act (FDCA), which was added by FSMA. Section 808 of the FDCA directs FDA to establish a new program for accreditation of third-party auditors to conduct food safety audits and certify that eligible foreign entities and the food they produce meet applicable FDA requirements. Under this voluntary program, FDA will recognize accreditation bodies, which will accredit third-party auditors to conduct food safety audits and issue certifications. Audit agents, who are employees or otherwise agents of an accredited third-party auditor, can conduct food safety audits on behalf of that third-party auditor.

Certification bodies and third-party auditors can be foreign governments/agencies or private third-party entities; a third-party auditor may also be an individual. The final rule contains requirements and procedures for recognition of accreditation bodies and accreditation of third-party auditors, including requirements for legal authority, competency, capacity, conflict-of-interest safeguards, quality assurance, and record procedures that third-party auditors must demonstrate to be eligible for accreditation.

¹ The Third-Party Auditor Final Rule is scheduled to be published in the Federal Register on November 27, 2015. It is currently available [online](#) in a pre-publication PDF. FDA issued a proposed Accredited Third-Party Certification rule in July 2013. FDA also published a proposed rule, in July 2015, establishing user fees for accreditation and certification bodies. Click [here](#) and [here](#) for our client alerts summarizing these proposals.

² See FSMA Final Rule on Accredited Third-Party Certification on [FDA's website](#).

Purpose of Food and Facility Certifications

Under the final rule, food and facility certifications may be used for two purposes:

- Importers may use certifications to establish eligibility for participation in the Voluntary Qualified Importer Program (VQIP), which offers participating importers expedited review and entry of food.³
- If FDA has made a risk-based determination under section 801(q) of the FDCA that certification is necessary as a condition of admissibility to prevent potentially harmful food from reaching U.S. consumers, the agency may require that a food offered for import be accompanied by a certification issued either by an accredited third-party auditor or by an agency or government representative of the country of origin.

In addition, the final rule provides that in circumstances where an audit is an appropriate supplier verification activity, facilities and importers may choose to use onsite audits conducted by accredited third-party auditors to meet the supplier verification requirements of a number of FDA's final FSMA rules, including the foreign supplier verification program (FSVP) final rule and the preventive controls final rules for human food and animal food.⁴

Types of Audits Conducted by Third-Party Auditors

The final rule carries forward FDA's proposal to establish two kinds of audits under the program: "consultative audits" and "regulatory audits." Consultative audits are performed for internal purposes, to determine whether the facility, its processes, and food are meeting FDA food safety requirements and also potentially industry standards and practices; FDA clarified that such audits are typically conducted in preparation for a "regulatory audit." These audits cannot be the basis for certification, however, as the final rule requires that a regulatory audit be performed to determine eligibility for food/facility certification.

Audits that fall outside the scope of the final rule (e.g., audits that are conducted by third-party certification bodies that are not accredited under this program, audits that determine compliance with standards other than the food safety requirements of the FDCA and FDA regulations, audits that are announced), are not covered by, or subject to, the third-party auditor final rule.

Requirements for Third-Party Auditors

Under the final rule, accredited third-party auditors must perform unannounced facility audits, notify FDA upon discovering "a condition that could cause or contribute to a serious risk to the public health," and submit to FDA reports of regulatory audits conducted for certification purposes. Food safety audits consist of two parts: (1) a records review portion; and (2) an onsite facility examination, which may take place at any time during the 30-day timeframe identified by the entity seeking certification. Although FSMA requires that the onsite facility examination be

³ In June 2015, FDA issued a draft guidance for industry on the VQIP. Click [here](#) for our client alert summarizing this draft guidance.

⁴ Click [here](#) for our client alert on the FSVP Final Rule. Click [here](#) and [here](#) for our client alerts on the preventive controls final rules for human and animal food, respectively.

unannounced, FDA revised the final rule to clarify that the records review may be scheduled with the entity seeking certification.

The final rule contains additional requirements regarding auditing and certification of foreign food facilities and food under the program, including:

- **Auditor competence and objectivity.** The third-party auditor must ensure that its audit agents are competent and objective. For example, the auditor must observe a “representative sample” of audits conducted by each audit agent. In addition, each audit agent must complete annual food safety training under the auditor’s training plan. FDA is not requiring all audit agents to have training equivalent to FDA investigator training standards. Specific recommendations on qualifications, such as the years and type of work experience in food safety and auditing, will be set forth in FDA’s Model Accreditation Standards final guidance.⁵
- **Documentation of observed deficiencies; verification of corrective actions.** In the regulatory audit report, the third-party auditor must record any deficiencies observed during the audit that meet FDA’s Class I or Class II recall standards. The auditor also must verify the effectiveness of the corrective actions to address such deficiencies. A certificate cannot be issued until the eligible entity takes corrective actions and the auditor verifies the effectiveness of such actions.
- **Monitoring of certain foreign facilities.** The final rule requires third-party auditors to conduct monitoring of an entity to which they have issued a food or facility certification, if the auditor has reason to believe that the entity may no longer be in compliance with relevant FDA requirements. Although some comments requested that the final rule specify the circumstances that would trigger the need for such monitoring, FDA declined to do so. The agency noted, however, that monitoring may be appropriate if the entity makes (1) significant changes to its audited facility, such as capital improvements; (2) major changes to its management system and processes; or (3) changes to the scope of operations, such as changes in manufacturing processes, that may affect its compliance status.
- **Self-assessment.** Each third-party auditor must have a written program for monitoring and assessing its own performance, identifying deficiencies in its program or performance, and quickly executing corrective actions.
- **Recordkeeping.** The third-party auditor must maintain and provide FDA access to records required to be kept under the program. For example, auditors must maintain records of consultative audit reports, but need not submit them to FDA. By contrast, regulatory audit reports and self-assessment reports must be submitted to FDA.

⁵ FDA issued its Model Accreditation Standards draft guidance in July 2015. See Draft Guidance for Industry and FDA Staff: Third-Party Auditor/Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards (July 2015) on [FDA’s website](#).

FDA Monitoring of Eligible Entities

FDA may conduct unannounced onsite audits of entities that have received food or facility certification from a third-party auditor. These audits may be conducted at any time, with or without the accredited third-party auditor present (if FDA determines this is necessary or appropriate), and may be preceded by a request for a 30-day operating schedule.

Implementation

Although the final rule will become effective 60 days after it is published in the Federal Register, FDA has announced that it does not intend to implement the third-party auditor program until after publication of the Model Accreditation Standards final guidance and the final rule establishing the third-party accreditation user fee program.

Once the third-party auditor program goes into effect, accreditation bodies could begin to apply for recognition by FDA. After that, third-party auditors could seek accreditation from any FDA-recognized accreditation body that is accepting applications. Once accredited, third-party auditors could begin performing onsite audits.

Covington & Burling LLP continues to monitor FDA's implementation of FSMA and to advise clients on relevant developments. If you have any questions concerning FSMA or other food regulatory matters, please contact any of the following attorneys in our Food & Drug Practice Group or visit our food and beverage practice website:

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