



National Milk Producers Federation

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"Connecting Cows, Cooperatives, Capitol Hill, and Consumers"

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Cooperative Milk Producers Assn.
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Dairymen's Marketing Cooperative, Inc.
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Scioto County Co-op Milk Producers' Assn.
Select Milk Producers, Inc.
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Tillamook County Creamery Assn.
United Dairymen of Arizona
Upstate Niagara Cooperative, Inc.
Zia Milk Producers

April 9, 2009

Division of Dockets Management (HFA-305)
Food and Drug Administration
Docket No. FDA-2002-N-0031 (formerly Docket No. 2002N-0273)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2002-N-0031 (formerly Docket No. 2002N-0273), Substances Prohibited From Use in Animal Food or Feed; Final Rule: Proposed Delay of Effective Date

Dear Sir or Madam:

The following comments are being submitted on behalf of the National Milk Producers Federation (NMPF) to the Food and Drug Administration (FDA) in response to the proposed delay of effective date in the Final Rule entitled *Substances Prohibited from Use in Animal Food or Feed* (Docket No. FDA-2002-N-0031 [formerly Docket No. 2002N-0273]). The National Milk Producers Federation, based in Arlington, VA, develops and carries out policies that advance the well being of dairy producers and the cooperatives they own. The members of NMPF's 31 cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of more than 40,000 dairy producers on Capitol Hill and with government agencies. NMPF members have a vested interest in protecting the U.S. from any disease which may threaten our national dairy herd, including Bovine Spongiform Encephalopathy (BSE). Therefore, NMPF appreciates the opportunity to comment on this proposed delay of effective date in the Final Rule related to changes in the agency's regulations to prohibit the use of certain cattle origin materials in the food or feed of all animals.

Comment Period

In a letter to FDA, NMPF and twelve other national organizations representing hundreds of thousands of livestock producers requested reopening of the comment period for 30-days. FDA has received similar requests from numerous members of the Senate and House of Representatives. A 7-day comment period does not provide sufficient time for our hard working dairy producers to respond to this FDA notice. *NMPF requests that FDA immediately open the comment period for a full 30 days.*

Implementation Delay

NMPF supports a delay in the implementation of the Final Rule until such time that FDA develops a National Specified Risk Materials (SRM) Disposal Plan in conjunction with the U.S. Department of Agriculture (USDA), the U.S. Environmental Protection Agency (EPA), and the livestock industry. We believe, at minimum, implementation of the rule must be delayed by 60 days for the development of National SRM Disposal Plan, although we have serious doubts that such a plan could be completed even within that extended timeframe. *To date no National SRM Disposal Plan has been developed or proposed at any level in the Federal government.*

Jerry Kozak, President/Chief Executive Officer

Randy Mooney, Chairman

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FDA estimates that the collection of dead cows and calves will decrease by 29.4 – 44.8% due to changes anticipated in the rendering industry (*FR*. Vol. 73. No. 81 Pp. 22730). FDA advises that “Dead animals no longer collected should be disposed of in an environmentally and legally acceptable manner” (*FR*. Vol. 73. No. 81 Pp. 22730). “FDA is ready to work with industry and other governmental agencies in identifying appropriate ways” for carcass disposal (*FR*. Vol. 73. No. 81 Pp. 22730). *To date no National SRM Disposal Plan has been developed or proposed at any level in the Federal government.*

Our request to FDA for a National SRM Disposal Plan is not new; in fact NMPF has requested that FDA develop such a plan numerous times. In response to the original FDA advanced notice of proposed rulemaking (Docket No. 2004N-0264, Federal Measures to Mitigate BSE Risks: Considerations for Further Action), NMPF voiced our great concern that if SRM materials from dead stock were prohibited from rendering for subsequent use in animal feed without the development of a comprehensive plan for the disposal, the rendering industry would not have sufficient economic incentive to continue dead stock pick-up on behalf of the producer community. NMPF renewed these concerns in comments to the proposed rulemaking (Docket No. 2002N-0273, Substances Prohibited from Use in Animal Feed). *To date no National SRM Disposal Plan has been developed or proposed at any level in the Federal government.*

Given that a minimal increment of further risk reduction can be achieved when this Final Rule is implemented compared to the current level of minimal risk which has been and continues to be achieved under the 1997 FDA rule (21 CFR Part 589.2000), FDA should delay further implementation until objective efforts can be made to address SRM and deadstock disposal issues that are being created by this Final Rule. The following facts support this consideration:

- “FDA’s vigorous inspection and enforcement program has helped us achieve a compliance rate of more than 99 percent with the feed ban rule, and we intend to increase our enforcement efforts to assure compliance with our enhanced regulations. Finally, we are continuing to assist in the development of new technologies that will help us in the future improve even further these BSE protections. With today’s actions, FDA will be doing more than ever before to protect the public against BSE by eliminating additional potential sources of BSE exposure.” (*then FDA Commissioner McClellan; January 26, 2004*)
- As of February 25, 2009, 758,070 cattle have been tested by USDA as part of the BSE Surveillance Program. To date, only 2 native born animals have been confirmed BSE positive and both animals were born prior to implementation of the FDA feed ban in 1997.
- The Harvard-Tuskegee Study contracted by USDA (April 1998) determined that the United States is highly resistant to any proliferation of BSE, and those measures taken by the U.S. Government and industry make the United States robust against the spread of BSE.

National SRM Disposal Plan

Efforts to develop a National SRM Disposal Plan need to be expedited as was recommended by the U.S. Animal Health Association: “*The United States Animal Health Association (USAHA) urges the Secretary of Agriculture to create a National Specified Risk Materials (SRM) Disposal Task Group to develop a viable national plan with state and affected industry stakeholders to utilize and/or dispose of SRM’s to be prohibited from entering the animal feed supply if the Food and Drug Administration (FDA) proposed rule of October 4, 2005 is adopted. The plan should:*

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- *Minimize the potential economic impact upon cattle producers and the rendering industry*
- *Maintain economical, on-farm, dead stock recovery by the rendering industry and enhance animal disease surveillance by the United States Department of Agriculture (USDA) and the states*
- *Develop value added markets for non-ambulatory and dead stock which cannot be utilized in the feed supply and develop safe utilization and disposal options which maximize public health and environmental concerns.”*

Specific to dairy producers, NMPF is concerned with the environmental and animal health implications for the disposal of dead stock from the farm and SRM from rendering facilities that the Final Rule creates. NMPF strongly encourages a National SRM Disposal Plan be put in place prior to implementation of the Final Rule. Since both the removal of SRM's for animals over 30 months of age and deadstock disposal for animals of any age have significant environmental and animal health implications, NMPF requests that FDA, in conjunction with USDA, EPA, and the affected industries, develop a comprehensive National SRM Disposal Plan that will:

- Maintain on-farm dead stock recovery by the rendering industry to facilitate animal disease surveillance which should be coupled to the National Animal Identification System (NAIS);
- Provide for safe and economical disposal and/or utilization options for rendered SRM's which will be excluded from the feed supply; and
- Discourage dead stock disposal options which pose either environmental or public health concerns.

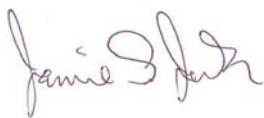
Summary

While NMPF supports the FDA Final Rule, we strongly believe that implementation of the Final Rule must be delayed until a National SRM Disposal Plan has been developed. Despite numerous requests to and FDA's own statements about developing a National SRM Disposal Plan, to date no National SRM Disposal Plan has been developed or proposed at any level in the Federal government.

It is unfortunate that in the preceding 5 years while as this rule developed from concept to proposal to finalization, FDA did not heed requests to assist affected industries so that the Final Rule could be implemented in a timely manner and without significant disruption. *A delay of implementation by 60 days or until a National SRM Disposal Plan has been developed is necessary.*

Thank you for the opportunity to provide these comments on the proposed implementation delay on the Final Rule to prohibit the use of certain cattle origin materials in the food or feed of all animals and on the need for a National SRM Disposal Plan. If you have any questions or would like to discuss this matter further, please contact me at 703-243-6111 or jjonker@nmpf.org.

Sincerely,



Jamie S. Jonker, Ph.D.
Senior Director, Regulatory Affairs

Jerry Kozak, President/Chief Executive Officer

Randy Mooney, Chairman