



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
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

August 13, 2004

Division of Dockets Management (HFA 305)
Docket No. 2004N-0264
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2004N-0264, Federal Measures to Mitigate BSE Risks: Considerations for Further Action; Advance notice of proposed rulemaking.

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's advanced notice of proposed rulemaking entitled *Federal Measures to Mitigate BSE Risks: Considerations for Further Action* (Docket No. 2004N-0264). 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 32 cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of 60,000 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 advance notice of proposed rulemaking related to additional BSE mitigation measures that are under consideration by FDA.

In the past, NMPF has worked with the Food and Drug Administration (FDA) to take a very strong proactive regulatory approach to prevent both the entry and potential for amplification of any possible source of BSE which might expose U.S. cattle. Our efforts began in 1996 when we encouraged our membership to avoid feeding any ruminant protein source. This effort was launched as a voluntary industry feed ban prior to the time when FDA could codify and implement the FDA Ruminant to Ruminant Feed Ban in 1997.

NMPF has also worked within the Government/Industry BSE Roundtable to encourage FDA to actively enforce the ruminant feed ban and has supported very strong compliance at all levels within the animal feed chain from manufacturer to the producer level. We commend FDA's Center for Veterinary Medicine for taking a

Jerry Kozak, President/Chief Executive Officer

Charles Beckendorf, Chairman

very aggressive regulatory compliance posture toward achieving a near 100 percent compliance with the current ruminant feed ban. NMPF continues to encourage FDA to strictly enforce the current feed ban.

The discovery of BSE in 1986 in the United Kingdom and the resulting disastrous economic impact that this disease created for those countries which imported infected ruminant material from the UK has provided an extremely important incentive for U.S. producers to honor the current FDA ruminant feed ban. This incentive has been further reinforced with the confirmation this past December of BSE in a Mabton, WA dairy cow imported from Canada. The resulting market volatility and uncertainty, including the immediate loss of beef exports to some 50 countries has reinforced the need to take extreme feeding precautions at the producer level. These recent disruptions to our domestic and international livestock markets have also had a chilling effect on cull cow dairy prices. NMPF, therefore, understands the importance of taking additional action, if necessary, to reduce any remaining significant risk that BSE might be present in the U.S. feed supply. NMPF, however, believes that any additional mitigation measures must be based on sound science and a clear need determined from a comprehensive risk/benefit analysis before additional FDA actions are proposed.

The following NMPF responses are provided to certain specific questions posed in the proposed rule.

Question # 1: Would there be value in establishing a specialized advisory committee or standing subcommittee on BSE? NMPF suggests that such a standing technical or scientific advisory committee could make appropriate recommendations to both USDA and FDA regarding what combination of alternative mitigation strategies would be most cost effective without sacrificing significant BSE risk reduction protection for the U.S. livestock industry. This Committee could evaluate the degree of on-going BSE surveillance needed by USDA related to the BSE risk reduction strategies determined necessary by FDA. These strategies should be based upon a comprehensive risk assessment of various alternative mitigation strategies for protecting the feed supply.

Question # 7: What would be the economic and environmental impacts of prohibiting SRM's from use in all animal feed? NMPF believes it is very important for FDA to conduct an extensive risk assessment and economic cost benefit analysis of the impact of removing all Specified Risk Material (SRM) from the animal feed supply. Such a drastic action may be expected to create significant economic dislocations throughout the entire feed, rendering and livestock industries. It will require the redesign of feed manufacturing facilities and processes, increase mammalian protein disposal costs, permanently reduce the value of livestock, increase milk production costs (if the current exemptions for blood and blood meal are eliminated) and negatively impact the future viability of many essential rendering outlets throughout the nation. The resulting disposal of SRM and dead stock will pose significant environmental impacts without extensive government support for safe and

efficient disposal options. Unless such a drastic action can be shown to significantly reduce the future BSE infectivity risk to our nation's cattle population from the level of risk now present under the current ruminant protein feed ban, NMPF believes such significant economic disruptions are not justified.

Given the uncertainty related to the actual level of BSE risk that might be circulating in the U.S. feed supply, NMPF encourages FDA to propose a number of BSE risk reduction alternatives as suggested in the Harvard Risk Assessment Model. Such an approach should attempt to measure the BSE risk reduction achieved by an integrated system of feed controls versus a complete SRM removal from animal feed. Such an approach would also permit the affected industries to comment on what alternatives might provide the greatest risk reduction at the lowest cost. Furthermore, such an approach would lay a sound basis for crafting and implementing the appropriate public policy necessary to mitigate resulting economic and environmental disruptions to the affected industry sectors, including the appropriate government support which might be necessary to address various SRM and animal protein utilization alternatives.

FDA has essentially adopted the FSIS definition of SRM. This action will govern the removal of such material from all human food and cosmetics. Therefore, the public health is being protected from any potential BSE risk. Because of these measures FDA's risk assessment should now be focused on what alternative integrated system of feed controls will significantly equate to the BSE risk mitigation resulting from removal of all SRM's from animal feed without the resulting severe economic consequences. For example, would the cumulative risk reduction effect of removing all dead or 4-D animals from the animal feed chain, plus removal of the brain and spinal cord of all animals over 30 months of age plus the risk reduction implicit in the rendering process substantially equate to the risk reduction gained from removal of all SRM's from animal feed?

NMPF believes that FDA should consider proposing various risk reduction alternatives which reflect the cumulative impact of mitigation from a number of potentially less costly integrated strategies compared to a complete SRM removal from all animal feed. FDA should also take into consideration the actual prevalence level of risk established by the expanded USDA BSE Surveillance Program, as well as the degree of compliance with the current FDA ruminant feed ban. The results of the expanded BSE Surveillance Program should have a profound impact on the need for additional BSE risk reduction actions on the part of FDA.

Unless substantial epidemiological evidence develops that cross-contamination cannot be adequately controlled by appropriate FDA enforcement of the current FDA ruminant feed ban, NMPF believes that the current risk of BSE amplification in the U.S. feed supply is minimal. Furthermore, if proper FDA enforcement is maintained, even a minimal risk, if it exists at all, will dissipate over time as predicted in the Harvard Risk Assessment. Therefore, NMPF believes that FDA should not prematurely propose to remove all SRM's from animal feed until other less costly risk

reduction strategies can be subjected to a comprehensive BSE risk assessment through the Harvard Risk Assessment Model and a comparative cost/benefit determined in relation to a complete SRM removal from all animal feed.

Question # 18: What would be the economic and environmental impacts of prohibiting bovine blood or blood products, plate waste, or poultry litter from ruminant feed? The need for high quality by-pass protein which supports and maintains high per cow milk production is of great importance to the dairy industry. Without the availability of blood meal in dairy ration formulations, NMPF expects milk production to be reduced by approximately 4 pounds of milk/head/day. Utilized as a high quality source of undegradable amino acids, blood meal is known to provide a concentrated source of lysine which cannot be efficiently replaced by other sources of protein, including synthetic lysine. According to a June 2001 report by The Sparks Company for the National Renderers Association, approximately 70 percent of the 171.7 million pounds of total ruminant blood meal produced in 2000 was utilized in ruminant diets, mostly dairy. This study estimated a \$45.3 million direct loss to the cattle sector if blood meal was prohibited in cattle diets. This figure did not include the additional indirect losses from reduced animal productivity. If blood meal were to be unavailable for use in dairy cattle rations, higher concentrations of protein would need to be fed which would increase production costs and increase urinary excretion of nitrogen. To prevent the increased nitrogen excretion, additional grain feeding would be necessary to provide an energy source to convert waste nitrogen into urea prior to excretion. The increased protein feeding could be expected to complicate reproductive performance, further hindering the efficiency of milk production. Utilizing an indirect cost of 4 pounds of milk/cow/day, the U.S. dairy industry could be expected to suffer an annual loss exceeding \$170 million if blood meal were to be prohibited from lactating dairy cattle diets. The combined loss in 2004 to the total cattle sector could well exceed \$200 million.

NMPF is also greatly concerned that specialty blood products utilized in milk and colostrums replacers not lose their current exemptions under the Mammalian to Ruminant Feed Ban in 21 CFR 589.2000. This class of processed blood products is utilized extensively in milk replacers and colostrum substitute products which have an important role in the control of Johne's disease. These products are extremely valuable in breaking the Johne's milk contamination cycle with calves born into Johne's infected herds.

NMPF believes the following statements of fact support the retention by FDA of the current mammalian protein ruminant feed ban exemption for ruminant blood and blood products:

1. In 1997, FDA excluded blood and blood products under 21 CFR 589.2000 because "the Agency believes that they represent a minimal risk of transmitting the TSEs to ruminants through feed. The excluded proteins and other items are materials that the available data suggest do not transmit TSE agents".

2. Bovine blood has never been shown to transmit BSE and is not classified as an SRM by the Office International Epizootics (OIE). Blood has never been implicated in bovine-to-bovine transmission of either natural or experimental BSE. Therefore, blood and plasma products are classified Category IV tissues indicating no detected infectivity.
3. Plasma, serum and fractions thereof contain biologically important components, including immunoglobulins, which may be used in colostrum supplements, colostrum replacers and feed supplements to reduce the risk of transmission of Johne's disease, brucellosis and other economically important diseases transmitted by via colostrum.
4. The International Review Team (IRT) did not recommend removal of the current feeding exemption for bovine blood or blood products.
5. Properly sourced, collected and processed blood products are safe and will not contribute to the spread of BSE. This is true for proteins derived from both blood and milk.
6. The Harvard Model Study demonstrated that the use of blood as a feed ingredient in ruminant rations would not result in the amplification of BSE in cattle.
7. Bovine blood products are collected only from cattle that pass USDA ante mortem inspection and are slaughtered under USDA regulations that minimize BSE risk (e.g. prohibition of air injection stunning).

Given the importance of blood and plasma products for maintaining desirable herd health and milk production in the dairy industry, NMPF requests that FDA not propose to eliminate the current exemption provided these products under 21 CFR 589.2000. Any action to remove this exemption should be preceded by a comprehensive risk assessment that clearly identifies any increased BSE transmission risk from bovine to bovine under natural conditions and taking into consideration the extensive economic impacts that will result if any portion of the current exemption is eliminated. NMPF continues to support the 1997 decision reached by FDA that blood and plasma products are safe and will not transmit BSE or other naturally occurring TSE's.

Question #22: What would be the economic and environmental impacts of prohibiting materials from dead stock and non-ambulatory cattle from use in all animal feed? NMPF is greatly concerned that if such material is banned from all animal feed without a comprehensive plan being developed for the disposal and utilization of both banned SRM's and dead stock, the rendering industry will not have the economic incentive to continue dead stock processing. FDA and USDA need to cooperatively develop a comprehensive national 4-D and SRM disposal and utilization plan that will provide the necessary economic incentives for producers to submit nonambulatory and dead stock for animal health monitoring and surveillance purposes and provide for the development of alternative market outlets for such rendered material. The more radical and innovative solutions recommended by the IRT will not materialize without considerable economic burden being placed upon the rendering and livestock industries, including local and state municipalities. Therefore, prior to

initiating a complete ban of dead stock and 4-D animals in all animal feed, FDA needs to work with USDA to bring the public and private sectors together to cooperatively develop a national 4-D livestock and SRM disposal and utilization plan. Such a plan must be designed to enable the rendering industry to survive throughout the nation as a most vital resource for collecting and disposing of this class of animals. Otherwise, serious long-term disposal problems may create untenable public and environmental health issues, including undesirable consequences of not maintaining the integrity of necessary animal disease monitoring and surveillance programs. Therefore, NMPF encourages FDA to work collaboratively with USDA and the affected industries to develop a national disposal and utilization plan for the processing and marketing of banned SRM and dead livestock. This is another very important area which could be examined and recommendations provided by a BSE advisory committee as discussed under Question #1.

Question #24: When and under what circumstances should the recently announced National Animal Identification System (NAIS) transition from voluntary to mandatory? NMPF supports the recommendations of the U.S. Animal Identification Plan (USAIP) Cattle Species Working Group which was requested to develop recommendations for implementation of a national animal identification program capable of tracking all livestock movements within 48 hours of an animal health event or emergency. The Working Group is recommending to the USAIP National Steering Committee and USDA that “following an initial voluntary phase in and successful implementation testing of the NAIS, a ‘critical mass’ level of participation (both in number of cattle moving through the marketing system and producer participation) should be determined, in order to assure successful traceback of any diseased animal within 48 hours. Assessment of the infrastructure’s capabilities in reading, recording and reporting cattle movements from herds of origin to other breeding herds to auction markets to order buying facilities to backgrounder/feeder to post-mortem inspection packing plants will determine if all cattle need to be identified and/or if all producers must participate. The ‘critical mass’ goal should be set and monitored by state animal health agencies and APHIS. USDA should be prepared to fund the implementation of a required animal identification program in 2007.”

Question #25: What species should be covered, both initially and in the longer term? NMPF would recommend that all cloven-hoofed species of livestock intended for food purposes be included in NAIS by 2007. This would include those species of livestock most susceptible to and most capable of spreading a highly contagious foreign animal disease such as Foot-and-Mouth disease. Because other species may serve as vectors to transmit such diseases, NMPF recommends a relatively tight time frame for all species to be covered under a mandatory NAIS system. NMPF recommends that all species of livestock, including pleasure and recreation species, be required to be identified by premises of location and by an official animal identification number under NAIS within 5 years.

Questions #34, 35 and 36 relating to the issue of equivalence. NMPF recommends that FSIS and FDA not exempt foreign countries from any provisions of the SRM rule that might ultimately be adopted in the U.S., regardless of the “BSE status” claimed by the exporting country. If additional BSE risk reduction safeguards are deemed appropriate to impose upon U.S. producers and livestock industries, then all importing countries should be evaluated independently on the basis of the same standards. These risk reduction safeguards add cost to the animal production system. FDA and FSIS should not place the U.S. industry at an economic disadvantage to other countries’ animal production industries. In addition, due to the long incubation period of BSE and the uncertainty of the BSE risk in any part of the world, NMPF believes equivalent precautions must be enforced on both domestically produced and imported product, regardless of the claimed BSE status of the exporting country or the OIE designation. Such a policy helps to enforce a comprehensive BSE risk reduction strategy throughout the world which is ultimately a prudent goal for all nations.

NMPF appreciates the opportunity to submit these comments to FDA on this advanced notice of proposed rulemaking. If we can be of additional assistance, please contact us.

Sincerely,

A handwritten signature in black ink, appearing to read "John B. Adams".

John B. Adams
Director, Animal Health and Farm Services