THE VOICE OF FOOD RETAIL
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January 27, 2014

Division of Dockets Management (HFA–305)
U.S. Food and Drug Administration
5630 Fishers Lane, rm. 1061,
Rockville, MD 20852

Re: Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications Proposed Rule[1]

Docket No. FDA–2011–N–0146

Dear Sir or Madam:

On July 29, 2013, the Food and Drug Administration (FDA or the Agency) published in the Federal Register a proposed rule entitled Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications (the "Proposed Rule"). The Proposed Rule would provide for accreditation of third-party auditors/certification bodies and food and facility certifications under the Food Safety Modernization Act (FSMA). The Food Marketing Institute (FMI) appreciates the opportunity to comment on this important matter.

FMI proudly advocates on behalf of the food retail industry. FMI's U.S. members operate nearly 40,000 retail food stores and 25,000 pharmacies, representing a combined annual sales volume of almost $770 billion. Through programs in public affairs, food safety, research, education and industry relations, FMI offers resources and provides valuable benefits to more than 1,225 food retail and wholesale member companies in the United States and around the world. FMI membership covers the spectrum of diverse venues where food is sold, including single owner grocery stores, large multi-store supermarket chains and mixed retail stores. For more information, visit www.fmi.org and for information regarding the FMI foundation, visit www.fmifoundation.org.

FMI supported the enactment of the Food Safety Modernization Act (FSMA). We believe the regulations issued to implement section 307 of FSMA, if crafted in a manner consistent with the following comments will enhance public health and strengthen our nation's food safety regulatory system.

[1] 78 Fed. Reg. 45782 (July 29, 2013).

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I. Audit Program Established by Proposed Rule Applies Only to Foreign Entities

Congress directed FDA in FSMA to "establish a system for the recognition of accreditation bodies that accredit third-party auditors to certify that eligible entities meet the applicable requirements of this section (section 307)."[2] An eligible entity is defined as a "foreign entity, including a foreign facility registered under section 415, in the food import supply chain that chooses to be audited by an accredited third-party auditor or the audit agent of such accredited third-party auditor."[3]

The law clearly limits the application of the audits contemplated in the Proposed Rule to foreign entities and it would thus be inconsistent with FSMA for FDA to apply it to domestic entities.

II. Audit Regulation

Immediate Notification to FDA of a Serious Risk to Public Health Should Not Include Class II Deficiencies

The Proposed Rule in § 1.651(b)(4) requires accredited auditors (hereinafter "auditors") and certification bodies (CBs) to immediately notify FDA electronically, in English, when any of its audit agents or the auditor/CB itself, discovers any condition found during a regulatory or consultative audit of an eligible entity, which could cause or contribute to a serious risk to the public health. FDA notes that 21 USC 384d(c)(4)(A),does not define "serious risk to the public health," nor does it give examples of "condition[s] that could cause or contribute to a serious risk to the public health."[4] The Agency states that they believe Congress intended the standard for notification to be a different standard than serious adverse health consequences or death to humans or animals (SAHCODHA). FDA states that it is particularly interested in input on whether the Agency's existing Class I and Class II recall standards taken together equate to a "serious risk to public health."

FMI does not believe that Class I and Class II recall standards taken together equate to a serious risk to public health. It is difficult to contemplate that was the intent of Congress when Class II recall standards include situations where "the probability of serious adverse health consequences is remote." Class II recall deficiencies should not require auditors to immediately

[2] 21 USC 384d(b)(1)(A)(i).
[3] 21 USC 384d(a)(6).
[4] 78 Fed. Reg. 45815

notify FDA. Under § 1.652(b)(6) all Class I and II deficiencies must be submitted to FDA as part of the regulatory audit report within 45 days of completion of the audit. If FDA defines "serious risk" to include both Class I and Class II standards under § 1.656(c), then the Agency would be immediately notified of all deficiencies noted in the regulatory audit report. FMI believes this is excessive and would pose significant challenges to the auditing process.

Requiring immediate notification of Class II deficiencies would be inconsistent with Reportable Food Registry (RFR) reporting requirements which mandate that responsible parties report on foods for which only a Class I deficiency applies. Reports must be made as soon as practicable or but in no case later than 24 hours after a responsible party determines that an article of food is a reportable food.

FMI seeks greater information as to how the immediate notification requirements under the Proposed Rule compare to the RFR reporting requirements and urges the Agency to minimize any duplicative burdens. FMI believes the Agency should consider making the immediate notification requirements under § 1.651(b)(4) consistent with RFR reporting requirements.

FMI has concerns that defining equating "serious risk" to Class I and Class II recall deficiencies collectively could lead to overreporting by auditors to FDA, taking Agency resources away from addressing the greatest threats to public health.

In addition, clear guidance to auditors on what triggers the immediate notification requirement is critical to prevent overreporting.

FMI seeks greater information from the Agency as to what constitutes immediate notification.

The Proposed Rule requires information to be submitted to the Agency electronically, in English. FMI seeks greater clarity as to the manner in which FDA will accept the information. Will the Agency receive it by e-mail or via a portal on a website. Is an auditor to stop an audit upon encountering such a condition? The Agency should contemplate that internet or wireless phone access may not be available at all locations auditors will be auditing—particularly foreign farms.

Furthermore, FMI requests more information on what the Agency intends to do with such information. What actions does the Agency intend to take to respond to such notifications?

Submission of Regulatory Audit Reports

The Proposed Rule requires that regulatory audit reports be submitted electronically, in English, to the Agency no later than 45 days after completion. FMI seeks greater information as to the mechanisms in which such audit reports are to be submitted. Will they be submitted via e-mail,

or via a web portal? Does the Agency intend to review each audit report? If so, how will this review be conducted and under what timetable?

Accessibility of Auditor Information

FMI seeks greater information as to what information collected by FDA pursuant to the program established under the Proposed Rule will be made available to importers and the public. FMI supports § 1.657(d) which requires accredited auditors/CBs to maintain up-to-date lists of eligible entities to which it has issued food or facility certifications and the duration and scope of the certifications. FMI supports having such information available on the FDA website as envisioned in § 1.690 would ease compliance for importers who choose to participate in the voluntary qualified importer program, import foods subject to mandatory import certification requirements, or rely on audit reports issued by accredited auditors for purposes of FSVP compliance.

Definition of Eligible Entity Should Include Foreign Farms

Under § 1.600, FDA has defined eligible entity as "a foreign entity that chooses to be subject to a food safety audit by an accredited auditor/certification body. Eligible entities include foreign facilities subject to the registration requirements of subpart H of this part." FMI believes that at the end of this definition FDA add "and foreign farms." We believe that Congress intended for foreign farms to be eligible to receive audits under section 307.

Regulation Should Include a Definition of the Term Farm

The regulation does not make clear that farms are eligible to be certified pursuant to sec. 307 and FMI believes it was the intent of Congress to make farms eligible for certification. As such, define the term farm under § 1.600 and make other changes to the Proposed Rule as appropriate to accommodate the new term.

Regulation Should Define the Term Food

FMI recommends FDA include a definition of the term food in the regulation consistent with how the term is defined in the Foreign Supplier Verification Program Proposed Rule for purposes of consistency and to indicate that producers of food contact substances are eligible entities.

III. Auditor Regulation

Capacity Issues

Under § 1650 (c), an auditor/CB cannot use an audit agent to conduct a regulatory audit at an eligible entity if such agent conducted a consultative or regulatory audit for the same eligible

entity in the preceding 13 months. Such limitation may be waived if the auditor/CB demonstrates to FDA pursuant to § 1.663, that there is insufficient access to auditors/CBs in the country or region where the eligible entity is located or in the country of export.

While FMI acknowledges that section 307 of FSMA is clear in imposing this restriction, we do have concerns about capacity issues in certain regions of the world. Indeed, even in regions with highly developed third-party food safety auditing systems, many capacity issues exist currently. The implementation of FSMA will impose significantly greater demands on the third-party auditing system and it will likely take time for the capacity of the global food safety auditing system to expand to meet these demands. FMI thus urges the Agency to act expeditiously upon all requests for waivers pursuant to § 1.663 to ensure sufficient capacity exists for the issuance food and facility certifications and to meet the demand of importers who seek to use accredited auditors for FSVP activities.

Single Auditor Performing Both Accredited and Unaccredited Audits

Because of the capacity issues mentioned previously, FMI believes that auditors and audit agents performing audits outside of the scope of the Proposed Rule for purposes of GFSI certifications and others should not lose the ability to continue doing so if they become accredited pursuant to the Proposed Rule. Limiting the ability of auditors accredited under the Proposed Rule to perform only regulatory or consultative audits pursuant to section 307 would be a significant disincentive for auditor participation in the FDA program and place substantial strains on the global food safety auditing system.

Working Within the Framework of Existing Global Food Safety Standards

Although FMI understands that Congress clearly restricted the authority to issue food and facility certifications to only auditors (accredited pursuant to the Proposed Rule), FMI believes that FDA should, to the greatest extent consistent with FSMA, acknowledge existing global food safety auditing programs and tailor regulations so that such programs may facilitate compliance. Global food safety programs have improved food safety practices around the world and regulations issued pursuant to FSMA should recognize such programs rather than supplant them.

Mandatory Withdrawal of Accreditation

Under § 1.664(a) FDA will withdraw accreditation from an auditor/CB if the food or facility certified under the Proposed Rule is linked to an outbreak of foodborne illness that has a reasonable probability of causing serious adverse health consequences or death to humans or animals. Pursuant to § 1.664(b), FDA may waive the mandatory withdrawal if the Agency conducts an investigation of the material facts related to the outbreak of the human or animal illness, reviews the steps or actions taken by the auditor/CB to justify the certification and

determines that the auditor/CB satisfied the requirements for issuance of a certification under applicable law and regulation.

FMI agrees with FDA that in the event of a withdrawal of accreditation, certifications previously issued by the auditor/CB losing accreditation remain valid until they expire.

FMI however seeks greater detail as to how the mandatory withdrawal process would function.

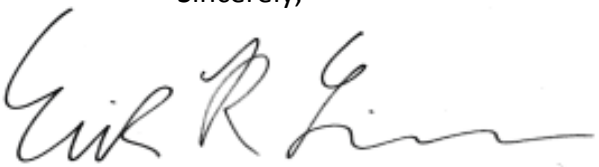
Pursuant to § 1.664(h), FDA will provide public notice on its website of its withdrawal of accreditation of an auditor/CB. FMI believes the details on the reasons for the withdrawal of such certification should also be posted.

Definition of Certification Body and Auditor

FMI notes that in the existing global food safety auditing system, CBs and auditors are not one in the same. FDA has created a single definition for both terms in the Proposed Rule which may lead to confusion. FMI suggests that the Agency consider creating separate definitions for each term.

We appreciate your consideration of these comments. Please do not hesitate to contact me at elieberman@fmi.org or (202) 810-4044 if you have any questions.

Sincerely,



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