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December 14, 2014

Submitted Electronically via Regulations.gov
Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals (Docket Number: FDA-2011-N-0922-0269)

The Pet Food Institute (PFI) appreciates the opportunity to provide comments regarding the food safety requirements outlined in the Food and Drug Administration's (FDA's or the Agency's) re-proposed rule regarding Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals, published in the Federal Register on September 29, 2014 (79 Fed. Reg. 58,476) and hereafter referred to as the "Notice," the "Re-proposed Rule," or the "Animal Food Rule."

Established in 1958, PFI is the voice of US cat and dog food manufacturers; our members sell more than $20 billion in dog and cat food annually and export an additional $1.5 billion. For more than 55 years, PFI has worked with its members to educate the world 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 members account for more than 95 percent of the cat and dog food produced in the United States. Among its members are 22 dog and cat food manufacturers and more than 100 affiliates who supply ingredients and raw materials to dog and cat food producers.

Pet food makers share the FDA's commitment to pet food safety and quality, and we are proud of the safety record of our products. PFI strongly supports the Food Safety Modernization Act (FSMA), as evidenced by our engagement with FDA throughout this rulemaking process, and we look forward to working with FDA for the successful implementation of this landmark law. We share FDA's goal of establishing a regulatory framework that protects public health, is science and risk-based, and is both practical and practicable.

We are pleased that FDA has re-issued this Proposed Rule in light of significant comments received from stakeholders. And while we acknowledge the court-imposed deadlines under which FDA is operating with respect to issuance of FSMA final rules, we believe the comment period for this Re-proposed Rule does not provide sufficient time for a thorough review of all the re-proposed rules – this Animal Food Re-proposed Rule in particular – to better understand how they will work together once finalized and implemented.

General Observations

PFI appreciates FDA's acknowledgment of some of the concerns expressed and changes recommended in our comment on the original Proposed Rule (78 Fed. Reg. 64,736, Oct. 29, 2013). The Re-proposed Rule includes significant improvements including: changes to key terms, such as elimination of the term "hazard reasonably likely to occur" and the introduction of definitions for the terms "known or reasonably foreseeable hazard" and "significant hazard"; modifications to the proposed Current Good Manufacturing Practices (CGMPs), including greater flexibility and discretion that acknowledges the manufacturing practices used by animal food producers; proposed CGMPs for holding and distribution of human food by-products for animal food production; and the explanation of concepts introduced but not explained in the original Proposed Rule, such as product testing and environmental monitoring. The Re-proposed Rule, in our view, represents a significant improvement with respect to these terms and concepts.

The Re-proposed Rule includes old and new challenges PFI would like to see addressed in the Final Rule, however. First, we are very concerned to see that the FDA, in the Re-proposed Rule, is again requiring compliance with 21 CFR Part 11 relating to electronic recordkeeping. This requirement, if imposed on animal food producers, will require millions of dollars and years of wholesale reconstruction of entire data networks by many animal food producers. Moreover, imposing this requirement will have no appreciable benefit to or improvement on product safety. Some global database systems cannot be validated by Part 11 – non-compliance would be rampant, especially among small animal food producers, many of whom will are unfamiliar with Part 11 requirements. Our concern is shared by many animal and human food producers and is in our view symptomatic of FDA's consistent and significant underestimation of the costs of FSMA implementation.

PFI strongly supports the good recordkeeping principles FDA identified for key food safety records in its original Proposed Rule (78 Fed. Reg. 64814), and we agree that recordkeeping systems used to document key food safety activities must be trustworthy and reliable. We disagree with FDA's apparent contention that compliance with 21 CFR Part 11 is necessary to achieve food safety goals under FSMA and urge FDA to remove this requirement from the Final Rule.

Second, we support FDA's inclusion of requirements for supplier approval and verification in its animal food preventive controls supplemental proposal. We continue to believe the establishment of a supplier approval and verification program is an important part of a preventive approach, and serves a critical function in an industry dependent upon raw materials. A robust supplier approval and verification program can help ensure that raw materials and ingredients are procured from suppliers that can meet company specifications. However, we believe the supplier program concept as proposed oversimplifies how hazards are addressed by animal food producers and their suppliers. Specifically, many hazards are addressed not exclusively by the animal food producer or a raw material/ingredient supplier, but jointly – the supplier program language in this Re-proposed Rule does not account for this reality. Our section-specific comments below offer observations and recommendations we believe will improve the Final Rule.

PFI is also concerned that FDA has chosen to define a "very small business" as one having less than $2.5 million in total annual animal food sales. As we stated in our comment on the original Proposed Rule, all animal food producers should be subject to all provisions of this rule, regardless of size – there is no business size threshold under which animal food safety deserves preferential treatment. Furthermore, FDA's proposal to include economically motivated adulteration as a required element in animal food producers' hazard analysis runs counter to our belief that such adulteration is best addressed in a facility's food defense plan. Finally, we note that several terms have different definitions in this Re-proposed Rule compared to others being promulgated under the FSMA. We believe this inconsistency in definitions could lead to confusion – we therefore urge FDA to (as appropriate) adopt a single definition for each term and incorporate that definition into each of the FSMA Final Rules.

PFI agrees with FDA that rulemaking is a collaborative process and we appreciate the opportunity to provide input to FDA, both through this comment and in our discussions with FDA CVM officials. Our interest in providing this input is to assist FDA in developing an Animal Food Final Rule that balances clear requirements with flexibility and discretion for animal food producers, enabling them to comply using methods and approaches that best suit their particular production situations.

To provide context to our section-specific comments below and our recommended changes, we would like to close this general observations section with some facts and figures regarding the risks to human and animal health posed by pet foods, and processed pet foods in particular. In our response to FDA's Notice of its Draft Approach to Identify High-Risk Foods Under Section 204 of FSMA, PFI summarized FDA and industry data that indicate the low risk that pet food poses to human and animal health. PFI found that, based on data from FDA and the Centers for Disease Control and Prevention (CDC), pet food accounts for an incredibly low percentage of foodborne illness. Specifically, we pointed to FDA's own data indicating that there are over 48 million cases of foodborne illness annually in the United States, resulting in an

estimated 128,000 hospitalizations and 3,000 deaths.[1] This translates to 5,479 incidents of foodborne illness per hour. PFI's evaluation of the historical data for foodborne illness cases indicates that pet foods accounted for 192 human illnesses since 1999, which is an average of less than fifteen incidents of foodborne illness per year. Accordingly, the fact that pet food plays such a minor role in human illness warrants a more flexible approach in the Animal Food Final Rule, which would also represent a more efficient allocation of FDA inspection and enforcement resources.

PFI Responses to FDA Specific Requests for Comment

FDA seeks comment on whether a range of newly proposed requirements – specifically, product testing, environmental monitoring, a supplier program and an analysis of hazards that may be intentionally introduced – "should be included in a final rule and, if so, what (if any) modifications to the proposed regulatory text would be appropriate." (79 Fed. Reg. at 58,477). PFI provides below some general comments regarding those newly proposed requirements.

Product testing: FDA concedes that there are limits to product testing but states that such programs, "when implemented appropriately based on the facility, the animal food, and the nature of the preventive control, could be used to verify that the preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards." (*Id.* at 58,493). FDA goes on to state that its proposed approach would "provide flexibility for a facility to make risk-based decisions on when product testing would be appropriate…" (*Id.* at 58,494).

PFI generally agrees with FDA that product testing is one tool animal food producers can use to verify the effectiveness of a facility's preventive controls. Regarding FDA's request for comment on whether requirements for product testing should be included in the Final Rule (for facilities that choose to employ product testing), we must refer to our comment on FDA's original Proposed Rule.

In that comment, we cited the complexity of pet food production, and explained that any testing program must be both risk-based and facility-specific. We suggested to FDA that, "[w]hile general statements in the rules can indicate support for appropriate testing programs, we recommend that details of suggested programs be captured via guidance documents instead of via codification in specific FSMA rules." (*PFI Comment - Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals (Docket Number: FDA-2011-N-0922; RIN 0910–AG10*, page 10) PFI continues to support the use of non-binding guidance to assist facilities with implementing the FSMA regulations.

PFI must again stress to the FDA that ingredient, finished product and/or environmental testing will significantly increase the operating costs of animal food producers. The pet food industry (both small and large producers) has already dedicated significant funds

[1] (Foodborne Illness-Causing Organisms in the U.S. – What You Need to Know, found at http://www.fda.gov/downloads/Food/FoodborneIllnessContaminants/UCM187482.pdf)

and resources in the last 5-7 years to update production facilities and processes in an ongoing effort to improve animal food safety and in anticipation of the full implementation of FSMA. Our members' efforts have been largely successful, as evidenced by FDA's microbial surveillance data of pet food products and treats, which found significant drops in positive findings for *Salmonella* in pet food and treats, from 15+% to around 2.5% over the last 7 years. It is our contention that FDA's cost estimates have failed to account for these recent and significant investments in food safety measures, measures that have largely addressed the food safety challenges that prompted congressional passage of FSMA.

Nonetheless, PFI generally agrees that the proposed product testing provisions achieve the balance between setting out requirements for product testing and providing sufficient flexibility for animal food producers to determine whether and how to use this tool.

Environmental monitoring: FDA states that "[c]urrently available data and information support the role of environmental monitoring in a food safety system that incorporates hazard analysis and risk-based preventive controls." (79 Fed. Reg. at 58,494). FDA adds that "[e]nvironmental monitoring would be required in the specific circumstances where an animal food product is exposed to the environment prior to packaging, such as dog and cat food kibble, and the packaged animal food does not receive a treatment that would significantly minimize an environmental pathogen that could contaminate the animal food when it is exposed." (*Id.*)

PFI agrees with FDA that environmental monitoring can be a useful tool to verify that preventive controls "are effectively and significantly minimizing or preventing the occurrence of identified hazards." (*Id.*) But we are concerned that FDA is seeking to require environmental monitoring in all instances in which animal food is exposed to the environment. Imposing such a blanket requirement would seriously impact all animal food producers and fails to acknowledge that mere exposure to the environment does not inherently increase the risk of contamination of animal food. For example, applying this requirement to animal food produced in bulk for later packaging by another facility would create significant new burdens for co-packers, with no evidence that this production method is inherently riskier than other methods. Moreover, because a co-packer of an animal food would not have the option of subjecting that food yet again to a pathogen mitigation/kill step, its only treatment option might be irradiation, a treatment that is neither required nor popular among consumers. FDA and industry data indicate that current pet food production methods, which include co-packing of animal food, are highly successful in preventing contamination of animal food. We therefore urge FDA to recommend rather than require environmental monitoring for animal food producers, thus giving animal food producers discretion to determine whether exposure to the environment has created the potential for introduction of significant hazards and what steps to take to effectively address any such hazards.

Supplier Programs: In response to stakeholder comments on the original Proposed Rule, FDA proposes a supplier program and provides detailed requirements in the Re-proposed Rule. PFI agrees with FDA that supplier programs can be an effective tool to

address food safety concerns, but we believe that FDA's approach is far too prescriptive, as described in our comments on proposed § 507.37 (below). Our proposed changes, in the section specific comments below, encourage a risk-based approach, based on sound science.

Although PFI acknowledges FDA's attempt to limit the scope of animal food producers to whom the supplier program requirements would apply, we feel that FDA may be oversimplifying the roles that ingredient/raw material suppliers and animal food producers play in addressing hazards – including significant hazards – in animal food. In many instances, the responsibility for addressing hazards in animal food is shared; FDA's approach in the supplier program draws a distinction that does not practically exist in that the effectiveness of an animal food producer's pathogen mitigation/kill step depends in part on whether/to what extent a raw material/ingredient supplier addresses that same hazard before delivering the raw material/ingredient to the animal food producer.

FDA requests comment on "what verification activities would be appropriate for receiving facilities to conduct, should a supplier verification program be included in any final rule, when a raw material or ingredient passes through more than one facility that would not be required to verify control of hazards if supplier programs are limited to manufacturers/processors." (79 Fed. Reg. at 58,497). This question illustrates our point above that addressing hazards is often a shared responsibility. Under the scenario proposed in the supplier program provisions of the Re-proposed Rule, a raw material/ingredient supplier that is a manufacturer/processor and sends its product to a distributor for ultimate delivery to an animal food producer could contend that it should not be subject to a supplier program because the receiving facility's food safety plan includes a pathogen mitigation/kill step that addresses a hazard present in the raw material/ingredient. This position belies the fact that the effectiveness of many pathogen mitigation/kill steps in the manufacture of animal food is enhanced by steps the raw material/ingredient supplier takes to address that hazard. We therefore urge FDA to include flexibility in the Final Rule to provide for the use of supplier programs when responsibility for addressing a hazard is shared between a raw material/ingredient supplier and the receiving facility.

Finally, FDA seeks comment on "whether (and, if so, how) the final preventive controls rule should address the potential for gaps in supplier controls when a hazard is controlled at Point A in the supply chain and Point B in the supply chain is a facility that only packs or holds animal food, but does not manufacture/process animal food (and therefore would not be required to have a supplier program) before passing it on to Point C in the supply chain." (79 Fed. Reg. at 58,497-98). As stated in our observation regarding environmental pathogens, we believe the determination of whether a facility such as a co-packer of animal food – involved in packaging finished animal food for distribution and sale – must implement preventive controls should be made on a case-by-case basis, taking into account the actual risk posed by exposure of the animal food to the environment. We see no need for this rule to address *the potential* for gaps in

supplier controls; rather, the focus of this rule should be on actual hazards to animal food.

Hazards that may be intentionally introduced: Regarding requirements to address economically motivated adulteration, FDA seeks comment on "whether this preventive controls rule would be the most appropriate rule to address hazards that may be intentionally introduced (for purposes of economic gain) and, if so, what (if any) modifications to the proposed regulatory text would be appropriate." (79 Fed. Reg. at 58,500). As we stated in our comment on the original Proposed Rule, PFI believes that intentionally introduced hazards, including those introduced for purposes of economic gain, are best addressed in a facility's food defense plan, a view that is consistent with the proposed rule on Focused Mitigation Strategies To Protect Food Against Intentional Adulteration. (78 Fed. Reg. 78013, Dec. 24, 2013) Accordingly, we urge FDA to exclude economically motivated adulteration as a required element in a facility's food safety plan.

If FDA includes economically motivated adulteration as a required element in a facility's food safety plan, PFI agrees with FDA that facilities should not be expected to "consider hypothetical economically motivated adulteration scenarios for their animal food products." (*Id.* at 58,500) Rather, facilities would be expected to "focus on circumstances where there has been a pattern of such adulteration in the past." (*Id.*) Accordingly, we urge FDA to include in the Final Rule the qualification that hazard identification must consider *previously known or familiar* hazards that may be intentionally introduced for purposes of economic gain.

FDA also requests comment on its tentative conclusion that "[p]roposed § 507.12(b) would not apply to human food by-products derived from animal products (other than dairy and eggs), such as meat, offal, or poultry," because "the hazards, particularly biological hazards, potentially associated with by-products from these animal products could be more substantial than those for the by-products addressed in the memorandum." As we discuss in our section-specific comments below, PFI believes that FDA and industry data clearly indicate that any hazards in human food by-products derived from animal products can be adequately addressed by the provisions in proposed § 507.28, Holding and distribution of human food by-products for use as animal food.

We next set forth detailed comments on specific provisions of the Re-proposed Rule.

Subpart A – General Provisions

§ 507.3 Definitions.

"Adequate" is defined as "that which is needed to accomplish the intended purpose in keeping with good public health practice."

PFI commented earlier that there is no standard or definition for "good public health practice" and that this term should be removed from the definition. FDA CVM conveyed to PFI during a teleconference on November 6, 2014 that this term is borrowed from a definition dating back to 1979 that referred specifically to human food. While we understand the need for clearly defined terms, certain terms and definitions may be appropriate for human food but inappropriate for animal food. For animal food producers, the term "good public health practice" creates more uncertainty than it removes. PFI, as in its earlier comment, urges FDA to modify the definition of "adequate" to read as follows: "that which is needed to accomplish the intended purpose ~~in keeping with good public health practice~~."

"Environmental Pathogen" is defined as "a pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food for animals may be contaminated and may result in foodborne illness if that animal food is not treated to significantly minimize or prevent the environmental pathogen. Environmental pathogen does not include the spores of pathogenic sporeformers."

PFI acknowledges FDA's approach in the re-proposal, which defines both "pathogen" and "environmental pathogen." As stated in our general observations, we believe the FSMA rules would benefit from a single definition for terms that are used in multiple rules. Accordingly, PFI recommends that the definition of "environmental pathogen" be changed to read as follows: "Environmental Pathogen means a pathogenic bacteria capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food ~~for animals~~ may be contaminated and may result in foodborne illness if that ~~animal~~ food is consumed ~~not treated~~ without further treatment to significantly minimize or prevent the environmental pathogen. Environmental pathogen does not include the spores of pathogenic sporeformers."

"Facility" is defined as "a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of 21 CFR part 1, subpart H."

As PFI indicated in its comment on the original Proposed Rule, this definition should clearly indicate that certain plants/facilities, including research and pilot plants/facilities that do not place food into commerce, are not subject to the rule. We therefore recommend that the following modification to the definition be made: "a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of 21 CFR part 1, subpart H. A facility that does not place food into commerce – for example, a research or pilot facility – is not considered a facility for the purpose of compliance with provisions in this rule."

"Hazard" is defined as "any biological, chemical (including radiological), or physical agent that is reasonably likely to cause illness or injury in the absence of its control."

PFI believes this definition would benefit from more precision. Accordingly, we recommend the following modification to make this definition more precise: "Hazard means any biological, chemical (including radiological), or physical agent that is reasonably likely to cause illness or injury in the intended species in the absence of its control."

"Known or reasonably foreseeable hazard" is defined as "a biological, chemical (including radiological), or physical hazard that has the potential to be associated with the facility or the food."

PFI notes that FDA proposes slightly different definitions for this term (and others) in the Animal Food and Foreign Supplier Verification Program (FSVP) Re-proposed Rules. We strongly recommend that, where appropriate, a single definition be adopted for terms used across multiple FSMA rules. Doing so will reduce confusion among stakeholders and enhance understanding of key concepts. Accordingly, we recommend incorporating the definition for "known or reasonably foreseeable hazard" that appears in the FSVP Re-proposed Rule: "a potential biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with a food or the facility in which it is manufactured/processed."

Packaging (when used as a verb) means "placing food into a container that directly contacts the food and that the consumer receives."

PFI notes that FDA declined our request to distinguish between consumers and customers of animal food. As we noted in our comment on the original Proposed Rule, the consumer of animal food is the target animal. The customer of the animal food – the purchaser – typically "receives" the container that directly contacts the food. We therefore urge FDA to consider modifying this definition – and all other references to consumers in this re-proposal – accordingly.

"Qualified auditor" is defined as "a person who is a qualified individual as defined in this part and has technical expertise obtained by a combination of training and experience appropriate to perform the auditing function as required by § 507.53(c)(2)."

PFI notes that this definition requires the qualified auditor to be a "qualified individual." Although certain aspects of a qualified individual's background, experience or training might be helpful for a qualified auditor, we believe that there is no need to link the definitions. PFI believes that, rather than require a qualified auditor to be a qualified individual, a qualified auditor should be identified by a qualified individual as possessing the required knowledge, skills and abilities to conduct onsite audits of suppliers. In addition, because FDA's proposed definition for "qualified auditor" relies on the definition for a "qualified individual," PFI refers FDA to our comment on this definition in response to the original FSVP Proposed Rule. There we urged FDA to define a "qualified individual" as an individual possessing a combination of education, training and experience, or combination thereof, that enables that individual to perform the activities needed to meet the requirements in the subpart. We believe it is imperative that the

"qualified individual" definition include flexibility with respect to how a qualified individual or a qualified auditor meets these requirements.

Accordingly, we recommend the following change to this definition: "Qualified auditor means a person who is or has been identified by a qualified individual (as defined in this part) ~~and has~~ as having technical expertise obtained by a combination of training and experience appropriate to perform the auditing function of foreign or domestic suppliers, in accordance with the applicable subpart ~~function as required by § 507.53(c)(2)~~."

"Qualified facility" is defined as "(when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) a facility that is a very small business as defined in this part…"

PFI notes that FDA has decided that a very small business is defined as a business having less than $2.5 million in annual sales. PFI, along with other animal food stakeholders, urged FDA to adopt a lower threshold for the very small business definition, in order to ensure compliance with FSMA provisions by all animal food producers. We reiterate our earlier point that covering a significant portion of animal food producers is insufficient to ensure the safety of animal food – all or virtually all animal food producers must be required to comply with all applicable FSMA provisions. Accordingly, and in order to have FSMA final rules that are more consistent with one another, PFI urges FDA to adopt one threshold that would apply to very small businesses under this Proposed Rule and to very small importers and very small foreign suppliers under the FSVP Proposed Rule. We propose that this threshold be $1 million, a figure that would provide greater coverage than the $2.5 million threshold in this Proposed Rule and would also simplify compliance with all FSMA rules for animal food producers.

"Quality control operation" is defined as "a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated."

Although PFI agrees generally with the definition of this term – animal food facilities should have plans and systems in place to prevent the adulteration of food – we disagree with the use of the term "quality control" in a rule focused on food safety. We believe the term "preventive controls" and its use throughout the FSMA proposed rules is sufficient to convey the concept of plans and systems to *prevent* the adulteration of food. We once again urge FDA to remove this definition from the final rule. We also note that this term appears nowhere in the Re-proposed Rule, so its removal from the definitions section will not affect any Final rule provisions.

"Receiving facility" is defined as "a facility that is subject to subpart C of this part and that manufactures/processes a raw material or ingredient that it receives from a supplier."

PFI believes FDA's approach with respect to this definition has the unintended consequence of absolving so-called "intermediate stakeholders" in the animal food

production chain (i.e., brokers) from any responsibility for the raw materials/ingredients they distribute to an animal food producer for manufacturing/processing. As the entity with the closest relationship to the supplier of the raw material/ingredient, PFI believes strongly that such an intermediate stakeholder should bear some responsibility to at least identify any hazards associated with the raw materials/ingredients it supplies to animal food producers and to make this information available to its customers. This view is consistent with our position throughout this comment that addressing hazards is often a shared responsibility and should not rest solely with the animal food producer.

Accordingly, we propose the following modification to this definition: "Receiving facility: means a facility that is subject to subpart C of this part and/or that manufactures/processes, packs or distributes for further manufacturing/processing a raw material or ingredient that it receives from a supplier."

"Significant hazard" is defined as "a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing/processing, packing, or holding of animal food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in an animal food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the control."

PFI acknowledges the changes FDA proposes in light of comments received to the original Proposed Rule regarding use of the term "hazard reasonably likely to occur," a term drawn from and based on HACCP principles. We generally agree that the newly proposed terms "hazard," "known or reasonably foreseeable hazard" and "significant hazard" provide a clearer understanding of the Agency's expectations for hazard analysis to be conducted by those involved in animal food production. During PFI's teleconference with FDA officials on November 6th, FDA informed us that a "significant hazard" should be viewed as a hazard that, in the absence of its control, is likely to cause severe adverse health consequences or death to humans or animals (SAHCODHA). We believe that including a reference in this definition to a widely known and commonly used food safety term is preferable to the existing terminology, which essentially defines a significant hazard as any known or reasonably foreseeable hazard that a knowledgeable person deems "significant."

Accordingly, we recommend the following modification to the definition: "Significant hazard: means a known or reasonably foreseeable hazard that a hazard analysis determines is likely to cause severe adverse health consequences or death to humans or animals in the absence of its control ~~for which a person knowledgeable about the safe manufacturing/processing, packing, or holding of animal food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in an animal food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the control~~."

"Validation" is defined as "that element of verification focused on collecting and evaluating scientific and technical information to determine whether the food safety plan, when properly implemented, will effectively control the identified hazards."

PFI is compelled to reiterate a point we made in our comment on the original Proposed Rule. In that comment, we stated that "Codex, in its role as an international standard setting body that promotes trade in safe foods, has developed a definition for this term. PFI recommends that FDA incorporate into the rule the Codex definition for 'validation.'"

Accordingly, we recommend the following modification to this definition: "Validation means obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome ~~that element of verification focused on collecting and evaluating scientific and technical information to determine whether the food safety plan, when properly implemented, will effectively control the identified hazards~~."

"Verification" is defined as "those activities, other than monitoring, that establish the validity of the food safety plan and that the system is operating according to the plan."

Again, PFI is compelled to reiterate a point we made in our comment on the original Proposed Rule. In that comment, we stated that "Codex, in its role as an international standard setting body that promotes trade in safe foods, has developed a definition for this term. PFI recommends that FDA incorporate into the rule the Codex definition for 'verification.'"

Accordingly, we recommend the following modification to the definition of this term: "Verification means an application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended ~~those activities, other than monitoring, that establish the validity of the food safety plan and that the system is operating according to the plan~~."

"Very small business" is defined as, "for purposes of this part, a business that has less than $2,500,000 in total annual sales of food for animals, adjusted for inflation."

PFI maintains that, if there is an exemption for adherence to this rule by a qualified facility based on annual sales, this exemption should be as small as possible to ensure the widest possible coverage of the rule to animal food producers. This approach led us to propose in our comment on the original Proposed Rule a $10,000 threshold for the definition of a "very small business." If FDA decides to proceed with a higher threshold for this definition, we note that consistency across the rules will facilitate compliance and a better understanding of the obligations animal food producers must meet. In the FSVP Re-proposed Rule, FDA proposes a $1 million threshold for the definition of both a "very small importer" and a "very small foreign supplier." We believe that adoption of this same threshold for the definition of "very small business" in the Animal Food Re-proposed Rule will provide maximum coverage of stakeholders and will eliminate the confusion that may result from different dollar thresholds for different stakeholders.

Accordingly, we recommend the following change: "Very small business means, for purposes of this part, a business that has less than ~~$2,500,000~~ $1,000,000 in total annual sales of food for animals, adjusted for inflation."

§ 507.7 Requirements that apply to a qualified facility.

Section 507.7(a)(2)(ii) states that "(a) A qualified facility is exempt from subpart C of this part provided that for the calendar year in which it is to be considered a qualified facility, the facility has submitted to FDA documentation that: … (2)(ii) Demonstrates the facility is in compliance with state, local, county, or other applicable non-Federal food safety law. This documentation may include inspection reports, certification by an appropriate agency (such as a State department of agriculture), or other documentation deemed appropriate by FDA."

The conditions a facility must meet to be considered a qualified facility are enumerated in this provision and include a requirement that the facility must either: identify potential hazards, implement preventive controls and monitor the performance of preventive controls to ensure that such controls are effective; or demonstrate that the facility is in compliance with state, local, county or other applicable non-Federal food safety law.

PFI questions what type of evaluation such a facility will be subjected to in order to ensure the safety of animal food it produces under conditions other than compliance with federal food safety requirements. Unless these non-Federal food safety laws are being updated now, they may not provide the same level of protection to consumers as is provided under the FSMA regulations. PFI seeks information as to what evaluation FDA will conduct of any non-Federal food safety law *before* determining that compliance with such law constitutes compliance under FSMA for a qualified facility.

Subpart B – Current Good Manufacturing Practice

§ 507.12 Applicability of this part to the holding and distribution of human food by-products for use in animal food.

PFI supports the approach FDA takes in this provision with respect to the holding of human food by-products for use in animal food. Human food by-products held for use in animal food should be subject to CGMPs appropriate to the human food facility, and all reasonable steps should be taken to prevent contamination during holding and transportation to animal food producers. As long as the human food from which the human food by-products are derived is subject to appropriate CGMPs and the human food by-products are held for distribution in compliance with § 507.28 of this Re-proposed Rule or other applicable USDA regulations, sufficient measures would be in place to ensure the safety of the human food products destined for use in animal food. These requirements are designed to encourage the continued use of these human food by-products in animal food, a practice all stakeholders agree is safe, economical and sustainable.

FDA also requests comment on its tentative conclusion that "[p]roposed § 507.12(b) would not apply to human food by-products derived from animal products (other than dairy and eggs), such as meat, offal, or poultry," because "the hazards, particularly biological hazards, potentially associated with by-products from these animal products could be more substantial than those for the by-products addressed in the memorandum."

Although the biological hazards potentially associated with by-products from certain animal products that could be more substantial than those for other human food by-products, FDA and industry data confirm that pet foods subject to a pathogen mitigation/kill step, including those containing animal-derived human food by-products, pose no significant risk to intended species or humans. Specifically, as we indicated in our comment on FDA's High Risk Foods Draft Methodology, FDA's own analysis of pet food found that only 2.23% tested positive for *Salmonella* spp*.* in fiscal year 2012[2] and that no human illnesses were attributed to dog or cat food during this period or during the period covered in the most recent RFR Annual Report. Accordingly, we believe that these human food by-products can be safely held under conditions required by proposed § 507.28 and we urge FDA to conclude in the Final Rule that § 507.28 applies to all human food by-products held for distribution as animal food.

§ 507.19 Sanitation.

Section 507.19(b)(1) states: "(b) Animal food-contact and non-contact surfaces of utensils and equipment must be cleaned and maintained and utensils and equipment stored as necessary and appropriate to protect against contamination of animal food, animal food-contact surfaces, or animal food packaging materials. When necessary, equipment must be disassembled for thorough cleaning. In addition: (1) When it is necessary to wet-clean animal food-contact surfaces used for manufacturing/processing, or holding low-moisture animal food, the surfaces must be thoroughly dried before subsequent use."

PFI believes that this provision denies animal food producers the flexibility they need to account for instances in which disassembly of equipment and thorough drying before subsequent use is not feasible and does not contribute to food safety. Some equipment used in food production (both human and animal) cannot be easily dried prior to subsequent use. Proper maintenance ensures the equipment does not create food safety concerns. Accordingly, we recommend the following modification: "(b) Animal food-contact and non-contact surfaces of utensils and equipment must be cleaned and maintained and utensils and equipment stored as necessary and appropriate to protect against contamination of animal food, animal food-contact surfaces, or animal food packaging materials. When necessary, equipment must be disassembled for thorough cleaning. In addition: (1) When it is necessary to wet-clean animal food-contact surfaces used for manufacturing/processing, or holding low-moisture animal food, the surfaces must be thoroughly dried<u>, as appropriate,</u> before subsequent use."

[2] FDA CVM Presentation to the 2014 International Production and Processing Expo. January 28, 2014. Slide 22.

§ 507.20 Water supply and plumbing.

Section 507.20(a) stipulates that "[w]ater may be reused for washing, rinsing, or conveying animal food if it does not increase the level of contamination of the animal food."

PFI generally agrees with this language but suggests rewording it as follows in order to remove the implication that reused water or animal food with which reused water comes into contact may be contaminated: "Water may be reused for washing, rinsing, or conveying animal food if it can be confirmed it does not increase the ~~level~~ potential ~~of~~ for contamination of the animal food."

Section 507.20(b)(4) states that "[p]lumbing must be designed, installed and maintained to: … (4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor."

This language appears to prescribe plumbing as the only method of floor drainage. Adequate floor drainage can be achieved by other means, however, such as through vacuuming. PFI therefore urges a change to the language in subsection (b)(4) as follows: "Provide adequate floor drainage or take other appropriate steps in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor."

Sections 507.20(c) and 507.20(d) impose requirements that are included elsewhere in the Re-proposed Rule, specifically in §§ 507.20(b)(2) and 507.17(b)(4), respectively. Similarly, the requirement set forth in proposed § 507.20(e) is, in our view, adequately addressed in § 507.14(a)(2). Accordingly, we recommend the removal of these subsections in Section 507.20.

If FDA does not omit subsection 507.20(e) in the Final Rule, PFI would like to reiterate a point made in our previous comment on the original Proposed Rule. Specifically, the term "hand-washing facilities" is too prescriptive because it does not include hand sanitizing as an adequate method for ensuring an employee's hands are not a source of contamination. We therefore would propose the following modification to this provision: "Each plant must provide, as necessary, hand-washing or sanitizing facilities designed to ensure that an employee's hands are not a source of contamination of animal food, animal food-contact surfaces, or animal food-packaging materials."

Alternatively, § 507.14(a)(2) could be modified as follows: "Plant management must take all reasonable measures and precautions to ensure that all persons working in direct contact with animal food, animal food-contact surfaces, and animal food-packaging materials conform to hygienic practices to the extent necessary to protect against contamination of animal food. The methods for maintaining cleanliness include: … (2)

Washing or sanitizing hands thoroughly in an adequate hand-washing/sanitizing facility as necessary and appropriate to prevent contamination."

§ 507.22 Equipment and utensils.

Section 507.22(a)(1) states that "The following apply to plant equipment and utensils: (1) All plant equipment and utensils must be designed and of such material and workmanship to be adequately cleanable, and must be properly maintained."

The language in this provision is far too prescriptive in that it would impose on all equipment in a plant a requirement that should only apply to equipment directly involved in the production of animal food. We are also concerned that the term "must" is used in this provision – we believe the term "should" is more appropriate and maintains consistency with other provisions in this same section in terms of providing animal food producers with the flexibility to use and maintain equipment and utensils in a manner most appropriate to their particular facility. We therefore recommend the following modifications to the language in this section: "The following apply to plant equipment and utensils: (1) All plant equipment and utensils ~~must~~ should be designed and of such material and workmanship to be adequately cleanable, and ~~must~~ should be properly maintained."

Section 507.22(a)(2) states that "The design, construction, and use of equipment and utensils must preclude the contamination of animal food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants."

We believe this provision also is too prescriptive because equipment and utensils are often designed and constructed by entities that are completely separate and independent from the animal food producers subject to this rule. Although the proper use and maintenance of such equipment and utensils can prevent or greatly reduce the potential for contamination of animal food, the use of the term "must preclude" creates a standard that would be difficult to achieve or enforce. We therefore recommend the following modification: "The design, construction, and use of equipment and utensils ~~must preclude~~ should prevent or reduce the potential for ~~the~~ contamination of animal food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants."

Section 507.22(c) states: "Each freezer and cold storage compartment used to hold animal food must be fitted with an accurate temperature monitoring device."

PFI agrees that knowledge of temperatures in compartments used to store animal foods, including raw materials and ingredients, is important to prevent or reduce the potential for contamination. We believe, however, that the proposed provision goes too far in requiring a temperature monitoring device *for each compartment*. A temperature control storage area can be effectively monitored with one temperature gauge, as opposed to one in each compartment, without sacrificing food safety. Accordingly, our recommended modification to this subsection is as follows: "Each ~~freezer and cold~~

~~storage compartment~~ temperature-controlled storage area used to hold animal food must be fitted with an accurate temperature monitoring device."

Section 507.22(e) states that "[c]ompressed air or other gases mechanically introduced into animal food or used to clean animal food-contact surfaces or equipment must be used in such a way that animal food is not contaminated."

PFI believes that, as with other provisions in this section, less prescriptive language would be more appropriate in order to set an appropriate and achievable standard for compliance and enforcement purposes. We therefore recommend the following modification: "Compressed air or other gases mechanically introduced into animal food or used to clean animal food-contact surfaces or equipment ~~must~~ should be used in such a way that protects against contamination of animal food ~~is not contaminated~~."

§ 507.25 Plant operations.

Section 507.25(a)(3) and 507.25(a)(4) state: "(a) Plant management must ensure that: … (3) The labeling for the finished animal food product contains information and instructions for safely using the product for the intended animal species; (4) Animal food-packaging materials are safe and suitable."

PFI agrees in principle with the first provision and its goal of ensuring that appropriate information is conveyed to the customer. We believe this provision can be stated more simply and effectively, however, by referring to FDA requirements, with which animal food producers are familiar. Accordingly, our recommended change to subsection (a)(3) is as follows: "(a) Plant management must ensure that: … (3) The labeling for the finished animal food product contains ~~information and instructions for safely using the product~~ relevant information per FDA requirements for the intended animal species."

With respect to § 507.25(a)(4), we believe a qualifier to the requirement is necessary to ensure a clear understanding of the standard that must be met. Accordingly, we recommend the following change: "(a) Plant management must ensure that: … (4) Animal food-packaging materials are safe and suitable for their intended use."

Next, Section 507.25(b)(1) states: "(b) Raw materials and ingredients: (1) Must be inspected to ensure that they are suitable for manufacturing/processing into animal food and must be handled under conditions that will protect against contamination and minimize deterioration."

This requirement for inspection of raw materials and ingredients is overly prescriptive because it applies regardless of whether an animal food producer will subject the raw material or ingredient to further processing that will address any hazards. Moreover, visual inspection of some raw materials or ingredients may provide no assurance of its suitability for use in animal food. Referral to a certificate of analysis may be more effective in determining suitability for use of a raw material/ingredient in manufacturing/processing. We therefore recommend the following modification to the

language: "(b) Raw materials and ingredients: (1) ~~Must~~ Should be inspected as appropriate and necessary to ensure that they are suitable for manufacturing/ processing into animal food and must be handled under conditions that will protect against contamination and minimize deterioration."

Section 507.25(b)(1)(i) states: "Shipping containers (for example, totes, drums, and tubs) and bulk vehicles holding raw materials and ingredients must be inspected upon receipt to determine whether contamination or deterioration of animal food has occurred."

Similar to our comment on § 507.25(b)(1), the new language here requiring inspection of containers upon receipt to determine whether contamination or deterioration of animal food has occurred is too prescriptive. Visual inspection of containers will not provide adequate assurance that contamination or deterioration has not occurred during shipping. PFI believes the language in the original Proposed Rule provided animal food producers with sufficient flexibility to select inspection as a method for determining whether containers have contributed to contamination or deterioration of animal food. We therefore propose that the original Proposed Rule language, with some slight modifications, be restored to the following provision: "Shipping containers (for example, totes, drums, and tubs) and bulk vehicles holding raw materials and ingredients ~~must~~ should be inspected upon receipt to determine whether contamination or deterioration of animal food ~~has~~ may have occurred."

Section 507.25(b)(ii) states: "Raw materials must be cleaned as necessary to minimize soil or other contamination."

PFI notes that this requirement may be appropriate for some, but not all, raw materials. Our recommended change here is minor but important to provide the flexibility animal food producers need to comply with this requirement. We believe the following modification should be made: "Raw materials must be cleaned as ~~necessary~~ appropriate to minimize soil or other contamination."

Section 507.25(b)(3) states: "(b) Raw materials and ingredients: … (3) And all rework, must be held in containers designed and constructed in a way that protects against contamination, and must be held under conditions, e.g., appropriate temperature and relative humidity, that will minimize the potential for growth of undesirable microorganisms and in a manner that prevents the animal food from becoming adulterated."

PFI believes the language in this provision is too prescriptive because it imposes temperature and humidity requirements for animal food inputs that may be subjected to a pathogen mitigation/kill step. PFI members understand the need to handle all raw materials, ingredients and rework appropriately in order to reduce the likelihood of contamination of the finished animal food. We therefore recommend the following modification: "(b) Raw materials and ingredients: … (3) And all rework, ~~must~~ should be

held in containers designed and constructed in a manner that prevents the animal food from becoming adulterated."

Section 507.25(c)(1) states: "(c) For the purposes of manufacturing/processing operations, the following apply: (1) Animal food must be maintained under conditions, e.g., appropriate temperature and relative humidity, that will minimize the potential for growth of undesirable microorganisms and prevent the animal food from becoming adulterated during manufacturing/processing, packing, and holding."

PFI is concerned that this requirement is overly prescriptive, especially if the animal food (including raw materials/ingredients) will be subject to a pathogen mitigation/kill step. The term "appropriate temperature and relative humidity" may be appropriate for some, but not all, animal food producers. Relative humidity may be a critical factor for a producer of feed grains but may not be a concern for pet food producers – the Final Rule must acknowledge this and other factors that characterize different animal food producers. Accordingly, PFI's recommended change to this subsection is as follows: "(c) For the purposes of manufacturing/processing operations, the following apply: (1) Animal food must be maintained under appropriate conditions~~, e.g., appropriate temperature and relative humidity, that will~~ to minimize the potential for growth of undesirable microorganisms and prevent the animal food from becoming adulterated during manufacturing/processing, packing, and holding."

Section 507.25(c)(6) states: "Animal food that relies on the control of aw for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe moisture level."

As we stated in our comment on the original Proposed Rule, control of the moisture level alone is insufficient to effectively address the growth of undesirable microorganisms. Only by controlling water activity (a_w) can one effectively control the growth of undesirable microorganisms. Thus, the following revision is suggested: "Animal food that relies on the control of a_w for preventing the growth of undesirable microorganisms must be processed to and maintained at a suitable a_w ~~safe moisture level~~."

§ 507.27 Holding and distribution.

Section 507.27(a) states: "Animal food held for distribution must be held under conditions that will protect against contamination and minimize deterioration, including the following: … "

PFI notes that the discussion section of the Re-proposed Rule relates deterioration to food refusal. Deterioration is but one of many factors than can lead to food refusal, but food refusal does not necessarily equal deterioration. PFI believes the concept of deterioration is not necessary in this rule – deterioration is better described in terms of already familiar concepts of shelf life and product integrity. Also, we discourage FDA from referring in the Final Rule to "deterioration" unless a clear definition and

background information are also issued to ensure a consistent understanding of the requirement by both animal food stakeholders and FDA inspectors.

In light of these observations, our recommended language is as follows: "Animal food held for distribution must be held under conditions that will protect against contamination and ~~minimize deterioration~~ ensure product integrity throughout the intended shelf life, including the following: …"

Section 507.28 Holding and distribution of human food by-products for use as animal food.

Section 507.28(a) states: "Human food by-products held for distribution as animal food must be held under conditions that will protect against contamination, including the following: (1) Containers used to hold animal food before distribution must be designed, constructed of appropriate material, cleaned, and maintained to prevent the contamination of animal food; (2) Animal food held for distribution must be held in a way to prevent contamination from sources such as trash and garbage; and (3) Labeling identifying the product by the common and usual name must be affixed to or accompany animal food."

PFI believes that, for purposes of consistency, the term "human food by-products" – not "animal food" – should be used throughout this provision. This change is important in order to make clear that human food by-products do not change in identity until they are transformed by an animal food producer into animal food. Accordingly, our recommended language for this section is as follows:

"Human food by-products held for distribution as animal food must be held under conditions that will protect against contamination, including the following: (1) Containers used to hold ~~animal~~ human food by-products before distribution must be designed, constructed of appropriate material, cleaned, and maintained to prevent the contamination of ~~animal~~ human food by-products; (2) ~~Animal~~ Human food by-products held for distribution must be held in a way to prevent contamination from sources such as trash and garbage; and (3) Labeling identifying the product by the common and usual name must be affixed to or accompany ~~animal~~ human food by-products."

Similarly, for § 507.28(b), PFI recommends that the term "animal food" be replaced with "human food by-products" to accurately denote that holding human food by-products for use in animal food is not part of the process of the food's transformation into animal food. Our recommended language for § 507.28(b) is as follows: "Shipping containers (for example, totes, drums, and tubs) and bulk vehicles used to distribute ~~animal~~ human food by-products must be inspected prior to use to ensure the container or vehicle will not contaminate the ~~animal~~ human food by-products."

Subpart C – Hazard Analysis and Risk-Based Preventive Controls

§ 507.33 Hazard analysis.

Section 507.33 (a)(1) states: "(a) You must: (1) Identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of animal food manufactured/processed, packed, or held at your facility to determine whether there are significant hazards."

This provision states the requirements for a hazard analysis, which includes identification and evaluation of known or reasonably foreseeable hazards (hazards with the potential to be associated with the food or the facility) to determine any significant hazards. PFI agrees generally with the approach FDA has taken in this provision but suggests, as we did in our comment on the original Proposed Rule, that a specific reference to FDA foodborne illness data be made so as to remove ambiguity as to what data should be reviewed as part of a hazard analysis. We also reiterate here our earlier comment regarding the definition of "significant hazard," based on input received from PFI's teleconference with FDA officials on November 6th, 2014.

Accordingly, we recommend the following modification to the language in this section: "(a) You must: (1) Identify and evaluate, based on experience, FDA foodborne illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of animal food manufactured/processed, packed, or held at your facility to determine whether there are significant hazards."

Section 507.33(b)(1)(ii) states: "(b) The hazard identification must consider: (1) Hazards that include: … (ii) Chemical hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and nutrient imbalances."

PFI notes the use of term "nutrient imbalances" in the re-proposal. FDA indicated support for our comment on the original proposed rule that this term should be replaced with a reference to "nutrient deficiencies and toxicities." We understand FDA is continuing its review of comments on the original proposed rule and we simply draw attention to our earlier point, which is that the term "nutrient imbalance" should be replaced with "nutrient deficiency" and "nutrient toxicity" to reflect potential risks or areas of concern for animal food producers. Thus, we strongly recommend the following modification to the language in this provision: "(b) The hazard identification must consider: (1) Hazards that include: … (ii) Chemical hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and nutrient ~~imbalances~~ deficiencies and toxicities."

Section 507.33(d)(10) states: "(d) The hazard evaluation must consider the effect of the following on the safety of the finished animal food for the intended animal: … (10) Any other relevant factors."

PFI agrees in principle with this provision in that a facility's hazard analysis must take into account all relevant factors. But we believe that this requirement would benefit from

some specificity regarding who bears the responsibility for considering "[a]ny other relevant factors." Accordingly, our recommended language for this subsection is as follows: "(d) The hazard evaluation must consider the effect of the following on the safety of the finished animal food for the intended animal: … (10) Any other relevant factors, as identified by the Qualified Individual."

§ 507.37 Supplier program.

Section 507.37(a)(1)(ii) states: "The receiving facility is not required to establish and implement a supplier program for raw materials and ingredients for which: (A) There are no significant hazards; (B) The preventive controls at the receiving facility are adequate to significantly minimize or prevent each of the significant hazards; or (C) The receiving facility relies on its customer to control the hazard and annually obtains from its customer written assurance that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard."

PFI agrees generally with the flexibility afforded to receiving facilities with respect to the need for supplier programs. Subparagraphs (B) and (C), however, prompt a few concerns that we must address. First, as noted generally earlier in these comments, the language in subparagraph (B) of this provision fails to account for the fact that controlling hazards is very often a shared responsibility between the supplier of a raw material/ingredient and the receiving facility. Raw material and ingredient suppliers routinely meet receiving facility specifications for log reductions of pathogens, specifications that play a critical role in the effectiveness of the receiving facility's pathogen reduction/mitigation step(s). Subparagraph (B) as proposed could have the unintended consequence of denying a receiving facility (that employs a pathogen mitigation/kill step to address a pathogen in a raw material/ingredient) the opportunity to ensure that it is receiving a raw material or ingredient with a pathogen level that greatly increases the effectiveness of a pathogen mitigation/kill step.

Subparagraph (C) of this provision poses a different challenge for animal food producers when they are the customer of a raw material/ingredient receiving facility. As stated earlier in these comments, PFI believes strongly that any receiving facility purchasing a raw material/ingredient from a supplier, with intent to sell that raw material/ingredient to a facility for use in animal food, has an obligation to at least conduct the hazard identification portion of a hazard analysis, in order to identify significant hazards associated with that product, and to communicate any identified hazards to its customer (the animal food producer) prior to transfer of the raw material/ingredient. Our position here is consistent with the position expressed above that controlling hazards is a shared responsibility among raw material/ingredient suppliers and their customers.

Accordingly, we recommend that FDA adopt one of the following two alternative changes to the language:

"The receiving facility is not required to establish and implement a supplier program for raw materials and ingredients for which~~: (A) T~~ the receiving facility has determined there are no significant hazards~~; (B) The preventive controls at the receiving facility are adequate to significantly minimize or prevent each of the significant hazards; or (C) The receiving facility relies on its customer to control the hazard and annually obtains from its customer written assurance that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard~~."

OR (retaining (A) and (B) as proposed):

"The receiving facility is not required to establish and implement a supplier program for raw materials and ingredients for which: … (C) The receiving facility relies on its customer to control the significant hazard and, at least every three years or when new information or developments warrant, ~~annually~~ obtains from its customer written assurance that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the significant hazard."

Section 507.37(a)(4) states: "When supplier verification activities are required under paragraph (c) of this section for more than one type of hazard in an animal food, the receiving facility must conduct the verification activity or activities appropriate for each of those hazards."

PFI believes this provision is arbitrary and does not provide the receiving facility with the necessary flexibility to conduct any verification activity that may be necessary. Specifically, the receiving facility's qualified individual should be able to delegate the verification activity/activities to a person possessing the knowledge skills and abilities necessary to complete the task(s). Accordingly, we recommend the following change to section 507.37(a)(4): "When supplier verification activities are required under paragraph (c) of this section for more than one type of hazard in an animal food, the receiving facility or an entity identified by the receiving facility must conduct the verification activity or activities appropriate for each of those hazards."

Section 507.37(b)(4) states: "(b) In determining and documenting the appropriate verification activities, the receiving facility must consider the following: … (4) Applicable FDA food safety regulations and information relevant to the supplier's compliance with those regulations, including an FDA warning letter or import alert relating to the safety of the animal food…"

PFI agrees with FDA that a supplier program may be necessary to ensure raw materials/ingredients are safe for use by a receiving facility, but we believe this provision fails to account for the likelihood that an animal food producer often receives raw materials/ingredients from human food producers that are not subject to animal food regulations. It is thus unclear whether or to what extent a receiving facility must consider a human food producer's adherence to human food regulations as part of its consideration of "[a]pplicable FDA food safety regulations." Although compliance with

those regulations may be helpful in determining appropriate verification activities, failure by a human food producer to comply with applicable FDA food safety regulations is only one factor a receiving facility that is an animal food producer should consider in its supplier program activities, especially if that failure relates indirectly or not at all to the human food by-products in question.

Accordingly, we recommend the following language modification to section 507.37(b)(4): "(b) In determining and documenting the appropriate verification activities, the receiving facility ~~must~~ should consider the following: … (4) Applicable FDA food safety regulations and information relevant to the supplier's compliance with those regulations related to the human food by-products in question, including an FDA warning letter or import alert relating to the safety of the animal food."

Section 507.37(c) lists supplier verification activities and when a receiving facility must carry them out. Such requirements place a significant burden on both suppliers and receiving facilities, many of which have long histories of compliance with applicable federal food safety regulations. One potential way to remedy the almost certain and sudden increase in supplier verification activities that must be conducted under this rule when it becomes effective is to create a general certification system for raw material/ingredient suppliers that receiving facilities could rely on *in lieu* of supplier verification activities. FDA has proposed such an approach for foreign suppliers, and we urge FDA to provide this same opportunity to domestic suppliers to animal food producers.

Section 507.37(c)(2)(i) states: "Except as provided by paragraph (c)(2)(ii) of this section, when a hazard in a raw material or ingredient will be controlled by the supplier and is one 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, the receiving facility must have documentation of an onsite audit of the supplier before using the raw material or ingredient from the supplier and at least annually thereafter."

PFI believes this provision is too prescriptive because it fails to provide an animal food producer with the discretion needed to tailor auditing of suppliers to address SAHCODHA hazards associated with raw materials or ingredients. PFI disagrees with FDA's contention that annual audits of suppliers are necessary if the raw material/ingredient in question poses a SAHCODHA risk. Many animal food raw materials/ingredients fall into this category, and imposing an annual audit requirement on animal producers and their suppliers is, in our view, out of proportion to the risks posed and ignores pet food safety, which is substantiated by both FDA and industry data.

Accordingly, our recommended revision to this section is as follows: "Except as provided by paragraph (c)(2)(ii) of this section, when a hazard in a raw material or ingredient will be controlled by the supplier and is one 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, the receiving facility must have documentation of an onsite audit of

the supplier before using the raw material or ingredient from the supplier and ~~at least annually~~ at least every three years or when new information or developments warrant ~~thereafter~~, based on a qualified individual's assessment of any significant hazards associated with the raw material or ingredient."

Section 507.37(d)(1) states: "An onsite audit of a supplier must be performed by a qualified auditor."

As noted in our recommended change to the definition of "Qualified Auditor," we believe that a qualified auditor need not be a qualified individual but must be a person identified by a qualified individual as appropriate to conduct an onsite audit. Accordingly, our recommended language is as follows: "(d)(1) An onsite audit of a supplier must be performed by a qualified auditor or someone identified by the qualified individual as possessing the skills necessary to conduct the audit…"

Section 507.37(f) states: "If the owner, operator, or agent in charge of a receiving facility determines through auditing, verification testing, relevant consumer, customer, or other complaints, or otherwise that the supplier is not controlling hazards that the receiving facility has identified as significant, the receiving facility must take and document prompt action in accordance with § 507.42 to ensure that raw materials or ingredients from the supplier do not cause animal food that is manufactured or processed by the receiving facility to be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act."

PFI questions why this provision is necessary. A receiving facility is already required under the Federal Food, Drug & Cosmetic Act (FD&C Act) to ensure that the animal food it places on the market is neither adulterated under FD&C Act § 402 nor misbranded under FD&C Act § 403. Adding this proposed provision does not improve the safety of animal food – we therefore recommend its removal.

Section 507.37(g)(3) states: "The receiving facility must document the following in records and review such records in accordance with § 507.49(a)(4): … (3) The annual written assurance that a receiving facility's customer who is controlling a significant hazard has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard."

As with other provisions in the supplier program section, PFI believes the requirement for an annual written assurance that a receiving facility's customer is controlling a significant hazard is well-intentioned but too prescriptive and fails to provide the necessary flexibility for animal food producers. This provision would significantly increase the paperwork and recordkeeping burden for receiving facilities and their customers. It does not allow the receiving facility to factor its relationship with the supplier into its determination of the frequency of these written assurances. It also would provide no measurable improvement in food safety. As stated above in our general observations, a science- and risk-based approach can and should guide FDA's

rulemaking, and in many cases the requirements for domestic and foreign supplier verification programs need not be identical.

Accordingly, we recommend the following revision to the language of section 507.37(g)(3: "The receiving facility must document the following in records and review such records in accordance with § 507.49(a)(4): … (3) ~~The annual written~~ Written assurance, obtained every three years or when new information or developments warrant, that a receiving facility's customer who is controlling a significant hazard has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard."

Section 507.38 Recall plan.

PFI agrees generally with the requirement that firms maintain recall plans. We firmly believe, however, that such a requirement should be facility-wide, not product- and process-specific. Consequently, we urge FDA to move this provision to Subpart B of this rule, Current Good Manufacturing Practice. Doing so will ensure that all facilities are required to develop and be able to execute a recall plan. Every facility, regardless of size, should have a recall plan and the statutory language supports such a requirement for all producers of human and animal food.

Section 507.40 Monitoring.

Section 507.40(a)(2) states: "(a) As appropriate to the preventive control you must: … (2) Monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed."

Section 507.40(b) states: "You must monitor the preventive controls with adequate frequency to provide assurance that the preventive controls are consistently performed."

These requirements are identical and, accordingly, one of them should be removed. We therefore recommend the deletion of § 507.40(b) and the renumbering of currently proposed § 507.40(c) to § 507.40(b).

§ 507.45 Verification.

PFI agrees generally with the provisions in this section regarding the elements of verification activities. However, we note in our recommendation above and also in our comment on the original Proposed Rule, that the Final Rule, instead of developing a new definition for "verification," should instead incorporate the definition developed by Codex, which we provide earlier in this comment.

§ 507.47 Validation.

PFI agrees generally with the provisions in this section regarding the elements of verification activities. However, we note in our recommendation above and also in our

comment on the original Proposed Rule, that the Final Rule, instead of developing a new definition for "validation," should instead incorporate the definition developed by Codex, which we provide earlier in this comment.

§ 507.51 Modified requirements that apply to a facility solely engaged in the storage of packaged animal food that is not exposed to the environment.

PFI agrees generally with the requirements proposed in this section. We do, however, note that the title of this section does not accurately reflect the scope of the requirements it contains. Specifically, we believe the addition of the word "refrigerated" to the section title will provide the appropriate limitation with respect to the modified requirements contained in the section.

Accordingly, we recommend the following change to the section heading: "§ 507.51 Modified requirements that apply to a facility solely engaged in the refrigerated storage of packaged animal food that is not exposed to the environment."

§ 507.55 Implementation records.

As PFI stated in its comment on the original Proposed Rule, we strongly disagree with FDA that 21 CFR Part 11 (Electronic Records; Electronic Signatures) requirements should be imposed on animal food producers. Facilities that utilize electronic records should have secure systems, but we believe compliance with Part 11 is unnecessary, would lead to considerable cost and complexity, would not contribute materially to improved safety of animal food and should therefore not be required.

While electronic systems are becoming the standard mode of record retention and management for animal food producers, compliance with Part 11 would require the type of wholesale construction or reconstruction of such recordkeeping systems that FDA has agreed in discussions is not warranted under FSMA. Furthermore, we do not believe that compliance with Part 11 will advance food safety for low-acid canned animal food or any other animal food. We also note that the time required for animal food producers to comply with Part 11 would make it impossible for many animal food producers to meet the one-year deadline for full FSMA compliance.

§ 507.60 Circumstances that may lead FDA to withdraw an exemption applicable to a qualified facility.

PFI agrees generally with FDA's approach in this section regarding the factors FDA may consider in withdrawing a qualified facility's exemption. We note, however, our earlier comment that the threshold for a very small business that would be considered a qualified facility should be consistent with the thresholds for a very small importer and a very small foreign supplier under the Foreign Supplier Verification Program Proposed Rule. We propose a $1 million annual sales threshold for all three categories. Such an approach will ensure broad coverage of animal food producers and suppliers – foreign

and domestic – while facilitating compliance by all stakeholders with one simple annual sales threshold to identify qualified facilities.

Conclusion

PFI thanks FDA for the opportunity to provide this comment. We also acknowledge the Agency's willingness over the past two years to engage with stakeholders in person and through the rulemaking process to ensure FSMA regulations, when they are finalized and implemented, address the food safety concerns identified by Congress and also provide animal food producers with the discretion and flexibility they need to effectively and efficiently allocate their resources to the foods and suppliers requiring the most attention. We share FDA's interest in realizing the goal of improved food safety through science- and risk-based regulations. We look forward to a continued and productive dialogue as the rulemaking process concludes and as finalization and implementation of these regulations get under way.

Sincerely,

Duane Ekedahl
President

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