International Dairy Foods Association
Milk Industry Foundation
National Cheese Institute
International Ice Cream Association

NATIONAL MILK PRODUCERS FEDERATION

Via electronic submission

March 31, 2014

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

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

To Whom it May Concern:

The International Dairy Foods Association (IDFA), Washington, D.C, represents the nation's dairy manufacturing and marketing industries and their suppliers, with a membership of 550 companies within a $125-billion a year industry. IDFA is composed of three constituent organizations: the Milk Industry Foundation (MIF), the National Cheese Institute (NCI) and the International Ice Cream Association (IICA). IDFA's nearly 200 dairy processing members run nearly 600 plant operations, and range from large multi-national organizations to single-plant companies. Together they represent more than 85 percent of the milk, cultured products, cheese, ice cream and frozen desserts produced and marketed in the United States.

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.

We supported passage of FSMA and have been pleased to assist the agency in its work to implement FSMA's many provisions. Strong collaboration between the agency and all stakeholders can help ensure clear, straight-forward regulatory requirements that improve food safety.

Executive Summary

IDFA and NMPF recognize the significant work that FDA has engaged in to develop the Animal Food proposed rule. Like the other six major proposed rules under FSMA, when finalized, these regulations will dramatically affect food production and manufacturing. We are concerned, however, that the proposed rule would have a substantial impact well beyond the industry the agency is

intending to regulate (the animal food industry) and, if not amended as described below, would significantly and negatively affect human food manufacturers without a commensurate benefit to animal food safety. We support comments to this proposed rule submitted by the Grocery Manufacturers Association and many of our allied trade associations from the human food sector.

In the comments that follow we explain that human food manufacturers like our members divert a number of different types of food, in-process food materials, and food waste (collectively referred to as "diverted food production materials") to the animal food production channel (either for further processing or directly to farmers) for a number of valid practical, economic, and environmental reasons. This activity has been going on for decades, and FDA has not cited any adverse impact on animal food safety as a result of it. Accordingly, there is no food safety need for our members in the human food industry to be subject to the extensive good manufacturing practices (GMPs) and Hazard Analysis and Risk-Based Preventive Controls (preventive controls) regulations directed to the animal food/feed industry.

The proposed rule, however, would impose demands on human food processors diverting food production materials that would make compliance impractical. Because of this impact and because we believe that additional requirements for human food manufacturers would not increase animal food safety, we recommend FDA clarify that the proposed rule only applies to materials that are manufactured with the intent to market a finished product or ingredient as animal food. In the alternative, FDA should either exempt human food manufacturers from the proposed rule or should reduce the compliance burden for those manufacturers who can document that the safety of their diverted food production materials is controlled by the recipient of the materials. Below, we provide a factual and legal basis for both of these options.

Because we believe that significant changes to the Animal Food proposed rule are needed, the agency should publish a revised proposed rule for public comment, including a revised economic analysis, which addresses our concerns. We are pleased that FDA recently announced that it will publish revised language for this proposed rule this summer.

I. Food Production Materials Diverted by the Dairy Industry

Scope and Diversity of Diverted Food Production Materials. Our members process dairy ingredients into wholesome milk, cheese, yogurt, ice cream, various milk powders and milk or whey derived powders. As a result of the manufacturing process used to produce these foods, our members have surplus food materials—referred to as "diverted food production materials"—that companies divert to the animal food production channel. These materials might be production over-run, food that is unsalable, or simply waste/by-product from the manufacturing process. For example, products that are under grade or out of specification are diverted to animal feed. These materials might be finished product that has reached shelf-life, material collected just after first rinsing the production line, whey, concentrated permeate, cheese scraps or trim, or even store returns. Food production materials are often diverted to third parties who process the materials with other raw materials and ingredients into animal food. In other cases these materials may be directly diverted to cattle and pig farms as well as fish or mink operations. In rare cases they may be diverted for pet food manufacturing. Diverting food production materials in this way makes sense practically, economically, and environmentally. It is a sustainable practice.

Complex Supply Chain. These materials may be diverted to processers who use or convert the materials into animal feed or, as stated above, these materials may be diverted directly to farmers. Some customers establish certain specifications for the food, others do not. No matter what the particular situation, however, our members often do not know the animals that will consume the food, the role it will play in their diet, or how the food will be further processed.

Safety of Food Production Materials. Food production diverted materials may not be acceptable for use as human food, but this does not mean these materials are not safe for animals. These materials currently are managed in compliance human food safety programs up until they are diverted. Once diverted, human food manufacturers have a legal obligation to ensure they are not adulterated under Federal Food, Drug and Cosmetic Act (FFDCA) Section 402(a). Furthermore, the safety of these materials with respect to animals is managed later in the animal food supply chain—either by the finished animal food/animal feed or ingredient processor, or by the farmer. These recipients understand their responsibility to ensure that the product they produce, deliver, or feed their animals is safe and appropriate for the animal that will consume it. This is in sharp contrast to our members who are in the business of producing and selling food for *human* consumption.

II. Compliance Challenges Posed by the Proposed Rule

FDA's Base Assumptions about Current Industry Practices are Incorrect. We are concerned that the proposed rule will impose unintended consequences on our members and that the demands posed by the rule will make compliance impractical. As a general matter, the proposed rule incorrectly assumes that diverted food production materials are addressed in facility food safety plans. They are not. Food safety plans cover foods for human consumption, but do not specifically address related materials such as by-products. For example, food safety plans address finished cheese for human consumption and provide a foundation for the safety of cheese scraps or trim that the production run may generate but do not analyze or control these materials specifically. This makes sense, given the intent of the food manufacturing process: to produce human food.

A Hazard Analysis Specific to Animal Food is Complex when Consuming Animal Species and Relevant Hazards are Unknown. As a practical matter, it would be extremely difficult for a dairy processor to develop and implement a food safety plan to address food production materials that may be diverted to animal food. Beginning with the hazard analysis—the most important step in a food safety plan—the challenges are significant. FDA's proposal would require the facility to conduct a hazard analysis tailored to the animal species consuming the diverted food. In a many cases our members do not know the animal species that will consume the diverted food production materials, what kind of further processing might occur, or the proportion of the diverted food production materials in the total diet of the receiving animal. But even if they did, or could determine all that information, our members lack the expertise to identify and assess the potential relevant hazards in the animal food context. Our members would need to retain consultants or direct our associations to spend considerable time and resources on this – certainly not what FSMA intended.[1] We are concerned that this could re-direct valuable resources away from ensuring the safety of our finished human food products. Similarly challenging is the proposed requirement to consider nutrient imbalances. This requirement is also unnecessary with respect to diverted food production materials as another entity (farmer or feed processor) in the animal food supply chain ensures that the animal(s) consume the appropriate balance of nutrients.

[1] Federal Food, Drug and Cosmetic Act (FFDCA) § 418(n)(3)(D).

GMPs are Inapplicable and Burdensome. We also believe that the proposed requirement that human food manufacturers comply with good manufacturing practices (GMP) regulations (either under proposed Part 117 or Part 507) with respect to these diverted food production materials is inappropriate. Under either Part 117 or Part 507, FDA has not tailored the proposed requirements to our members' role in the animal food supply chain. In general, there is concern that the proposed GMPs in Part 507 essentially apply the GMPs for human food to animal food. The GMPs in Part 117 were not developed to apply to diverted food production materials. For example, the proposed requirements do not reflect the differences between humans and animals. Animals frequently eat off the ground and in a manner in which animal and wildlife excrement comes in contact with the food they are fed. To require diverted food production materials to meet the same sanitation standards as human foods does not make sense. Similarly, while humans do not prefer to consume sour milk (or other off-quality products), to a pig or a cow it is immaterial. Therefore, diverted milk for animal food does not need to be refrigerated.

More problematic is the general concept reflected in FDA's proposal. Quite simply, compliance with many of the GMP requirements with respect to diverted food production materials would impose sizeable burdens that are not necessary for animal food safety. Our members ensure that diverted food production materials are handled in a way that ensures they are not adulterated and do not compromise the safety of their finished human foods. It is the recipients of their diverted food production materials who ensure that the materials are safe for animal consumption.

III. Animal Food Regulations Should Apply Only to Manufacturers Who Intend to Manufacture Animal Food

Dairy Manufacturers Do Not Treat Diverted Food Production Materials as "Animal Food" As a threshold matter, the proposed requirements should only apply to manufacturers that intend to produce animal food—those foods that are designed and marketed for animal food use. Our members, as human food companies, intend their finished products to be sold for human consumption; they are not intended for animal food. What does enter the animal food supply chain are simply food production materials that are diverted to animal feed because it is economically and environmentally advantageous to so, but those same materials could be and are on occasion diverted to other venues (e.g., bio-digesters, composting operations or landfills).

Intended Use Determines Scope of Coverage. From a legal perspective, FDA considers the intended use of a product when determining its regulatory status. Significantly, the FFDCA defines "animal feed" as an "article which is intended for use for food for animals other than man."[2] Therefore, materials that are not intended for use for food for animals—those that are not produced with that intent—are not "animal food" as that term is legally defined. Accordingly, FDA should revise the proposed rule to clarify that the Animal Food regulations (GMPs and preventive controls) apply only to materials that are manufactured with the **intent** to market a finished product as animal food (or an animal food ingredient).

Diverted Food Production Materials Must be Safe. Because diverted food production materials are not "animal food," these materials should not be subject to Animal Food GMPs and preventive control regulations. Although human food finished products will be subject to Part 117 (both GMPs and preventive controls), human food manufacturing facilities should not have to manage diverted food production materials through their food safety plans or Part 117 GMPs. These materials would,

[2] FFDCA § 201(w).

however, be managed under Part 117 (GMPs and preventive controls) up until they are diverted. And once diverted, human food manufacturers must ensure they are not adulterated (that they are not prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to animal health; that they are not unfit for animal food, that they do not contain any poisonous or deleterious substance that may render the material injurious to animal health, or violate FFDCA Section 402(a) in any other way) consistent with the in-process status of these materials. Thus, the underlying statutory prohibition against adulteration provides adequate protection against harmful materials being diverted to the animal food supply channel.

IV. FDA Can and Should Exempt Human Food Manufacturers from the Animal Food Regulations

FSMA Provides a Legal Basis for Exemption. If FDA disagrees with our legal position on intended use, we recommend that FDA affirmatively exempt human food manufacturers from the proposed requirements. Specifically, the law states that FDA may "exempt or modify" the requirements for preventive controls for "facilities that are solely engaged in the production of food for animals other than man."[3] Additionally, the law provides that FDA's regulations must "acknowledge differences in risk and minimize, as appropriate, the number of separate standards that apply to separate foods."[4] We strongly encourage FDA to give effect to these principles by exempting human food manufacturers that do not intend to produce animal food from compliance with the Animal Food regulations. FDA's current proposed standards, as applied to diverted food production materials, do not recognize the significantly different (lower) risk posed by these materials, would impose separate standards for a waste stream in human food facility, and do not reflect the inherent differences between foods for human and animal consumption.

Existing Statutory Obligations Provide a Factual Basis for Exemption. An exemption is appropriate given the complexities and the compliance challenges posed by subjecting diverted food production materials to the Animal Food proposed regulations, and the lack of an animal food safety need. We note that an exemption from the Animal Food regulations would not result in a lack of safety standards for diverted food production materials. As stated above, food manufacturers have always had and will continue to have a legal obligation to ensure that diverted food production materials are not adulterated, consistent with the "in process" status of these materials. Further, the finished human food made by our members will be subject to GMPs and preventive controls for human food, up until the point of diversion, providing a foundation for ensuring the safety of diverted food production materials. Additionally, the safety of diverted food production materials for animal consumption is handled by the downstream processor or farmer. Finally, as noted earlier, FDA has not cited any circumstances involving animal food safety issues that have arisen as a result of food production materials being diverted into the animal food production channel.

V. In the Alternative, FDA Should Reduce the Compliance Burden for Human Food Manufacturers

Allow Safety to Be Controlled Later in the Supply Chain. If FDA concludes that human food manufacturers who divert food production materials to animals are covered by the proposed rule because they handle "animal food," FDA, nonetheless, should exempt from coverage those human

[3] FFDCA § 418(m).

[4] FFDCA § 418(n)(3)(C).

food manufacturing facilities that can document that the safety of their materials diverted to animal food is controlled by the customer. Specifically, FDA could follow the same approach taken in the produce safety and Foreign Supplier Verification Program (FSVP) proposed rules where the agency exempted farmers/importers from compliance with the proposed requirements, provided they could demonstrate that food safety issues are addressed later in the supply chain. In those proposed rules, FDA recognized that it does not always make sense to impose the same responsibilities on all entities in a supply chain. This is particularly true when another entity will ensure that the food will be safe. In the context of the Animal Food proposed rule, it is appropriate to exempt human food manufacturers from compliance provided they can document that their customer (or another party further down the supply chain) controls any relevant hazards before the food is consumed by animals.[5] This would help alleviate the compliance burdens posed by the proposed rule in a practical way and would place responsibility on the entity in the best position to ensure the safety of animal food.

VI. FDA Should Reconsider the Economic and Environmental Costs Associated with its Proposal

Finally, we note that any course FDA chooses must consider the financial cost of compliance to human food manufacturers and the animal food industry, as well as the potential environmental impact. We want to ensure that any additional requirements FDA would impose on human food manufacturers are not so burdensome as to result in much of these food production materials no longer being diverted, and instead sent to landfills or other less environmentally friendly means of disposal.

Cost of Compliance May Lead to Diversion to Another Channel. We are concerned that the proposed rule and associated Preliminary Regulatory Impact Analysis assumes that the food industry can easily comply with the proposed rule and will not have any implementation costs. As discussed above, this is not the case. Moreover, we are worried that the cost and burdens of compliance may outweigh the cost of sending food production materials to an alternate channel that is less sustainable. This, of course, would be at the detriment of the animal food industry and farmers, who currently have access to low cost, high quality food material and would have to seek food and feed ingredients elsewhere, which would affect the price of both the livestock and the crops they consume, as well as consumers in the long run.

Diversion Elsewhere Would Impose Environmental Costs. Furthermore, if food production materials are no longer diverted to animal feed, the only remaining options are to land apply it, digest it, compost it, send it to a landfill, or incinerate it— some of these options could have a significant adverse impact on the environment. We expect much of the materials would be sent to a landfill or incinerated, which could result in a dramatic increase in greenhouse gases emissions. Similarly, the incineration process also can result in harmful toxic and particulate emissions. Further, if farmers who currently rely on diverted food production materials to feed their animals no longer have access to this source of animal food, they will be forced to purchase other foods (likely at a higher price or from a less environmentally-friendly source) to feed their animals.

[5] With respect to food production materials diverted directly to farmers, it should be sufficient for the facility to document that the farmer has concluded that the food he receives is safe for consumption by the intended animal.

FDA should take these economic and environmental issues into account as it reevaluates its proposal and considers reissuing the proposed rule for public comment.

VII. Incorporation by Reference of Prior Comments to the Human Food Preventive Control Rule

We incorporate by reference our comments filed on the human food preventive controls proposed rule.[6] Many of our comments there with respect to the hazard analysis, the flexibility needed when implementing preventive controls, and the need for specific regulatory language concerning testing and supplier verification are equally applicable here. In addition, we support the more extensive comments on the human food preventive controls proposed rule submitted by the Grocery Manufacturers Association.

Conclusion

In sum, we believe that FDA's animal food proposed rule only should apply to those manufacturers who expressly intend their food to be sold, as finished ingredients or as finished food products, for consumption by animals. We do not believe that this proposed rule should apply to human food manufacturers who merely divert food production materials into the animal food production channel. Any animal food safety concerns can be adequately addressed downstream by those directly responsible for the safe production and use of animal food and feed. Additional requirements on human food manufacturers would add cost without a commensurate food safety benefit and could have the unintended consequence of creating an adverse economic and/or environmental impact. FDA should take a step back and reconsider this proposed rule with these issues in mind.

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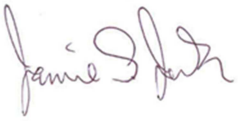
IDFA and NMPF appreciate the opportunity to provide these comments to FDA. We look forward to continuing to work with the agency to make FSMA a success. Thank you for considering our views and do not hesitate to contact us if we can answer any questions or provide additional information.

Respectfully submitted,



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[6] Docket No. FDA-2011-N-0920; Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.