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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; Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications

The Association of Food Industries, Inc. (AFI) and the Cheese Importers Association of America (CIAA) appreciate the opportunity to submit comments regarding the Food and Drug Administration's (FDA) proposed rule on Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications (the Proposed Rule).

AFI is an international trade association which fosters international trade in food products, with its primary focus on U.S. food imports. The association has approximately 1,000 member companies throughout the world, though its core members are approximately 450 U.S. companies importing food products from companies across the globe.

The CIAA is a non-profit trade association comprised of the vast majority of firms engaged in the business of importing, selling, promoting, and distributing cheese, cheese products, and butter in the United States.

The Proposed Rule would create an FDA-supervised system for the accreditation of third-party auditors/certification bodies to audit and certify foreign facilities and foods. This system is intended to improve the rigor and objectivity of third-party food safety audits. As added benefits, the system is also expected to increase consumer confidence in third-party audits and the safety of imported foods and to increase efficiency and reduce costs by reducing the need for redundant audits. Participation in the system – by accreditation bodies, third-party auditors/certification bodies, and eligible entities – would be voluntary.

AFI and CIAA believe it is essential that the rule balance the need for meaningful FDA oversight with the equally important imperative to create a system that does not

discourage participation. The success of the system depends on the voluntary participation of a variety of industry entities.[1] These include the third-party auditors to do the auditing, the foreign eligible entities to be audited, and the U.S. importers that will import food from the audited eligible entities. If third-party auditors do not seek accreditation, eligible entities do not request audits by accredited auditor/certification bodies, or U.S. importers do not use regulatory audits by accredited auditors/certification bodies to meet their Foreign Supplier Verification Program (FSVP) requirements or do not think that the benefits of participation in the Voluntary Qualified Importer Program (VQIP) outweigh the downsides, the system FDA is proposing to create will fail. If the accreditation system fails due to lack of participation, that would have negative implications for the FSVP rule, which depends on the ability of foreign suppliers to use a single audit by an accredited auditor/certification body for multiple U.S. importers.

While we appreciate the difficulty of balancing these two imperatives, and the effort FDA has made in the Proposed Rule to achieve the right balance, we fear that the Proposed Rule contains a number of provisions that are likely to act as significant disincentives to participation. These include the following:

- FDA's expansive interpretation of the requirement to notify the agency if an accredited auditor/certification body discovers a condition that could cause or contribute to a serious risk to public health;
- The proposed requirement that laboratory tests be performed by an accredited laboratory, which must send the lab test results to FDA;
- FDA's authority to obtain copies of consultative audit reports and other records under FD&C Act Section 414; and
- The lack of protection from public disclosure for audit reports and records;

We are also concerned about the potential chilling effect of these requirements on consultative audits. Consultative audits offer eligible entities the opportunity to communicate freely with auditors and to aggressively look for problems with the understanding that the audit findings will not go beyond the two parties. By whittling away at that confidential relationship, the proposed rule has the potential to discourage consultative audits by accredited auditors/certification bodies. An unintended consequence could be that many eligible entities either forego consultative audits altogether or have them done by unaccredited auditors.

We have the following specific comments on the Proposed Rule:

1. **FDA should clarify that the definition of "consultative audit" does <u>not</u> include informal consulting, counseling, training, education, continuous improvement programs, limited purpose audits, and similar activities that fall short of an "audit" as defined in the Proposed Rule.**

FDA should clarify that accredited third-party auditors/certification bodies may continue to provide a range of services short of an "audit" as defined in the Proposed Rule, and that those services would not be subject to the requirements of the proposed

[1] FDA is optimistic about participation, noting "we believe this new program will draw a significant number of participants and will be broadly accepted by industry." 78 Fed. Reg. 45782, 45790 (July 29, 2013).

rule. This clarification would make it possible for accredited auditors to continue to provide those services on a strictly confidential basis, thus encouraging eligible entities to seek out the assistance of accredited auditors without fear of any regulatory consequences.

The Proposed Rule would define an "audit" as a "*systematic*, independent, and documented examination (through observation, investigation, records review, and as appropriate, sampling and laboratory analysis)… to assess the entity, its facility, system(s), and food… including compliance with any applicable requirements for preventive controls, sanitation, monitoring, verification, corrective actions, and recalls, and, for consultative audits, also includes an assessment of compliance with applicable industry standards and practices."[2] An audit is therefore a thorough review of a food facility or other eligible entity's food safety system for compliance with relevant FDA requirements (and, in the case of a consultative audit, private industry standards).

FDA should clarify that all services of an accredited auditor/certification body that fall short of the proposed definition of "audit" are not covered by the Proposed Rule. These services include informal consulting, counseling, training, education, continuous improvement programs, limited purpose audits, and similar services.

2. The requirement that an accredited auditor/certification body immediately notify FDA of "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" should be limited to SAHCODHA hazards.

Under the Proposed Rule, an accredited auditor/certification body must immediately notify FDA electronically if it or any of its audit agents discover, during a regulatory or consultative audit, any condition that could cause or contribute to "a serious risk to the public health." The notification must include the following information: (a) the name and address of the eligible entity; (b) the name and address of the facility where the condition was discovered (if different from the eligible entity) and, where applicable, the facility's FDA registration number; and (c) the condition discovered.

In the preamble to the Proposed Rule, FDA requested comments on the meaning of the term "a serious risk to the public health." FDA believes that Congress intentionally did not use the term "serious adverse health consequences or death to humans or animals" (SAHCODHA) in this provision, and that the word "could" (in "a condition… which could cause or contribute to a serious risk to the public health") suggests a broader scope. FDA therefore is considering whether this notification requirement should apply to both Class I and Class II recall situations. A Class II recall is one involving a violative product that may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

We read the statutory language very differently. We interpret the phrase "a serious risk to the public health" to describe a condition that is *more,* not less, serious than SAHCODHA. We think the operative word in the statutory provision is "public."

[2] Proposed 21 C.F.R. § 1.600(c)(emphasis added).

A "serious risk to the *public* health" is one that could cause a serious public health problem such as a large outbreak of foodborne illness. A SAHCODHA hazard, on the other hand, includes lesser hazards such as failure to declare a major food allergen, which, although potentially life-threatening to some individuals, does not represent a serious risk to public health. FDA's suggestion that "a serious risk to the public health" should encompass Class II recall situations ignores the plain meaning of that phrase. A condition that may cause temporary, medically reversible adverse health consequences cannot, in any sense, be said to pose "a serious risk to the public health." Moreover, if accredited auditors were required to notify FDA of any condition that could cause or contribute to a Class I or Class II recall situation, FDA would be flooded with notifications, most of them of little public health concern, that the agency would need to investigate. The result would likely be a waste of FDA and industry resources and a needless disruption of trade.

Although we believe that "a serious risk to the public health" is more serious than a SAHCODHA hazard, in the absence of any clear way to distinguish between the two, we recommend that FDA consider "a serious risk to the public health" to be equivalent to a SAHCODHA hazard. The SAHCODHA standard is one that both FDA and the food industry have become accustomed to in connection with recall classification and reporting to the FDA Reportable Food Registry.

We request that consultative audits be exempt from this notification requirement. Under FD&C Act Section 808(a)(5)(B), consultative audits are "for internal purposes only," and their very purpose is to uncover deficiencies that could lead to food safety hazards. It makes no sense to require FDA notification of food safety hazards found during a consultative audit, and we think this is not what Congress intended. We note that the term "audit" is used elsewhere in Section 808 to refer exclusively to regulatory audits, and we think that is how Congress used the word here.[3] Applying this notification requirement to consultative audits would be a significant, and unnecessary, disincentive to use accredited auditors/certification bodies to perform consultative audits.

We also request that FDA provide clarification regarding the procedure for submitting the notification. FDA should clarify that an accredited auditor/certification body may satisfy its notification obligation by sending an email, with the information items listed in the proposed rule and no other information, to a designated email address at FDA. FDA should specify the email address to which the notification should be sent.

Finally, a notification should <u>not</u> be required if:

(1) The condition that could cause serious adverse health consequences or death to humans or animals originated with the eligible entity;
(2) The eligible entity has not transferred the food any other person; and
(3) The eligible entity either corrects the condition or destroys the affected food.

[3] *See, e.g.*, Section 808(a)(4) defining "accredited third-party auditor" as an auditor accredited "to conduct audits of eligible entities to certify that such eligible entities meet the applicable requirements of this section." The term "audit" here clearly refers only to regulatory audits, since only regulatory audits may result in issuance of certifications.

This exemption from the notification requirement would be comparable to the exemption from the Reportable Food Registry reporting requirement in FD&C Act Section 417(d)(2).

3. Laboratory analyses performed as part of a consultative audit should <u>not</u> be submitted to FDA.

The Proposed Rule would require that a food safety audit must include, where appropriate, environmental or product sampling and analysis, using validated procedures, and the analysis of samples must be performed by a laboratory accredited under FD&C Act Section 422.[4] Section 422 requires that the results of testing by an accredited laboratory must be sent directly to FDA, "except the Secretary may by regulation exempt test results from such submission requirement if the Secretary determines that such results do not contribute to the protection of public health."[5] Thus, under the Proposed Rule, lab test results for any samples taken by an accredited auditor/certification body during a regulatory or consultative audit would be sent to FDA.

We are concerned that this automatic sharing of lab test results with FDA undermines the confidentiality appropriate for a consultative audit. Eligible entities may be reluctant to initiate a consultative audit by an accredited auditor/certification body if they know that the audit is likely to include sampling and the test results will go to FDA. As discussed above, it is in the interest of public health to encourage eligible entities to make full use of consultative audits. Therefore, we request that FDA exercise its authority to exempt lab test results of samples taken during consultative audits from this requirement. Accredited laboratories should not be required to submit test results to FDA for samples taken by accredited auditors/certification bodies during consultative audits.

4. FDA should make clear that it will exercise its authority to access consultative audit reports and other records only in the most serious cases.

Under the Proposed Rule, an accredited auditor/certification body must maintain electronically for 4 years audit reports and other documents from a consultative audit (including audit agent observations, lab testing records and results, correspondence with the eligible entity, and corrective actions). The accredited auditor/certification body must make these records available to FDA in accordance with FDA regulations at 21 C.F.R. Part 1, Subpart J (*i.e.*, when FDA has a reasonable belief that an article of food manufactured, processed, packed, or held at that eligible entity is adulterated and presents a SAHCODHA hazard).[6]

We think that the potential for such records to be made available to FDA, and through FDA to be disclosed to the public, is inconsistent with the confidential nature of a consultative audit and may deter many eligible entities from using the services of accredited auditors/certification bodies. We do not think this result is compelled by the statute, which provides that FDA "*may* access the results of a consultative audit in

[4] *Proposed* 21 C.F.R. § 1.651(c)(2).

[5] FD&C Act Section 422(b)(2).

[6] *Proposed* 21 C.F.R. § 1.658(b).

accordance with section 414."[7] Further, the statute states that consultative audits "are for internal purposes only."[8] We recommend that FDA clarify that it will normally not seek access to consultative audit reports and records, but may do so only in the most serious situations.

5. FDA should provide greater protection for audit reports and records made available to the agency, particularly consultative audit reports and records.

Audit reports and other records obtained by FDA would be subject to public disclosure under the Freedom of Information Act, unless FDA acts to prevent that result. This could potentially include an eligible entity's hazard analysis, food safety plan, monitoring records, and verification records. This could include records that contain trade secrets or confidential information, including information about the eligible entity's facility, production process, and product formulation. These records could also include information that could be used by criminals or terrorists to defeat an eligible entity's food safety plan.

We urge FDA to give audit records the same level of protection the agency has granted to HACCP records under the seafood and juice HACCP regulations. HACCP records are not subject to public disclosure unless (1) the records have been previously disclosed to the public or are otherwise publicly available; (2) the records relate to a product or ingredient that has been abandoned and no longer represent a trade secret or confidential information; or (3) disclosure of the records could not reasonably be expected to cause a competitive hardship.[9] Audit records should be given the same level of protection.

6. FDA should <u>not</u> require use of a DUNS number.

The Proposed Rule would require that audit reports and certifications issued by accredited auditors/certification bodies identify the eligible entity and the facility audited using a "unique facility identifier."[10] FDA has tentatively concluded that the UFI should include two elements: (1) the eligible entity's DUNS (Dun & Bradstreet Data Universal Numbering System) number; and (2) the facility's Global Positioning System (GPS) coordinates. FDA notes that the DUNS number would give FDA access to business information such as the eligible entity's trade names, names of corporate officers and directors, and additional ownership information.[11]

AFI and CIAA oppose any requirement that eligible entities obtain DUNS number and the proposed use of DUNS numbers by FDA. Some of our members tell us that the DUNS system frequently contains errors and must be pursued aggressively to correct errors. We do not understand why FDA would require use of a privately-issued number when eligible entities already possess, or could easily obtain, other government-

[7] FD&C Act Section 808(c)(3)(C)(emphasis added).

[8] FD&C Act Section 808(a)(5)(B).

[9] 21 C.F.R. §§ 120.12(f) and 123.9(d).

[10] Proposed 21 C.F.R. §§ 1.652(a)(2), (b)(1)(i), (2); 1.653(b)(2)(ii), (iii).

[11] *See* 78 Fed. Reg. at 45812.

issued numbers that would serve the same purpose. The vast majority of foreign companies that export food to the United States have both an Internal Revenue Service taxpayer identification number (TIN) and an FDA facility registration number. A foreign company that does not have a TIN can request one from U.S. Customs and Border Protection. While some foreign farms may not have an FDA registration number, such farms could voluntarily register with FDA. Requiring companies to obtain yet another identification number is unnecessary. We do not think it is appropriate for FDA to require companies to use a particular business's product.

7. FDA should <u>not</u> require accredited auditors/certification bodies to verify corrective actions through onsite observation.

The Proposed Rule provides that an accredited auditor/certification body may not issue a food or facility certification until it verifies that the eligible entity has implemented the corrective action plan (if corrective actions are needed as a result of observations during a regulatory audit), and verification of corrective actions (except for corrective actions to address recordkeeping deficiencies) must be accomplished "through onsite observation."[12]

A blanket requirement that accredited auditors/certification bodies verify corrective actions by onsite observation is likely to significantly increase the cost of regulatory audits, since the auditor would need to remain in country until all corrective actions were completed or make a return trip to the audited facility. While onsite observation may often be an appropriate method to verify corrective actions, we think a blanket requirement is unnecessary. With contemporary technologies, it should often be possible to verify corrective actions be means of photographs, live web-cam transmissions, or other devices.

AFI and CIAA appreciate the opportunity to share our comments with FDA. We are ready to assist FDA in any way we can.

Respectfully submitted,

Robert Bauer
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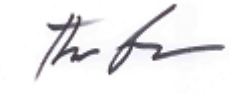

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[12] *Proposed* 21 C.F.R. § 1.653(a)(2).