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Summary of Key Points from PFI Comments on FDA's Proposed Rule
For Current Good Manufacturing Practice and
Hazard Analysis and Risk-Based Preventive Controls for Food for Animals

General Observations

- We acknowledge FDA's decision to issue a separate proposed rule for animal food but note with regret that the apparent use of the Human Food Preventive Controls proposed rule as a template for the Animal Food Preventive Controls proposed rule has resulted in many provisions that do not adequately address the characteristics of animal food production.
- We would have appreciated more time to review the proposed rule and to develop comments for FDA's consideration. We note that FDA provided approximately eleven months for stakeholders to review and provide comment on the Human Food Preventive Controls proposed rule – animal food stakeholders have been given less than half that time. We joined other animal food stakeholders in submitting a comment period extension request and were disappointed to learn that FDA has declined our request.
- We believe FDA is in some instances too prescriptive with respect to provisions in the proposed rule, especially considering the range of animal food producers that will be subject to these provisions once they are finalized and implemented. We urge FDA to provide sufficient discretion and flexibility to account for the wide variety of animal food production methods and practices.
- We are dismayed by the Preliminary Regulatory Impact Analysis for this proposed rule, which presents figures that, in our view, drastically underestimate the costs associated with FSMA implementation. We have provided figures based on input from our members that we feel more accurately reflects the true costs of FSMA implementation.
- We urge FDA to impose one date for compliance with the rule for all stakeholders, when finalized and implemented. While we acknowledge that company size will impact the ability to comply with the rule, we do not agree with FDA that larger businesses will be able to meet new regulatory requirements more quickly than will smaller businesses. Accordingly, we believe that one deadline – three years from entry into force of the final rule – will allow businesses of all sizes to adjust their practices and methods accordingly, with a minimum of confusion for animal food producers and their ingredient suppliers.
- We submit that there should essentially be no exemptions from this rule for qualified facilities based on company size (i.e., number of

employees or annual sales). We therefore propose that FDA set the threshold for defining a very small business (for the purpose of identifying qualified facilities) as those with average annual sales less than \$10,000.

Current Good Manufacturing Practices (CGMPs)

- We note that, while FDA references PAS 222 and the AAFCO Model CGMPs, it declined to incorporate them into the proposed rule. We urge FDA to reconsider its decision and to incorporate either of these CGMP approaches in the final rule. Both are specific to animal food and both were the product of significant consultation with a range of animal food stakeholders, including FDA CVM.
- If FDA declines our invitation to incorporate either PAS 222 or AAFCO CGMPs into the final rule, our comments strongly recommend the proposed CGMP provisions be modified to provide a greater measure of discretion that accounts for the wide variety of animal food products, methods and practices.
- We note that many of the CGMPs in this proposed rule are set forth as requirements, as opposed to recommendations. We propose that all CGMPs be set forth first as recommendations, to allow animal food producers time to implement new practices without running the risk of failing to meet a requirement immediately following entry into force of the final rule. We remind FDA that human food producers have operated with CGMPs as recommendations for approximately thirty years – only now is FDA proposing to make these CGMPs requirements. Animal food producers should be given sufficient time to adjust their practices and methods before CGMPs are enforced as requirements.

Preventive Controls

- We believe FDA has exceeded the mandate Congress gave it in the statute with respect to the use of terms and concepts from the HACCP approach to food safety. In particular, we believe FDA, in its proposal to require the “reasonably likely to occur” (RLTO) standard in hazard analysis, went beyond the “known or reasonably foreseeable” standard Congress provided in the statute. We therefore recommend elimination in the proposed rule of the RLTO standard and its replacement with the statutorily mandated “known or reasonably foreseeable” standard Congress identified in the statute.

Provisions not proposed in this rule but on which FDA seeks comment; training

- We note that FDA seeks comment on several requirements it considered including in this proposed rule – product testing, environmental monitoring and testing and supplier approval and verification. We urge FDA to provide complete language regarding any such proposals and to request public comment on these proposals before the rules are finalized and implemented.
- We urge FDA to provide training for both stakeholders subject to this final rule and also for FDA inspectors charged with enforcing the rule. Such training will be crucial to successful implementation of the final rule.

Based on the concerns we have expressed and the extent of the revisions we urge FDA to consider, we will request that FDA re-propose this rule for comment so that stakeholders may provide further input to FDA, with the shared goal in mind of ensuring animal food producers have the wide range of tools at their disposal necessary to improve animal food safety.