POULTRY PROTEIN & FAT COUNCIL

U.S. POULTRY & EGG ASSOCIATION

1530 Cooledge Road, Tucker, GA 30084-7303
Phone: 770/493-9401 • Fax: 770/493-9257 • www.poultryegg.org

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VIA E-DOCKET

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

Re: Comments on "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals," Docket No. FDA-2011-N-0922.

The Poultry Protein and Fat Council (PPFC) submits this statement in response to the Food and Drug Administration's (FDA) request for comments 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 (Federal Register Volume 78, Number 209 , Pages 64736-64837).

The Poultry Protein and Fat Council is a consortium of renderers who are members of the U.S. Poultry and Egg Association. These renderers' process poultry related by-products generated at facilities processing poultry and eggs for consumers in the United States and around the world. While humans do not consume these by-products, they provide beneficial nutrition to numerous animal species after they have been processed.

The US Poultry and Egg Association is the world's largest poultry organization, whose membership includes producers of broilers, turkeys, ducks, eggs, and breeding stock, as well as allied companies. The Association progressively serves the industry through research, education, communication and technical services. Formed in 1947, the association has affiliations in 27 states and member companies worldwide. Companies involved in the production and processing of poultry provide 1,378,000 jobs that pay $64.9 billion in wages to families throughout the country, generate over $273.9 billion in annual economic impact, and provide about $23.5 billion in state and federal taxes.

PPFC is closely associated, and often actually integrated with the National Renderers Association, the American Feed Industry Association, and the Animal Protein Producers Industry along with the pet food and livestock industries. These comments are submitted on behalf of the PPFC, but will address many concerns in which we agree upon with other industry partners.

As an essential link in the food chain, the rendering industry is responsible for the repurposing of billions of pounds of under-used materials from the human food industry. This industry produces and provides safe feed ingredients for livestock, poultry, aquaculture, and pets. Without the rendering industry, these product streams would cause a burden upon the environment and potentially result in a public health risk.

The PPFC appreciates the great effort that the Agency (FDA) has made to solicit extensive comments and input from the industry with regards to the proposed animal food rule. However, PPFC has many concerns that the proposed rule does not take into account the differences and complexities found within the animal food industry when compared to the human food industry. Therefore, PPFC submits the following comments to inform the Agency of important industry-specific information before the Agency implements the proposed rule into a complex and far-reaching law. The implementation of the animal food rule should proceed in a manner that uses sound scientific evidence to enforce the principles that our industry currently utilizes to insure safe and wholesome food for animals and safe and wholesome food for humans worldwide produced from these animals. PPFC feels that if the rule were implemented as currently written, it would establish regulations that would add unnecessary regulatory burden and cost as well as establish precedence for implementing rules that are not scientifically based but rather are established through emotions and perceptions. Furthermore, PPFC feels that the rules as proposed would undermine the entire animal food industry in its efforts to provide an abundant and affordable food supply to U.S. and world consumers.

Please note our objection in regards to the inadequate amount of time that was provided to comment on such an extensive set of rules. While the FDA had over two years to write the rules (much of which have been previously already written in industry guidance documents) the Agency has only provided 153 days to submit comments. Throughout these comments there are many points that could be challenged with scientific literature; however, provided the very limited amount of time, we are unable to appropriately provide all of the publications and data necessary to demonstrate such arguments. We feel that it is illogical for the Agency to have provided such a limited timeline when there is so much scientific published research and other appropriately collected data that should be evaluated in this process. If the Agency truly wants to base its rules on science-based research and data then we feel that it should evaluate all available data as well as work with the industry to produce these data where none exist.

The proposed rule appears to take a dogmatic approach to identifying and managing preventive controls and goes beyond what is authorized by FSMA. An effective food safety system is built on a foundation of prerequisite programs, but FDA has defined preventive controls in the proposed rule as if FSMA mandated Hazard Analysis and Critical Control Point (HACCP) systems instead of Food Safety Plans which the law describes. A HACCP program is only designed to focus on the most critical controls in a process (i.e., critical control points, or CCPs), and is just one of the many components that make up an effective food safety system. Use of the HACCP concept which already also has legal definitions for others food products also would cause confusion within the Agency and for consumers regarding the actual differences between foods for humans and foods for animals. The rendering industry in the U.S. employs plants in many different configurations employing specialized equipment depending on the type of raw materials and the types of product being made. A prescriptive one-size-fits-all set of requirements cannot efficiently and effectively improve food safety.

Currently in the human food industry different standards are allowed for ready-to-cook vs. ready-to-eat products. Food for humans also have different standards for different types of foods as is demonstrated by the different HACCP standards, so it is confusing as to why the Agency thinks one rule should cover all types of animal food and all ingredients. We feel that feed ingredients vs. finished feeds should be allowed separate standards as well as have the standards based upon their “intended use”. Foods for livestock and

poultry should also have a separate set of guidelines when compared to foods for companion animals (defined here as in the household). You cannot expect such a diverse industry to apply the same rules across the many different products produced and the different methods used when supplying these products to the animals. The major complication with the current rule as written is that it has taken one set of rules for human food and applied it the same across an extremely diverse industry.

By using the human food rules as guidelines, the Agency is actually impairing the industry in its ongoing efforts for continuous improvement. It is imperative that the Agency listen to the different factions of the animal food industry when re-writing these rules. The pet food industry has one set of guidelines to insure safe food for companion animal species. They are collaborating with their ingredient suppliers to insure that their specific needs are met. The cattle industry would have a completely different set of guidelines and they currently work with their suppliers to insure that these needs are fulfilled. Each of these industries needs to be allowed to determine their hazards and translate those into useful programs for their individual industries. Many of these procedures have been developed and would be useful to the Agency when implementing the final animal food rules.

The implementation and introduction of these rules have also been handled in a manner that is burdensome to the industry. Aside from the items listed prior in these comments, it is essential that the Agency recognize the distinct differences in facilities that produce and use food for animals (as well as the variations among these) and those that produce and serve food for humans. Most facilities that produce human foods have had close to twenty years to effectively implement food safety practices. They have designed new facilities or redesigned older facilities to provide the highest biosecurity possible. They have been graded on hazard prevention and cGMP's for many of those years including the requirements by their customers to hold third party audits to insure these measures are effectively implemented. The have chosen equipment that not only make food safety procedures easier by also enhances food safety.

On the other hand, as the rules are currently written, the animal food industry is faced with almost immediate requirements to live up to the same standards as human food producers. Animal food facilities have never been exposed to such regulations (although they have proactively implemented quality food safety programs such as AFIA's Safe Feed /Safe Food program or the Animal Protein Producers Industry's Code of Practice) and should not be forced to almost immediately comply with rules that do not even take into account their manufacturing techniques. Animal food producers almost solely use closed, secured conveyance methods to prevent additional contamination as opposed to open conveyance. They also use bulk storage and transportation and do not possess the same ability to cleanly separate batches or lots as human foods that are packaged. Ingredients and commodities such as rendered products are not commonly fed to the animal without secondary thermal processes being applied (However, we do recognize that this may occur in some cases). Our industry uses carbon vs stainless steel in much of the production of animal feeds as they are later provided to the animals on the ground or outside in open feeders. These items illustrate some of the vast diversity of animal food production as well as the distinct difference from the methods employed for food that is produced for humans.

On page 143 of the complete document, the Agency requests comment on the need to differentiate between different animal foods. We concur that this is necessary for both individual ingredients vs. completed feeds as well as for the different types of animal food

produced for different species of animals. It is imperative that the Agency correct the rules and make them truly applicable to the animal food industry. It is also as important to change the compliance dates to first launch the cGMP's for the varying aspects of the industry and then implement the hazard analysis and preventive controls rules at a later date. We would suggest, at a minimum, a one-year compliance with corrected cGMP's after they are published as guidance by the Agency (note not the publication of the final rule since we do not believe that the guidance will be available at that time) and an additional year afterward for compliance with the hazard analysis and preventive controls rules. This would provide a 1 and 2 year compliance timeline for the largest firms and an additional year for the others.

The rendering industry has long accepted the recognized general prerequisite programs that "provide the basic environmental and operating conditions that are necessary for the production of safe and wholesome foods" as described by the National Advisory Committee on Microbiological Criteria for Foods. We appreciate that FDA has identified some prerequisite programs as preventive controls, but the proposed rule does not adequately account for the role of many other prerequisite controls for ensuring product safety. This HACCP focus means that many preventive controls will be subject to a management approach typically reserved for CCPs, and this is reflected in the requirements of the proposed rule. Applying a CCP-like approach to the full range of preventive controls does not accommodate existing effective systems already in use.

This creates needless duplication of procedures and records and will require unnecessarily prescriptive and confusing changes in existing food safety programs. The proposed rule thus contradicts FDA's economic analysis, which assumes few changes to existing food safety programs. It would create requirements that are not needed for animal feed or pet food safety and divert focus away from measures that have been proven to be effective in our industry. Many hazards in rendering facilities can be exclusively controlled through prerequisite programs without a need for CCPs. It is important to emphasize that while HACCP plans may be part of Food Safety Plans, Food Safety Plans are broader, covering control measures that are not managed with CCPs alone.

PPFC also recognizes the shift in regulatory philosophy FSMA represents in terms of placing the principal focus on prevention of hazards that can pose a risk to human or animal health. Our members have a long history of using preventive measures to produce safe products and have long understood the responsibility they hold for distributing safe products. We welcome this shift in regulatory focus provided it is reasonable and flexible in its implementation. We are concerned that inadequate resources will be devoted to training FDA staff and informing contracted state inspectors of this change in regulatory philosophy to ensure that on-site facility inspections are meaningful and consistent.

In its latest published data, the Agency itself recognized drastic reductions in microbial contaminants in animal proteins. While this publication definitely demonstrates an improvement on its own, it is contradictory to several additional published sources as well as data collected through the APPI self-monitoring programs. The rules for animal foods as well as the language used in of the entire FSMA program demands improvements in food safety utilizing scientific data and proven techniques. It is somewhat troublesome that while there is scientific data suggesting that animal proteins are potential contributors to microbial contamination, (along with positives observed in grains and plant proteins) the data is in conflict with other peer-reviewed publications as well as industry data

collected over many years. If these rules are going to be implemented using science, then all science must be evaluated not simply the Agency's own limited data.

The fact that the text of the proposed rule "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals" is for the most part cut-and-pasted from the proposed rule "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food" published earlier in the year is evidence of the desire of the Agency to equate animal feeds to human and pet foods, in spite of specific language in the FSMA statute to treat animal feed differently. If implemented as proposed, the rule will have a significant adverse effect on the animal feed industry and feed ingredient suppliers, and will significantly increase the cost of manufacturing animal feeds, which will ultimately increase the cost of food for humans. Animal food is manufactured appropriately in very different systems than human food, in much larger volumes using many different raw materials. It is not appropriate to equate animal feeds to human and pet foods in regulation. Also, in many cases, requirements that may be appropriate for finished products would yield no food safety benefit for rendered ingredients.

Since 1985, APPI has coordinated a program of education and laboratory testing for renderers to control *Salmonella*. Currently APPI is a standing committee of NRA, which offers training on hazard analysis, appropriate controls and practices, and process verification testing services. Currently, APPI recommends periodic testing to check the effectiveness of process controls and to check the effectiveness of cleaning programs and cross-contamination avoidance in the plant. Nearly all renderers in the U.S. are APPI members (listed in *Render* magazine: https://d10k7k7mywg42z.cloudfront.net/assets/51b11df1aa707a36e5002f58/June13Render.pdf, page 16). Multiple data sources show dramatic decreases in the occurrence of microbial contamination in rendered products since these programs have been in effect.

Preventive controls are also currently commonplace in the rendering industry. In addition to basic APPI testing requirements, 117 rendering plants representing more than 90% of the total tonnage of rendered products produced in the U.S. are certified in the voluntary Rendering Industry Code of Practice (including some that are not NRA members but participate in the open APPI programs). Nearly all renderers have quality and safety control systems in place via formal programs such as the Rendering Industry Code of Practice, Hazard Analysis and Critical Control Point (HACCP) Program, Safe Feed/Safe Food, and/or Good Manufacturing Practices. In these programs, a concerted effort is made to foresee hazards likely to occur and prevent those occurrences. Process controls in rendering assure that cooking temperatures control pathogenic microbial contamination. These programs also address rodent control for feed ingredient processing, plant and transport sanitation, and other biosecurity measures such as traffic control. Product testing is used to spot check to verify that rendering processes are correctly managed and operated. The program involves employee training and recordkeeping and is followed up by independent third party audits to make certain that plants are following their plans to ensure product safety. Certification lasts two years, at which time plants re-certify with another third party audit and re-examination of the processes in the plant. The Rendering Industry Code of Practice is updated as needed to reflect new regulations or new information on how to best produce safe rendered products. Rendering industry research continues to support the program and update documentation available to renderers on cooking temperatures and other important manufacturing practices.

Each rendering plant develops its own Process Control Plan based on the raw materials processed and the products manufactured. A plant's Process Control Plan is similar to a HACCP plan in that it identifies possible hazards, determines whether physical, biological, and chemical hazards exist, and establishes ways to monitor and control them within appropriate standards. Accurate records, product traceability, and documentation are also required. The rendering industry also supports the adoption and use of the Rendering Industry Code of Practice through continuing education and training certification programs, which are offered annually. After these new regulations are finalized, NRA will make whatever changes necessary to our Rendering Industry Code of Practice, and expect it to meet all FDA requirements for education and training. We expect our members trained in our Rendering Industry Code of Practice program to be recognized as "qualified individuals" by FDA.

We continue to add new plants to the list of currently certified plants, and that list can be found on the NRA website: http://www.nationalrenderers.org/biosecurity-appi/code/certified-plants/.

PPFC seeks clarification about whether the new rules will accommodate existing industry Food Safety Plans, such as the Rendering Industry Code of Practice or the Safe Feed/ Safe Food program from AFIA. The proposed rules also require facilities to prepare a written food safety plan that includes hazard analyses and preventive controls, written procedures for monitoring, corrective actions, verification and a written recall plan. Given the uncertainty as to whether existing control points and current Good Manufacturing Practices (cGMPs) would align with those required by the proposed rules, new demands from FDA could require redrafting of existing Food Safety Plans that are already in place and which have worked effectively for years. We feel that FDA should avoid the unnecessary disruption of successful industry programs. Rendering plants should not be required to rewrite existing plans that effectively manage food safety hazards. Such a requirement would divert resources from the most critical areas. Companies need the flexibility to adapt their programs to focus resources on the specific areas that most affect food safety as it pertains to them, and apply the proper controls in the right way. One size will not fit all. While some hazards are likely to occur at all plants, each facility may differ in the potential exposure to other given hazards based on the source and type of raw material processed, facility design and end-use of the products made by a facility.

Costs Estimates:

PPFC is of the opinion that the costs associated with implementing these rules have been grossly underestimated. Since the rules primarily follow the guidelines set for human food, the actual costs of compliance would also include drastic changes to facilities and equipment. The Agency has not taken into account the fact that animal feeds and even pet food products have been produced historically to a completely different set of standards than those applied to human food. While PPFC agrees with the concepts of production of safer foods for animals, the standards in the equipment and facilities between those for human food and those for animal food do not currently compare. It is clear the Agency failed to use "intended use of the final product" in any of the costs estimates.

We have determined that there are several deficiencies in the preliminary Regulatory Impact Analysis (PRIA). The estimated costs of compliance with FSMA are low based on the lack of understanding of the inherent differences between the production of food for humans vs. food for animals. There will have to be significant changes in both facility

design and equipment design and selection in order for the animal feed industry to adhere to the same rules as are applied to human food production. We were made to understand that the rules for animal foods were supposed to be different. However, the Agency has not clearly demonstrated this is the case since it appears to utilize the same standards for both.

The costs of additional labor are only the beginning. Many facilities do not have extra personnel to keep up with the additional recordkeeping requirement that is expected with the proposed rule. Additional clerical costs in the form of personnel, computers, digital controls, and software are also not included in the estimates. Furthermore, the use of consultants or other third parties to validate equipment such as magnets, metal detectors, scales, meters, etc. has not been included. There will also be additional costs involved in annual third party audits of each facility.

Laboratory costs for sampling required in the proposed rule are not accurately calculated. While the Agency has attempted to develop a figure that may cover laboratory analytics, they have not considered costs associated with additional personnel and training that will be necessary to collect environmental and product samples required by the proposed rule. While most laboratories charge a fee or $25 to $30 to test theses samples, realistically the overall cost of each sample will approach $200 when you factor in the cost of hiring a qualified individual to collect, track and record the collection and sampling process.

The proposed rule does not attempt to calculate the additional resources required per facility to hire and properly train a “qualified individual”. We would estimate the annual wages of such a person to be from $35,000 to $85,000. Providing the necessary benefits, training, and technical support to this qualified individual brings the estimate to nearly $120,000 per year. Many animal food producers would have to employ multiple “qualified individuals” to properly sample all of their facilities that are also not geographically near one another.

Many of the estimated costs that have been established by the Agency have only included the minimal apparent costs involved in items such as recordkeeping, sample collection, and other clerical duties. A major factor in the implementation of these rules as they are currently written has been completely ignored. That factor is the facility and equipment differences found in the manufacture of foods for animals. Microbial sampling is easy if you have flat surfaces like conveyor belts typically found in facilities that produce food for humans; however, in most animal food facilities all of the conveyance is closed and secured to keep unintended contaminants from entering the production stream. Closed screw conveyors, bucket elevators, drag conveyors, etc., are designed to prohibit access to protect the safety of employees and the food supply. In order to properly perform environmental monitoring and or food contact surface testing, the equipment must be shut down (that means stopping production) and an employee must remove covering in order to sample these areas. Equipment may have to be replaced to facilitate this testing to insure safety and prevent contamination. Materials may have to be changed from carbon steel designs to stainless steel designs which are much more costly. In most cases additional storage (for hold and test programs) and/or equipment to meet human food standards are required, the costs could easily exceed $1 million or more per facility and more than $200 million across the U.S. industry and the Agency has not taken these costs into account anywhere within the PRIA.

As stated previously, a comment period of 153 days in length is not enough to prepare more in-depth studies of projected costs of all the different regulatory scenarios that could be in the final rule. The Agency took nearly two years to publish the proposed rule including the faulty PRIA and research based data to refute suspect assumptions and impacts cannot be collected in 153 days. Even if there was enough time to do the work, which regulatory scenario would we study? It seems there are very many decisions left for FDA to make before the rules are finalized.

The PRIA states (page 99) that "FDA expects only independent renderers to be subject to this rule, as the packer/renderer facilities would be subject to the human foods GMP revised rule." This is obviously not true since *every* packer/renderer facility produces animal feed ingredients and the meat side is regulated by USDA/FSIS, not FDA. The rendering facilities in these meat processing establishments are separate from the food producing portions of the plants, are not regulated by USDA/FSIS, and are thus not subject to the FDA cGMPs and HARBPC for human food. FDA also makes it clear in the proposed rule that "any facility that manufactures, processes, packs, or holds human food and is subject to the cGMP requirements for human food" and also manufactures animal food is subject to the animal food rules. The fact that FDA will allow compliance with the human food cGMPs and HARBPC standards instead of the animal food cGMPs and HARBPC standards does not mean these plants are exempt. All packer/renderers are likely not exempt and will incur significant additional costs to comply with the animal feed rules. The PRIA estimates "the number of ingredient manufacturers subject to the proposed rule to about 155 facilities (231 renderer establishments times an estimated two-thirds which are believed to be independent renderers)." Correcting for the faulty assumption that only independent renderers are impacted leaves 231 rendering establishments subject to the proposed rule.

The PRIA further states that "numerous independent renderers would still qualify as small entities" because they have fewer than 500 employees. However, this qualification means very little because these establishments are still subject to the rule, only receiving an additional year to comply. Very few rendering plants, if any, will qualify as very small businesses, because the average plant with less than 20 employees still grosses more than $2,500,000 annually. The PRIA states on page 100, "There would likely be some facilities with less than 20 employees whose compliance costs represent more than 1% of revenues due to low current compliance rates with provisions of the rule. Impacts on these facilities could also be significant." PPFC believes the estimate of compliance cost of 1% of revenues is quite low, but agrees that the impact on these facilities would be significant. Very few renderers would not be impacted in a significant way. Even if exempt, plants would be subject to "modified requirements," expected to follow cGMPs, and be subject to supplier verification requirements of their customers. There would also be considerable expense involved in documenting and defending a qualified exempt status as required by the proposed rule.

We feel that the Agency's current economic evaluations grossly underestimate the true costs to the rendering industry as well as others who produce food for animals. It would appear that the set of assumptions being used to minimize the economic impact of this regulation, by the Agency are in opposition to the actual costs that the current rules would place upon not only our companies as renderers but the entire animal food industry.

Exemptions:

If the goal of the legislation is to promote the manufacture of food for animals that is safe for both animals and humans then we ask why there would be any exceptions at all. It appears to be a very confused message when the Agency decides that it is alright for a small firm to provide unsafe products, but not for a large firm. If the Agency's economic evaluations were thought to be calculated correctly (which we state again that we do not believe this was the case) then every producer no matter the size should not have a problem to comply. It's only 1% of the revenue per the Agency's calculations. The whole set of rules as they are currently written based on the human food rules do not take into perspective the differences in the number of cases of illness that have been linked to unsafe food for animals vs. those recorded in food for humans.

While our industry believes that one illness is too many, it does appear that some of the efforts are poorly focused. If a small producer produces enough animal food to provide nutrition for 50 animals and this food is produced in an unsafe manner there could easily be as many cases of illness as were seen in a recent case of *Salmonella* contamination linked to pet food. Therefore, we believe that it is unwise to exempt entire classes of animal food facilities, including grain elevators that are solely engaged in the storage of grains that are raw agricultural commodities. Hazards can occur in this part of the animal feed ingredient chain as in any other, and programs to ensure the safety of these animal feed ingredients should be in place and regulated. We believe that the threshold for "very small businesses" should be $10,000 rather than the higher thresholds, despite the fact that few renderers will be in the very small business category with even the $2,500,000 threshold.

Establishments that process grains or oilseeds for animal feed ingredients, such as those who crush soybeans, should certainly be covered by these rules unless covered by the farm exemption. Even on the farm level, ingredients for the production of foods for animals are stored in facilities that may not be free of pests that are proven vectors of transmission for potential pathogenic bacteria or viruses. It seems very confusing that the Agency has exempted such a large portion of the ingredient suppliers while at the same time not accurately calculating the costs to the remainder of the industry to bear the burden that results from the lack of controls for those being exempted.

Employee education and training and the definition of a Qualified Individual:

PPFC does not agree with the Agency's reasoning that the Agency is the determining authority when distinguishing if an individual is "qualified." Rather, it should be industry that determines if an individual is "qualified." There are already many industry programs such as the Code of Practice (COP) offered by the Animal Protein Producers Industry (APPI), Safe Feed/Safe Food (SFSF) certifications offered by the American Feed Industry Association (AFIA) as well as GFSI, PAS222 and other industry developed standards that allow for the industry to educate their own employees. Using such programs allows the industry to train, educate, and "qualify" their own individuals under standards that can apply directly to their businesses. PPFC believes the Agency should accept current proven industry standards that have developed by experts in their specific fields. It would be very difficult for the Agency to establish 'qualifications" for individuals that would be specific to our industry. It is our belief that the current industry practices of training of qualified individuals through already established programs should be deemed sufficient, if not preferred to limitations that may be produced by training individuals to set generic standards established by FDA. Designing a standard curriculum for the entire

animal food industry will stop the ability of individual companies and industry associations to adapt to the ever changing environment of food safety. Rather than strengthen the training programs that currently exist, such rules regarding qualification requirements will unintentionally stifle the ability of the industry to move swiftly to remedy, update and be proactive in their current training programs.

The standards for nutritional adequacy including deficiencies and excesses:

The Agency discusses the requirement to insure that animal foods are nutritionally adequate. This is problematic for many reasons. First and foremost this determination is currently written in the proposed rules as a broad all-encompassing statement. Historically, the Agency has not used clear guidelines for the enforcement of such rules. The Agency includes individual ingredients in its definition of food for animals. Since no individual ingredient can completely meet the needs of any animal's dietary requirements, this alone would negate the rule in the broad fashion in which it is written. While it may seem unreasonable to state that the Agency does not realize that this is the case, there have been multiple incidences where because of the language of the rule or law, the Agency has left itself no room to distinguish between the two. In fact there have been items in the past where because of a misunderstanding of a rule along with the fact the language used in the rule itself have caused ingredients to be treated as final feeds. This should never be the intent of any rule. Individual ingredients each contribute their nutrients to develop a nutritional program for animals. If the wording is such that it cannot be clearly interpreted then this allows for ingredients to be treated the same as a completed feed. This is a recurring theme within this set of rules. There is so much complexity within the feed industry that broad all-encompassing statements will not allow the industry to supply safe food for all species. The feed industry is tasked with supplying all or the same nutrients for many species that the food industry supplies for human food.

The industry already determines the nutritional adequacy using the latest scientific research. Nutritionists that work in the animal feed industry are trained professionals and work regularly to test the nutritional adequacy of their feeds. The suggestion that there should be requirements established regarding nutritional adequacy should not be determined by a set of rules but rather by the industry itself.

Finally, in the case of a diet sold that is nutritionally inadequate, there are already mechanisms in place to allow for consumers to address these inadequacies under local laws.

References to Filthy, Putrid, or Decomposed Substances in Proposed Rule:

In the preamble of the proposed rule, on pages 64740-64741 describing Section 402 of the FD&C Act (21 U.S.C. 342) where it deems food, including animal food, adulterated in several circumstances, this statement is included: "If it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food." PPFC is concerned that this statement will cause confusion among consumers and inspectors with respect to the determination of the acceptability of raw materials processed for animal food.

The definition in the 78 Federal Register on page 64782 reads that "Decomposition of animal food consists of microbial breakdown of the normal food product tissues and the subsequent enzyme-induced chemical changes. These changes are manifested by

abnormal odors, taste, texture, color, etc., and can lead to reduced food intake or rejection of the food by the intended animal species, resulting in illness or death." Many products utilized within the animal food industry, such as hydrolyzed proteins, palatants, and rendered materials have all begun the decomposition process when they arrive, but are processed in a control system to halt decomposition before harmful toxins are formed. However, based on the broad definitions referenced in the proposed rule, raw materials would potentially need to be identified as hazards within facility utilizing these are materials even though they have been demonstrated to be safe for use in animal foods. Acknowledging that chemical changes can be manifested by abnormal odors, taste and texture is true but that is subjective and if there is concern amongst the industry that these types of materials may be unfairly criticized and improperly classified.

The FDA has long recognized that differing standards should apply for animal food and for human food. In its Compliance Policy Guide (CPG), 716.20 *Diversion of Adulterated Food to Acceptable Animal Feed Use*, FDA acknowledged section 402(a)(3) and (4) of the Federal Food, Drug, and Cosmetic Act were interpreted to allow different standards for foods intended for human use vs. food intended for animal use. The example given explained that defect action levels for filth in a food intended for human use are not the same as for the same food intended for animal use. Even though this CPG was published in 1995, its relevance was reinforced by reference on page 25 of the *Draft Guidance for Industry, Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007 (edition 2)* which was released in 2010 (page 25).

PPFC believes the Agency's intent was to identify hazards in animal food associated with uncontrolled decomposition or spoiled foods that may contain potential hazardous natural toxins. Since natural toxins are a sub-grouping of biological hazards it is redundant and unnecessary to reference decomposition when not all levels of decomposition represent a food safety risk. It is also difficult to define decomposition as once any plant or animal product has stopped actively growing or producing, it is the extreme sense of the definition, "beginning to decompose." Under the literal interpretation of this section, any ingredient used for animal or human food is in essence decomposing. While it seems unreasonable to think that anyone would use this extreme interpretation, there have been cases in the past where the Agency or its investigators have used the letter of the law rather than the intent.

We suggest that references to decomposition be removed or the definition be clarified to be unintended or undesirable decomposition that poses a food safety risk. It needs to be recognized that decomposition of animal tissues begins the moment slaughter takes place, and some time is needed to get these materials into the rendering process. Decomposition is not always a negative for product quality and food safety. The rendering process effectively "re-sets the clock" by processing raw materials including offal, outdated meat, and fallen animals that may be deemed filthy, putrid, or decomposed substances with respect to human food into safe, wholesome, and useful feed ingredients for animals. Any requirements for animal food to be free of "filthy, putrid, or decomposed substances" should refer to finished feed products and ingredients rather than unprocessed raw materials.

Changing the current standards for animal feed to human standards with respect to "filthy, putrid, or decomposed substances" for unprocessed raw materials will not improve animal food safety and will only increase the amount of by-product from human food

production and animal agriculture diverted to disposal options much less environmentally acceptable than rendering.

Product Testing:

Within these rules, testing is listed as a preventive control measure under FSMA. We do believe that some testing programs may be helpful in the verification of a specific process; they will not necessarily prevent, reduce, or eliminate any hazards. Due to inconsistencies when testing bulk commodities, the results may suggest that products are safe or unsafe when a sample of a few grams is used to represent several if not hundreds of tons of finished product. Statistically, 25 grams of sample out of 20 tons of finished material does not provide strong levels of confidence in the testing procedure. Certain analytical techniques that utilize polymerase chain reactions can often provide false positives when testing. Additionally, adequate or aseptic sampling can be difficult to perform under typical animal food manufacturing conditions. The rendering industry has funded more than two million dollars of microbiological and verification research over the past eight years and continues to do so. These efforts have helped industry reduce microbial concentrations in animal proteins and they demonstrate a need for additional science in this area. We believe that the Agency should allow the industry to develop guidelines for what is appropriate when testing various animal foods. It also is important to stress that FSMA references the broad phrase "product testing," – not "finished product testing." Finished product testing is frequently of limited value and not cost-effective, in part because of the low likelihood of detecting contamination that could cause the product to reach the statutory threshold of being adulterated or misbranded (which is also unknown). In most cases, other verification activities are more appropriate to evaluate the effectiveness of control measures. Regulatory testing requirements can give an appearance of procedural protection without really improving food safety at all.

The vast majority of animal food produced in the industry is stored and transported in bulk. Feed and ingredient facilities that produce bulk commodities rarely have the storage capacity to follow standard hold and release programs. In order to perform quality consistent testing most animal food manufacturers would have to invest significant capital to increase the size and number of their storage facilities. In order for a typical feed manufacturing facility to perform product contact testing the typical closed conveyers that are used would have to be stopped for sampling as well as equipment changes made to allow for regular sampling. Food contact surface testing also presents challenges in animal food facilities as most of the conveyance is closed to prevent contamination and would have to be upgraded to provide areas to collect samples. We do not believe that the Agency has taken the additional costs of such changes into account when developing their economic evaluation of the proposed rules and the economic impact costs of testing.

The Agency has suggested that all Food Safety Programs should be based on sound scientific methods. While we agree with this, it is clear that there are many discrepancies in the science for testing. The Agency has conducted Salmonella testing for several years now and has demonstrated that all commodities can contain viable Salmonella. If the goal of these regulations is to improve the safety of food for animals and humans, then why have raw agricultural commodities been exempted from these rules? During a recent investigation by the Agency in a case of Salmonella found in animal foods, the agencies personnel reported that the fats used in the foods had not been tested for Salmonella. Since there is currently no approved methodology for testing fats for Salmonella, it raises that question of the scientific basis of the testing for food at all. The

industry needs to have better scientific methods to quickly and adequately test for bacteria in order to comply with these suggested rules. When adequate testing is not currently available how is the industry supposed to comply in a scientifically sound manner? We would suggest that the Agency allow companies to investigate other avenues of finished product testing such as water activity as this allows for faster testing and would demonstrate that the food should not allow for additional growth of potential pathogens. We further suggest that general positives are not sufficient for microbial testing. It is important that the Agency work with industry to identify only those serovars of bacteria that are actually risks to the animals. To make a broad statement that all sub-categories of any species of bacteria are not allowed is not basing the recommendation on science. It is important that the Agency allows the industry, government, and academia to develop analytics that target only those specific bacterial strains that are of serious concern to human and animal health. If such tests are not available or are not accurate then the testing process itself is not grounded in sound science.

Many animal food ingredients are subjected to additional processes that significantly reduce or eliminate the microbial populations present. In these cases we suggest that the Agency not require testing. For instance, most protein meals that are ingredients for finished pet food products undergo the aforementioned additional processing steps. Also, feed ingredients with low levels of microbial contamination as is common in most livestock and poultry feeds do not pose an actual hazard to the animals.

Test results, whether derived via a voluntary company program to verify process controls, or mandated by regulation should not be required to be submitted to FDA unless they indicate serious human health consequences (i.e. necessitate a Class I recall with risk of serious adverse health consequences or death to humans or animals). This would be consistent with existing requirements for the Reportable Food Registry which is working well.

Environmental Testing:

While environmental testing may provide some guidance for the cleanliness of facilities, it does not aid in the prevention of microbial contamination of animal food. We would also like to express our concern at the Agency's suggestion of requiring testing in facilities where there are not clear areas of aseptic spaces in which to take appropriate samples. The role of rendering is to eliminate microbial contamination from by-products which commonly have high concentrations of bacteria and viruses. Naturally, the environment in parts of the plant will test positive for pathogens because of the expected contamination of incoming raw materials. More important and more deserving of the time and investment required for testing is the cooking process and food handling system *after* the raw materials become feed ingredients via the rendering process. Risk-based monitoring would focus attention on verifying that pathogens do not migrate to post-kill-step processing areas. The costs to rendering companies to do unnecessary environmental sampling to the extent required in ready-to-eat human food plants could be extremely high and this sort of testing would not improve food safety.

We question why environmental testing should even be conducted in an effort to reduce microbial contamination of animal foods when many of the animals who consume these foods are fed either on the ground or in an environment that is certainly not free from high concentrations of microbes. In addition, many of the animals that this testing would be aimed at "helping" routinely engage in coprophagy. We agree that animal food manufacturing facilities should utilize the appropriate cGMP's. However, the key word is

appropriate. Animal feeding facilities are not sterile facilities. There are numerous chances for bacteria to be introduced at these facilities. This circumstance emphasizes the need to design and implement a testing program specific to the animal food product, the respective manufacturing facility, and the intended use of the product. The industry needs the flexibility to determine its own hygienic and testing requirements that will fit its needs more closely than those established for human food production.

It is important for the Agency to use the proper perspective when establishing guidelines for animal foods. The term “as appropriate for the intended use” keeps coming to mind when reviewing the Agencies proposed rules. We feel that it is the duty of the Agency to keep this phrase in mind when re-drafting these rules for final publication and implementation. It is simply not scientific to require human food rules for animal food production.

Comments with regards to supplier verification:

The practice of supplier verification is much more complex than is suggested in the proposed rule. We believe, that under any appropriate food safety system, there would be no additional benefit in performing additional supplier verification. The animal food industry has historically used product specifications to determine the qualifications of a supplier. Our entire industry is dependent upon the rearing of healthy animals. Therefore, requirements for companies to supply wholesome, nutritionally adequate (based, of course, on the intended use of the individual ingredient) ingredients is already controlled by the industry.

The act of supplier verification will also do very little to prevent an actual food safety incident from occurring. This has been demonstrated by recent cases where organizations have received high grades from qualified third party auditors and there have still been cases of hazards that have not only occurred but have affected the consumer.

In some situations materials used for animal foods have been rejected for use in food for humans. This does not mean that they are not suitable for animals but quite often simply means that these products are not used in the United States because of social or cultural reasons. There is also the fact that any risks that have been determined for humans are not necessarily of detriment to or are of concern in animals. Furthermore, the products used for animal foods quite often will be exposed to further processing to remove any risk for animals. The diversion of these materials away from the animal food industry would result in unwarranted economic burdens on the animal food industry. They could also result in unwanted negative impacts upon the environment because these materials will then have to be disposed of instead of recycled.

Each segment of the animal food industry has determined those requirements that are specific to reduce risks within the industry. Also under these rules, any risks that may be introduced by a supplier would be taken into account by the hazard analysis and preventive controls implemented by the producer of the animal food.

Any requirement for supplier verification would end up producing results that would go against the requirement to produce safe animal foods. As items in these rules are “required” by definition, the effect is to relegate the industry to continuously do only those items required to pass an inspection as opposed for nurturing a culture of innovative ideas for the improved production of safer and safer foods.

Confidential information that is used to differentiate the top producers with regards to food safety is also at risk when there is a requirement for supplier verification. If suppliers are using systems and procedures that place themselves above the competition then these systems and procedures could be released to their competitors. This could damage the effectiveness of a free market system in which the industry partners themselves have been responsible for the development of unrivaled food safety systems.

Finally, the requirement to verify suppliers in the area of animal foods would cause the industry to bear unnecessary economic impacts that would consequently endanger the market. When looking at the producers of animals foods, there are multiple cases in which a producer receives ingredients from thousands of suppliers. If RAC's were included in the rules every farming operation would have to be verified. With the use of co-products in the feed industry every human food producer, retailer and animal operation would also have to be verified. Since these industries are supposed to be exempt, how does the Agency profess any open market fairness when other areas of the industry would be subject to supplier verification when the grain and plant protein industry would be exempt from the economic impact of supplier verification? Through this rule the Agency could easily be implicated in the creation of an unbalanced marketplace for ingredients.

Current Good Manufacturing Practices (cGMPs) for the Animal Food Industry:

As has been addressed previously in this document, the human standards for cGMPs should not be used directly for the animal food standards. We appreciate the exemption of allergens that are not proposed in these rules; however, most of the human standards would not apply to the way that feeds are supplied to the animals. Animals are raised under standards where they are fed on the floor or on the ground. There are much fewer concerns regarding microbial related illnesses due to the differences in immune status and exposure of animals as well as health care products used in animal rearing. We agree that feed should be provided that does not include risks of causing the animal a health issue. Hair and beard nets would not limit any known hazards to the animal feds as compared to the foods produced for humans. The food that is produced for animals should be produced using cGMPs that are realistic and applicable for the animal food industry. The differences in the mechanism of the way animal foods are produced are quite different than those employed for food for humans. We appreciate the thoughts that in some cases animals are included as family and in no way want to endanger them or place any risks upon them; however, that fact remains that the equipment used to produce, store, transport, and supply food to animals is so different from that used for humans it is simply unrealistic to attempt to apply like standards for cGMP's.

There are already excellent industry produced guidelines for the production of animal foods such as Safe Feed/Safe food, APPI's code of practice, PAS 222, and others that establish clear guidelines for the best practices to be utilized in the production of food for animals. These programs recognize the distinct differences between food produced for humans and the food produced for animals.

As stated by FDA in the proposed rule, "The Agency does not expect that all possible preventive measures and verification procedures would be applied to all animal foods at all facilities." Why not then leave these decisions to those who know industry processes best? Rendering companies and their employees take their role in animal feed ingredient safety very seriously. These are the people with the greatest experience and competence

in rendering processes, and their livelihood depends on designing and implementing effective feed safety programs.

If FDA continues to apply human standards to animal feed as it promulgates the final FSMA rules, the new cGMP expectations would be significantly different than the industry's currently successful practices. It would take considerable time, effort and expense not allocated within the Agency's economic impact considerations for the animal feed industry to comply with the rules written with the human food standards as they currently are.

Finally, since the cGMPs guidance for industry will likely not be issued prior to the implementation of the final rules, it would be impossible for the industry to be compliant within the one year time frame allowed. We feel it is imperative to insure compliance as well as to achieve the desired results with regards for animal food safety that all guidance be produced and properly vetted prior to issuance of the final rules and the beginning of the compliance period.

Sanitation, Cleanliness, and Sanitary Conditions:

Our industry agrees that cleanliness with regards to the manufacture of foods for animals is an important factor in producing safe feeds and ingredients. Reducing microbial concentrations and removal or prevention of physical or chemical hazards is imperative in the production of safe products for the entire food chain. However, as written these rules allow for a tremendous amount of subjective interpretation that could either impose restrictive standards or allow for the production of sub-standard products. The first item is how are sanitation and cleanliness defined? To some there is no difference, to others there is a distinct difference between cleaning (cleansing and removal of detritus without the use of antimicrobial agents) and sanitation (the use of antimicrobial agents). Quite often in literature these are used interchangeably. It is imperative that these guidelines better define such issues to allow for proper interpretation and compliance. As long as ingredients and feeds are deemed suitable for use as outlined by current AAFCO definitions then we feel that they meet the necessary safety concerns based on their intended use.

Secondly, as for the majority of these rules for animal feeds, the standards for human food have been utilized as a template. There are distinct differences in the sanitation level needed for foods for animals and those needed for foods for humans. There are often legal differences in the analytical requirements for water for animals and those for humans. The way that animal foods are transported, stored and fed to different species are often very different than those conditions under which human food is treated. Therefore, we believe that the standards for sanitation and cleanliness should be defined by the industry that is using the final animal feed that is being produced. There needs to be a clear distinction between the use of food for humans and the use of foods for animals.

We believe that the intent of the rule as written is to increase the use of antimicrobial agents in the facilities that produce foods for animals. This will not provide any additional food safety for those animals. In addition since there appears to be no distinction between ingredients and finished foods for animals, and since individual ingredients are often subjected to further processing to insure decreases in microbial concentrations, the use of antimicrobial agents in individual ingredients is unnecessary and would not be an economically viable practice.

We further believe that cleaning and sanitation should be limited to meet the "required use" of the final product. There are vast differences in the sanitation desired for different food products a great example are the differences in ready-to-cook vs. ready-to-eat products. Most feed ingredients should only be treated as ready-to-cook products since they are either submitted to a secondary thermal process or they are fed to animals under conditions that are far from sterile.

We believe that the Agency has written these rules much too closely to the rules for human food without taking into account the differences in products, how they are processed, how they are distributed, and how they are fed to the animals. The Agency has also seemed to ignore the fact that in their own egg rule they have determined that they have not been able to demonstrate a link between microbial contaminants in feed and outbreaks in food.

Finally, the economic analysis performed by Agency has not included the costs of sanitation under current manufacturing techniques. The feed industry has closed conveyance equipment, bulk storage, bulk transport, and open facility designs that would inhibit true sanitation as is done in the food industry. These differences in facility design as well as equipment design are not conducive for typical sanitation practices and in many cases would require a complete rebuild of a majority of the facilities. This would be an economic catastrophe to the majority of our industry if such rules were applied as written and undifferentiated between the multiple aspects of the industry.

Transport of food for animals:

The Agency has made a conscious decision to exclude several raw agricultural commodity facilities from these rules. We are concerned as to how this is actually going to assist in helping produce safer animal foods. The transportation and storage of these products are as important early on in the process as it is later after further processing occurs. In rendering we knowingly accept product that because of its nature contains biologicals. Therefore, we ask that the Agency remove or better clarify the use of the term "biologicals" from page 158 of the proposed rules. Also, as stated previously, the conditions for the transport of animal foods need to be determined based on the final intended use of the food. For most livestock "sanitary transportation" will not affect the conditions under which the food is consumed. Most food for animals is transported using bulk transportation. It is important to make certain that all agricultural commodities are placed under the same requirements for transportation of bulk animal foods. By exempting some and requiring others to alter their standards for transport there will be a tremendous amount of confusion within the animal food industry. It will also cause a deficit in the amount of transport carriers that can receive these products.

FDA Review of Written Feed Safety Plans, and Confidentiality:

We have been asked to comment on the question of the requirement to submit facility profiles that summarize hazards and controls. We believe that the authority for this is overreaching and places our industry at a disadvantage to other industries as well as other aspects of the animal food industry that are not compliant in these rules (i.e. raw agricultural commodities and those institutions exempt from the rule due to size). Furthermore, the requirement of these plans would have no obvious impact on the safety of animal foods.

Food Safety Plans can only be evaluated through the use of on-site inspections and audits. Every facility is designed differently and it is not possible to know what these differences are when only evaluating the plan on paper.

There is also the concern that any information provided to the FDA could be subject to a Freedom of Information Act (FOIA) request. This is unacceptable as it would provide competitors with extensive details regarding a competitor's procedures. Some of these would be utilized to develop a differentiated product or system used to achieve a competitive edge in the market. This practice would undermine the ability of firms to competitively compete in an open market and would reduce our current system of open capitalism at risks without providing any additional benefit to animal food safety.

Food Safety Plans are by design active, living documents, and can and should be modified to increase its effectiveness. This provision in the rule does not allow for continual improvement of the document and would actually hinder the advancement of food safety in some cases.

We feel that it is also important to allow firms to utilize their audits to improve their food safety programs. The requirement for a third party auditor to report a finding immediately to the FDA would not actually solve or improve a food safety issue. It would also not benefit the overall progress of food safety programs rather it would slow down the use of such audits more often than required to improve conditions by companies.

Recordkeeping and Storage of Records:

Recordkeeping for a good food safety program should encompass all aspects of a company. Records may be kept at multiple sites that are pertinent to a given facility. We believe that the request of records should be flexible enough to allow for time to properly collect and deliver specific records from a corporate office to the manufacturing facility which may be quite distant. Records request should only be considered under an inspection or investigation and not made on an arbitrary basis for a simple review. Remote access to records by the Agency should not be allowed as there are serious implications for confidentiality and potential breaches in security. We agree that facility records should be available for review on-site. These requests should be made in a concise manner that covers only the aspects and the dates that are involved in the inquiry. We also agree that electronic records should be acceptable by FDA, and that electronic signatures and handwritten signatures executed to electronic records as equivalent to paper records and handwritten signatures executed on paper. However, we believe compliance with 21 CFR Part 11 is unnecessary, would lead to considerable cost and complexity, and should not be required.

Intentional Hazards:

PPFC agrees with the Agency's decision to allow food for animals to be exempt from the proposed rule with regards to intentional or economically driven adulteration. These are not reasonably foreseen hazards in production of food for animals.

Hazard Analysis and Risk Based Preventive Controls (HARBPC) Expected Under FSMA:

Since every rendering facility is different, and every animal food facility is different, it is important to allow each facility to establish its own development of hazards reasonably

likely to occur. This has always been the tenant of any well developed HACCP or Food Safety Plan. Each facility will have very different potential hazards based on the raw materials used, the processes used and the environment of the facility. It is also important that the industry is able to recognize its own hazards based upon the intended use of the product that is produced. Typical Human Food hazards will not apply to most animal food production. The Agency has defined preventive controls as being "risk based and reasonably appropriate" measures. These are to be "consistent with current scientific understanding". We agree with the Agency that these rules need to be based on the use of the product and the specific hazards that may be of concern when the product is being used as intended. This would allow the industry to use the best determinations possible for animal food hazards rather than simply using an estimation made by the Agency based upon human food hazards.

Any HARBPC should be science and risk-based, non-prescriptive, and should allow for sufficient flexibility to allow facilities to develop practices that are practical and effective for their specific, individual operations. Many members of PPFC work in conjunction with the NRA and AFIA through the HACCP based programs such as the Rendering Industry Code of Practice and Safe Feed/ Safe Food. The principles included in these programs have been determined by the industry to be the most appropriate guidelines for the development of individual HARBPC's and for the production of safe animal foods.

Both the AFIA's Safe Feed/ Safe Food program and the APPI's Rendering Industry Code of Practice require facilities to:

- Establish known effective cGMP for the production of animal foods.
- Evaluate known or reasonably foreseeable hazards associated with the facility. Once a hazard is identified to be external to the facility, preventive controls are neither required, nor appropriate. (It is imperative not to overreach the statute language.)
- Identify and implement preventive controls to significantly minimize or prevent the occurrence of such hazards.
- Routinely monitor the performance of the preventive controls they implement and maintain records of such monitoring activities.
- Make appropriate decisions about corrective actions to implement if preventive controls are found to be deficient.

We believe that the industry already has excellent guidelines for the safe production of animal foods as found in these and additional industry programs. We would suggest that rather than re-write and/or apply human food guidelines to the industry (which would not be based on sound science) the Agency should utilize the guidelines that already exist and where possible implement them into the revision of these rules. These programs have been developed by the industry and have been tested and proven to aid in the production of safe animal foods. The desire of the Agency to apply human food rules to the manufacturing of food for animals has no scientific base and could actually result in products that are unsafe for animals.

"Reasonably likely to occur" is a probability term, but the standard has been applied in many contexts without a realistic evaluation of probability. A determination that a hazard is reasonably likely to occur without a realistic assessment of probability does not allow consideration of the impact cGMP's have upon the ability for a hazard to occur. The rendering industry uses truck driver checklists, investigations of unusual raw material variation, and supplier affidavits of compliance with "Animal Proteins Prohibited from Animal Feed," the BSE feed regulation (21 CFR 589.2000 and 589.2001), among many

other successful prerequisite programs. These issues need not be handled with preventive controls if effectively eliminated by routine prerequisite programs.

If the Agency's' goal is truly to improve the safety of food for animals, forcing an industry which has voluntarily and pro-actively written and implemented food safety programs, does nothing to improve this goal and actually detracts from what the industry has already accomplished. By working with the existing programs as opposed to changing them to human food rules, the Agency can better equip itself and the industry in the fight to improve the safety of all foods. It is clear by the design of the current rules that the Agency does not have the depth of understanding of how the industry functions or how they have already addressed many of the issues regarding food safety. To make the industry spend an exorbitant amount of time and effort simply changing from a working program to a different program will not be a successful effort in the prevention of hazards. We suggest that the Agency work closely with the industry and incorporate the existing programs into the rules and guidelines. Extensive debate about how to classify particular controls, whether they are "preventive controls," prerequisite programs, cGMPs, or HACCP plans, does not further the goals of food safety and conflicts with the statute. Also, FDA's economic analysis concludes that facilities with effective HACCP plans would need to make minimal changes to their existing Food Safety Plans. While the Rendering Code of Practice is not a formal HACCP plan per se, it is based on HACCP principles and has been effective.

The rendering and the feed industries are in agreement with the Agency that the efforts towards making food safer should be conducted in a scientific manner. However, they should also be reasonable and manageable. To think that facilities that manufacture animal foods can quickly be upgraded to meet the requirements of those that manufacture human food is not reasonable or realistic. It will also do little to further the safety of the food for animals. It is unrealistic for the Agency to expect HACCP when cGMP's are really the cornerstone of most of the industries programs. By implementing good quality programs and these GMP's much of the industry is currently excelling at food safety. Implementing vague changes and requiring specific HACCP rules that do not fit the industry is not realistic and will be burdensome to the industry while tearing down the food safety programs that have already been established and have proven effective. We would ask that instead of making wholesale changes to the current programs, the Agency uses these programs and assists the industry in conducting research that allows for scientific based continuous improvement of these programs.

The rules as they are currently written contain a wide range of preventive controls that appear to be applied to all of the very different areas of the industry in the same way. The use of preventive controls as well as the remainder of the Food Safety Plan for each individual facility should be site and process specific. We ask that the Agency insure that when evaluating a facility and or the facilities Food Safety Plan that the agency's personnel take into account that every listed hazard, preventive control, critical control point (CCP) or GMP should not be expected in every facility or plan. These should be site and process specific and the Agency should work with each manufacturer to insure that these fit their site and process, not simply use them as a check off list. We feel that the use of CCP's should be left up to the various industry and even specific for a particular facility.

Validation and Verification of Preventive Controls:

As with the HARBPC, the verification of preventive controls should be allowed to be developed by individual facility and process. The written Food Safety Plan should be specific for that facility and or process and should not be required to add verification procedures that do not apply. Since there are so many different and unique facilities and processes across the rendering and animal food industry, it should be through cooperation among the Agency, feed industry and academia to develop scientific research data that applies directly to a specific process or facility.

The final use or next step in the life of each product must also be considered. For example, if a product is to be placed under further treatment to control microbial populations then the burden of the final verification should not be placed upon those applying the processes leading up to that final treatment. If the animal food is to be presented to the animal under conditions that because of the environment is less than sterile or even "clean" then the verification of a given process should come under less scrutiny. There is simply not any scientific basis to force a facility that is several places removed from the final use of the product to be held to insure that the final product is verified across all hazards that may occur. It is important that the Agency realizes that along each step of the production of a final diet each individual facility should only be responsible for its portion of the verification process. In addition, in cases where processes are similar between facilities or when there is scientific data supporting the effectiveness of a particular process then the Agency should utilize this information as a guide for all similar processes, not require individual validation.

Additionally, the suggested timelines or requirements of 3 to 6 weeks for a complete scientific validation of a process that is suggested by the Agency is in itself not realistic or scientific. Every facility should be allowed to use current scientific data or to demonstrate to them that a process is sufficient in the removal of a particular hazard. This may or may not be accomplished in a set time frame. Placing a time limit on said verification also would inhibit future improvements and changes by creating a checklist that a facility has to complete to be in compliance. Checklists will only create reactive environments rather than proactive ones. The industry has already demonstrated through its many current programs that they themselves (not the Agency nor the Government, nor an individual inspector) can and will continue to improve upon their processes for the sake of food safety as well as efficiency. A period of 90 days is currently allowed for validation by the USDA-FSIS (FSIS Compliance Guideline on HACCP Systems Validation, April 2013) even this may not be enough as long as the facility can continue to demonstrate improvements over time.

The frequency and types of verification activities should be decided by the establishment, and these types of decisions should be science and risk-based, not mandated by FDA. There are some specific control measures and procedures for which scientific validation is not applicable, available, or necessary. Validation and verification techniques are numerous and it is appropriate to apply different validation and/or verification requirements based on risk and the intended use of the product. The Agency does not have the knowledge or the data to prescribe specific procedures for validation and verification. Individual facilities should have the flexibility to determine what verification activities are appropriate based on their own assessment of risk. A hazard that could result in a Class I recall in finished products may not be a hazard at all in ingredients or raw materials destined for additional processes. We state again that the Agency seems to be taking an all or none approach to the criteria that each facility must meet regardless

of its place in the whole process. At the same time they have provided many exemptions to areas of the animal food industry that may contribute just as must risk as those they are trying to regulate. There should be flexibility allowed for facilities to determine when validation or verification is appropriate.

We feel that there should be more distinction in the rules between ingredients and complete/finished foods. There should also be more distinction allowed based on the final intended use of the product. A raw material producer should not be required to have a complete microbial elimination step when there are further processes down the line that will accomplish this task. Also, an ingredient manufacturer should not be held responsible for the actions of others after his product has entered commerce and has left his facility. All of these guidelines should be better evaluated by the Agency for correct placement based on the final intended use of the product once it enters commerce from that individual facility.

As currently written, these rules are also extremely confusing because the description of "validation" and "verification" are often interchanged within the text. A definition of verification in FSMA that includes validation will continue the common confusion between procedures and activities to validate that control measures are capable of significantly minimizing or preventing an identified food safety hazard, and the ongoing activities to verify the Food Safety Plan and component control measures are operating as planned. PPFC would request that the Agency consider using clearly separate definitions of validation and verification, consistent with Codex Alimentarius definitions, to help avoid confusion about activities related to these important processes. Validation activities should also be included in a separate section of the final rule from verification activities. We recommend these definitions:

- Validation means obtaining evidence that a control measure or combination of control measures, when properly implemented, is capable of effectively controlling the hazard to a level necessary for product safety.
- Verification means the 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.

The Agency should regard monitoring, testing, and any other food safety programs to be successfully implemented if any problems found in testing are subsequently addressed. FDA inspectors should not penalize facilities for finding potential problems through verification if appropriate corrective actions are taken. No single set of regulations can encompass all of the different processes utilized in the production of food for animals. There must be a better understanding by the Agency and its inspectors and investigators of the distinctions of the final intended use of the individual products. They must also recognize that a simple checklist of activities is not going to help improve the safety of food. The Agency must recognize that an effective Food Safety Plan is ever changing and improving. These changes that may lead to corrective actions should not be looked at as items for which to punish the producers of food. Rather they should be viewed as part of an ongoing effort by the industry to further improve the safety of the food it produces. When the Agency or one of its members punishes a facility for not reporting a minor deficiency when the facility has demonstrated that it has recognized said deficiency and produced a corrective action, this will not improve the production of safer foods. It will only stifle ingenuity and vision that the industry itself has already demonstrated through its proactive and voluntary efforts.

Corrective Actions:

Corrective actions are an important part of continuous improvement for a food safety program. Records are important to address how and why problems occur and how the corrections are accomplished. However, many items can be and are addressed with little formality and there for requirements and rules regarding such records may be actually impair the process rather than a enhance it. It is also important to realize that every facility is different from the next so prescriptive corrective actions required by rules may not be applicable or possible in all cases. It is important for the Agency to allow for flexibility in such cases rather than demand that blanket guidelines be followed when they cannot fit every case.

Customer Complaints:

The recording of customer complaints in no way improves food safety. Also, any requirement for sharing such records would not benefit an investigator. As the Agency itself has observed, quite often customer complaints are generated by lack of actual knowledge and do not have any scientific basis. Food Safety Programs have to be based on science not emotion. Emotion is ever changing and does nothing to actually improve such programs. Many complaints are based on emotion not science and should therefore not be applicable to the production of animal food.

Radiological Hazards:

PPFC understands the concern of the Agency with regards toward the potential contamination of food with radiation when radiation is used to “sterilize” foods or when there is concern for an act of bioterrorism. However, as this practice is not utilized in the production of foods for animals, it should only be included in a hazard evaluation if some radiological process is being implemented.

FSMA requires FDA to develop regulations consistent with existing domestic and international programs. Creating a specific hazard category for radiological hazards is inconsistent with established guidelines. The NACMCF HACCP guidelines, the Codex HACCP Annex, and federal HACCP regulations for seafood, juice, meat and poultry do not require examinations of radiological hazards as a separate and distinct hazard subject. As such, PPFC does not believe the animal food rule should differ from these established programs in this regard.

FDA stated in the Preliminary Regulatory Impact Analyses for the proposed rule, that the proposed preventive controls rule would not impose additional costs on large animal food companies. Considering radiological hazards as a separate hazard will result in developing new templates for ingredient and process step assessments and the re-documentation of all existing plans and it is reasonable to anticipate that all large animal food companies will incur expenses if they revise their food safety plans to address radiological hazards in their hazard analyses. This is an undue burden that will lack a food safety gain; these issues are already considered as part of chemical hazard analysis.

Inspection and Compliance:

This is the primary area where the Agency can make the greatest strides in improving the overall safety of the food production industry. Through outreach and cooperation with the industry partners and academia, the Agency can produce better scientific efforts that can be applied to a diverse and complicated food system. It is through the proper

cooperation of the Agency and the training of its personnel that we can achieve the desired outcome of the goals of these regulations.

The Agency currently has responsibility to monitor many different industries. Pharmaceuticals, cosmetics, tobacco, human foods, and animal foods are each very different from the other and each very complex in their own right. The Agency has to be able to place qualified individuals into the animal food industry that can aid and assist in these programs designed to make food safer rather than to enforce rules and regulations that may not even apply to our industry. The animal food industry has extended its desire to assist the Agency in the recruitment and training of qualified individuals to work with the industry to improve the current system. These individuals should be educated in the mechanism of cooperative involvement rather than in the mechanisms of enforcement. As written, the current proposed rules cannot and will not aid in the improvement of the safety of foods if the designated personnel are instructed to apply a one size fits all formula to the industry. The only thing that will evolve from this line of thinking is an organized witch hunt that stifles the creativeness of both the Agency and the animal food industry to implement actions that actually achieve the desired goals. The rules after they are re-written and improved should be used only as a guideline for the inspectors and investigators and they should be trained to engage the industry representatives at a facility in order to design an appropriate and encompassing program for food safety for that particular facility. This should be done with the knowledge that each facility will be different and this approach will be repeated often as the knowledge of producing safer foods increases for both parties.

Since the guidance for industry will likely not be completed until after the rule is rewritten and presented in its next format, we again ask the Agency to reconsider the timelines currently suggested for implementation. During these periods, the Agency would be better able to instruct its personnel regarding the different areas of our industry, as well as work in cooperative efforts with industry leaders to develop sound scientific documentation for the benefit of both the Agency and the industry.

Just as it was unjust for the Agency to require complete and substantiated comments on the rule in such a short amount of time, we feel the Agency would be committing a grave error in thinking that the industry and Agency personnel could be prepared to implement any standards much less improve upon them in the allotted amount of time.

Since it is impossible to train anyone to completely understand every aspect of animal food production, we urge the Agency to provide an effective appeal format in which highly trained personnel from both the industry and the Agency can discuss a finding as opposed to implementing punishments incorrectly.

Summary

In summation of our comments on the proposed rules, the members of the PPFC ask the following of the Agency.

We ask that the Agency become more engaged with the animal food industry as well as academia whose expertise lies in this area and make an effort to develop better guidelines and produce scientific evidence to substantiate the provisions included in the rules to insure improvement in the safety of animal foods.

We ask that the Agency not only use discretion in the implementing of said rules after they are re-written in an effective manner but use them as a guide to allow the industry the time necessary to advance the understanding of the requirements for safe food production.

We ask that the Agency take a more advisory as opposed to an adversarial approach that can actually alter the current culture of both the Agency and the industry. Specifically, the Agency's personnel should be trained to be effective directors of policy rather than enforcers. These personnel should be allowed to work with companies on an individual basis to assist them in implementing policies that will improve the overall safety of the products they produce. If the industry is forced by the actions of the Agency and its personnel to prepare only for a checklist of items that may or may not apply to their individual operation, then the focus and vision of producing safer foods is lost by both parties. Furthermore the ingenuity and aspirations to exceed the baseline requirements will be lost and the goals of the regulations and rules will fail to improve food safety for all.

We ask that the Agency be cognoscente of the efforts already made by the animal food industry and use these industry-specific programs when able. The focus of the rules is to insure a safe food supply not to hamper the efforts of forward thinking individuals who have already developed outstanding policies and continue to raise the bar and accelerate learning in the area of food safety.

We ask the Agency to be respectful of the timelines of implementation and that rather than providing a cut-off date, the policies implemented in the re-written rules are accelerated through education and advisement. The current one year timeline will achieve nothing but the successful completion of a check off list that the industry uses to get past the next audit. If the rules are implemented over an extended time where improvement rather than enforcement is the direction then the goal of safer foods can be achieved. We understand the necessity of time limits. However, these should be developed in conjunction with each facility with the thought that continuous improvements are frequently occurring.

We ask that the Agency itself respects the need for improvements based on sound science, and that facilities be allowed ample time to appropriately validate and verify that their systems are effective. A snapshot in time in which a process achieves the desired level of efficacy does not mean that this process will achieve this goal in a continuous manner once exposed to a different set of variables. This is also true for testing. Testing is a useful tool in the advancement of knowledge and can be used for the development of improvements. However, it is not useful when the only purpose is to collect continuous data that supports the completion and checking of one box on a task list. Testing should be utilized by a facility to validate and verify only when it is a part of a larger continuous improvement program. Testing should also not be considered as a negative by the industry as it is currently because the Agency looks to use it as a tool for reporting deficiencies or reviewing past results with the thought of implementing a punishment. We understand that the Agency wants the industry to use scientific procedures to insure safe foods. The industry cannot do this when the Agency uses failed test as a reason to punish. Testing should be looked at as a tool for a facility to continually improve their parameters and a facility should not be punished for test results that demonstrate deficiencies as long as they are pursuing corrective actions to remedy those deficiencies.

We ask that the Agency not continue with the current approach of making all animal foods and ingredients be treated alike and placed in the same category as human foods.

We believe that this is not the written intent of the Food Safety Modernization Act. By treating all foods and ingredients equally and assuming they have the same potential hazards, the Agency actually fails at the goal of improving food safety. This all-encompassing approach limits science and allows unknown or unregulated hazards to present themselves with one of the many very different food types. We instead suggest the rule when re-written allow for distinctions between complete foods and individual ingredients, between foods for animals and foods for humans, and between foods for different animals per their intended use. Rules are only effective if applied based on the final intended use of the food. While this approach will take significantly more effort on the part of everyone involved, it is the only scientific approach to insuring and improving the safety of foods.

We ask for flexibility in the implementation of these rules once re-written. The challenges that each manufacturer faces are unique to each facility, depending on the raw materials used and feed ingredients produced. There are different contractual specifications for different customers and regional differences in many variables depending on the part of the country in which each facility is located, and inherent variability within raw materials. The Agency personnel who inspect food and feed producing plants must recognize that food and feed plants are not the same within a given industry, with even greater differences occurring between different animal food industries. The Agency and its personnel must provide flexibility within the animal food regulations to accommodate the vast differences necessary to manufacture safe feed ingredients in an efficient manner. The Agency should approach food safety with an attitude of engagement advisement rather than enforcement.

Please contact us by email at charles.starkey@amprot.com or pbredwell@uspoultry.org or by phone at 770-493-9401 with questions regarding these comments.