



National Milk Producers Federation

National Milk Producers Federation • 2101 Wilson Blvd., Arlington, VA 22201 • 703-243-6111 FAX 703-841-9328

Agri-Mark, Inc.
Arkansas Dairy Cooperative Association
Associated Milk Producers, Inc.
California Dairies, Inc.
Cass-Clay Creamery, Inc.
Continental Dairy Products, Inc.
Cooperative Milk Producers Assn.
Dairy Farmers of America, Inc.
Dairymen's Marketing Cooperative, Inc.
Dairylea Cooperative Inc.
Ellsworth Cooperative Creamery
Farmers Cooperative Creamery
First District Association
Foremost Farms USA
Just Jersey Cooperative, Inc.
Land O'Lakes, Inc.
Lone Star Milk Producers, Inc.
Manitowoc Milk Producers Coop.
MD & VA Milk Producers Cooperative Association, Inc.
Michigan Milk Producers Assn.
Mid-West Dairymen's Company
Niagara Milk Cooperative, Inc.
Northwest Dairy Association
Prairie Farms Dairy, Inc.
St. Albans Cooperative Creamery, Inc.
Scioto County Co-op Milk Producers' Assn.
Select Milk Producers, Inc.
Southeast Milk, Inc.
Swiss Valley Farms, Co.
Tillamook County Creamery Assn.
United Dairymen of Arizona
Upstate Farms Cooperative Inc.
Zia Milk Producers

December 20, 2005

Division of Dockets Management (HFA 305)
Docket No. 2002N-0273
RIN 0910-AF46
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2002N-0273, Substances Prohibited From Use in Animal Feed

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 in response to the proposed rule entitled *Substances Prohibited from Use in Animal Food or Feed* (Docket No. 2002N-0273). NMPF, headquartered in Arlington, VA, develops and carries out policies that advance the well-being of U.S. dairy producers and the cooperatives they collectively own. The members of NMPF's 33 cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of 50,000 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 rule related to changes to the agency's regulations to prohibit the use of certain cattle origin materials in the food or feed of all animals.

NMPF understands the Food and Drug Administration (FDA) purpose in proposing this rule is to strengthen existing safeguards designed to help prevent the spread of BSE in U.S. cattle. All of the proposed prohibitions, except for those related to tallow, have been applied to cattle feed since 1997. As applied to all feed, the proposed rule would prohibit the following cattle origin materials in the food or feed of all animals:

- The brains and spinal cords from cattle 30 months of age and older

Jerry Kozak, President/Chief Executive Officer

Charles Beckendorf, Chairman

- The brains and spinal cords from cattle of any age not inspected and passed for human consumption
- The entire carcass of cattle not inspected and passed for human consumption if the brains and spinal cords have not been removed
- Tallow that is derived from the materials prohibited by this proposal that contains more than 0.15 percent insoluble impurities, and
- Mechanically separated beef that is derived from the materials prohibited by this proposal.

In response to the earlier FDA advanced notice of proposed rulemaking (Docket No. 2004N-0264, *Federal Measures to Mitigate BSE Risks: Considerations for Further Action*), NMPF commented to FDA about our great concern that if all materials from dead stock and non-ambulatory cattle (disabled, downed, diseased or dead—4-D category) were prohibited from rendering for use in animal feed without developing a comprehensive plan for the disposal and utilization of such material, the rendering industry would not have the economic incentive to continue dead stock pick-up on behalf of the producer community. NMPF is now aware of at least one large rendering organization on the East Coast which has notified their dairy producer suppliers that, if promulgated, this FDA proposed rule will cause them to substantially increase service charges or stop dead stock removal from dairy farms.

Previously NMPF commented, and we strongly reiterate now, that FDA and the United States Department of Agriculture need to cooperatively develop a comprehensive national 4-D and Specified Risk Material (SRM) utilization and disposal plan in concert with all affected stakeholders, including state veterinary animal and public health officials, producers and the rendering industry. Such a plan must continue to encourage producers to submit non-ambulatory and dead stock for animal health monitoring and surveillance purposes and provide for the development of alternative market outlets for such rendered material to ensure the continued viability of the rendering industry to process dead stock. If this FDA proposed rule is implemented without a national 4-D livestock and SRM utilization and disposal plan in place, disposal alternatives will become fewer. Disposal alternatives are already increasingly limited due to more enforced restrictions at the local and state levels. NMPF, therefore, recommends that the implementation of this proposed rule be contingent upon the development and implementation of a national SRM and dead stock disposal plan.

Given that a minimal increment of further risk reduction can be expected to be achieved if this proposal 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), NMPF believes that FDA should delay further implementation of this rule until objective efforts can be made to address SRM and dead stock animal disposal issues that will be created by this proposal. The following facts support this consideration:

1. From the FDA website—on January 26, 2004, then Commissioner Mark B. McClellan, M.D., Ph.D., stated: “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.”
2. As of December 19, 2005, USDA/APHIS/VS has tested, as part of their expanded BSE Surveillance Program, 556,143 cattle. To date, only 1 native born animal has been confirmed BSE positive and that animal was born prior to implementation of the FDA feed ban in 1997. As originally designed, this program was capable of detecting 1 in 10 million BSE infected head at a 200,000 sampling rate of cattle over 30 months of age with a 95 percent confidence level.
3. The Harvard-Tuskegee Study contracted by USDA in April of 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 Utilization and Disposal Plan

Efforts to develop a national SRM utilization and 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:*

- *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 economic, environmental, and animal health implications for the disposal of dead stock from the farm and SRM from rendering facilities. NMPF strongly encourages an SRM disposal plan accompany any final FDA rulemaking, particularly if such rulemaking will significantly reduce the income from dairy slaughter animals over 30 months of age or significantly increase the costs to producers for dead stock recovery. Since both the removal of SRM's for animals over 30 months of age and dead stock disposal costs for animals of any age will be significant and will be transferred back to the producer level, NMPF requests that FDA, in conjunction with USDA, develop a comprehensive SRM disposal plan that will:

1. Minimize the potential significant economic impact to dairy producers;
2. 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);
3. Provide for safe and economical disposal and/or utilization options for rendered SRM's which will be excluded from the feed supply; and
4. Discourage dead stock disposal options which pose either environmental or public health concerns.

Economic Impact

If FDA rulemaking alters the ability of the rendering industry to market SRM materials from dairy cattle, the value of dairy cows for slaughter will decrease with this cost borne by the dairy producer. This does not consider the potential costs to the rendering industry of the disposal of SRM, which would also likely be passed onto the dairy producer as a decrease in value of dairy cows for slaughter. Also, the dairy industry is currently dependent upon the rendering industry to dispose of dead animals at a cost to the dairy producer. NMPF believes that FDA rulemaking could raise the cost of dead stock recovery significantly or eliminate the service entirely in many parts of the country. In some areas, NMPF anticipates dead stock recovery will cease altogether leading to alternate disposal of dead stock which may have commensurate potential future environmental and animal health impacts. NMPF is now aware of at least one large rendering organization on the East Coast which has notified their dairy producer suppliers that, if promulgated, this FDA proposed rule will cause them to substantially increase service charges or stop dead stock removal from dairy farms.

Animal Health Impact

The rendering industry plays a vital role in the monitoring of animal diseases. Dead stock recovered by the rendering industry is monitored by animal health officials for disease status as a part of the national effort to maintain a healthy dairy cattle population. NMPF believes that any FDA rulemaking which causes a reduction in dead stock recovery, either through reduced service or economic disincentive, would disrupt the monitoring of animal diseases or jeopardize the national effort to maintain a healthy dairy cattle population.

Conclusions

NMPF believes such additional economic burdens should not be imposed upon producers without an organized and coordinated national initiative to adjust resources and disciplines to minimize the overall economic impacts upon all stakeholder groups. Additionally, potential animal health impacts warrant a national SRM disposal plan. We hope you can help facilitate a high level government interface with the affected industries so an effective national policy to eliminate SRM's from the feed supply will not create unwanted economic and environmental burdens upon dairy producers. Therefore, NMPF encourages FDA to work with experts within producer organizations, the rendering industry, U.S. Department of Agriculture, and the U.S. Animal Health Association on a comprehensive SRM disposal plan that will meet the above stated key objectives. This rule should be delayed until a disposal plan can be implemented.

Thank you for the opportunity to provide these comments on the proposed changes to amend the agency's regulations to prohibit the use of certain cattle origin materials in the food or feed of all animals and on the need for a comprehensive SRM disposal plan. If you have any questions or would like to discuss this matter further, please contact me at 703-243-6111 or jadams@nmpf.org.

Sincerely,

A handwritten signature in black ink, appearing to read "John B. Adams". The signature is fluid and cursive, with a long horizontal stroke at the end.

John B. Adams
Director, Animal Health and Farm Services