



National Milk Producers Federation

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

February 23, 2000

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

Dear Sir or Madam:

The purpose of this letter is to communicate the views of the undersigned organizations on a Citizen Petition, dated February 10, 2000 and submitted to FDA on behalf of the National Cheese Institute, the Grocery Manufacturers of America, and the National Food Processors Association (hereafter, "NCI petition"). The NCI petition seeks an amendment to the definitions of milk, nonfat milk, and a new definition for filtered milk in 21 CFR 133.3. The intent of the petition is to allow for ultrafiltered milk to be used as an ingredient in cheesemaking. While the NCI petition has merit in advocating certain uses of ultrafiltration as a technology for use in cheesemaking, the undersigned organizations unconditionally object to a provision in the petition that would allow for dried forms of ultrafiltered milk to be used as an ingredient in cheesemaking. For this very compelling reason, we are obliged to take the preliminary action of submitting this letter at this time as an objection to the NCI petition.

The undersigned organizations represent dairy producers and producer-owned cooperatives across the United States. Virtually all of the milk produced in the U.S. comes from the dairy producer members of the organizations who have signed this letter. The changes indicated in the NCI petition will have a severe impact on all U.S. milk producers if the standards of identity for cheeses are changed to allow for imported milk products to displace the domestic milk supply.

In addition, the changes proposed in the NCI petition are not reflective of the collective opinion of the U.S. cheese industry. In fact, the dairy cooperatives represented by this letter manufacture 40% of the natural cheese in the U.S. The NCI petition references that one of the petitioners markets 80% of the natural and processed cheese sold in the U.S. This representation is an exaggeration in that it refers to the *marketing* of natural and processed cheese and cheese products and not the *manufacturing* of these products. The impact of the proposed changes on the

petitioners' membership, therefore, is overstated. The potential negative impact of the NCI petition on dairy producers, however, is very real and we consider this to be one of the most threatening issues facing dairy producers in recent times. We unequivocally urge the Agency to reject the petitioner's request.

UF technology

The petitioners reference the potential for use of ultrafiltration (UF) technology as a benefit to the dairy industry. While UF itself is a worthwhile technology, dried forms of this product represent an entirely different matter. In fact, dry UF ingredients are a combination of UF and evaporation, two separate and distinct processes. UF technology has been used in the dairy industry for many years and should be allowed to continue as a separate and distinct process. The drying of ultrafiltered milk and the resultant product, however, should be treated independently from the process of filtering fluid milk.

Economic Impact of the Petitioner's Request

Allowing for dried forms of UF milk in standardized cheeses will have a significant adverse impact on dairy producers throughout the United States. In fact, our preliminary analysis indicates that the impact will be classified as a significant regulatory action, as defined in Executive Order No. 12866 (Regulatory Planning and Review), in that the annual effect of the change on the dairy farm sector of the economy will be greater than \$100 million.

Dry forms of UF milk cannot be effectively sourced within the U.S. due to the fact that manufacturers of these products in other countries are heavily subsidized by their governments. Permitting dry forms of UF milk to be used will allow the unrestricted importation of these ingredients into the United States. Due to the lack of import controls (i.e., tariffs and quotas) on these ingredients, these heavily subsidized products will directly displace domestic dairy ingredients if they are permitted for use in cheesemaking under federal standards of identity. These displaced dairy ingredients will, in turn, enter other domestic market channels, further depressing dairy prices paid to producers. In other words, the proposed change in the NCI petition would, in effect, endorse the distortion of current trade practices and would undermine U.S. efforts to achieve fair trade in the ongoing international trade negotiations.

Impact on Small Business

Many of the dairy producers who will be adversely affected by the petitioner's request are also classified as small businesses by the Small Business Administration. The negative impact of lowering domestic milk prices could very well result in many of these small enterprises going out of business. The devastating impact on these operations cannot be ignored as the Agency considers the petitioner's request.

Import Control

The NCI petitioners, in a press release announcing their petition, have publicly identified this request as a scientific, technical regulatory matter rather than a trade policy issue. In doing so, the petitioners themselves recognize the consequences of

their request. The Agency cannot ignore the more global trade implications of regulatory changes as well as the impact on the domestic industry. In addition to the adverse trade impact of the petitioner's request, concerns about the integrity, safety, and nutritional equivalence of the dried form of these ingredients exist within the U.S. cheese manufacturing community.

While the petitioners believe their proposed amendments would assist USDA with plant inspection requirements, we find the proposed changes to have the opposite effect. Allowing for dry forms of UF milk will hinder, rather than help, the work of USDA since imported ingredients (and the facilities where they were manufactured) will not be subjected to review by that Department's inspectors. In addition, allowing for the use of the dry UF ingredients will exacerbate the difficulty both state and federal inspectors will have in ensuring that caseinates, which have been explicitly excluded in the NCI petition, are not used. The potential for fraudulent practices such as substituting caseinates for dry forms of UF milk is very real since no practical test presently exists to confirm the composition of the product in use. The only means, therefore, to differentiate an imported supply of dried UF milk from caseinates would be to rely on the accuracy of the labeling information accompanying the imported product. The validity of this information may be difficult to verify.

If the FDA and USDA personnel do not have access to the foreign facilities that manufacture these ingredients, the integrity of the ingredients cannot be ensured. The safety and quality of these ingredients will not be under the purview of any U.S. government agency and the safety of the U.S. food supply cannot be guaranteed. Liquid products produced by UF technology in the U.S. have the benefit of both state and federal oversight from the farm to the processing facility.

Alternate Make Procedure

The NCI petition references the use of UF milk as an alternate make procedure under the standard of identity for some cheeses. The alternate make procedure is intended to recognize different *processing* techniques within the same facility, not to provide justification for alternate *ingredients*. Extending the concept of the alternate make procedure to allow for ingredients not permitted under the standard of identity is not an appropriate interpretation of the intent of the alternate make procedure provisions of the standard.

Nutritional Equivalence

The petitioners provide data comparing the nutritional profile of cheese manufactured using UF milk as an ingredient to traditionally manufactured cheese. The data supplied as justification for nutritional equivalence refers to cheese made from milk subjected to a UF process. No indication is given as to whether the resulting cheese has been manufactured from liquid or dry forms of UF milk. It is our belief that the cheese being compared to "traditional" cheese has been manufactured from *liquid* UF milk. Consequently, no data has been provided to support the use of *dry* forms of UF milk. The potential loss of nutrients in the drying process should be investigated and

further demonstrates the need to consider the use of liquid UF milk separately from dried forms.

Conclusion

In conclusion, the undersigned organizations vehemently oppose the use of dried forms of UF milk for cheesemaking. We are also aware that a Citizens Petition was filed with FDA on December 2, 1999 by the American Dairy Products Institute advocating the use of liquid UF milk as an ingredient. This is an alternative approach and deserves consideration. In addition, we believe the NCI petition should be considered as ill-conceived on the basis of questions surrounding product integrity, safety, quality, and nutritional equivalence as it relates to the dried forms of UF milk.

As we have indicated, the NCI petition will have far-reaching consequences for many other federal agencies, including the U.S. Department of Agriculture, the U.S. Trade Representative's Office, and the Small Business Administration. We encourage FDA to discuss this issue with the affected agencies before proceeding. As mentioned earlier, we believe the severe negative economic consequences of the changes requested by the petitioners will also require Congressional review.

Thank you for the opportunity to provide these comments. We would be pleased to answer any questions or provide additional information, upon request.

Sincerely,

Jerry Kozak, CEO
National Milk Producers Federation

On behalf of the:
American Farm Bureau Federation
National Council of Farmer Cooperatives
National Farmers Organization
National Farmers Union
National Grange
Alliance of Western Milk Producers

cc: The Honorable Daniel R. Glickman, Secretary of Agriculture
The Honorable Donna E. Shalala, Secretary of Health and Human Services
Ambassador Charlene Barshefsky, USTR
Administrator Aida Alvarez, SBA
Commissioner Jane E. Henney, FDA
Joseph A. Levitt, Director of CFSAN, FDA