FSMA Facts

FDA FOOD SAFETY MODERNIZATION ACT

Proposed Rule on Accreditation of Third-Party Auditors

Summary
On July 26, 2013, the FDA published for public comment its proposed rule to establish a program for accreditation of third-party auditors, also known as certification bodies, to conduct food safety audits and issue certifications of foreign facilities and the foods for humans and animals they produce. The proposed rule would implement Section 307 of the FDA Food Safety Modernization Act (FSMA).

Importers will not generally be required to obtain certifications, but in certain circumstances the FDA may use certifications from accredited auditors in determining whether to admit certain imported food into the United States that the FDA has determined poses a food 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.

Background
FSMA, signed into law on January 4, 2011, enables the FDA to better protect public health by helping to ensure the safety and security of the food supply. The vision of FSMA is prevention – preventing food safety problems before they occur, rather than reacting to problems when they happen. FSMA also gives the FDA important new tools to hold importers accountable for verifying, in a manner transparent to the FDA, that the food they import is safe.

One of the FSMA mandates directs the FDA to establish a program for the Accreditation of Third-Party Auditors for foreign food facilities. Under this program, the FDA would recognize accreditation bodies, which would in turn accredit third-party auditors to, among other things, conduct food safety audits and issue certifications for foreign facilities and food under specified programs.

Having comprehensive oversight of a credible and reliable program for third-party audits and certifications of foreign food facilities and food may help in making admissibility decisions when the FDA has determined that an imported food poses a food safety risk and in facilitating rapid entry of food under a new voluntary program the FDA is developing for that purpose.

The Accredited Third-Party Audits and Certification Program is central to a global system that provides significantly elevated assurances about the safety of FDA-regulated food moving in international trade in a more efficient way.

Highlights of the Proposed Rule
This proposal contains requirements for accreditation bodies seeking recognition by the FDA as well as requirements for third-party auditors seeking accreditation. These requirements will help ensure the competence and independence of the accreditation bodies and third-party auditors participating in the program.

In addition, it contains FDA procedures for recognition and accreditation as well as requirements relating to monitoring and oversight of participating accreditation bodies and auditors. These include procedures that the FDA will follow when removing an auditor or an accreditation body from the program.

The proposed rule also contains requirements relating to auditing and certification of foreign food facilities and food under the program and for notifying the FDA of conditions in an audited facility that could cause or contribute to a serious risk to the public health.

The proposed requirements for monitoring, oversight, and notification are needed to give the FDA, consumers, and other stakeholders confidence in the program.

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. In developing model standards for the third-party auditor accreditation program, the FDA is required by the statute to look to standards already in place when FSMA was enacted 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. The FDA will issue the Model Accreditation Standards in draft and open a docket to accept comments. After considering the comments received, the FDA will finalize the standards.

Requirements for Recognized Accreditation Bodies

The proposed rule 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.

Requirements for Third-Party Auditors

The proposed rule 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;
- submit reports of 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 be closely monitoring these systems and could revoke an accreditation body's recognition or withdraw an auditor's accreditation for good cause.

Use of Accredited Third-Party Auditors Under FSMA

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. In order to participate in VQIP, importers must import food from certified facilities. The criteria and procedures for VQIP participation are outside the scope of the third-party auditor rulemaking. The FDA will issue a draft guidance establishing VQIP in the future and will solicit public comment on VQIP at that time.

Second, section 303 of FSMA gives the FDA authority to require certification under section 801(q) of the Federal Food, Drug, and Cosmetic Act (FD&C 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.

Implementation

The FDA intends to implement this program as soon as possible after publication of the final rule and the final Model Accreditation Standards, which will be published separately. 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.

Costs

The proposed rule has an annualized cost of $57 million using a 7 percent discount rate according to Office of Management and Budget guidelines. This does not include costs to FDA.

This proposed rule would be an important mechanism for improving and ensuring compliance with the Preventive Controls and Produce Safety proposed regulations as they would apply to imported food. For this reason, we account for its public health benefits in the economic analyses for those proposed rules and other applicable food safety regulations, instead of in the analysis for this proposed rule.

The Preliminary Regulatory Impact Analysis for the proposed rule is available at http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.

Rulemaking Process and How to Submit Comments

When the FDA issues a proposed rule on a matter, it publishes the proposed rule in the Federal Register so that the public can review it and submit comments. The FDA considers comments received during the comment period on a proposed rule and then considers revising the rule based on its review of the comments, before issuing a final rule. In the preamble to the final rule, we discuss the significant comments received. The proposed and final rules and supporting documents are filed in the FDA's official docket on http://www.regulations.gov and also can be accessed at www.fda.gov/fsma.

Comments on the proposed rule, "Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications," which published in the July 29, 2013 Federal Register, are due 120 days after publication on November 26, 2013.

The FDA is developing draft Model Accreditation Standards to qualify third-party auditors for accreditation and will seek comment on the draft standards. The FDA intends to implement the program at the earliest date possible after publication of the final rule and the final Model Accreditation Standards.

The FDA has conducted extensive outreach to industry, the consumer community, other government agencies, and the international community to gain input and perspective on how to structure this and other proposed rules required by FSMA. That input and perspective helped shape the proposed rules in a way that will help to ensure that they are practical and flexible as well as effective. The FDA intends to hold three public meetings during the comment period on this and the FSVP proposed rule in order to provide additional opportunity for input.

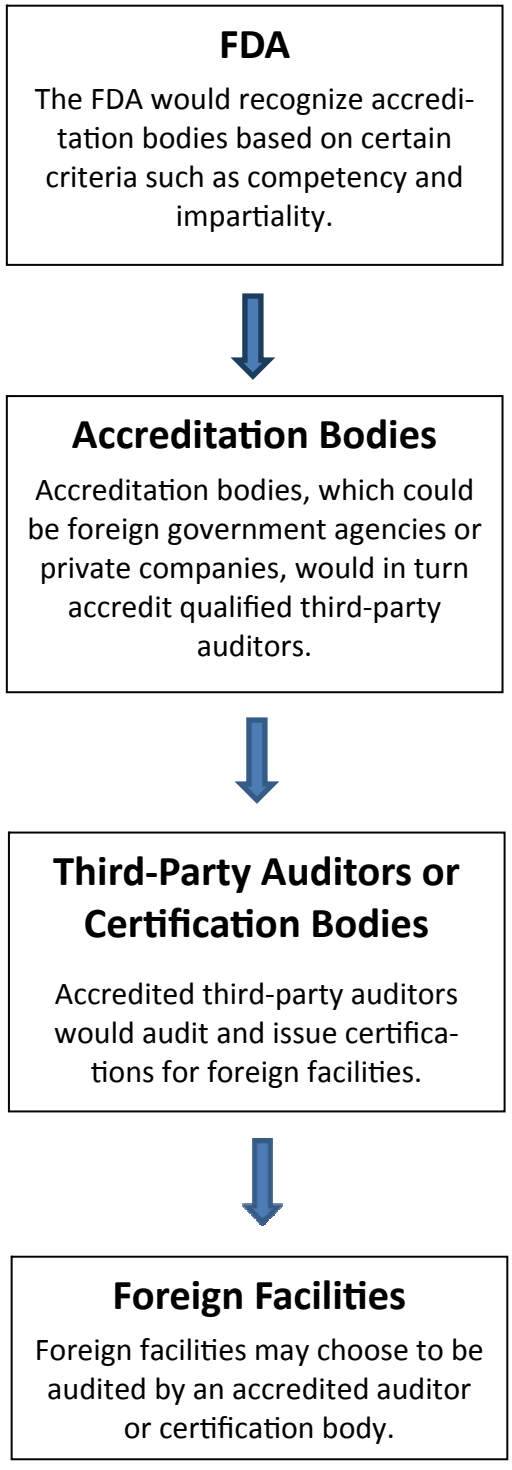
Proposed Rule on Accreditation of Third-Party Auditors

For additional information

- FR Notice
- Preliminary Regulatory Impact Analysis
- FDA Food Safety Modernization Act web site: www.fda.gov/fsma
- Fact Sheet: Foreign Supplier Verification Program
- The Food Safety Law and the Rulemaking Process: Putting FSMA to Work
- Fact Sheet: Preventive Controls for Human Food
- Fact Sheet: Standards for Produce Safety
- Video: The Rulemaking Process: A Primer by FDA
- Video: FDA Food Safety Modernization Act: A Primer

Updated 7/26/13

Structure of the Accredited Third-party Audits and Certification Program



Proposed Rule on Accreditation of Third-Party Auditors

Current System:

- Food processors and retailers currently use private third-party audits to oversee their operations, but FDA does not oversee foreign or domestic food safety audits.
- Audits vary in rigor and standards.
- Although audit reports are generated by certification bodies there is no requirement to submit reports to FDA, and no FDA requirements for content, records maintenance, or access.
- Some third-party certification bodies have failed to adequately protect against conflicts of interest.

Under the Proposed Rule:

- FDA establishes a program for accreditation of third-party auditors of foreign facilities by FDA-recognized accreditation bodies.
- The accreditation body must meet FDA standards and requirements.
- FDA receives reports of third-party audits conducted for certification purposes (referred to as regulatory audits).
- FDA exercises monitoring and oversight of participating accreditation bodies and auditors, including procedures that FDA will follow to remove an auditor or an accreditation body from the program, for good cause.
- The accreditation body must maintain records, provide FDA access to records, monitor its own performance, and protect against conflicts of interest.
- FDA can conduct an onsite audit of a certified foreign facility at any time, with or without the accreditation body or auditor/certification body present.