January 24, 2014

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2011-N-0146 (RIN 0910-AG66); *Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications*; 78 *Fed. Reg.* 45782 (July 29, 2013).

To Whom It May Concern:

The American Meat Institute (AMI) is the nation's oldest and largest meat packing and processing industry trade association. AMI members slaughter and process more than 90 percent of the nation's beef, pork, lamb, veal, and a majority of the turkey produced in the United States. In addition, some AMI members operate beef facilities in Brazil, Australia, and Canada, and many members import meat and other food products. Finally, approximately 80 percent of AMI member companies are small or very small based on Small Business Administration standards.

The safety of the meat and poultry products AMI members produce is their top priority. Although Food and Drug Administration's (FDA or the agency) proposed rule (the proposal) does not directly affect Food Safety and Inspection Service (FSIS) inspected establishments, many federally inspected meat and poultry processing establishments use inputs from FDA regulated facilities, many of them imported inputs.

AMI supports development of a third-party auditor accreditation system for the purposes provided in the Food Safety Modernization Act (FSMA) and the above-referenced proposal provides a sound starting point. There are, however, several problems with the proposal and FDA should reconsider those elements consistent with the following comments.

1. The Agency Should Make Clear that the Third-Party Accreditation Rule Applies Only to Imported Food.

Ambiguous from the proposal is that this third-party accreditation rule would apply to imported food only. Although the statutory text is unambiguous that the accredited third-party auditing framework applies only to imported food and specifically to Mandatory Import Certification (MIC) and the Voluntary Qualified Import Program (VQIP), FDA should make this point explicitly in the final rule.

2. Requiring FDA-Accredited Third Party Auditors Should Be Limited to MIC and VQIP

The proposed requirements for FDA-accredited third-party auditors should only apply to imports subject to MIC for high-risk imports and imports offered under VQIP. The statute does not establish, and FDA should not extend, certification requirements to audits conducted to fulfill other responsibilities, *e.g.*, a Foreign Supplier Verification Program (FSVP).

Specifically, FSMA provides that third-party audit and certification requirements apply to "regulatory audits," which are required for two specific import categories: (1) imports identified by FDA as posing an unusually high risk that justify mandatory import certification; and (2) imports qualifying for expedited entry under VQIP.[1] Regulatory audits are linked to mandatory reporting to FDA in three ways. First, FDA-accredited auditors are required to immediately report to FDA any conditions presenting a "serious risk of public health" identified during a regulatory audit.[2] Second, accredited auditors must send copies of regulatory audit reports to FDA within 45 days of completing the audit.[3] Third, accredited auditors are required to use accredited laboratories, which in turn are required to report all testing results (positive or negative) directly to FDA.[4]

There are, however, many other kinds of audits. For example, the statute recognizes and defines "consultative audits," *i.e.*, those conducted to determine compliance with the law and "for internal purposes only." In addition, there are other audits of food facilities not listed in the statute, *e.g.*, audits conducted for the purposes of assessing a supplier's capabilities, supplier verification, *etc*. Such audits are characterized generally as "evaluative audits" and are routinely done because their purposes can be several, *e.g.*, is to assess the facility's conformance to recognized procedures and practices, *etc*.

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[1] 21 USC 384d(c)(2)(B).
[2] 21 USC 384d(c)(4)(A).
[3] 21 USC 384d(c)(3)(A).
[4] 21 USC 350k(b)(1)(A).

Importantly, FSMA only identifies two programs -- MIC and VQIP -- as subject to the accredited third-party auditor framework and the accompanying mandatory reporting requirements. For that reason FDA must follow the statute and only require mandatory reporting for the regulatory audits required for MIC and VQIP. Abiding by the third-party accreditation standard should not be required when a U.S. importer *voluntarily* elects to use an audit by an FDA-accredited auditor to conduct other audits or meet other responsibilities, *e.g.*, FSVP.

3. A Class I Recall Risk Level Should be the Standard for Reporting Observations to FDA

FSMA provides that an FDA-accredited third-party auditor must report immediately to FDA any condition found during an audit that "could cause or contribute to a serious risk to the public health."[5] The proposal, however, seeks to broaden that scope and would require reporting for issues commensurate with Class I and Class II recalls, rather than just for a Class I risk level. In doing so the proposal oversteps the statutory boundaries and the standard for immediate reporting should be a Class I recall level of risk.

Including the Class II standard, by definition, conflicts with the statute. FDA regulations define a Class II recall as "a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote."[6] This standard does not meet the "could cause or contribute to a serious risk to the public health" standard set by law. Because the proposal exceeds the agency's statutory authority it should be revised.

4. Mandatory Reporting Requirements Should Not Apply to Consultative Audits

The mandatory reporting requirements should not apply to consultative audits because 1) FSMA does not require it and 2) it would adversely affect food safety because it would discourage facilities from using FDA-accredited third-party auditors to conduct such audits.

As discussed earlier, under FSMA, "regulatory audits" have two specific purposes: (1) to determine whether an eligible entity is in compliance with the law; and (2) the results of which determine whether the entity can receive a food certification under the MIC program or be certified to participate in VQIP.[7] In contrast, FSMA establishes that "consultative audits" are different because they are

[5] 21 USC 384d(c)(4).
[6] 21 CFR §7.3(m)(2).
[7] 21 USC 384d(c)(2)(B).

done to determine whether the facility is in compliance with the law and the "results of which are for internal purposes only."[8] In short, any entity seeking to participate in MIC or VQIP must be subject to a regulatory audit but no facility is required to conduct a consultative audit. Indeed, when a facility elects to conduct a consultative audit, that facility is not required use an FDA-accredited auditor. Thus, there is no official regulatory role for "consultative audits," demonstrating a critical distinction between the two.

The proposal seeks to require an accredited third party auditor to report instances of noncompliance for both types of audits. This effort effectively circumvents the limits imposed by the statute and impermissibly broadens FDA's authority. That the proposal overreaches is evident not only be reviewing the definitions above, but by reviewing the other statutory language. Specifically, section 307(c)(4)(A)-(B) provides:

> (A) RISKS TO PUBLIC HEALTH—If, at any time during *an audit,* an accredited third-party auditor or audit agent of such auditor discovers a condition that could cause or contribute to a serious risk to the public health, such auditor shall immediately notify the Secretary of—
> (1) the identification of the eligible entity subject to the audit; and
> (2) such condition.
> (B) TYPES OF AUDITS – An accredited third-party auditor or audit agent *may* perform consultative and regulatory audits of eligible entities.
> (Emphasis added.)[9]

Section 307(c)(4), when read in context, does not support FDA's interpretation. Subsection (A) provides for direct reporting when conducting an "audit," not when conducting a "consultative audit." Subsection (B) simply authorizes FDA-accredited auditors to conduct consultative audits, in addition to regulatory audits, as a predicate for the subsection (C) conflict-of-interest limitation and its 13-month buffer period. In short, section 307(c)(4) does not expressly provide that consultative audits are subject to direct reporting by an accredited third party auditor and, without more, FDA should not read such an interpretation into the statute.

That accredited auditors do not and should not have a direct reporting requirement is supported by other statutory language as well as policy reasons. First, by statute, "consultative audits" are to be kept confidential. More specifically, the statute provides that the "results of [consultative audits] are for internal purposes only."[10] Moreover, Congress provided that audit reports prepared

[8] 21 USC 384d(a)(5).
[9] 21 USC 384d(c)(4)(A)-(B).
[10] 21 USC 384d(a)(5).

following a consultative audit are to remain confidential except in extraordinary circumstances. Unlike regulatory audit reports, consultative audit reports are accessible by the agency only when it has a reasonable belief that an article of food from that facility is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.[11]

Confidentiality is the foundation of consultative auditor/facility relationship. Congress recognized that foundation and took steps to help ensure the free flow of information so that potential issues and deficiencies can be identified and promptly addressed in order to enhance food safety. To impose the reporting requirements on consultative auditors runs contrary to this Congressional direction on confidentiality and is therefore contrary to the statute.

There is also a practical aspect of requiring accredited third party auditors to report as proposed. FSMA was enacted to enhance food safety programs and imposing the proposed reporting requirement likely will be counter to that goal. Simply put, incorporating into the final a reporting requirement for accredited third-party auditors conducting consultative audits will have a chilling effect on a company's willingness to use an FDA-accredited auditor for that purpose. When faced with this threat, a company may elect to use an auditor who is not FDA accredited or it may elect to forgo an audit altogether in some cases. Rather than implement procedures that will adversely affect food safety systems FDA should support company efforts to identify and correct problems. Requiring an accredited third-party auditor to report to FDA as proposed is contrary to that objective. For the foregoing reasons FDA should limit required reporting to accredited third party auditors conducting regulatory audits.

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In summary, in addition to clarifying that this rule would apply only to imported food, the agency should amend the proposal in following ways: 1) limit reporting requirements for FDA-accredited third-party auditors to "regulatory audits" identified in the statute; 2) set the Class I recall risk as the trigger for reporting observations to FDA; 3) abandon the proposal to mandate reporting requirements with respect to consultative audits.

[11] 21 USC 384d(c)(3)(C).

AMI appreciates the opportunity to submit these comments. If you have any questions regarding these comments or anything else regarding this matter, please contact me at (202) 587-4229 or mdopp@meatami.com.

Respectfully submitted,

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