



December 15, 2014

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

**Re: Docket No 2011–N–0922 and RIN 0910–AG10, Food and Drug Administration; Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals; Proposed Rule; 79 Fed. Reg. 58476 (Sept. 29, 2014).**

Dear Sir/Madam:

The American Meat Institute (AMI) and the North American Meat Association (NAMA) (collectively the associations) submit this letter in response to the Food and Drug Administration's (FDA or the agency) request for comments regarding the above-referenced proposed rule.

AMI is the nation's oldest and largest meat packing and processing industry trade association. AMI members slaughter and process more than 90 percent of the nation's beef, pork, lamb, veal, and a majority of the turkey produced in the United States. In addition, some AMI members operate beef facilities in Brazil, Australia, and Canada, and many members import beef. Finally, approximately 80 percent of AMI member companies are small or very small based on Small Business Administration standards.

NAMA is a trade association with more than 600 member companies in the United States, Canada, and Mexico, representing every segment of the meat industry. NAMA provides its members with regulatory advocacy, educational opportunities, and informational resources.

The safety of the meat and poultry products the associations' members produce is their top priority. The proposed rule (the proposal) would directly affect some Food Safety and Inspection Service (FSIS) inspected establishments because those facilities generate products that may be used in the production of animal and pet food. The associations have a vested interest in the above-referenced proposed rule and submit the following comments.

**The Proposed Rule Creates Ambiguity Regarding its Applicability to Federally Inspected Meat and Poultry Processing Establishments.**

The September 29 proposal creates ambiguity and suggests that FDA may intend to promulgate regulations that could affect FSIS inspected establishments. Specifically, the preamble includes a discussion about FDA's review of the Reportable Food Registry and its scientific literature review to identify hazards associated with human food by-products used to make animal food.<sup>1</sup>

Interestingly, although the agency "did not include hazards associated with human food by-products derived from animal products" in the review it subsequently concluded that "[P]rotein ingredients derived from meat, offal, poultry, and oil seed meal were found to be the most common source of biological hazards in animal food."<sup>2</sup> FDA then asserts that "[F]acilities providing byproducts from these sources for use as animal food would be subject to proposed part 507, as explained in the discussion of proposed § 507.12 in this section."<sup>3</sup> Indeed, FDA says that

Proposed § 507.12(b) would not apply to human food by-products derived from animal products (other than dairy and eggs), such as meat, offal, or poultry. We tentatively conclude that the hazards, particularly biological hazards, potentially associated with byproducts from these animal products could be more substantial than those for the by-products addressed in the memorandum. We request comment on this conclusion.<sup>4</sup>

Although FDA's review of the hazards associated with human food by-products did not include by-product derived from meat and poultry, the agency has concluded those by-products must be treated differently and not exempt as other human food by-products. This conclusion has no basis and contradicts the demarcation of jurisdiction separating FDA and FSIS.

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<sup>1</sup> 79 *Fed. Reg.* at 58488.

<sup>2</sup> *Id.* at 58487-88.

<sup>3</sup> *Id.* at 58488.

<sup>4</sup> *Id.* at 58489

**The Food and Drug Administration Should Make Clear that the Final Rule does not Apply to Establishments Subject to Inspection by the Food Safety and Inspection Service.**

*A. The Longstanding Statutory and Regulatory Scheme Conflicts with Applying Proposed Part 507 to Federally Inspected Establishments.*

In October 2013 the agency requested comment on whether the requirements in the initial proposal should apply to establishments inspected by FSIS.<sup>5</sup> The associations submitted comments contending that any final rule should not apply to establishments that operate under a grant of inspection provided by FSIS under the Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA) (collectively the Acts).<sup>6</sup> That same conclusion applies in response to the agency's September 29, 2014, proposed rule.

Congress enacted the nation's food laws to avoid the regulatory overlap that would occur if a final rule is written to cover materials from FSIS-regulated facilities. The Federal Food, Drug, and Cosmetic Act (FDCA) exempts "[m]eats and meat food products . . . from the provisions of this Act to the extent of the application or the extension thereto of the Meat Inspection Act."<sup>7</sup> This statutory framework establishes that FSIS and FDA should not assert overlapping authority and the two agencies have carefully created regulatory systems reflecting this Congressional intent.

Similarly, under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) FDA specifically exempted from registration facilities "that are regulated exclusively, throughout the entire facility" by FSIS under the FMIA, PPIA, or the Egg Products Inspection Act.<sup>8</sup> Specifically, FDA's regulations provide that

"This subpart does not apply to the following facilities: ...

(g) Facilities that are regulated exclusively, throughout the entire facility, by the U.S. Department of Agriculture under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*)"

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<sup>5</sup> 78 *Fed. Reg.* 64755 (Oct. 13, 2013).

<sup>6</sup> 21 U.S.C. 601 *et seq.* and 21 U.S.C. 451 *et seq.* AMI's earlier comments are attached as Appendix A.

<sup>7</sup> See also 21 U.S.C. § 679(a) ("Notwithstanding any other provisions of law, including section 1002(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 392(a)), the provisions of this chapter shall not derogate from any authority conferred by the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 *et seq.*] prior to December 15, 1967.")

<sup>8</sup> 21 C.F.R. § 1.226(g).

Likewise, in a guidance document revised in November 2014, more than a month after the new proposed rule, the agency reiterated that FSIS facilities are not subject to registration.

**1.2 Q: Has the scope of who is required to register under section 415 of the FD&C Act changed?**

**A:** No. At this time, the same type of food facilities that were required to register with FDA under section 415 of the FD&C Act before FSMA are required to register with FDA and renew such registrations every other year. Those facilities are domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States (21 CFR 1.225). For purposes of section 415, the term “facility” in relevant part does not include farms, restaurants, and retail food establishments (section 415(c)(1) of the FD&C Act; 21 CFR 1.226).<sup>9</sup>

FDA has not proposed to amend rules that form a critical part of the regulatory foundation, the facility register, and even since the proposal was published the agency has reiterated that no change is forthcoming.

Not only do the statutory and regulatory frameworks establish this rule should not apply to meat and poultry processing facilities the practical considerations support such a conclusion. Meat and poultry product food processing by-product materials are already subject to FSIS regulation and inspection. To apply the additional requirements in the proposal to operations in FSIS inspected establishments would create confusing and overlapping food safety requirements, which is contrary to the division of authority between FDA and FSIS established by Congress and agreed to by the respective agencies.<sup>10</sup>

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<sup>9</sup><http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm331959.htm>. November 2014.

<sup>10</sup> See, e.g., Memorandum of Understanding between the Food Safety and Inspection Service, United States Department of Agriculture, and the Food and Drug Administration, United States Department of Health and Human Services, MOU 225-99-2001 (Feb. 23, 1999), <http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomeesticMOUs/ucm117094.htm> (referencing the need to use FDA and FSIS resources “as efficiently as possible to avoid duplication of efforts” and establishing information-sharing procedures for FSIS and FDA inspection of dual-jurisdiction facilities but calling for regulatory action only by the agency with jurisdiction over the particular production process); FSIS Directive 5730.1 (June 28, 2005) (instructing that “FSIS inspection program personnel are not to routinely enter or inspect an area of the establishment in which nothing that is subject to FSIS jurisdiction occurs” and noting that “[i] Inspection program personnel are not to take any control action or other administrative enforcement action against the FDA products or the production of the FDA products”).

In that regard, FSIS already has regulatory requirements addressing meat and poultry food processing waste materials. Specifically, FSIS requires that animal food prepared from materials derived from livestock or poultry carcasses be labeled to identify the product as animal food, not be represented as human food, and be denatured to distinguish it from human food.<sup>11</sup> There is no mention in the preamble or the proposal of these requirements. Compliance with the FSIS requirements and what FDA offers in the proposed rule would create needless regulatory duplication, which reinforces the importance of not applying the proposal to FSIS establishments.

FDA identified no inadequacy concerning how animal derived materials are handled by federally inspected establishments that would warrant subjecting them to FDA regulations and FDA offered no basis for concluding that human food by-products derived from meat and poultry present any risk greater than other human food by-products. In addition, neither the original proposed rule, this supplemental proposed rule, nor the corresponding “Memorandum on Biological, Chemical and Physical Hazards Associated with Human Food By-Products Used for Animal Food” indicate there is systemic microbiological contamination of animal food that can be traced to meat by-products diverted from human food facilities.

There is no “gap” in the existing regulatory structure that might make animals more vulnerable if they consume food in whole or in part derived from meat or poultry. Absent evidence that such products present a greater a risk to animal safety, and FDA has not articulated one with supporting evidence, there is no basis to conclude that human food by-products derived from meat and poultry are more risky than other food products. Rather, FDA should clarify that the proposed rule does not apply to FSIS inspected facilities because to do so is unnecessary and would be duplicative.

*B. Subjecting Federally Inspected Meat and Poultry Establishments to the Proposed Rule Would Result in Unnecessary Waste.*

Subjecting FSIS inspected meat and poultry establishments to Part 507’s requirements on by-products derived from meat and poultry will add unnecessary costs to the system and likely would lead at least some of those facilities to abandon the practice of diverting those products for animal food.

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<sup>11</sup> 9 C.F.R. § 325.11(d)(1) (meat); § 381.152 (poultry).

There are more than 6000 federally inspected meat and poultry processing establishments and thousands more state inspected plants in the 26 states with such programs. The vast majority of federal plants are small or very small using the Small Business Administration definitions and virtually all of the state plants meet those definitions. Simply put, it is unrealistic to believe that many of these smaller operations in particular will comply with the proposed requirements.

Compliance with proposed Part 507 would be burdensome for large facilities but it would be even more so for small and very small establishments. These smaller facilities generally are too far removed from the finished animal food to know what animal will consume food made in whole or in part from the input they provided. Even if a meat or poultry processing facility knows of the animal(s) at issue, that facility is not in the animal food business and likely does not have the expertise to satisfy the multiple requirements in part 507, *e.g.*, conduct the hazard analysis specific to the animal(s) or assess issues such as nutrient imbalance. FSIS facilities, like others, rely upon the animal food processor or farmer to conduct these activities.

Requiring small and very small plants to perform the hazard analysis would force them to expend substantial sums to comply and the likely result of that requirement will be those facilities electing not to divert the by-product material. Not only would that decision result in a lost revenue stream for the company it would be the antithesis of the environmentally sustainable practice of diverting by-products to the animal food stream in exchange for the wasteful practice of diverting them to landfills.

**Conclusion**

For the foregoing reasons FDA should clarify in the preamble and in the final rule that the proposed requirements in Part 507 requirements do not apply to FSIS inspected establishments.

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The associations appreciate the opportunity to participate in this rulemaking process. If you have questions regarding these comments or anything else regarding this matter, please contact us at [mdopp@meatinstitute.org](mailto:mdopp@meatinstitute.org) or [bcarpenter@meatinstitute.org](mailto:bcarpenter@meatinstitute.org).

Respectfully submitted,



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# Appendix A



March 31, 2014

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

**Re: Docket No 2011–N–0922 and RIN 0910–AG10, Food and Drug Administration; Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals; Proposed Rule; 78 *Fed. Reg.* 64736 (Oct. 29, 2013).**

Dear Sir/Madam:

The American Meat Institute (AMI) is the nation's oldest and largest meat packing and processing industry trade association. AMI members slaughter and process more than 90 percent of the nation's beef, pork, lamb, veal, and a majority of the turkey produced in the United States. In addition, some AMI members operate beef facilities in Brazil, Australia, and Canada, and many members import beef. Finally, approximately 80 percent of AMI member companies are small or very small based on Small Business Administration standards.

The safety of the meat and poultry products AMI members produce is their top priority. The Food and Drug Administration's (FDA or the agency) proposed rule (the proposal) directly affects some Food Safety and Inspection Service (FSIS) inspected establishments because those facilities generate products that may be used in the production of animal and pet food. For that reason AMI has a vested interest in the above-referenced proposed rule and submits the following comments.

**The Final Rule Should not Apply to Establishments Subject to Food Safety and Inspection Service Jurisdiction.**

The agency requested comment on “the applicability of the requirements of this proposed rule to FSIS official establishments that manufacture, process, pack, or hold food for animals. And, if applicable, to what extent should the requirements

apply to these establishments?”<sup>1</sup> For the reasons set forth below, the final rule should not apply to establishments that operate under a grant of inspection provided by FSIS pursuant to the Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA) (collectively the Acts).<sup>2</sup>

Congress took great pains in crafting the nation’s food laws to avoid the type of regulatory overlap that would occur if the proposal were finalized to cover food processing materials from FSIS-regulated facilities. Section 1002 of the Federal Food, Drug, and Cosmetic Act (FDCA) exempts “[m]eats and meat food products . . . from the provisions of this Act to the extent of the application or the extension thereto of the Meat Inspection Act.”<sup>3</sup> The PPIA includes a complementary provision stating that “[p]oultry and poultry products shall be exempt from the provisions of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 *et seq.*] to the extent of the application or extension thereto of the provisions of this chapter” except for any authority granted under the FFDCA prior to August 18, 1968.<sup>4</sup> This statutory framework establishes that FSIS and FDA should not assert overlapping authority and the two agencies have carefully created regulatory systems reflecting this Congressional intent.

More recent legislative activity confirms this Congressional intent. For example, in implementing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), FDA specifically exempted from registration facilities “that are regulated exclusively, throughout the entire facility” by FSIS under the FMIA, PPIA, or the Egg Products Inspection Act.<sup>5</sup> FDA has also concluded that it is preferable for the agency not to assert jurisdiction “where another Federal agency has the types of specific and comprehensive authority described above to regulate the safety of certain substances.”<sup>6</sup> Nothing has changed in the meat and poultry inspection system such that FSIS inspected establishments are no longer regulated “exclusively” by that agency. Because FSIS establishments operate under a separate, comprehensive regulatory scheme and because meat and poultry food processing waste material is not properly considered animal food FDA should not extend the proposal to operations in FSIS official establishments.

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<sup>1</sup> 78 *Fed. Reg.* 64755 (Oct. 13, 2013).

<sup>2</sup> 21 U.S.C. 601 *et seq.* and 21 U.S.C. 451 *et seq.*

<sup>3</sup> See also 21 U.S.C. § 679(a) (“Notwithstanding any other provisions of law, including section 1002(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 392(a)), the provisions of this chapter shall not derogate from any authority conferred by the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 *et seq.*] prior to December 15, 1967.”).

<sup>4</sup> 21 U.S.C. § 467f(a).

<sup>5</sup> 21 C.F.R. § 1.226(g).

<sup>6</sup> 68 *Fed. Reg.* 58960, 58911 (Oct. 10, 2003). Although this statement was made regarding pesticides regulated by the Environmental Protection Agency, the same reasoning applies for meat or poultry processing regulated by FSIS.

Not only does the legislative scheme not support including FSIS inspected establishment within the scope of this rulemaking, applying any such final rule to those facilities would have consequences that are inconsistent with FSIS regulatory system, which was not intended by Congress when enacting FSMA. Applying any final rule to FSIS establishments would require them to register with FDA as food facilities, a step that layers FDA inspection on top of the continuous presence of FSIS inspectors in those establishments and arguably triggers numerous other FDA requirements, such as causing companies operating FSIS inspected establishments to be covered by the Reportable Food Registry requirements as responsible parties required to report reportable meat and poultry foods to FDA.<sup>7</sup> Such a result is at odds with Congressional intent because: 1) FSIS inspected facilities have never before been subject to that registration requirement; 2) the Acts have established their own reporting requirement;<sup>8</sup> and 3) there is no indication in FSMA or its legislative history that Congress intended such a fundamental change.<sup>9</sup>

Not only do the statutory and regulatory frameworks establish that any final rule not apply to meat and poultry processing facilities the practical considerations support such a conclusion. Meat and poultry product food processing waste materials are already subject to FSIS regulation and inspection. To apply the additional requirements included in any final rule to operations in FSIS inspected establishments would create confusing and overlapping food safety requirements, which is contrary to the division of authority between FDA and FSIS established by Congress and agreed to by the respective agencies.<sup>10</sup>

In that regard, FSIS already has regulations addressing meat and poultry food processing waste materials. Specifically, FSIS requires that animal food prepared from materials derived from livestock or poultry carcasses be labeled to identify the product as animal food, not be represented as human food, and be

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<sup>7</sup> FDCA §417.

<sup>8</sup> 9 C.F.R. §418.2.

<sup>9</sup> If Congress had intended that FDA insert itself into the FSIS regulatory scheme it easily could and would have said so. Congress, however, did not do that.

<sup>10</sup> See, e.g., Memorandum of Understanding between the Food Safety and Inspection Service, United States Department of Agriculture, and the Food and Drug Administration, United States Department of Health and Human Services, MOU 225-99-2001 (Feb. 23, 1999), <http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/Dome%20sticMOUs/ucm117094.htm> (referencing the need to use FDA and FSIS resources “as efficiently as possible to avoid duplication of efforts” and establishing information-sharing procedures for FSIS and FDA inspection of dual-jurisdiction facilities but calling for regulatory action only by the agency with jurisdiction over the particular production process); FSIS Directive 5730.1 (June 28, 2005) (instructing that “FSIS inspection program personnel are not to routinely enter or inspect an area of the establishment in which nothing that is subject to FSIS jurisdiction occurs” and noting that “[i]nspection program personnel are not to take any control action or other administrative enforcement action against the FDA products or the production of the FDA products”).

denatured to distinguish it from human food.<sup>11</sup> The proposed rule does not take these requirements into account, and compliance with the FSIS requirements and what FDA offers in the proposed rule would create needless regulatory duplication, which reinforces the importance of not applying the proposal to FSIS establishments.

Similarly, applying a final rule to meat and poultry food processing waste materials would require those plants to implement FDA-compliant Good Manufacturing Practices (GMPs) and preventive controls at processing stages before the meat or poultry food processing waste materials are diverted from the human-food production process. Given that FSIS regulated facilities must have and implement Hazard Analysis, Critical Control Point (HACCP) plans and Sanitation Standard Operating Procedures, in addition to many facilities having GMPs and other prerequisite plans, layering an FDA compliant plan on top of those FSIS mandated programs would, at a minimum, be duplicative and could be counterproductive.

In short, FDA should not develop regulations directly addressing the production of meat and poultry products that may be consumed by animals. To do so would be inconsistent with longstanding agency and Congressional policies separating FDA and FSIS jurisdiction.

### **The Animal Food Rule is and should be Distinctly Different from the Human Food Rule.**

Fundamentally, the proposal is flawed because it would apply to animal food many of the same rules and concepts that FDA developed for its proposed human food rules.<sup>12</sup> Such a result conflicts with Congressional intent and in some cases the language in the statute. The discussion that follows elaborates in several areas why the rulemakings need to and should be distinctly different.

### **Hazard Analysis Critical Control Point References should be removed from the Rule.**

The Food Safety Modernization Act does not include the term Hazard Analysis Critical Control Point and yet that concept is embodied throughout the proposal. For example, the proposal uses the phrase “reasonably likely to occur.” In contrast, the statute uses the term “reasonably foreseeable hazard.” Those standards are not the same.

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<sup>11</sup> 9 C.F.R. § 325.11(d)(1) (meat); § 381.152 (poultry).

<sup>12</sup> Recognizing that there are certain limited situations in which FDA has jurisdiction on the same situs as an FSIS inspected establishment, *e.g.*, inedible rendering, AMI submits the following comments to aid the agency as it develops the regulations.

Similarly, the proposed rule would require all preventive controls, absent specific exemptions, to be treated as if they were critical control points (CCPs) in a system. FSMA, however, defines “preventive controls” more broadly than CCPs are typically viewed in a HACCP system. Rather than the more narrowly considered concepts in CCPs “preventive controls” should include the spectrum of controls needed to achieve the statute’s food safety goals. For that reason the final rule should refer to “known and reasonably foreseeable hazards” rather than “hazards reasonably like to occur.” More specifically, the final rule should provide that a facility has programs and people in place to ensure that it can identify and evaluate known or reasonably foreseeable hazards for the products manufactured, processed, packed, or held at the facility. This approach is more consistent with the Congressional intent embodied in the statute.

### **Quality References Should be Removed from the Final Rule.**

The term “quality” is replete throughout the proposal. In some cases feed quality programs can include a safety component, but not always. Indeed, many companies have substantial quality programs, of which safety is one of the components. These quality programs are often proprietary and access to them is carefully guarded and limited. For that reason, the term “quality” should be removed from the final rule. In the alternative, that term should be used judiciously such that a final rule limits agency access to the feed safety aspects of a feed quality program.

### **Existing Language and Programs Regarding Current Good Manufacturing Practices are More Appropriate.**

To the extent that animal food CGMP regulations apply, the human foods CGMPs are not the proper foundation for developing or applying animal food CGMPs. Indeed, several currently existing options are more suitable. For example, the Codex Animal Production and Health Manual of Good Practices and the Prerequisite Programmes for Food Safety in the Manufacturing of Food and Feed for Animals (PAS 222), both international standards, are preferable for animal food CGMPs.

In addition, two domestic standards developed in conjunction with FDA's technical expertise also are better suited. Specifically, the medicated feed CGMPs were developed by FDA in 1976 and the CGMPs published by the Association of American Feed Control Officials (AAFCO) were developed with input not only from FDA but also with the benefit of state regulators’ expertise.<sup>13</sup> Inexplicably, FDA has chosen not to use these resources as a starting point for the proposed animal food CGMPs.

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<sup>13</sup> See 21 CFR Part 225.

Finally, with the exception of medicated feed mills, CGMP utilization in animal food production historically has been voluntary. In that regard, FDA's hypothesis that all animal food manufacturers follow CGMPs that are based on their human food counterparts is likely in error. The better approach is to develop and implement CGMPs intended for animal food and not human food. For that reason, again, FDA should utilize CGMPs from established animal food and feed programs instead of human food CGMPs.

**Because All Animal Food Facilities Are Not the Same, Flexibility is Necessary.**

Fundamentally, different risks are presented with different animal foods and different manufacturers. Although the distinction among different animal foods is not as extreme as between animal food and human food, there are still notable demarcations among various animal foods. To that end, CGMPs must accommodate the diversity among animal food manufacturers.

To accomplish that objective, the final rule should include phrases such as "as appropriate" or "as necessary" to allow for the differences in risk among animal food products and their manufacturers. This flexibility would allow companies to delineate between various animal food production practices and apply the necessary CGMPs to best produce safe animal food.

Also significant is the fact that animal food may have different functions or purposes. In that regard, the phrase "for intended use" should be recognized in the final rule and included in appropriate CGMPs. To do so allows the process to be risk-based without compromising safety.

Likewise, when it comes to other regulatory requirements such as recordkeeping, it is imperative that the final rule provide for flexibility with respect to record storage and maintenance. Companies with multiple production facilities may keep records 1) in a central location, 2) at each facility, or 3) some combination thereof. For example, records relating to suppliers, raw materials, consumer comments, validation, and similar topics that are relevant to multiple facilities likely are kept in a central location while other records may be kept at specific production locations. The ability to make records available promptly with proper notice should obviate the need to mandate how and where records be kept. Likewise, FDA should not prescribe the types of records to be kept. Rather, records should reflect the type of facility and products produced.

**The Risk to Animal Health from Feed Mill Employees Health is Minimal.**

The proposal overemphasizes the impact the health of facility employees can have on animal food. To that end, FDA should adopt currently accepted language reflected in AAFCO, or PAS 222 models rather than the proposed language. For example, the proposal incorporates microbial considerations found in the human food rule. The AAFCO model, in contrast, provides that: "(P)ersons working in direct contact with feed and/or feed ingredients shall conform to good hygienic practices to minimize the risk of adulteration." This standard is more than sufficient to help ensure animal food safety.

**The Final Rule Should Reflect the Appropriate Management Oversight for Preventive Controls.**

The proposed rule overreaches and would require "full management oversight" and subject all preventive controls to monitoring, corrective actions, and verification. There is, however, a broad array of preventive controls attendant to the animal food industry and for that reason the final rule should not require that they all be managed in the same way. Each plant should be empowered to determine the oversight necessary to minimize and prevent any food safety hazards based on the nature of the risks or hazards and the controls employed.

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AMI appreciates the opportunity to participate in this rulemaking process. If you have any questions regarding these comments or anything else regarding this matter, please contact me at (202) 587-4229 or mdopp@meatami.com.

Respectfully submitted,



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