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Wednesday, 23 November 2016

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

Delivered via www.regulations.gov

Re: Docket No. FDA-2016-D-1229 (Current Good Manufacturing Practice Requirements for Food for Animals; Draft Guidance for Industry; Availability)

Dear Sir or Madam:

The Pet Food Institute (PFI) appreciates the opportunity to provide comments regarding the Food and Drug Administration's (FDA's or the Agency's) issuance of a Draft Guidance for Industry – Current Good Manufacturing Practice Requirements for Food for Animals, published in the Federal Register on August 25, 2016 (Docket Number: [FDA-2016-D-1229](http://www.fda.gov/oc/ohrt/fda-2016-d-1229)) and hereafter referred to as the "Draft Guidance."

Established in 1958, the Pet Food Institute (PFI) is the voice of US cat and dog food manufacturers. Our members have an unwavering commitment to product safety and quality, in keeping with our mission to help dogs and cats live long and healthy lives. PFI is comprised of 23 producer members and over 70 suppliers of ingredients, equipment and services to pet food makers. Our members account for approximately 98 percent of the cat and dog food produced in the United States, selling more than \$24 billion in dog and cat food annually here in the United States, and another \$1.3 billion in exports.

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

General Observation

FDA indicates it will issue guidance on how to conduct a hazard analysis and implement preventive controls. We seek confirmation from FDA regarding when it will issue this hazard analysis and preventive controls guidance and whether it will be issued in draft form, as was this guidance for FSMA CGMPs. We note that this

CGMPs Draft Guidance was issued less than one month before the expected compliance date for subpart B of the FSMA animal rule, so we urge FDA to factor this lack of final guidance for industry into its plans for compliance and surveillance activities. We also urge FDA to provide other promised Guidance for Industry in draft form as soon as possible so stakeholders can provide comment and FDA can issue final Guidance for Industry documents well in advance of the expected compliance dates.

Specific Observations

FDA states in this Draft Guidance that it considers CGMPs to be “one of many prerequisite programs that can support the effective implementation of preventive controls.” (Draft Guidance, page 4) And FDA also acknowledges that proper implementation of a prerequisite program could sufficiently reduce the probability of a hazard occurring or the severity of the illness or injury such that “a facility may conclude that the hazard does not require a preventive control.” (Draft Guidance, page 4) PFI notes that this determination that a prerequisite program can sufficiently reduce a hazard, thus eliminating the need for a preventive control, is a hazard-specific exercise – such a determination must be made for each hazard identified in a facility’s hazard analysis. For hazards requiring a preventive control, the animal food rule requires the facility to develop and implement the preventive control – this could be a procedure already in place – and must include that preventive control in its written food safety plan.

FDA makes clear that “CGMPs serve as baseline standards for producing safe animal food ...” and that “[a]nimal food that is not manufactured, processed, packed, and held according to CGMPs may be considered adulterated.” (Draft Guidance, page 5) This statement by FDA could mean that any food would be considered adulterated not because it violates provisions of section 402 of the Food, Drug and Cosmetic Act but because a minor infraction of the CGMPs provisions was observed during an investigation. PFI agrees with FDA that full compliance with FSMA animal food rule CGMPs “should reduce the likelihood that the animal food will be adulterated...” (Draft Guidance, page 5) and we’re actively working with PFI members to ensure full compliance with all applicable FSMA provisions. We seek clarification from FDA on this point, however, since a minor CGMPs infraction may not be grounds for a determination, without further information, that food produced under these conditions is adulterated. While all CGMPs infractions should be identified and addressed as soon as possible, we urge FDA to instruct (federal and state) investigators to exercise regulatory discretion here. Food produced in a facility in which a minor CGMPs infraction is noted, absent additional evidence to indicate the food is adulterated, should not necessarily be considered adulterated.

FDA indicates that qualified individuals must “receive training in the principles of animal food hygiene and animal food safety.” (Draft Guidance, page 10) FDA also indicates that such training “may be provided by any reasonable means, for example, on the job, in a classroom setting, or online.” FDA also requires that facilities maintain records to document training – training records can be “in a format that is convenient, for example: (1) training check-list for new employees; (2) sign in sheets for specific trainings; or (3) computerized training records.” (Draft Guidance, page 11) PFI seeks clarification from FDA regarding proper documentation of on the job training, which is identified as one possible way to provide training to qualified individuals. We seek this clarification since 21 CFR 507, subpart F requires that records, including records documenting training, be made available to FDA upon request and that “[f]ailure to provide access to the required training records during an inspection could be considered a violation.” Valuable on the job training could be delivered informally or not on a set schedule, thus

making recordkeeping for such training difficult. We thus seek clarification from FDA as to the proper method for documenting on the job training.

FDA indicates that training records it obtains “are subject to the records disclosure requirements of 21 CFR part 20,” which means FDA “may release them in response to a Freedom of Information Act [FOIA] request...” (Draft Guidance, page 11-12) PFI seeks clarification from FDA as to criteria it will use to determine whether to release training records in response to a FOIA request. Releasing such training records, without providing any additional information, may provide an incomplete picture of a facility’s overall food safety plan or the role of training in the food safety plan.

FDA indicates in this Draft Guidance that “required training records must (documenting the training in principles of animal food hygiene and animal food safety) should be kept for two years after the individual who was trained stops working for the facility.” (Draft Guidance, page 12) This requirement in the Draft guidance far exceeds the requirement in the animal food final rule (§ 507.208(a)(1)) that “[a]ll records required by this part must be retained at the plant or facility for at least 2 years after the date they were prepared.” PFI urges FDA to make its FSMA guidance consistent with applicable provisions of the rule to which each guidance applies – in this case, FDA’s CGMPs guidance should require training records be retained for two years after they were prepared. Plants or facilities may decide to retain records for longer, including for the duration of an employee’s time with the plant or facility, but the guidance should be consistent with the final rule provisions on this matter.

In its discussion of CGMPs as they apply to personnel, FDA indicates that “hand-washing should occur at a minimum when: individuals enter the food production area; after they handle or touch anything other than food or food contact surfaces, such as the floor, door handles, or hoses...” (Draft Guidance, page 12) PFI seeks clarification from FDA as to whether the animal food rule CGMPs require hand-washing every time a qualified individual handles a utensil in the food production area, even if that utensil – a shovel, for example – is not a food contact surface. PFI believes facilities and their supervisory personnel are best positioned to make determinations of when hand washing is necessary to ensure food safety.

PFI acknowledges that FDA has recognized the value of discretionary language in both this Draft Guidance and in the animal food rule. PFI appreciates FDA’s recognition that facilities are in many instances best positioned to identify and take the necessary steps to ensure product safety generally and FSMA compliance specifically, including allowing facilities and their PCQIs the latitude to implement appropriate CGMPs for the hazard and facility characteristics.

Regarding plants and grounds, FDA indicates that “[d]riveways, yards and parking areas must be maintained so they are not a source of contamination for exposed animal food” and that “these areas should be well-drained and free of debris to reduce the introduction of foreign material into the animal food.” (Draft Guidance, page 14) PFI is concerned that such prescriptive language could be construed to mean no puddles are allowed in a facility’s parking lot. We therefore seek clarification from FDA that requirements to maintain the plant and grounds does not include incidental water (such as puddles in parking lots) if the facility has other measures in place to prevent contamination (for example, mats to dry feet and/or a requirement to wear booties in food production areas).

PFI appreciates that, with respect to plant size, construction and design, FDA does not expect “existing plants to be redesigned and reconstructed to meet the requirements in 21 CFR 507.17(b).” (Draft Guidance, page 15) Language in the animal food rule left some doubt on this important question and FDA’s confirmation is helpful and will allow facilities to focus their energy and resources on identifying and implementing necessary modifications to ensure compliance with the rule.

In FDA’s discussion of the use of water in a facility, it again states that “the water supply must be sufficient for its intended purpose, in keeping with good public health practice.” (Draft Guidance, page 19) PFI has expressed concern to FDA that this requirement is based on a concept – “good public health practice” – that is not defined. We feel compelled to once again raise this issue with FDA and to urge FDA to consider replacing this vague term in the animal food rule with a requirement that water be fit for purpose or adequate for its intended purpose.

FDA also stresses that “[d]rainage should be designed, installed, and maintained to immediately remove the standing water so that standing water cannot contaminate the animal food or animal food contact surfaces.” (Draft Guidance, page 20) While this language is clear, it does not indicate whether vacuuming can be a suitable method for removing standing water. PFI accordingly seeks confirmation that other forms of water removal such as vacuuming are acceptable for the purpose of removing standing water to avoid contamination of animal food or animal food contact surfaces.

FDA indicates, in its discussion of plant operations, that “compliance with the CGMPs is the responsibility of the management of the establishment” and FDA recommends that “management of the establishment develop and implement a system of oversight and checks (e.g., standard operating procedures)...” (Draft Guidance, page 23) PFI expects that FDA could request to see such standard operating procedures (SOPs) during an investigation. We seek clarification as whether such SOPs could be subject to a FOIA request. As with our comment above regarding training records, we are concerned that such documents, provided in response to a FOIA request and without proper context, could be subject to misinterpretation. Some facilities may also classify such records as confidential business information, so we urge FDA to provide clarification as to the criteria it will use in determining whether to include a facility’s SOPs in a response to a FOIA request.

FDA states, in its discussion of plant operations, that “[m]anagement of the establishment must ensure that chemical, microbial, or extraneous-material testing procedures are used where necessary to identify sanitation failures or possible animal food contamination.” (Draft Guidance, page 24) FDA goes on to state its expectation that facilities “use these testing procedures as necessary to confirm adherence to CGMPs.” (Draft Guidance, page 24) PFI agrees with FDA that chemical, microbial or extraneous-material testing procedures can be effective as preventive controls, but we question whether it is appropriate to include reference to them in a guidance document on CGMPs. Such testing procedures are implemented pursuant to a hazard analysis that has identified and evaluated hazards, not as part of a facility’s CGMPs. PFI therefore requests that FDA consider removing reference to these testing procedures in the final FSMA CGMPs Guidance for Industry and consider including such reference in any Guidance for Industry regarding compliance with subpart C, hazard analysis and risk-based preventive controls.

In its discussion of requirements for raw material and other ingredients, FDA specifies that “[s]hipping containers (e.g., totes, drums and tubs) and bulk vehicles holding raw materials and other ingredients

must be examined upon receipt to determine whether contamination or deterioration of animal food has occurred.” (Draft Guidance, page 25) PFI believes this requirement does not acknowledge two important points. First, since visual inspection may be insufficient to determine whether contamination or deterioration has occurred, we seek clarification from FDA whether examination of bulk containers could include shippers, carriers and receivers exchanging information to determine whether contamination of animal food may have occurred. We believe a more efficient and effective approach is to have shippers, carriers and receivers work together to ensure the integrity of each shipment, including by adhering to applicable provisions in the FSMA sanitary transport rule. Our second observation is that this requirement fails to account for the possibility that raw materials and other ingredients may contain a hazard that the receiving facility will address, through a pathogen mitigation/kill step, for example. Animal food producers and their suppliers must work together to ensure each understands their role in addressing any hazards associated with an animal food and we urge FDA to acknowledge this reality in its FSMA Guidance for Industry documents.

Finally, and in light of the fact that FDA must review comments received on this Draft Guidance before issuing the guidance in its final form, PFI urges FDA to: provide sufficient time for facilities to review the final Guidance for Industry and fully understand their obligations under subpart B of the animal food rule; and commence animal food rule subpart B compliance and enforcement activities only after FDA and state officials carrying out these activities have received appropriate education and training on the rule and its requirements.

PFI would like to thank FDA, as always, for this opportunity to provide input on FSMA implementation. As both regulators and pet food makers take steps to ensure compliance with FSMA’s animal food rule, PFI will continue to offer the perspective and insights of our members, with an eye towards improving product safety and quality in a manner that is efficient and effective for regulators and pet food makers.

Sincerely,

A handwritten signature in black ink that reads "Cathleen Enright". The signature is written in a cursive, flowing style.

Cathleen Enright, PhD
President & CEO