SFA Export Library Market Reports on Food Import Regulations and Standards

Country of Origin	Singapore (SG)
Country of Destination	United States of America (US)
Food Product Category	Milk and Dairy Products
Product Code	HS Codes: 0401 - 0406, 15179069, 19019031/32/39, 2105, 22029910/40/50

The information in this document has been compiled and provided by the Singapore Food Agency (SFA). SFA emphasises that importers and exporters have the responsibility to find out the import requirements of destination countries/regions/markets. Exporters are advised to confirm with their importers on the import requirements and eligibility of their product before exporting.

SN	Sub-header	Details
1	**Product eligibility / ineligibility**	Dairy products are eligible to be exported from Singapore to the United States of America (US).
2	**Importing country authority**	Food and Drug Administration (FDA) is the regulatory agency responsible for ensuring that imported milk and milk products are safe, wholesome, correctly labelled and packaged through the Federal Food, Drug and Cosmetic Act (FD&C). This is accomplished, in part, by inspecting the production, processing, and distribution of foods and examining samples to ensure compliance with the FDA's statutory requirements. United States Department of Agriculture (USDA) is the lead agency on issuing US dairy sanitary certificates, coordinating interagency collaboration related to the exports of US milk and milk products to overseas destination countries.
3	**Pre-export approvals by the importing country**	**(1) Establishment-level approval** According to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, any facility (domestic and foreign) engaged in manufacturing, processing, packing, or holding food for consumption in the United States must register with FDA, and FDA should be given advance notice on shipments of imported food. Information and tips on how to register a facility can be found at Registration of Food Facilities and Other Submissions. Registration is valid for two years. There are specific registration procedures and process filing for acidified and low-acid canned food (LACF)

		commercial processor. **(2) Import license and permit** As the imports of dairy products into the US are subject to the dairy import licensing program, an import license may be required by the USDA's Foreign Agricultural Service (FAS), depending on the tariff rate tier classification assigned to the consignment. To apply, please click here. An import permit is required by the FDA for milk and cream products. To apply, please click here for application form. According to Compliance Policy Guide (CPG) 560.400 Imported Milk and Cream - Federal Import Milk Act (FIMA), FDA intends to consider the following dairy products as subject to FIMA's permit requirement for import: a) milk, low-fat milk, skim or nonfat milk, fortified milk, flavored milk, concentrated milk, and ultra-filtered milk b) cream, half-and-half, heavy cream, light cream, and light whipping cream. **(3) Animal health permit** Importers should apply for an Animal Health Permit when importing foods of animal origin. An Animal Health Permit is required by the USDA Animal and Plant Health Inspection Service (APHIS), for dairy products (excluding butter and cheese) exported from countries with livestock diseases exotic to the US. According to Code of Federal Regulations (CFR), Title 9 Animals and Animal Products, Chapter I, Subchapter E, Part 122 Organisms & Vectors, Section 122.2 Permits required, no organisms or vectors shall be imported into the US without a permit. For more information on application of such permit, see Animal Health Permits. **(4) Prior notice of imported foods** The FDA Food Safety Modernization Act (FSMA) signed on 4th January 2011 aims to ensure the US food supply is safe by shifting the focus of federal regulators from responding to foodborne illness to preventing it. On 5th May 2011, the FDA published an interim final rule requiring that a person submitting prior notice of imported food, including food for animals, to report the name of any country to which the article has been refused entry. For more information on the Prior Notice System Interface (PNSI), see Filing Prior Notice.
4	**Export certificates for food**	Depending on the import conditions stated on your import permit, an Export Health Certificate issued by the Singapore Food Agency (SFA) may be required for each consignment. For exports that require an Export Health Certificate, you may forward the import permit to the SFA here. SFA will determine if the conditions can be met for the issuance of certificate.

		The conditions which must be met by the exporter for the issuance of health certificate include but not limited to the following: 1. The milk/milk product in the exported material originated in (country) and has not been in any country/ region considered by U.S. Department of Agriculture to be affected with foot-and-mouth disease. 2. The milk/milk product was processed at an officially approved manufacturing plant. 3. The milk/milk product does not contain any harmful additives and is unconditionally passed fit for human consumption. SFA will apply specific health certificate attestations based on the US-issued import permit.
5	**Regulations and standards**	Interested exporters who wish to export dairy products to the US must meet all their regulations and standards. The following contents are provided as a guide: **(1) Pesticide residues** Environmental Protection Agency (EPA) regulates the amount of each pesticide that may remain in and on foods. FDA tests food produced in the US and food imported from other countries for compliance with these residue limits. USDA tests meat and milk. The list of tolerances and exemptions is compiled in the CFR, Title 40 Protection of Environment, Chapter I, Subchapter E, Part 180 Tolerances and Exemptions for Pesticide Chemical Residues in Food. **(2) Animal drug residues** FDA's Center for Veterinary Medicine (CVM) makes sure an animal drug is safe and effective before approving it. The list of specific tolerances in CFR, Title 21 Food and Drugs, Chapter I, Subchapter E, Part 556 Tolerances for Residues of New Animal Drugs in Food including Subpart B pertain only to approved or conditionally approved new animal drugs. **(3) Contaminants** FDA also oversees the safety of the US food supply (domestic and imports) by monitoring contaminants in food and assessing the potential exposure and risk posed by chemical contaminants. For more information, refer to Environmental Contaminants in Food, Process Contaminants in Food, and Natural Toxins in Food.

		Compliance Policy Guides (CPGs) explain FDA's policy on regulatory issues related to FDA laws or regulations. CPG Sec. 555.400 Aflatoxins in Human Food provides guidance for FDA staff on aflatoxins in human food. CPG Sec. 555.425 Foods, Adulteration Involving Hard or Sharp Foreign Objects stipulates the requirements for hard or sharp foreign objects in food. CPG Sec. 555.450 Foods – Adulteration Involving Infestation stipulates the requirements for rodenticide in food. CPG Sec. 555.880 Guidance Levels for Radionuclides in Domestic and Imported Foods stipulates the requirements for radionuclides in food. For more information, refer to Chapter 5 - Food, Colors, and Cosmetics. CFR, Title 21 Food and Drugs, Chapter I, Subchapter B, Part 109, Subpart B, Section 109.30 Tolerances for polychlorinated biphenyls (PCB's) stipulates tolerances for polychlorinated biphenyls (PCB's) in various foods. According to Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed, action levels and tolerances are established based on the unavoidability of the poisonous or deleterious substances and do not represent permissible levels of contamination where it is avoidable. Action levels and tolerances represent limits at or above which FDA will take legal action to remove products from the market. Where no established action level or tolerance exists, FDA may take legal action against the product at the minimal detectable level of the contaminant. FDA has issued Guidance for Industry on Action Levels for Lead in Baby Foods. FDA also published the Draft Guidance for Industry: Action Levels for Lead in Food Intended for Babies and Young Children. **(4) Microorganisms** The following are the guidelines for microbial limits in food issued by FDA: CPG Sec. 527.300 Microbial Contaminants & Alkaline Phosphatase Activity (dairy products) CPG Sec. 555.320 Listeria monocytogenes The list of microbial risks published by FSIS includes *Listeria monocytogenes*, *Salmonella*, shiga toxin producing *Escherichia coli* (STEC) and *Escherichia coli* O157:H7 and specified risk material (SRM). For more information, refer to Microbial Risk. **(5) Food additives**

		CFR, Title 21 Food and Drugs, Chapter I, Subchapter B, Part 170 to 190 stipulates the list of food additives and generally recognised as safe (GRAS) substances that are allowed to be used in food. In particular, CFR, Title 21 Food and Drugs, Chapter I, Subchapter B, Part 189 Substances prohibited from use in human food stipulates the list of substances prohibited to be used in human food. FDA has issued a direct final rule in Dec 2023 to determine that partially hydrogenated oils (PHOs) are no longer GRAS and revoke its use in food. CFR, Title 21 Food and Drugs, Chapter I, Subchapter B, Part 70 to 82 specifies the list of colour additives that can be used in food. Food Additives Status List provides short notations on use limitations of each additive specified in the regulations promulgated under the Federal Food, Drug and Cosmetic Act, under Sections 401 (Food Standards) and 409 (Food Additives). Separately, Flavor and Extract Manufacturers Association of the United States (FEMA) contains a flavor ingredient library for members to utilise. FDA is extending the comment period for the colour additive petition to revoke colour additive listing for use of titanium dioxide in food. **(6) Product specifications** CFR, Title 21 Food and Drugs, Chapter I, Subchapter B, Part 131 Milk and cream stipulates the requirements for milk and cream. CFR, Title 21 Food and Drugs, Chapter I, Subchapter B, Part 133 Cheeses and related cheese products stipulates the requirements for cheeses and related cheese products. CFR, Title 21 Food and Drugs, Chapter I, Subchapter B, Part 135 Frozen desserts stipulates the requirements for frozen desserts. CFR, Title 21 Food and Drugs, Chapter I, Subchapter B, Part 107 Infant Formula stipulates the requirements for infant formula.
6	**Labelling, packaging and marking requirements**	**(1) Labelling** CFR, Title 21 Food and Drugs, Chapter I, Subchapter B, Part 101 Food labeling stipulates the relevant requirements for food labeling, including the principal display panel, information panel, identity labeling, designation of ingredients, name and place of business, declaration of net quantity of contents, nutrition labeling, reference amounts, nutrient content claims, health claims, prominence of required statements, and food labeling warning. For more information, refer to Labeling & Nutrition Guidance Documents & Regulatory Information. Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) stipulates the labeling requirements of

		allergens in food. Such eight major food groups include milk, eggs, fish (e.g., bass, flounder, or cod), crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans. CFR, Title 7 Agriculture, Subtitle B, Chapter I, Subchapter C, Part 66 National bioengineered food disclosure standard and Subchapter M, Part 205 National Organic Program stipulate the labeling requirements of respectively bioengineered foods and organic foods. If the label or labeling will be claimed concerning the fact that bioengineering or genetically-modified (GM) ingredients were not used in the meat, poultry, or egg products, see Labeling Guideline on Statements that Bioengineered or Genetically-Modified Ingredients or Animal Feed were not used in Meat, Poultry, or Egg Products. If the food was irradiated, the label and labeling of retail packages should bear the necessary logo along with either the statement prescribed in CFR, Title 21 Food and Drugs, Chapter I, Subchapter B, Part 179, Subpart B Radiation and radiation sources. **(2) Packaging** CFR, Title 21 Food and Drugs, Chapter I, Subchapter B, Part 174 to 179 specifies the requirements on food contact packaging materials which are termed as indirect food additives for compliance purpose.
7	**Other information**	**(1) Foreign Supplier Verification Programs (FSVP)** All food imported into the US are subject to the Foreign Supplier Verification Programs (FSVP) requirements unless there is exemption as expressly stated in CFR, Title 21 Food and Drugs, Chapter I, Subchapter A, Part 1, Subpart L, Section 1.501. For more information, please see Food Safety Modernization Act (FSMA) Final Rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals. **(2) WTO Import Licensing Procedures** United States of America's legislation and notifications **(3) Other Relevant Rules** Basic Importing and Exporting Importing Food Products into the United States

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