

# **Compliance Policy Guide**

## **Guidance for FDA Staff**

### **Sec. 560.400 - Imported Milk and Cream – Federal Import Milk Act (CPG 7119.05)**

**Comments and suggestions regarding this Compliance Policy Guide (CPG) should be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with docket number 2004D-0453.**

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**U.S. Department of Health and Human Services  
Food and Drug Administration  
Office of Regulatory Affairs  
Center for Food Safety and Applied Nutrition**

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**U.S. Department of Health and Human Services  
Food and Drug Administration  
Office of Regulatory Affairs  
Center for Food Safety and Applied Nutrition**

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# Compliance Policy Guide

## Sec. 560.400 - Imported Milk and Cream – Federal Import Milk Act (CPG 7119.05)

This guidance document represents the Food and Drug Administration's (FDA) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

### Sec. 560.400 Imported Milk and Cream – \*Federal\* Import Milk Act (CPG 7119.05)

#### I. INTRODUCTION:

\*The purpose of this document is to provide guidance regarding which imported dairy products require a permit under the Federal Import Milk Act.

FDA's guidance documents, including this Compliance Policy Guide, do not establish legally enforceable responsibilities. Instead, guidance documents describe the agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in agency guidance documents means that something is suggested or recommended, but not required.

#### II. BACKGROUND:

The Federal Import Milk Act (FIMA) was passed by Congress in 1927 to "regulate the importation of milk and cream into the United States for the purpose of promoting the dairy industry of the United States and protecting the public health" (Public Law 69-625, codified as 21 U.S.C. 141-149). Under the FIMA, only the holder of a valid import milk permit may "ship or transport" milk or cream into the United States. The FIMA defines "United States" as "the fifty States and the District of Columbia" (21 U.S.C. 149). Therefore, the FIMA's permit requirement does not apply to milk and cream that is shipped to jurisdictions other than a State or the District of Columbia (e.g., United States Trust Territories and Protectorates).

Under the FIMA, FDA issues import permits, which expire in 1 year. Prior to such permit being issued, the FIMA requires that: (1) all cows must be physically examined and found healthy within 1 year previous to the time of importation; (2) if the milk or cream is raw when imported, all cows must pass a tuberculin test within 1 year previous to the time of importation; (3) the dairy farm and each plant in which the milk or cream is processed or handled must be inspected and must meet certain sanitary requirements; (4) bacterial counts of raw milk, raw cream, pasteurized milk, and pasteurized cream at the

time of importation must not exceed specified limits; and (5) the temperature of the milk or cream at the time of importation must not exceed 50° F (10° C) (21 U.S.C. 142). Regulations under the FIMA are found in 21 CFR Part 1210. Requests for permit applications may be made to the Food and Drug Administration, Office of Plant and Dairy Foods, Division of Dairy and Egg Safety, HFS-367, 5100 Paint Branch Parkway, College Park, MD 20740.

Section 148 of the FIMA provides that nothing in the FIMA shall be construed "to affect the powers of any State, or political subdivision thereof, to regulate the shipment of milk or cream into, or the handling, sale, or other disposition of milk or cream in, such State or political subdivision" after it has been lawfully imported under a FIMA permit. In addition, FDA and the states participate in a cooperative program, known as the Interstate Milk Shippers Program, to ensure the safety of Grade "A" milk and milk products. For more details regarding how this program relates to the importation of milk, refer to the Federal Register Notice of June 28, 2000 (65 FR 39912-39914) and to "Final Guidance: Importation of Pasteurized Milk Ordinance (PMO) Defined Dairy Products (M-I-00-4)." These documents are available on the Internet at <http://vm.cfsan.fda.gov/~lrd/fr000628.html> and <http://www.cfsan.fda.gov/~ear/mi-00-4.html>, respectively.

FDA published a notice in the Federal Register of March 22, 1968 (33 FR 4881) announcing its determination, based on an opinion from the Department of Justice, that imported milk products in hermetically sealed cans, so processed by heat as to prevent spoilage, are not subject to the provisions of the FIMA. Similarly, FDA intends to consider sweetened condensed milk and evaporated milk as not subject to the provisions of the FIMA. Sweetened condensed milk is required by 21 CFR 131.120 to contain a quantity of nutritive carbohydrate sweetener sufficient to prevent spoilage, and evaporated milk is required by 21 CFR 131.130 to be sealed in a container and so processed by heat as to prevent spoilage. In addition, FDA has viewed the literal language of the FIMA as applicable only to milk and cream and not to products predominately comprised of milk and cream. Furthermore, FDA has applied the FIMA to imported milk and cream whether intended for use as human or animal food, and whether intended for direct consumption or manufacture into other foods.

### **III. DISCUSSION:**

#### **A. Definitions:**

The following definitions apply to this guidance:

The term "milk" refers to milk from domesticated (dairy) cows (genus *Bos*).

The term "United States" refers to the fifty States and the District of Columbia.

## **B. Application of the FIMA:**

1. FDA intends to consider the following dairy products as subject to the FIMA's permit requirement for importation:
  - i. Milk, Lowfat Milk, Skim or Nonfat Milk, Fortified Milk, Flavored Milk, Concentrated Milk, and Ultra Filtered Milk.
  - ii. Cream, Half-And-Half, Heavy Cream, Light Cream, and Light Whipping Cream.
2. FDA intends to consider the following dairy products as not subject to the FIMA's permit requirement for importation:
  - i. Sour Cream, Cultured Milk, Acidified Milk, Yogurt, Cheese, Ice Cream, and Eggnog.
  - ii. Sweetened Condensed Milk, Evaporated Milk, Dried Milk, Nonfat Dry Milk, Nonfat Dry Milk fortified with vitamins A and D, and other dehydrated milk products.
  - iii. 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 the requirements of 21 CFR 108.35 and 113.
3. The importation of milk and/or cream into the United States Trust Territories and Protectorates does not require a permit under the FIMA because these jurisdictions are not within the FIMA's definition of "United States." FDA intends to consider any subsequent distribution of milk or cream from United States Trust Territories and Protectorates to the United States or the District of Columbia as importation into the United States requiring a permit under the FIMA. Regardless of whether a permit is required, dairy products must comply with the applicable provisions of the Federal Food, Drug, and Cosmetic Act, Public Health Service Act, and implementing regulations.

## **IV. REGULATORY ACTION GUIDANCE:**

The following represent criteria for direct reference detention by District Offices:

Milk or cream or other dairy product identified in III.B.1. that is offered for importation and is not accompanied by a valid import milk permit, as required by the FIMA.

**V. SPECIMEN CHARGE:**

The article of [milk] [cream] is not accompanied by a valid import milk permit, as required by the Federal Import Milk Act (21 U.S.C. 141-149).

Note: Import detention and refusal documents must reference the FIMA as the authority for detention and refusal. Section 801(a) of the Federal Food, Drug, and Cosmetic Act should not be cited for this violation.\*

\*Material between asterisks is new or revised.\*

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