



Dear AFIA Members,

The U.S. Food and Drug Administration published the proposed animal food rules required by the Food Safety Modernization Act entitled, “Current Good Manufacturing Practices and Hazard Analysis and Risk Based Preventive Controls for Food for Animals” on October 29, 2013. They were more than 400 pages and asked for comments on more than 40 questions in addition to the CGMP proposed rules (not required by FSMA) and the PC proposed rules required by FSMA. Originally, FDA allowed only 120 days to comment on the rules. AFIA led a coalition to request an additional 33 days, which was the limit allowed under a court order with the U.S. District Court, Northern California. FDA granted our request and extended the comment period to March 31.

AFIA and the same coalition requested an additional 90 days for comments recently, as FDA and the plaintiffs in the lawsuit reached an agreement that would remove the comment period deadlines previously imposed by the court and extend the final comment FDA publication deadline to August 2015 (previously it was June 2015). As of today, we have not heard if the extra 90-day extension will be granted or denied. If it is granted, AFIA will use additional time to strengthen and expand these comments.

More than 60 AFIA member firms and AFIA staff have labored many hours in two Working Groups and several sub-groups to prepare these comments. AFIA is very grateful for the efforts of many in this effort.

We are allowing you a week to review them, as there are AFIA committees reviewing the draft comments and providing their inputs as well. AFIA staff will take all the comments received, weigh them with respect to whether they constitute substantive changes or not and may change the comments or ask the specific working groups if any suggested change is needed. Where the comments are deemed substantive, AFIA will respond to the commenter about what decision was made with respect to the suggested change needed and its rationale for agreeing with the suggestion(s) or not. We have allowed the staff two weeks to determine if changes in the comments will be needed and to adjust the comments in time to file them by the deadline.

These [draft comments](#) are going out to all members via the Official Contacts. Your comments are earnestly solicited and will be given serious consideration by the review team. As this is still a work in progress, please do not distribute the draft comments outside of your company.

Please provide any comments back to AFIA via [Leah Wilkinson](#) by March 14.

For ease of review, here is the link to the rules for which these comments were developed:

<http://www.gpo.gov/fdsys/pkg/FR-2013-10-29/html/2013-25126.htm>

This is the largest rulemaking effort ever imposed on the animal food industry since FDA was created in 1938. In addition, it's the shortest comment period I've ever seen relative to the size of the proposed rules. I'm very proud of my staff and the members that have labored for several months to develop what I believe to be sound, well-reasoned and practical comments. It doesn't end here, though.

FDA will likely propose some additional animal food rules in the summer on supplier verification, environmental monitoring and product testing. Moreover, there are open proposed rules on intentional adulteration (from which FDA is proposing to exempt animal food) and safe food transportation. FDA has also asked for comments on a risk modeling document. AFIA has joined coalitions requesting additional comment time for these two proposed rules and the risk document.

Your urgent attention is requested to these comments. We need you review and input to assist us in addressing all facets of our industry.

Thank you for your review, comments and cooperation!

Regards,
Richard

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