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January 27, 2014

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

Re: Docket No. FDA-2011-N-0146, RIN 0910-AG66 - Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications

The Pet Food Institute (PFI) would like to thank the Food and Drug Administration (FDA or the agency) for the opportunity to comment on the Food Safety Modernization Act (FSMA) Accreditation of Third-Party Auditors/Certification Bodies proposed rule (Third-Party rule/proposed rule). Like FDA, PFI members are most interested in continuing to improve the safety of the US food supply, including cat and dog food. We are highly motivated to ensure that the Animal Food Preventive Controls, Foreign Supplier Verification Program (FSVP) and Third-Party rules, when finalized and implemented, represent the best efforts of FDA and stakeholders to use science- and risk-based approaches to identify and address potential food safety hazards.

Established in 1958, PFI is the voice of US pet food makers. PFI members account for more than 95 percent of the cat and dog food produced in the United States. For more than 55 years, PFI has worked with its members and US Government agencies (including FDA and the US Department of Agriculture) to educate dog and cat owners, veterinarians and others about pet nutrition and health, the need to balance pet ownership rights with responsibilities, and to maintain the highest standards of product integrity, safety and quality control. PFI counts among its membership 30 dog and cat food makers and more than 100 affiliate members who supply ingredients and raw materials to dog and cat food producers. Our members sell more than \$20 billion in cat and dog food products annually and export an additional \$1.5 billion.

General Comments

FSMA and its proposed rules represent the most comprehensive changes to FDA food safety regulation since the Food, Drug and Cosmetic (FD&C) Act was enacted in 1938, more than seventy years ago. In light of the novelty and magnitude of these proposed rules, as well as the interrelationship among them, animal food and agriculture stakeholders should have been given more than five months to conduct our review and provide comment. PFI acknowledges the deadlines set by Congress

in FSMA for publication of proposed rules, as well as the judicial constraints under which FDA is operating as a result of the U.S. District Court for the Northern District of California decision in the case filed by the Center for Environmental Health and the Center for Food Safety. As it is both PFI's and FDA's goal to promulgate FSMA final rules that ensure a robust food safety system, PFI would have appreciated more time to provide constructive and useful comments. Ultimately, PFI strongly supports FSMA and looks forward to working with FDA for the successful implementation of this revolutionary law. We appreciate FDA's engagement with stakeholders during the pre-rule making process and your readiness for open dialogue during the public comment period. We share the FDA's goal of establishing a regulatory framework that is protective of public health, risk-based and practical.

FDA has prepared this proposed rule in order to help it "ensure the competence and independence of third-party auditors/certification bodies who conduct foreign food safety audits." 78 Fed. Reg. 45,782 (July 29,2013). This rule and its accreditation program will also "ensure the reliability of food and facility certifications issued by third-party auditors/certification bodies that FDA will use in making certain decisions relating to imported food (including pet food and animal feed)" 78 Fed. Reg. 45,782 (July 29,2013). FDA also states its belief that "a trusted program for foreign food safety audits and food and facility certifications – with clear requirements, standards, and procedures and operated under government oversight – will be appealing to accreditation bodies, auditors/certification bodies, and foreign food facilities" 78 Fed. Reg. 45,782 (July 29,2013). Although PFI acknowledges that such an accreditation system may provide FDA with more information regarding foreign food and facilities, FDA's goal of creating a trusted system will have value only if the system is functional. In order for this system to function, FDA must recognize accreditation bodies in key trading partners, and those recognized accreditation bodies must accredit sufficient numbers of auditors/certification bodies that are qualified to audit/certify *both* human and animal foods as well as facilities that handle both categories of products. PFI also believes that FDA should not require certification for foods that the agency has identified as high risk or encourage companies to have their facilities certified until a recognized accreditation system for a particular country or region is able to certify foods and facilities, including those related to animal food production.

FDA stipulates in this proposed rule that certifications issued by accredited third-party auditors/certification bodies will be used to determine "whether to admit certain imported food into the United States that FDA has determined poses a safety risk." 78 Fed. 45,783 (July 29, 2013). PFI requests that FDA consider developing – and submitting for public review and comment – proposed criteria for the determination that a food poses a safety risk, as well as the criteria by which FDA will remove the designation from an imported food.

FDA, in issuing separate preventive controls proposed rules for human and animal food, acknowledges that separate regulatory approaches are necessary for human and animal food under FSMA. Despite this acknowledgment, PFI is concerned that the proposed rule for accreditation of third-party auditors and certification bodies has not sufficiently taken into account the characteristics of animal food production (including raw materials and ingredients) that require auditors and certification bodies to have qualifications and expertise that can differ significantly from those required for auditors and certification bodies of human foods and facilities. An auditor/certification body must have the necessary skills and expertise to evaluate a food or facility that handles raw materials, ingredients or finished animal food. We are concerned that an auditor/certification body might apply standards that should only apply to human food when auditing a facility producing raw materials, ingredients or finished food for pet food. For example, one of the differences between the requirements for human and animal food relates to cross-contact for allergens. Another example is that many of the imported

ingredients for human consumption are ready to eat and, by contrast, animal food ingredients typically are intended for incorporation into another food that will undergo further processing. Misapplication of human food standards to animal foods or facilities may result in an incorrect evaluation of an animal food or facility or failure to issue a certification. Program success will require any accreditation system recognized by FDA for a country or region to have sufficient auditors/certification bodies with the skills required to evaluate foods and facilities related to animal food production and, more specifically, pet food.

PFI objects to the proposal that FDA be notified regarding results of consultative audits when the accredited auditor/certification body identifies a hazard that constitutes a public health risk. Imposing such a requirement would have the effect of discouraging the use of the consultative audit as a valuable hazard identification tool. Moreover, access to such information is unnecessary because companies with food products in the US market already have a legal obligation to report to FDA, through the Reportable Food Registry, any food that the company believes or knows has a reasonable probability of causing serious adverse health consequences or death in humans or other animals. A significant unintended consequence of mandatory disclosure of consultative third-party audit findings will result in industry reluctance to use this valuable tool.

PFI supports FDA's efforts under FSMA to ensure the safety of the US human and animal food supply as well as the need to address risks posed by imported foods using limited resources. PFI is concerned, however, that the manner in which FDA implements this third-party accreditation system – together with the Foreign Supplier Verification Program – could profoundly impact both US access to imported foods and also US exporter access to foreign markets. For these reasons, we urge FDA to proceed with extreme caution and to implement these rules in a way that reduces the likelihood for any retaliatory action by foreign governments against either US access to foreign foods or US exporter access to foreign markets.

Finally, should FDA make any substantive additions to the accreditation system requirements in its final rule, PFI requests that the public and affected stakeholders be given another opportunity to comment. Significant changes to the regulations should be subject to notice-and-comment rulemaking procedures before they are implemented and imposed on importers and foreign suppliers.

Section-specific Comments

All section-specific comments are based on and make reference to the official version of the proposed rule issued by FDA and published in the Federal Register.

II. Background

Authority to Require Import Certifications for Food

FDA indicates that the certifications issued under this proposed rule will serve as the basis for entry of foods identified by FDA as subject to mandatory certification due to FDA's determination of a risk to public health or as the basis for a foreign facility to participate in the Voluntary Qualified Importer Program (VQIP). PFI believes strongly that FDA should not identify any food as high risk under Section 801(q) of the FD&C Act or encourage voluntary facility certification until an FDA-recognized accreditation system is in place for a particular country or region to issue certificates for foods and facilities, including those related to animal food production.

In order to target food safety resources to address legitimate food safety concerns, FDA must develop and rely on science- and risk-based criteria to determine whether a foreign food poses a public health risk, thereby triggering the mandatory certification requirement under FD&C Act Section 801(q). Information on such criteria is readily available within international bodies such as Codex, and organizations such as the Global Food Safety Initiative have extensive experience with foreign foods and facilities that will assist the agency in establishing and applying these criteria in a way that facilitates trade in safe, high quality foods.

III. FSMA Imports Public Meeting and Stakeholder Input

Capacity

FDA seeks comment on possible effects associated with the creation of an FDA program for accredited third-party audits and certification, with an emphasis on the availability of competent auditors/certification bodies to participate in FDA's program. FDA notes industry concern about "access to sufficient numbers of qualified third-party auditors/certification bodies under certain conditions." 78 Fed. Reg. 45,790 (July 29, 2013). PFI believes access to competent auditors/certification bodies is critical to the success of any accreditation system. Both the recognition of an accreditation body and accreditation of sufficient auditors/certification bodies must be complete before certification is required for any food imported into the United States.

FDA also asks if there are particular types of food firms or products "or certain areas of the world in which capacity issues are more likely to be prevalent and to what degree[.]" 78 Fed. Reg. 45,790 (July 29,2013). PFI members source raw materials, ingredients and finished foods from around the world and have significant experience working with foreign suppliers in a wide range of countries. PFI thus is well-positioned to provide input to FDA regarding capacity issues related to food firms, products or countries. Some specific concerns are enumerated below.

- PFI members have significant experience working with officials from foreign food safety regulatory bodies and have observed a wide range of expertise among officials in these regulatory bodies. With FDA recognition of an accreditation system for a given country or region, the recognized accreditation body will be responsible for accrediting auditors/certification bodies that will in turn be responsible for auditing/inspecting a wide range of foods and facilities. PFI is concerned that:
 - recognized accreditation bodies may be ill-equipped to accredit the number and type of auditors/certification bodies necessary for the accreditation system to function properly;
 - recognized accreditation bodies may focus their accreditation efforts on auditors/certification bodies that specialize in human foods and human food facilities; and
 - accredited auditors/certification bodies with little or no experience evaluating animal foods or facilities may audit/inspect such a food or facility and inappropriately apply human food criteria instead of animal food criteria.
- PFI believes that any fee structure for audits of eligible entities should not favor auditing of facilities producing human food over auditing of facilities producing animal food. Our concern is that it may be difficult to schedule an audit of a facility related to pet food if the number of auditors/certification bodies of animal food foreign suppliers is limited potentially due to a

disparity in audit fees. FDA's selection of accreditation bodies and other actions may affect the facility auditing fee structure for a country or region.

- FDA must ensure that there is capability among third-party auditors and certification bodies to issue certifications for human food and animal food facilities. This is particularly important for facilities that produce both categories of food. A single audit/inspection of such a facility should yield a certification that can cover both the human food and pet food ingredients/raw materials/finished products it produces.

IV. Purpose and Description of the Proposed Rule

Proposed §1.601: Who is subject to this subpart?

Foods determined to pose a public health risk

The proposed rule stipulates that facility certification under this proposed rule will serve two purposes – to determine eligibility for VQIP and to assist FDA in its efforts to control access for foods it has determined pose a public health risk. PFI believes strongly that no country should be deemed high-risk, but that a more targeted approach should be employed in order to meet the mandate set forth in § 801(q) of the FD&C Act. We also note that any attempt by FDA to deem all foods from a particular country as posing a US food safety risk would run afoul of the United States' World Trade Organization obligations, which require science-based regulations for food safety. Finally, FDA must establish a process for how a food identified as high risk can, at the appropriate time, have this designation removed.

Proposed §1.611: What legal authority must an accreditation body have to qualify for recognition?

Reassessments or surveillance necessary to monitor compliance of accredited third-party auditors/certification bodies

FDA stipulates in proposed § 1.611(a)(3) that an accreditation body, in order to qualify for recognition, must have the legal authority to, among other things, “[p]erform any reassessments or surveillance necessary to monitor compliance of accredited auditors/certification bodies...” which can include witnessing the performance of personnel and other agents conducting assessments. 78 Fed. Reg. 45,827 (July 29, 2013). Audits and/or inspections are time- and resource-intensive, so a foreign supplier, especially one in good standing that has been audited or inspected in the past year, may find it difficult to respond to random or unannounced audits/inspections that are unrelated to that facility's status but instead relate to the accreditation body's reassessment of an auditor's/certification body's performance. Accordingly, FDA must provide guidance regarding how a facility might be selected for an audit/inspection that relates to an accreditation body's reassessment of an auditor/certification body. Every attempt must be made to minimize the burden on foreign suppliers by reducing the frequency and likelihood of audits or inspections that are unrelated to a food or facility certification that either is mandatory for a high-risk food or required for facility participation in the Voluntary Qualified Importer Program.

Proposed § 1.613: What protections against conflicts of interest must an accreditation body have to qualify for recognition?

PFI appreciates the approach FDA has taken regarding conflicts of interest in the proposed rule, seeking to ensure the integrity of accreditation bodies. 78 Fed. Reg. 45,797, 45,828 (July 29, 2013). PFI believes

strongly that the accreditation system must remain independent of other processes and developments, including those related to food safety, agriculture and other issues. We urge FDA to ensure the independence and integrity of accreditation bodies and the auditors/certification bodies that are accredited. For example, we FDA must give careful consideration to which government ministry/agency may be eligible for recognition as an accreditation body and to solicit input from stakeholders as to which ministries/agencies in a given country are best positioned to perform this function.

Proposed § 1.614: What quality assurance procedures must an accreditation body have to qualify for recognition?

PFI supports FDA's approach regarding the accreditation body quality assurance requirement. 78 Fed. Reg. 45,797, 45,828 (July 29, 2013). A program through which accreditation bodies monitor performance and effectiveness, "identify[ing] areas of improvement and quickly execute[ing] corrective actions," is essential to ensuring food safety. 78 Fed. Reg. 45,797 (July 29, 2013). These criteria already are established by food safety systems used around the globe, and PFI encourages the FDA to utilize established accrediting, auditing and certifying standards.

Proposed § 1.615: What records procedures must an accreditation body have to qualify for recognition?

Confidentiality

FDA notes that clause 4.4 of ISO/IEC 17011:2004 requires accreditation bodies to have "adequate arrangements to maintain the confidentiality of information obtained through its accreditation activities." 78 Fed. Reg. 45,798 (July 29, 2013). FDA states earlier in the proposed rule that it has chosen not to adopt/incorporate private standards into the accreditation body regulations. 78 Fed. Reg. 45,796 (July 29, 2013). FDA goes on to state that the accreditation body must grant FDA "access to confidential information, including information contained in records, without prior written consent of the auditor/certification body involved." 78 Fed. Reg. 45,798 (July 29, 2013). PFI members acknowledge that a properly functioning third-party auditing system requires the sharing of information and data to adequately determine compliance with regulatory requirements. However, PFI is particularly concerned about the maintenance of confidentiality when sharing information between FDA, accreditation bodies and third-party auditors/certification bodies. Information shared with auditors and food safety authorities is often sensitive in nature and may include confidential business information. It is imperative that only information required to ensure food safety is collected during third-party audits and that information is shared only with appropriate food safety authorities (i.e., FDA or recognized accreditation bodies).

PFI urges FDA to require accreditation bodies and auditor/certification bodies to implement stringent measures to protect all information gathered through audit activities, as the release of such information could have detrimental effects on US stakeholders and their foreign suppliers. Confidentiality protections are necessary for audits to be effective and to encourage robust scrutiny and open dialogue without creating fears about consequences from the resulting paper trail. PFI members support the use of Confidential Disclosure Agreements as a common business practice that enhances the protection of sensitive information.

As also stated in our comments to the Foreign Supplier Verification Program proposed rule, PFI is concerned that the proposed use of electronic records access introduces an opportunity for sensitive information to be compromised. The final rules thus must include stringent requirements for both

accreditation bodies and auditors/certification bodies in order to ensure the integrity of electronic systems used to transmit and store confidential information.

Proposed § 1.621: How must a recognized accreditation body monitor the performance of auditors/certification bodies it accredits?

Proposed § 1.621 requires accreditation bodies to evaluate annually each of its accredited auditors “to determine whether the auditor is complying with the applicable provisions of this rule.” 78 Fed. Reg. 45,799 (July 29, 2013). PFI applauds FDA in requiring this evaluation to be “a comprehensive assessment of the performance of each auditor/certification body it accredited under this subpart by reviewing the auditor’s/certification body’s self-assessments...; its regulatory audit reports and notifications submitted to FDA under § 1.656; and any other information reasonably available to the accreditation body.” 78 Fed. Reg. 45,828-29 (July 29, 2013). FDA seeks comment on whether its approach in proposed § 1.621 “will provide an appropriate basis for recognized accreditation bodies to use in evaluating auditors/certification bodies they accredited.” 78 Fed. Reg. 45,800 (July 29, 2013).

Although PFI understands the need for an accreditation body to “determine whether the auditor/certification body continues to meet the applicable program requirements and the conditions of its accreditation...” we are concerned that required annual reviews of all auditors/certification bodies will reduce an accreditation body’s ability to accredit new auditors/certification bodies. 78 Fed. Reg. 45,799 (July 29, 2013). Accordingly, we propose that the language section 1.621 be changed to read as follows: “A recognized accreditation body must, once every two years, conduct a comprehensive assessment of the performance of each auditor/certification body it accredited under this subpart...” This proposed change conforms with the approach in ISO/IEC 17011:2004 and would strike the right balance for accreditation bodies between the important tasks of accrediting new auditors/certification bodies and reviewing already accredited auditors/certification bodies to ensure they are meeting their requirements.

PFI supports FDA’s efforts in § 1.621 of the proposed rule to require accreditation bodies to ensure the compliance of accredited auditors/certification bodies. However, there should be certain limits established regarding the extent of such accreditation body assessments. Specifically, an incident involving a human food foreign supplier should only impact the accreditation body’s review of an accredited auditor’s/certification body’s certifications for human food and should not necessarily involve review of already issued certifications; rather, the accreditation body should seek to identify changes the auditor/certification can implement going forward. Such an approach would ensure that an accreditation body’s evaluation of an accredited auditor/certification body will focus on matters relevant to the certification, reducing the likelihood that a certification related to animal food will be jeopardized by a negative evaluation related to human food.

PFI also recommends that an instance in which a foreign supplier becomes the subject of an FDA import alert should not prompt a wholesale review of all suppliers audited by the same auditor/certification body. Such a review would be unwarranted no two audits are equal; each must take into account unique characteristics of the eligible entity (including, but not limited to, food type, facility, processing and end use).

Proposed §1.622: How must a recognized accreditation body monitor its own performance?

Coordination of accreditation body self-assessments with regulatory audits

As stated in our general comments above, an accreditation system will only be trusted if it is functional, and it will only be functional if there are in place adequate numbers of auditors/certification bodies for both human and animal foods and facilities. Accordingly, PFI agrees with FDA's proposed self-assessments by accreditation bodies as an efficient tool for accreditation bodies and FDA to assess and improve the accreditation system; however, the self-assessment should be done in concert with the accreditation body's reassessment of an auditor/certification body it has accredited. This approach would increase efficiency and reduce the burden on eligible entities and would be consistent with our comment on proposed § 1.621 to require assessments every two years. Again, internationally recognized industry standards (ISO IEC, for example) and practices can provide guidance to FDA that will improve the efficiency and effectiveness of an accreditation body's assessment of its own performance.

Proposed § 1.624: How must a recognized accreditation body protect against conflicts of interest?

Scope of Accreditation

Proposed § 1.624(c) would require a recognized accreditation body to maintain on its website a list of accredited auditors/certification bodies and "identify the duration and *scope* of each accreditation ..." (emphasis added). 78 Fed. Reg. 45,829 (July 29, 2013). The term "scope" must specify whether an accreditation will be for human food, for animal food, for specific rules, for preventive controls, for GMPs, etc. We also would like to propose that the scope of any accreditation clearly indicate whether an auditor/certification body is accredited to audit/certify foods or facilities related to human or animal food. This approach is justified by the fact that FDA has issued separate proposed rules for human and animal food preventive controls, in recognition of the different risks associated with each type of food and the different methods that can be used to address them.

Proposed § 1.625: What records requirements must a recognized accreditation body meet?

21 CFR Part 11

Proposed §1.625 would require a recognized accreditation body to "maintain electronically for 5 years records (including documents and data), in English, demonstrating its compliance with this subpart..." 78 Fed. Reg. 45,830 (July 29, 2013). PFI supports this proposal. PFI also supports the documentation of data chain of custody by requiring records to be signed and dated when created or modified. Although there is no reference to 21 CFR Part 11, Electronic Records; Electronic Signatures, within the proposed rule, PFI members would discourage FDA from mandating compliance with system controls as documented within 21 CFR Part 11. Requiring compliance with 21 CFR Part 11 would be onerous and costly to implement, ultimately increasing the cost burden on industry, with no appreciable improvement in food safety. Allowing reasonable records chain of custody procedures would permit resources to remain focused on food safety rather than on a costly data system.

Proposed § 1.631: How will FDA review applications for recognition and for renewal of recognition?

Evaluation of completed recognition or renewal application

PFI believes that stakeholders will have information relevant to any FDA consideration and review of a potential accreditation body and seeks assurance from FDA that such information will be solicited and used by FDA in any review of an accreditation body seeking FDA recognition. Importers and their foreign suppliers will have critical information based on firsthand experience regarding the capacity of proposed accreditation bodies. The final rule should include a mechanism for stakeholders to provide feedback to FDA concerning the capacity and functioning of recognized accreditation bodies. Accordingly, PFI proposes that § 1.631(b) be modified to read as follows: “FDA will evaluate any completed recognition or renewal application to determine whether the applicant meets the eligibility requirements in § 1.610 and will also solicit and consider information provided by stakeholders, including importers and foreign suppliers subject to the accreditation body’s jurisdiction, to assist in the recognition or renewal application review process. FDA will notify the applicant, in writing, whether the application has been approved or denied. FDA may make such notification electronically.”

In its discussion of the review of applications for recognition and for renewal of recognition (§ 1.631), FDA declines to include specific timeframes for review, citing the difficulty in projecting “the amount of resources that will be available for application review...” and an expectation that FDA will “become more efficient in processing applications as [it gains] experience...” 78 Fed. Reg. 45,803 (July 29, 2013). Although PFI acknowledges these factors are important and will no doubt impact FDA’s ability to review applications and issue recognitions or recognition renewals, we believe strongly that time limits for these reviews must be set in order to ensure the timely establishment of this new system. FDA notes that the accreditation review system is authorized to be funded by user fees (under Section 808(c)(8) of the FD&C Act), so resources for FDA’s activities under this section should be readily available.

In particular, we believe that a time limit of no more than ninety days would be appropriate and feasible for FDA to review a completed recognition application and no more than forty-five days would be appropriate and feasible for FDA to review a completed recognition renewal application. The final rule also should state clearly that these reviews will be undertaken and concluded in a timely manner so that trade will not be unnecessarily impacted. Imposing such a time limit for review of an application has significant precedent – FDA and other regulatory agencies routinely operate under time limits that not only facilitate decision making and accountability, but also create a necessary measure of transparency and predictability that is essential to foreign and domestic stakeholders seeking a federal government agency decision. Accordingly, we propose that section 1.631(a) of the proposed rule be modified to read as follows: “FDA will review a recognition or renewal application on a first in, first out basis according to the date on which the application was submitted in complete form. FDA will notify an applicant seeking recognition of a decision on its recognition application no more than ninety calendar days after receipt of a complete application. FDA will notify an applicant seeking renewal of its recognition of a decision on its recognition renewal application no more than forty-five calendar days after receipt of a complete application.”

Proposed § 1.634: When will FDA revoke recognition?

Revocation of accreditation body’s recognition

FDA proposes in § 1.634 that, following the revocation of an accreditation body’s recognition, FDA will notify each third-party auditor/certification body that was accredited by that accreditation body. The

proposed regulation also would establish that the accredited auditor/certification body will have no more than one year after the recognition revocation to become accredited by another recognized accreditation body or by FDA through direct accreditation. 78 Fed. Reg. 45,805 (July 29, 2013). PFI believes that this proposed requirement must be accompanied by a requirement that FDA either will renew the recognition of the recently revoked accreditation body or recognize a new accreditation body in time for any affected accredited auditor/certification body to comply with proposed § 1.634(d). If FDA will not renew/reinstate the recognition of the revoked accreditation body, the rule should state that FDA will solicit applications for a new recognized accreditation body after an accreditation body's recognition is revoked. For purposes of transparency and predictability, we believe that FDA also should be obligated to complete its review of any accreditation body recognition applications within a certain timeframe (we propose ninety days above) in order to allow the new accreditation body to accredit auditors/certification bodies. In the event FDA does not recognize an accreditation body within the required time period, the rule language should require FDA to grant extensions for auditors/certification bodies to meet the requirement in § 1.634(d)(ii) for accreditation by a recognized accreditation body or by FDA through direct accreditation.

Effect of revocation of recognition on food or facility certifications issued to eligible entities

PFI also notes in proposed § 1.634(e) that a food or facility certification issued by an accredited auditor/certification body prior to revocation of the relevant accreditation body's recognition "will remain in effect until the certificate terminates by expiration." 78 Fed. Reg. 45,831 (July 29, 2013). While this provision may not pose a problem for a food or facility that received its certification just prior to revocation of the accreditation body's recognition, we foresee a potential for trade to be disrupted for any food or facility with a certification set to expire in weeks or months following the revocation of an accreditation body's recognition, particularly if other accreditation bodies are not available in that country. Auditors/certification bodies will have to comply with self-assessment (§ 1.655) and reporting (§ 1.656(b)) requirements following the revocation of an accreditation body's recognition. With auditors/certification bodies focusing their attention on maintaining their status with FDA and then seeking accreditation with any recognized accreditation body, there is potential for the certifications of eligible facilities to lapse due to lack of auditors/certification bodies. Accordingly, we propose that the final rule stipulate that, in the event of revocation of an accreditation body's recognition, all certifications issued by auditors/certification bodies accredited by that accreditation body will remain in effect for one year from the date of the revocation of the accreditation, in order to reduce the likelihood that eligible facilities' certifications will lapse and to provide time for FDA select a new accreditation body that can begin accrediting auditors/certification bodies.

Proposed § 1.650 How must an accredited auditor/certification body ensure its audit agents are competent and objective?

Annual food safety training and Model Accreditation Standards

FDA proposes in § 1.650(a)(3) that all audit agents must participate in annual food safety training. 78 Fed. Reg. 45,810, 45,832 (July 29, 2013). However, the language in § 1.650(a)(3) makes no mention of the specific training audit agents must receive. PFI's position is that the required annual training for audit agents must relate to all relevant aspects of the FD&C Act so that audit agents can assess food facilities and food products properly.

FDA states that under § 808(b)(2) of the FD&C Act, it must develop “model accreditation standards to qualify third-party auditors for accreditation under this FDA program.” 78 Fed. Reg. 45,785 (July 29, 2013). The proposed rule includes a framework for the model accreditation standards, and FDA notes that it will be issuing draft standards that elaborate on the framework in order to seek public comment. PFI requests that FDA share with foreign and domestic stakeholders a timeline for publication and entry into force of these Model Accreditation Standards.

Proposed restriction on audit agents conducting regulatory audits

FDA, in § 1.650(c), proposes a thirteen-month minimum between regulatory or consultative audit visits by an accredited auditor/certification body to the same eligible entity. 78 Fed. Reg. 45, 810 (July 29, 2013). We note that this limitation is intended to ensure the competence and/or objectivity of accredited auditors/certification bodies, but we question whether an accredited auditor/certification body’s objectivity will be compromised by auditing an eligible entity more than once in a thirteen-month period. Indeed, an accredited auditor/certification body that has observed deficiencies during a recent audit of an eligible facility may be best positioned to ensure that those deficiencies have been addressed. The proposed limitation on visits also appears to presume that an accredited auditor’s/certification body’s objectivity will somehow be compromised by conducting more than one audit of an eligible facility within a specified time period, a presumption we believe merits reconsideration. Accordingly, PFI recommends that § 1.650(c) be removed from the proposed rule and that there be no restrictions on the frequency of audits an accredited auditor/certification body may conduct of an eligible entity in a given time period.

Proposed § 1.654: When must an accredited auditor/certification body monitor an eligible entity with food or facility certification?

Monitoring eligible entity based upon a “reason to believe” non-compliance with the FD&C Act

Section 1.654 addresses accredited auditor/certification body monitoring of an eligible entity with food/facility certification. Such a monitoring requirement is imposed “if an accredited auditor/certification body has *reason to believe* that an eligible entity to which it issued a food or facility certification may no longer be in compliance with applicable requirements of the FD&C Act” (emphasis added). 78 Fed. Reg. 45,834 (July 29, 2013). PFI is concerned that this standard may become subject to abuse by auditors/certification bodies and that the auditor/certification body conducting monitoring on this “reason to believe” basis should be required to notify the eligible entity immediately and before conducting such monitoring of the basis for its belief that the eligible entity may no longer be in compliance with the FD&C Act. Again, science- and risk-based decision making must be the standard for all aspects of this proposed rule.

Proposed § 1.656: What reports and notifications must an accredited auditor/certification body submit?

Consultative Audit Reporting

Consistent with the FSMA definition, FDA proposes in § 1.600 to define a consultative audit as an audit of an eligible entity, “the results of which are for internal purposes only and cannot be used to determine eligibility for a food or facility certification issued under this subpart or in meeting the requirements for an onsite audit of a foreign supplier under subpart L of this part”. 78 Fed. Reg. 45,792, 45,826 (July 29, 2013). FDA then proposes in § 1.656(c) to require that an accredited

auditor/certification body immediately notify FDA of any condition it or its audit agent discovers during a regulatory *or consultative audit* that “could cause or contribute to a serious risk to the public health...” 78 Fed. Reg. 45,815 (July 29, 2013).

PFI objects to this proposed notification regarding the results of consultative audits. Consultative audits are an important tool for importers and their actual or potential foreign suppliers to identify and evaluate food safety risks that may require preventive controls. These audits are widely used by the industry as a learning tool to assess and improve manufacturing processes and food safety practices. Importers may wish to conduct a consultative audit with a potential foreign supplier before establishing a business relationship or in advance of a regulatory audit as a way to identify and address any food safety risks. These consultative audits will take into account which entity – the foreign supplier or the importer – is responsible for or is addressing a risk. Furthermore, an unintended consequence of mandatory disclosure of consultative third-party audit findings will result in the reluctance of the industry to use this valuable tool. Finally, as noted in our General Comments above, companies are already under a legal obligation to report to FDA via the Reportable Food Registry any food that the company believes or knows has a reasonable probability of causing serious adverse health consequences or death in humans or other animals. Thus, the proposed requirement is redundant and would not enhance the food safety system.

Proposed § 1.660: Where do I apply for accreditation or renewal of accreditation by a recognized accreditation body?

Accreditation process timing

FDA describes the process for an accreditation body to accredit an auditor/certification body but does not indicate a time limit for the issuance of a decision by the accreditation body regarding an application submitted by an auditor/certification body. 78 Fed. Reg. 45,818, 45,836 (July 29, 2013). In order to enhance the value of this new system and to avoid negatively impacting trade, we propose that FDA establish a clear timeline for the accreditation process, both to set clear, measurable standards for the process and also to ensure an adequate supply of accredited auditors/certification bodies. We propose that the Model Accreditation Standards stipulate that an accreditation body that has received a complete application from an auditor/certification body seeking accreditation should issue a decision on the application within no more than ninety calendar days.

Proposed § 1.663: How do I request an FDA waiver or waiver extension for the 13-month limit for audit agents conducting regulatory audits?

Who may request an FDA waiver or waiver extension?

Under proposed § 1.633, FDA would provide a path by which an accredited auditor/ certification body “may submit a request to FDA to waive the requirements of § 1.650(c) preventing an audit agent from conducting a regulatory audit of an eligible entity if the agent has conducted a food safety audit of the entity during the previous 13 months.” 78 Fed. Reg. 45,836 (July 29, 2013). FDA makes no provision for a similar request by the foreign supplier or by the importer or any combination thereof. Notwithstanding our comment above that no arbitrary time limit should apply that restricts an eligible entity’s access to an auditor/certification body, PFI encourages FDA to provide an avenue by which such a request for waiver of the requirements of § 1.650(c) could be submitted by a foreign supplier and/or by an importer. Open communication between all parties involved in the third-party accreditation system should be encouraged, as transparency will lead to increased food safety.

Proposed §§ 1.691, How do I request reconsideration of a denial by FDA of an application or a waiver request?; 1.692, How do I request internal agency review of a denial of an application or waiver request upon reconsideration?; and 1.693, How do I request a regulatory hearing on a revocation of recognition or withdrawal of accreditation?

Opportunity for interested stakeholders to provide information to FDA

We note that FDA, in §§ 1.691, 1.692 and 1.693, would provide procedures for accreditation bodies and auditors/certification bodies to seek reconsideration by FDA of an application or waiver request, a denial upon reconsideration of an application or waiver request, or a revocation of recognition or withdrawal of accreditation. PFI suggests that FDA provide an opportunity for interested stakeholders to provide information to FDA that will inform its decision making on any such reconsideration request or during a regulatory hearing. Importers that have worked with an accreditation body or with third-party auditors or certification bodies can provide information that might be useful to FDA in any review it takes during a reconsideration request or regulatory hearing.

Timing of FDA decision regarding reconsideration

PFI also notes that, although submission of a request for reconsideration must be submitted within ten business days of the date of the denial of an application (proposed § 1.691(a)), FDA indicates only that it will notify the requestor in writing of its decision “[w]ithin a reasonable time after completing its review and evaluation of the request for reconsideration and the supporting information (if any) submitted...” 78 Fed. Reg. 45,822 (July 29, 2013). PFI believes this open-ended timeframe for FDA’s review of a reconsideration request may place an undue burden on the party seeking such reconsideration and establishes no clear time limit for FDA to conduct its review, reach a decision and notify the requestor of such decision. Accordingly, PFI proposes that the final language of § 1.691(d) stipulate that, “Within twenty business days after submission of a request for reconsideration, FDA will notify the requestor, in writing, of its decision to grant the application or waiver request upon reconsideration, or its decision to deny the application or waiver request upon reconsideration.”

Proposed § 1.698: May importers use reports of regulatory audits by accredited auditors/certification bodies for purposes of subpart L of this part?

Use of accredited auditors to conduct domestic food safety audits

Following its discussion of the use of regulatory audits for purposes of Subpart L of this part, FDA seeks comment “on the value of, and need for, a program established and administered by FDA for the use of accredited auditors/certification bodies to conduct domestic food safety audits.” 78 Fed. Reg. 45,823 (July 29, 2013). PFI seeks clarification from FDA as to what purpose such a program would serve and whether FDA is proposing to implement a domestic accreditation/ certification system similar to the one proposed for foreign facilities. Although PFI supports FDA’s efforts to ensure the safety of the US food supply, we question whether the statutory language supports any move by FDA essentially to privatize a major food safety function, that of audits and inspections of US food producers. PFI also notes that most US producers of human and animal food already engage in extensive evaluation and review of their ingredient and raw material suppliers. Imposing on US food producers another layer of regulation should be considered only if doing so will improve food safety appreciably – does FDA have evidence that privatizing its food safety operations through the establishment of an accreditation system of auditors/certification bodies for the purpose of conducting food safety audits is necessary to address specific food safety issues? Has FDA considered who would bear the costs for imposing such a

requirement on US food producers? PFI posits that such costs ultimately would be borne by US consumers. In light of the fact that FDA admits it cannot quantify the benefits of implementing third-party audits as part of the Animal Food preventive controls proposed rule, PFI discourages FDA from further consideration of a scheme to require food safety audits conducted by accredited auditors/certification bodies.

Conclusion

PFI members continue to enhance their approaches and methods for improving the safety and quality of their products, including the safety and quality of imported foods. The Third-Party proposed rule seeks to impose on pet food makers a range of new requirements that prompt concern. Our primary concerns are the following:

- 1) No mandatory certification for a food can be required unless and until there is a fully functioning accreditation system, with auditors/certification bodies available to certify foods and facilities for both human and animal food.
- 2) The rule must include specific criteria that accreditation bodies and auditors/ certification bodies must meet with respect to the secure storage and maintenance of information related to foreign suppliers and their importers, which may include confidential business information.
- 3) FDA must incorporate into this rule language obligating FDA to ensure that recognition and recognition renewal applications are reviewed and decisions issued in a timely manner.
- 4) The rule must make every attempt to shield foreign suppliers and their importers from redundant and unnecessary audits by ensuring that reassessments and reviews of accreditation bodies and auditors/certification bodies are conducted in concert with any required audits or inspections of foreign facilities. The rule also must ensure sufficient access to auditors/certification bodies by not imposing arbitrary limits on contact between those entities and foreign suppliers.

PFI would like to thank FDA for the opportunity to provide comments on the proposed rule for Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications. We appreciate FDA's use of industry discretion and flexibility in the proposed rule and encourage FDA to maintain the theme of importer discretion. Our members believe giving importers who have had longstanding relationships with suppliers sufficient flexibility in determining the best approach to foreign supplier verification will provide the best assurance of safety in regards to food being imported into the United States as well as permit efficiencies. As always, PFI remains interested in an open and continuous dialogue with FDA throughout the process of finalizing and implementing FSMA rules.

Sincerely,



Duane Ekedahl
President