



NATIONAL MILK
PRODUCERS FEDERATION

James Mulhern, *President & Chief Executive Officer* | Randy Mooney, *Chairman*

Agri-Mark, Inc.
Arkansas Dairy
Cooperative
Association
Associated Milk
Producers Inc.
Continental Dairy
Products, Inc.
Cooperative
Milk Producers
Association
Dairy Farmers of
America, Inc.
Dairymen's Marketing
Cooperative, Inc.
Ellsworth
Cooperative
Creamery
Farmers
Cooperative
Creamery
FarmFirst Dairy
Cooperative
First District
Association
Foremost
Farms USA
Land O'Lakes, Inc.
Lone Star Milk
Producers
Maryland & Virginia
Milk Producers
Cooperative
Association
Michigan Milk
Producers
Association
Mid-West
Dairymen's
Company
Northwest Dairy
Association
Prairie Farms
Dairy, Inc.
Premier Milk Inc.
Scioto County
Cooperative
Milk Producers'
Association
Select Milk
Producers, Inc.
Southeast Milk, Inc.
St. Albans
Cooperative
Creamery, Inc.
Swiss Valley Farms
Company
Tillamook County
Creamery
Association
United Dairymen
of Arizona
Upstate Niagara
Cooperative, Inc.
Zia Milk
Producers, Inc.

March 31, 2014

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

Re: Proposed Rule – Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals [Docket No.: FDA-2011-N-0922]

Dear Sir or Madam:

The National Milk Producers Federation (**NMPF**), 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 cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of more than 32,000 dairy producers on Capitol Hill and with government agencies.

NMPF supported passage of the Food Safety Modernization Act (**FSMA**) and recognizes that a robust food safety system is crucial for both public health and the success of our dairy cooperative and dairy producer members. We appreciate the need for an enhanced food safety system and support the Food and Drug Administration's (**FDA**) efforts to issue rules implementing the FSMA. NMPF will submit comments on the suite of FDA proposed rules implementing FSMA. These comments pertain to the proposed rule on Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals (**Animal Feed Rule**), issued under authority of the FSMA.

While dairy farms will not be directly regulated by the Animal Feed Rule, the rule may affect the availability and price of feeds used for dairy animals. NMPF is concerned that the proposed rule is not consistent with the statutory framework of FSMA, and that the proposal would cause the animal feed industry to direct resources toward complying with regulatory obligations that will not benefit the safety of animal feed.

NMPF has collaborated with the regulated industries in developing comments and supports the extensive comments submitted by the American Feed Industry Association and the National Grain and Feed Association. Additionally, as a primary user of spent brewers' grains (a by-product of beer manufacturing), NMPF also supports the extensive comments of the Beer Institute and American Malting Barley Association. NMPF offers the following general comments, which support the extensive comments of the groups mentioned above.

Exemption for Low Risk Holding and Packing Activities of Raw Agricultural Commodities

As authorized by FSMA, the proposed Animal Feed Rule exempts from regulation facilities solely engaged in storing raw agricultural commodities (except fruits and vegetables) intended for further distribution or processing. This includes elevators that store grains and oilseeds. However, the proposed rule defines "holding" – or storage – in a very narrow manner. The definition would not encompass activities – such as drying, screening, conditioning, fumigating and blending – customarily performed for the safe or effective storage a raw agricultural commodities (except fruits and vegetables). Therefore, if a facility performs any such activity, it

would not be exempt from the proposed regulation. This is unrealistic, impractical and counterproductive.

Further, the proposed rule would not exempt from its requirements facilities engaged in packing raw agricultural commodities (except fruits and vegetables) that are intended for further distribution or processing. In contrast, NMPF believes that such packing activities are an extension of the distribution process for raw agricultural commodities, such as grains and oilseeds, and present minimal risks to public health.

Accordingly, the NMPF urges FDA to modify its regulation to state that facilities solely engaged in the storage and packing of raw agricultural commodities (except fruits and vegetables) intended for further distribution or processing are exempt for the regulation's requirements.

CGMPs Requirements for Animal Feed Should Differ from those Established for Human Food

The proposed rule establishes an overarching set of Current Good Manufacturing Practice (CGMPs) requirements that generally would apply to facilities involved in the manufacture and distribution of animal feed that are required to register under the Bioterrorism Act. In doing this, FDA states that CGMPs similar to those for human food are appropriate for animal feed.

While NMPF agrees that CGMPs for the production and distribution of animal feed is appropriate to ensure the safety, we do not agree that CGMPs similar to those for human food are appropriate for animal feed. We believe that a clear distinction between manufacturing and distribution practices for human foods versus animal feed is proper and has a sound scientific basis. The innate hygienic standards of humans exceed the hygienic standards of livestock, poultry and other animals. Further, animal feed is typically exposed to environmental and hygienic conditions associated with the animal's domicile. Therefore, NMPF urges FDA to propose CGMPs for animal feed that reflect the hygienic safety standards necessary for the manufacture and distribution specific to animal feed.

Preventive Controls Regulation Should Not Mandate HACCP

FSMA instructs FDA to implement regulations for facilities registered under the Bioterrorism Act that require an analysis of hazards associated that are "known or reasonably foreseeable." Further, FSMA instructs FDA to use appropriate preventive controls so that animal feed products are not adulterated or misbranded. As such, FSMA provides for the use of various types of preventive controls commensurate with the risk associated with the hazard. In contrast, the Animal Feed Rule proposes that facilities implement preventive controls for hazards that are "reasonably likely to occur" and that all such controls be managed in a manner similar to a "critical control point" established within a formal hazard analysis and critical control point (HACCP) plan.

While the NMPF supports the use of prudent, appropriate and risk-based practices to assure the safety of animal feed, we strongly believe that the Animal Feed Rule is not aligned with the intent of Congress in providing FDA authority under FSMA to promulgate hazard analysis and preventive controls requirements. Clearly, the statutory language within FSMA does not mandate that animal feed facilities implement HACCP plans. Further, the statute does not mandate that animal feed facilities address all hazards that are "reasonably likely to occur" in the same demanding and burdensome manner that would be required within a formal HACCP plan. NMPF strongly urges FDA to follow more closely the legal framework provided by FSMA and

provide flexibility for management oversight of hazards and preventive controls that is tailored to each facility's operation and commensurate with animal feed safety risk that may be present.

References to "Quality" Should be Removed

One term that appears frequently throughout the proposed rule is the word "quality." While animal feed quality is important to NMPF members, it is not necessarily part of an animal feed safety program. Most animal feed firms have quality programs developed over years of research for producing animal feed products that allow for competition in the marketplace for dairy producers who purchase animal feed. Therefore, NMPF urges the agency to remove references to "quality" in the Animal Feed Rule.

Additional Requirements without Proposing Codified Language for Stakeholder Comment

Within the Animal Feed Rule proposal, the FDA seeks comment on whether to establish requirements for several additional preventive controls and verification measures not mandated by FSMA and for which the agency does not propose codified language. Specifically, FDA asks for comments concerning the appropriateness of establishing additional requirements for: 1) raw material and finished product testing; 2) environmental monitoring; 3) domestic supplier approval and verification programs; 4) review of customer complaints; and 5) submission of facility profile information to the agency.

NMPF is concerned about the process by which FDA may choose to establish such requirements through an interim final rule. FDA should give stakeholders ample opportunity to review and comment on proposed codified language related to any additional requirements before these requirements are incorporated into final regulations. As such, we urge FDA to publish proposed codified language pertaining to any additional requirements for which the agency is interested, and expressly provide for stakeholder review and comment if it seeks to establish such requirements within its final regulation.

Spent Brewers' Grain Exemption

NMPF believes that the Animal Feed Rule interpretation of the FSMA Section 116 exemption for alcohol products is too restrictive. For spent brewers' grains, the rule contains the flawed and erroneous assumption that the mere act of separating insoluble particulates during brewing amounts to a separate manufacturing process. This transforms an exempt activity into a non-exempt activity, triggering regulation if the by-products or residue of beverage alcohol manufacture are used as animal food. The regulation of spent brewers' grains and other by-products of brewing is unnecessary given FDA's own acknowledgement that there is no known public health risk. The brewing industry is already subject to heavy regulation, and already engages in activities that minimize or eliminate the need for additional regulation.

The regulation of spent brewers' grains under the Animal Feed Rule will result in unnecessary increased costs to dairy producers, since brewers' will pass on increased costs of spent brewers' grains without any appreciable change in feed safety. Therefore, NMPF requests that FDA use its authority under FSMA Section 116 to exempt spent brewers' grains as part of the exemption for products made during the production of alcoholic beverages.

Modify and Re-Propose the Regulation for Further Comment

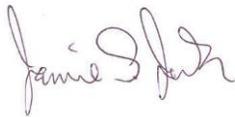
Given these comments and those submitted by the American Feed Industry Association, the National Grain and Feed Association, the Beer Institute and American Malting Barley Association, NMPF believes that FDA should make significant changes to its proposed rule so that requirements will conform to FSMA's intent. Therefore, NMPF believes that FDA should issue a second draft of the proposed regulation that reflects the agency's views after reviewing stakeholders' comments. Issuing a second draft through a re-proposal would give stakeholders with another opportunity to comment on the requirements that FDA foresees within its final rule. Given the very significant nature of these regulations, a second opportunity for stakeholder comment is essential to ensure the final rule is practical, achievable and fosters the safe production and distribution of animal feed and pet food. Further, we believe FDA has the authority to re-propose the regulations and still comply with the court-ordered deadline to publish a final rule by August 30, 2015.

Conclusions

While dairy farms will not be directly regulated by the Animal Feed Rule, the rule may affect availability and price of feeds given to dairy animals. As a result, NMPF is submitting these comments to assure that the Animal Feed Rule will be consistent with the statutory framework provided by FSMA. Additionally, NMPF supports the extensive comments submitted by the American Feed Industry Association and the National Grain and Feed Association. As a primary user of spent brewers' grains (a by-product of beer manufacturing), NMPF also supports the extensive comments of the Beer Institute and American Malting Barley Association.

Thank you for consideration of these comments.

Sincerely,

A handwritten signature in black ink that reads "Jamie Jonker". The signature is written in a cursive, flowing style.

Jamie Jonker

Vice President, Sustainability & Scientific Affairs