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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; RIN 0910–AG10)

The Pet Food Institute (PFI) appreciates the opportunity to provide comments regarding the food safety requirements outlined in the Food Drug and Administration's (FDA's or the Agency's) 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 October 29, 2013 (78 Fed. Reg. 64736) and hereafter referred to as the "Notice," "Rule" or "Proposed Rule."

Established in 1958, PFI is the voice of US cat and dog food manufacturers. 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 28 dog and cat food manufacturers and more than 100 affiliates who supply ingredients and raw materials to dog and cat food producers. Our members sell more than $20 billion in dog and cat food annually and export an additional $1.5 billion.

Pet food makers share the FDA's commitment to pet food safety and quality, and we're proud of the strong safety record of pet food. PFI strongly supports the Food Safety Modernization Act (FSMA) and looks forward to working with FDA for the successful implementation

of this landmark law. We appreciate FDA's engagement with stakeholders during the rulemaking process and its readiness to engage in open dialogue during the public comment period. 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.

FSMA and the Agency's implementing regulations represent the most comprehensive changes to FDA food safety regulation since the Food, Drug and Cosmetic (FD&C) Act was enacted in 1938. In light of the breadth, complexity and magnitude of the Animal Food Proposed Rule; the interrelationship between the rules for human and animal food; and the fact that human food sector had twice the time to review the Human Food Proposed Rule, we respectfully submit that pet food and agriculture stakeholders should have been given more than five months to conduct our review and provide comment.

PFI acknowledges the FSMA publication deadlines set by Congress. We also understand the judicial constraints under which FDA is operating as a result of the seemingly arbitrary deadlines set by the U.S. District Court for the Northern District of California in the claim filed by the Center for Environmental Health and the Center for Food Safety. As it is both PFI's and FDA's goal to promulgate FSMA final rules that ensure a robust food safety system, PFI would have appreciated more time to develop our comments.

We are encouraged by FDA's decision, published on March 19, that it will publish revised language for this proposed rule. We urge FDA to re-issue the entire Animal Food Proposed Rule for comment – as opposed to re-issuing "key provisions" – so that stakeholders can review the rule in its entirety and see how all the provisions interact. If FDA issues only revised language for comment, we urge FDA to provide explanations and justifications that will enable this revised language to be understood and reviewed within the context of the Rule. We look forward to the opportunity later this year to review the updated Proposed Rule and to provide comment to FDA that assists in the refinement of the Rule before it is issued in its final form.

We appreciate FDA's recognition that animal food is not human food, evidenced by the issuance of separate rules for human food and animal food. However, it is apparent from even a cursory review that the Human Food Proposed Rule served as the basis for the Animal Food Proposed Rule. Our comments explain why and how there must be more substantive differences between the two. Further, Congress expressed no intent in the statute to separate animal food into sub-categories. Therefore, PFI supports FDA's approach in this Notice to promulgate one rule applying to all animal food.

In these comments, PFI provides an executive summary and a detailed review following the outline below. For areas of concern, we provide the excerpt from the October 29 Federal Register Notice, our comment, and any recommended revision we believe will address our concern and satisfy the intent of Congress in enacting FSMA.

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Executive Summary

PFI respectfully submits the following comments based on member discussion and consensus. These comments are based on the following core principles: 1) the Rule should reflect the Congressional intent specified in the statute requiring that the rules be based on science and risk analysis; 2) animal food is not human food, and FDA regulations should accommodate the differences; 3) there should be one animal food regulation applicable to all animal food categories; and 4) there should be no exemptions for animal food producers based on either number of employees or volume of sales.

<u>Subpart A – General Provisions</u>

507.1 Applicability and status

PFI strongly recommends that research and pilot plant facilities that manufacture animal food that is not intended for commercial distribution should be completely exempt from all parts of the Proposed Rule.

507.3 Definitions

PFI has included several new definitions that we believe are critical to clarify the proposed rule. These new definitions include “consumer,” “customer,” “nutrient deficiency” and “nutrient toxicity”. As described further below, we suggest that the word “consumer” in the text of the Proposed Rule be replaced by the word “customer” in order to provide more accuracy. Similarly, in the final rule, 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.

Additionally, we would like to highlight our recommendation for changes to the definitions of small and very small business, described in the discussion of exemptions below.

507.5 Exemptions

Congress in the statute created modified requirements for qualified facilities, instructing FDA to define in the regulation a very small business. FDA proposes three options for the definition of a very small business – annual gross sales of $500,000, $1 million or $2.5 million – and requests comment from stakeholders as to which threshold should be used to define a very small business for the purpose of identifying qualified facilities.

PFI believes that none of these thresholds is sufficient to ensure the safety of all animal food. We therefore propose that $10,000 in annual gross sales be the threshold for very small businesses – any business earning up to $10,000 would be a very small business under the regulation. This threshold will ensure that essentially all animal food producers: follow (as appropriate) Current Good Manufacturing Practices as laid out in the Rule when finalized and implemented; conduct a thorough hazard analysis to identify know or reasonably foreseeable hazards; establish and implement preventive controls to address identified and evaluated hazards; monitor those controls to ensure hazards are effectively addressed; and maintain relevant records pertaining to preventive controls. This approach is consistent with our beliefs that all animal food producers should establish science-based food safety programs and that company size – regardless of how it is calculated – should not be a factor in determining adherence to food safety regulations.

FDA must also ensure that this approach to qualified facilities and exemptions should apply to all animal food producers under this proposed rule and under other proposed rules to which animal food producers may be subject, including the Foreign Supplier Verification Programs and Accreditation of Third-Party Auditors/Certification Bodies. Doing so will avoid confusion for animal food producers that source ingredients from abroad.

Subpart B – Current Good Manufacturing Practice

The FDA requests comment on its thinking that CGMPs similar to those of human food are appropriate for animal food. We disagree that human food CGMPs should be the basis for animal food CGMPs. Although there are some similarities, human food and animal food facilities are vastly different, use very different ingredient streams and have different levels of risk compared to human food facilities. We believe that animal food safety principles can indeed be similar in some respects to those of human food facilities, but animal food CGMPs should be less prescriptive, as described in our detailed comments below, in order to better reflect the realities of animal food production.

In the preamble to the proposed rule, FDA noted that it had considered the international standard PAS 222:2011 (*Prerequisite programmes for food safety in the manufacture of food and feed for animals*, hereafter referred to as PAS 222:2011) and the Association of American Feed Control Officials (AAFCO) *Model Good Manufacturing Practice Regulations for Feed and Feed Ingredients* (hereafter referred to as AAFCO Model GMPs) in the development of the CGMPs for this proposed rule. PFI was very surprised and disappointed, however, to see that the animal food CGMPs so closely resemble the human food CGMPs. As such, they fail to account for significant differences between animal and human food production methods. We strongly believe that the international standard PAS 222:2011 or the AAFCO Model GMPs should have been the basis for this subpart of the proposed rule. The AAFCO Model GMPs were the result of a long, collaborative process between AAFCO, FDA and animal food industry stakeholders and represents CGMP language that was acceptable to all stakeholders, including FDA's Center for Veterinary Medicine (CVM). Similarly, PAS 222:2011 was developed through a long, collaborative process that involved representatives from the animal food industry, academia and international standard setting bodies. Although we disagree with the approach in the proposed rule, if the human CGMP regulation remains the basis for the new animal food CGMP regulation,

we have significant comments on the proposed rule to make it more suitable for animal food.

Regarding FDA's question whether CGMP requirements "would be more appropriate for some types of animal food may not be appropriate for other types, and, if so, how the agency can or should distinguish between those types during the various stages of animal food processing," PFI strongly recommends that one set of CGMP requirements be promulgated for all animal foods. (78 Fed. Reg. 64772) Differences in risk across animal food products can be addressed in each animal food facility's food safety plan, thus eliminating the need for product-specific CGMPs.

Product-specific CGMPs would be very problematic for those companies supplying across the animal food sector. Such an approach would likely result in the unintended consequence of companies refusing to supply key animal food ingredients due to increased requirements. Incorporation in this proposed rule of either the PAS 222:2011 or AAFCO Model GMPs would improve food safety and provide animal food producers and their suppliers with the flexibility they need to operate efficiently.

Throughout this Proposed Rule (but mostly in the discussion and rules pertaining to CGMPs), FDA uses the term "utensils" when referring to tools used in animal food preparation. While this term may be appropriate in the human food preparation context, PFI, along with other animal food stakeholders, believes that "tools" is a more appropriate term for use in this Rule and we urge FDA to replace the term "utensils" with "tools" in the discussion and general provisions of the Proposed Rule. We note that section 11 of PAS 222:2011 uses the term "tools" while AAFCO uses "equipment." Accordingly, our section-specific comments recommend replacement of the word "utensils" with "tools" throughout the Proposed Rule.

<u>Subpart C – Hazard Analysis and Risk-Based Preventive Controls</u>

<u>General comment on hazards that are reasonably likely to occur</u>

We believe FDA's attempt to create and implement the concept of "reasonably likely to occur" (RLTO) is unnecessary in light of the statutory requirement that an owner, operator or agent in charge of a facility "identify known or reasonably foreseeable hazards that may be associated with the facility…" (Pub. L. 111-353) The statute does not require the application of a Hazard Analysis and Critical Control Point (HACCP) approach – of which is RLTO is an integral part – but instead introduces the broader preventive controls concept, which facilitates the effective use of resources to address hazards throughout the animal food production process. We therefore join human and other animal food industry stakeholders in calling for the removal of the term RLTO and

any attempt to incorporate HACCP principles in this rule. We recommend that the final rule replace "RLTO" with "known or reasonably foreseeable hazards."

General comment on testing

The role of and need for testing varies greatly and depends on a range of factors, including the types of products manufactured and production methods used. The owner, operator or agent in charge of a facility must consider these and other factors in determining whether and how to establish an appropriate testing program.

Any testing program must be based on a clear understanding of the production process, including identification and evaluation of any food safety risks. As FDA has acknowledged in this and other proposed rules, there can be no single, one-size-fits-all approach. Testing resources must be focused on the most appropriate point in the production process. FDA should allow flexibility for animal food producers to determine which approach or approaches best address identified and evaluated hazards.

PFI agrees that ingredient, environmental and finished product testing are each useful tools that can enable animal food producers to address identified and evaluated hazards. Testing is an effective tool that can be used as part of an overall food safety program. The objective of a reasonable and sound testing program is to assure food safety. Testing data is a tool that can be used to track and trend the effectiveness of the food safety program and should be evaluated within the context of the food safety program and relevance to food safety. Due to the diversity of animal food production methods and approaches, qualified individual(s) should have the flexibility under this rule to develop and implement, as appropriate, a science-based testing program that identifies and determines: appropriate indicator organism(s), the sampling plan, appropriate corrective actions and other relevant factors.

Related to this discussion regarding the value of testing, FDA, in the December 9, 2013 webinar organized by PFI, generally agreed with the proposal that nutritional controls should be process-based and that animal food producers should be responsible for determining the prerequisite programs and verification activities they deem most effective with respect to nutritional controls.

General comment on recall program being part of CGMPs

PFI agrees with FDA that establishment of a recall plan should be required. However, such a requirement should be part of a prerequisite program in Proposed Subpart B – Current Good Manufacturing Practice, rather than Subpart C – Hazard Analysis and Risk-Based Preventive Controls. A recall program will have value in removing

potentially adulterated product from the marketplace and as such should be considered a CGMP.

General comment on "Prerequisite Programs" not having CCPs or CLs

As FDA acknowledges in the preamble to the proposed rule, and as PFI would like to emphasize, not all preventive controls will have critical control points, nor will critical limits be required for all preventive controls. PFI believes this point is of paramount importance when discussing CGMPs. Many aspects of food safety can be and are addressed through "prerequisite programs" rather than "preventive controls." PFI supports FDA's adoption of animal food CGMPs to "establish such a prerequisite program for the preventive controls program for animal food under section 418 of the FD&C Act." (78 Fed. Reg. 64771) Many prerequisite programs, including pest control programs, training programs, documentation and facility maintenance, are not amenable to a critical control point approach. These are important prerequisite programs to be included in the food safety plan that do not lend themselves to having critical control points or critical limits.

Subpart D – Withdrawal of an Exemption Applicable to a Qualified Facility

PFI does not believe that any animal food facility should be exempt from Part C requirements. However, if exemptions for qualified facilities are part of this final rule, we support a process that allows FDA to remove the exemption for any qualified facility that violates relevant FSMA and/or FD&C Act provisions. We have always maintained that, at a minimum, all animal food producers should establish and implement science- and risk-based food safety programs.

Subpart F – Requirements Applying to Records That Must Be Established and Maintained

PFI appreciates FDA's recognition that electronic systems may be used to meet the recordkeeping requirements proposed in Part 507 regulations. Facilities that utilize electronic records should have secure systems, but we believe compliance with 21 CFR Part 11 (Electronic Records; Electronic Signatures) is unnecessary, would lead to considerable cost and complexity, and should not be required. PFI strongly supports the good recordkeeping principles FDA has identified for key food safety records. (78 Fed. Reg. 64814) PFI agrees that recordkeeping systems used to document key food safety activities must be trustworthy and reliable.

General comments on compliance dates

Proposed CGMPs and preventive controls are new for the animal food industry and sufficient time will be necessary to achieve compliance with any CGMPs. PFI disagrees with FDA's contention that it will be easier for larger than for smaller animal food producers to achieve compliance, a contention FDA cites as a basis to justify a longer implementation period for small businesses. All animal food producers will face challenges in implementing any new requirements. Indeed, it may be more difficult for a larger animal food producer to implement this rule than for a smaller enterprise to do so. Larger producers may have multiple facilities to bring into compliance, more suppliers, more employees to train, more sophisticated systems to integrate, etc. The facility-specific nature of food safety plans may make compliance with this regulation much more complex for a larger business with multiple facilities than for a smaller business.

Because animal food ingredient suppliers must comply with these regulations when they are finalized and implemented, some ingredient suppliers will be classified as small or very small businesses with compliance dates after the compliance date for the animal food producers they supply. These disparate timeframes will create challenges for proper implementation of an animal food producer's food safety plan. The implementation of food safety plans and subsequent validation and verification as required by the regulation is highly complex, with many elements that must work together to be effective. Adding to this complexity are the provisions for implementation of both CGMPs and preventive controls, which leads PFI to recommend that the compliance date for **all** animal food producers (including ingredient suppliers), regardless of size, should be three years from the effective date of the final rule. FDA can and should use an extended implementation period to properly train its investigators/auditors and to develop educational and training materials necessary for effective, efficient implementation of the rule. This last point cannot be overemphasized – training for animal food producers and for FDA officials will be essential to the proper implementation of the Rule, when finalized.

General comment on Appendix

I. The Role of Testing as a Verification Measure in a Modern Food Safety System

In the proposed animal food rule, FDA does not include specific requirements for either environmental, ingredient or product testing, but instead solicits comments on whether these requirements should be included. FDA has specifically stated that "[a]lthough testing is rarely considered a control measure, it plays a very important role in ensuring the safety of food. An important purpose of testing is to verify that control measures, including those related to suppliers and those verified through environmental monitoring, are controlling the hazard." (78 Fed. Reg. 64748)

PFI generally agrees with FDA's statement above. However, due to the complexity of pet food production, it is critical that any testing program be both risk-based and facility-specific. While 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.

Animal foods – and pet food products in general and production methods in particular – are too diverse to adequately capture all potential scenarios in a set of specific rules. Flexibility in any testing program will enable animal food producers to design and implement a tailored approach that leads to improved food safety. As a result, PFI strongly supports the use of guidance to assist facilities with implementing the FSMA regulations, provided that guidance is appropriately treated as illustrative and non-binding. The Agency's Good Guidance Practices regulation, 21 CFR § 10.115, very clearly explains that guidance does "not legally bind the public or FDA" and companies "may choose to use an approach other than one set forth in a guidance document." FDA's investigators must acknowledge this limit so they do not enforce guidance as imposing regulatory requirements. Rather, FDA investigators should treat guidance as a "safe harbor" that represents an acceptable compliance approach but not the only compliant approach. In addition, FDA should properly train its investigators to ensure they conduct inspections with the correct understanding of applicable requirements and recommendations of the Animal Food Rule.

PFI vehemently disagrees with FDA's assertion that ingredient, finished product or environmental testing will not add costs to large companies or significant costs to the industry overall. The pet food industry (both small and large producers) has proactively made significant investments 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. FDA's microbial surveillance data of pet food products and treats support the dramatic impact of these improvements, with products found to be positive for *Salmonella* in the FDA surveillance program dropping from 15+% to around 2.5% over the last 7 years. These improvements have come at significant cost to pet food producers. This investment in animal food safety will continue to support further improvements, including appropriate testing programs.

The cited costs of testing programs in the proposed rule do not reflect any reasonable approximation of the actual costs of a scientifically robust and ongoing testing program. FDA underestimates testing program costs by orders of magnitude. Regardless of the low risk to animal or public health historically associated with pet food products, pet food makers continue their commitment to improvements in the safety of the products they

sell. It is inaccurate to assume minimal costs or financial impact to either large or small pet food makers associated with full implementation of FSMA.

General comment on cost and benefit

PFI begins by noting that FDA's Preliminary Regulatory Impact Analysis (PRIA) (FDA-2011-N-0922) on this proposed rule was unable to identify any quantifiable benefits resulting from its implementation.

As noted above, PFI disagrees with FDA's assumptions that finished product or environmental testing will not add costs to large companies or significant costs to the industry overall. PFI conducted a survey of its members to ascertain the quantity and nature of investments over the last 5-7 years to improve the safety of pet food and in anticipation of the full impact of FSMA. Our survey results indicate that total pet food industry investment in food safety far exceeds any calculations developed by FDA in its PRIA. This investment will continue and could exponentially increase depending on requirements in the Animal Food final rule.

FDA's own microbial surveillance data of pet food products and treats support the dramatic impact of these efforts, with pet food and treat products found to be positive for *Salmonella* dropping from 15+% to around 2.5% in the last 7 years. These results are due in part to the extraordinary steps PFI members take to ensure product safety.

According to PFI's survey data from member companies, FDA has significantly underestimated the costs for FSMA compliance. For example, FDA estimates environmental monitoring will cost approximately $3,457 per facility annually and $636,000 industry-wide. However, PFI members utilize a wide range of testing programs (including environmental, ingredient and finished product testing), costing up to $800,000 annually for each facility depending on the type of pet food produced. FDA also includes in the Animal Food proposed rule PRIA an estimate of the one-time cost for compliance of approximately a $93-$95 million for the entire animal food industry, of which pet food is a relatively small category. (FDA-2011-N-0922, page 75) As mentioned above, this amount has already been exceeded by PFI member company investments in capital food safety improvements since 2007. The survey of PFI members also shows that an increased recordkeeping requirement alone could cost as much as $500,000 per company; increased personnel costs could easily exceed $1 million and be as high as $11 million per company annually; and increased audit costs will average more than $150,000 annually per company (going as high as $750,000 for one company). Consequently, the increased costs of FSMA implementation to pet food makers are far from "one-time" or "insignificant."

Although PFI members are strongly committed to improving the safety and quality of the pet food and treats they produce, the cost of FSMA compliance is completely out of proportion to the low public health risk posed by our products. Publicly available data show that over the last 40 years there have been fewer than 200 cases of human salmonellosis, with no mortality, attributed to pet food or treats, compared to more than 40,000 cases of human salmonellosis every year caused by human food. (Data from the Centers for Disease Control and Prevention's Laboratory-based Enteric Disease Surveillance and its National Notifiable Diseases Surveillance System) For years in which human salmonellosis has been associated with a pet food or treat, the reported cases have represented less than 0.1% of the reported cases of human salmonellosis in that (or any) year. (Ibid) Instead, the vast majority of reported human salmonellosis cases has been attributed to restaurants and to raw poultry, produce and eggs in our homes and kitchens.

Despite the low risk to animal or public health historically associated with pet food products, pet food makers are committed to continuously improving the safety of their products. It is simply inaccurate to assume minimal costs or minimal financial impact to either large or small pet food makers from the full implementation of FSMA and/or that this Rule will improve public health beyond steps pet food makers have taken and will take to improve product safety.

Detailed Comments

Subpart A – General Provisions

507.1 Applicability and status
PFI strongly recommends that research and pilot plant facilities that do not manufacture animal food intended for commercial distribution be completely exempt from all parts of the proposed regulation. Such facilities do not present a food safety risk.

507.3 Definitions
PFI recommends that a number of defined terms either be added or modified in order to improve the clarity of the proposed rule.

Recommended New Definitions:

Consumer means the animal(s) consuming the food.

> **PFI comment:** The animal for which the animal food is intended should be defined as the "consumer" and should not be misconstrued with the purchasers of the product (i.e., individuals, retailers or distributors).

Customer means the purchaser of the animal food.

> **PFI Comment:** If FDA agrees with PFI's proposed definition of "consumer," it would be reasonable for it also to define "customer" as indicated above. In developing the final rule, PFI urges FDA to replace the term "consumer," as appropriate, with "customer." Most animal food manufacturers maintain customer complaint records instead of consumer complaint records. Under the proposed definition above, "customer" could include individuals, retailers, distributors or farm owners.

Control point means a point, step, or procedure in the production of an animal food at which a control may be applied.

> **PFI Comment:** To improve the clarity of the language used in the proposed regulation, FDA should define control point in the manner above.

Nutrient deficiency means the absence or insufficient presence of an essential nutrient in an animal food that can interfere with normal healthy growth, development, reproduction or maintenance of the animal for which that animal food is intended.

Nutrient toxicity means the overabundance of an essential nutrient in an animal food that can interfere with normal healthy growth, development, reproduction or maintenance of the animal for which that animal food is intended.

> **PFI Comment:** We urge FDA to replace the term "nutrient imbalance" in the Animal Food Proposed Rule with two terms related to an imbalance of nutrients of health consequence to animals: 1) "nutrient deficiency" and 2) "nutrient toxicity."

Parameter means a measurable attribute.

> **PFI Comment:** The concept of a parameter is used throughout the proposed rule, but it is not defined. The Grocery Manufacturers Association (GMA) identified this issue in its comments to FDA on the Human Food Proposed Rule (GMA Comments on Food Safety Plan Requirements, page 46). PFI supports

the same approach proposed by GMA with respect to the Animal Food Proposed Rule.

Prerequisite Program (PRP) means basic practices and procedures in animal production that are necessary for the manufacture, handling and provision of safe end products and safe food for animal consumption.

PFI Comment

PFI recommends that the final rule include a definition for "prerequisite program" for use in the discussions of CGMPs, in order to clarify a term used throughout the Notice. The definition proposed above is adapted from the International Standards Organization's (ISO) food safety standard, ISO 22000:2005 ("basic conditions and activities that are necessary to maintain a hygienic environment throughout the food chain (3.2) suitable for the production, handling and provision of safe end products (3.5) and safe food for human consumption").

Reanalysis means a reassessment of the effectiveness of a preventive control or food safety plan to control a hazard.

PFI Comment

We generally support GMA's recommendation in its Human Food Proposed Rule comments to include a definition of "reanalysis."

Suitable water activity (a_w) means a level of water activity (a_w) at or below which available data indicate an animal food will not support the growth of undesirable microorganisms.

PFI Comment

Addressing moisture alone is not sufficient to control the growth of undesirable organisms. However, the growth of these organisms can be controlled by management of water activity (a_w). Therefore, we propose replacing the definition of "safe moisture level" with "suitable water activity (a_w) level."

Undesirable microorganisms means those microorganisms that are of animal or human health significance, thereby rendering the animal food unfit for consumption or distribution.

PFI Comment

PFI recommends that the final rule include a new definition for undesirable microorganisms, as there are some microorganisms that are desirable and can

be added to animal food per AAFCO guidelines (36.14 Direct Fed Microorganisms 2014 OP, page 384).

Proposed definitions supported:

PFI supports the following definitions as proposed:

- Affiliate
- Animal food
- Batter
- Blanching
- Calendar day
- FDA
- Harvesting
- Holding
- Lot
- Manufacturing/processing
- Mixed-type facility
- Packing
- Pest
- Sanitize
- Should
- Subsidiary
- Water activity

Proposed definitions and suggested revisions:

PFI recommends revisions to the following definitions in the Notice.

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

PFI Comment

Because no standards for good public health practice have been established, PFI recommends that “in keeping with good public health” be removed from the definition.

Recommended Revision

Adequate means that which is needed to accomplish the intended purpose ~~in keeping with good public health practice.~~

Critical control point means a point, step or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level.

PFI Comment

Codex, an international body whose standards facilitate trade in safe foods, has developed a definition for this term. Compliance with Codex standards is viewed as *de facto* compliance with World Trade Organization member obligations. PFI recommends that the Codex definition for "critical control point" be incorporated in the Animal Food proposed rule.

Recommended Revision

Critical control point (CCP) means a step at which a control can be applied that is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level. ~~means a point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level.~~

Environmental pathogen means a microorganism that is of animal or human health significance and is capable of surviving and persisting within the manufacturing, processing, packing or holding environment.

PFI Comment

The term "environmental pathogen" is difficult to define and we believe FDA's proposed definition is too broad. PFI agrees that some foodborne pathogens may be present in the animal food production environment, but the definition of this term must provide animal food producers with clearer limitations on pathogens that require identification and evaluation in a hazard analysis. PFI suggests the definition read as follows below.

Recommended Revision

Environmental pathogen means ~~a microorganism that is of public health significance and is capable of surviving and persisting within the manufacturing, processing, packing, or holding environment.~~ a foodborne microorganism of animal and human health significance the presence of which in the food processing environment may result in product contamination at levels that data indicate could result in foodborne illness.

Facility means 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.

PFI Comment

FDA should combine the definition of Facility and Plant, as they are used interchangeably. This definition should also 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.

Recommended Revision

Facility/Plant means a domestic facility or a foreign facility, other than one exempted under this regulation, 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.

Farm means farm as defined in § 1.227(b) of this chapter.

PFI Comment

For clarity, PFI recommends that the full definition of § 1.227(b) of this chapter be included.

Recommended Revision

Farm means farm as defined in § 1.227(b) of this chapter, "a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. Washing, trimming of outer leaves of, and cooling produce are considered part of harvesting. The term ''farm'' includes: (i) Facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership; and (ii) Facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership."

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

PFI Comment

PFI recommends that specific language from section 201(f) be included which would make the need to include a specific reference to "raw materials and ingredients" unnecessary.

Proposed Revision

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act, "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." For the purposes of enforcing this regulation, "animal food" and "animal feed" are interchangeable ~~includes raw materials and ingredients~~.

Food-contact surfaces are those surfaces that contact animal food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. "Food-contact surfaces" include food-contact surfaces of utensils and equipment.

PFI Comment

The term "drainage" could be interpreted too broadly or incorrectly, thus creating confusion for FDA and animal food producers. Consistent with our general comment that the term utensil is inappropriate in a rule governing the production of animal food, we propose that "utensils" be replaced in this section with "tools."

Proposed Revision

Food-contact surfaces are those surfaces that contact animal food and those surfaces from which ~~drainage, or other~~ transfer~~,~~ onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. "Food-contact surfaces" include food-contact surfaces of tools ~~utensils~~ and equipment.

Hazard means any biological, chemical, physical, or radiological agent that is reasonably likely to cause illness or injury in animals or humans in the absence of its control.

PFI Comment

Radiological hazards are event-based hazards, and thus would best be managed separately from the food safety plan in an animal food facility's crisis management plan and/or food defense plan. Because radiological events are foreseeable, but not reasonably likely to occur, any response may be similar to that in the instance of an unforeseen natural disaster. If a radiological event were to occur, radiological hazards should be evaluated, as appropriate, as a subset of chemical hazards. Analysis following a radiological event may include an analysis of potential new hazards and a reassessment of the facility's food safety plan.

As FDA has acknowledged, radiological contamination occurs very infrequently. For example, in the proposed Human Food rule, FDA concludes, "Radiological contamination of foods is a rare event." 78 Fed. Reg. 3646, 3667 (Jan. 16, 2013) In addition, FDA's *Draft Qualitative Risk Assessment Risk of Activity/Food Combinations for Activities Conducted in a Facility Co-Located on a Farm* states, "...the Hazard Identification section of this document does not include radiological hazards because they are too rare in food to be considered associated with any food category other than water." (February 2013, found at http://www.fda.gov/downloads/AnimalVeterinary/Products/AnimalFoodFeeds/UCM366906.pdf, page 18) The document goes on to state (page 33-34):

> *"The presence of detectable radiological hazards in animal foods is rare and derives from plants grown in certain types of mineral soil or from water in similar areas. Use of water that contains a radionuclide to manufacture an animal food is not reasonably likely when using water from a domestic municipal source subject to regulation by 40 CFR 141.66 (see 65 FR 76708, Federal Register of December 7, 2000). Exposure of humans to radionuclide hazards as a result of contact with contaminated animal food or consumption of human food of animal origin from animals that have consumed contaminated animal food as a result of naturally occurring radioactive material is very low. When events (such as accidents or natural disasters) occur that could result in radiological contamination of water sources, there is generally much publicity that would alert a farm mixed-type facility to a risk in using a potentially contaminated water source, and we expect that government agencies, including FDA, would be likely to take specific actions based on the circumstances to prevent consumer exposure."*

We believe FDA should use the internationally recognized definition developed by Codex. Although PFI recognizes that FSMA listed radiological hazards as one of the four hazard types requiring identification and evaluation, we believe that Congressional intent can still be satisfied with the inclusion of radiological hazards as a subset of chemical hazards.

In addition, consistent with our objection to the reference in the rule to HACCP concepts, including the "reasonably likely to occur" standard, we recommend modifying the language in the definition to more accurately reflect what we believe to be the relevant criteria for a hazard. We note that Congress identifies "known or reasonably foreseeable" as the standard when referring to hazards in

the statute. We see no reason for FDA to go beyond the standard identified by Congress.

Proposed Revision

Hazard means any biological, chemical, or physical~~, or radiological~~ agent ~~that is reasonably likely to cause illness or injury in animals or humans in the absence of its control~~ the presence of which in food may cause an adverse health effect.

Hazard reasonably likely to occur means a hazard for which a prudent person who manufactures, processes, packs, or holds food would establish controls because experience, illness data, scientific reports, or other information provides a basis to conclude that there is a reasonable possibility that the hazard will occur in the type of food being manufactured, processed, packed, or held in the absence of those controls.

PFI Comment

We believe FDA's attempt to create and implement the concept of "reasonably likely to occur" (RLTO) is unnecessary in light of the statutory requirement that an owner, operator or agent in charge of a facility "identify known or reasonably foreseeable hazards that may be associated with the facility…" FDA, in its discussion of proposed 507.33(a), introduces the RLTO concept and identifies it as analogous to concepts in various other HACCP approaches, including the Federal HACCP regulations for seafood, juice, meat and poultry. As GMA noted in its comments on the Human Food proposed rule, "[b]y using this HACCP standard, the proposed rule appears to treat all preventive controls as substantially similar to CCPs (i.e., either equal or very similar to CCPs). This approach is well-intended but problematic due to the way the statute is written (with a broad definition of preventive controls) and the inherent difficulty in interpreting what RLTO means." (GMA Comments on Food Safety Plan Requirements, page 14)

PFI believes that the Animal Food Proposed Rule would benefit from stricter adherence to the concepts laid out in the statute with respect to known or reasonably foreseeable hazards. Otherwise, the FDA proposal regarding RLTO would subject all preventive controls to the requirements reserved for critical control points (CCPs) in a HACCP system, because HACCP requires CCPs for all RLTO hazards. The statute does not require the application of a HACCP approach but instead introduces the broader preventive controls concept, which facilitates the effective use of resources to address identified and evaluated hazards throughout the animal food production process. We therefore join other

human and animal food industry stakeholders in calling for the replacement throughout the proposed rule of the term "RLTO" with "known or reasonably foreseeable hazards."

In short, we urge FDA to revise the Proposed Rule to:

1. Apply the statutory language by using hazards "known or reasonably foreseeable" as the basis for hazard analysis with an evaluation of probability and severity in order to determine how hazards are controlled within the food safety system, taking a broader view of the definition of "preventive controls" as directed by the statute; and
2. Allow flexibility for the application of management elements for preventive controls so that such controls are managed with a level of rigor commensurate with the nature of the risk and the type of control employed. Thus, PFI recommends that the proposed definition be deleted.

Proposed Revision

~~Hazard reasonably likely to occur means a hazard for which a prudent person who manufactures, processes, packs, or holds food would establish controls because experience, illness data, scientific reports, or other information provides a basis to conclude that there is a reasonable possibility that the hazard will occur in the type of food being manufactured, processed, packed, or held in the absence of those controls.~~

Microorganisms means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species having animal or human health significance. The term "undesirable microorganisms" includes those microorganisms that are of animal or human health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

PFI Comment

PFI proposes that the definition of "microorganisms" be revised in consideration of the new definition we propose above for "undesirable microorganisms."

Proposed Revision

Microorganisms means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites. ~~and includes species having animal or human health significance. The term "undesirable microorganisms" includes those microorganisms that are of animal or human health significance, that~~

~~subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.~~

Monitor means to conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control and to produce an accurate record for use in verification.

PFI Comment

Codex, the international standard setting body that promotes trade in safe foods, has defined this term. PFI has modified the Codex definition slightly and recommends that FDA incorporate it into this proposed rule.

Proposed Revision

Monitor means ~~to conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control and to produce an accurate record for use in verification.~~ to conduct a planned sequence of observations or measurements of control parameters to assess whether a control measure is under control.

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

PFI Comment

As stated above, we recommend FDA clarify the differences between "consumer" and "customer" with respect to the purchase and consumption of pet food. The definition of "packaging" should be revised accordingly.

Proposed Revision

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

Plant means the building or establishment, or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of animal food.

PFI Comment

FDA should combine the definition of Facility and Plant, as they are used interchangeably. In addition, the definition should acknowledge those facilities that are exempt from registration.

Recommended Revision

Please refer to revised proposed definition of "facility" above.

Preventive controls means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

PFI Comment

PFI generally agrees with this definition, but because it could create confusion owing to its relationship to HACCP principles, PFI has proposed the term "prerequisite program" above and encourages its use in place of the term "preventive controls" throughout the document when referring to CGMPs.

PFI shares the concerns regarding the application of "preventive controls" described in GMA's comments on the Human Food Proposed Rule that **not all** preventive controls require a CCP. Regarding the concepts of preventive controls and CGMPs, GMA states that "[b]ecause there is such a wide range of preventive controls under FSMA, the regulations should not require all preventive controls to be managed in the same way. Each facility should determine, in the first instance, what level of management oversight is needed to accomplish the food safety goal of significantly minimizing and preventing hazards. For CCPs, the appropriate level of oversight would be consistent with that in the proposal (i.e., all CCPs should be subject to monitoring, corrective actions, and verification). But for the much broader range of preventive controls that are not CCPs, the level of management oversight applied should be commensurate with the nature of the risk and the type of control being used. Full management oversight is only needed for CCPs. FDA suggests this type of flexibility in different places in the preamble. We therefore urge the Agency to modify the codified language to more directly reflect this principle in the content of the final rule." (GMA Comments on Food Safety Plan Requirements, page 3 of 134)

Qualified end-user, with respect to an animal food, means the consumer of the food (where the term does not include a business); or a restaurant or retail food establishment (as those terms are defined in § 1.227(b) of this chapter) that:
(1) Is located:
(i) In the same State as the qualified facility that sold the food to such restaurant or retail food establishment; or
(ii) Not more than 275 miles from such facility; and

(2) Is purchasing the food for sale directly to consumers at such restaurant or retail food establishment.

PFI Comment

PFI recommends revising the definition of the term "qualified end-user" to make it consistent with PFI's proposed definition of "customer" above. In addition, the § 1.227(b) definitions referenced in the provision notwithstanding, we request that the term "restaurant" be removed from the proposed definition of "qualified end-user" and replaced with the appropriate definitional terms for "restaurant" provided in 21 CFR 1.227(b)(10)(ii): pet shelters, kennels and veterinary facilities in which animal food is provided to animals.

Proposed Revision

Qualified end-user, with respect to animal food, means the ~~consumer~~ customer of the food (where the term does not include a business)~~; or a restaurant~~ or pet shelters, kennels, veterinary facilities or retail food establishments that:
(1) Is located:
(i) In the same State as the qualified facility that sold the food to such ~~restaurant or~~ pet shelters, kennels or veterinary facilities or retail food establishments; or
(ii) Not more than 275 miles from such facility; and
(2) Is purchasing the food for sale directly to ~~consumers~~ customers at such ~~restaurant or~~ pet shelters, kennels, veterinary facilities or retail food establishment.

Qualified facility means (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, or a facility to which both of the following apply:

(1) During the 3-year period preceding the applicable calendar year, the average annual monetary value of the animal food manufactured, processed, packed, or held at such facility that is sold directly to qualified end-users (as defined in this part) during such period exceeded the average annual monetary value of the animal food sold by such facility to all other purchasers; and
(2) The average annual monetary value of all animal food sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.

PFI Comment

PFI asserts that there should be no exemption from this rule based on annual sales or number of employees. However, if FDA proceeds with exemptions in the final rule, PFI proposes the following definition. Although we recognize the additional regulatory burden associated with requiring all animal food producers to implement this rule, we believe strongly that the entire animal food industry can and must adhere and be held accountable to the food safety principles and requirements outlined in the Rule.

Proposed Revision

Qualified facility means (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, or a facility to which both of the following apply:

(1) During the 3-year period preceding the applicable calendar year, the average annual monetary value of the animal food manufactured, processed, packed, or held at such facility that is sold directly to qualified end-users (as defined in this part) during such period exceeded the average annual monetary value of the animal food sold by such facility to all other purchasers; and

(2) The average annual monetary value of all animal food sold during the 3-year period preceding the applicable calendar year was less than $10,000~~$500,000~~ adjusted for inflation.

Qualified individual means a person who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA, or is otherwise qualified through job experience to develop and apply a food safety system.

PFI Comment

PFI recommends that FDA recognize formal education as acceptable to meet the criteria for a qualified individual. Many people involved in animal food production have completed education that provides the basis for their role as a qualified individual – this type of educational background should be given equal consideration along with training and experience.

Proposed Revision

Qualified individual means a person who ~~has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as~~

~~adequate by FDA, or is otherwise qualified through job experience to develop and apply a food safety system~~ is qualified through education or job experience to develop and apply a food safety system or has successfully completed training in the development and application of risk-based preventive controls.

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

PFI Comment

PFI recommends deleting this definition because a "food safety plan" is clearly defined in § 507.30. Quality control is a broader term that relates to much more than the elements of food safety, the purpose of this proposed rule.

Proposed Revision

~~Quality control operation means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated.~~

Reasonably foreseeable hazard means a potential biological, chemical, physical, or radiological hazard that may be associated with the facility, or the food.

PFI Comment

As mentioned in our comment regarding the definition of "hazard," radiological hazards should be considered event-based.

We also recommend that FDA replace "potential" with "probable," as the definition of probable as stated in The Merriam-Webster Dictionary is "supported by evidence strong enough to establish presumption but not proof" and is more in line with "foreseeable."

Proposed Revision

Reasonably foreseeable hazard means a probable ~~potential~~ biological, chemical, or physical, ~~or radiological~~ hazard that may be associated with the facility, or the animal food.

Rework means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

PFI Comment

PFI believes that the proposed definition for "rework" is too narrow and does not represent its use in animal food production. Accordingly, we recommend the definition be modified to more accurately reflect industry practice.

Proposed Revision

Rework means ~~clean, unadulterated~~ food that has been removed from processing ~~for reasons other than insanitary conditions or that has been successfully~~ and is intended to be reconditioned by reprocessing ~~and that is~~ to make it suitable for use in animal food.

Safe moisture level is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, processing, packing, and holding. The safe moisture level for a food is related to its water activity (a_w). An a_w will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given a_w will not support the growth of undesirable microorganisms.

PFI Comment

The moisture level in an animal food is not a clear indicator of the ability to control the growth of undesirable organisms. Control of water activity (a_w) would limit growth of undesirable organisms. Therefore, we propose replacing the definition of "safe moisture level" with PFI's proposed definition of "suitable water activity (a_w) level" noted above.

Proposed Revision

~~Safe moisture level is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, processing, packing, and holding. The safe moisture level for a food is related to its water activity (a_w). An a_w will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given a_w will not support the growth of undesirable microorganisms.~~

Significantly minimize means to reduce to an acceptable level, including to eliminate.

PFI Comment

The definition of this term should state more clearly that elimination may only be necessary in certain instances to achieve reduction to an acceptable level.

Proposed Revision

Significantly minimize means to reduce to an acceptable level, ~~including to~~ which may include elimination.

Small business means, for purposes of this part, a business employing fewer than 500 persons.

PFI Comment

PFI believes that there should be no exemption from compliance with this Rule based on total annual sales or number of employees. All companies regardless of size should have food safety programs in place. However, if FDA proceeds with exemptions in the final rule, PFI proposes the following definition. We include in our proposed revision language regarding compliance with State, local, country or other applicable non-Federal food safety law in order to ensure maximum applicability of this Rule to animal food producers.

Proposed Revision

Small business means, for purposes of this part, a business ~~employing fewer than 500 persons~~ that has between $10,000 and $25,000 in total annual sales of animal food, adjusted for inflation and that is in compliance with State, local, county or other applicable non-Federal food safety law.

Validation means 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 Comment

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.”

Proposed Revision

Validation means ~~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.~~ obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome.

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

PFI Comment

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."

Proposed Revision

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

Option 1 for Definition of "Very Small Business"

Very small business means, for purposes of this part, a business that has less than $500,000 in total annual sales of animal food, adjusted for inflation.

Option 2 for Definition of "Very Small Business"

Very small business means, for purposes of this part, a business that has less than $1,000,000 in total annual sales of animal food, adjusted for inflation.

Option 3 for Definition of "Very Small Business"

Very small business means, for purposes of this part, a business that has less than $2,500,000 in total annual sales of animal food, adjusted for inflation.

PFI Comment

The requirement of an animal food producer to adhere to food safety regulations should have no relation to annual dollar sales – to the extent possible, no business should be exempt, regardless of size. The definition for "very small business" should therefore include a very low annual sales threshold to ensure the largest number of animal food companies are covered under the Rule. If the definition is to be based on total annual sales, PFI proposes that a "very small business" be one with total annual sales not to exceed $10,000. We include in our proposed revision language regarding compliance with State, local, country

or other applicable non-Federal food safety law in order to ensure maximum applicability of this Rule to animal food producers.

Proposed Revision

Very small business means, for purposes of this part, a business that has less than ~~$2,500,000~~ $10,000 in total annual sales of animal food, adjusted for inflation and that is in compliance with State, local, county or other applicable non-Federal food safety law.

507.5 Exemptions

Consistent with our comments on exemptions for qualified facilities based on total annual sales or number of employees, PFI believes that no animal food facility should be exempt from Subpart C requirements. All animal food companies should establish science-based food safety programs.

We urge FDA to ensure consistency among the different proposed regulations under FSMA with respect to exemptions for small/very small businesses whereby two criteria are being utilized (number of employees and dollar sales).

Subpart B – Current Good Manufacturing Practice

Given the preamble comment that the Agency considered both PAS 222:2011 (*Prerequisite programmes for food safety in the manufacture of food and feed for animals*, hereafter referred to as PAS 222:2011) and the AAFCO Model Good Manufacturing Practice Regulations for Feed and Feed Ingredients (hereafter referred to as AAFCO Model GMPs) in the development of the cGMPs in this rule, PFI was very surprised and disappointed that the animal foods CGMPs so closely resemble the human food CGMPs. For the reasons stated below, we strongly believe that the international standard PAS 222:2011 or the AAFCO Model GMPs should be incorporated into the proposed rule.

PAS 222:2011 was developed through a long, collaborative process that engaged various animal food manufacturing stakeholders, including industry, academia and international standard setting body officials. Similarly, the AAFCO Model GMPs were the result of a long, collaborative process between AAFCO, FDA and various industry stakeholders and represents cGMP language that was acceptable to all parties, including FDA's CVM. Unlike the human food CGMPs on which the CGMPs in this Proposed Rule are based, both the PAS 222:2011 and the AAFCO Model GMPs are

specific to animal food, making them the logical choice as the basis for animal food CGMPs in this proposed rule. Accordingly, we urge FDA to consider incorporating either of these animal food-specific cGMP approaches into the final rule. If FDA proceeds with the human food CGMPs as the basis for CGMPs in the Animal Food Proposed Rule, PFI proposes a significant number of critical and substantive revisions to the CGMP language in the Proposed Rule and we reiterate our earlier comment that these CGMPs should apply to all animal foods.

PFI agrees with GMA's comments on the Human Food Proposed Rule that CGMPs as a prerequisite program are essential to effective preventive controls, but are not necessarily a part of those preventive controls. (GMA Comments on Food Safety Plan Requirements, page 3 of 134)

With respect to all sections of this Proposed Rule, including CGMPs, PFI believes that training of both animal food facility personnel and FDA inspectors will be critical to ensure that key provisions of the rule are successfully implemented. Although we maintain that animal food producers should be subject to one set of CGMPs, we urge FDA to consider providing its inspectors with sector-specific training that will enable them to inspect animal food facilities efficiently and effectively. We would request that any such training documentation (issued as guidance or otherwise) be made available for public comment and review prior to implementation.

We thank FDA for sharing its view (in several open meetings) that it was not the Agency's intention that compliance with CGMP provisions would require the construction of new facilities. We also appreciate FDA's acknowledgment that the Rule is intended to apply solely to animal food facilities that place animal food into commerce. The Rule should not apply to pilot plants or research facilities that do not place animal food into commerce. We agree with FDA's position that pilot plants and research facilities that meet this criterion should be exempt from this Rule and request that FDA's position be made clear in the Final Rule.

In our view, the CGMP provisions in the Animal Food Proposed Rule are too prescriptive in some areas and lack the flexibility needed to facilitate compliance for the various characteristics (e.g., manufacturing methods, ingredients, product formulation, etc.) of animal food production. As our section-specific comments below will show, we believe the proposed CGMPs can, with some modification, be made suitable for application to all animal food facilities, thus ensuring appropriate steps are taken to adhere to good manufacturing practices.

PFI supports FDA's proposal in some provisions of Subpart B that CGMPs should serve as recommendations (specified as "should") rather than requirements (specified as "must") and we would encourage FDA to employ this approach for all CGMPs. Recommending rather than requiring adherence to CGMPs provides animal food producers with the necessary time and flexibility to develop and implement specific practices that achieve the objectives of the Rule. CGMPs have been in place in the human food sector for more than three decades, and are only now being proposed as requirements for human food producers. In comparison, CGMPs are new for animal food producers. FDA should recognize that the successful implementation of these CGMPs will take time by first introducing them as recommendations.

The FDA requests comment on its thinking that CGMPs similar to those for human food are appropriate for animal food. As stated above, PFI does not agree that human food CGMPs are appropriate as the basis of animal food CGMPs. Although there are some similarities, human food and animal food facilities are vastly different, use different ingredient streams and must address different levels of risk. We believe that animal food safety principles can indeed be similar to those of human food facilities, but CGMPs should be less prescriptive to better reflect the characteristics of all animal food producers.

Regarding FDA's question whether "CGMP requirements that would be more appropriate for some types of animal food may not be appropriate for other types, and, if so, how the Agency can or should distinguish between those types during the various stages of animal food processing," PFI reiterates that one set of standards for all animal foods should be promulgated. (78 Fed. Reg. 64772) Differences in risk across animal food facilities can and should be addressed in each facility's food safety plan. As stated earlier in our comments, multiple CGMP requirements among animal food categories would create significant challenges for animal ingredient suppliers to different types of animal food producers. These challenges could quite easily lead some of these ingredient suppliers to determine that the costs of additional requirements outweigh the benefits of continuing to supply animal food producers. We are compelled to once again point out that incorporation in this proposed rule of the PAS 222:2011 or AAFCO Model GMPs – which are specific to animal food production – would in our view achieve the food safety objectives set forth in the statute using familiar and widely accepted approaches. Additionally, if FDA finalizes the CGMPs as recommendations rather than as requirements (specified as "should" rather than as "must"), flexibility would be built into the CGMP framework that obviates the need for creating separate standards.

Proposed Rule or Concern: § 507.14(a)(2) – Personnel

"(a) Plant management must take all reasonable measures and precautions to ensure that
(1) Any person who, by his own acknowledgement, by medical examination, or by supervisory observation, is shown to have, or appears to have any illness, open skin lesion, or other source of abnormal microbial contamination by which there is a reasonable possibility of animal food, animal food-contact surfaces, or animal food-packaging materials becoming contaminated, is excluded from any operations which may be expected to result in such contamination until the condition is resolved;
(2) Personnel have been instructed to report such health conditions to their supervisors;"

PFI Comment

PFI is concerned that requiring employees to report health conditions relating to themselves or other employees may violate state and federal privacy laws. Also, in some facilities a supervisor may not be the appropriate person to receive such information.

Recommended Revision

(2) Personnel have been ~~instructed~~ encouraged to report such health conditions to their supervisors or other employer personnel authorized to receive such information;

Proposed Rule or Concern: § 507.14(a)(3)(iv) – Personnel

"(3) All persons working in direct contact with animal food, animal food-contact surfaces, and animal food-packaging materials conform to hygienic practices while on duty to the extent necessary to protect against contamination of animal food. The methods for maintaining cleanliness include:
(iv) Storing clothing or other personal belongings in areas other than where animal food is exposed or where equipment or utensils are washed; and"

PFI Comment

Consistent with our general comment that the term utensil is inappropriate in a rule governing the production of animal food, we propose that "utensils" be replaced in this section with "tools."

Recommended Revision

"(iv) Storing clothing or other personal belongings in areas other than where animal food is exposed or where equipment or ~~utensils~~ tools are washed; and"

Proposed Rule or Concern: § 507.14(b) – Personnel

"(b) Personnel responsible for identifying sanitation failures or animal food contamination should have a background of education or experience, or a combination

thereof, to provide a level of competency necessary for production of clean and safe animal food. Animal food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and unsanitary practices."

PFI Comment

Employee training is an important element of CGMPs, and PFI generally agrees with these recommendations addressing employee training. It should be the responsibility of each animal food producer to determine the appropriate frequency and scope of training, as well as the type of records that should be kept to document that appropriate training has been conducted. This position is consistent with the concept in the food safety plan of tailoring controls to the specific facility and operations, and also aligns with the Global Food Safety Initiative's (GFSI) approach on this topic, which is based on Codex recommendations. Training is more appropriately considered a prerequisite program, rather than a preventive control with a measurable output. We recommend alternate language such as that in PAS 222:2011 (referenced below) or AAFCO (also referenced below) would provide the flexibility required to facilitate proper implementation of this recommendation.

In response to the request for comment posed by FDA, PFI recommends that the training requirements be placed only under Subpart B.

FDA also requests comment on whether to change the recommendations to requirements for education or training in proper handling techniques and food-protection principles. In light of points made earlier in these comments regarding the challenges animal food producers will face in implementing both CGMPs and preventive controls under this Rule, PFI urges FDA to recommend rather than require this provision.

Recommended Revision

(b) ~~Personnel responsible for identifying sanitation failures or animal food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe animal food. Animal food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and unsanitary practices.~~ The animal food producer shall train and supervise personnel, including contractors and visitors, in the application of the animal food safety principles and practices commensurate with their role and

activity in the animal food production process. Training of personnel with respect to animal food safety principles and practices shall be documented. (PAS 222:2011, Section 19)

OR

(b) ~~Personnel responsible for identifying sanitation failures or animal food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe animal food. Animal food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and unsanitary practices.~~ Persons, who receive, store, manufacture, process, package, label, sample, transport or distribute feed and/or feed ingredients shall be trained for the persons' areas of responsibility. (2014 AAFCO Official Publication, page 211)

Proposed Rule or Concern: § 507.17(b)(3) – Plant and grounds

"(b) The plant's buildings and structures must be suitable in size, construction and design to facilitate maintenance and sanitary operations for animal food production purposes (i.e., manufacturing, processing, packing, and holding). The plant must: (3) Permit the taking of proper precautions to protect animal food in outdoor bulk vessels by any effective means, including:"

PFI Comment

To account for practical differences between different characteristics of animal food production (e.g., manufacturing methods, ingredients, product formulation, etc.) and to provide flexibility for application of this requirement among all animal food producers, we recommend the following revision in the proposed language.

Recommended Revision

(b) The plant's buildings and structures must be suitable in size, construction and design to facilitate maintenance and sanitary operations for animal food production purposes (i.e., manufacturing, processing, packing, and holding). The plant must: (3) Permit the taking of proper precautions to protect animal food in outdoor bulk vessels by any effective means, which may ~~including~~ include:

Proposed Rule or Concern: 507.17(b)(4) – Plant and Grounds

"(b) The plant's buildings and structures must be suitable in size, construction and design to facilitate maintenance and sanitary operations for animal food production purposes (i.e., manufacturing, processing, packing, and holding). The plant must:
(4) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts, and pipes does not contaminate animal food, animal food-contact surfaces, or animal food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating animal food, animal food-contact surfaces, or animal food packaging materials."

PFI Comment

Based on FDA's clarification in recent public meetings that construction of new animal food production facilities would not be required in order to comply with CGMP regulations, and taking into account the variety in the design of animal food/feed manufacturing facilities, we recommend the following revision to the language.

Recommended Revision

(b) The plant's buildings and structures must be suitable in size, construction and design to facilitate maintenance and sanitary operations for animal food production purposes (i.e., manufacturing, processing, packing, and holding). The plant must:
(4) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts, and pipes does not contaminate animal food, animal food-contact surfaces, or animal food-packaging materials; and that ~~aisles or working spaces~~ access ~~are~~ is provided between equipment and walls ~~and are adequately unobstructed and of adequate width~~ to permit employees to perform their duties and to protect against contaminating animal food, animal food-contact surfaces, or animal food packaging materials.

Proposed Rule or Concern: 507.17(b)(5)

"(b) The plant's buildings and structures must be suitable in size, construction and design to facilitate maintenance and sanitary operations for animal food production purposes (i.e., manufacturing, processing, packing, and holding). The plant must:
(5) Provide adequate lighting in hand-washing areas, toilet rooms, areas where animal food is examined, processed, or stored, and areas where equipment or utensils are cleaned; and provide safety-type light bulbs, fixtures, and skylights, or other glass items suspended over exposed animal food in any step of preparation, or otherwise protect against animal food contamination in case of glass breakage."

PFI Comment

Consistent with our general comment that the term utensil is inappropriate in a rule governing the production of animal food, we propose that "utensils" be replaced in this section with "tools."

Recommended Revision

"(5) Provide adequate lighting in hand-washing areas, toilet rooms, areas where animal food is examined, processed, or stored, and areas where equipment or ~~utensils~~ tools are cleaned; and provide safety-type light bulbs, fixtures, and skylights, or other glass items suspended over exposed animal food in any step of preparation, or otherwise protect against animal food contamination in case of glass breakage."

Proposed Rule or Concern: 507.17(b)(6)

"(b) The plant's buildings and structures must be suitable in size, construction and design to facilitate maintenance and sanitary operations for animal food production purposes (i.e., manufacturing, processing, packing, and holding). The plant must:
(6) Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate animal food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating animal food, animal food-packaging materials, and animal food-contact surfaces."

PFI Comment

Strong odors may not be unusual in animal food facilities and their presence may not constitute a food safety or employee hazard. Furthermore, steam is not necessarily a contaminant. We therefore suggest the following revision.

Recommended Revision

(b) The plant's buildings and structures must be suitable in size, construction and design to facilitate maintenance and sanitary operations for animal food production purposes (i.e., manufacturing, processing, packing, and holding). The plant must:
(6) Provide adequate ventilation or control equipment to ~~minimize odors and vapors (including steam and noxious fumes)~~ remove excess or unwanted steam ~~and fumes~~ in areas where it may ~~contaminate~~ come into contact with animal food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating animal food, animal food-packaging materials, and animal food-contact surfaces.

Proposed Rule or Concern: § 507.19(a) – Sanitary operations

"(a) Buildings, fixtures, and other physical facilities of the plant must be maintained in a sanitary condition and must be kept in repair sufficient to prevent animal food from becoming adulterated. Cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against contamination of animal food, animal food-contact surfaces, or animal food packaging materials."

PFI Comment

The process of cleaning and sanitizing does not necessarily involve separate, sequential events. For example, adding an aqueous-based cleaning and sanitizing procedure can be an effective method to address identified and evaluated food safety hazards in operations such as low moisture food production. Cleaning and/or sanitizing should be risk-based as determined by the animal food facility's identification and evaluation of hazards. We recommend the following revision. Consistent with our general comment that the term utensil is inappropriate in a rule governing the production of animal food, we propose that "utensils" be replaced in this section with "tools."

Recommended Revision

§ 507.19(a) Buildings, fixtures, and other physical facilities of the plant must be maintained in a sanitary condition and must be kept in repair sufficient to prevent animal food from becoming adulterated. Cleaning and/or sanitizing of ~~utensils~~ tools and equipment must be conducted in a manner that protects against contamination of animal food, animal food-contact surfaces, or animal food packaging materials.

Proposed Rule or Concern: § 507.19(e) – Sanitary Operations

"(e) All animal food-contact surfaces, including utensils and animal food-contact surfaces of equipment, must be cleaned as frequently as necessary to protect against contamination of animal food."

PFI Comment

Consistent with our general comment that the term utensil is inappropriate in a rule governing the production of animal food, we propose that "utensils" be replaced in this section with "tools."

Recommended Revision

(e) All animal food-contact surfaces, including ~~utensils~~ tools and animal food-contact surfaces of equipment, must be cleaned as frequently as necessary to protect against contamination of animal food.

Proposed Rule or Concern: § 507.19(e)(2) – Sanitary Operations

"(2) In wet processing, when cleaning is necessary to protect against the introduction of microorganisms into animal food, all animal food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the animal food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and animal food-contact surfaces of the equipment must be cleaned and sanitized as necessary."

PFI Comment

All animal food producers are concerned with growth and introduction of undesirable microorganisms. Interruptions occur during normal processing and are generally covered by individual plant standard operating procedures. Therefore, we believe this provision should be revised to read as follows. Consistent with our general comment that the term utensil is inappropriate as a term in a rule governing the production of animal food, we propose that "utensils" be replaced in this section with "tools."

Recommended Revision

§ 507.19(e)(2) In wet processing, when cleaning is necessary to protect against the introduction and/or growth of undesirable microorganisms into animal food, all animal food-contact surfaces must be cleaned and sanitized before use ~~and after any interruption during which the animal food-contact surfaces may have become contaminated~~. Where equipment and ~~utensils~~ tools are used in a continuous production operation, the ~~utensils~~ tools and animal food-contact surfaces of the equipment must be cleaned and sanitized as necessary.

Proposed Rule or Concern: § 507.19(e)(3) – Sanitary Operations

"(3) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and must be handled, dispensed, used and disposed of in a manner that protects against contamination of animal food, animal food-contact surfaces, or animal food-packaging materials."

PFI Comment

FDA requests comment on whether to change this recommendation for the storage of the single-service articles in appropriate containers to a requirement. PFI agrees that single-service articles should be stored in appropriate containers and also agrees that this provision should remain a recommendation. Consistent with our general comment that the term utensil is inappropriate as a term in a rule governing the production of animal food, we propose that "utensils" be replaced in this section with "tools."

Recommended Revision

"(3) Single-service articles (such as ~~utensils~~ tools intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and must be handled, dispensed, used and disposed of in a manner that protects against contamination of animal food, animal food-contact surfaces, or animal food-packaging materials."

Proposed Rule or Concern: § 507.19(f) – Sanitary Operations

FDA states in the Notice that "[p]roposed § 507.19(f) recommends that non-animal food-contact surfaces of equipment used in the operation of the plant be cleaned in a manner and as frequently as necessary to protect against contamination of animal food, animal food-contact surfaces, and animal food packaging materials. As discussed in section IX.C, FDA also is requesting comment on whether to change proposed § 507.19(f) to require rather than recommend that non-animal food-contact surfaces of equipment used in the operation of a food plant be cleaned in a manner and as frequently as necessary to protect against contamination of animal food, animal food-contact surfaces, and animal food-packaging materials." (78 Fed. Reg. 64774)

PFI Comment

In response to the request for comment, PFI supports the current language that proposes CGMPs as recommendations (specified as "should") rather than as requirements (specified as "must"). This approach provides the animal food sector with necessary discretion and time to develop specific practices to fulfill the objectives of the rule. CGMPs have been in place in the human food sector for more than three decades, and are only now being proposed as requirements. In comparison, CGMPs are new for animal food producers and their implementation will have a profound impact on the industry.

Recommended Revision

No revision to rule proposed.

Proposed Rule or Concern: § 507.19(g) – Sanitary Operations

"(g) Cleaned and sanitized portable equipment with animal food-contact surfaces and utensils should be stored in a location and manner that protects animal food-contact surfaces from contamination."

PFI Comment

"Manner" is a broad enough term to cover location. Also, FDA requests comment on whether to change proposed § 507.19(g) to require rather than recommend that cleaned and sanitized portable equipment with animal food-contact surfaces and utensils be stored in a location and manner that protects

animal food-contact surfaces from contamination. This provision should remain a recommendation as originally proposed by FDA. We recommend the following revision. Consistent with our general comment that the term utensil is inappropriate in a rule governing the production of animal food, we propose that "utensils" be replaced in this section with "tools."

Recommended Revision

§ 507.19(g) Cleaned and sanitized portable equipment with animal food-contact surfaces and ~~utensils~~ tools should be stored in a ~~location and~~ manner that protects animal food-contact surfaces from contamination.

Proposed Rule or Concern: § 507.20(a) – Sanitary facilities and controls

"(a) The water supply must be sufficient for the operations intended and must be derived from an adequate source. Any water that contacts animal food, animal food-contact surfaces, or animal food-packaging materials must be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, must be provided in all areas where required for the processing of animal food, for the cleaning of equipment, utensils, and animal food-packaging materials, or for employee sanitary facilities."

PFI Comment

Consistent with our general comment that the term utensil is inappropriate in a rule governing the production of animal food, we propose that "utensils" be replaced in this section with "tools."

Recommended Revision

(a) The water supply must be sufficient for the operations intended and must be derived from an adequate source. Any water that contacts animal food, animal food-contact surfaces, or animal food-packaging materials must be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, must be provided in all areas where required for the processing of animal food, for the cleaning of equipment, ~~utensils~~ tools, and animal food-packaging materials, or for employee sanitary facilities.

Proposed Rule or Concern: § 507.20(b)(3) – Sanitary facilities and controls

"(b) Plumbing must be of adequate size and design and adequately installed and maintained to:
(3) Avoid constituting a source of contamination to animal food, water supplies, equipment, or utensils or creating an unsanitary condition;"

PFI Comment

Consistent with our general comment that the term utensil is inappropriate in a rule governing the production of animal food, we propose that "utensils" be replaced in this section with "tools."

Recommended Revision

(b) Plumbing must be of adequate size and design and adequately installed and maintained to:
(3) Avoid constituting a source of contamination to animal food, water supplies, equipment, or ~~utensils~~ tools or creating an unsanitary condition;

Proposed Rule or Concern: § 507.20(b)(4) – Sanitary facilities and controls

"(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; and"

PFI Comment

There are many older animal food facilities that may not have sloping floors, in which case additional steps (e.g. squeegee or vacuum) are taken through standardized work instructions to remove unwanted water or liquid waste. We therefore recommend the following revision.

Recommended Revision

§ 507.20(b)(4) 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.

Proposed Rule or Concern: § 507.20(e) – Sanitary facilities and controls

"(e) Each plant must provide hand-washing 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, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature."

PFI Comment

In dry pet food manufacturing facilities, introduction of water can contribute to contamination. Therefore, a standard industry practice is for employees to utilize a hand sanitizer solution, rather than water. Ultimately, the decision regarding the appropriate hand-washing method should be based on the characteristics of the animal food being produced. We therefore recommend the following revision.

Recommended Revision

§ 507.20(e) Each plant must provide hand-washing or sanitizing ~~facilities~~ capabilities, taking into account the characteristics of the animal food being produced, ~~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~~, by providing facilities that are adequate, convenient, and furnish running water as appropriate and at a suitable temperature~~.

Proposed Rule or Concern: § 507.22 – Equipment and utensils

PFI Comment

Consistent with our general comment that the term utensil is inappropriate in a rule governing the production of animal food, we propose that “utensils” be replaced in this section with “tools.”

Recommended Revision

Proposed Rule or Concern: § 507.22 – Equipment and ~~utensils~~ tools

Proposed Rule or Concern: § 507.22(a)(1) – Equipment and utensils

“(1) All food plant equipment and utensils must be designed and of such material and workmanship to be adequately cleanable and must be properly maintained.”

PFI Comment

PFI recommends revising the language to allow the flexibility and discretion needed by the various animal food producers seeking to comply with this provision. In addition, PFI suggests that the scope be clarified as applying to “food contact” equipment – which is critical to the safe production of animal food – compared to all equipment (i.e. condenser, air conditioner, etc.). Consistent with our general comment that the term utensil is inappropriate in a rule governing the production of animal food, we propose that “utensils” be replaced in this section with “tools.” We therefore recommend the following language revision.

Recommended Revision

§ 507.22(a)(1) Where applicable, all animal food contact plant equipment and ~~utensils must~~ tools should be designed and of such material and workmanship to be adequately cleanable and must be properly maintained for their intended use.

Proposed Rule or Concern: § 507.22(a)(2) – Equipment and utensils

"(2) The design, construction, and use of equipment and utensils must preclude the adulteration of animal food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants;"

PFI Comment

PFI recommends the following language change to allow the flexibility and discretion required by the various animal food producers seeking to comply with this provision. Our recommended change simplifies the provision language and also would enable animal food producers to effectively address any contaminants that might pose a food safety risk. Consistent with our general comment that the term utensil is inappropriate in a rule governing the production of animal food, we propose that "utensils" be replaced in this section with "tools."

Recommended Revision

§ 507.22(a)(2) The design, construction, and use of equipment and ~~utensils must~~ tools should be appropriate for their intended purpose and preclude the adulteration of animal food. ~~with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.~~

Proposed Rule or Concern: § 507.22(a)(3) – Equipment and utensils

"(3) All equipment should be installed and maintained in such a way to facilitate the cleaning of the equipment and all adjacent spaces;"

PFI Comment: PFI agrees that equipment and facilities should be maintained to ensure safe animal food production. However, PFI maintains that this Proposed Rule should focus on animal food manufacturing equipment and not equipment that may have little to no impact on the food product or process. The safety of animal food will be improved by ensuring that equipment and utensils directly used to make animal food meets these guidelines – accordingly, the following revision is proposed.

Recommended Revision

§ 507.22(a)(3) ~~All~~ Animal food manufacturing equipment should be installed and maintained in such a way to facilitate the cleaning of the equipment and ~~all~~ adjacent spaces.

PFI Proposed Rule or Concern: § 507.22(a)(4) – Equipment and utensils

"(4) Animal food-contact surfaces must be made of materials that resist corrosion when in contact with animal food;"

PFI Comment

PFI recommends, as a means to provide flexibility and discretion for animal food producers, that the animal food producer be allowed to determine the need for corrosion resistant materials in the production process. Therefore, the following revision in the language is requested.

Recommended Revision

§ 507.22(a)(4) As appropriate, ~~A~~animal food-contact surfaces must be made of materials that resist corrosion when in contact with animal food.

PFI Proposed Rule or Concern: § 507.22(a)(5) – Equipment and utensils

"(5) Animal food-contact surfaces must be made of nontoxic materials and designed to withstand the environment of their intended use and the action of animal food, and if applicable the action of cleaning compounds and sanitizing agents; and"

PFI Comment

To address the wide variety of production methods for animal food, including wet pet food, dry pet food and treats, PFI suggests the following change to this provision, which takes into account the range of cleaning and sanitizing approaches employed by animal food producers.

Recommended Revision

§ 507.22(a)(5) Animal food-contact surfaces must be made of nontoxic materials and designed to withstand the environment of their intended use and the action of animal food, and if applicable the action of cleaning compounds and/or sanitizing agents; and

PFI Proposed Rule or Concern: § 507.22(b) – Equipment and utensils

"(b) Seams on animal food-contact surfaces must be maintained so as to minimize accumulation of food particles, dirt, and organic matter, and thus minimize the opportunity for growth of microorganisms."

PFI Comment

PFI recommends, as a means to provide flexibility for the wide range of animal food producers, a change from "must" to "should" in this provision, as indicated below.

Recommended Revision

§ 507.22(b) Seams on animal food-contact surfaces ~~must~~ should be maintained so as to minimize accumulation of food particles, dirt, and organic matter, and thus minimize the opportunity for growth of undesirable microorganisms.

Proposed Rule or Concern: § 507.22(c) – Equipment and utensils

"(c) Equipment in the animal food manufacturing or handling area that does not come into contact with animal food must be constructed in such a way that it can be kept in a clean condition."

PFI Comment

PFI recognizes the contributions made previously by the GMA coalition in its comments on the Human Food Proposed Rule and agrees with the GMA coalition's comments concerning the concept of "clean." GMA has stated that "clean" is understood to mean "free from foreign matter and unadulterated" (GMA Comments on Subpart B (Current Good Manufacturing Practices), page 10) PFI agrees that the animal food manufacturing areas should be clean, but notes that these provisions must be applicable to all animal food producers – accordingly, less prescriptive language may be more appropriate. Therefore, the following revision is requested.

Recommended Revision

§ 507.22(c) Where applicable, ~~E~~equipment in the animal food manufacturing or handling area that does not come into contact with animal food must be constructed in such a way that it can be kept in a clean condition.

Proposed Rule or Concern: § 507.22(d) – Equipment and utensils

"(d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed and automated systems, must be of a design and construction that enables them to be maintained in an appropriate sanitary condition."

PFI Comment

Language should be added that allows the continued use of cleaning methods determined by a risk assessment to be effective. Such methods may include dry cleaning, with no sanitizing step. Thus, the following revision – from must to should – is requested. As with other suggested revisions to this subpart, the revision below also provides the flexibility and discretion that will make this provision appropriate for all animal food producers.

Recommended Revision

§ 507.22(d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed and automated systems, ~~must~~ should be of a design and construction that enables them to be maintained in an appropriate sanitary condition, where applicable.

Proposed Rule or Concern: § 507.25(a)(2) – Processes and controls

"(2) Containers holding animal food, raw materials, or ingredients are labeled to accurately identify the contents;"

PFI comments

The term "label" implies a physical label and could be interpreted as excluding electronic identification. Regardless of the format of identification, it is the appropriate identification of containers that this provision addresses. Due to the potentially restrictive nature of the term "label," PFI requests the following revision.

Recommended Revision

§ 507.25(a)(2) Containers holding animal food, raw materials, or ingredients are labeled and/or identified to accurately identify the contents;

Proposed Rule or Concern: § 507.25(a)(3) – Processes and controls

"(3) The labeling for the finished animal food product contains the specific information and instructions needed so the food can be safely used for the intended animal species;"

PFI Comment

For pet food, the term "finished" may imply product in its final form with appropriate packaging and/or labeling, but for animal food/feed ingredients, this provision as written may not convey a clear expectation of what is needed. PFI proposes the following revision.

Recommended Revision

§ 507.25(a)(3) ~~The labeling for the f~~ Finished commercial animal food product in its final container should be properly labeled to include the specific information and instructions so the food can be safely used for the intended animal species;

Proposed Rule or Concern: § 507.25(a)(7) – Processes and controls

"(a) Plant management must ensure that:

(7) Chemical, microbial, or extraneous-material testing procedures are used where necessary to identify sanitation failures or possible animal food contamination; and"

PFI Comment

PFI agrees with FDA regarding the importance of having methods in place to identify sanitation failures. However, chemical, microbial or extraneous material testing are steps that may (or may not) be appropriate elements of an animal food facility's food safety plan, based on its hazard analysis. Accordingly, less prescriptive language will provide the flexibility animal food producers need, and we propose the following revision.

Recommended Revision

§ 507.25(a)(7) ~~Chemical, microbial, or extraneous-material~~ testing ~~p~~ Procedures are used where necessary to identify sanitation failures that may lead to ~~or~~ possible animal food contamination; and

Proposed Rule or Concern: § 507.25(a)(8) – Processes and controls

"(a) Plant management must ensure that:
(8) All animal food that has become contaminated to the extent that it is adulterated is rejected, or if permissible, treated or processed to eliminate the contamination."

PFI Comment

PAS 222:2011, Section 14.1 provides the basis for language that may be better suited for the various manufacturing methods, ingredients and product formulations of animal foods. Therefore we recommend the following revision.

Recommended Revision

§ 507.25(a) Plant management must ensure that:
(8) All animal food that has become contaminated to the extent that it is adulterated is stored, handled and used in such a way that animal food safety, traceability and regulatory compliance are maintained. ~~is rejected, or if permissible, treated or processed to eliminate the contamination.~~

Proposed Rule or Concern: § 507.25(b)(1) – Processes and controls

"(b) Raw materials and ingredients:
(1) Must be inspected and segregated or otherwise handled as necessary to ensure that they are clean and suitable for processing into animal food and must be stored under conditions that will protect against contamination and minimize deterioration. In addition:"

PFI Comment

To allow for more flexibility, given the variety of products and manufacturing methods utilized in the animal food sector, we recommend the following changes to the language.

Recommended Revision

§ 507.25(b) Raw materials and ingredients:
(1) ~~Must~~ Should be inspected and segregated or otherwise handled as necessary to ensure that they are clean and suitable for processing into animal food and ~~must~~ should be stored under conditions that will protect against contamination and minimize deterioration. In addition:

Proposed Rule or Concern: § 507.25(b)(1)(i) – Processes and controls

"(i) Raw materials must be washed or cleaned as necessary to remove soil or other contamination;"

PFI Comment

PFI recommends the Agency remove § 507.25(b)(1)(i) because 507.25(b)(1) covers use of clean and suitable materials, therefore making this provision of the proposed rule unnecessary.

Recommended Revision

~~§ 507.25(b)(1)(i) Raw materials must be washed or cleaned as necessary to remove soil or other contamination;~~

Proposed Rule or Concern: § 507.25(b)(2) – Processes and controls

"(b) Raw materials and ingredients:
(2) Must not contain levels of microorganisms that may render the food injurious to the health of animals or humans, or they must be treated (e.g., heat) during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated;"

PFI Comment

PFI recommends the following revision to allow the use of existing technologies other than heat or new technologies that may be used in the manufacture safe animal food products.

Recommended Revision

§ 507.25(b) Raw materials and ingredients:

(2) Must not contain levels of undesirable microorganisms that may render the food injurious to the health of animals or humans, or they must be treated (e.g., heat or other measures) during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated;

Proposed Rule or Concern: § 507.25(b)(4) – Processes and controls

"(4) Including rework, must be held in bulk, or in containers designed and constructed in a way that protects against contamination, and must be held at a temperature and relative humidity and in a manner that prevents the animal food from becoming adulterated. Material scheduled for rework must be identified as such;"

PFI Comment

Materials should be held in a manner that protects against adulteration. PFI recommends the simplified, less prescriptive language provided below, which achieves FDA's fundamental intent of protecting raw materials and ingredients, including rework, from becoming adulterated.

Recommended Revision

§ 507.25(b)(4) Including rework, must be held ~~in bulk, or in containers designed and constructed in a way that protects against contamination, and must be held at a temperature and relative humidity and~~ in a manner that prevents the animal food from becoming adulterated. Material scheduled for rework must be identified as such;

Proposed Rule or Concern: § 507.25(c)(1) – Processes and controls

"(1) Equipment, utensils, and finished animal food containers must be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. When necessary, equipment must be taken apart for thorough cleaning;"

PFI Comment

Maintaining sanitary conditions in an animal food facility can be accomplished in many ways, but certain cleaning and sanitizing techniques can actually increase animal food safety risks if used improperly. For example, adding an aqueous-based cleaning and sanitizing procedure could increase animal food safety risks in certain operations such as low moisture animal food production. Therefore, sanitizing does not always follow cleaning as a sequential event. The use of cleaning and/or sanitizing methods should be risk-based and determined by the hazard analysis conducted for each animal food facility. Consistent with our general comment that the term utensil is inappropriate in a rule governing the

production of animal food, we propose that "utensils" be replaced in this section with "tools." We therefore recommend the following changes.

Recommended Revision

§ 507.25(c)(1) Equipment, ~~utensils~~ tools, and finished animal food containers ~~must~~ should be maintained in an acceptable condition through appropriate sanitation, including cleaning ~~and~~ or sanitizing, as appropriate. When necessary, equipment ~~must~~ should be taken apart for thorough cleaning;

Proposed Rule or Concern: § 507.25(c)(3) – Processes and controls

"(3) Animal food that can support the rapid growth of undesirable microorganisms must be held at temperatures that will prevent the animal food from becoming adulterated during manufacturing, processing, packing, and holding;"

PFI Comment

This provision is duplicative of § 507.25(c)(2) and therefore should be removed from the Proposed Rule. If an animal food producer ensures compliance with § 507.25(c)(2), there is no need for § 507.25(c)(3) as the animal food will not become adulterated.

Recommended Revision

~~§ 507.25(c)(3) Animal food that can support the rapid growth of undesirable microorganisms must be held at temperatures that will prevent the animal food from becoming adulterated during manufacturing, processing, packing, and holding;~~

Proposed Rule or Concern: § 507.25(c)(4) – Processes and controls

"(4) Measures taken to destroy or prevent the growth of undesirable microorganisms, such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling a_w, must be adequate under the conditions of manufacture, handling, and distribution to prevent animal food from being adulterated;"

PFI Comment

PFI notes that other measures may be equally effective to prevent the growth of undesirable microorganisms, including measures that have yet to be developed or adapted to animal food production. This is in alignment with the GMA coalition's comments on the Human Food Proposed Rule. (GMA Comments on subpart B (Current Good Manufacturing Practices), page 17 of 22) We therefore recommend the following revision.

Recommended Revision

§ 507.25(c)(4) Measures taken to destroy or prevent the growth of undesirable microorganisms, such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, ~~or~~ controlling a_w or other measures, must be adequate under the conditions of manufacture, handling, and distribution to prevent animal food from being adulterated;

Proposed Rule or Concern: § 507.25(c)(7) – Processes and controls

"(7) Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or animal food must be constructed, handled, and maintained during manufacturing, processing, packing, or holding in a manner that protects against contamination of animal food;"

PFI Comment

Consistent with our general comment that the term utensil is inappropriate in a rule governing the production of animal food, we propose that "utensils" be replaced in this section with "tools."

Recommended Revision

(7) Equipment, containers, and ~~utensils~~ tools used to convey, hold, or store raw materials, work-in-process, rework, or animal food must be constructed, handled, and maintained during manufacturing, processing, packing, or holding in a manner that protects against contamination of animal food;

Proposed Rule or Concern: § 507.25(c)(9) – Processes and controls

"(9) Adulterated animal food, raw materials, and ingredients must be disposed of in a manner that protects against the contamination of other animal food or, if the adulterated animal food, raw materials, or ingredients are capable of being reconditioned, they must be reconditioned using a method that has been proven to be effective;"

PFI Comment

PFI requests that "proven" be replaced with "shown" to better reflect current animal food practices. "Reconditioned" may also be an inappropriate description of methods utilized as compared to the term "reworked," which is more commonly used by animal food producers. For example, if a metal detector is utilized and malfunctions, product may be reworked (and not reprocessed/reconditioned) through the metal detector. Thus, the proposed language is suggested below.

Recommended Revision

§ 507.25(c)(9) Adulterated animal food, raw materials, and ingredients must be disposed of in a manner that protects against the contamination of other animal

food or, if the adulterated animal food, raw materials, or ingredients are capable of being reconditioned, they must be ~~reconditioned~~ reworked using a method that has been ~~proven~~ shown to be effective.

Proposed Rule or Concern: § 507.25(c)(11) – Processes and controls

"(11) Heat blanching, when required in the preparation of animal food, should be effected by heating the animal food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the animal food or passing it to subsequent manufacturing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning;"

PFI Comment

Blanching is not a common practice among animal food producers. PFI believes this recommendation is redundant with § 507.25(a)(6), which requires that "all reasonable precautions are taken so that production procedures do not contribute to contamination from any source." We therefore recommend this proposed provision be removed.

Recommended Revision

~~§ 507.25(c)(11) Heat blanching, when required in the preparation of animal food, should be effected by heating the animal food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the animal food or passing it to subsequent manufacturing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning;~~

Proposed Rule or Concern: § 507.25(c)(14) – Processes and controls

"(14) Animal food, including dry mixes, nuts, intermediate moisture animal food, and dehydrated 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 safe moisture level;"

PFI Comment

Control of the moisture level alone is insufficient to effectively address the growth of undesirable microorganisms. Only by controlling a_w can one effectively control the growth of undesirable microorganisms. Thus, the following revision is suggested. Also, we see no need for the mention of nuts in this section – there is no need for this ingredient to be singled out.

Recommended Revision

§ 507.25(c)(14) Animal food, including dry mixes, ~~nuts,~~ intermediate moisture animal food, and dehydrated 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 ~~safe moisture level~~ a_w;

Proposed Rule or Concern: § 507.25(c)(16) – Processes and controls

"(16) When ice is used in contact with animal food, it must be made from water that is safe and of adequate sanitary quality, and must be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part."

PFI Comment

PFI believes this requirement is redundant with § 507.25(a)(6), which requires that "all reasonable precautions are taken so that production procedures do not contribute to contamination from any source." We therefore recommend elimination of this provision.

Recommended Revision

~~§ 507.25(c)(16) When ice is used in contact with animal food, it must be made from water that is safe and of adequate sanitary quality, and must be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.~~

Proposed Rule or Concern: § 507.28 – Warehousing and distribution

"Storage and transportation of animal food must be conducted under conditions that will protect against biological, chemical, physical and radiological contamination of animal food as well as against deterioration of the animal food and the container."

PFI Comment

Radiological contamination is generally an event-based potential hazard and therefore not known or reasonably foreseeable. In line with previous comments regarding categorization of hazards, we recommend removing "radiological" from this section so radiological or event-based hazards can instead be evaluated and addressed by each animal food producer's risk assessment process, crisis management plan or food defense plan. If deemed necessary by the animal food producer, such hazards can further addressed in the hazard analysis as part of the chemical hazards identification and evaluation.

Recommended Revision

§ 507.28 Storage and transportation of animal food must be conducted under conditions that will protect against biological, chemical, and physical ~~and radiological~~ contamination of animal food as well as against deterioration of the animal food and the container.

Subpart C – Hazard Analysis and Risk-Based Preventive Controls

Proposed Rule or Concern: § 507.5(b) – Exemption

Regarding § 507.5(b), FDA states:

> "A facility that is required to comply with, and is in compliance with, § 500.23 and part 113 also would be subject to the requirements in proposed subpart C for biological hazards not regulated under § 500.23 and part 113. For example, the heat-stable toxin produced by the *Staphylococcus aureus* is a biological hazard that would not be inactivated or destroyed by the processing required under § 500.23 and part 113 (Ref. 37) (Ref. 38).
>
> The Agency requests comment on the criteria that should be used to determine whether a facility is in compliance with § 500.23 and part 113." (78 Fed. Reg. 64762)

PFI Comment

PFI is in agreement with the language of the proposed rule as follows:

> § 507.5(b) "Activities in animal food facilities that are regulated under, and are in compliance with, § 500.23 and part 113 of this chapter (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers) are exempt from subpart C of part 507 only with respect to those microbiological hazards regulated under part 113. The facilities must comply with subparts C and F of this part regarding all other potential hazards and must comply with subparts A and B of this part."

However, PFI recommends that the criteria specified in the preamble and noted in § 507.5(b) (78 Fed. Reg. 64762) need not to be mandated separately, but should be based on the hazard analysis performed by the qualified individual(s).

Proposed Revision

No revision proposed.

Proposed Rule or Concern: § 507.33(a) - Hazard Analysis

"(a) The owner, operator, or agent in charge of a facility must identify and evaluate known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at the facility to determine whether there are hazards that are reasonably likely to occur and develop a written hazard analysis."

PFI Comment

Animal food producers may address known or reasonably foreseeable hazards related to food for cats and dogs in a single, common food safety plan when the hazard analysis shows these hazards to be essentially the same for both types of food. Salvage pet food may be utilized in animal food for species other than cats and dogs. The AAFCO 2014 Official Publication defines salvage pet food as "start-up and over-run product, unfinished pet food, pet food fines and other product not suitable for packaging for retail sale." The Animal Food Proposed Rule should not require specific food safety plans for these materials, but rather the materials and their subsequent distribution would be included in the organization's main hazard analysis and food safety plan. During the FDA-PFI Webinar on December 9, 2013, FDA generally agreed with the request that individual hazard analyses would not be required for each animal food type manufactured (i.e. one plan for both cat and dog food) nor would a separate plan be required for each type of animal (zoo animals, pigs, etc.) that may receive production byproducts.

PFI requests that FDA modify the above referenced wording to allow one hazard analysis for the identification and evaluation of risks for both dog and cat food produced in a facility. This change would then allow the development of a common food safety plan when the hazard analysis shows the hazards to be essentially the same.

Recommended Revision

(a) The owner, operator, or agent in charge of a facility must identify and evaluate known or reasonably foreseeable hazards for ~~each type of~~ the animal food manufactured, processed, packed, or held at the facility to determine whether there are hazards that are reasonably likely to occur and develop a written hazard analysis.

Proposed Rule or Concern: § 507.33(a) - Hazard Analysis

"(a) The owner, operator, or agent in charge of a facility must identify and evaluate known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at the facility to determine whether there are hazards that are reasonably likely to occur and develop a written hazard analysis."

FDA explains "The written hazard analysis would include the justification for whatever conclusion the owner, operator, or agent in charge of a facility reaches, including a conclusion that no hazards are reasonably likely to occur. Thus, proposed § 507.33(a) would not limit the requirement for a written hazard analysis to those circumstances where the owner, operator, or agent in charge of a facility identifies one or more hazards that are reasonably likely to occur. Under proposed § 507.33(a), a written hazard analysis would be required even if the conclusion of the analysis is that there are no hazards reasonably likely to occur." (78 Fed. Reg. 64781)

PFI Comment

PFI agrees with FDA on the need for a written hazard analysis to document the identification and evaluation of known or reasonably foreseeable hazards. Consistent with our earlier request that FDA remove the term "reasonably likely to occur" from the proposed rule, we propose that FDA allow the use of hazard tables or hazard registries to document hazards determined through the hazard analysis as not reasonably foreseeable. For example, an animal food facility's hazard analysis would not list deoxynivalenol (DON) as a hazard for salt, but may address it in a hazard table, hazard registry or similar document. The animal food facility could have a hazard summary list to assess materials relevant for that facility. Then the facility could list only the preventive controls and potential hazards appropriate for specific materials and process steps. During the FDA-PFI Webinar on December 9, 2013, FDA generally agreed with the request that hazard summary tables would be appropriate in this context.

Recommended Revision

PFI is not requesting a revision to this language of the rule, but instead recommends that FDA's interpretation of the proposed rule as outlined at 78 Fed. Reg. 64781 ("written hazard analysis would be required even if the conclusion of the analysis is that there are no hazards reasonably likely to occur") should not require a hazard analysis beyond inclusion in a hazard table or registry for hazards determined to be not reasonably foreseeable.

Proposed Rule or Concern: § 507.33(b)(1) - Hazard Analysis

"(b) The hazard analysis must consider hazards that may occur naturally or may be unintentionally introduced including:
(1) Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other microorganisms of animal or human health significance;

PFI Comment

As discussed earlier in these comments, animal food producers should be allowed to address known or reasonably foreseeable hazards related to food for cats and dogs in a single, common food safety plan when the hazard analysis shows these hazards to be essentially the same. Potential risks to human health should be limited to environmental pathogens.

Allergens are not specified as a hazard in animal food, as acknowledged by FDA regarding the distinctions between the preventive controls rules for human food and animal food, and we therefore support their exclusion in any animal food hazard analyses.

As previously stated in Subpart B of the Proposed Rule…. "[t[he proposed animal food CGMPs are not identical to the current and proposed human food CGMPs. The proposed animal food CGMPs do not address 'cross-contact,' which for human foods is related to the inadvertent incorporation of allergens into foods. The Agency is not aware of evidence indicating that foodborne allergens pose a significant health risk to animals, or to humans through handling animal food." (78 Fed. Reg. 64771)

During the FDA-PFI Webinar on December 9, 2013, FDA generally agreed with PFI's request that the known or reasonably foreseeable hazards of significance to human handlers should be limited to environmental pathogens.

Proposed Revision

(b) The hazard analysis must consider hazards that may occur naturally or may be unintentionally introduced including:
(1) Biological hazards, including microbiological hazards such as parasites~~,~~ and environmental pathogens~~, and other microorganisms~~ of animal or human health significance;

Proposed Rule or Concern: § 507.33(b)(2) - Hazard Analysis

"(b) The hazard analysis must consider hazards that may occur naturally or may be unintentionally introduced including:

(2) Chemical hazards, including substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and nutrient imbalances;"

PFI Comment

As discussed in the Definitions section of our comments, we urge the FDA to remove any reference to "nutrient imbalance" in the proposed rule in favor of more accurate terms related to animal health: 1) nutrient deficiency and 2) nutrient toxicity, both of which are defined earlier in our comments. Furthermore, PFI suggests language to focus necessary attention on the harmful byproduct(s) of decomposition.

Proposed Revision

(b) The hazard analysis must consider hazards that may occur naturally or may be unintentionally introduced including:
(2) Chemical hazards, including substances such as pesticide and drug residues, natural toxins, harmful byproducts of decomposition, unapproved food or color additives, ~~and nutrient imbalances~~ nutrient toxicities and nutrient deficiencies;

Proposed Rule or Concern: § 507.33(b)(4) - Hazard Analysis

"(b) The hazard analysis must consider hazards that may occur naturally or may be unintentionally introduced including:
(4) Radiological hazards."

PFI Comment

As stated previously in these comments, radiological hazards are best addressed as event-based hazards managed separately from the food safety plan in programs such as an animal food facility's crisis management and/or the food defense plan. As appropriate, radiological hazards should be addressed as a subset of chemical hazards.

PFI therefore requests that FDA delete radiological hazards from the hazard analysis provisions.

Proposed Revision

~~(4) Radiological hazards.~~

Proposed Rule or Concern: § 507.33 - Hazard Analysis

The Proposed rule states "[a]s discussed in section II.C.2.f, proposed part 507 is not intended to address 'hazards that may be intentionally introduced, including by acts of

terrorism.' Therefore, the Agency would not be implementing section 418(b)(2) of the FD&C Act in this proposed rule." (78 Fed. Reg. 64745)

PFI Comment

PFI generally agrees with the above statement and would ask FDA to modify the statement to include, "…and/or economic adulteration" to the end of that statement. This would maintain consistency with FDA's proposed rule on Focused Mitigation Strategies To Protect Food Against Intentional Adulteration. (78 Fed. Reg. 78013, Dec. 24, 2013)

The preamble to the Proposed Rule, currently at 78 Fed. Reg. 64745, would be updated as recommended below.

Recommended Revision

As discussed in section II.C.2.f, proposed part 507 is not intended to address "hazards that may be intentionally introduced, including by acts of terrorism and/or economic adulteration."

Proposed Rule or Concern: § 507.33(c) - Hazard Analysis

FDA states that "[i]n other instances, the focus of the evaluation for chemical hazards would be directed to their long term effects, such as liver diseases in animals or humans exposed to aflatoxin over long periods (Refs. 65 and 66). Proposed § 507.33(c) would require that such chemical hazards be considered to determine whether they are reasonably likely to occur even if the chemical hazard occurs infrequently." (78 Fed. Reg. 64783)

PFI Comment

PFI requests that FDA modify the statement and remove the words "or humans" to maintain consistency with our previous comment that analysis of human hazards should be limited to environmental pathogens.

PFI recommends modifying the preamble, at 78 Fed. Reg. 64783, as noted below.

Recommended Revision

In other instances, the focus of the evaluation for chemical hazards would be directed to their long term effects, such as liver diseases in animals ~~or humans~~ exposed to aflatoxin over long periods (Refs. 65 and 66).

Proposed Rule or Concern: § 507.33(d)(10) - Hazard Analysis

FDA states that "[p]roposed § 507.33(d)(10) would require that the hazard evaluation consider the effect of any other relevant factors that might potentially affect the safety of the finished animal food. For example, an unexpected natural disaster could flood some or all of a facility, creating insanitary conditions and potentially contaminating the facility with harmful microorganisms or chemical residues. Following a natural disaster, environmental contaminants that could be brought into the facility could be hazards reasonably likely to occur in a facility that manufactures, processes, packs, or holds animal food." (78 Fed. Reg. 64785)

PFI Comment

Because the above mentioned hazards are unexpected (i.e., not known), it is not possible or practical to include an assessment of hazards arising from unforeseen natural disasters in an animal food facility's hazard analysis. Determining the appropriate response to a natural disaster should be part of an animal food facility's crisis management/emergency response plan, which may include identification of potential new hazards and a reassessment of the facility's food safety plan.

PFI recommends clarifying in the final rule that food safety plans do not need to address responses to a natural disaster.

Recommended Revision

Proposed 507.33(d)(10) would require that the hazard evaluation consider the effect of any other relevant factors that might potentially affect the safety of the finished animal food. ~~For example, an unexpected natural disaster could flood some or all of a facility, creating insanitary conditions and potentially contaminating the facility with harmful microorganisms or chemical residues. Following a natural disaster, environmental contaminants that could be brought into the facility could be hazards reasonably likely to occur in a facility that manufactures, processes, packs, or holds animal food.~~

Proposed Rule or Concern: § 507.36 – Preventive Controls for hazards that are reasonably likely to occur

FDA states that "[t]he Agency believes that the preventive controls discussed in this section (i.e., a supplier approval and verification program), when implemented appropriately in particular facilities, are 'risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent [identified hazards] and that are consistent with current scientific understanding of safe food manufacturing, processing, packing, or holding ....' The verification

procedures discussed in this section (i.e., environmental and product testing programs), when implemented appropriately in particular facilities, could be used to verify that the preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards. The use of and need for these preventive controls and verification measures, which are science-based, are widespread and commonly accepted in many sectors of the food industry. The Agency requests comment on these conclusions." (78 Fed. Reg. 64804-64805)

PFI Comment

Ingredient, environmental or finished product testing are each useful tools that allow flexibility for animal food facilities to monitor the effectiveness of preventive controls designed to address identified and evaluated hazards. Qualified individual(s) should develop a science-based, reasonable and sound testing program where applicable, that identifies and designates appropriate indicator organism(s), sampling plans, appropriate corrective actions and other relevant factors. Testing data is a tool that can be used to track and trend the effectiveness of the food safety program, and should be evaluated within the context of the food safety program and relevance to food safety. Carried out in this way, different testing approaches can be an important part of an overall food safety program.

Proposed Rule or Concern: 507.36(d)(2)(i)(A) Preventive Controls for hazards that are reasonably likely to occur

"For hazards identified in the hazard analysis as reasonably likely to occur:
(d) Preventive controls must include, as appropriate:
(2) Sanitation controls:
(i) Where necessary to significantly minimize or prevent hazards that are reasonably likely to occur, procedures for the:
(A) Cleanliness of animal food-contact surfaces, including animal food-contact surfaces of utensils and equipment; and"

PFI Comment

Consistent with our general comment that the term utensil is inappropriate in a rule governing the production of animal food, we propose that "utensils" be replaced in this section with "tools."

Recommended Revision

For hazards identified in the hazard analysis as reasonably likely to occur:
(d) Preventive controls must include, as appropriate:
(2) Sanitation controls:

(i) Where necessary to significantly minimize or prevent hazards that are reasonably likely to occur, procedures for the:
(A) Cleanliness of animal food-contact surfaces, including animal food-contact surfaces of ~~utensils~~ tools and equipment; and

Proposed Rule or Concern: 507.36(e)(2) Preventive Controls for hazards that are reasonably likely to occur

FDA "requests comments on whether to include a requirement for a mock recall as verification activity in the final rule." (78 Fed. Reg.64788)

PFI Comment

PFI generally agrees that mock recalls can be helpful in assessing recall procedures and identifying areas for improvement, but mock recalls should not be mandated. Rather, animal food facilities should be allowed to evaluate the recall plans they are required to establish under § 507.38 and determine the need for/frequency of mock recalls, as appropriate.

Proposed Rule or Concern: § 507.38(a) - Recall Plan for Animal Food with a Hazard That is Reasonably Likely to Occur

"(a) The owner, operator, or agent in charge of a facility must develop a written recall plan
for animal food with a hazard that is reasonably likely to occur and assign responsibility for performing all actions in the plan."

PFI Comment

PFI agrees that animal food facilities should be required to establish a recall plan. However, we believe this requirement for a recall plan is more appropriate as a provision in Subpart B, Current Good Manufacturing Practice, as a prerequisite program, as it is not a preventive control.

Recommended Revision

The requirement for a recall plan should be addressed as a prerequisite program in Proposed Subpart B – Current Good Manufacturing Practice and should read as follows:

"507.XX(a) Recall plan for an animal food with a hazard that is known or reasonably foreseeable

The owner, operator, or agent in charge of a facility must develop a written recall plan for animal food with a known or reasonably foreseeable hazard and assign responsibility for performing all actions in the plan..."

Proposed Rule or Concern: § 507.38(b)(2) – Recall Plan for Animal Food with a Hazard That is Reasonably Likely to Occur

"(b) The written recall plan must include procedures for:
(2) Notifying the public about any hazard presented by the animal food when appropriate to protect animal and human health;"

PFI Comment

Steps taken during a recall to protect human health should address environmental pathogens found in finished animal food. We appreciate FDA's acknowledgment that allergens are not a hazard in animal food and should not be included in any hazard analysis.

As previously stated in the proposed rule…. "[t]he proposed animal food CGMPs are not identical to the current and proposed human food CGMPs. The proposed animal food CGMPs do not address 'cross-contact,' which for human foods is related to the inadvertent incorporation of allergens into foods. The Agency is not aware of evidence indicating that foodborne allergens pose a significant health risk to animals, or to humans through handling animal food." (78 Fed. Reg. 64771)

During the FDA-PFI Webinar on December 9, 2013, FDA generally agreed with the request that hazards of significance to human handlers of animal food should be limited to environmental pathogens. For these reasons, PFI recommends that this section be modified to specify that a recall plan address human health risks associated with environmental pathogens only, as noted below.

Recommended Revision

(b) The written recall plan must include procedures for:
(2) Notifying the public about any hazard presented by the animal food when appropriate to protect animal health ~~and human health~~, or the presence of an environmental pathogen of concern to human health;

Proposed Rule or Concern: § 507.45(a)(1)(i) - Verification

"(a) Except as provided by paragraph (a)(3) of this section, the owner, operator, or agent in charge of a facility must validate that the preventive controls identified and implemented in accordance with § 507.36 to control the hazards identified in the hazard analysis as reasonably likely to occur are adequate to do so. The validation of the preventive controls:
(1) Must be performed (or overseen) by a qualified individual:

(i) Prior to implementation of the food safety plan or, when necessary, during the first 6 weeks of production; and"

PFI Comment

A specific timeframe for validation of preventive controls should not be mandated as long as a qualified individual(s) can determine that the animal food poses no safety risks and that no adulterated animal food has entered or will enter commerce. The primary focus for validation should be on CCP(s), not elements of an animal food facility's prerequisite program (e.g., scientific validation of training, integrated pest management, etc.).

Recommended Revision

(a) Except as provided by paragraph (a)(3) of this section, the owner, operator, or agent in charge of a facility must validate that the preventive controls identified and implemented in accordance with § 507.36 to control the hazards identified in the hazard analysis as reasonably likely to occur are adequate to do so. The validation of the preventive controls:
(1) Must be performed (or overseen) by a qualified individual:
(i) Prior to implementation of the food safety plan or, when necessary, in sufficient time to prevent potentially adulterated product from entering commerce ~~during the first 6 weeks of production~~; and

Proposed Rule or Concern: § 507.45(a)(3) – Verification

"(a) Except as provided by paragraph (a)(3) of this section, the owner, operator, or agent in charge of a facility must validate that the preventive controls identified and implemented in accordance with § 507.36 to control the hazards identified in the hazard analysis as reasonably likely to occur are adequate to do so. The validation of the preventive controls:
(3) Need not address:
(i) The sanitation controls in § 507.36(d)(2); and
(ii) The recall plan in proposed § 507.38." (78 Fed. Reg. 64831)

PFI Comment

This list of preventive controls for which validation is not required should include other prerequisite programs (i.e. integrated pest management, training programs, documentation and facility maintenance, etc.). Also, as mentioned in our comments on **§** 507.38, PFI maintains that the recall plan be addressed in the Proposed Rule in Proposed Subpart B – Current Good Manufacturing Practice.

PFI recommends revising proposed § 507.45(a)(3) as follows.

Recommended Revision

(a) Except as provided by paragraph (a)(3) of this section, the owner, operator, or agent in charge of a facility must validate that the preventive controls identified and implemented in accordance with § 507.36 to control the hazards identified in the hazard analysis as reasonably likely to occur are adequate to do so. The validation of the preventive controls:

(3) Need not address preventive controls that cannot be readily measured such as, but not limited to:

(i) The sanitation controls in § 507.36(d)(2); ~~and~~

(ii) ~~The recall plan in § 507.38.~~The training program;

(iii) Documentation;

(iv) Facility maintenance; and

(v) Integrated pest management.

Proposed Rule or Concern: § 507.45(b)(2) – Verification of Corrective Actions

The Proposed Rule states "Proposed § 507.45(b)(2) would not specify the verification activities that must be conducted for corrective actions. The Agency requests comment on whether proposed § 507.45(b)(2) should do so, and if so, what verification activities should be required." (78 Fed. Reg. 64796)

PFI Comment

PFI requests that FDA not mandate or specify verification activities that must be conducted for corrective actions. As FDA itself notes, verification of a corrective action could be as simple as observation of the corrective action being taken. PFI agrees with this approach because it acknowledges that not all prerequisite programs will have CCPs or critical limits. In fact, PFI strongly emphasizes that for a majority of prerequisite programs, CCPs or critical limits would not be appropriate or relevant.

Proposed Rule or Concern: § 507.45 (c)(1)(i) – Records review

"(c) The owner, operator, or agent in charge of a facility must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards that are reasonably likely to occur by ensuring that a qualified individual is conducting (or overseeing):

(1) A review of the following records in the timeframe specified:

(i) Monitoring and corrective action records within 1 week after the records are made; and" (78 Fed. Reg. 64831)

PFI Comment

PFI requests that this statement be modified to be consistent with proposed § 507.45(c)(1)(ii). While records review can be an important element of the verification process, we see no need for an arbitrary deadline for records review, which provides no flexibility for animal food producers.

Recommended Revision

(c) The owner, operator, or agent in charge of a facility must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards that are reasonably likely to occur by ensuring that a qualified individual is conducting (or overseeing):
(1) A review of the following records in the timeframe specified:
(i) Monitoring and corrective action records ~~within a week~~ within a reasonable time after the records are made.

Proposed Rule or Concern: § 507.45(e)(1)(vi) - Verification

The Proposed Rule states that "[t]he Secretary may require a reanalysis under section 418(i) of the FD&C Act to respond to new hazards and developments in scientific understanding, including, as appropriate, results from the Department of Homeland Security biological, chemical, radiological, or other terrorism risk assessment." (78 Fed. Reg. 64793)

PFI Comment

Terrorism risk should be addressed under an animal food facility's food defense or crisis management plan. PFI suggests removing the statement referencing Department of Homeland Security terrorism risk assessment. We also reiterate our earlier comment that radiological hazards are event-based and should be addressed in a facility's food defense or emergency response plan.

PFI recommends that the final rule make clear that a Department of Homeland Security terrorism risk assessment is not required under this section. The preamble language on 78 Fed. Reg. 64793 should be modified as noted below.

Recommended Revision

The Secretary may require a reanalysis under section 418(i) of the FD&C Act to respond to new hazards and developments in scientific understanding for~~,~~ ~~including, as appropriate, results from the Department of Homeland Security~~ biological, chemical, and physical risks ~~radiological, or other terrorism risk assessment~~.

Proposed Rule or Concern: § 507.45(e)(2) – Implementation of additional controls

"(e) The owner, operator, or agent in charge of a facility must:
(2) Complete the reanalysis and implement any additional preventive controls needed to address the hazard identified before the change in activities at the facility is operative or, when necessary, during the first 6 weeks of production;" (78 Fed. Reg. 64831)

PFI Comment

As with previous comments in response to proposed specific timeframes for verification activities, these should not be mandated, as long as a qualified individual(s) can determine that the animal food poses no safety risks. PFI recommends modifying the language of proposed § 507.45(e)(2) as follows.

Recommended Revision

(e) The owner, operator, or agent in charge of a facility must:
(2) Complete the reanalysis and implement any additional preventive controls needed to address the hazard identified before the change in activities at the facility is operative or, when necessary, ~~during the first 6 weeks of production~~ in sufficient time to prevent potentially adulterated product from entering commerce.

Proposed Rule or Concern: § 507.48(a)(4)(iii) – Modified Requirements That Apply to a Facility Solely Engaged in the Storage of Packaged Animal Food That Is Not Exposed to the Environment

"(a) The owner, operator, or agent in charge of a facility solely engaged in the storage of packaged animal food that is not exposed to the environment must conduct the following activities for any such refrigerated packaged animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin formation by, microorganisms of animal or human health significance:
(4) Verify that temperature controls are consistently implemented by:
(iii) Reviewing records of monitoring and corrective actions taken to correct a problem with the control of temperature within a week after the records are made;" (78 Fed. Reg. 64831-64832)

PFI Comment

Facilities engaged in storage of unexposed packaged animal food should not be held to an arbitrary deadline (i.e., within a week) to verify that temperature controls are implemented. Instead, and similar to previous comments, the rule should provide such facilities with flexibility to determine the appropriate amount of time for review of records related to monitoring of temperature controls and any corrective actions taken.

Recommended Revision

(a) The owner, operator, or agent in charge of a facility solely engaged in the storage of packaged animal food that is not exposed to the environment must conduct the following activities for any such refrigerated packaged animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin formation by, microorganisms of animal or human health significance:

(4) Verify that temperature controls are consistently implemented by:

(iii) Reviewing records of monitoring and corrective actions taken to correct a problem with the control of temperature within a ~~week~~ reasonable amount of time after the records are made;

Proposed Rule or Concern: Proposed 507.48, Subsection 2 – Approach to Modified Requirements under Section 418(m) of the FD&C Act

FDA states that "[t]his subset of requirements would be to:

- Implement temperature controls (section 418(c) of the FD&C Act);
- Monitor temperature (section 418(d) of the FD&C Act);
- Take appropriate corrective actions when there is a problem with temperature control (section 418(e) of the FD&C Act);
- Conduct applicable verification activities (review of records) (section 418(f) of the FD&C Act); and
- Establish and maintain certain records (section 418(g) of the FD&C Act).

The Agency seeks comment on the proposed list of modified requirements." (78 Fed. Reg. 64801)

PFI Comment

PFI generally agrees with FDA's proposed subset of requirements.

Proposed Rule or Concern: Proposed 507.48(a)(2)

FDA states that "[p]roposed § 507.48(a)(2) is modified relative to the analogous monitoring requirement that would be established in proposed § 507.39(a) in subpart C in that proposed § 507.48(a)(2) would not require written procedures for monitoring. The records of monitoring (which would be required by proposed § 507.48(a)(5)(i)) would demonstrate the frequency of monitoring. The Agency requests comment on whether there would be a benefit to requiring a facility to develop written procedures for monitoring temperature." (78 Fed. Reg. 64802)

PFI Comment

Written procedures for monitoring temperature should not be mandated. The requirement for corrective actions in Proposed § 507.48(a)(3) is sufficient to address procedures for monitoring temperature.

Proposed Rule or Concern: Proposed Subpart C--Hazard Analysis and Risk-Based Preventive Controls; K. Request for Comment on Additional Preventive Controls and Verification Procedures Not Being Proposed; 2. Product Testing

FDA "requests comment on when and how product testing programs are an appropriate means of implementing the statutory directives set out above. Although the Agency has not included these provisions in the proposed rule, the Agency requests comment on their inclusion in a final rule. Should a product testing program be limited to finished product testing or include raw material testing? What is the appropriate level of specificity for a product testing program? For example, should the Agency simply require that the owner, operator, or agent in charge conduct, as appropriate to the facility and the animal food, finished product testing, when appropriate based on risk, to assess whether the preventive controls significantly minimize or prevent the hazards that are reasonably likely to occur? This would provide flexibility to account for the wide diversity of animal food and animal food manufacturing, processing, packing, and holding systems subject to this rule and be consistent with the discussions within this proposed rule.

"FDA also requests comment on whether more detail would be appropriate, by, for example:

- Specifying particular hazards, situations or product types for which finished product testing would be required
- Specifying the frequency of testing and, if so, whether this frequency should depend on the type of product
- Identifying appropriate sampling plans for finished product testing;
- Requiring periodic testing for trend analysis and statistical process control
- Requiring written procedures for conducting finished product testing and, if so, also require that procedures for finished product testing be scientifically valid and include the procedures for sampling and the sampling frequency." (78 Fed. Reg. 64806)

PFI Comment

FDA has acknowledged that "The statute does not indicate the specific circumstances where product testing would be required or the specific manner in which such testing should be performed." (78 Fed. Reg. 64805)

The role of and need for testing varies with the type of animal food and facility production methods and characteristics. The owner, operator, or agent in charge of a facility must consider a number of factors in determining whether and how to establish an appropriate program. Assessment of the process and the risks inherent in that process is critical – there can be no one-size-fits-all approach. An accurate, facility-specific assessment can determine whether and how testing resources should be utilized. Accordingly, FDA should allow flexibility for animal food facilities to determine the best approach to address identified and evaluated hazards.

PFI agrees that ingredient, environmental and finished product testing can each serve as useful tools that allow flexibility for animal food facilities to address identified and evaluated hazards as part of an overall food safety program. Qualified individual(s) should develop a science-based, reasonable and sound testing program, where applicable, that identifies and designates appropriate indicator organism(s), sampling plans, appropriate corrective actions and other relevant factors. Testing data is a tool that can be used to track and trend the effectiveness of the food safety program and should be evaluated within the context of the food safety program and relevance to food safety. Carried out in this way, different testing approaches can be an important part of an overall food safety program.

Proposed Rule or Concern: Proposed Subpart C--Hazard Analysis and Risk-Based Preventive Controls; K. Request for Comment on Additional Preventive Controls and Verification Procedures Not Being Proposed; 3. – Environmental Monitoring

FDA states that, "[a]s discussed in section I.E.2 of the Appendix to this document…FDA's current thinking is that Listeria spp. may be an appropriate indicator organism for L. monocytogenes, because tests for Listeria spp. will detect multiple species of Listeria, including L. monocytogenes. However, FDA's current thinking is that there are no currently available indicator organisms for Salmonella spp. The Agency requests comment on these findings and conclusions." (78 Fed. Reg. 64806)

PFI Comment

Testing for the presence or levels of indicator organisms can demonstrate whether conditions exist that could be conducive to the growth of an undesirable microorganism. Monitoring for indicator organisms is beneficial in that it casts a broader net than does specific pathogen testing, allowing an investigation and corrective actions to be taken even when the pathogen has not been detected. Indicator organisms can be used to determine whether sanitation programs are effective and plant operating conditions are under control. They do not indicate the presence of a pathogen, but their levels may indicate circumstances requiring

improvement of or modification to cleaning and sanitation activities. The U.S. Department of Agriculture's Food Safety and Inspection Service established in 2012 that a finding of an indicator organism for a foodborne pathogen indicates conditions exist that could lead to the presence or harborage of the pathogen. Many food industry and pet food industry firms utilize certain other organisms, such as Enterobacteriaceae, as an indicator for the presence of conditions in which *Salmonella* spp. could be present.

Proposed Rule or Concern: Request for Comment on Other Potential Provisions Not Explicitly Included in Section 418 of the FD&C Act – Consumer Complaints

FDA notes that it "has received a number of animal food submissions to the RFR (Ref. 48) that have suggested that environmental pathogens hazards were not adequately addressed in a supplier's food safety plan. Some of these were identified through customer verification testing and others through complaints from consumers to a facility. A facility may also receive alerts as a result of state surveillance and testing programs.

The Agency requests comment on whether and how a facility's review of complaints, including complaints from customers or other parties, should be required as a component of its activities to verify that its preventive controls are effectively minimizing the occurrence of hazards." (78 Fed. Reg. 64809)

PFI Comment

Review of customer complaint data can be a meaningful and useful tool when evaluated in context of aggregated and trended data, but we do not believe review of customer compliant data should be required in the rule to verify that a facility's preventive controls are effectively minimizing the occurrence of hazards. Customer complaint data may be misleading if not reviewed in the proper context and could incorrectly suggest that a food safety plan or preventive measures are ineffective. Finally, animal food producers with more than one facility may maintain their customer comment records at the corporate level, not at the individual facilities.

Proposed Rule or Concern: Request for Comment on Other Potential Provisions Not Explicitly Included in Section 418 of the FD&C Act – Submission of Facility Profile to FDA

FDA states that, "[i]n light of the large number of facilities that would be covered by this proposal, FDA recognizes several potential benefits to having a facility's food safety plan in advance of an inspection, if the Agency were to require facilities to do so." (78 Fed. Reg. 64809)

PFI Comment

PFI previously provided extensive comments to FDA regarding problems associated with companies providing food safety plans to the Agency electronically, including as part of a facility's voluntary profile information. PFI would like to reiterate the point that "the safety of the food produced at a particular facility cannot be measured simply by reviewing identified hazards and preventive controls, but must be determined within the context of the facility's application of the food safety plan and adherence to good verification procedures." PFI's full comments on this issue were submitted to FDA on August 22, 2011 in reference to docket number FDA-2011-N-0238 and on July 10, 2012 in reference to docket number FDA-2012-N-0430.

Proposed Rule or Concern: Request for Comment on Other Potential Provisions Not Explicitly Included in Section 418 of the FD&C Act – Submission of Facility Profile to FDA

FDA states that "[t]he use of an electronic form would enhance the Agency's ability to store the information in a searchable form." (78 Fed. Reg. 64809)

The Agency also noted that "food facility profile information voluntarily provided to FDA would help FDA to determine whether a firm is high-risk or non-high-risk and that the Agency will use the profile information to assist in determining the frequency at which it will inspect the firm. In contrast to the voluntary submission of food facility profile information described in that notice, in this document, the Agency is also requesting comment on whether the submission of such information should be required." (78 Fed. Reg. 64810)

PFI Comment

We do not believe that the collection of facility profile information, as explained in the preamble, can help FDA achieve the goals laid out in the statute. Certain information such as facility location, product category, size and operating hours may be useful to know ahead of an inspection, but information about a facility's hazard analysis, process controls, and other information cannot be fully understood, is subject to misinterpretation, and is of little value when examined outside of the animal food facility and outside the presence of a qualified individual knowledgeable about that facility. There is significant diversity among pet food producers, with numerous product and operational characteristics that often justify different approaches to food safety. Likewise, some facilities with written food safety plans might appear compliant, but when reviewed on site may be found to have numerous gaps and deficiencies. PFI members participated in the June 2013 usability test of the facility profile system and

identified for FDA numerous deficiencies that revealed the system is unlikely to advance FDA's goals.

PFI also has considered the resources that would be required to comply if FDA were to mandate submission of facility profiles, particularly if they include hazards, controls, and verification inputs. PFI confirmed through participation in the June 2013 usability study that FDA's facility profile plan would require significant resources to collect and assemble the necessary information into a standard template for submission. Additionally, PFI has examined the potential legal basis for a facility profile requirement, and has been unable to identify any authority that would permit such a system to be mandated, in contrast to the voluntary system FDA had previously suggested.

Although the facility profiles discussed in the preamble are problematic, there is much FDA can do to develop better tools to efficiently and effectively identify and assess risk, thus facilitating better decision making regarding the expenditure of resources to enforce FSMA, in line with the underlying statute's goals of improving foods safety and public health. Key information for FDA to use in evaluating risk and prioritizing inspections is collected by its investigators and contracted state investigators on site through an interactive process. Rather than invest in a facility profile system of limited utility, PFI urges FDA to update the Establishment Inspection Report (EIR) process to assure that EIRs are capturing useful information and are communicated using a proactive and collaborative process with the animal food facility, and that the information is readily accessible through an integrated data system. PFI provided extensive comment to FDA on this issue on August 22, 2011 in reference to docket number FDA-2011-N-0238 and on July 10, 2012 in reference to docket number FDA-2012-N-0430.

Proposed Rule or Concern – Appendix – I. The Role of Testing as a Verification Measure in a Modern Food Safety System: B. Scientifically Valid Sampling and Testing

FDA states that, "[c]onsistent with the Agency's discussion of the term 'scientifically valid' in the proposed rule to establish CGMP requirements for dietary ingredients and dietary supplements for humans (68 FR 12158 at 12198), the Agency uses the term 'scientifically valid' with respect to testing to mean using an approach to both sampling and testing that is based on scientific information, data, or results published in, for example, scientific journals, references, text books, or proprietary research. A scientifically valid analytical method is one that is based on scientific data or results published in, for example, scientific journals, references, text books, or proprietary research (68 FR 12158 at 12198). Sampling and testing used for verification in a food

safety system must be scientifically valid if they are to provide assurance that preventive controls are effective." (78 Fed. Reg. 64835)

PFI Comment

In the Proposed Rule, FDA defines the term "scientifically valid" to mean "using an approach to both sampling and testing that is based on scientific information, data or results published in, for example, scientific journals, references, text books or scientific research." (78 Fed. Reg. 64835)

PFI agrees that analytical methods for testing of products and ingredients need to be reasonable and sound to confirm that they are capable of detecting or quantifying the analyte/microorganism(s) in the sample matrix evaluated. When finished product testing is appropriate and necessary, the sampling plan used should be based on the inherent risk of the product/material, sensitivity of the animal, other verification information about the hygienic status of the process or production environment, and the effect on the risk of handling in distribution and by the customer. When ingredient testing is appropriate and necessary, the sampling plan should be based on the effect of process controls at the manufacturer and receiving factory on the identified hazard. PFI concludes that the identification of sampling plans based upon meaningful and sound evaluation by the manufacturer would meet the definition of "scientific."

The International Commission for the Microbiological Specifications for Foods (2002) notes that environmental sampling plans are not statistically designed and are based on experience and knowledge of the sites most likely to detect a failure in good hygiene practices. Therefore, it may be difficult for a facility to provide scientific evidence, such as journal articles, to justify choice of sampling locations or the number of samples collected. Another example of an element of testing based upon practical considerations rather than scientific studies is the selection of sampling tools. Although the sampling methods and tools should not interfere with the recovery or survival of the analyte or microorganism(s), selection of such tools is generally based on a meaningful and sound evaluation and not a formal validation relative to the specific analyte or application.

PFI therefore concludes that certain aspects of sampling and testing are scientifically validated and others are not, but all aspects must be based on sound technical and practical considerations. To account for the various aspects of testing programs and to avoid confusion with formal validation procedures, PFI proposes the term "meaningful and sound" instead of "scientifically valid" when referring to sampling and testing. However, PFI would agree with the use of

"validated" when referring to specific program aspects amenable to scientific validation, such as analytical methods. Such methods need to be formally evaluated to confirm their suitability for use in the specific application.

Although it does not appear that FDA is requiring the use of accredited laboratories in any testing programs, it appears that "findings" from accredited laboratories must be reported to FDA. Accredited laboratories are an important and valuable tool for assuring high-quality test results in support of an ongoing testing program and/or in testing against an investigation or issue. PFI has serious concerns that a requirement to report to FDA the results from accredited laboratories would have the unintended consequence of discouraging the use of such laboratories.

Accordingly, PFI recommends a revision to the language as noted below.

Recommended Revision

Consistent with the Agency's discussion of the term 'scientifically valid' in the proposed rule to establish CGMP requirements for dietary ingredients and dietary supplements for humans (68 FR 12158 at 12198), the Agency uses the term 'scientifically valid' with respect to testing to mean using an approach to both sampling and testing that is based on scientific information, data, or results published in, for example, scientific journals, references, text books, or proprietary research. A scientifically valid analytical method is one that is based on meaningful and sound ~~scientific~~ data or results published in, for example, scientific journals, references, text books, or proprietary research (68 FR 12158 at 12198). Sampling and testing used for verification in a food safety system must be ~~scientifically valid~~ meaningful and sound if they are to provide assurance that preventive controls are effective.

Subpart D – Withdrawal of an Exemption Applicable to a Qualified Facility

PFI does not agree that any animal food facility should be exempt from Part C requirements; however, we do support the existence of a withdrawal process if qualified (exempt) facilities are allowed. We have always believed that at a minimum all animal food producers should establish and implement science-based safety programs.

Subpart F – Requirements Applying to Records That Must Be Established and Maintained

Under the Proposed Rule, the general requirements for records (proposed 21 CFR § 507.102) identify key principles that facilities must adhere to in keeping FSMA and CGMP related records under proposed part 507. For example, the proposed

regulations advise that records must contain actual values; be accurate, indelible, and legible; be created concurrently with performance of documented activities; and be as detailed as necessary. PFI supports the following statements made by GMA in its comments on the Human Food Proposed Rule:

> "GMA strongly supports the good recordkeeping principles FDA has identified for key food safety records. GMA agrees that recordkeeping systems used to document key food safety activities must be trustworthy and reliable..." (GMA Comments on Records- and Registration-Related Issues, page 17 of 34)

> "GMA strongly recommends that FDA remove the reference to part 11 in the proposed regulations. Part 11 contains requirements that are unnecessary to produce secure and reliable records. Consequently, industry would be required to significantly redesign and replace existing systems without any corresponding benefit or risk reduction. The cost and time involved would be significant and burdensome, and would not advance food safety. In addition, the inclusion of part 11 compliance would result in an unnecessary enforcement burden for FDA in the area of electronic systems security." (GMA Comments on Records- and Registration-Related Issues, page 18 of 34)

PFI recommends that proposed § 507.108 provide flexibility for records retention. FDA proposes that, with the exception of the food safety plan, offsite storage of records should be permitted after six months following the date the record was made, provided that the record can be retrieved and provided onsite within 24 hours of a request for official review (proposed § 507.108(c)). The food safety plan would always be required to be maintained onsite. Additionally, electronic records would be considered to be onsite if accessible from an onsite location.

Also with respect to records retention, we request that FDA clarify in the preamble to the final rule that the two-year record retention requirement in section 507.108 should only apply to records created after the compliance date for the final rule. When the Rule takes effect, facilities may not have two years of historical records on-hand because retention of such records is not legally required prior to the entry into force of the rule.

PFI also supports the GMA recommendation that "the final rule permit offsite storage of records other than the food safety plan upon their creation and simply specify expectations for efficient record availability." (GMA Comments on Records- and Registration-Related Issues, page 25 of 34) PFI members typically keep many important records at corporate headquarters or other central locations, not at individual facilities. For example, suppliers and raw materials may be relevant to multiple facilities

and records pertaining to them are often maintained in a central location. Similarly, validation studies and support (e.g., microbiological, thermal processing, and other scientific materials that support a process or control point) often are kept in corporate files. Pilot plant, research and development data, and recall-related materials are additional examples of materials that often are not stored at an individual facility.

Requiring all of these records to be kept at individual facilities would be duplicative and unnecessary to ensure an animal food facility is producing safe animal food. Establishing a six-month onsite retention policy is arbitrary, particularly given the breadth of records that must be maintained. Instead of prescribing a specific location for storage of the records, FDA's regulations should simply require that records must be produced promptly for official review within 24 hours of an appropriate request. Specifying the location for record storage will increase costs and will not contribute to the safety of animal food.

The Notice clarifies that electronic records will be considered "to be onsite" if they are accessible from an onsite location. PFI appreciates this flexibility but is concerned that this wording could be read to suggest each facility needs to have a direct portal or connection to access electronic records stored elsewhere. Animal food facility personnel often must contact corporate personnel familiar with the relevant data to identify records that respond to specific requests; as a result, individual facility operators usually will not be able to call up requested records on their own. Rather, the records may only be available electronically upon consultation with an expert in a central office.

Accordingly, PFI asks that the final rule simply provide that records must be made available to FDA in physical or electronic form within 24 hours of an onsite request for official review. Ensuring that facilities respond to requests for required records in a timely manner should be a higher focus for FDA than should mandating specific locations for record storage.

Compliance Dates

Proposed Rule or Concern

The Notice specifies an effective date of 60 days after publication of the final rule in the Federal Register with compliance dates staggered at one year for every business other than small or very small businesses, two years for small businesses and three years for very small businesses.

PFI Comment

PFI agrees with the FDA that the requirement of CGMPs and preventive controls are new for the animal food industry and will require sufficient time for compliance. As stated earlier in these comments, however, PFI does not agree that it will be easier for larger animal food producers to achieve compliance than for their smaller counterparts – consequently we do not support a longer implementation timeframe for smaller animal food producers. All animal food producers must be in compliance with all parts of FSMA – there should be no exemptions based on company size – and indeed it might be even more difficult for larger animal food producers to implement this rule than for their smaller counterparts. Larger producers may have multiple facilities to bring into compliance, more suppliers, more employees to train, more complex systems to integrate, etc. The facility-specific nature of implementing food safety plans may make compliance with this regulation much more complicated for a larger business that operates multiple facilities.

Additionally, the suppliers of ingredients to animal food producers must also comply with these proposed regulations. If some suppliers are classified as small or very small businesses with compliance dates after the compliance date of the animal food producer, there could be significant challenges to proper implementation of the animal food producer's food safety plan. The implementation of food safety plans and subsequent validation and verification as required by the regulation is highly complex, with many elements that must work together to be effective. Because of this complexity and the requirement to implement CGMPs plus preventive controls within the same timeframe, PFI recommends that the compliance date for **all** businesses, regardless of size, be three years from the entry into force of the final rule. FDA would also benefit from an extended implementation timeframe to properly train its investigators/auditors and to develop educational and training materials necessary for the proper and efficient implementation of the rule.

Support for Other Industry Comments

PFI thanks FDA for the opportunity to share these comments and looks forward to providing additional input to FDA as the Agency proceeds with rulemaking under FSMA. These comments are the result of thousands of hours of review by PFI members, along with extensive consultation with trade associations representing the full spectrum of animal food producers and animal food ingredient suppliers, all of which have a keen interest in seeing final rules that enable our members to continue supplying the United States and foreign markets with safe, high quality animal food and ingredients. Accordingly, we would like to thank our colleagues at the various trade associations, including the American Feed Industry Association, the National Grain and Feed Association and the National Renderers Association, for their valuable insight in and contribution to what was in many respects a collaborative effort to deliver comments to

FDA on this proposed rule. We would also like to thank GMA for sharing valuable insights from their review and comments on the Human Food Proposed Rule. We will continue to work closely with our trade association colleagues to share information so that we may deliver clear, constructive comments to FDA on all FSMA rules affecting animal food.

Conclusion

PFI members share with FDA an abiding interest and desire to ensure the safety of animal food – pet food in particular – and we view this Proposed Rule as an important tool in advancing this goal. We trust our comments will be reviewed by FDA in the same spirit with which they were developed – with the goal of implementing a final rule that enables animal food producers to use all available methods and approaches to maintain and improve the safety of animal food. While we would have appreciated more time to develop these comments, we look forward to the opportunity to provide further substantive input when this Proposed Rule is re-issued for comment in the coming months, per FDA's March 19th announcement. We urge FDA to re-issue the entire Rule for comment, to facilitate a thorough review of the Rule in its entirety. In closing, we appreciate the opportunity to submit these comments and look forward to continuing to work with FDA to ensure FSMA implementation is a success.

Sincerely,

Duane Ekedahl
President

Members of the Pet Food Institute

Ainsworth Pet Nutrition
American Nutrition, Inc.
Big Heart Pet Brands
Bil-Jac Foods, Inc.
Blue Buffalo Company
C.J. Foods, Inc.
Cargill Animal Nutrition
Central Garden & Pet
Diamond Pet Foods
Doctors Foster & Smith, Inc.
Hill's Pet Nutrition, Inc
Mars Petcare US, Inc.
Merrick Pet Care, Inc.
Midwestern Pet Foods, Inc.
Nestle Purina PetCare Company
Ohio Pet Foods, Inc.
P&G Pet Care
Pro-Pet, LLC
Simmons Pet Food, Inc.
Southern States Cooperative, Inc.
Sunshine Mills, Inc.
Texas Farm Products Company
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August 22, 2011

Preventive Controls for Registered Human Food and Animal Food/Feed Facilities
Notice; Request for Comments
Docket Number: FDA-2011-N-0238,

The Pet Food Institute (PFI) respectfully submits these comments in response to the request published by the United States Food and Drug Administration (FDA or the Agency) on May 23, 2011 regarding the availability of FDA's "Preventive Controls for Registered Human Food and Animal Food/Feed Facilities Notice; Docket Number: FDA-2011-N-0238. PFI represents the companies that manufacture over 98% of the dog and cat food sold in the United States, a $20 billion industry as well as affiliated ingredient, packaging and other companies that serve the industry.

Members of PFI are pleased to respond to the Agency's request for information and discussion that will provide background and information for the development of guidance on the following: (1) Hazard identification (biological, chemical, radiological, and physical) and (2) control measures associated with specific types of food or specific methods of manufacturing, processing, packing, or holding food. In particular, PFI will provide input on the following general categories with respect to animal food/feed (specifically pet food).

Discussion:

It is critical that the Agency understand that the manufacture of food safe for consumption and healthy for pets is the primary goal of pet food manufacturers. Unlike most foods for food producing animals, pet foods are developed to support animals for a long, healthy life, and many products provide complete nutrition for all life stages of the pet. All decisions regarding the hazard or risk level of an ingredient, process, facility or product MUST be science- and risk-based. Public policy must not be based upon anecdotal evidence.

Pet food production facilities may appear to be similar, but each facility is unique, in terms of the ingredients they select, the recipes they follow, the equipment and processes they use, and/or the products which they create. Even when owned by the same company, different facilities may use different ingredients, different processes and will make different products than other facilities. Animal feed facilities, including those that make pet food, source raw agricultural commodities and formulated

ingredients from many sources and there are many issues variables may alter certain ingredient characteristics.

Management of each facility will need to identify potential hazard(s) and then assess if, indeed, each hazard is reasonably likely to exist within the confines of the facility in question. For example, , it is highly likely that the same ingredient could be identified as a hazard in some facilities and not in others, depending on how the ingredient is processed, stored, or handled within the facility, , Thus,, specifying that a particular ingredient is hazardous for all facilities is likely not to be appropriate. In addition, a specific type of hazard may be controlled by different methods or techniques in different facilities, even when they use similar manufacturing processes, so identifying a specific preventive control to be used for that particular hazard for all facilities may likely not be appropriate as one solution does not fit all situations.

When evaluating facilities, a possible matrix may deal with the issues of ingredient hazard/risk parameters and the level of controls within a facility. That is, if an ingredient is evaluated for a level of risk, and the level of control within the facility is evaluated for its strength, then the relative "safety level" of the facility/product produced in the facility could be weighted as shown in Table 1.

Table 1. Level of Finished Product Safety Risk

		Level of Process Control in the Facility	
		Low	**High**
Level of Ingredient RISK	**High**	High Risk Product	Low Risk Product
	Low	Low Risk Product	Low Risk Product

If a company is using an ingredient that is of high risk, but the facility has a low level of process controls, a high risk product could result. If that same ingredient is used in a facility with a high level of control, it would most likely result in a low risk product. Further, if a low risk ingredient is used in a plant with a low level of controls, it would most likely produce a product with a low level of risk, but could require additional action by the facility to maintain safe products. A low risk ingredient processed in a plant with a high level of control would produce a low risk product.

As discussed in previous comments to the Agency, attempting to provide FDA copies of current operating specifications for each facility to be held on file by FDA would be less than useful for the Agency as well as for each of the thousands of affected facilities concerned. Providing a copy to FDA of each hazard analysis or control point within a single facility is time-consuming and provides no benefit to either the Agency or

the submitter, and may well be in violation of the Paperwork Reduction Act of 1995, intended to relieve the public burden. The implied benefit to the Agency is the opportunity to understand and evaluate a facility's hazard analysis and the suitability of its preventive controls from a remote location, but such details can really only be judged within the physical context of the facility itself. Further, because of the variations noted earlier, these are "living, breathing documents" that may change fairly frequently in some cases. It certainly is more appropriate to discuss the facility plan when an inspector/investigator is at the facility, so that the plan is not evaluated in a vacuum, or against a "standard" which might not be appropriate in operation.

Each question posed in the docket is shown here, with responses in *italics*.

1. Conducting a hazard analysis to determine the hazards associated with specific animal food/feed and processes (e.g., the procedures used to determine potential hazards and to assess whether they are reasonably likely to occur).

   Each manufacturer is responsible for producing safe food/feed and because of that responsibility must continuously determine for each facility the risk levels of certain ingredients, foods, or processes that could possibly be associated with a risk to the health of animals which consume the finished product. Analysis should be based on certain known entities, such as historical data regarding the subject, correlations that exist, scientific data and real world findings.

2. Implementing process controls (e.g., processes employed to prevent, eliminate, or reduce to acceptable levels the occurrence of any hazards that are reasonably likely to occur).

   Each manufacturer is responsible for developing, maintaining and documenting process controls for each facility which results in the prevention, elimination or sufficient reduction of hazards to produce safe food and training personnel to maintain those programs.

   Rules for the safe production of animal feed may be extrapolated from 21 CFR 110, which provides guidelines for the manufacture of human food. Further, the AAFCO Official Publication also contains Model Guidance documents used by State regulators and the feed industry to provide guidance for the production of safe feed, as found in the Model Feed Safety Program Plan, the Guidance/Framework for BMPs (Best Management Practice), the Medicated Feed Program (for food producing animals), the Model Good Manufacturing Practice Regulations for Feed and Food Ingredients and the AAFCO Non-licensed Medicated Feed Compliance Program. Each of these documents has been developed by and with the cooperation of FDA, AAFCO and the feed industry to enhance the production of safe feed and reduce the possibility of adverse health effects to animals or humans.

Additionally, low acid hermetically sealed pet foods produced in the wet state must comply with the requirements of 21 CFR Section 113. These rules already address process controls and should be referenced within any additional rules implemented under FSMA.

3. Validating food/feed safety controls (e.g., information on procedures used to determine that control measures are capable of controlling the identified Hazards).

   Each manufacturer is responsible for the development of and utilization of appropriate validation procedures for each facility to address the preventive control measures in place to deal with potential hazards. This may be done in concert with suppliers, equipment manufacturers, 3rd party experts, or as standalone studies.

4. Implementing sanitation controls (e.g., procedures and practices utilized to minimize the risk of contamination) for human food and animal food/feed.

   Sanitation controls will vary with the type of facility and food produced, and the ingredients, formulas, methods and practices used in each facility which produces pet food. The methodology used may vary from day to day or week to week depending on the company, the variety of the product to be produced, and many other individual characteristics. Attempting to artificially control those characteristics or actions by a "one size fits all" process will not be effective. Systems widely used in the sanitation of wet products will not be appropriate for dry products, and vice versa, thus it is always incumbent upon facility management to determine the most effective controls to be used, depending upon the hazard and risk factors that have been identified.

5. Implementing supplier controls (e.g., procedures and practices used to ensure raw materials and ingredients are safe for their intended use).

   Each manufacturer is responsible for the development and utilization of supplier controls, including but not limited to extensive contractual agreements, individual reviews and on-site inspections and/or audits by company representatives.

6. Allergen control (human food), including procedures to ensure that ingredients are accurately declared on the label, procedures to ensure the proper label is applied to the food, and procedures and practices to prevent the unintentional incorporation of a major food allergen into a food by cross contact during manufacturing, processing, and holding food.

   Allergen control is not applicable to animal feed, including pet food.

7. Environmental monitoring for *Salmonella* and for *Listeria monocytogenes* for specific types of food facilities (e.g., ready-to-eat food facilities, pet food facilities).

Environmental or other types of monitoring for various pathogens may be appropriate when considered when evaluating the possible hazards and risks of an individual facility, but should not be considered mandatory. Types of monitoring will vary with the hazard profile of a facility. Each manufacturer is responsible for producing safe food and must use controls appropriate for each specific facility.

8. Microbiological and other testing used to help ensure the safety of specific human food and animal food/feed.

   Microbiological, or other types of monitoring for various pathogens may be appropriate when considered when evaluating the possible hazards and risks of an individual facility, but should not be considered mandatory. Types of monitoring will vary with the hazard profile of a facility. Each manufacturer is responsible for producing safe food and must use controls appropriate for each specific facility.

   In evaluating criteria for risk, as PFI commented in the Public Meeting on June 6, 2011, it would appear that a continuum exists from highest to least risky in terms of the potential for microbiological contamination. Foods on the continuum listed in descending order of risk could be:

   > fresh, raw products for consumption by humans;
   > minimally processed food for consumption by humans;
   > raw products brought into the home for consumption by pets;
   > animal parts (chews) for consumption by pets;
   > minimally processed food for consumption by pets;
   > shelf stable products for consumption by humans or pets;*
   > food for consumption by food producing animals.

   **"Shelf stable" refers to a process(es) that allows processed food products of any kind to be held safely without refrigeration for an extended period of time*

   However, microbiological testing may be ustilized as a check of the system, but it is not the core of the system, itself. It is not a "control step", nor does it make food safe. Preventive controls make food safe by reducing or eliminating food safety hazard from production to consumption. Preventive controls must be the highest priority in the facilities' food safety program. Product testing should not be a mandatory step, but rather left to the discretion of the manufacturer, as it is his responsibility to ensure finished product safety

9. Specific biological, chemical, radiological, and physical hazards and controls for food types such as (but not limited to) spices, nuts, ready-to-eat food, bakery products, fresh-cut produce, milk products, and medical food.

   Each manufacturer is responsible for producing safe food/feed and because of that responsibility must continuously determine for each facility the risk levels of certain ingredients, foods, or processes that could possibly be associated with a risk to the

health of animals which consume the finished product. Analysis should be based on certain known entities, such as historical data regarding the subject, correlations that exist, scientific data and real world findings.

10. Specific biological, chemical, radiological, and physical hazards and controls for animal food/feed including feed ingredients.

    Each manufacturer is responsible for producing safe food/feed and because of that responsibility must continuously determine for each facility the risk levels of certain ingredients, foods, or processes that could possibly be associated with a risk to the health of animals which consume the finished product. Analysis should be based on certain known entities, such as historical data regarding the subject, correlations that exist, scientific data and real world findings.

11 Preventive control approaches and practices (e.g., for validation, supplier controls) that are practical for small and very small businesses to implement.

    There should be no difference in the safety of products produced by any food producer. The "safety" of food products should certainly not depend upon the size of the company producing the product.

    The principles of Hazard Analysis and Critical Control Points and Good Manufacturing Practices are achievable by all sizes of manufacturers and should not be dependent upon a number of people working for or the number of dollars earned by a company. Unsafe food products should not be allowed in commerce, regardless of their origin.

The members of Pet Food Institute applaud the Agency's willingness to reach out to the food and feed industry to provide guidance and to receive inputs on this important rule. The Food Safety Modernization Act will help all facets of food production, from growing through processing and including regulation. Extensive outreach and training will be necessary to accomplish the goals set in FSMA, and it will be imperative for the Agency to apply its rules uniformly and clearly so that there is no variability between District offices.

Further to the point of responsibility of animal feed and pet food manufacturers is the fact that their suppliers are asked to meet parameters established by the purchasers of these ingredient materials and of necessity, suppliers AND purchasers will need to put more stringent controls in place to lower the risk profile of some ingredients. This will again, take some time and organization, as well as input from FDA to assist the affected industries in producing safer ingredients for the human and animal food chains.

It is critical that all manufacturers have a food safety plan specific to each facility which encompasses the identification of hazards, preventive controls, effective monitoring programs, documented corrective actions and verification procedures. The criteria of that food safety plan is at the discretion of the manufacturer and will be based on the variables

within that ONE facility. FDA should only publish rules regarding the analysis of hazards and controls that prevent them in a manner that is general and non-proscriptive. Again, all rule-making must be science- and risk-based; flexible and seated within existing good manufacturing practices used to prevent, eliminate or prevent hazards.
Please do not hesitate to contact Pet Food Institute for any clarification and we will make every attempt to provide it.

Sincerely,

Nancy K. Cook
Vice President

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DATE 7/10/2012

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***Re: Docket No. FDA-2012-N-0430 - Agency Information Collection Activities; Proposed Collection; Comment Request; Voluntary Submission of Food/Feed Facility Profile Information*; 77 Fed. Reg. 27779 (May 11, 2012)**

The Pet Food Institute (PFI) thanks the U.S. Food and Drug Administration (FDA or the Agency) for the opportunity to submit this statement in response to the Agency's May 11, 2012 request for comments regarding FDA's proposed information collection of voluntary submissions of food facility profile information (the Request for Comments).

PFI represents the manufacturers of over 98% of the food for cats and dogs produced in the United States. This is an $18.3 billion domestic market with an additional $1.3 billion in export sales. In addition, PFI represents the manufacturers and suppliers of equipment, ingredients and other goods and services to the pet food industry. PFI members are committed to producing safe and nutritious pet food, and fully support FDA's efforts to implement its statutory authority based on the best information available about the industries the Agency regulates.

In the Request for Comments, the Agency proposed requesting information including the following:

- The facility type (e.g., manufacturer/processor, repacker/packer, or warehouse/holding facility);
- The products, and hazards (e.g., biological, physical, chemical) and preventive control measures associated with those products where either there is a regulation in place requiring identification of hazards and preventive control measures, e.g., seafood and juice, or the firm as a matter of its own business practices voluntarily identifies hazards and implements preventive control measures; and
- Other facility information (e.g., food safety training, facility size, operational schedule, and number of employees).

PFI's comments address each of these topics in turn, along with general statements regarding the burden associated with collecting and submitting the information FDA has proposed to request.

Regarding Collection of Information on "Facility Type"

We agree that information regarding facility type is practical and appropriate for the FDA to possess. However, this information is redundant in that the Agency already requests this information on an optional basis when the facility registers under the Bioterrorism Preparedness and Response Act of 2002. Currently, when completing the requirements in the Food Facility Registration Module (Form 3537) Section 9 "Type of Activity Conducted at the Facility" and Section 11(b) "General Product Category – Food for Animal Consumption", facilities provide FDA virtually the same information FDA requests here.

Regarding Collection of Information on "Products, Hazards and Preventive Controls"

As FDA moves forward with implementation of the Food Safety Modernization Act (FSMA), it will be critical for the Agency to prioritize its limited resources and to understand what firms are high-risk and non-high-risk for inspection scheduling purposes. However, the information FDA proposes to seek here is not the most efficient or effective means to make those determinations.

Often, pet food manufacturing facilities make diverse types of products which may require multiple, diverse safety plans tailored to individual products. Moreover, each written food safety and food defense plan may be a complex document that can be subject to change as new hazards are identified or better approaches for controlling risk are identified. As discussed more fully below, maintaining and updating these voluntary submissions to FDA would constitute a significant reporting burden.

Pet food production facilities may appear to be similar, but each facility is unique in terms of the ingredients selected, the recipes followed, the equipment and processes used, and/or the products created. It is the food safety team at each facility who will need to identify potential hazards and then assess whether identified potential hazards are reasonably likely to occur within the confines of that facility. For example, it is likely that the same ingredient could be identified as a potential hazard in some facilities and not in others, depending on how the ingredient is processed, stored, or handled within a particular site. A specific type of hazard may be controlled by different methods or techniques in different facilities, even when different facilities use similar manufacturing processes.

While it may be helpful to FDA to review voluntarily submitted facility identified potential hazards and associated preventive controls to assist in the Agency's preparation of guidance documents, these voluntary submissions alone are not likely to prove helpful in determining risk status of individual facilities, as the Request for Comments would indicate. As previously stated, the safety of the food produced at a particular facility cannot be measured simply by reviewing identified hazards and preventive controls, but must be determined within the context of the facility's application of the food safety plan and adherence to good verification procedures. PFI has stated in earlier comments (FDA-2011-N-0238, Preventive Controls for Registered Human Food and Animal Food/Feed Facilities - August 22, 2011) that food safety and food defense plans are reviewed most appropriately by the Agency during on-site facility inspections in the context of the operations at the facility. We believe that

to obtain a true picture of a facility's potential risk, FDA must observe how a written plan is applied in practice.

As the Agency is aware, food and feed safety or quality-assurance plans contain sensitive, often proprietary information about a facility's products or manufacturing processes or methods. Companies treat these documents as confidential business information (CBI) and, should the companies choose to submit them to FDA, they expect FDA to treat them as CBI, as well. The challenge of safeguarding the confidentiality of volunteered information is magnified when those records are in electronic form. Data could be compromised through hacking or other unauthorized release (i.e. WikiLeaks scenario). Furthermore, a data storage device could be lost as has occurred in the past with other agencies. PFI would like to emphasize to FDA the importance of developing adequate procedures to preserve the confidentiality of facility records to which FDA may access under FSMA. Of equal, if not greater, importance is the need to preserve the confidentiality of facilities' vulnerability assessments and food/feed defense plans, which if inappropriately disclosed, could compromise the facility's security. FDA should provide companies who submit CBI or other confidential information to the Agency with clear instruction on how to appropriately identify this information to ensure that it maintains its confidential nature.

PFI would like to describe to the agency scenarios in which information could be released publicly. Information could be released in response to a Freedom of Information Act request. Alternatively FDA could release a report summarizing submission data such as percentage of companies that volunteer this information. Due to the possibility for the information to be misunderstood, particularly information on identified potential hazards, PFI urges the Agency to give special consideration to issues relating to the release of data (intentional or unintentional).

PFI urges FDA to articulate how it plans to protect the confidential nature of such records and encourages FDA not to request the electronic submission of such plans.

Lastly, one potential unintended consequence of requesting the voluntary submission of this information could be the over representation of information submitted by those facilities with less complex or less thorough hazard analyses or preventive control programs because such programs could be entered into FDA's system more easily. Companies with more extensive hazard analyses or preventive controls might be less inclined to enter information into the facility profile because it may not be practical to provide complete information and because incomplete information would give FDA an inaccurate view of the situation within a facility. Under this scenario, FDA would have an inaccurate view of the level of hazard analysis conducted by facilities and the preventive controls in place because the facilities with the most comprehensive information would not have utilized the system due to the burdens associated with it.

Regarding Collection of "Other Facility Information"

PFI does not believe that the collection of data described in the Request for Comments under "Other Facility Information" is relevant to a facility's risk status (e.g., facility size, operational schedule, and number of employees). A facility's food safety risk is not determined by its size, operational schedule or number of employees. It would be helpful if the Agency could explain how collection of the data listed under "Other Facility Information" could enhance FDA's ability to make a risk determination for a particular facility or would otherwise improve the Agency's ability to exercise its regulatory authority.

Regarding more effective means to determine the risk status of particular facilities.

The Request for Comments states that the information it is proposing to collect "will help us to determine whether a firm is high-risk or non-high-risk. We will use the profile information to assist us in determining the frequency at which we will inspect the firm." [77 Fed. Reg. at 27779]. The FSMA sets forth the criteria on which FDA is required to base this assessment [21 USC § 421(a)(1)]. PFI recognizes the difficulties inherent in making such a facility-specific determination for the many facilities FDA regulates. However, as discussed more fully above, aside from the collection of information listed under "Facility Type", PFI does not believe that the information outlined in the Request for Comments will prove helpful to the Agency in making its risk determination. Hazard analyses and preventive controls cannot be evaluated effectively outside the facility for which they were developed. Plus, material listed under "Other Facility Information" is not relevant to safety and may be considered business confidential. If this information were collected at a high volunteer rate, the FDA would then have to demonstrate how it will effectively gather, mine, secure and utilize the information. It is our belief that the effort needed to implement such steps would prove to be more time consuming to the FDA than the return on investment would warrant.

The Request for Comments also states that facilities that voluntarily submit the food facility profile information would benefit from interaction with better-informed investigators and potentially reduced inspection duration. However, an investigator may have preconceived ideas about the appropriateness of a preventive control for the identified hazard without the context of the entire manufacturing process for the facility. PFI recognizes FDA's need to prioritize inspections and to educate inspectors on potential hazards and appropriate control processes. PFI is willing to partner with FDA to provide industry-specific information based on products produced and develop risk facility criteria for the pet food industry through a more efficient and effective process.

Additionally, PFI has concerns that the information requested in the Request for Comments will not remain voluntary in practice. For example, the Agency could compel companies to "voluntarily" submit information by spotlighting companies through public communication based on whether they have submitted information. This potential practice would be inappropriate and effectively would render submission mandatory.

If FDA proceeds with collecting the proposed voluntary information, PFI encourages the Agency to make great efforts to ensure that all online forms clearly and distinctly indicate which information is mandatory and which is voluntary. Similar to the scenario described above, failure to clearly indicate which information is voluntarily provided would have the practical effect of rendering such information to be mandatory.

Concern that FDA grossly underestimates the frequency of facility profile updates and burden associated with them

The Request for Comments estimates the burden associated with the proposed collection of information. Based on the fact that a facility's hazard analysis and preventive controls may be revised frequently, PFI believes that the estimated number of facility updates of voluntary profile information is low by several-fold if the facility intends to provide accurate and up-to-date information. Furthermore, information related to hazard analysis and preventive controls is likely to be complex and lengthy, making it likely that substantial time will be needed to enter information on hazard analysis and

preventive controls beyond FDA's estimate and only reflect the time to complete the on-line portal, ignoring the many hours of preparation which may be in addition to the process used to complete the mandatory Hazard Analysis. In practice, individuals responsible for facility registration are not likely to be intimately familiar with the food safety plans and will need to seek input from the appropriate facility employee(s) in order to accurately enter the data, thereby extending the amount of time and effort to input and update the requested information. Also, because facilities are to keep information in their registration profile current, significant time may need to be devoted to performing updates.

In conclusion, the Pet Food Institute appreciates this opportunity to provide its views on the collection of voluntary facility profile information. We look forward to continued interactions with the Agency on how risk determinations can be made most efficiently and effectively and other regulatory actions related to food safety and implementation of various provisions of FSMA.

Sincerely,

Duane Ekedahl
President