



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

0065 '00 APR -5 AIO :02

March 29, 2000

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

Dear Sir or Madam:

This letter is in response to comments recently submitted by the National Milk Producer's Federation objecting to a Citizen Petition prepared by the National Cheese Institute. NCI is a constituent of the International Dairy Foods Association whose 95 member companies represent approximately 80 percent of the natural and processed cheese and cheese products sold in the U.S. We would like to take this opportunity to respond to each individual objection as outlined in their letter.

UF Technology – While the letter refers to UF technology as “worthwhile”, it objects to the *combined* use of filtration and evaporation to process milk into dry retentate. However, these processes are used routinely in combination at dairy processing plants in the U.S. to process skim milk into nonfat dry milk. Filtration and evaporation are used in sequence in order to maximize the efficiency of the water-removal process. In some cases, a filtration process is most efficient at the front end when the skim has the highest water content. Evaporation is used as a second step to remove the remaining water and convert the product into a powder with the same nutritional and functional characteristics as the liquid from which it was derived. This is how much of the dry whole milk, dry skim milk, and dry cream are prepared for use in standardized cheese varieties today.

00P-0586

Page 1

C2

Dockets Management Branch
March 29, 2000
Page Two

Processors need flexibility to use the technologies required to obtain the best ingredient in the most efficient manner possible. There is no logical reason to restrict one technology simply because it may be used in combination with another technology.

Economic Impact of the Petitioner's Request – The letter states that allowing dry forms of filtered milk to be used in standardized cheeses will have an economic impact to dairy farmer exceeding \$100 million due to importation of dry retentate. This assertion is questionable, since many plants making standardized cheeses in the U.S. are inspected and certified by USDA, and cannot use foreign-sourced retentate. These plants may only use USDA-inspected ingredients and there are no USDA-inspected plants in foreign countries.

Filtered milks in dry form are classified under U.S. customs rules as “milk protein concentrate” with their own tariff line item and a relatively low tariff and no tariff-rate quota. A substantial amount of these products are imported today, for use in non-standardized food products. The use of imported milk protein concentrate in standardized cheeses would likely be limited because of the aforementioned lack of USDA-inspected suppliers in foreign countries.

The letter also states that their governments heavily subsidize foreign manufacturers of dry retentate. In fact, the biggest source of dry retentate into the U.S. currently is New Zealand, which does not subsidize exported dry retentate.

Impact on Small Business – The NMFP letter suggests that disallowing use of dry filtered milks in standardized cheeses will increase the economic viability of small dairy farmers. However, it is difficult to see how restricting use of valuable and proven technologies can improve the economic viability of businesses in any industry. Indeed, even today some family owned dairy farmers have organized into groups that share the benefits gained by a central milk filtering operation. These farmers realize that economic benefits gained by milk filtration technology can be distributed among the participants.

Import Control – The NMFP letter states that FDA must consider “... global trade implications of regulatory changes as well as the impact on the domestic industry.” However, according to the Federal Food, Drug, and Cosmetic Act, the agency is charged

Dockets Management Branch
March 29, 2000
Page Three

“...to promote honesty and fair dealing in the interest of the consumer...” Nowhere are trade issues mentioned in FDA’s mandate.

NMPF’s letter also suggests that allowing dry filtered milk as an ingredient in standardized cheeses will hinder USDA inspection efforts because “...imported ingredients (and the facilities where they were manufactured) will not be subjected to review by that Department’s inspectors.” USDA enforces its rules on manufacture of USDA-approved cheeses by inspecting ingredients at the cheese plant where they are used, not the plant that is the source of the ingredient. Foreign-sourced ingredients would be inspected in the same manner. Since there are no USDA-approved plants outside the U.S., an inspector can easily identify unapproved ingredients not only by labels indicating USDA approval, but also by the simple fact that the ingredient was not produced domestically.

NMPF also expresses concern that importers may substitute caseinates for dry filtered milk with impunity because no test can tell the difference. Actually, caseinates are very different than dry retentate because they contain over 98% casein while dry retentate contains at least 15% solids that are not casein. There are several tests capable of making this determination.

The letter also raises concerns about the safety and quality of dry retentate that may be imported into the U.S. Eighty-eight million pounds of these types of dry products were imported into the U.S. in 1998 and used to make a variety of foods, including dairy products for U.S. consumers. NCI is not aware of any food safety issues associated with these products. Also, it is difficult to see how restricting its use to its most perishable form, in this case wet retentate, enhances the safety and stability of any ingredient.

Alternate Make Procedure – NMPF’s letter suggests that the alternate make procedure should not be used to justify use of filtered milks in standardized cheese. The alternate make procedure is a provision intended to promote technical and economic advancement in cheese manufacture, so long as the final product is the same as its conventionally made counterpart. NCI believes that use of filtered milk to make standardized cheese has proven itself in the 15 years since FDA approved its use based on the alternate make procedure. The National Cheese Institute prepared and submitted the Citizen Petition for filtered milks at the request of FDA and USDA after USDA delisted some plants that were using retentate prepared at a distant plant. NCI submitted the petition even though

Dockets Management Branch
March 29, 2000
Page Four

the association strongly maintains that use of filtered milks is allowed under the alternate make procedure regardless of where the milk is filtered. Contrary to NMPF's belief, the Code of Federal Regulations does not require that innovation in cheesemaking take place at a particular site.

Nutritional Equivalence – The letter raises questions about the possibility that nutrients may be lost when retentate is dried. If this were a problem, it would be apparent when nonfat dry milk is used to make cheese. NCI is not aware of any data that would support such an assertion.

Conclusion – Much of NMPF's letter is focused on inclusion of dry filtered milk in NCI's petition. NCI believes that use of dry filtered milk increases efficiencies within the cheese industry. These efficiencies reduce transportation costs and, because of its ease of storing, better utilization of milk solids throughout the year. The issue of importation of dry retentate, if there is one, should be resolved domestically through the U.S. Department of Commerce, the U.S. Trade Representative, or USDA's Foreign Agricultural Service and internationally within a trade forum such as the World Trade Organization. To exclude dry forms of retentate makes no sense technically or economically.

Sincerely,



C. Gordon Brown, Ph.D.
Senior Vice President, Scientific and Regulatory Affairs
The International Dairy Foods Association

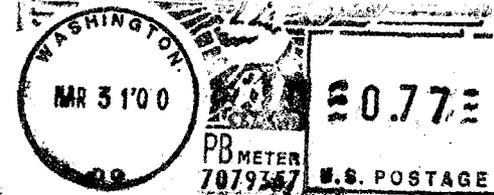
cc: The Honorable Daniel R. Glickman, Secretary of Agriculture
The Honorable Donna E. Shalala, Secretary of Health and Human Services
Ambassador Charlene Barshefsky, USTR
Administrator Aida Alvarez, SBA
Commissioner Jane E. Henney, FDA
Joseph A. Levitt, Director of CFSAN, FDA



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

1250 H St., NW, Suite 900
Washington, DC 20005

RETURN SERVICE REQUESTED



First Class Mail

DOCKETS MANAGEMENT BRANCH (HFA-305)
FOOD AND DRUG ADMINISTRATION
ROOM 1061
5630 FISHERS LANE
ROCKVILLE, MD 20852