



Doug Anderson
Vice President/Rendering

(757) 357-3003 tel
(757) 357-3018 fax

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

REQUEST FOR EXTENSION OF COMMENT PERIOD

Docket No. 2004N-0264

The undersigned submits this request that the Commissioner of Food and Drugs extend the comment period in the above matter for an additional 60 days.

A. Decision involved

The Food and Drug Administration (FDA) has announced that it will publish an advance notice of proposed rulemaking (ANPRM) on possible changes to its feed regulation (21 C.F.R. § 589.2000) and other additional measures being considered to mitigate the risk of bovine spongiform encephalopathy (BSE). 69 Fed. Reg. 42288 (July 14, 2004).

B. Action requested

The undersigned requests that FDA extend the comment period on this ANPRM from 30 days to 90 days.

I request that FDA give expedited consideration to this Request for Extension of Comment Period.

I urge FDA not to publish a proposed rule banning SRMs from animal feed until the agency has reviewed and considered the comments on this ANPRM relevant to an SRM ban.

C. Statement of grounds

As Dr. Stephen Sundlof, Director of FDA's Center for Veterinary Medicine, acknowledged during the press and briefing on the ANPRM on July 9, the changes being considered to FDA's feed rule are highly complex. Moreover, the ANPRM represents a

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DougAnderson@smithfieldfoods.com

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sharp change in direction from FDA's January 26, 2004 announcement regarding planned changes to the feed rule. Instead of taking steps to enhance the existing mammalian-to-ruminant feed ban, FDA now is considering an entirely different approach in response to the report of the International Review Team. This new approach would involve removal of specified risk materials (SRMs) from the entire animal feed chain, as well as a ban on all mammalian and avian protein in ruminant feed. This is why FDA has taken more than five months to publish the ANPRM since receiving the International Review Team report. It seems inconsistent and unwarranted for FDA to expect the affected industries to prepare comments and collect data on these complex questions in only 30 days.

I believe that such a short comment period is exceptionally rare for an ANPRM, especially one that raises so many questions and is seeking such extensive data. FDA proposed regulations customarily provide a norm of 60 days, which FDA may shorten or lengthen for good cause. 21 C.F.R. § 10.40(b)(2). We note that FDA allowed a comment period of 90 days following its previous ANPRM considering changes to the feed rule. 67 Fed. Reg. 67572 (Nov. 6, 2002). The U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) and Animal and Plant Health Inspection Service (APHIS) provide for a 60-day comment period in this ANPRM, even though those agencies are posing significantly fewer questions and requesting much less data.

The rationale offered by FDA for the 30-day comment period raises questions about the agency's objectivity in evaluating comments on the ANPRM. FDA states that it needs to receive comments as soon as possible so that it can publish a proposed rule to ban SRMs in all animal feed, a proposed rule that would be published as early as next month. If the comment period for the ANPRM closes on August 13, and FDA intends to publish a proposed rule on the issues covered by the ANPRM later that same month, we wonder what level of review and serious consideration the comments and data submitted on the ANPRM will receive. The timeline that FDA appears to have in mind does not seem realistic if comments are to receive full consideration.

In the ANPRM, FDA requests comments and scientific data with respect to a total of 25 questions pertaining to the feed rule. Given the number and complexity of the issues and the volume of scientific and economic data FDA is requesting, it is simply not possible for interested parties to prepare comments in such a short time period. Many of the questions posed in the ANPRM are new to industry. During the past few months, FDA has given conflicting signals about how it intended to revise the feed rule. As recently as April 2004, in public statements to the National Institute of Animal Agriculture, FDA Acting Commissioner Lester Crawford indicated that FDA would not ban SRMs in feed and that FDA's plans depended in part on whether additional cases of BSE were discovered under USDA's enhanced surveillance program. Because of this uncertainty, it was not possible for industry to begin preparing comments prior to release of the ANPRM on July 9. The undersigned organizations now have a lot of work to do before they can submit helpful comments and data to FDA. They may need to survey their members to develop positions and hire outside experts to collect economic and scientific data requested by FDA. For example:

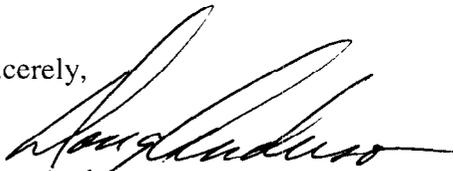
- Question 3: As previously noted, removal of SRMs from all animal feed is a new issue that was not included in FDA's January 26 announcement. The undersigned organizations will need to conduct surveys of their members to develop comments. Information on the occurrence of cross-contamination and on-farm feeding errors will require a literature review and will take time.
- Question 4: This question regarding the definition of SRMs for animal feed purposes is new. We note that the list of tissues that potentially harbor the BSE agent changes frequently as results of ongoing experiments are reported.
- Question 5: The undersigned organizations will need to consult with experts regarding the availability of methods for verifying that feed or feed ingredients do not contain SRMs.
- Question 7: The economic and environmental impacts of a ban on SRMs in all animal feed is a critical question. The undersigned organizations cannot possibly assemble this data in 30 days.
- Question 8: We will need to search for data on human exposure to animal feed, including pet food. We do not have this data handy and do not know if it exists.
- Question 9: The undersigned organizations can generate and analyze data on whether dedicated facilities would be necessary if FDA were to prohibit SRMs in all animal feed, but we cannot do so in 30 days.
- Question 10: The undersigned organizations have begun to collect data, with the help of outside consultants, on the economic and environmental impacts of requiring dedicated facilities, equipment, storage, and transportation. After five months, we have some data, but the data collection is not complete. We would also like to see FDA's data on this issue.
- Question 11: In 1997, FDA stated that the cleanout procedures prescribed in FDA's medicated feed good manufacturing practices (GMPs) were adequate for BSE purposes. Now, FDA is asking whether cleanout would provide adequate protection against cross-contamination if SRMs were to be banned from all animal feed. The undersigned organizations will need more than 30 days to collect and analyze data relevant to this question.
- Questions 12 through 14: The question of banning avian protein in ruminant feed is new and has not been previously raised by FDA. Given the large number of poultry slaughtered in the United States, banning avian protein from ruminant feed raises serious economic and environmental issues. The undersigned organizations need more than 30 days to generate and analyze such a large data set.

- Question 18: The undersigned organizations believe it would normally take as long as three months to generate data on the environmental impact of banning blood and blood products from animal feed. We would also like to see FDA's data on this issue.
- Question 19: The question of whether tallow made from SRMs, dead stock, and/or nonambulatory disabled cattle but containing less than 0.15 percent insoluble impurities would pose a risk of BSE transmission is a new question. It will take more than 30 days to generate and analyze data in response to this question.
- Question 20: The question of whether SRMs can be effectively removed from dead stock and nonambulatory disabled cattle has not previously been raised by FDA. The undersigned organizations would need more than 30 days to respond.
- Question 21: We will need to hire outside experts to research methods available for verifying that a feed or feed ingredient does not contain materials from dead stock or nonambulatory disabled cattle.
- Question 22: Regarding the economic impact of prohibiting materials from dead stock and nonambulatory disabled cattle in all animal feed, the National Rendering Association prepared a study of this question in 2001, but that study will need to be updated to reflect changes in the pricing structure. This would take about six months.

For all of the foregoing reasons, the undersigned urges FDA to allow a 90-day comment period for the ANPRM.

Thank you for consideration of this request.

Sincerely,



Doug Anderson
Vice President / Rendering