



International Dairy Foods Association

Milk Industry Foundation

National Cheese Institute

International Ice Cream Association

November 29, 2004

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

**Re: Docket No. 2004D-0453
Draft Revised Compliance Policy Guide Sec. 560.400--Imported Milk and Cream--
Federal Import Milk Act (CPG 7119.05)**

Dear Sir or Madam:

The International Dairy Foods Association (IDFA) appreciates the opportunity to comment on the Draft Revised Compliance Policy Guide Sec.560.400 - Imported Milk and Cream - Federal Import Milk Act (FIMA). These comments are submitted on behalf of IDFA and its constituent organizations, the Milk Industry Foundation, the International Ice Cream Association, and the National Cheese Institute. The approximately 500 member companies of these associations operate more than 650 processing and manufacturing plants, which account for 85% of the dairy products consumed in the United States.

We support the Food and Drug Administration's (FDA) initiative to revise the compliance policy guide to clarify and update its policy on dairy products that require Federal Import Milk Act (FIMA) permits. Currently, FIMA policy on the FDA website (http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg560-400.html) states:

"the following dairy products defined in title 21 of the Code of Federal Regulations (CFR) and/or in the Grade "A" Pasteurized Milk Ordinance (PMO), may be entered legally only by the holder of a valid permit obtained previous to the time of importation: milk, lowfat milk, skim milk, half-and-half, light cream, light whipping cream, heavy cream, sour cream, cultured sour cream, acidified sour cream, sour half-and-half, acidified sour half-and-half, sour cream dressing, sour half- and-half dressing, Vitamin D milk, fortified milk, homogenized milk, flavored milk, eggnog flavored milk, cultured buttermilk, yogurt, concentrated milk, sweetened condensed milk (unless it can be conclusively demonstrated that the condensed milk has been hermetically sealed and sterilized), and similar products."

The draft compliance policy guide intends to clarify the list of products that need a permit to the following products:

- i. milk, lowfat milk, skim milk, fortified milk, flavored milk, concentrated milk, evaporated milk, sweetened condensed milk, and ultra filtered milk.
- ii. cream, half-and-half, heavy cream, light cream, and light whipping cream.

IDFA supports the proposal to limit the number of items that require import permits. However, we are concerned that ultra filtered milk, which had not been previously included in products

requiring FIMA permits, now has been added to the list. We note that ultra filtered milk is not defined in either Title 21 Part 131 of the CFR or the Grade "A" PMO. Since there is no established FDA standard of identity or definition for ultra filtered milk, it would be difficult to properly identify the product. For this reason, IDFA believes it would be ill-advised to require that a non standard product be subject to FIMA requirements. Unlike ultra filtered milk, all the other products which FDA intends to consider as subject to FIMA have a standard of identity and are defined in Title 21 Part 131 of the CFR and/or in the Grade "A" PMO. FDA should not subject ultra filtered milk to a permit requirement when there was none before, until such time as a standard is established for this product.

Therefore, we recommend that ultra filtered milk be deleted from III.B.1.i. of the draft Compliance Policy Guide. Secondly, we recommend that III.B.1 be revised to "FDA intends to consider the following dairy products defined in Title 21 Part 131 of the Code of Federal Regulations and/or the Grade "A" Pasteurized Milk Ordinance as subject to the FIMA's permit requirement for importation."

With regards to the list of dairy products that the FDA intends to consider as not subject to the FIMA requirements for importation, IDFA would recommend inclusion of an additional category of milk products. IDFA recommends that III B. 2. i, ii, and iii, listing dairy products not subject to FIMA policy be stated as follows:

- "i. Sour Cream, Cultured Milk, Acidified Milk, Yogurt, Cheese, Ice Cream and Eggnog
- ii. Dried Milk, Nonfat Dry Milk, Nonfat Dry Milk fortified with vitamins A and D, and other dehydrated milk products.
- iii. Any milk-derived ingredient from milk or any component or fraction of milk such as milk fat, milk proteins (casein, and /or whey proteins and their constituents, fractions, hydrolysates or polymers), milk sugars and minerals.
- iv. Any of the dairy products for which a permit is otherwise required (see III.B.1) if they have been processed and packaged in hermetically sealed containers so as to be commercially sterile in accordance with requirements of 21 CFR 108.35 and 113."

IDFA appreciates the opportunity to comment on the draft revision of the compliance policy guide for FIMA and would welcome the opportunity to discuss these issues. We are also glad to answer questions or provide additional information.

Respectfully submitted,



Clay Hough
Senior Vice President and General Counsel