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	Fish and Seafood Products
Product Code	HS Codes: 0302 - 0309, 1604/1605

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**	Fish and seafood products (excluding Siluriformes) are eligible to be exported from Singapore to the United States of America (US).
2	**Importing country authority**	All fish and seafood products are regulated by Food and Drug Administration (FDA), except for Siluriformes fish and fish products, which are regulated by United States Department of Agriculture (USDA).
3	**Pre-export approvals by the importing country**	**(1) Country-level approval** Siluriformes fish and fish products must come from a country approved by USDA. Countries wishing to become eligible to export Siluriformes fish and fish products to the US must demonstrate that they have a regulatory food safety inspection system that is equivalent to that of the US. Equivalence does not mean that the country is required to develop and implement the same procedures that the US does, but rather the country must objectively demonstrate how its procedures meets the US level of protection. Guideline for Countries on the Food Safety and Inspection Service's Equivalence Process provides information about USDA's Food Safety and Inspection Service (FSIS) international equivalence process for meat, poultry, and egg products, including background on the process, the different types of equivalence determinations, and steps that countries should follow to obtain an equivalence determination. FSIS has also published the list of eligible countries and their corresponding products on its Import & Export Library. **(2) Establishment-level approval**

a. Listing and registration of Siluriformes fish and fish products establishments as regulated by FSIS
According to FSIS Guidance for Importing Meat, Poultry, and Egg Products into the United States (also applicable to Siluriformes fish), after a country is determined to have an equivalent food safety regulatory system, FSIS relies on the country's central competent authority (CCA) to carry out inspection activities. Foreign establishments desiring to export to the US must apply to their own CCA. And a responsible official of that country's inspection system must certify to FSIS those establishments that meet requirements equivalent to those of the US. In addition to re-inspecting product presented for import into the US, FSIS conducts periodic audits to ensure that the foreign country's food safety regulatory system remains equivalent to that of the US. These audits include an assessment of selected exporting establishments.

b. Listing and registration of all food establishments (including Siluriformes fish) as regulated by FDA
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.

c. Listing and registration of fish farms and exporters as regulated by NMFS
All foreign commercial fisheries (including aquaculture farms) are required to be listed on List of Foreign Fisheries (LOFF) by the National Marine Fisheries Service (NMFS) before exporting any fish and seafood products to the US. LOFF for 2020 can be accessed here.

All exporters of fish and seafood products are required to be listed on List of Intermediate Nation or Products (LOIN) by the NMFS before exporting such products to the US. These exporters must also ensure their fish and seafood products are sourced from the LOFF. LOIN for 2020 can be accessed here.

To considered for listing by NMFS, please submit your application to the Singapore Food Agency (SFA),

		who will verify before recommending to the NMFS for listing. **(3) Relevant permit** An International Fisheries Trade Permit (IFTP) is required by the NMFS for the importation of certain fish and seafood products such as sharkfin, swordfish, tuna and toothfish. For more information on application of such permit, see NOAA Fisheries Permit. Importers should apply for an Animal Health Permit when importing foods of animal origin. 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**	An Export Health Certificate issued by the Singapore Food Agency (SFA) is required for each consignment of fish and seafood products. For these exports, you may forward the import permit / conditions to SFA here. According to CFR, Title 9 Animals and Animal Products, Chapter III, Subchapter A, Part 327 Imported Products, Section 327.4 Foreign inspection certificate requirements, each consignment imported into the US must have an electronic foreign inspection certification or a paper foreign inspection certificate issued by an official of the foreign government agency responsible for the inspection and certification of the product. The electronic foreign inspection certification must be in English, be transmitted directly to FSIS before the product's arrival at the official import inspection establishment and be available to the inspection personnel. The official must certify that any product described on the official certificate was produced in accordance with the regulatory requirements in Section 557.2 (for importation of fish and fish products). The paper official inspection certificate must accompany each consignment; be submitted to import inspection personnel at the

		official import inspection establishment; be in English; and bear the official seal of the foreign government responsible for the inspection of the product, and the name, title, and signature of the official authorized to issue inspection certificates for products imported to the US. **Model Catch Certificate or Model Aggregated Catch Certificate** As certain fishery products (such as abalone, Atlantic cod, Atlantic blue crab, dolphinfish (mahi mahi), grouper, red king crab, Pacific cod, red cod, sea cucumber, sharks, shrimp, swordfish, and tuna (albacore, bigeye, skipjack, yellow bluefin) are regulated under National Marine Fisheries Service (NMFS)' Seafood Import Monitoring Program (SIMP), a Model Catch Certificate or a Model Aggregated Catch Certificate for both wild-captured and aquaculture may be requested for traceability to confirm the product is sourced from NMFS' List of Foreign Fisheries or Intermediate Nation.
5	**Regulations and standards**	Interested exporters who wish to export fish and seafood products to 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. 555.300 Foods, Except Dairy Products - Adulteration with Salmonella 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. In addition, CFR, Title 9 Animals and Animal Products, Chapter III, Subchapter A, Part 381 Poultry products inspection regulation and Subchapter E, Part 424 Preparation and processing operations stipulate additional requirements for the use of food additive and colour additive in poultry products that is deemed unsafe. 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 123 Fish and fishery products stipulates the requirements for fish and fishery products. CFR, Title 21 Food and Drugs, Chapter I, Subchapter B, Part 161 Fish and shellfish stipulates the labelling requirements and requirements for specific standardized fish and shellfish.
6	**Labelling, packaging and marking requirements**	**(1) Labelling** According to FSIS Guidance for Importing Meat, Poultry, and Egg Products into the United States, meat (including Siluriformes fish), poultry, and egg products that are imported into the United States must adhere to all applicable statues and regulations (including labeling requirements) found in the Federal Meat Inspection Act, Poultry Products Inspection Act and CFR, Title 9 Animals and Animal Products, Chapter III Food Safety and Inspection Service, Department of Agriculture. Imported products must meet the same labeling requirements as domestically produced products.

		CFR, Title 21 Food and Drugs, Chapter I, Subchapter B, Part 123 Fish and fishery products stipulates the general requirements for the labeling of fish and fishery products, including food name and other labeling requirements. CFR, Title 9 Animals & Animal Products, Chapter III, Subchapter E, Part 412 Label approval stipulates the need for label approval. For more information see A Guide to Federal Food Labeling Requirements for Meat, Poultry, and Egg Products and Label Verification of Imported Meat, Poultry, and Egg Products - Revision 2. 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) FSIS Product Categorization (Import)** Importers and exporters should accurately identify the process category of meat, poultry and egg products certified for export to the US according to the FSIS Product Categorization. It is essential that the product is properly categorized, as this impacts what types of inspection the products will be subjected to, including examinations and laboratory sampling. **(3) WTO Import Licensing Procedures** United States of America's legislation and notifications **(4) Other Relevant Rules** Basic Importing and Exporting Importing Food Products into the United States Importing and Exporting Seafood Commodities Final Rule on Sanitary Transportation of Human and Animal Food (2016) Fish and Fishery Products Hazards and Controls Guidance (2020)

Disclaimer: SFA is providing this document for information purposes only. While care has been expended in the preparation of this report, SFA makes no representation or warranty, express or implied, as to the accuracy or completeness of any information contained in this document. Appropriate professional advice should be obtained before relying on or acting on any of the information contained in this document, and neither SFA nor any of its officers, employees or agents shall be held liable for any loss or damage, whether direct or indirect, as a result of any improper or incorrect use of the information in this document.