Association of Food and Drug Officials

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January 20, 2014

Department of Health and Human Services
Food and Drug Administration

RE: Comments from the Association of Food and Drug Officials
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 and Drug Officials (AFDO) is pleased to provide comments to the U.S. Food and Drug Administration regarding its proposed rule "Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications".

AFDO is the preeminent organization of federal, state and local regulatory officials in the United States. AFDO's membership also includes non-voting representatives from industry, academia, and consumer groups who actively participate in AFDO committees, workgroups, and other organization efforts. During its 117 year history, AFDO has promoted uniform, science-based food safety laws and regulations and is well-recognized for advocating a nationally integrated food safety system that would coordinate government resources at all levels in order to reduce duplication of efforts and allow government officials to meet food safety challenges in a more strategic fashion. AFDO also supports the concept of an integrated and coordinated global food safety system which we believe can be advanced, in part, through this proposed rule.

This proposal contains requirements for accreditation bodies seeking recognition by the FDA as well as requirements for third-party auditors seeking accreditation. As FDA wishes to leverage the food safety efforts of accreditation bodies and third-party auditors, it will be critical for FDA to assure the competence and independence of those participating in this program.

Imported foods have created a number of issues for state and local government regulatory agencies. Imported foods that pass through the scrutiny of federal agencies and are marketed domestically become the primary responsibility of state and local agencies that perform the overwhelming majority of food safety inspections in this country. Although some state and local agencies may not have the resources to evaluate the safety of imported foods that have been marketed, there are a number of states that have active imported food programs and who report to FDA or other federal agencies significant concerns for violative imports entering this country.

AFDO believes it will be critical for FDA to communicate closely with state and local food safety officials to remain aware of any imported food issues encountered domestically. In its comments to FDA on the Foreign Supplier Verification Program (FSVP) proposed rule, AFDO provided data from the NYS Department of Agriculture & Markets that clearly illustrates New York's issues associated with imported foods.

Issues such as uneviserated processed fish, illegal colors, illegal food additives, knockoff products, undeclared allergens, and food products found to be adulterated with pathogens or high levels of aflatoxin have been documented in New York for over a decade. NYS Department of Agriculture & Markets communicates these matters with FDA and other states. AFDO is also aware of other state food safety programs which have expressed concerns with the safety of imported food. AFDO and the states anxiously await advancement of this proposed rule and what we hope will be the overall improvement of marketed foreign produced food products. We ask FDA to strengthen communication with state agencies to be mindful of any food safety issues state agencies encounter with imported foods.. We also expect that FDA will recognize the important role of state and local food safety agencies in the overall systematic control being designed for imported foods.

As with our comments relative to FSVP, AFDO believes it is important that a level playing field is maintained in our system for controlling food safety globally. This rule however places specific requirements on foreign manufacturers that are not necessary for domestic manufacturers. It is also true, however, that domestic manufacturers are routinely inspected by state or local government food safety agencies, where enforcement actions are taken as appropriate. According to FDA, in 2011 there were 167,033 domestic food and feed establishments registered under 21 CFR; Section 415 Registration of Food Facilities. The 2008 State and Local Resource Survey published by AFDO in 2009 indicates that state and local agencies perform approximately 4.6 million food safety inspections annually which includes over 290,000 inspections at food and feed processing, packaging, warehousing, and distributing facilities. In many states establishments considered to be high risk are inspected more frequently than once a year. In addition state and local agencies conducted over 170,000 enforcement actions, 1200 food recalls, and collected over 390,000 food products that were tested in their laboratories. It is unlikely that foreign manufacturing establishments are exposed to this level of government oversight. FDA has indicated there were 254,088 foreign facilities registered in 2011.

AFDO's comments are as follows:

1.) The proposed rule contains procedures for recognition and accreditation as well as requirements relating to monitoring and oversight of participating accreditation bodies and auditors. This information must be shared with the states, since states are providing the majority of oversight over domestic firms. Imported foods may be marketed from an unaccredited body or from a source where monitoring or oversight have not been provided. Information will leverage States resources in identifying and removing unapproved foods from the marketplace.

2.) The proposed rule contains requirements relating to auditing and certification of foreign food facilities and food manufactured in these facilities, and for notifying the FDA of conditions in an audited facility that could cause or contribute to a serious risk to the public health. Under the proposed rule, a third-party auditor/certification body would have to notify FDA immediately upon discovering, during a food safety audit, a condition that could cause or contribute to a serious risk to the public health, as a condition of its accreditation. While this requirement will allow FDA to respond quickly, it is unclear when the food plant is notified. In addition to early notification to FDA, it is important that the plant be notified immediately so that corrective action could be taken. In addition, the proposed rule is unclear as to when such a condition discovered at a plant would be required for reporting in the Reportable Food Registry [RFR]. Without alerting the plant immediately a condition could continue to exist beyond the 24 hour RFR reporting requirement.

3.) The Foreign Supplier Verification Programs (FSVP) proposal does not require the use of accredited third-party auditors, which we believe is problematic. FDA anticipates that once the FDA accreditation system is in place, importers may increasingly rely on audits by accredited third parties to meet their supplier verification requirements under FSVP. AFDO does not support the use of non-accredited third-party auditors to assure the safety of imported foods. We believe there can be suitable numbers of accreditation bodies to accredit auditors.

4.) AFDO fully supports the functions of accreditation bodies as proposed in this rule to:

- assess third-party auditors for accreditation;
- monitor performance of the third-party auditors it accredits and notify the FDA of any change in, or denial of, accreditation;
- assess and correct any problems in its own performance;
- submit reports and other notifications to the FDA;
- protect against conflicts of interest; and
- maintain and provide the FDA access to records.

AFDO, also, believes that accreditation bodies should provide assistance and support to auditors while they are performing their auditing function. This should include real time scientific and technical support.

5.) AFDO does believe FDA should provide examples of specific types of entities that may meet the definition of "eligible entity". We do not believe that producers located in geographic proximity organized under a single management and marketing system and whose farms are "uniform in most ways" should be certified as a group. As such, we do not support the National Organic Program (NOP) relevant in determining whether a cooperative organization is an eligible entity nor do we support group food certifications.

6.) As a representative of state agencies, AFDO fully supports the requirement to have an accreditation body or third-party auditor/certification body perform a self-assessment to determine whether it meets the proposed rule requirements. This is consistent with the Manufactured Food Regulatory Program Standards (MFRPS) for State food regulatory programs. MFRPS require States to conduct periodic self-assessments of their food regulatory programs and to maintain consistency and fairness; we believe accreditation bodies and third-party auditor/certification bodies should be held to comparable standards. Records including an improvement plan should be provided to FDA and where applicable, to accreditation bodies.

7.) The international community has stated they intend to impose the same regulations on exports from the United States that this rule will impose on them. If this is true, these countries may require accreditation of federal and state inspectors to certify certain products, or as part of a voluntary importer program.

State regulators would prefer, however, to be considered equivalent to FDA as measured by the Manufactured Food Regulatory Program Standards. In our view, states will not want to be categorized with private companies that receive accreditation. This potential issue should encourage FDA to work on state system recognition and domestic equivalency determinations, and fund states to conduct the work to help meet demand.

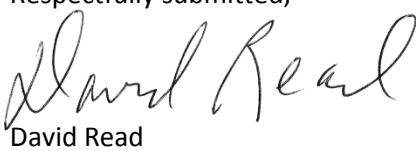
8.) The rule is not clear what requirements exist, if any, for unaccredited auditors performing consultative audits. AFDO requests clarification from FDA on this issue.

9.) Accreditation bodies will play a key role in this proposed rule and we, therefore, believe these bodies must have adequate legal authority to meet the requirements. Failure to have the ability to withdraw accreditation greatly weakens the desired accreditation system. It could permit the existence of an accreditation body which does not meet the competency and capacity requirements for recognition. We do not support accreditation bodies that lacked this particular authority.

10.) There will need to be protections in place against conflicts of interest when an accreditation body has to qualify for recognition. Written quality assurance plans should include assurances of independence and safeguards to address any possibility of conflicts with accrediting auditors/certification bodies.

AFDO believes the enactment of all proposed FSMA rules should occur fairly close together. The rules all interact and their application will be a huge advancement in developing a globally integrated food safety system.

Respectfully submitted,



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