Food & Drug

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FDA Releases Guidance on Voluntary Third-Party Certification Programs for Foods and Feeds

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On January 12, 2009, the Food and Drug Administration ("FDA" or "the agency") released its Guidance for Industry on Voluntary Third-Party Certification Programs for Foods and Feeds ("the Guidance").[1] The Guidance describes the general attributes that FDA believes a third-party certification program should possess in order for the agency to have confidence that the program reliably provides verification of product safety and compliance with applicable FDA requirements. The Guidance applies to any third-party certification program, including those administered by private entities or federal, state, local or foreign regulatory bodies.

Background and Purpose of the Guidance

The Guidance finalizes a draft published on July 10, 2008, and follows upon the recommendation for verification of third-party certification programs made by an interagency working group convened by Presidential order in the group's "Action Plan for Import Safety: A Roadmap for Continual Improvement" (Action Plan).[2] The Action Plan was released on November 6, 2007, in the wake of several incidents of imported food and feed contamination, sparking nationwide concern about the safety of such imports.

FDA states that the Guidance is intended as one of the steps in the agency's future recognition of one or more voluntary third-party certification programs for particular product types. FDA observes that there are many established third-party certification programs for food and feed safety currently being used by industry, and concludes that such programs are helpful in ensuring that products meet U.S. safety and security standards by allowing Federal agencies to target their resources more effectively. FDA states that recognition of existing programs may lessen the need for establishments to be subject to audits from multiple certification bodies.

Although FDA encourages participation in recognized third-party certification programs, the Guidance makes clear that participation is voluntary and neither establishments nor certifying bodies are under an obligation to participate. The agency states that participation may be beneficial, however, because FDA may take into consideration a recognized certification when:

(i) determining its establishment inspection priorities, as well as entry admissibility decisions and field exam and sampling priorities;

(ii) determining "may proceed" rates for imports, potentially expediting entry for certain product types from particular establishments;

(iii) considering an establishment's requests to have its products removed from

[1] The Guidance is available at http://www.fda.gov/oc/guidance/thirdpartycert.html.
[2] The Action Plan is available at http://www.importsafety.gov/report/actionplan.pdf.

an FDA Import Alert; and

(iv) investigating a foodborne illness outbreak, because certified establishments with effective product tracing systems in place may be more easily and quickly investigated and excluded as a source of contamination.

Recommended Criteria for Voluntary Third-Party Verification Programs

FDA states that it will recognize a certification program if it has sufficient confidence in the credibility and the validity of the decisions the certification body makes. FDA may perform a certification program assessment to determine a certification body's level of conformance to these attributes prior to recognition, including observing on-site audits.

The Guidance sets forth a number of recommended attributes for third-party certification programs, including the following key features:

(i) A formal application process should include disclosures relating to regulatory standing, such as whether an FDA warning letter has been issued to the establishment, whether an FDA legal action has been filed against the establishment or its products, and whether the establishment or any of its key personnel has been prosecuted or convicted of a crime relating to FDA regulatory requirements.

(ii) Under the formal arrangement between the supplier and the certification body, the certifier should be given authorities to perform auditing activities, including: access to the establishment for auditing purposes (including unannounced audits); examination of records; collection and analysis of samples; and reporting to FDA regarding compliance with certification criteria and governing FDA requirements.

(iii) Auditors should have appropriate qualifications and training pursuant to a training plan implemented by the certification body. Training should include coursework in areas relevant to food safety and sanitation, field training, and continuing education.

(iv) An effective audit program should be risk-based, grounded in written policies and procedures, and should provide the certification body with reasonable assurance that the audited establishment produces, manufactures, processes, packs, or holds foods that are safe and in compliance with applicable certification criteria. The certification body should retain the documentation for all audit findings.

(v) The certification body should implement a quality assurance program that monitors its auditors, audits, and sample collection processes for consistency and competency, to identify areas that need improvement, and to quickly execute appropriate corrective actions when problems are found.

The Guidance also states that a recognized certification body should notify FDA when:

(i) its auditors have identified situations in which there is a reasonable probability that the use of, or exposure to, food or feed produced, manufactured, processed, packed, or held in that establishment will cause serious adverse health consequences or death to humans or animals (*i.e.*, a Class I recall situation). This is a narrower, more specific set of circumstances than FDA previously indicated would merit notification to the agency.

(ii) the certification body is withdrawing certification of an establishment, and the basis for withdrawal.

(ii) the certification body is making signification changes to its certification program.

FDA states that it may provide additional guidance regarding recognition of third-party certification programs for particular product types in the future.

The agency makes clear that its recognition of a particular certification program would not restrict FDA from taking necessary enforcement actions should the need arise, and that establishments will not be released from their legal responsibilities or liabilities simply because they have a certification from a recognized third-party certification body. Such establishments must continue to take all necessary steps to ensure that their products meet governing U.S. food safety and security standards.

Potential Benefits and Drawbacks to Third-Party Certification Programs

FDA recognition of voluntary third-party certification programs may be beneficial in the current regulatory environment to expedite importation and agency investigation in the event of food contamination concerns, as noted above. Such certification programs could potentially become even more valuable if Congress enacts restrictions on importation of certain products or imposes substantial hurdles to importation, as were proposed in the 110th Congress.

Companies considering the use of such programs, however, should be mindful of the certification bodies' obligations to notify FDA of serious safety hazards, company noncompliance with agency requirements or certification criteria, or the reasons for withdrawal of certification. Companies using third-party certification programs also should ensure the protection of confidential, trade secret, or otherwise sensitive documents that may need to be revealed to auditors.

Finally, the food industry should continue to monitor legislative and regulatory developments to ensure that such voluntary third-party certifications do not effectively become mandatory, which could cause hardships to small businesses and could increase the cost of food to consumers.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our food & drug practice group:

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