FDA

Milk and milk products are defined in 21 CFR 1240.3 (i) and 21 CFR 1240.3(j). All milk and milk products delivered into interstate commerce must be pasteurized per 21 CFR 1240.61.

Milk and milk products exported to the U.S. is regulated as a Grade "A" dairy product under the Definition JJ, page 8 of the 2019 Grade "A" Pasteurized Milk Ordinance (PMO). **Milk and milk products** must be labeled as Grade "A" unless it is dried. Milk and milk products which have been concentrated (condensed) or dried are only included in this definition if they are used as an ingredient to produce any milk or milk product defined in the PMO, Definition JJ (Page 10) of the PMO or if they are labeled as Grade "A" as described in Section 4. of the PMO. **All milk and milk products must be labeled as such, and must meet the mandatory pasteurization requirements per 21 CFR 1240.61 and all other applicable FDA food import requirements as outlined below in the section entitled, "Importing Food – Requirements Overview."**

Grade "A" milk and milk products are required to fall under one of options below. This must be exercised by the milk plant outside the United States and Puerto Rico to export the product to the U.S. The first option can be found in M-I-00-4, which is attached below and can be found at https://gams.fda.gov.

M-I-00-4-FINAL.pdf

1. A dairy firm outside of the United States could contract with any current National Conference on Interstate Milk Shipments (NCIMS) Member's Regulatory/Rating Agency to provide the "Grade A" milk safety program in total. This would include the regulatory licensing, dairy farm and milk plant inspection and sampling, pasteurization equipment testing, laboratory certification and rating/NCIMS listing certification. To use this option the firm would be required to abide by all applicable NCIMS regulatory and rating requirements, and the regulatory/rating agency would have to agree to treat the firm as if it were located within its jurisdiction for all purposes, including inspection and enforcement. Ratings of the firm would be check-rated by FDA.

2. NCIMS has an International Certification Program (ICP) that certifies private third-party assessors to evaluate firms located outside of the U.S. and to evaluate the firms' compliance with the NCIMS requirements. This option for the listing of ICP milk companies in the Interstate Milk Shippers (IMS) List provides another means for NCIMS member States to accept Grade "A" milk and milk products from these IMS-Listed foreign ICP milk companies. Two (2) Third Party Certifiers (TPCs), which are non-governmental entities, are currently participating in the NCIMS International Certification Program. The two (2) TPCs implement, regulate, enforce, rate and verify compliance with the regulations contained in the most current edition of the Grade "A" *Pasteurized Milk Ordinance* (PMO) and related NCIMS documents for the purpose of listing outside of the boundaries of the United States.

The two approved TPCs are listed below.

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Dairy companies located outside the United States may contact these firms directly to inquire about certification opportunities offered under the Voluntary ICP.

Additional information concerning this voluntary ICP program is also available from: Jamie Jonker, International Certification Program Committee (ICPC) Chair, National Milk Producers Federation: 703-244-4344, jjonker@nmpf.org

As you consider these options above,

- The requirements of M-I-00-4 (65 FR 39912) are in addition to the other FDA requirements for importing food into the U.S., including Low Acid Canned Foods (LACF) requirements if applicable.
- Option 1 can and has been exercised with limited success in the past but is not currently being utilized by any NCIMS member (any facility within the United States or Puerto Rico).
- Option 2 is the only option that is actively being utilized with Grade "A" dairy processors outside the United States and has been successful for the past several years.

NOTES:

- If PMO-defined Grade "A" milk and milk products produced outside the United States have not been produced, processed, transported and packaged in accordance with one of the four options cited above, they are subject to the state's seizure requirements or other regulatory actions, notwithstanding that they may meet the requirements of the Federal Food, Drug and Cosmetic Act.

- Federal Import Milk Act (FIMA) and CPG-560.400-Imported Milk and Cream-Federal Import Milk Act regulations apply to the importation of milk and cream into the United States. The FIMA defines "United States" as "the fifty States and the District of Columbia" (21 U.S.C. 149).

Importing Food – Requirements Overview

All foods imported into the United States are subject to the provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and, if offered for sale as a consumer commodity, to the FDA Labeling Requirements and FDA New Nutrition Facts Label. In general terms, the FD&C Act requires food to be prepared from sound, wholesome raw materials, to be prepared, packed and held at all times under sanitary conditions, the food itself to be a safe, clean, and wholesome article and its labeling to be honest and informative. Labeling regulations provide for additional labeling for consumer size packages, so that the labels will enable consumers to obtain accurate information as to the quantity of contents and to facilitate value comparisons. Other FDA food information, including the Food Traceability Rule, can be found at https://www.fda.gov/food

To import a food product into the U.S., all firms, foreign and domestic, that manufacture, process, pack or hold the food need to be registered with FDA as Food Facilities. The registration only applies to physical

locations where the food is being manufactured, processed, packed, or held. Please do not register office addresses that do not perform one of these activities. (Step-by-Step Guide to Food Facility Registration).

After you receive your food facility registration number, the next step would be to visit the Import Program Overview – Food and Drug Administration and the Overview of Requirements for a Food Business on the FDA website for packaging, labeling and facility information. Please visit the commodity specific information related to your product to ensure you are aware of any additional regulations specific to the product that you will be importing to the U.S.

As of May 30, 2017, there are Key Requirements for all Foreign Supplier Verification Programs (FSVP) Importers, including obtaining a unique identifier called a Data Universal Numbering System (DUNS) # for their U.S. facility that will hold all of their FSVP records for FDA inspection. This must be a facility in the U.S. You will need the DUNS # to transmit entries to FDA or an exemption code if the food is exempt from FSVP requirements. You can read more on obtaining a DUNS # here. This FSVP Q & A is also very helpful.

Please review FDA's Import Alerts. Import Alerts are a tool used by FDA to prevent potentially violative goods from entering U.S. commerce. Import Alerts can be product/manufacturer specific, product specific, and/or country specific. Please read the specific instructions in the Import Alert for more information.

Once you have verified your food is manufactured in compliance with all U.S. regulations, all required food facilities are registered, and you are ready to import into the U.S., you will need to ensure that Prior Notice is filed before the goods arrive in the U.S. Your Customs Broker can do this for you when filing your entry or you can file online yourself (Step-by-Step Guide). Prior Notice informs FDA when a shipment of your product will be coming to the U.S. Please be mindful that you must submit the prior notice 8 hours prior to arrival if by sea, 4 hours prior to arrival if by air, 4 hours prior to arrival if by rail, and 2 hours prior to arrival if by truck.

FDA Guidance

GENERAL IMPORTS INFO	FOOD REGULATIONS	SYSTEMS INFORMATION
Importing Human Foods Overview	How to Start a Food Business	FDA-ACE Supplemental Guide
Import Basics | FDA	Food Facility Registration	Product Code Builder
Entry Submission Process | FDA	Prior Notice	Product Code Builder Tutorial
Actions & Enforcement	Foreign Supplier Verification Program	
Import Alerts	Food Labeling	
	Good Manufacturing Practices	
	Food Guidance Documents	

In addition to the general food import requirements, please review which products are subject to the Federal Import Milk Act (FIMA) permit requirement.

See CPG 560.400 Imported Milk and Cream - Federal Import Milk Act

Application of the FIMA:

1. FDA intends to consider the following dairy products as subject to the FIMA's permit requirement for importation:
   - Milk, Lowfat Milk, Skim or Nonfat Milk, Fortified Milk, Flavored Milk, Concentrated Milk, and Ultra Filtered Milk.
   - 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:
   - Sour Cream, Cultured Milk, Acidified Milk, Yogurt, Cheese, Ice Cream, and Eggnog.
   - Sweetened Condensed Milk, Evaporated Milk, Dried Milk, Nonfat Dry Milk, Nonfat Dry Milk fortified with vitamins A and D, and other dehydrated milk products.
   - 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.

If you are not importing a product subject to FIMA permit requirements, the standard food requirements apply. See below.

Other Government Agency Resources

- Customs Border Patrol (CBP) Importing Info: https://help.cbp.gov/app/answers/detail/a_id/197/noIntercept/1
- Locate a Port: http://www.cbp.gov/contact/ports
- USDA Importing Goods: http://www.usda.gov/wps/portal/usda/usdahome?navid=IMPORTING_GOODS
- For import questions not related to prior notice, contact the Division of Import Operations at FDAImportsInquiry@fda.hhs.gov
- For Automated Commercial Environment (ACE) questions relating to imports and exports reports, contact ACESupport@fda.hhs.gov
- For FSVP questions, please contact CFSAN's Technical Assistance Network: https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm

GENERAL REQUIREMENTS FOR FOOD PRODUCTS

Here is some information regarding Importing Human Foods to the United States. Human food is defined as articles for eating or drinking, including for research use and personal use. For product-specific or regulatory questions, please contact FDA's Center for Food Safety and Applied Nutrition (CFSAN).
Watch Importing FDA-Regulated Products: the Import Process on YouTube now!

What to Consider Before You Import a Human Food

Food imported into the United States must meet the same laws and regulations as food produced in the United States. It must be safe and contain no prohibited ingredients, and all labeling and packaging must be informative and truthful. It is the importer's responsibility to ensure that the imported food is in compliance and to follow the conditions of their customs bond. Please visit the How to Start a Food Business page for a list of requirements.

1. **Ensure product is compliant with all FDA laws, regulations, and policy/guidance.**

   - Applicable Regulations: 21 CFR Part 1, 100-169
   - Applicable Guidance
     - Food Guidance & Regulation (by topic)
     - Compliance Policy Guides: Food
     - Compliance Policy Manual Guides: Food
     - Labeling & Nutrition
     - Food Good Manufacturing Practices
   - Labeling Requirements
     - Human Food: 21 CFR Part 101
     - Food Labeling Guide
     - Small Business Nutrition Labeling Exemption
   - Registration Requirements
     - Food Facility Registration
     - FSVP Importer Identifier: D-U-N-S number
   - Other Requirements
     - Must submit Prior Notice before goods arrive in the U.S.
     - Foreign Supplier Verification Program

2. **Check FDA's Import Alerts** to determine if your product/manufacturer is subject to Detention without Physical Examination (DWPE) and requirements to secure a release of the shipment.

3. **Review FDA's Entry Submission and Review Process.**

4. **Consider providing the following information to your Customs broker to transmit to FDA.** Complete and accurate information and documentation will help expedite the review process.
   - Product name(s) and/or descriptions (might be listed on commercial invoice)
   - Intended use of the product(s) in the U.S.
   - Name and address of the physical location of the manufacturer, shipper, importer, and the deliver to party.
     - If any of the entities have an FEI or D-U-N-S number, they may optionally be supplied.
   - A full list of required data elements can be found in the FDA Supplemental Guide by commodity.
     - Please also see: FDA ACE External Outreach Presentation-Human & Animal Food

What to Consider During the Import Process

At the time of import, the importer will have to provide information about the shipment, related firms, and products to FDA. Once the shipment is transmitted to FDA for review, our systems will conduct an initial evaluation to determine if the product can proceed into commerce or if more information is needed. If more information is needed, the shipment information will be sent electronically to the local FDA office where the goods entered the United States for additional review. The local FDA office may request documents and/or request a physical examination of the

products. If a physical examination is performed, FDA will be evaluating the product and labeling for compliance. FDA may collect samples of the products for FDA labs to analyze for known hazards. Depending on the results of the exam and/or sampling, the products will either be proceeded into commerce or held for a compliance review. The local FDA office also makes the final admissibility decision (release or refuse). This page on FDA's Entry Review Process provides additional information.

1. **Stay in contact** with your Customs broker and/or FDA and provide requested information in a timely manner.
   - If FDA requests documents or an inspection, provide the requested information and/or documents via ITACS.
     - Documents might include invoices, shipping documents, ingredients list, copies of labels, photos of product, formulations, processing methods, etc.
   - You may provide any information that would help the reviewer determine your product is in compliance with U.S. laws and regulations.

2. **Monitor the status** of your entry on ITACS for final admissibility decision.

3. **Submit questions** about your shipment to the local FDA office at the port of entry.

Additional Resources

Regulations	Guidance	Labeling	Registration	Other	Systems Information
21 CFR Part 1, 100-169	Guidance & Regulation (by topic)	Food Labeling Guide	Food Facility Registration	Prior Notice	FDA Supplemental Guide for ACE
Color Additives: 21 CFR Part 70-82	Compliance Policy Guides: Food		Food Facility Registration Step-by-Step Guide	PNSI Step-by-Step Guide	Product Code Builder
Food Additives: 21 Part 170-189	Compliance Policy Manual Guides		FSVP Importer Identifier: D-U-N-S number	Prior Notice Q & A	Product Code Builder Tutorial
	Labeling & Nutrition			Foreign Supplier Verification Program	
	Food Good Manufacturing Practices			FSVP Q & A	
				Import Alerts	

ACE Transmission Requirements: Human Foods

A full list of data elements can be found in the FDA Supplemental Guide.

Program Code: FOO

Processing Code:	PRO (processed food) or NSF (natual state food) or ADD (food or color additive)
Intended Use Code:	See the FDA Supplemental Guide for ACE
Affirmations of Compliance:	See the FDA Supplemental Guide for ACE

Please also see: FDA ACE External Outreach Presentation-Human and Animal Food

APHIS

Regulations in title 9, Code of Federal Regulations (9 CFR), section 94.16, describe the requirements under which milk and milk products can be imported into the United States.

APHIS recognizes Ukraine as a region affected with foot-and-mouth disease (FMD). Milk and milk products from regions recognized as having FMD need to be accompanied by a Veterinary Services (VS) import permit. Only a U.S. resident or business can apply for a VS import permit.

The U.S. importer is required to complete an application for permit (VS Form 16-3), which is available through utilization of the VS Permitting Assistant (VSPA).

The permit application process requires the importer to supply APHIS with information regarding the treatment of the material prior to importation into the U.S. (such as temperature and time). If it is determined from the information provided in the application that a permit can be issued, it will be valid for one year. The VS import permit must accompany the products upon entry into the United States.

APHIS requires that milk and milk product be mitigated as if for animal use because of its concern for the possibility that the imported products could ultimately be diverted into the animal population. APHIS will accept milk and milk products for import that only use milk that is exposed to one of the following treatments:

- a minimum temperature of 72 degrees C for 15 seconds followed by a minimum temperature of 72 degrees C for 15 seconds, OR
- a minimum temperature of 72 degrees C for 15 seconds followed by a pH treatment of less than 6 for at least one hour, OR An Equal Opportunity Provider and Employer
- a single ultra-high temperature (UHT) of 148 degrees C for 3 seconds, OR
- a single UHT of 140 degrees C for 5 seconds.

APHIS may accept another heat mitigation if it is equivalent to or exceeds the above heat treatments.