Consumer Federation of America

January 27, 2014

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

RE: Docket No. 2011-N-0146

Consumer Federation of America appreciates the opportunity to comment on the proposed rule on Accreditation of Third Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certification [Docket No. FDA-2011-N-0146] (Third Party Certification Rule). This rule is important to the prevention of human illnesses from contaminated imported food.

Introduction

Imported foods make up approximately 15 percent of the average American's diet, and in some categories of FDA-regulated foods, imported products are the majority. About 80 percent of seafood consumed in the U.S. is imported; as is about 50 percent of fresh fruits and 20 percent of fresh vegetables. Food and feed imports originate from more than 250,000 foreign establishments in 200 countries each year. Food imports have grown by an average of nearly 10 percent annually from 2002 to 2009.[1] However, FDA is only able to inspect a small fraction (2 percent) of the foods that are imported in the U.S.

It is critical that these imports meet food safety standards set by the FDA. Each year contaminated food causes 48 million illnesses, 130,000 hospitalizations and 3,000 deaths, some of which are caused by imported products.[2] Recent foodborne outbreaks linked to papayas and cucumbers from Mexico, pine nuts and sesame paste from Turkey, and tuna scrape from India only underline the importance of assuring the safety of imported foods. FDA notes that between 2000 and 2007, between 70 percent and 85 percent of import refusals of produce and seafood were for potentially dangerous violations including the presence of pathogens, chemical contamination, and "other sanitary violations."[3] The Centers for Disease Control and Prevention found that from 2005 to 2010, 39 foodborne illness outbreaks and 2,348 illnesses were linked to imported food from 15 countries.[4] CDC found that 17 of the

[1] Food and Drug Administration, "Ensuring a Safe Food Supply: A Report to Congress."
[2] Comment by Stephen Stich, Director, New York State Department of Agriculture and Markets, that 70 percent of 300 recalls issued by the New York State Department of Agricultural Markets were for imported foods, Meeting Transcript, pp. 172-73, (March 29, 2011); Julie Schmit, "U.S. Food Imports Outrun FDA Resources," *USA Today*, March 18, 2007.
[3] Food and Drug Administration, "Ensuring a Safe Food Supply: A Report to Congress."
[4] Centers for Disease Control and Prevention, "CDC research shows outbreaks linked to imported foods increasing." March 14, 2012 via http://www.cdc.gov/media/releases/2012/p0314_foodborne.html.

outbreaks occurred in 2009 and 2010 and that fish was the most common source of foodborne disease outbreaks followed by spices. The CDC also found that 45 percent of imported foods causing outbreaks came from Asia.

The Food Safety Modernization Act (FSMA), passed with bipartisan support in Congress and signed into law by President Obama in January 2011, shifts FDA's approach to food safety from reaction to prevention, with the goal of reducing foodborne illness among consumers. One of the key components of FSMA is a set of provisions to better assure the safety of imported food.

CFA urges the FDA to implement its imported food title consistent with the law's prevention-based, public health focus. It is important to remember that FDA is obligated, under FSMA, to conduct inspections of foreign food facilities. In order to provide assurances that foreign plants are producing food safely, FDA must have some presence in these facilities. The Foreign Supplier Verification Program, Voluntary Qualified Importer Program, and the Third Party Certification program are all additive to a robust government inspection program.

CFA generally supports the requirements in FDA's proposed rule, even thought CFA remains skeptical of third party certification programs generally. The following five points highlight key issues raised in CFA's comments on the proposed rule. However, CFA provides comments on numerous other provisions in the proposal where changes should be made to better protect consumers.

1. Transparency is essential to the credibility of the third party certification program. Providing the public with robust information about the entities involved in the program as well as posting regulatory audit reports and self-assessment reports will enhance transparency efforts.
2. Adequate oversight of the program is essential. FDA must ensure adequate funding and capacity to effectively oversee the program, including onsite audits of facilities, auditors and CBs.
3. CFA supports the requirement that auditors/CBs immediately notify the FDA if the auditor discovers a condition which "could cause or contribute to a serious risk to the public health." This should encompass what would be considered both Class I and Class II food recall standards.
4. Unannounced audits are important to the integrity of the program and FDA should ensure the integrity of its approach to unannounced audits.
5. CFA strongly opposes efforts to use accredited auditors/CBs to conduct domestic food safety audits. Instead FDA should focus its efforts on developing a robust and credible program for third party certification for imported foods, as required under FSMA.

Concerns about Third Party Certification

Numerous incidents over the past several years have significantly reduced public confidence in the utility of third party certification. Three high-profile examples raise an array of concerns about whether the current third party certification system offers any improvements to food safety.

- Third party auditor AIB International gave the Peanut Corporation of America's Blakely Georgia plan a "superior" rating in 2008. Peanut butter contaminated with *Salmonella* from that facility made 714 people sick and contributed to 9 deaths in 46 states. In January 2009, FDA inspectors visited the plant and found dead cockroaches and water stains above a packing line, among numerous other problems. PCA is now out of business and its owners and managers are facing criminal charges.

- AIB auditors also gave glowing reviews to Wright County Egg farms in Iowa, rating the egg producer "superior" twice in 2008 and four times in 2009.[5] When FDA inspected the farms in 2010 as part of its investigation into a nationwide *Salmonella* outbreak, inspectors found 8 foot high piles of chicken manure and rodent infestation, plus "live and dead maggots too numerous to count." The resulting *Salmonella* outbreak sickened 1,939 people and led to a recall of half a billion eggs nationwide.

- In 2011, a subcontractor, Bio Food Safety Inc., of third party auditing firm Primus Group Inc., gave Jensen Farms a score of 96/100 and a "superior" rating after spending only four hours on site. *Listeria*-contaminated cantaloupe from Jensen Farms would go on to sicken 147 consumers and kill 33 others in 28 states.[6] The Jensen Brothers pleaded guilty to federal misdemeanor charges, but have sued Primus Labs, saying that much of the blame should lie with the auditor.[7]

In addition, FDA's oversight of contracted State inspections raises concerns about FDA's capacity to oversee a third party certification program for international entities. In 2011 the Department of Health and Human Services' Office of Inspector General reported that FDA did not complete 38 percent of the required oversight audits in one-third of the states with FDA contracts (14 of 41 states), citing a lack of resources and limited training for FDA staff, and did not always follow up on identified systemic problems.[8] This lack of adequate oversight has been a recurring problem at FDA and CFA is concerned that a similar outcome will occur with FDA's oversight of overseas third party certification bodies.

Powell et al proposed recommendations for improving the third party auditing system which would be useful for FDA to consider as the agency develops its approach on third party certification. One quote from the report:

> Third-party audits are only one performance indicator and need to be supplemented with microbial testing, second-party audits of suppliers and the in-house capacity to meaningfully assess the results of audits and inspections. Any and all raw product suppliers should be included in the audit scope. More effective audit systems incorporate unannounced visits along with supplemental information into their framework and require extensive documentation of internal audits, regulatory compliance, laboratory results and raw product certifications.[9]

Lessons from FDA's Shrimp Pilot

In 2008-2009, FDA conducted a pilot program on aquaculture shrimp to explore the potential benefits and challenges of using third-party certification. FDA's Shrimp Pilot Project identified fundamental deficiencies of certification bodies which would need to be addressed in order for FDA to rely on the information provided by a certification body (CB). In particular, FDA found that:

- The observed CB program did not always match the CB's self assessment.

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[5] Armour S, Lippert J, Smith M, "Food Sickens Millions as Company-Paid Checks Find It Safe." *Bloomberg News,* October 11, 2012, via http://www.bloomberg.com/news/2012-10-11/food-sickens-millions-as-industry-paid-inspectors-find-it-safe.html.

[6] *Ibid.*

[7] Flynn D, "Jensen Brothers Take Responsibility But Blame Primus Labs, *Food Safety News,* October 21, 2013 via http://www.foodsafetynews.com/2013/10/jensen-brothers-sue-primus-over-third-party-audit-they-say-was-faulty/#.UnPvoydUB3E.

[8] U.S. Department of Health and Human Services, Office of the Inspector General, *Vulnerabilities in FDA's Oversight of State Food Facility Inspections,* Washington, D.C., December 2011.

[9] Powell DA, Erdozain S, Dodd C, Morley K, Costa R, Chapman BJ (2013). "Audits and inspections are never enough: A critique to enhance food safety." *Food Control,* Volume 30, Issue 2, Pages 686–691, April 2013.

- The food safety scheme classifications used by some CBs differ from those of FDA. Areas that FDA would consider critical were identified as non-critical by some of the CB auditors.
- CB programs that initially appeared comparable to FDA's requirements were found to not be comparable following further review of audit reports and program implementation.
- Some CBs did not use risk-based criteria to determine which firms to audit or what types of products and processes to focus on during the audit. Instead, firms were chosen based on contractual agreements.
- Some CBs' auditing personnel were not trained nor had specific knowledge regarding FDA's general food, seafood, labeling, or other regulatory requirements.[10]

FDA states that it will have to clarify the required attributes for CBs in its third party certification program. This is true; however it is clear that ensuring that CBs actually meet these attributes through FDA oversight and assessment will be just as important. FDA will also have to develop training for auditors to ensure that they understand FDA regulatory requirements, have adequate food safety knowledge and training, and meet FDA standards for conducting audits.

FDA notes in its Shrimp Pilot Report that three critical elements were not met in 70 percent or more of the observed processor audits. These elements include:

- Understanding how to identify, evaluate and control food safety hazards associated with the product and process being audited.
- Recognizing deficiencies through HACCP plan and record review.
- Recognizing deficiencies in identification and control of hazards through in-plant observations.[11]

These elements are fundamental to any food safety inspection. If those elements are missing, auditors would not be able to identify whether a food safety system is working properly. FDA would not tolerate such a lack of competence among its own inspection force. If auditors cannot adequately carry out these elements, they should be considered unacceptable for the Third Party Certification Program. Any CB which allows such auditing to take place should be considered unacceptable as well. The fact that these elements were not met in 70 percent or more of the observed audits raises serious concerns about whether FDA would be able to rely on CBs and auditors to conduct this work at all.

The Shrimp Pilot report also listed some key considerations in developing a third party certification program that are worthwhile to note. These speak specifically to internal challenges the agency must overcome in order for FDA to adequately administer a third party certification program.

- FDA needs to provide a well-defined point of coordination and decision-making within the Agency.
- FDA needs significant logistical and resource support to establish and maintain a third party certification program. Direct accreditation by FDA of third-party certification bodies would be particularly resource intensive.
- FDA should enhance existing and create new IT data systems to capture and report on results of assessments and audits. This is especially important in order to provide sufficient transparency to stakeholders.

[10] Food and Drug Administration, "Assessment of the Third Party Certification Pilot for Aquacultured Shrimp," July 2011.
[11] *Ibid.*

- FDA should be clearer about its expectations for application to a third-party certification program. FDA should make its application process more clear and transparent with more opportunities for early interaction with FDA.
- FDA should create standardized procedures and forms to use in evaluating participants in a third-party certification program and train FDA personnel in these standards.[12]

Transparency and Credibility

In order for FDA's proposal to be effective, it will have to be considered credible, particularly to the public. One important key to that credibility is transparency of the entire process, including all the entities involved. The public will need access to information about the process as well as the entities involved to feel confident that the program has sufficient safeguards and oversight to operate effectively.

Consequently, CFA strongly supports FDA's proposal to post on its website a list of recognized accreditation bodies and accredited auditors/certification bodies. However, FDA should also provide public access, through posting on the agency' website, the regulatory audit reports and self-assessment reports required under the rule. This would provide the public with a better understanding of how accreditation bodies and certification bodies were conducting their business as part of the Third Party Certification Program and whether they were meeting their obligations under the rule.

CFA further supports posting additional information concerning the scope of the accreditation body and certification body, duration of accreditation, scope of accreditation, payments made to those bodies, and whether accreditation has been withdrawn or suspended, among other requirements.

Accreditation Bodies

Recognition of Accreditation Bodies

CFA supports FDA's determination that an accreditation body (AB) must demonstrate that it has the legal authority, competency, and capacity to conduct its responsibilities under the proposed rule and that it has sufficient conflict of interest requirements in place. In particular, an accreditation body should have authority to withdraw accreditation for cause, something which could be included in the contractual agreement between an AB and a certification body (CB).

Requirements for Recognized Accreditation Bodies

CFA generally supports FDA's proposed requirements for accreditation bodies, including the requirement for ABs to observe a statistically significant number of onsite food safety audits by a third party auditor seeking accreditation. CFA strongly supports the requirement for ABs to annually assess each of its accredited auditors/CBs to determine whether they are complying with the requirements of the rule. The Government Accountability Office pointed to a challenge of ensuring the competency of third parties to consistently apply standards.[13] An annual review of CBs to ensure they are meeting the requisite standards will be important to improving their reliability and ensuring their competency. This is especially important as the program is getting started. Consequently, CFA supports more frequent reviews as necessary.

[12] *Ibid.*

[13] Government Accountability Office, "FDA Can Better Oversee Food Imports by Assessing and Leveraging Other Countries' Oversight Resources." GAO-12-933, September 2012.

CFA also supports the requirement that ABs immediately notify the FDA when they grant accreditation to an auditor/certification body or when they withdraw, suspend or reduce the scope of an accreditation under the program. This will be important to keep FDA regularly informed about the accreditation activities occurring under the program and allow the agency to take any requisite action based on this information in a timely manner.

CFA further supports the conflict of interest requirements which will help build credibility into the system. FDA should define the de minimis value for onsite meals to ensure consistency and clarity across the system.

Procedures for Recognition of Accreditation Bodies
CFA supports FDA's proposed procedures for ABs to follow when applying for recognition or renewal. These procedures are a reasonable way to provide basic information for the agency about the ABs' eligibility to participate. CFA supports FDA's determinations regarding the circumstances under which the agency will revoke recognition of the AB as well as the subsequent processes described in the proposed rule. FDA should not hesitate to take these actions if necessary; this will encourage other entities in the system to conduct their activities appropriately in order to avoid losing recognition. CFA supports FDA's decision to provide public notice on the agency's website when an AB's recognition is revoked. Doing so will help ensure credibility and transparency of the system.

CFA strongly supports FDA's intention to conduct onsite audits of certified entities with or without the presence of the auditor or CB. By conducting an onsite audit with an auditor or CB, FDA could better understand how the auditor was conducting the audit. However, FDA may still wish to conduct an onsite audit without an auditor or CB to verify that the auditor's findings were consistent with FDA's expectations. CFA strongly encourages FDA to regularly implement this authority to verify the credibility and adequacy of the audits being conducted, particularly in the first several years of the program. FDA must ensure it has sufficient funding and capacity to conduct adequate oversight of the entire program.

Third Party Auditors/Certification Bodies

Requirements for Third Party Auditors/Certification Bodies
CFA generally supports FDA's proposed requirements for third party auditors/certification bodies, including requirements to conduct audits to FDA standards, submit reports and notifications to FDA as necessary, and have written conflict-of-interest policies.

FDA indicates in the proposed rule that it will release draft model accreditation standards for auditors. These standards would be helpful to review in combination with FDA's proposed rule and we encourage the agency to release the draft standards in the near future.

FDA should strongly consider providing auditors/CBs with a standardized audit tool for regulatory audits so that the agency will be provided with standardized data that can be easily analyzed. FDA could require auditors/CBs to use a standardized tool as a condition of participation in the program.

Requirements for Recognized Third Party Auditors/Certification Bodies
CFA generally supports FDA's proposed requirements for recognized third party auditors and certification bodies. CFA supports FDA's determination that the competency of an auditor must be

determined, in part, by observations of the auditor conducting food safety audits under FDA standards. Conducting audits under private standards will likely be different than conducting audits to FDA/FSMA standards under the auspices of FDA's Third Party Certification Program. Considering some of the important differences, such as the statutory requirement for auditors to report conditions "that could cause or contribute to a serious risk to the public health," it is important that FDA and CBs have confidence that the auditor can adequately perform the necessary audit functions under this program. It was clear from FDA's Shrimp Pilot program that some auditors were not trained nor had specific knowledge regarding FDA's food safety regulatory requirements.[14]

CFA supports FDA's determination that auditors must participate in annual food safety training. It is important that individuals assessing a company's food safety system, whether they are government inspectors or third party auditors, have the most up to date and relevant training to adequately do their jobs. FDA should consider how best to communicate to training programs or institutions any important issues the agency has identified in its oversight of the Third Party Certification Program which it thinks would be useful to include in training courses.

CFA supports FDA's determination regarding the type of information that should be included in both consultative audits and regulatory audits. CFA further supports FDA's determination on the type of information that should be submitted to the agency for each certification.

CFA supports requirements for auditors/CBs to perform annual self-assessments and submit those assessments to the AB. Identifying problems and documenting corrective actions will be particularly important as part of these self-assessments. CFA further supports FDA's requirement that auditors/CBs immediately notify the agency upon withdrawing or suspending a certification. This will be important so that FDA is aware of a facility's current status and can take other actions as necessary in a timely manner.

CFA generally supports the conflict of interest requirements in the proposed rule, which are important to maintaining the integrity of the program. In particular, CBs should post on their website the list of certified entities including information about the duration and scope of the certification. FDA should then either repost the same information or provide a link from its website to this information so that the public can be adequately informed. FDA should also define the de minimis value for onsite meals to assure consistency and clarity across the system. Finally, CFA supports FDA's recordkeeping requirements for auditors/CBs.

- **Auditor notification obligation**

An important provision of Section 808 of FSMA is subsection (c)(4) which requires auditors or CBs to immediately notify the FDA if the auditor discovers a condition which "could cause or contribute to a serious risk to the public health." CFA supports the inclusion of "immediately" in the regulation; immediate notification is critical in situations where the public may be at risk. While the law does not define "serious risk to public health" CFA agrees with FDA that the definition should be broader than the SAHCODHA standard and should encompass what would be considered both Class I and Class II food recall standards. It should also be clear that this requirement applies not only to regulatory audits but to consultative audits as well. Additionally, FDA should consider whether reporting the condition to the CB which then reports the condition to FDA might result in delays in FDA receiving important information. A

[14] Food and Drug Administration, "Assessment of the Third Party Certification Pilot for Aquacultured Shrimp," July 2011.

better approach to protect public health would be for FDA to require the auditor to directly report the condition to both FDA and the CB at the same time.

- **Unannounced audits**

Another important provision of Section 808 of FSMA is subsection (c)(5)(C)(i) which requires audits to be unannounced. Unannounced audits are important so that auditors, to the extent possible, can witness the typical conditions in a food facility rather than atypical conditions that could be imposed in advance of an announced audit. While CFA would prefer that audits under this program could occur at any time, FDA has proposed a reasonable approach for scheduling an audit by requiring auditors to ask for an eligible entity's 30-day operating window. This balances the requirement that the audit be unannounced with the need to ensure that the appropriate personnel are available at the food facility during the audit. However, FDA's proposal to require auditors to review an entity's records via an announced visit prior to conducting an unannounced onsite audit erodes the utility of requiring "unannounced" audits. A records review could be unannounced just like an onsite audit could be. If an auditor conducts an announced records review, the facility will be on notice that an onsite audit will likely be occurring very soon. This narrows the window from 30 days to a much shorter timeframe. CFA urges FDA to maintain the integrity of the unannounced onsite audit component of this provision.

Procedures for Third Party Auditors/Certification Bodies

CFA supports FDA's determination to require ABs to annually assess the performance of each auditor/CB as well as FDA conducting its own assessment of each auditor/CB at least once every three years. Both these assessments are important to build credibility and oversight into the program.

CFA supports FDA's proposal regarding withdrawal of accreditation from an auditor/CB. The mandatory withdrawal is required under FSMA, while the discretionary withdrawal identifies when FDA can find good cause to withdraw accreditation. FDA should not hesitate to exercise its authority in either case to maintain the integrity of the program. Strong action by FDA will encourage other entities in the system to conduct their activities appropriately in order to avoid losing accreditation. As proposed, a demonstrated bias or lack of objectivity or performance that calls into question the validity of an auditor's food safety audits and certifications are both valid reasons to withdraw accreditation from an auditor/CB. Any withdrawal of accreditation should be posted to FDA's website so the public can be informed.

Proposed Requirements for Eligible Entities

In addition to regular and thorough oversight of accreditation bodies, certification bodies, and auditors, FDA may also conduct an onsite audit of an eligible entity that has received certification under this program. FDA should conduct random as well as targeted audits of eligible entities, especially in the early years of the program to ensure the program is operating as intended. (FDA should conduct random and targeted audits of ABs, CBs and auditors as well.) FDA should also conduct onsite audits of a sample of entities if FDA withdraws accreditation for that entity's auditor/CB. Finally, FSMA requires, and FDA specifies in its proposed rule, that a food safety audit under this program is not considered an inspection under Section 704 of the FD&C Act, a concept CFA endorses.

Domestic Third Party Certification Program

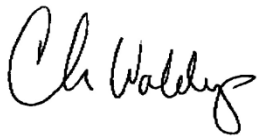
FDA seeks comment on whether the agency should establish a program administered by FDA for the use of accredited auditors/certification bodies to conduct domestic food safety audits. CFA strongly opposes this. FSMA expressly states that third party certification can be used for imports but the law does not allow third party certification for domestic use. If Congress had wanted FDA to develop a third party

certification program for domestic use, Congress would have made such an option explicit in the legislation. Instead Congress established, for the first time, minimum inspection frequencies for the agency, emphasizing the importance of FDA maintaining a dedicated inspection regime, particularly for domestic facilities.

CFA strongly urges FDA to focus its efforts regarding third party certification on building a credible system for imports as directed by FSMA. It is especially premature to consider third party certification domestically when the program for imports is only in the proposed rule stage.

CFA appreciates the opportunity to comment on this important proposed rule.

Sincerely,



Chris Waldrop
Director, Food Policy Institute