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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-0143, RIN 0910-AG64 - Foreign Supplier Verification Programs for Importers of Food for Humans and Animals

The members of the Pet Food Institute (PFI) would like to thank the Food and Drug Administration (FDA) for the opportunity to comment on the Food Safety Modernization Act (FSMA) Foreign Supplier Verification Program (FSVP) 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, FSVP and Accreditation of Third-Party Auditors/Certification Bodies proposed 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 FDA's goal of establishing a regulatory framework that is protective of public health, risk-based and practical.

As you will see in our section-specific comments below, our fundamental concerns include:

- The need for flexibility and discretion to allow pet food makers to source raw materials, ingredients and finished foods from foreign suppliers using science- and risk-based methods to identify and address food safety hazards;
- The need for clear language in the rule that facilitates entry of an imported food containing a hazard that the importer (or the importer's customer) will address;
- The need to minimize duplication and redundancy between FSVP and any supplier approval and verification elements that may be incorporated into the Preventive Controls for Animal Food rule; and
- The potential requirement for records access, including electronic records access.

We are particularly concerned with the records access provisions of the proposed rule, specifically the proposal to require electronic records access. Nowhere in the statute is there a requirement that facility records must be sent to FDA electronically. While the Internet Age in which we now live might prompt one to conclude that such records access makes sense, we would contend that onsite records access is the only way to provide FDA with the information it needs to develop a complete picture of any aspect of a facility's food safety plan. Viewing food safety records that are obtained electronically provides FDA with no context – for example, there may be facility characteristics that justify one approach or practice over another – nor does it provide an opportunity for a facility's qualified individual to answer questions or provide additional information. In light of these realities, we will comment to FDA that facilities can and should make records available to FDA officials onsite in order to provide FDA with a more complete and accurate picture of various aspects of FSVP implementation at any given facility.

Finally, should FDA make any substantive additions to the FSVP 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 their foreign suppliers.

PFI applauds and emphatically supports a science- and risk- based approach to guide decision making by FDA, food producers and food importers regarding which activities are best suited to address particular hazards in imported foods, to ensure food safety and to facilitate the efficient use of regulatory and industry resources. Our section-specific review below of the proposed rule includes references to the sections of concern, the basis for our concern, and suggested changes that we believe address our concerns and meet the goals of FSMA and FDA.

Section-Specific Comments

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

Proposed §1.500: Definitions

Hazard reasonably likely to occur

The FSVP proposed rule would define “hazard reasonably likely to occur” as a “hazard for which a prudent importer would establish controls or verify that the supplier controls because experience, illness data, scientific reports, or other information provides a basis to conclude that there is a reasonable possibility that the hazard will occur in the type of food being imported in the absence of those controls.” 78 Fed. Reg. at 45,742-43 (July 29, 2013). PFI proposes replacing the word “possibility” with “probability” in order to acknowledge that addressing probable hazards is a reasonable expectation. Use of the word “possible” implies one must consider **anything** that might be a hazard (even if it’s not likely to occur), which could be a futile exercise. We believe changing the word from “possible” to “probable” connotes a more realistic scenario (e.g., considering only hazard data where the chance of occurrence is reasonable). Such a change provides the necessary flexibility for a food producer or importer to use relevant information to identify hazards reasonably likely to occur and to then determine appropriate steps to address such hazards.

Second, with respect to this definition, PFI proposes that “illness data” be interpreted as referring to FDA foodborne illness data only. 78 Fed. Reg. at 45,743 (July 29, 2013). Consumer complaints must be assessed appropriately in order to be used for trend analysis of potential issues. As an element of hazard analysis, PFI contends that only verified illness data, along with other experience, scientific reports or other information, should be the basis for an importer’s determination of whether there exists a reasonable probability that an identified hazard will occur in the type of food being imported in the absence of preventive controls.

Importer

The FSVP proposed rule would incorporate and refine the FD&C Act Section 805(a)(2) definition of “importer,” which is defined as “(A) the United States owner or consignee of the article of food at the time of entry of such article into the United States; or (B) in the case where there is no United States owner or consignee as described in subparagraph (A), the United States agent or representative of a foreign owner or consignee of the article of food at the time of entry of such article into the United States.” 78 Fed. Reg. at 45,743 (July 29, 2013). Under proposed § 1.500, FDA would further define importer as the “the person in the United States who has purchased an article of food that is being offered for entry into the United States; if the article has not been sold at the time of U.S. entry, the importer would be the person in the United States to whom the article has been consigned at the time of entry; if the article of food has not been sold or consigned at the time of U.S. entry, the importer would be the U.S. agent or representative of the foreign owner or consignee at the time of entry.” 78 Fed. Reg. at 45,743 (July 29, 2013).

PFI agrees with FDA’s approach here. For cases in which a food has not been sold or consigned to a person in the United States at the time of entry, the US agent or representative of the foreign owner or consignee at the time of entry, as the importer, must be responsible for meeting all applicable FSVP requirements.

Entities under the same corporate ownership

FDA seeks comment on “whether importers should not be required to conduct foreign supplier verification, or should be subject to different FSVP requirements, when importing food from entities under the same corporate ownership and, if so, the specific justifications and conditions under which foreign supplier verification should not be required or should be modified.” 78 Fed. Reg. at 45,743 (July 29, 2013). PFI would like to comment on the treatment of imports of food (including raw materials or ingredients used in pet food) from a foreign supplier that is under the same corporate ownership as the importer. FDA notes, in its 2011 Special Report titled “Pathway to Global Product Safety and Quality,” that “[p]roducts entering the U.S. will come from new and different markets and will flow through long, multi-step processes to convert globally sourced materials into finished goods.” As FDA acknowledges in this proposed rule, “[s]ome importers obtain food from foreign suppliers who are part of the same corporate structure as the importer and who may, along with the importer, be subject to a single integrated, company-wide approach to food safety in which hazards are controlled and verified by a common supply chain management system.” 78 Fed. Reg. at 45,743 (July 29, 2013).

PFI members that import ingredients, raw materials and finished pet food take steps to ensure that all foods destined for the US market meet applicable federal Food, Drug and Cosmetic Act provisions. Some importers have expended considerable resources to develop and implement corporate global food safety systems that ensure the safety and quality of ingredients, raw materials and finished foods. PFI believes that importers that have developed and implemented such corporate global food safety systems should be exempt from FSVP requirements because their systems already efficiently and effectively provide sufficient assurance that foods imported under that corporate global food safety system meet the appropriate safety and quality metrics.

Qualified individual

PFI supports FDA’s acknowledgement of the need for flexibility in its definition of “qualified individual.” The proposed rule 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.” 78 Fed. Reg. at 45,743, 45,773 (July 29, 2013). The proposed rule also would note that “a qualified individual must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and implement a food safety system.” 78 Fed. Reg. at 45,743, 45,773 (July 29, 2013). Although PFI agrees in general with this definition of qualified individual, we believe the definition could benefit from a clearer statement that a combination of education, training and experience can enable an individual to perform the activities needed to meet the requirements of Subpart L. Accordingly, PFI proposes the following definition for “qualified individual”: “[a] person having the necessary education, training, experience or combination thereof to perform the activities needed to meet the requirements of this subpart.”

Requirement to use only accredited auditors in the future

On the topic of third-party auditors, FDA “invites comment on whether, at some future date and/or under particular circumstances, importers should no longer be permitted to rely on third-party auditors who are not accredited in accordance with section 808 to conduct onsite audits or other FSVP activities.” 78 Fed. Reg. at 45,744 (July 29, 2013). The FSVP and Third-Party Accreditation regulations are not finalized or implemented, and FDA also has committed to issue model accreditation standards,

which will play a significant role in the third-party accreditation system. At this time, it is unclear whether some countries will be able to establish accreditation and certification systems. For those countries that can establish such systems, it is unclear how long it will take for these systems to be fully functional in order to meet the needs of both US importers and their foreign suppliers.

While an audit by a qualified individual can be a critical element of an importer's foreign supplier verification program, there should be no requirement that such an audit be conducted only by an accredited third-party auditor. An importer that is not required to seek mandatory certification (i.e., not for a high-risk food) and that is not participating in the Voluntary Qualified Importer Program should be allowed to use a qualified internal or external auditor to meet FSVP requirements. As with many provisions in the FSMA implementing regulations, including the FSVP proposed rule, the need for importer discretion is critical – there can be no one-size-fits-all approach here. Moreover, PFI requests that FDA include in the final rule language stipulating that it will consult closely with potentially affected stakeholders when contemplating any changes to audit requirements under the FSVP.

Microbiological hazards controlled by the importer or its customer

FDA's proposed definition of "importer," coupled with the requirement set forth in § 1.506(e) requiring an importer that will control a hazard to document that it is controlling the hazard, also poses logistical challenges that we believe the final rule must address. 78 Fed. Reg. at 45,752 (July 29, 2013). Pet food producers import raw materials and ingredients that may contain a hazard, including a hazard reasonably likely to occur, which the pet food producer has identified and for which the pet food producer has established and implemented preventive controls. Proposed § 1.506(e) provides that there is no need for an importer to conduct foreign supplier verification activities for a hazard the importer will control. This rule must then provide clear guidance regarding information that must accompany an imported food containing a hazard the importer will address when that food is offered for import at a US port of entry. The rule should state, for example, that importers of foods, including ingredients and raw materials used in pet food, can/should accompany such foods offered for import with a statement/declaration of further processing or an end use statement that effectively conveys to officials at a US port of entry that the imported product will undergo a treatment that will address a hazard reasonably likely to occur.

Proposed §1.501: Applicability and Exemptions

Food imported for research and evaluation or for personal consumption

PFI supports FDA's inclusion in the FSVP proposed rule of an exemption for Food Imported for Research or Evaluation or for Personal Consumption. 78 Fed. Reg. at 45,745, 45, 773 (July 29, 2013). FDA notes that under proposed § 1.501(c), "food is considered to be imported for research or evaluation purposes only if it is imported in a small quantity that is consistent with a research, analysis or quality assurance purpose and the entire quantity is used for this purpose." 78 Fed. Reg. at 45,745, 45, 773 (July 29, 2013). PFI agrees that exemptions for food imported for research or evaluation purposes are critical. PFI also agrees that the conditions that must be met under proposed § 1.501(c) will provide the necessary safeguards to ensure that the imported food entering under this exemption will not be sold or enter the stream of commerce. We would propose that § 1.501(c) be modified to require that unused amounts of "Food Imported for Research or Evaluation" be properly managed in order to ensure they do not enter the stream of commerce.

Proposed §1.502: Scope of FSVP

Food Imported by Facilities Subject to the Preventive Controls Requirements

FDA notes in the FSVP proposed rule the “importance of coordinating the final preventive controls and FSVP regulations to avoid duplicative requirements...” 78 Fed. Reg. at 45,747 (July 29, 2013). FDA acknowledges the need to avoid duplication when it seeks comment on whether the FSVP regulations should state that “an importer that is also required to establish a supplier approval and verification program under the preventive controls regulations for a food, and is in compliance with those regulations, is deemed to be in compliance with the FSVP regulations that address the same matters[.]” 78 Fed. Reg. at 45,748 (July 29, 2013). PFI believes that a company’s compliance with any supplier verification provisions in the preventive controls rules should be viewed as compliance with similar provisions in the FSVP regulations. This approach reflects an efficient use of resources for all stakeholders, including FDA. A food producer has the responsibility under the FD&C Act to ensure the food it places on the US market is not adulterated or misbranded – these requirements must be met regardless of the source of any raw materials, ingredients or finished foods. As with the issue of corporate ownership of both an importer and a foreign supplier discussed above, PFI urges FDA to adopt a flexible approach that allows stakeholder and FDA resources to be efficiently and effectively directed while ensuring the safety of raw materials, ingredients and finished foods, regardless of origin.

FDA also seeks comment on “how to coordinate the FSVP and preventive controls regulations to avoid imposing duplicative requirements on importers whose customers could be subject to any supplier verification requirements that are ultimately included in the preventive controls regulations.” 78 Fed. Reg. at 45,748 (July 29, 2013). Similar to our comment above, but related to requirements for importers who may have customers implementing safety programs, we reiterate our request for discretion and flexibility in the final rule. PFI agrees with FDA that in some circumstances “to conduct verification activities that their customers would have to conduct would not provide additional assurance of the safety of the imported food.” 78 Fed. Reg. at 45,748 (July 29, 2013). FDA asks whether it would be “appropriate for the FSVP regulations to state that an importer whose customer is required to establish a supplier approval and verification program under the preventive controls regulations for a food is deemed to be in compliance with the FSVP regulations.” 78 Reg. at 45,748 (July 29, 2013). PFI supports such a statement in the final rule and appreciates FDA’s acknowledgment that an importer’s customer may be better positioned to conduct supplier approval and verification activities than is the importer.

Whether to require supplier approval and verification is a slightly more complex issue. PFI members review current and potential ingredient and raw material suppliers, both domestic and foreign. So a proposal to require such steps be taken for domestic suppliers in principle may not impose additional burdens on pet food makers; however, without seeing any of the requirements of a domestic supplier approval and verification program – the Animal Food preventive controls proposed rule does not contain them – it is impossible to comment constructively on whether such a program will impose unnecessary burdens or clearly improve food safety. No such program requirement exists in the statute; further information is needed to justify such a proposal or continue with developing such a program.

Proposed §§ 1.504, 1.513: Review of Food and Foreign Supplier’s Compliance Status

Verification of foreign supplier’s compliance status

FDA seeks comment on “what compliance information about a food or foreign supplier an importer should be required to obtain and consider as part of its food/supplier compliance status review.” 78

Fed. Reg. at 45,749 (July 29, 2013). Some examples FDA provides regarding the potential elements of this due diligence include FDA warning letters, import alerts or requirements for certification. PFI notes that much of the information that would comprise a compliance status review is maintained by FDA and available on FDA's website. Indeed, FDA indicates in the FSVP proposed rule that it will maintain a list of imported foods that require certification under § 801(q) of the FD&C Act. 78 Fed. Reg. at 45,723, 45,748 (July 29, 2013). PFI believes that a review of FDA's website for relevant information should provide adequate assurance regarding whether a food or foreign supplier is in good compliance status with respect to FDA requirements. Accordingly, an importer seeking to verify a foreign supplier's status with FDA should be required only to check FDA's website to determine whether the foreign supplier is the subject of an import alert or warning letter. This approach correctly places on FDA the responsibility to furnish information and on an importer the responsibility to obtain this information and use it as part of its compliance status review.

A FDA warning letter or import alert connected to a food/facility the importer seeks to import/do business with clearly has value to an importer, but many factors can impact the value of such letters/alerts, including how long ago the FDA action took place, the relationship of the FDA action to the specific food/facility that is of interest to the importer and whether such FDA action prompted corrective steps related to the food/facility. All these factors are relevant to an importer's decision making regarding use of a foreign supplier, but the relevance of each factor will vary. PFI suggests that § 1.504 include language allowing an importer to make its own determination as to the impact a FDA warning letter or import alert should play in the decision to import a particular food from a particular facility or foreign supplier.

A foreign supplier's compliance standing with the food safety authority of the country in which it is located

FDA also seeks comment (proposed § 1.504) on whether the foreign supplier compliance status review "should include information about a foreign supplier's compliance standing with the food safety authority of the country in which it is located." 78 Fed. Reg. at 45,749 (July 29, 2013). As emphasized throughout these comments, PFI members take measures to ensure the safety of all imported foods from all foreign suppliers, with the goal of ensuring *compliance with US federal regulations*. PFI believes that an importer should not be required to determine a foreign supplier's compliance standing with the food safety authority of the country in which it is located as part of its assessment of compliance status. It is our understanding that FDA allows the production of foods in the United States that do not meet FDA requirements if those foods are destined for a foreign market and will not enter the US stream of commerce.

PFI proposes that, just as US producers of food intended exclusively for export need not comply with FDA requirements, US importers of foods should not need to obtain as a pre-condition for import any information regarding the food or foreign supplier's status with respect to any foreign food safety authority.

PFI believes any compliance status review requirements can and should be flexible and allow an importer to consider a range of factors, including the foreign supplier's performance history with the importer (including relevant certificates of analysis and results from any verification testing); infrastructure of the facility supplying the foreign food; supplier practices/processes; the verified risk of the imported food; how the food will be used by the importer (or the importer's customer); the results

of any previous audits; whether the foreign supplier is engaged in continuous improvement activities; and other factors the importer considers to be appropriate.

An importer's past experience with a foreign supplier can and should play a significant role in any compliance status review. Many PFI members have long and well-established relationships with their foreign suppliers. These relationships can and should be considered as factors in the compliance status review that FDA proposes to be part of the importer's Foreign Supplier Verification Program. PFI is willing to work with FDA to identify documents or other information related to an importer's relationship with a foreign supplier that could be considered as part of a compliance status review.

FDA proposes in § 1.513 that an importer must "determine and document whether the foreign supplier of the food is in good compliance standing with the food safety authority of the country in which the foreign supplier is located" and seeks comment as to "what should constitute good compliance standing under proposed § 1.513, as well as what documents or other information issued by a food safety authority should be acceptable to demonstrate that a foreign supplier of a food is in good compliance standing with that food safety authority." 78 Fed. Reg. at 45,769 (July 29, 2013). FDA also seeks comment on "what FSVP requirements might be appropriate for food imported from countries whose food safety authorities have entered into commodity-specific arrangements or agreements with FDA." 78 Fed. Reg. at 45,769 (July 29, 2013).

PFI believes that FDA should ensure that any foreign food safety authority it recognizes as comparable or determines to be equivalent should be required to maintain and publish lists available on the Internet that allow an importer to comply with proposed §§ 1.513(b)(1) and (b)(2). We believe that the maintenance of such lists should be an element of the recognition of comparability or determination of equivalence of any foreign food safety authority. Maintenance of and easy Internet access to such lists will facilitate trade for both foreign suppliers and US importers, and it would place a relatively low burden on all involved stakeholders.

Proposed §1.505: Hazard Analysis

Economically motivated adulteration

Regarding intentional hazards, PFI agrees with FDA that "it is appropriate to require importers to consider only those hazards that occur naturally or may be unintentionally introduced." 78 Fed. Reg. at 45,749 (July 29, 2013). We agree that intentional hazards are best dealt with under separate regulations addressing food defense. But we also acknowledge that certain potential hazards, such as those intentionally introduced for economic reasons, may be amenable to identification and evaluation by an owner, operator or agent in charge of a registered food facility. For example, many food producers and consumers would agree that the addition of melamine to certain food products to enhance perceived quality and/or protein content is now reasonably foreseeable. However, importers should be required under FSMA only to evaluate reasonably foreseeable intentional hazards that are economic in nature. Importers should have the discretion to determine which potential economic adulterants are reasonably foreseeable and to use a science- and risk-based approach to conduct activities required to investigate and/or mitigate the potential economic adulteration.

Section 420 of the FD&C Act indicates that Congress intended the Secretary of Health and Human Services to work with Homeland Security and the Secretary of Agriculture to develop a food defense plan, and to then "specify appropriate science-based mitigation strategies or measures to prepare and protect the food supply chain at specific vulnerable points, as appropriate." PFI supports the approach

laid out in the statute. PFI also sees an opportunity for engagement with HHS, Homeland Security and the Department of Agriculture to share information regarding the identification and evaluation of hazards, including economically motivated hazards. Accordingly, we encourage FDA to seek input from all interested stakeholders in the development and implementation of these science- and risk-based strategies or measures.

Hazard Evaluation

The FSVP proposed rule, in §§ 1.505(c)(1) through 1.505(c)(9), would require an importer's hazard evaluation to "consider the effect of several factors on the safety of the finished food for the intended consumer." 78 Fed. Reg. at 45750 (July 29, 2013). These factors include: ingredients; the condition, function and design of the foreign supplier's establishment and equipment; transportation practices; harvesting, raising, manufacturing, processing and packing procedures; packaging and labeling activities; storage and distribution; intended or reasonably foreseeable use; sanitation, including employee hygiene; and any other relevant factors. The proposed rule on preventive controls for food for animals includes current Good Manufacturing Practice (cGMP) requirements that address all the factors cited in these proposed FSVP sections. Accordingly, PFI believes that any review of a foreign supplier to determine compliance with proposed §§ 1.505(c)(1) through 1.505(c)(9) also should satisfy any requirements for supplier verification and approval in a final preventive controls rule for animal food.

Proposed §1.506 Foreign Supplier Verification and Related Activities

List of Foreign Suppliers

FDA proposes in § 1.506(a) to require that each importer maintain a written list of foreign suppliers and requests comment on "how the foreign suppliers should be identified in this list to ensure the information is accurate and not ambiguous to the importer or FDA." 78 Fed. Reg. at 45,751 (July 29, 2013). FDA also requests comment on "whether the identity of the foreign supplier of the food should also be provided when the food is offered for import, ... and if so, how the foreign supplier should be identified to ensure that the information is accurate and not ambiguous". 78 Fed. Reg. at 45,751 (July 29, 2013). PFI notes that an importer currently must provide the foreign food facility registration number (which includes company name and foreign entity contact information) or the full name and address of the foreign supplier at the time of import as a requirement under the Bioterrorism Act's prior notice requirement. PFI proposes the continued use of the food facility registration number or full name and address of the foreign supplier as a means to identify the foreign supplier in any written list an importer may be required to maintain, consistent with the information provided at the time of import.

Foreign Supplier Verification Procedures

FDA proposes, in § 1.506(b), "that importers establish and follow adequate written procedures for conducting foreign supplier verification activities with respect to the foods they import." 78 Fed. Reg. at 45,751, 45,774 (July 29, 2013). PFI agrees that this requirement will play a key role in ensuring the safety of imported foods by requiring an importer to document that reasonably foreseeable hazards associated with an imported food are being addressed by the foreign supplier, the importer or the importer's customer. PFI also notes, as stated earlier in these comments, that it is imperative for this information to be made available to FDA and/or CBP officials at the port of entry in order to facilitate and expedite the entry of such foods. PFI thus reiterates its proposal that an importer be allowed to provide a statement/declaration of further processing (an end use statement) at the time of import in

order to facilitate entry of a food that may contain a hazard the importer (or importer's customer) will address.

Hazards Controlled by the Importer

FDA seeks comment regarding its proposal in § 1.506(e) to require "importers that control the hazards in food they import to document their control of these hazards, including on the frequency with which importers should be required to document this control." 78 Fed. Reg. at 45,752 (July 29, 2013). PFI agrees with the proposal that an importer should document that it has established and is following procedures that adequately control a hazard. PFI would propose, however, that the final rule employ a science- and risk-based approach rather than specifying an annual requirement for this documentation. This proposal is consistent with FDA's current approach for domestic facilities, which examines a facility's compliance history from the previous five years to determine if the facility poses a food safety risk. In addition, the Global Food Safety Initiative (GFSI) states "[t]he frequency of audits may be influenced by a number of factors such as previous audit history..." (GFSI Guidance Document, 6th Edition, v6.3). PFI urges FDA to employ the same science- and risk-based approach for importers – doing so will encourage an effective and efficient use of industry resources.

Hazards controlled by your foreign supplier for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals (SAHCODHA).

PFI has several comments with respect to the audit requirements set forth in the proposed rule. First, we note that, for SAHCODHA hazards identified by the importer that are to be controlled by the foreign supplier, FDA cites an example in which an onsite audit would not by itself be sufficient "to ensure that the hazard is adequately controlled." 78 Fed. Reg. at 45,754 (July 29, 2013). FDA uses an example of a cheese importer that, in addition to performing an onsite audit, "might become aware that such cheese *from that supplier's country* frequently does not meet FDA's standards for the presence of *L. monocytogenes*" (emphasis added). 78 Fed. Reg. at 45,754 (July 29, 2013). FDA goes on to state that, in addition to the onsite audit, "periodic sampling and testing of the cheese for the pathogen would also be needed," concluding that "proposed § 1.506(g)(1) under Option 1 would require that, when onsite auditing alone cannot provide adequate assurances that such a hazard is adequately controlled, the importer must conduct one or more additional verification activities to provide such assurances." 78 Fed. Reg. at 45,754 (July 29, 2013).

We agree that any information that an importer obtains about its foreign supplier should be used to determine the appropriate level of oversight in order to ensure that the foreign supplier is adequately addressing an identified SAHCODHA hazard. We do not agree, however, that information about a particular product *from a supplier's country* is relevant or needs to be taken into account by the importer – rather, only information about the product the importer is importing from its foreign supplier is relevant and should be taken into consideration by the importer. FDA already has included in this proposed rule (§ 1.504) a requirement that an importer, before importing a food from a foreign supplier, assess the compliance status of the food and the foreign supplier. This requirement is sufficient to enable an importer "to determine whether it would be appropriate to import the food from the foreign supplier." 78 Fed. Reg. at 45,748 (July 29, 2013).

Accordingly, we urge FDA to modify the language regarding SAHCODHA hazards that will be controlled by the foreign supplier so that the final rule requires an importer to focus its resources on the foreign

supplier and the particular product it plans to import from that foreign supplier. Specifically, we propose that the following language in § 1.506(g)(1): “[w]hen onsite auditing alone cannot provide adequate assurances that the hazard is adequately controlled, the importer must conduct one or more additional verification activities to provide such assurances.” be changed to read: “[w]hen onsite auditing alone cannot provide adequate assurances that the hazard is adequately controlled, you should consider whether conducting one or more additional verification activities is necessary and take appropriate steps to address the hazard.” 78 Fed. Reg. at 45,754 (July 29, 2013).

Subsequent periodic onsite audits

PFI also is concerned that the proposed § 1.506(g)(1)(ii) requiring “the importer to conduct (and document) or obtain documentation of an onsite audit of the foreign supplier at least annually” is overly prescriptive and does not allow for an efficient use of importer and foreign supplier resources. 78 Fed. Reg. 45,755 (July 29, 2013). PFI believes that a more sound approach would be to require that importers review periodically the preventive controls a foreign supplier has in place – including their effectiveness – and determine based on this review whether additional steps are necessary. Accordingly, we request that the language in § 1.506(g)(1)(ii) be changed to read, “The importer should conduct (and document) a periodic, risk-based review of foreign supplier verification activities and their frequency and determine based on this review whether any modifications are necessary to adequately verify that the hazard is adequately controlled.”

Option 1 versus Option 2 Approaches to Address Hazards Controlled by a Foreign Supplier

In the proposed rule, FDA requests comment on Options 1 and 2 of the co-proposal regarding supplier verification activities for hazards controlled by the foreign supplier. 78 Fed. Reg. 45,757 (July 29, 2013). PFI appreciates FDA’s co-proposal of options related to supplier verification. Option 1 provides an extensive list of required FSVP activities an importer must employ (or choose from) in order to ensure the safety of foods it imports when the importer’s foreign supplier is controlling a hazard. FSVP activities depend on the nature of the hazard (SAHCODHA versus other hazards) and include: periodic onsite auditing; periodic or lot-by-lot sampling and testing of the food, periodic review of the foreign supplier’s food safety records; and any other procedure considered to be appropriate. Option 1 would establish mandatory importer activities for SAHCODHA hazards a foreign supplier will address, including onsite audits of foreign suppliers.

Option 2 of the co-proposal for supplier verification activities for hazards controlled by the foreign supplier would require the importer to choose “whatever verification activity would enable the importer to adequately verify that a hazard has been adequately controlled, whether it is a SAHCODHA hazard or a non-SAHCODHA hazard.” 78 Fed. Reg. at 45,757 (July 29, 2013). Therefore, Option 2 would allow the importer to exercise discretion as to which foreign supplier verification activity/activities to conduct before using or distributing the imported food and periodically thereafter.

We support the adoption of Option 2 in the final rule. This alternative provides importers with the greatest flexibility and discretion to use a science- and risk-based approach to identify and carry out appropriate foreign supplier verification activities in order to address both SAHCODHA and non-SAHCODHA hazards that will be controlled by the importer’s foreign supplier. This approach also allows importers to use additional factors, such as their history with a foreign supplier, when choosing the appropriate verification activity/activities. Such a flexible approach focuses resources on activities that can provide the greatest assurance of food safety.

FDA makes reference in this proposed rule to its request for comment in the Human Food and Animal Food Preventive Controls proposed rules on whether it should require food producers to take additional measures such as finished product testing and supplier approval and verification. As with our preference for Option 2 above, we urge FDA to provide flexibility and discretion to food producers to choose the preventive controls that will most effectively address identified and evaluated hazards. PFI believes that testing (of finished product and ingredients) is one of many tools that can be of value to human and animal food producers in their constant efforts to improve the safety and quality of their products. PFI members support and employ a range of methods designed to address identified and evaluated hazards earlier in production. A science- and risk-based approach must guide decision-making by FDA, food producers and food importers regarding which foreign supplier verification activities are best suited to address particular hazards, thereby both ensuring food safety and facilitating the efficient use of regulatory and industry resources. This science- and risk-based approach should apply equally to domestic as well as imported foods – the country of origin of a food should not by itself dictate that such food be subjected to more onerous requirements than would apply to its domestic counterparts.

Proposed § 1.507 Complaints, Investigations, and Corrective Actions

Review of complaints

Proposed § 1.507(a) requires the importer to promptly conduct a review of any complaint received “to determine whether the complaint relates to the adequacy of the importer’s FSVP.” 78 Fed. Reg. at 45,760 (July 29, 2013). This approach pre-supposes that the problem – if any – lies with a foreign-supplied ingredient and could result in a misdirection of resources just to comply with the regulatory requirement. PFI members source a range of raw materials, ingredients and finished foods both domestically and abroad. There should be no bias against imported foods or food ingredients during a food producer’s review of complaints. A food producer, including one that imports raw material or ingredients for the manufacture of pet food, must have discretion to review complaints, using established criteria, in order to determine whether a complaint has merit and to respond effectively to complaints that constitute legitimate food safety concerns. PFI is borrowing from the FDA playbook, so to speak, in advocating a science- and risk-based approach under FSVP specifically and FSMA generally in order to permit resources to be targeted effectively at legitimate food safety hazards.

Proposed § 1.509: Identification of Importer at Entry

Monitoring compliance with the FSVP regulations

Proposed § 1.509 is “intended to ensure that the importer of each food imported or offered for import into the United States is accurately identified so that the Agency can effectively implement and monitor compliance with the FSVP regulations.” 78 Fed. Reg. at 45,761 (July 29, 2013). Proposed § 1.509(b) would require each importer to obtain a DUNS number in order to permit FDA to accurately identify importers. FDA cites a need to “allocate its resources for examining imported products based on certain risk factors, including the rigor and effectiveness of the importer’s FSVP.” 78 Fed. Reg. at 45,761-62 (July 29, 2013). FDA officials have stated on several occasions that the agency cannot inspect its way to food safety, so PFI questions this proposed monitoring requirement. Moreover, proposed § 1.509(a) would require the identification of an importer of food imported or offered for import into the United States. FDA acknowledges that it already receives information identifying the importer as part of entry and prior notice requirements. Accordingly, PFI proposes that the requirement that importers obtain a DUNS number be eliminated from the rule.

Proposed § 1.510: Records

Importers must sign and date records

Proposed § 1.510(a) would “require importers to sign and date records concerning their FSVPs upon initial completion and upon any modification of the FSVP.” 78 Fed. Reg. at 45,763 (July 29, 2013). PFI 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 greatly discourage FDA from mandating compliance with system controls as documented within 21 CFR Part 11. Any requirement referencing 21 CFR Part 11 would not improve food safety and would be both onerous and costly to implement. Reasonable records chain of custody procedures allow importers and suppliers to focus resources on food safety versus a maintenance of a costly data entry and management system.

Records access

Proposed § 1.510(b) states “If requested in writing by FDA, you must send records to the Agency electronically rather than making the records available for review at your place of business.” 78 Fed. Reg. at 45,777 (July 29, 2013). PFI believes strongly that written records should be made available to FDA: 1) when appropriate in the event of a SAHCOHHA; 2) in person at the facility where the records are maintained; and 3) in the presence of the qualified individual, so that the FDA inspector has the opportunity to view/review the records with relevant context. A review of the FSMA statute reveals the following. First, section 414(a)(2) of the FD&C Act lays out the conditions for records access: “presentation of appropriate credentials and a written notice to such person, at reasonable times and within reasonable limits and in a reasonable manner...” Section 414(a)(2) goes on to say that if these conditions are met, FDA shall have “access to and copy all records relating to such article and to any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner.” Section 414(a)(2) also makes clear that records access is to be provided to FDA on the premises of the person who “manufactures, processes, packs, distributes, receives, holds or *imports*” an article of food (emphasis added). Section 805(d) of FD&C Act states that “records of an importer related to a foreign supplier verification program ... shall be made available promptly to a duly authorized representative of the Secretary upon request.” The language in both the broader sections 414(a)(2) and 805(d) of FD&C Act, make clear the legislative intent that records access should be provided promptly and under reasonable circumstances at the place of business of the person responsible for the article of food. PFI believes records access is appropriate as outlined above (points 1-3), and that such an approach would provide the necessary context and background information that will enable a complete review and clear understanding of the records.

Records retention

Proposed §1.510(d) sets requirements for the retention of FSVP records. The proposed section would “require importers to maintain all records for a period of at least 2 years, but the start of the 2-year period would differ depending on the type of record.” 78 Fed. Reg. at 45,763 (July 29, 2013). The proposed rule specifies that records referenced in Subpart L must be maintained for at least 2 years after their use is discontinued, while “[r]ecords that concern actual performance of supplier verification activities, relate to complaints, investigations, and corrective actions associated with particular foods, or involve the documentation of FSVP reassessments are not records that remain in use until revised” and must be retained for a period of 2 years from the time the records are created or obtained. 78 Fed. Reg.

at 45,763 (July 29, 2013). PFI believes that having two specifications for the retention of records is confusing and may lead to insufficient records maintenance. PFI suggests consolidating the records retention requirement so that all records should be retained for a period of 2 years after the record is no longer in use. This approach would provide adequate assurances that records will be retained for a period sufficient to facilitate records access when necessary.

Conclusion

PFI would like to thank FDA for the opportunity to comment on the proposed rule for Foreign Supplier Verification Programs for Importers of Food for Humans and Animals. We appreciate FDA's efforts in the proposed rule to give importers a variety of science- and risk- based approaches to ensure the safety and quality of animal food. In closing, we would like to reiterate our key points:

1. Pet food sold in the United States has a strong record of safety and quality. The overwhelming majority of foodborne illnesses reported in the United States involve human food, not pet food. The pet food track record of safety is due in large part to the extraordinary steps pet food makers take to ensure and improve the safety and quality of their products, using science- and risk-based approaches and methods.
2. We urge FDA, in all sections of the FSMA proposed rules, to employ a science- and risk-based approach that allows the most efficient and effective utilization of resources to ensure food safety and quality, while also facilitating trade. This approach should: permit greater discretion with respect to the frequency of any onsite audits an importer may conduct of a foreign supplier; only require an importer to verify foreign supplier compliance with appropriate FD&C Act provisions; and provide clear guidance for securing the entry of imported food that may contain a hazard the importer will address.
3. Records access can be a valuable tool for FDA and stakeholders in addressing food safety incidents and improving processes to reduce their likelihood. But access to records, including access to records related to FSVP activities, must have the proper context; specifically, the context provided by review of those records in the importer's facility and while accompanied by a qualified individual. The proposed records access is not authorized by the FSMA statute, nor does it provide FDA with the comprehensive view necessary to make an accurate assessment of an importer or its foreign supplier.
4. Finally, our members believe strongly that an importer's longstanding relationship with a foreign supplier, and the supplier's record of safety, can and should be a critical factor for consideration in any supplier verification program. FSMA final rules addressing supplier verification should allow an importer to modify its foreign supplier verification activities based on its relationship with an imported food or foreign supplier.

As always, PFI looks forward to further interaction and exchange of ideas and information with FDA as these proposed rules are finalized and implemented under FSMA. We will continue delivering comments to FDA as part of the open and continuous dialogue we trust will result in FSMA final rules that improve food safety and quality, while also facilitating trade.

Sincerely,



Duane Ekedahl
President