

RECOGNIZING MILK AND MILK PRODUCTS AS GRADE "A" WHEN PRESENTED FOR IMPORT INTO THE US

Regional Milk Specialists have asked for a procedure, including a definition for Grade "A" milk and milk products, that FDA Import and Customs people could use to determine the classification (Grade "A" or Manufactured) when milk and milk products are presented for import into the United States.

1) When a milk or milk product arrives at a port for importation into the U.S., one of the first determinations that should be made is how would this milk or milk product be classified and regulated within the U.S. If this milk or milk product is determined to be classified as a Grade "A" product, as referenced below, it would be regulated under the National Conference on Interstate Milk Shipments (NCIMS) and; therefore, regulated by the individual State Grade "A" Milk Regulatory Agency(s) within the State(s) that the product will be delivered. If it is determined to be a non-Grade "A" milk or milk product (Manufactured Grade) then it would be regulated under the Food, Drug and Cosmetic Act (FD&C Act). Also, at this time, it would be required to determine if the product (raw, pasteurized or frozen (plastic) bovine milk or cream) is required to have a permit under the Federal Import Milk Act (FIMA). A FIMA permit is not required for aseptic milk and dairy products if they have a filed process with FDA. These questions are separate issues and sometimes difficult to answer.

2) Following are examples of Grade "A" milk and milk products: pasteurized, ultra-pasteurized (280^oF for 2 seconds for labeling purposes) and aseptically processed fluid milk and milk products (whole, 2% reduced fat, lowfat and nonfat [skim]), flavored fluid milk products (chocolate, strawberry, etc. at all different fat levels), cultured milk (buttermilk, kefir, etc.), creams (whipping, heavy, light, whipped-in a pressurized can, etc.), half & half, sour cream, (flavored sour cream [chive, onion, etc.]), yogurts (different ways of spelling [i.e., yoghurt], spoonable, drinkable, does not include frozen yogurt), cottage cheese (4%, 2% reduced fat, lowfat, and nonfat [skim]), flavored cottage cheese (pineapple, vegetables, etc., at different fat levels), cottage cheese mixed with yogurt, yogurt drinks (smoothies), milk drinks (dairy beverages). They may be labeled with unfamiliar names common to the country from which they are being exported.

Standards of Identity for milk and milk products are cited in 21 CFR Part 131 and for cottage cheese in Part 133. The problem is there are many **NON-STANDARDIZED Grade "A"** milk and milk products that are being imported into the U.S. Some milk and milk products can be classified under both Grades (Grade "A" and Manufactured). Some examples of these are non-fat dry milk, whey protein concentrate, milk protein concentrate, condensed and/or evaporated milk, etc. (If any of these products are to be used as ingredients in Grade "A" products they are required to be labeled as Grade "A"). Standards of Identity for concentrated (condensed) milk, sweetened condensed milk, evaporated milk, dry whole milk, nonfat dry milk and "nonfat dry milk fortified with vitamins A and D" are also cited in 21 CFR Part 131. Standards of Identity for whey, whey protein concentrate and various other whey products are cited in 21 CFR Part 184.

Grade "A" milk and milk products are those products covered under the definitions of the Grade "A" Pasteurized Milk Ordinance (PMO). The 2001 Edition of the PMO is available on the FDA web site at <http://www.cfsan.fda.gov/~ear/p-nci.html>.

When you need assistance in making this Grade "A" determination, you need to contact your respective FDA Regional Milk Specialist.

3) The following can be used to assist you in your classification determination:

- The imported milk or milk product is packaged in similar packaging as found for Grade "A" milk and milk products in grocery stores across the U.S. This packaging includes: paper cartons ("brik paks" for aseptic products) and plastic jugs ranging from ½ pt., pint, quart, ½ gallon and gallon; plastic tubs or cups ranging in size from coffee creamers to cereal bowls (1 oz., 4 oz., 6 oz., 8 oz. 16 oz., etc); and large plastic buckets or plastic bags, either by themselves or placed in boxes or plastic cases (2 ½ gallon, 5 gallon, etc.).
- The imported milk or milk products is being presented for sale to the public in the usual fashion as found for Grade "A" milk and milk products in grocery stores across the U.S.

4) If you encounter a milk or milk product labeled Grade “A”, you need to refer to the Interstate Milk Shippers List (IMS List) to determine if the manufacturing firm is included in the listing, as required in the NCIMS Milk Safety Program and also as required in M-I-00-04. This document provides a list of all Regional Milk Specialists and all State Grade “A” Milk Regulatory Personnel (names, addresses, telephone numbers, etc.) and a listings of all Grade “A” firms (domestic & foreign) participating in the NCIMS Milk Safety Program. Foreign firms are currently listed under the State that listed them. States currently listing foreign firms are Florida, New York and Vermont. The IMS List can be found at <http://www.cfsan.fda.gov/~ear/ims-toc.html>. M-I-00-4 can be found at <http://www.cfsan.fda.gov/~ear/mi-00-4.html>.

5.) When you find a Grade “A” milk product, but the manufacturing firm is not included in the IMS List, the product is in violation of the NCIMS Milk Safety Program, unless the country has been found to be equivalent to the NCIMS Milk Safety Program by FDA. Currently, there is no foreign country granted equivalent status for Grade “A” milk and milk products.

6) If the milk product is determined to be Grade “A”, but is not labeled Grade “A”, the product is in violation of the NCIMS Milk Safety Program and the labeling requirements of the PMO and is regulated by the individual State Milk Regulatory Agency. There may also be other labeling violations, such as FD&C Act labeling violations, which are FDA’s responsibility.

7) When you have made the determination that the product is Grade “A” and not included in the IMS List you should contact the identified State Grade “A” Milk Safety Program Official(s) of the receiving State(s) and the appropriate Regional Milk Specialist(s) prior to releasing the product. State Grade “A” Milk Safety Program Officials should be willing to assist with the Grade “A” issue.

Hopefully, you already have standing arrangements with the State Grade “A” Milk Safety Program to notify them of the importation of Grade “A” milk and milk products into their State. If not, we would advise you that these arrangements be made. If you know where the milk product is going, you may want to give the receiving State Officials a call also. State Officials can be most helpful with these Grade “A” issues and will appreciate cooperation from FDA.

8) Any questions concerning the requirements for a permit under the FIMA should be directed to Mr. John Sheehan or Mr. Robert N. Childers in CFSAN’s Division of Dairy and Egg Safety.