

2013-2014 AFDO FINAL COMMITTEE REPORT

Attachments



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Comments Third
Party Accreditation R



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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA-2011-N-0143]

RIN 0910-AG64

Foreign Supplier Verification Programs for Importers of Food for Humans and Animals

Official Comments from the Association of Food & Drug Officials [AFDO]

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 “Foreign Supplier Verification Programs for Importers of Food for Humans and Animals”.

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.

General Comments

AFDO recognizes that the primary purpose of the proposed regulations is to ensure that imported food is produced in a manner consistent with U.S. standards. Although FDA applies the same food safety standards to all food marketed in the United States regardless of where it was produced, FDA has taken different regulatory compliance approaches to products produced domestically and abroad.

FDA has indicated that there are more than 250,000 foreign food facilities registered to export food to the United States and it would be impractical to expect that FDA could routinely inspect all of these facilities in a comprehensive manner. AFDO supports, for this reason, FDA’s effort to advance a verification system to assist in dealing with foreign manufactured foods. Whatever the form of verification that is applied to foreign manufacturers, however, must be credible in order to assure these foods have been manufactured under the same sanitary conditions to be required of domestic producers. To properly address a global food supply system and for the purpose of fairness, we believe there must be a level playing field between domestic and foreign produced food when mandating food safety controls.

Role of State and Local Agencies

AFDO believes that state and local food safety regulatory authorities can play an important role in assuring the effectiveness of this verification system through the inspection and surveillance of imported food products marketed domestically to establishments routinely inspected by state and local agencies. State and local agencies inspect food processors, warehouses, ethnic retail food stores, and restaurants where imported foods are commonly encountered. In addition, foodborne illness outbreaks are generally first reported to and investigated by state or local health agencies. We would caution FDA not to ignore state and local oversight of domestic facilities where imported products are marketed and during any illness outbreaks investigated by state or local health agencies where imported products are involved. This information that can be provided by state and local agencies can, in part, be a mechanism for measuring the effectiveness of the proposed rule.

We refer FDA to the NYS Department of Agriculture & Markets; Division of Food Safety & Inspection data in Attachment 1 and Attachment 2:

Attachment 1 Food Recall Summary 2000-2012

Attachment 2 Recalls by Country

The data clearly illustrates, in our view, the critical role that state and local food safety agencies could play in the oversight of imported food and its association to a foreign verification system. It leads us to ask the following of FDA:

Does FDA have a specific vision relative to the roles state and local agencies might play with regard to imported foods?

Will FDA accept state or local food sampling analysis as grounds for taking action against a foreign manufacturer or importer?

Will FDA continue to work with states in issuing import alerts based on state food sampling analysis?

How will enforcement of violative imported food products be addressed and would there be circumstances where state and local agencies might be utilized?

FDA must recognize the value of state and local agency inspection efforts and the foodborne illness and food testing surveillance that may be conducted for imported foods. In a truly integrated food safety system, such a partnership must exist. AFDO is willing to work with FDA on training of state and local officials to expand this opportunity for partnering.

Furthermore, where states are willing and have the resources to conduct surveillance on imported food products, FDA should develop a formal mechanism for the states to supply this information to FDA so that FDA may combine the state surveillance information with internal FDA information in order to better target import inspection and review of problem products, companies and countries.

FDA can expand state influence and impact with imported food issues by becoming more open and transparent with records of imported foods distributed within the states. This consideration should be made within states that are able to dedicate some of their resources to imported foods.

Inspection frequency

FDA indicates that it will only be able to inspect foreign facilities at a frequency of 10 years or more, while domestic food facilities can expect an inspection rate of once every 3 to 5 years depending on the level of risk. In our view, this inspection rate is inadequate to ensure a level playing field between domestic and foreign producers.

Recognizing the work of the states enrolled in the Manufactured Food Regulatory Program Standards can help FDA meet its inspection obligations internationally while relying on equivalent state inspections performed domestically. In order for FSMA to be successful, FDA needs to pursue funds to invest in state agencies that can assist them in meeting inspection mandates.. Congress did not provide all necessary funds when it passed FSMA, and FDA needs to position itself to get the proper funds. FSMA cannot be an unfunded mandate.

Definitions

Proposed § 1.500 would define qualified individual as a person who has the necessary education, training, and experience to perform the activities needed to meet the requirements of this subpart; this person may be, but is not required to be, an employee of the importer. FDA is directed to establish a system for determining whether an individual is qualified and whether the education and training provided to a qualified individual is from an accredited source. In our opinion, whatever system is established, it should include a set of minimum qualifications approved by FDA for determining what a qualified individual is.

AFDO is a strong supporter of the various Alliances that have been formed within the seafood, juice, produce, and food manufacturing industries to provide necessary food safety assurance training for individuals working in these industries. We believe similar Alliances could be formed to develop and deliver standardized training for auditors conducting foreign verifications. We further believe that foreign manufacturers should not be permitted to rely on third-party

auditors who have not received food safety preventive control training that is from an accredited source using a standardized training program. Importers can verify that individuals have received this necessary training through a data management system which identifies approved courses and individuals that have successfully completed the training course. This is precisely how this matter is addressed in the Seafood HACCP Alliance. The approval and numbering of courses is most useful in controlling issues associated with fraudulent certificates.

Proposed § 1.500 would define very small importer as an importer, including any subsidiary, affiliate, or subsidiaries or affiliates, collectively, of any entity of which the importer is a subsidiary or affiliate, whose average annual monetary value of sales of food during the previous 3-year period (on a rolling basis) is no more than \$500,000, adjusted for inflation. AFDO generally opposes the use of monetary values in regulations for the purpose of determining the size of an establishment or determining the importance or significance of circumstances there. In our view they are generally unenforceable. Will there be a need to determine the monetary value of an importer, and if so, who will make this determination?

Applicability and Exemptions

Proposed § 1.501(b) through (e) set forth exemptions and exceptions from subpart L for several types of foods: food from juice and seafood HACCP facilities that are in compliance with the HACCP regulations; food imported for research or evaluation purposes; food for personal consumption; alcoholic beverages; and food that is transhipped or imported for further processing and export. This is another area that AFDO traditionally opposes as exemptions and exceptions are usually unenforceable, as well. While we understand the logic in providing exemption and exception for juice and seafood facilities, food imported for research or evaluation, food for personal consumption, and alcoholic beverages, we would caution exempting food to be transhipped or imported for further processing. This, in our view, shifts the burden of food safety assurance of an imported ingredient to a domestic manufacturer. While the domestic manufacturer will be required to develop a food safety plan, they will be denied assurance that an imported product used in their product has been safely produced. This seems unwise to us and we ask that FDA clarify its reasoning here.

The proposed rule would require food for research or evaluation be labeled with the statement "Food for research or evaluation use". Furthermore, when entry for the food is made with U.S. Customs and Border Protection [CBP], the importer of record must provide an electronic

declaration that the food will be used for research or evaluation purposes only and will not be sold or distributed to the public. Our only suggestion here would be to require the labeling to be permanent and affixed to the product to eliminate any misgivings.

Under proposed § 1.501(d), the regulations in subpart L would not apply to food that is imported for personal consumption, provided that such food is not intended for retail sale and is not sold or distributed to the public. This is an area where we believe problems can occur. As representatives of the state and local officials who conduct the overwhelming majority of retail food establishment inspections, we are well aware of the numerous issues and infractions which occur at retail with imported foods. Proposed § 1.501(d) states that food is considered to be imported for personal consumption when it is purchased or otherwise acquired by a person in a small quantity for a non-commercial purpose and is not sold or distributed to the public. Our experiences have shown that small ethnic food stores have offered for sale food from their native countries that they have shipped or smuggled in for personal use. Identifying a quantity of product for controlling this is very difficult, in our view. Controlling this at the retail establishment is difficult as well, since the establishments that violate this rule generally do not maintain any shipment records or invoices. AFDO believes the best way for controlling this is for state and local agencies to better coordinate with FDA Import Operations and U.S. Customs and Border Patrol [CBP] and share information where violations occur domestically. AFDO members especially from border states and states that receive high volumes of imported foods may have a good perspective on how this matter could be best handled and we encourage FDA to discuss this with those state and local regulators. AFDO is willing to assist in advancing this discussion. Sanctions against violating individuals and establishments should be strong and integrated.

Review of Compliance Status

Proposed § 1.504 would require an importer, before importing a food from a foreign supplier, to assess the compliance status of the food and the foreign supplier, including whether either is the subject of an FDA warning letter, import alert, or requirement for certification relating to the safety of the food, for determination of whether it would be appropriate to import the food from the foreign supplier. AFDO again references data Attachments 1 and 2 from New York Agriculture & Markets; Division of Food Safety & Inspection. This enforcement data and any other from state and local regulatory agencies should not be neglected, but integrated into any compliance information to be made available to importers. FDA should consider working with AFDO to identify methods for collecting and recording state and local data that may exist pertaining to imported food products for this purpose. We believe this is an area that has been sorely lacking and must be improved upon. If FDA is committed to integration, AFDO believes this is an area that must be included.

FDA has requested comment on what compliance information an importer should be required to obtain and consider regarding a food or foreign supplier as part of its food/supplier

compliance status review. At a minimum, AFDO believes the following information should be considered:

Recent inspection reports

Sample testing results [food product and environmental]

Adverse finding reports including those from all domestic and foreign government agencies. This information should include information about a foreign supplier's compliance standing with the food safety authority of the country in which it is located.

Records that indicate how recognized food safety hazards are controlled

FDA has requested comments on whether to include potential hazards that may be intentionally introduced for economic reasons. AFDO believes a review of data from FDA and state surveillance data could identify specific areas of concern. For instance, in New York State there have been documented issues of species substitution in imported ground fish found to contain raw pork and raw poultry. Raw poultry from SE Asia was recently banned from import into the U.S. because of concern for the spread of avian influenza. These matters were referred to FDA and USDA/FSIS and are an example of an economically motivated adulterant.

AFDO believes other circumstances including “knock off products” could be identified with a closer working relationship between FDA and state agencies. AFDO is willing to assist FDA in building closer relationships with state agencies that are active in imported food surveillance.

Verification Activities

Proposed § 1.506(d) states that if an importer conducts a hazard analysis in accordance with § 1.505 and determines that there are no hazards that are reasonably likely to occur with a food, the only requirement in § 1.506 with which the importer must comply with respect to that food is to maintain a list of its suppliers of this food in accordance with § 1.506(a). The importer would also need to reassess this determination at least every 3 years in accordance with proposed § 1.508. AFDO believes importers should be required to document, at least annually, their control of these hazards whenever a compliance event occurs with the product. . This should also be required for imported foods that are controlled through procedures implemented by the importer's U.S. customer.

Furthermore, an importer should be required to obtain, at least annually, written assurance from its customer that the customer is following procedures to adequately control a food safety hazard following a compliance event which occurs with the product.

AFDO supports the proposed Option 1 requirement to conduct or obtain documentation of onsite audits of foreign suppliers with respect to those hazards designated as "serious adverse health consequences or death to humans or animals" [SAHCODHA]. In our view, Option 1 creates more stringent auditing requirements on high risk foods and less stringent requirements on low risk foods while Option 2 creates less stringent requirements on all foods. Our preference is clearly Option 1.

Many in the food industry already rely on third-party auditors to accomplish verification of food safety controls and we expect that they will continue to do so. AFDO agrees there is considerable variance in the quality of auditing services and the nature of audit criteria. There is also a great lack of uniformity and we are well aware of the difficulty this can cause industry. Good Agricultural Practices [GAPs] audits provided by federal and state government can be much different from those provided by the private sector. In many cases producers are being required to obtain several food safety audits in order to market their product more broadly. AFDO supports the concept of a standardized audit by a competent auditor that has the education/experience from a standardized advanced HACCP training and a minimum amount of auditing expertise.

AFDO does not support allowing the importer to use other procedures that it may have established unless those procedures have been approved by FDA or a recognized authority as being appropriately based on the risk associated with the hazard.

Any audit performed as a result of this proposed rule should include a review and approval of all supplier food safety and quality programs.

AFDO believes importers should be permitted to rely on an inspection of a foreign supplier by FDA or an officially recognized or equivalent food safety authority in substitution of an onsite audit. It is doubtful, however, that FDA will be in these foreign firms on a routine basis unless there is a significant reason to do so. Therefore, if the importer is allowed to rely on an FDA inspection as "verification" of compliance, it should be time limited, but not more than 2 years. We further believe these inspections should be limited to specific products or activities that concern the same hazard(s) as the food for which the onsite audit would have been required.

Complaints, Investigations, and Corrective Actions

An importer might learn that a food it imported is adulterated or misbranded as a result of investigating a complaint (such as a consumer reporting becoming ill after eating an imported food), being notified by FDA (such as during an Agency investigation of possible contamination), through media reports, or by other means. This is another area where state and local food

safety regulatory agencies must play an important role given the local intelligence they maintain and their work with consumer complaints and food product investigations.

Does FDA plan to capture and utilize complaint and investigation data on imported foods developed by state and local agencies? We strongly suggest they do.

Food from Countries with Officially Recognized or Equivalent Food Safety Systems

FDA indicates it is developing an approach for systems recognition of food safety systems of foreign countries and determining whether their systems may be deemed comparable to that of the United States. AFDO believes the Manufactured Food Regulatory Program Standards are one acceptable model that can be used and recommend they be considered.

Consequences of Failure to Comply

AFDO believes the consequence of a failure to comply with the FSVP is grounds for refusal of entry of the food product into the U.S. from the supplier or importer that has failed to comply. Products which may have been marketed from these foreign suppliers should be found and placed under embargo or stop sale. FDA should work with state and local government authorities whenever possible.

AFDO has long believed that greater emphasis for regulating imported foods should be placed at the source of manufacturing and not solely at the domestic point of entry. In addition, these efforts should be harmonized with routine domestic surveillance of imported foods from federal and willing state agencies to form a more integrated oversight approach. This proposed rule is a strong and necessary step for fulfilling this objective.

Respectfully submitted,

Dave Read; AFDO President

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Parts 1 and 16
[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

Official Comments from the Association of Food & Drug Officials [AFDO]

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:

Dave Read

AFDO President

AFDO's 118th Annual Education Conference
International and Government Relations Committee
Sunday, June 22, 2014
Denver, Colorado

2:00 pm	Welcome	Committee Co-Chairs Bob Scales & Mark Roh
2:10 pm	Committee Intent for Globalization and International Integration and Cooperation	AFDO Rep Ron Klein and Joe Corby
2:15 pm	FDA's perspective on International Food Safety and Medical Product Regulatory Integration	FDA Rep Mark Roh
2:30 pm	Canadian Perspective Canadian Food Inspection Agency	Canadian CFIA Rep Stephen Baker
2:45 pm	Canadian Perspective Health Canada	Canadian HC Rep Robert Scales
3:00 pm	Mexican Perspective Comisión Federal para la Protección contra Riesgos Sanitarios	Ricardo Cavazos Cepeda Director General, COFEPRIS
3:15 pm	Facilitated Open Discussion between Audience and Panel Members	Joe Corby and Ron Klein
4:00 pm	Summation of Ideas and Potential Action Items	Committee Co-Chairs Bob Scales and Mark Roh
4:15 pm	Adjourn	

Handout materials: AFDO's International Engagement Concept Paper
Speaker Biography Summaries