December 15, 2014

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

Re: Docket No. FDA-2011-N-0143 and RIN 0910-AG64- Foreign Supplier Verification Programs for Importers of Food for Humans and Animals

Dear U.S. Food and Drug Administration:

The American Feed Industry Association (AFIA) is the world's largest organization devoted exclusively to representing the business, legislative and regulatory interests of the U.S. animal feed industry and its suppliers. Founded in 1909 as the American Feed Manufacturers Association, the name changed to AFIA in 1985 to recognize the importance of all types of companies involved in the feed manufacturing industry—from ingredient suppliers, equipment manufacturers to commercial and integrated feed manufacturers. AFIA is also the recognized leader on international industry developments and holds membership in the International Feed Industry Federation, where AFIA's President and CEO, Joel G. Newman, serves as chair of the IFIF Policy Committee.

AFIA membership includes more than 575 domestic and international companies and state, regional and national associations. Member companies are livestock feed and pet food manufacturers, integrators, pharmaceutical companies, ingredient suppliers, equipment manufacturers and companies which supply other products, services and supplies to feed manufacturers.

The feed industry makes major contributions to food and feed safety, nutrition and the environment, and it plays a critical role in the production of healthy, wholesome meat, milk, fish and eggs. More than 75 percent of the commercial feed in the U.S. is manufactured by AFIA members. Approximately 70 percent of the non-grain ingredients, including soybean meal, distillers' co-products, vitamins, minerals, amino acids, yeast products and other miscellaneous/specialty ingredients are also manufactured by AFIA members.

AFIA strongly supported development and passage of the Food Safety Modernization Act (FSMA), supports and provides comments to FDA regarding FSMA, and belongs to the Food Safety Preventive Controls Alliance's (FSPCA) Animal Food Steering Committee.. This committee is reviewing the human food training outline, which was developed by the FSPCA human food steering committee, and is adjusting it for animal food. AFIA will provide future training workshops based on the FDA-endorsed training framework developed by the alliance. AFIA has agreed to draft or be involved in a review of domestic guidance documents including those for dry and liquid feed, pet food, vitamin/mineral/specialty ingredients, and products derived from plants and animals.

AFIA is committed to a continuing dialogue with FDA on FSMA rules and implementation. We are also strongly committed to a full and successful implementation of FSMA across all our varied industries. We greatly appreciate FDA's approachability, openness to new ideas, offers to discuss the rules, and assistance in notifying our members of the law and rules via FDA's participation at our meetings and webinars. We also appreciate FDA issuing this supplemental proposed rule to allow the industry another opportunity to comment on the modified regulations and a first chance to comment on the newly proposed items included in the rule. We look forward to more cooperation as the rules are finalized and implemented.

GENERAL COMMENTS AND SUGGESTIONS

AFIA applauds FDA for publishing the supplemental proposed rules. It appears FDA utilized some of AFIA's suggested changes. As such, AFIA appreciates the opportunity to comment on this important issue for our members. The U.S. feed industry has a long history of providing safe animal food and feed ingredients for use domestically and abroad, and in fact feed safety was one of the primary reasons for AFIA's founding in 1909.

In FSMA, Congress directed FDA to take into account differences among importers and types of products imported. We urge FDA to recognize that one regulatory solution may not be appropriate for both human food and animal feed. FDA has separated the human and animal food preventive controls rules. Although there will be a single Foreign Supplier Verification Program (FSVP) rule for food for humans and animals, FDA should consider different approaches for animal food where appropriate. Additionally, with FDA's release of the proposed domestic risk-based supplier program under the preventive controls supplemental proposed rule, it is imperative that the FSVP also align with the requirements domestically.

AFIA appreciates that FDA's supplemental proposed rule for the required supplier verification activities is a hybrid of the two options presented in the original proposed rule. This will allow flexibility and takes into account varying products and circumstances, as well as the existing relationships between importers and their foreign suppliers.

One concern AFIA has with this proposed supplemental rule is FDA's reference to Preventive Controls for Human Food, and not for animal food, such as in proposed § 1.504(g). The failure to reference the animal food rule must have been a drafting oversight, as AFIA cannot think of a logical reason why FDA would reference the human food rule but not its animal food counterpart. As FDA develops a final rule, AFIA urges the agency to consider that this regulation will apply to both human food and animal food, and to be cognizant of not only the differences between the two, but also the areas where they must align.

AFIA also does not support the inclusion of "modified FSVP requirements" in any capacity, and certainly not for *very small importers* or importers importing from *very small foreign suppliers*. Providing "modified FSVP requirements" for a select group of importers, whether they are defined as a "very small importer" or if that importer is importing from a "very small foreign supplier," has several negative implications, which can be found below in our detailed comments. Most importantly, "modified FSVP" requirements do not advance food safety.

Finally, FDA must ensure that the final rule is not more stringent on imported products than that on U.S. products thus causing World Trade Organization (WTO) inconsistencies such as a violation of the principles of non-discrimination. All efforts should be made to coordinate the final preventive controls and FSVP regulations, not only to avoid confusion, but also to comply with WTO rules as required for WTO members, of which the U.S. is one.

COMMENTS OVERVIEW

AFIA's comments follow the flow of the supplemental proposed rule. In each of these supplementary proposed rule sections, we provide general comments and, where applicable, we note the specific proposed provision, AFIA's recommendation and rationale for the change. For the purposes of editing, new language is underlined and deleted language is stricken through.

AFIA PROVIDES COMMENTS ON SPECIFIC ISSUES BELOW

§ 1.500: Definitions

AFIA has reviewed the proposed new and re-proposed definitions in the supplemental proposed rulemaking and provides details below where we offer suggestions for improvement of the definition.

Supplemental Proposed Rule with AFIA Recommendations

Proposed § 1.500 defines "pathogen" as:

"…a microorganism of such severity and exposure that it would be deemed of public (human or animal) health significance."

AFIA Comments

AFIA believes that the significance of pathogens to public health is dependent on the organism's severity and exposure nature and the definition should be modified as such.

Supplemental Proposed Rule with AFIA Recommendations

Proposed § 1.500 defines "qualified auditor" as:

"…person who is a qualified individual as defined in this section and has technical expertise obtained by a combination of training, education ~~and~~or experience appropriate to perform the auditing function. A foreign government employee could be a qualified auditor."

AFIA Comments

AFIA strongly believes FDA should recognize the role of the education of a potential qualified individual or auditor as well as training and experience to meet the criteria. If FDA accepts education as training, then the final rule should say so.

Supplemental Proposed Rule with AFIA Recommendations

Proposed § 1.500 defines "significant hazard" as:

"…a known or reasonably foreseeable hazard for which a ~~person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis,~~ qualified individual would establish controls to significantly minimize or prevent the hazard in a food ~~and components to manage those controls (such as monitoring, corrections and corrective actions, verification, and records)~~ based on the severity of the illness or injury to humans or animals if the hazard were to occur and the probability that the hazard will occur in the absence of a preventive control as appropriate to the food, the intended use of the food, the facility, and the control."

AFIA Comments

AFIA urges the adoption of the above edits to this definition. FDA has proposed a definition for a "qualified individual," and therefore we believe referencing the qualified individual, who will be in charge of the hazard analysis, is more appropriate in the definition instead of listing out requirements separately for this definition. Moreover, FDA should include a reference to severity and probability in the significant hazard definition. Without such reference, the use of the term in § 1.504(a) could be interpreted as indicating that all identified hazards would require preventive controls equivalent to a critical control point.

Supplemental Proposed Rule with AFIA Recommendations

Proposed § 1.500 defines "very small importer" as:

"…~~an importer, including any subsidiary, affiliate, or subsidiaries or affiliates, collectively, of any entity of which the importer is a subsidiary or affiliate, whose average annual monetary value of sales of food during the previous 3-year period (on a rolling basis) is no more than $1 million, adjusted for inflation~~."

Proposed § 1.500 defines "very small foreign supplier" as:

"…~~a foreign supplier, including any subsidiary, affiliate, or subsidiaries or affiliates, collectively, of any entity of which the foreign supplier is a subsidiary or affiliate, whose average annual monetary value of sales of food during the previous 3-year period (on a rolling basis) is no more than $1 million, adjusted for inflation.~~"

AFIA Comments

AFIA recommends that all importers and foreign suppliers follow the same requirements, and does not support "modified FSVP requirements" in any capacity. Therefore, AFIA believes that definitions for "very small importer" and "very small foreign supplier" are unnecessary and should be deleted. Providing "modified FSVP requirements" for a select group of importers, whether they are defined as a "very small importer" or are importing from a "very small foreign supplier," has several negative implications.

First, it likely will provide an unfair advantage to smaller foreign suppliers over larger ones. Importers could be inclined to make their foreign supplier selections based on a foreign supplier's status as a "very small foreign supplier" rather than the safety of their product and the controls they have in place, thereby increasing the risk for importation of a product with a significant hazard that may not be appropriately controlled. If such exemptions to the FSVP were allowed, AFIA believes that there would be a higher risk for intentional economic adulteration, the majority of which are not foreseeable.

Second, it likely will provide an unfair advantage to smaller importers over larger ones. If "very small importers" are not required to implement all FSVP requirements, there also lies the risk for importation of a product with a significant hazard that may not be appropriately controlled. AFIA is unaware of any data that demonstrates that the size of an importer or a foreign supplier is directly related to the likelihood that a product with a significant hazard will be imported. Defining these at an arbitrary average annual monetary value of sales does not preclude or reduce the potential for risk from such companies. However, proper implementation by all importers of food of all FSVP requirements may reduce such risks.

Third, allowing such "modified FSVP requirements" could not only increase the risk for importation of a product with a significant hazard that is not properly controlled, but should such

importation happen for a product, it could do damage to the entire ingredient line. For the feed industry, there are some imported ingredient categories that have limited sources of foreign suppliers and little or non-existent domestic production, e.g., vitamins. Should an adulteration event occur, it could affect all suppliers of that product and be detrimental to the importers that depend on the importation of that product, thereby reducing the already short supply. Importers should not put the concerns of time and money that would be required to implement FSVP over the safety and potential risk of imported products. The "modified FSVP requirements" do not require the key components in the FSVP – proposed to ensure that imported products meet the same requirements as domestic products. Providing "very small importers" or importers importing from "very small foreign suppliers" an exemption from the majority of the FSVP requirements is contrary to the entire purpose of the proposed rule.

Additionally, if these exemptions for "very small importer" and "very small foreign supplier" were to remain in the final rule, AFIA still does not support that the average monetary value of sales of food used to determine these definitions differ from the value of "very small business" used in the proposed preventive controls regulations.

Lastly, AFIA members say they are not likely to import from very small foreign suppliers due to the higher risk they pose, thereby putting them at an economic disadvantage.

Supplemental Proposed Rule with AFIA Recommendations
§ 1.502(c) Importers subject to section 418 of the Federal Food, Drug, and Cosmetic Act. If you are required to establish and implement a risk-based supplier program under § 117.136 or § ~~507.43~~ 505.37 of this chapter for a food you import and you are in compliance with that section, then you are deemed to be in compliance with the requirements of this subpart, except for the requirements in § 1.509.

AFIA Comments
FDA references § 507.43 as the risk-based supplier program, however § 507.43 does not exist in the preventive controls regulations for animal food. AFIA proposes that FDA correct this and replace it with § 507.37, which is the risk-based supplier program under the supplemental proposed preventive controls rule for animal food.

AFIA agrees that if an importer is required to establish and implement a risk-based supplier program under the supplemental proposed preventive control rule for animal food and such importer is in compliance with those requirements, that the importer, therefore, should be deemed in compliance with the requirements of this subpart, except those of § 1.509.

Supplemental Proposed Rule with AFIA Recommendations
§ 1.502(d) If your customer is required to establish and implement a risk-based supplier program under § 117.136 or § ~~507.43~~ 505.37 of this chapter for a food you import ~~and you annually obtain from your customer written assurance that it is in compliance with that section~~ then you are deemed to be in compliance with the requirements of this subpart, except for the requirements in §§ 1.509 and 1.510.

AFIA Comments
FDA references § 507.43 as the risk-based supplier program; however § 507.43 does not exist in the supplemental proposed preventive control rule for animal food. AFIA assumes that this was a drafting oversight and proposes that FDA correct this and replace it with § 507.37, which is the risk-based supplier program under the supplemental proposed preventive control rule for animal food.

AFIA agrees that if an importer's customer is required to establish and implement a risk-based supplier program under the supplemental proposed preventive control rule for animal food, that the importer should be deemed to be in compliance with the requirements of this subpart, except §§ 1.509 and 1.510.

Additionally, AFIA does not believe that an importer should be required to annually obtain written assurance from its customer that the customer is in compliance with that section. It is not practical, nor reasonable, to expect that a customer provide the importer (which is the customer's supplier) written assurances that they are in compliance with a risk-based supplier program. This is beyond what a customer/supplier relationship should be. If such customer is required to establish and implement a risk-based supplier program under the preventive controls regulations for animal food, that customer can document its compliance with such requirements in its domestic risk-based supplier program; the importer in this case should not be required to obtain these assurances as part of its FSVP.

Supplemental Proposed Rule with AFIA Recommendations
§ 1.504(a) You must identify and evaluate, based on experience, illness data, scientific reports, ~~and~~ or other information, known or reasonably foreseeable hazards for each food you import to determine whether there are any significant hazards. Your hazard analysis must be written.

AFIA Comments
AFIA understands and supports the need to identify acceptable information to utilize in a hazard evaluation and appreciates the agency's recognition of our comments regarding "reasonably likely to occur" by utilizing "known or reasonably foreseeable" in this section. AFIA believes "or" is the most appropriate qualifier in this listing of information as not every hazard in animal food may have all of these types of information to include in the facility's hazard analysis.

This proposed provision also contains a new reference to "significant hazards" causing two main concerns. First, the definition for significant hazards states they are "known or reasonably foreseeable," which is circular logic in the context of 1.504(a). Second, without including a reference to the severity and probability in the significant hazard definition, this section could be interpreted to mean that all identified hazards would require preventive controls equivalent to a critical control point. Therefore, AFIA strongly urges FDA to modify the definition of significant hazard as noted above.

Supplemental Proposed Rule with AFIA Recommendations
§ 1.504(b)(1) Your analysis of the known or reasonably foreseeable hazards in each food must include the following types of hazards:

(i) Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens;
(ii) Chemical hazards, including radiological hazards, pesticide and drug residues, natural toxins, ~~decomposition,~~ unapproved food or color additives, ~~and~~ food allergens, and nutrient deficiencies or toxicities; and
(iii) Physical hazards.

AFIA Comments
AFIA appreciates that the agency has included radiological hazards within the chemical hazard categorization, as we believe this simplifies the preparation of animal food safety plans. However, these hazards in the Foreign Supplier Verification Program should align with those in the

supplemental proposed preventive controls animal food rule. Therefore, AFIA is reemphasizing our previous request from our March 31 comments to the proposed preventive control rule to remove decomposition and to replace "nutrient imbalances" (and in the case of FSVP, add) with "nutrient deficiencies or toxicities."

Removal of Decomposition

Many products used in the animal food industry, including hydrolyzed proteins, palatants and rendered materials, have begun decomposition but are processed in a controlled system to halt decomposition before harmful toxins are formed. Based on FDA's broad description in the original preamble, these products may need to be identified as hazards within a facility manufacturing or utilizing these materials as ingredients even though they are demonstrably safe for use in animal foods.

AFIA is concerned that these types of materials may be subject to unnecessary regulatory scrutiny. AFIA understands the agency's intent was to identify hazards associated with uncontrolled decomposition or spoiled foods that result from chemical changes induced by the microbial breakdown that subsequently releases potentially hazardous natural toxins. The original Preventive Controls proposed rule and supplemental proposal already identify natural toxins as a subgroup of chemical hazards. Thus, it is redundant and unnecessary to refer to decomposition when some (lower) levels of decomposition do not pose an animal food safety risk. Accordingly, AFIA recommends that "decomposition" be deleted from the list of chemical hazards in this provision.

Nutrient Imbalances

FDA's inclusion of nutrient imbalances to the definition of chemical hazards within the preventive controls supplemental rule is surprising, because the term "nutrient imbalance" is broad and encompasses nutritional design rather than animal safety. Typically, animal safety is related to established nutrient deficiencies and toxicities. In fact, nutritional design and formulation must consider multiple factors including all the sources of nutrients. Furthermore, adjustments are necessary to insure the animal does not receive too much or too little of a nutrient based on the total consumed ration. Therefore, to align the animal food preventive control supplemental proposed rule with the foreign supplier verification program supplemental, AFIA recommends the inclusion of "nutrient deficiencies or toxicities" and utilization of the definitions for each proposed term from our March 31 comments to the proposed preventive control animal food rule.

Supplemental Proposed Rule with AFIA Recommendations

§ 1.504(b)(2) Your analysis must include hazards that may be present in a food for any of the following reasons:

(i) The hazard occurs naturally;
(ii) The hazard may be unintentionally introduced;
(iii) The hazard, based on historical precedent, may be intentionally introduced for purposes of economic gain.

AFIA Comments

It seems the agency's intent is that facilities consider hazards that have been documented as being introduced for economic gain in the past, such as melamine in protein sources. However, the codified language could be interpreted to mean that facilities should consider all potential economic adulterants. AFIA recommends that language be added to clarify the agency's expectation that only known or reasonably foreseeable economic adulterants that might pose a safety risk be considered. With this addition and the requirement provided under §1.508 for a reanalysis of a firm's FSVP when

new information becomes available on potential risks associated with the food or foreign supplier of the food, AFIA believes that economic adulteration would be sufficiently addressed in a robust animal food safety plan.

Supplemental Proposed Rule with AFIA Recommendations
§ 1.504(d) Review of the foreign supplier's hazard analysis. If your foreign supplier has analyzed the known or reasonably foreseeable hazards for the food to determine whether there are any significant hazards, you may meet your requirement to determine whether there are any significant hazards in a food by reviewing and assessing the analysis conducted by the foreign supplier.

AFIA Comments
While AFIA believes the opportunities to use this option may be limited because many foreign suppliers are not keen on sharing their hazard analysis or similar documentation, AFIA appreciates the additional option to meet this requirement.

Supplemental Proposed Rule with AFIA Recommendations
§ 1.504(g) Significant hazards controlled by you and/or your customer. If the preventive controls that you and/or your customer implement in accordance with subpart C of part 117 of this chapter and subpart C of part 507 are adequate to significantly minimize or prevent all significant hazards in a food you import, you are not required to determine what foreign supplier verification and related activities you must conduct under § 1.505 and you are not required to conduct such activities under § 1.506. ~~If your customer controls one or more such hazards, you must annually obtain from the *customer* written assurance that it has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard.~~

AFIA Comments
FDA has added a reference to Part 117, subpart C (Preventive Controls for Human Food), but not to Part 507, subpart C (Preventive Controls for Animal Food). AFIA assumes this was a drafting error and, as FSVP applies to both human food and animal food, proposes that FDA correct this by adding Part 117, subpart C, with Part 507, subpart C (Preventive Controls for Animal Food). If the preventive controls that the importer and/or the importer's customer implement in accordance with subpart C of Part 507 are adequate to significantly minimize or prevent all significant hazards in the animal food that is imported, the importer should not be required to determine what foreign supplier verification and related activities they must conduct under § 1.505, and should not be required to conduct such activities under § 1.506. This exemption should not be limited to applicability to human food.

Additionally, it is not practical to expect a customer to provide the importer (which is the customer's supplier) written documentation that it is controlling a potential hazard for a material. This is beyond what a customer/supplier relationship should be. Intended use of a material by a customer determines the potential hazards from a material. The customer is in the best position to assess these hazards through their own risk assessment. They can determine whether they want or need to control the hazard or require the supplier to control. Documentation from the customer to the importer is irrelevant and not needed.

Supplemental Proposed Rule with AFIA Recommendations
§ 1.506: What foreign supplier verification and related activities must I conduct?

FDA seeks comment on circumstances under which it might be necessary and appropriate to receive food from unapproved foreign suppliers and on the types of verification activities that an importer should conduct on food from an unapproved supplier.

AFIA Comments
AFIA is supportive of this allowance for special circumstances under which an approved foreign supplier may not be available. The importer should provide reestablished guidelines on conditional approval and conduct a reassessment of their hazard analysis, if appropriate. The importer would already have language in its operating procedures, which would be the importer's established guidelines in such a circumstance. The importer presumably would already have a program in place for the significant hazard and can address the significant hazard with the appropriate verification activity/activities. The importer could, as an example, conduct product testing or obtain a certificate of analysis (COA) as verification activities.

FDA requests comment on whether the regulations should specify the form of such documentation and, if so, what form such documentation should take.

AFIA Comments
AFIA does not believe that the regulations should specify the form of such documentation as this could depend on the product, hazard, importer and supplier. This would limit what information a firm should collect or maintain, which should be part of the firm's records and documentation for the facility's animal food safety plan.

Supplemental Proposed Rule with AFIA Recommendations
§ 1.506(d)(5)(i) Substitution of inspection by FDA or an officially recognized or equivalent food safety authority. Instead of an onsite audit conducted under paragraph (d)(1) or (2) of this section, an importer may rely on the results of an inspection of the foreign supplier by FDA or the food safety authority of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States, provided that the inspection was conducted within 2 years ~~1 year~~ of the date it was determined that an onsite audit was the appropriate verification activity ~~that the onsite audit would have been required to be conducted~~. You must document the inspection results on which you rely.

AFIA Comments
The inclusion of onsite audits being fulfilled by FDA or the food safety authority of a country, whose food safety system FDA has recognized as comparable or has determined to be equivalent to that of the U.S., is an acceptable option to meet the onsite audit requirement. However, it is unrealistic that an onsite audit could always be implemented within one year of determining that an audit is required. AFIA suggests changing the language to require that the onsite audit, whether by the receiving facility, FDA or the food safety authority of a foreign country, be conducted within two years of the date it was determined an onsite audit was the appropriate verification activity to control the hazard for the imported food in question.

Supplemental Proposed Rule with AFIA Recommendations
§ 1.510 (d)(2) You must maintain records required under §§ 1.502(d) ~~and 1.504(g) (customer assurances)~~, § 1.506(d)(1)(i)(C), (d)(1)(ii)(B), (d)(1)(iii), and (d)(1)(iv) (certain verification

activities), § 1.507 (investigations and corrective actions), § 1.508 (FSVP reassessments), § 1.511(b) (assurances from customers subject to certain dietary supplement current good manufacturing practice regulations), § 1.511(c)(5)(i)(C), (c)(5)(ii)(B), (c)(5)(iii), and (c)(5)(iv) (certain verification activities for importers of certain dietary supplements), and § 1.513(b) (food imported from a country with an officially recognized or equivalent food safety system) for a period of at least 2 years after the records were created or obtained, except that you must maintain records of any changes to your FSVP in accordance with § 1.507(d) or § 1.508(b) until at least 2 years after their use is discontinued.

AFIA Comments

Please see comments above for 1.504(g) as this activity should not be required.

Supplemental Proposed Rule with AFIA Recommendations

~~**§ 1.512**~~

~~(a) Eligibility. This section applies only if you a very small importer or the food you are importing is from a very small foreign supplier.~~

~~(b) Applicable requirements.~~

~~(1) If this section applies and you choose to comply with the requirements in this section, you must document, at the end of each calendar year, that you meet the definition of very small importer in § 1.500 or that the foreign supplier meets the definition of very small foreign supplier in § 1.500, whichever is applicable. For the purpose of determining whether you satisfy the definition of very small importer or the foreign supplier satisfies the definition of very small foreign supplier, the baseline year for calculating the adjustment for inflation is 2012. If you or the foreign supplier conduct any food sales in currency other than U.S. dollars, you must use the relevant currency exchange rate in effect on December 31 of the year in which sales occurred to calculate the value of these sales.~~

~~(2) Additional requirements. If this section applies and you choose to comply with the requirements in paragraph (b) of this section, you also are required to comply with the requirements in §§ 1.502, 1.503, and 1.509, but you are not required to comply with the requirements in §§ 1.504 through 1.508 or § 1.510.~~

~~(3) Foreign supplier verification activities. For each food you import, you must obtain written assurance, before importing the food and at least every 2 years thereafter, that your foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 or 419 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350g or 350h), if either is applicable, and is producing the food in compliance with sections 402 and 403(w) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342, 343(w)). The written assurance must include a brief description of the processes and procedures that the foreign supplier is following to ensure the safety of the food.~~

~~(4) Corrective actions. You must promptly take appropriate corrective actions if you determine that a foreign supplier of food you import does not produce the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 or 419 of the Federal Food, Drug, and Cosmetic Act, if either is applicable, or produces food that is adulterated under section 402 or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act. The appropriate corrective actions will depend on the circumstances but could include discontinuing use of the foreign supplier until the cause or causes of noncompliance, adulteration, or misbranding have been adequately addressed. You must document any corrective actions you take in accordance with this paragraph (b)(4). This~~

~~paragraph (b)(4) does not limit your obligations with respect to other laws enforced by FDA, such as those relating to product recalls.~~

~~(5) Records. (i) Availability. You must maintain records required under this subpart, in English, and make them available promptly to an authorized FDA representative, upon request, for inspection and copying. You must maintain records at your place of business or at a reasonably accessible location; records are considered to be at a reasonably accessible location if they can be immediately retrieved from another location by computer or other electronic means. If requested in writing by FDA, you must send records to the Agency electronically or by mail rather than making the records available for review at your place of business.~~

~~(ii) Record quality. All records must be legible and stored to prevent deterioration or loss.~~

~~(iii) Record retention. You must maintain records required under this subpart for a period of at least 2 years after the records were created or obtained.~~

AFIA Comments

See comments above under the definitions of "very small importer" and "very small foreign supplier."

SUMMARY AND CONCLUSIONS

Again, AFIA reiterates its appreciation for FDA's publication of another round of the supplemental proposed foreign supplier verification rule. AFIA feels strongly about the risks of inclusion of modified FSVPs in the final rule and asks FDA to seriously reconsider these allowances. AFIA believes that it is imperative that the final FSVP rule correspond with the requirements and definitions of similar terms in the final rules on preventive controls for both human and animal food. All efforts should be made to coordinate the final preventive controls and FSVP regulations; not only to avoid confusion, but also to comply with WTO rules. The final FSVP rule cannot be more stringent on imported products than those on U.S. products thus causing WTO inconsistencies such as a violation of the principles of non-discrimination.

Continued support by FDA is strongly urged for the joint industry/agency efforts in the FSPCA. This group should spend quality time on developing relevant, clear and practical guidance documents for the following animal food industry segments: dry feed liquid feed, pet food, animal-derived products, plant-derived products, vitamin/mineral/amino acid trace ingredients and miscellaneous/special purpose ingredients. AFIA pledges it support and technical assistance in developing these guides.

Finally, AFIA is grateful for FDA's cooperation in offering a number of public sessions, providing speakers for industry seminars and listening to industry concerns about this massive rulemaking process. AFIA pledges its continuing support to developing sound industry practices for compliance with this rule.

Sincerely,

Gina Tumbarello
Director, International Policy and Trade

Henry Turlington
Director, Quality & Manufacturing Regulatory Affairs