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MEMORANDUM

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RE: FDA Releases FSMA Final Rule on Accreditation of Third Party Certification Bodies

The Food and Drug Administration (FDA) has released its final rule on accreditation of third party certification bodies who conduct food safety audits of foreign entities and issue food and facility certifications under the FDA Food Safety Modernization Act (FSMA). Importantly, in the final rule, FDA has clarified the narrow scope of such food safety audits and when the agency's requirements for third party certification bodies apply. Clear understanding of the scope of the regulations for third party certification bodies is essential for any company considering participation in the voluntary qualified importer program (VQIP), as certification is required as a condition of participation in that program. This memorandum explains those elements of the final rule and FDA's requirements for third party certification bodies of most importance to food companies.

Overview

FSMA requires FDA to establish a program for accreditation of third party certification bodies to conduct food safety audits and issue certifications of facilities and foods for humans and animals. FSMA specifies only two uses for the food and facility certifications issued by accredited third party certification bodies under this program. First, as noted above, facility certification is required as a condition of participation in VQIP, a program offering participating importers expedited review and entry for food that is part of VQIP. 1/ Second, FSMA gives FDA the authority to require that certain foods offered for import into the United States be accompanied by a certification, or other assurance deemed appropriate by FDA, if the food fits a high-risk profile (based on the food, region of origin, and the food safety standards in that region) identified by FDA. This is referred to as "mandatory import certification" (MIC) and is expected to be required in very limited circumstances.

Accordingly, the final rule on accreditation of third party certification bodies establishes the framework for this certification system. FDA will recognize accreditation bodies, which in turn will accredit third-party certification bodies that will audit and issue certifications to eligible foreign entities. The final rule establishes procedures FDA will follow for recognizing accreditation bodies, procedures accreditation bodies will follow in accrediting certification bodies, and procedures certification bodies will follow in issuing certifications to eligible foreign entities. More specifically, the rule sets requirements for the legal authority, competency, capacity, conflict of interest safeguards, quality assurance, and records procedures that accreditation bodies must demonstrate for recognition and that certification bodies must demonstrate for accreditation.

1/ FDA issued a draft guidance on VQIP on June 5, 2015. *See* HL Memo, *FDA Issues Draft Guidance on the FSMA Voluntary Qualified Importer Program* (June 16, 2015).

Importantly, the rule requires accredited third party certification bodies to perform unannounced facility audits, notify FDA upon discovering a condition that could cause or contribute to a serious risk to the public health, and to submit reports of "regulatory audits" to FDA (i.e., the "bells and whistles" as sometimes referred to informally). Notably, these requirements only apply to the narrow scope of food safety audits conducted under the program.

Scope of Audits Covered by the Requirements for Third Party Certification Bodies

As noted above, in the final rule FDA clarified the narrow scope of audits covered by the requirements for third party certification bodies. Again, this is significant because of the audit process, report content, and notification requirements applicable to covered audits. Under the rule, third party certification bodies will conduct "food safety audits." The term "food safety audit" includes "regulatory audits" and certain "consultative audits" of eligible entities by certification bodies. Those terms are defined as follows:

- Regulatory Audit. An audit by a certification body of an eligible entity to determine whether the eligible entity complies with FDA food safety requirements. Regulatory audits are used to determine whether food or a facility can be certified by the certification body.

- Consultative Audit. An audit by a certification body of an eligible entity to evaluate compliance with FDA food safety requirements and industry standards and practices. A consultative audit is for internal purposes only and *is conducted in preparation for a regulatory audit* (emphasis added).

In light of these definitions, audits that fall outside the scope of this rule include, but are not limited to:

- Audits conducted by certification bodies not accredited under FDA's program;
- Audits conducted to determine compliance with industry standards;
- Audits that are announced; and,
- Audits conducted solely for Preventive Controls supplier verification purposes or the Foreign Supplier Verification Program (FSVP).

To reemphasize this critical point of the rule's narrow coverage:

- A "regulatory audit" is only an audit conducted to obtain certification under VQIP or MIC; and
- A "consultative audit" is only an audit conducted *in preparation for* (i.e., a trial run) for a VQIP or MIC regulatory audit.

Importantly, accredited third party certification bodies can offer both "food safety audits" and other services outside the scope of the rule. Therefore, in light of the requirements applicable to both "consultative audits" and "regulatory audits" it will be extremely important that when a foreign entity is working with an accredited third party the entity clearly identify the type of audit it is requesting, particularly with respect to consultative audits. It is quite likely that new terminology with be needed to distinguish FDA defined "regulatory audits" and "consultative audits" from the other services offered by accredited third party certification bodies. This is the best way to ensure that the requirements for accredited third party certification bodies (direct reporting of serious risks to the public health, filing of audit reports with the agency, etc.) will not apply.

Audit Process and Audit Reports

Under the final rule, both "regulatory audits" and "consultative audits" (as narrowly defined) must be conducted unannounced within a 30-day window provided by the eligible entity. The audit must

include both a records review and an on-site assessment of the facility, its processes, and the food products. The records review component of the audit may be scheduled, but must take place prior to the onsite audit. Environmental or product sampling will be conducted as appropriate or when required by FDA. Samples must be analyzed by a laboratory accredited to ISO/IEC 17205:2005 or an equivalent standard. There is no requirement that test results be sent directly to FDA. FDA and the recognized accreditation body must be allowed to observe both "regulatory" and "consultative audits."

The audit must be sufficiently rigorous for the certification body to determine that the facility is in compliance with FDA food safety requirements, and for "consultative audits," also includes conformance with applicable industry standards and practices. For a "regulatory audit," the certification body must be able to determine the eligible entity is likely to remain in compliance with FDA requirements for the next 12 months (the duration of the certification). When an accredited third party certification body identifies a deficiency requiring corrective action, it may verify the effectiveness of corrective actions once implemented, but must not recommend or provide input to the entity in identifying, selecting or implementing the corrective action. Audit observations and other data and information gathered must be documented, maintained as a record, and used to support the audit report.

Accredited third party certification bodies must prepare food safety audit reports within 45 days of completing the audit. "Regulatory audit" reports must be submitted electronically, in English, to FDA, regardless of whether a certification was issued. The "regulatory audit" report must include:

- Information identifying the eligible entity (including the facility registration number where applicable, the FDA Establishment Identifier, and "a unique facility identifier, if designated by FDA), and the date, scope, and duration of the inspection;
- Any observed deficiencies that present a reasonable probability that the use of or exposure to a violative product
    - will cause serious adverse consequences or death (i.e., FDA's standard for a Class I recall); or
    - may cause temporarily reversible adverse health consequences or where the probability of serious adverse health consequences is remote (i.e., FDA's standard for a Class II recall,);
- The corrective action plan for addressing each such deficiency, unless the corrective actions were implemented immediately and verified onsite;
- Whether the facility conducts any laboratory sampling or analysis; and,
- Whether the entity has made any significant changes to the facility, its processes, or food products during the last two years.

An eligible entity is permitted to appeal an adverse determination in a "regulatory audit."

Accredited third party certification bodies must retain "consultative audit" reports for at least four years (including observations, laboratory records, and correspondence with the eligible entity) and make those reports available to FDA in accordance with the emergency access to records provision of the Bioterrorism Act (FFDCA § 414(a)(1)). "Consultative audits" reports must contain information specified in the regulations, including information identifying the entity and any deficiencies observed related to compliance with FDA food safety requirements that require corrective action. The "consultative audit" report also must include the corrective action plan and the date the corrective actions were completed. "Consultative audit" reports do not need include deficiencies solely associated with compliance with industry standards.

Reporting and Recordkeeping Requirements for Certification Bodies

Accredited third party certification bodies are required to report immediately to FDA any condition found during a "regulatory audit" or "consultative audit" (as those terms are defined by FDA) that "could cause or contribute a serious risk to the public health." The certification body is required to notify the eligible entity and its accreditation body as well, but only either after or simultaneous to reporting to FDA.

Importantly, FDA interprets the immediate reporting requirement more broadly than reporting conditions that could create "a reasonable probability of serious adverse health consequences or death." In addition, there is no exception from reporting when food adulterated as a result of a notifiable condition has not left the facility. FDA does explain in the preamble, however, that accredited third party certification bodies should consider certain factors when considering whether a condition is notifiable, including whether it relates to incoming ingredients that will be subject to control within the facility, whether the condition relates to the post-processing environment, and whether it relates to food that is destined for the U.S.

Accredited third party certification bodies must maintain records electronically for four years. Except for "consultative audit" reports and associated documents, records must be available for inspection and copying upon written request either at the certification body's place or business or at a reasonably accessible location. If the records are requested by FDA electronically, they must be submitted electronically within ten days. Records required under the rule are subject to the standard Freedom of Information Act (FOIA) disclosure provisions and exemptions from disclosure.

Certifications

Accredited third party certification bodies may issue certifications based on "regulatory audits." Any food or facility certification must be submitted to FDA electronically and in English. Certifications are for a term of up to 12 months. Certifications cannot be issued until the accredited third party certification body verifies that the entity has implemented its corrective action plan to address any deficiencies observed. Onsite verification is required for deficiencies that "could cause or contribute a serious risk to the public health." FDA may refuse to accept any certification if FDA determines that it is not valid or reliable.

If an accredited third party certification body has reason to believe that an eligible entity to which it issued a certification may not longer be in compliance with FDA food safety regulations, then it must conduct monitoring, including an onsite audit to determine whether the entity is still in compliance. The circumstances FDA envisions that might trigger monitoring include: (1) significant changes to the facility such as capital improvements; (2) major changes to the entity's management system and processes; or (3) changes to the scope of operations.

Public Information on the Program

Accredited certification bodies must maintain on their websites a list of entities to which they have issued certifications, including the duration and scope of certification and the date the entity paid certification body. FDA will have a website registry of recognized accreditation bodies (and those denied or had recognition revoked) and accredited third party certification bodies (and those denied or had their accreditation withdrawn). Generally, FDA will not post audit reports on the web.

Implementation

Although this final rule is effective 60 days after publication in the Federal Register, FDA will not begin implementing the program until after it finalizes user fees for accreditation and certification bodies. FSMA requires FDA to establish a user-fee program to reimburse the agency for its work establishing and administering the third party certification program. FDA issued a proposed rule for user fees in July 2015.

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The final rule on third-party audits and certification of some foreign entities represents another significant step forward in FDA's efforts to implement FSMA. Food companies considering participating in VQIP should review closely the requirements to understand how they will affect the use of third party audits in their operations. Please do not hesitate to contact us for additional information.