Food Export Library

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The information listed below reflects CFSAN's current understanding of our trading partners' certification requirements for food that has been exported from the U.S. If a country is not listed, exporters are advised to work closely with the importer for information regarding the certification requirements for the country into which the product will be imported. For more information on the types of export certification available from CFSAN, please visit Food Export Certificates (/food/exporting-food-products-united-states/food-export-certificates) and Food Export Lists (/food/exporting-food-products-united-states/food-export-lists).

Other U.S. government agencies also publish information on importing country requirements for food products. Please visit the links below for more information.

- The National Oceanic and Atmospheric Administration (NOAA) provides information on country-specific requirements for exporting seafood.
 - Export Requirements by Country and Jurisdiction (A-F) (https://www.fisheries.noaa.gov/export-requirements-country-and-jurisdiction-f).
 - Export Requirements by Country and Jurisdiction (G-M) (https://www.fisheries.noaa.gov/export-requirements-country-and-jurisdiction-g-m-2)
 - Export Requirements by Country and Jurisdiction (N-Z) (https://www.fisheries.noaa.gov/export-requirements-country-and-jurisdiction-n-z)
- The U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) provides information on requirements for exporting
 plants, animals, and animal products.
 - APHIS Animal and Animal Product Export Information
 (https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/export/ct animal and animal product export information).
 - · APHIS Plant Health Export Information (https://www.aphis.usda.gov/aphis/ourfocus/planthealth/SA_Export)
- The U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) provides information on requirements for exporting meat, poultry, and processed egg products.
 - FSIS Export Library Requirements by Country (https://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/exporting-products/export-library-requirements-by-country)
- The United States Department of Agriculture Global Agriculture Information Network (GAIN) provides information related to trade in agricultural products. The Food and Agricultural Import Regulations and Standards Reports (FAIRS) contain useful information about certification requirements for various food products.
 - o GAIN Reports Search (https://gain.fas.usda.gov/Lists/Advanced%20Search/AllItems.aspx)

Australia

The Australia Department of Agriculture, Fisheries and Forestry (DAFF) requires an official certificate for imports of human milk and human milk products. DAFF has agreed to accept an FDA-issued "Certificate to a Foreign Government" (CFG) for U.S. exports of FDA-regulated human milk and human products.

Industry may request a CFG for these products by submitting an online application in the CFSAN Export Certification Application and Tracking System (CFSAN eCATS). Please visit Online Applications for Export Certificates for Food (/food/food-export-certificates/online-applications-export-certificates-food) for a link to CFSAN eCATS and general instructions for submitting an application. U.S. applicants should select "Infant Formula" as the product type for any products regulated by FDA as an infant formula and "Conventional Food" for any other human milk products. Please see below for a list of certification data elements and additional certification statements required by DAFF for these products and instructions on how to provide this information in CFSAN eCATS.

Certification Data Elements Required by DAFF

- 1. Manufacturer/Processor Name and Address: This information is a required field on the application and applicants should check "Display on Certificate" to include this information on the certificate.
- Exporter Name and Address: Applicants should provide this information on the application and check "Display on Certificate" to include this information on the certificate.
- 3. Product Name: This is a required field in the Product Information section of the CFSAN eCATS application and will always be printed on the certificate. Applicants should use the product name that appears on their Australian import permit.
- 4. Lot Number: Applicants should provide this information in the Product Details section of the application and select this field as one of the headers to be printed on the certificate.
- 5. Type of Packaging: Applicants should provide this information in the Product Details section of the application and select this field as one of the headers to be printed on the certificate. The information required for this field will vary depending on the type of product(s) included in each shipment. Here is an example as to what DAFF expects to see in this field: 24/10 mL vials/bottles per box, 12 x 20 mL vials/bottle per carton, 30 mL x 12 vials/bottles per case.
- 6. Quantity, and Unit of Measure: Applicants should provide this information in the Product Details section of the application and select this field as one of the headers to be printed on the certificate.
- 7. Container/Seal Number: Applicants should provide this information in the Additional Information section of the application.
- 8. Means of Transport (e.g., cargo ship, air): Applicants should provide this information in the Additional Information section of the application.
- 9. Place of Loading (e.g., San Francisco port, airport): Applicants should provide this information in the Additional Information section of the application.
- 10. Point of Entry (e.g., Sydney): Applicants should provide this information in the Additional Information section of the application.
- 11. Conditions for Transport/Storage (e.g., Refrigeration): Applicants should provide this information in the Additional Information section of the application.
- 12. Consignee/Importer name and address (as it appears on the import permit issued by the Australian government): Applicants should provide this information in the Additional Information section of the application.
- 13. Applicants should provide the following information in the "Additional Information for Certificate" free-text field box in the "Additional Information" section of the application:
 - a. Australian Registration Number: [insert your Australian Registration Number]
 - b. Import Permit Number (for the Australian consignee/importer that appears on the import permit): [insert the Import Permit Number]

∨ Additional Certification Statements for Human Milk and Human Milk Products

Please note that DAFF also requires additional certification statements for human milk and human milk products. Applicants should copy and paste the following statements into the "Additional Information for Certificate" free-text field box in the "Additional Information" section of the application. Please note that applicants should update the language for the heat treatment statement to match the language in their import permit.

The manufacturer attests that the following statements are true and that it maintains records to demonstrate:

- 1. The donor milk originated in the United States of America only.
- 2. The milk or milk product was processed and packaged in the United States of America only.
- 3. Systems are in place to verify that milk used to produce the milk or milk product is sourced from eligible donors and does not contain any pathogenic microorganisms or other contaminant that has the potential to adversely impact on the safety of the milk or milk product.
- 4. Systems are in place to verify the donated milk can be linked to the individual donor.

- 5. The milk, or the milk product from which the final milk product was made, has been treated using: [insert heat treatment language from Australian import permit]
- 6. Testing has been conducted on the milk pre and post processing to verify its safety for human consumption.
- 7. The manufacturer ensures traceability of the supply chain from donation by individual through to the batch/lot of human milk or human milk product being exported.

Applicants will be required to attest that the statement they requested to print on the certificate is factual when they electronically sign the CFSAN eCATS application.

Additional Documentation to Upload in CFG Application

Firms that want to export human milk and human milk products to Australia must submit documentation of their intent to source human milk from only U.S. donors for the products they intend to export. You must upload this documentation to the additional documents section of the CFG application. Please use your company's letterhead for this documentation.

The certificates for these products are valid for one year from the date of issuance. For more information on DAFF's requirements, please visit DAFF's website for https://www.agriculture.gov.au/biosecurity-trade/import/goods/food/type/human-milk) (https://www.fda.gov/about-fda/website-disclaimer). To apply for an import permit to Australia please visit Biosecurity Import Conditions Database (https://bicon.agriculture.gov.au/BiconWeb4.0)) (https://www.fda.gov/about-fda/website-policies/website-disclaimer).

Brazil

Brazil's Ministry of Agriculture, Livestock, and Food Supply (MAPA) requires those looking to import into Brazil products of animal origin products, including dairy and seafood products, to register and provide establishment and product information. Originally, companies could provide written authorization to Brazil granting USDA staff in Brazil the right to represent them in their Brazil ventures and navigate the online registration system as their company's principal user. Effective immediately, the principal user must be an official representative of the establishment. As part of this process, Brazil is requiring that the principal representative submit a notarized letter to Brazil recognizing them as a legal company representative. Questions about the registration process can be sent to USDA's Office of Agricultural Affairs in Brasilia, Brazil at agbrasilia@state.gov (mailto:agbrasilia@state.gov).

Canada

The Canadian Food Inspection Agency (CFIA) requires an official certificate for imports of certain food products of meat origin. CFIA has agreed to accept an FDA-issued "Certificate to a Foreign Government" (CFG) for U.S. exports of FDA-regulated products that contain bovine-, porcine-, or poultry-derived ingredients.

Industry may request a CFG by submitting an online application in the CFSAN Export Certification Application and Tracking System (CFSAN eCATS). Please visit Online Applications for Export Certificates for Food (/food/food-export-certificates/online-applications-export-certificates-food) for a link to CFSAN eCATS and general instructions for submitting an application. Please see below for a list of certification data elements required by CFIA and instructions on how to provide this information in CFSAN eCATS.

Certification Data Elements Required by CFIA

- 1. Product Name: This is a required field in the Product Details section of the CFSAN eCATS application and will always be printed on the certificate. Applicants are required to indicate whether products intended for export to Canada contain bovine-, porcine-, or poultry-derived ingredients.
- 2. Type of Packaging: Applicants should provide this information in the Product Details section of the application and select this field as one of the headers to be printed on the certificate. The information required for this field will vary depending on the type of product. CFIA has provided the following examples as to what they expect to see in this field: 12 cans per box, 12 x 16oz/pouch per carton, 20 liter pail.
- 3. Name, license number, and address for the *Safe Food for Canadians* (SFC) license holder importing the product: Applicants should provide this information in the Additional Information section of the application using the consignor/importer name and address fields or the "Additional Information for Certificate" field. When provided, this information will be printed on the certificate.

∨ Additional Statement for Products Containing Poultry-Derived Ingredients

Please note that CFIA requires an additional certification statement for products containing poultry-derived ingredients. Applicants should copy and paste one of the following statements into the "Additional Information for Certificate" field in the Additional Information section of the application.

The finished products or the poultry-derived ingredients in the finished products have been heat treated to reach a minimum core temperature of 70C for a minimum of 3.6 seconds

The finished products or the poultry-derived ingredients in the finished products have been heat treated to reach a minimum core temperature of 74C for a minimum of 0.5 seconds.

The finished products or the poultry-derived ingredients in the finished products have been heat treated to reach a minimum core temperature of 8oC for a minimum of 0.03 seconds.

Applicants will be required to attest that the statement they requested to print on the certificate is factual when they electronically sign the CFSAN eCATS application.

Please note that the certificates for these products are valid for one year from the date of issuance. For more information on CFIA's requirements, please visit CFIA's websites for Food-specific import requirements (Food-specific-requirements/eng/1536170455757/1536170495320). (<a href="https://www.inspection.gc.ca/importing-food-plants-or-animals/food-imports/food-specific-requirements/broth-flavour-and-extract-of-meat-origin/eng/1587059233544/1587059301507). (https://www.inspection.gc.ca/importing-food-plants-or-animals/food-imports/food-specific-requirements/broth-flavour-and-extract-of-meat-origin/eng/1587059233544/1587059301507). (<a href="https://www.inspection.gc.ca/importing-food-plants-or-animals/food-imports/food-specific-requirements/broth-flavour-and-extract-of-meat-origin/eng/1587059233544/1587059301507). (<a href="https://www.inspection.gc.ca/importing-food-plants-or-animals/food-imports/food-specific-requirements/broth-flavour-and-extract-of-meat-origin/eng/1587059233544/1587059301507). (<a href="https://www.inspection.gc.ca/importing-food-plants-or-animals/food-imports/food-specific-requirements/broth-flavour-and-extract-of-meat-origin/eng/1587059233544/1587059301507). (<a href="https://www.inspection.gc.ca/importing-food-plants-or-animals/food-imports/food-specific-requirements/broth-flavour-and-extract-of-meat-origin/eng/1587059233544/1587059301507). (<a href="https://www.inspection.gc.ca/importing-food-plants-or-animals/food-imports/food-specific-requirements/broth-flavour-and-extract-of-meat-origin/eng/1587059233544/1587059301507). (<a href="https://www.inspection.gc.ca/importing-food-plants

Chile

U.S. exporters of dairy products to Chile are subject to importing country listing and certification requirements for manufacturers/processors as a precondition for market access. For more information, please visit <u>Food Export Lists (/food/exporting-food-products-united-states/food-export-lists)</u>.

Please be advised that Chile requires that the company information (name, address, plant/approval number) on all labels match the information on the export certificate. This requirement applies to the labels for individual products, boxes of individual products, and other bulk packaging. If the company information on the labels does not match the information on the export certificate, shipments are likely to be rejected.

Industry may request export certificates produced by listed manufacturers/processors from the <u>United States Department of Agriculture</u>, <u>Agricultural Marketing Service, Dairy Grading Branch (Dairy Grading Branch) (https://www.ams.usda.gov/services/imports-exports/dairy-exports)</u>.

The <u>United States Department of Agriculture</u>, <u>Agricultural Marketing Service</u>, <u>Dairy Grading Branch (https://www.ams.usda.gov/services/imports-exports/dairy-exports)</u> issues veterinary health certificates for dairy products produced in listed establishments for export to Chile.

China

China has two levels of requirements for most imported products: facility registration and certificates.

Establishment Listing and Registration Requirements

China's General Administration of Customs (GACC) has implemented registration requirements that affect all overseas food manufacturers, processors, and storage facilities of food products exported to China. These requirements are described in China's Decree 248. Articles 7 and 8 of the Decree require the exporting countries' competent authorities to recommend registration of establishments involved in the export to China of certain food categories. As the U.S competent authority for many of the product categories that require registration, FDA will continue to collect information via the Export Listing Module (ELM) for firms that export products covered by Article 7. U.S. establishments that produce or store FDA-regulated products within the categories listed in Chart 1 may submit an application in the ELM to provide information for products they currently export to China.

Important note:

All U.S. establishments that are subject to GACC's facility registration requirements including dairy, infant formula, and seafood should ensure that their ELM applications are up to date with HS codes to the 8- or 10-digit level. In the ELM, the HS codes should correlate with the correct product category. For example, if an establishment produces a dairy product, infant formula product, and healthy food / functional food

product, there should be three separate ELM applications for each product category. Please consult the latest <u>USDA/FAS GAIN report</u> (https://gain.fas.usda.gov/#/search) for most recent information on HS Codes for list of products for which GACC requires exporting countries' competent authorities to recommend firms for registration.

GACC's CIFER System

GACC distributes usernames and passwords directly to FDA regulated U.S. establishments via email to allow access to their accounts within the GACC Single Window System, also known as the China Import Food Enterprise Registration (CIFER) system. When a user logs into CIFER, we understand that the system directs establishments to change their passwords and allows registration for additional products that do not require competent authority recommendation under Decree 248 (e.g., a dairy products manufacturer can add lactose to its registration). FDA cannot confirm the legitimacy of emails received by U.S. firms. FDA is aware of fraudulent websites posing as the CIFER system and suggests that firms double check any hyperlinks received via email or access the system directly via https://cifer.singlewindow.cn (https://cifer.singlewi

Chart 1: New Product Categories for Registration Pursuant to Articles 7 and 8 of China's Decree 248

roduct Category	GACC Description (unless otherwise noted)
1. Casings	Animal tissues that are salted or dried on the retained parts by using organs such as small intestine, large intestine and bladder of healthy livestock, after special processing such as scraping and de-oiling, and is the casing for sausage.
2. Bee products	Natural sweet substances made from nectar, secretions or honeydew of plants collected by honeys and mixed with their own secretions, as well as edible substances formed naturally or made by special techniques during reproduction and reproduction, including royal jelly, royal jelly powder, honey pollen, royal jelly freeze-dried powder, etc.
3. Eggs and egg products	Note from FDA: It's FDA's understanding based on HS codes referenced in GACC system that shell eggs and other FDA regulated egg products are include in this category. However, GACC's initial description did not include these products. Additionally, FDA understands that USDA/FSIS regulated egg product are currently not eligible for export to China.
4. Edible fats and oils	Vegetable oil and edible vegetable oil for processing or consumption, and single products or mixtures of vegetable fat processed by one or more methods of refining and fractionation. Edible oil refers to the seeds of oil plants used for extracting edible vegetable oil, mainly including peanut and sesame for oil.
5. Stuffed wheaten products	Cooked or uncooked frozen products made with various raw materials as fillings and wheat flour as skins, such as steamed stuffed buns, jiaozi or pie
6. Edible grains	Seeds, roots and tuber products of cultivated plants such as cereals and potatoes, mainly including edible products of gramineous herbaceous seeds after rough processing, such as rice, oats and sorghum. (Note from FDA: GACC expects grain elevators and packing facilities to register - whichever is the last processing facility for the edible grain prior to exp to China.)
7. Milled grain industry products and malt	Fine powdery products in which seeds, roots and tubers of cultivated plants such as cereals, potatoes, fruits and nuts are ground and screened for edible powder, or malt products formed after hydrolysis processing.
8. Fresh and dehydrated vegetables and dried beans	Fresh vegetables or dried vegetable products processed by fresh-keeping, dehydration, drying and other drying processes and dried beans.
9. Condiments	Natural plant products such as plant fruits, seeds, flowers, roots, stems, leaves, skins or whole plants, which can be used directly with the functions of fragrant, flavouring and seasoning.
10. Nuts and seeds	Seeds of woody plants with hard shells, including walnuts, chestnuts, apricot kernels, almond kernels, pecans, pistachios, torreya grandis, Hawaiian fruits and pine seeds. Seeds refer to the seeds of melons, fruits, vegetables and other plants, including watermelon seeds and pumpkin seeds.
11. Dried fruits	Dried fruit products made from fresh fruits by sun drying, drying and other dehydration processes
12. Unroasted coffee beans and cocoa beans	Note from FDA: No description provided by GACC.

Product Category	GACC Description (unless otherwise noted)
13. Foods for special dietary purposes	(1) Soy based infant formula: Refers to soy and soy protein products as the main raw material, adding the right amount of vitamins, minerals and / or other ingredients, using only physical methods of production and processing made suitable for normal infants and young children to eat liquid or powder products.
	(2) Special medical use formula: In order to meet the eating restrictions, digestive and absorption disorders, metabolic disorders or specific disease states of people with special needs for nutrients or diet, specially processed and formulated formula. Such products must be under the guidance of a doctor or clinical nutritionist, eaten alone or in conjunction with other foods.
	(3) Infant and toddler complementary foods: Including infant and toddler canned complementary foods and infant and toddler cereal complementary foods. Infant and toddler filling supplements are food materials processed, filling, sealing, sterilization or aseptic filling to commercial sterility, can be stored at room temperature for infants and toddlers over 6 months of age; infant and toddler cereal supplements are one or more cereals as the main raw material, and cereals account for more than 25% of the dry matter composition, add the appropriate amount of nutritional fortification and (or) other auxiliary ingredients, made by processing The supplementary food suitable for infants and toddlers above 6 months of age.
	(4) Others (supplemental nutritional supplements, sports nutrition food, etc.): Other to meet the special physical or physiological conditions and (or) to meet the special dietary needs of disease, disorders and other states, specially processed or formulated food.
14. Healthy foods / Functional food	Claim and have a specific health function or to supplement vitamins, minerals for the purpose of food. That is, suitable for consumption by a specific group of people, has the function of regulating the body, not for the purpose of treating disease, and does not produce any acute, subacute or chronic harm to the human body food.

Seafood, Dairy, and Infant Formula

GACC will continue to recognize existing registrations for establishments that export seafood, dairy, and infant formula products. FDA currently facilitates the registration of U.S. establishments for these products by providing lists of certified establishments and products. U.S. firms that have applied in the ELM and are currently registered with GACC to export these products do not need to take any action at this time. For more information about China's registration requirements for these product categories, please visit Food Export Lists (/food/exporting-food-products-united-states/food-export-lists) and the following webpages:

- <u>Dairy Exports Lists (/food/food-export-lists/dairy-export-lists)</u>
- Infant Formula Export List (/food/food-export-lists/infant-formula-export-list)
- <u>Seafood Export Lists (/food/food-export-lists/seafood-export-lists)</u>

Other food products

For products that do not fall within the 18 product categories listed in Article 7, U.S. establishments may self-register on <u>GACC's website (https://app.singlewindow.cn/cas/login?</u>

loginAb=1&service=https%3A%2F%2Fcifer.singlewindow.cn%2Fciferwebserver%2Fj_spring_cas_security_check). (http://www.fda.gov/about-fda/website-policies/website-disclaimer). The USDA's Foreign Agricultural Service (FAS) has published several resources on the self-registration process via their Global Agriculture Information Network (GAIN) database. You may use the GAIN database (https://gain.fas.usda.gov/#/search) search function to access these resources.

∨ Certificate Requirements

Certificate Requirements

Once relevant establishments are registered and listed, China also requires official certificates for shipments of dairy (including formula for infants and young children) and seafood products.

The <u>United States Department of Agriculture, Agricultural Marketing Service, Dairy Grading Branch</u>

(https://www.ams.usda.gov/services/imports-exports/dairy-exports) issues sanitary certificates for dairy products exported from the United States to China.

The National Oceanic and Atmospheric Administration (NOAA) Seafood Inspection Program (https://www.fisheries.noaa.gov/topic/seafood-commerce-and-trade) issues export certificates for seafood products exported from the United States to China.

European Union

The European Union (EU) has three levels of requirements for most imported products containing animal-derived ingredients: country/territory listing, establishment listing, and certificates. The information below applies to dairy, eggs, seafood, bivalve molluscan shellfish, collagen, and gelatin products, as well as certain products containing ingredients derived from such products.

∨ Country/Territory Listing Requirements

For many products of animal origin, the EU will only accept imports that originate in countries or territories that appear on the EU's lists of third countries and territories from which imports of that product are permitted. The U.S. appears on the EU lists of third countries and territories from which imports of dairy, eggs, seafood, bivalve molluscan shellfish, collagen, and gelatin products are permitted.

Please note that the EU only allows shellfish imports from U.S. states or territories that are listed in Annex I of Commission Implementing Regulation (EU) 2019/626 (https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:32019R0626) (http://www.fda.gov/about-fda/website-policies/website-disclaimer). Please visit Questions and Answers on Shellfish Traded Between the United States and Certain Member States of the European Union (/food/international-cooperation-food-safety/questions-and-answers-shellfish-traded-between-united-states-and-certain-member-states-european) for more information about U.S. states eligible to export to the EU.

∨ Establishment Listing Requirements

For many products of animal origin, the EU will only accept imports that originate from third country establishments that appear on the EU's lists of third country establishments from which imports of that product are permitted. The EU maintains these lists based on submissions from the competent authorities of exporting countries. FDA is the U.S. competent authority for dairy, shell eggs, food products containing eggs, seafood, bivalve molluscan shellfish, collagen, and gelatin products. For ease of reference, FDA refers to the EU lists for these products as the EU dairy export list, EU egg and egg product export list, EU seafood export list, EU shellfish export list, EU collagen export list, and the EU gelatin export list. Establishments involved in the production of dairy, egg and egg products, seafood, bivalve molluscan shellfish, collagen, or gelatin products may apply with FDA to be included on these lists via the Export Listing Module. For more information about the EU establishment listing requirements for each product type, please visit Food Export Lists (https://www.fda.gov/food/exporting-food-products-united-states/food-export-lists).

- <u>Dairy Export Lists (/food/food-export-lists/dairy-export-lists)</u>
- Egg and Egg Product Export Lists (/food/food-export-lists/egg-and-egg-products-export-lists)
- <u>Collagen and Gelatin Export Lists (/food/food-export-lists/collagen-and-gelatin-export-lists)</u>
- <u>Seafood Export Lists (/food/food-export-lists/seafood-export-lists)</u>
- Shellfish Export Lists (/food/food-export-lists/shellfish-export-lists)

The EU regulates food containing both products of plant origin and processed products of animal origin as composite products. Any processed product of animal origin used in composite products exported to the EU must be sourced from listed establishments as described above. Please visit EU import conditions for composite products (https://ec.europa.eu/food/horizontal-topics/international-affairs/import-conditions/eu-import-conditions-composite-products en) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) for more information.

Please note that relevant establishments must be officially listed by the EU for products to be eligible for entry. FDA sends updates to these lists on a quarterly basis, but it may take 8-15 weeks for the EU to publish the updated lists. Please consult the official lists posted on the EU website https://webgate.ec.europa.eu/tracesnt/directory/publication/establishment/index#!/search?

 $\underline{countryCode=US\&sort=classificationSection.translation}) \ \underline{C}^{\bullet}\underline{(http://www.fda.gov/about-fda/website-policies/website-disclaimer)} \ to \ ensure that the establishment is listed by the EU before attempting to export products.$

\checkmark Certificate Requirements

Once relevant establishments are listed, the EU also requires official health certificates for shipments of food products of animal origin and certain composite products. Exports of non-shelf-stable composite products and shelf-stable composite products that contain meat products other than gelatin, collagen, or highly refined products derived from meat must be accompanied by an official certificate that identifies the approved establishment(s) that supplied each processed product of animal origin. Exports of shelf-stable composite products that do not contain meat products except gelatin, collagen or highly refined products derived from meat do not need an official certificate and must be accompanied by a private attestation established in Annex V of Commission Implementing Regulation (EU) No 2020/2235 (https://eurlex.europa.eu/eli/reg_impl/2020/2235/oj) (http://www.fda.gov/about-fda/website-policies/website-disclaimer). Please visit EU import

conditions for composite products (https://ec.europa.eu/food/horizontal-topics/international-affairs/import-conditions/eu-import-conditions-composite-products en) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) for more information about the certificate requirements for composite products.

FDA advises exporters to confirm the certification requirements for all products with their EU importers or the certifying agencies below.

Dairy Products

The <u>United States Department of Agriculture</u>, <u>Agricultural Marketing Service</u>, <u>Dairy Grading Branch</u>

(https://www.ams.usda.gov/services/imports-exports/dairy-exports) issues veterinary health certificates for dairy products produced in listed establishments for export to the EU.

Eggs and Egg Products

The <u>United States Department of Agriculture</u>, <u>Agricultural Marketing Service (https://www.ams.usda.gov/services/imports-exports/eggs-egg-products)</u> issues export certificates for shell eggs and FDA-regulated egg products exported from the United States to the EU.

Seafood Products

The <u>National Oceanic and Atmospheric Administration (NOAA) Seafood Inspection Program (https://www.fisheries.noaa.gov/topic/seafood-commerce-certification)</u> issues export certificates for seafood products exported from the United States to the EU.

Shellfish Products

The <u>National Oceanic and Atmospheric Administration (NOAA) Seafood Inspection Program (https://www.fisheries.noaa.gov/topic/seafood-commerce-certification)</u> issues export certificates for shellfish products exported from the United States to the EU.

Collagen and Gelatin Products

FDA issues veterinary health certificates for collagen and gelatin products produced in listed establishments for export to the EU. Please visit Food Export Certificates (https://www.fda.gov/food/exporting-food-products-united-states/food-export-certificates) for more information on how to request veterinary health certificates for collagen and gelatin products.

Guyana

Guyana requires a Certificate of Free Sale for U.S. exports. Guyana will accept and industry stakeholders may request a "Certificate to a Foreign Government" (CFG) for FDA-regulated food products exported from the United States, including those manufactured in other countries. Industry stakeholders may request to print "Certificate of Free Sale" as a subtitle on the CFG. For more information on the Certificate to a Foreign Government, please visit Examples of CFSAN-Issued Food Export Certificates (/food/food-export-certificates/examples-cfsan-issued-food-export-certificates) and Food Export Certificates (/food/exporting-food-products-united-states/food-export-certificates). Industry may request a CFG by submitting an online application in the CFSAN Export Certification Application and Tracking System (CFSAN eCATS). Please visit For a link to CFSAN eCATS and general instructions for submitting an application.

India

In October 2022, India's Ministry of Health and Family Welfare and the Food Safety and Standards Authority of India (FSSAI) announced new registration requirements for foreign food manufacturing facilities intending to import the following products into India: milk and milk products; meat and meat products including poultry, fish, and their products; egg powder; infant food; and nutraceuticals. The implementation date is August 31, 2024.

FDA is currently implementing an export list for milk and milk products (dairy). Establishments involved in the production of dairy products for export to India may apply with FDA to be included on these lists via the Export Listing Module (ELM). For more information about FDA export lists, please visit Food Export Lists. To view the U.S. establishments eligible to export dairy products to India, visit the List of exported food establishments.

The FDA will maintain a list of establishments that have expressed interest in exporting dairy to India and that we have found to be in compliance with applicable U.S. requirements, and we expect to send an initial list of such firms to FSSAI by September 1, 2024. Establishments that wish to be included in the initial list should request to be added to the lists through August 23, 2024, using the ELM. Going forward, the FDA will send updates to these lists on a quarterly basis as described on the Food Export Lists webpage.

At this time, the full impact of these requirements on U.S. food exports to India is uncertain. Industry stakeholders that experience shipment detentions or delays as a result of these requirements may contact the U.S. Department of Agriculture's Foreign Agricultural Service at AgNewDelhi@usda.gov (mailto:AgNewDelhi@usda.gov) for assistance.

FDA continues to engage with U.S. government agencies and FSSAI on behalf of U.S. exporters of these specific products to India.

 $Please\ visit\ \underline{India's\ FSSAI\ Requires\ Mandatory\ Registration\ of\ Foreign\ Food\ Manufacturing\ Facilities\ for\ the\ Import\ of\ Certain\ Categories\ of\ Foods\ for\ more\ information\ (https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?$

 $\underline{fileName=India\%27s\%20FSSAI\%20Requires\%20Mandatory\%20Registration\%20of\%20Foreign\%20Food\%20Manufacturing\%20Facilities\%20for\%20th \underline{oo86.pdf}).}$

Indonesia

Indonesia requires U.S. companies that import into Indonesia products of animal origin, including certain dairy products, to prelist their establishments with the Ministry of Agriculture. Please consult the latest <u>USDA/GAIN Food and Agricultural Import Regulations and Standards (FAIRS) Report (https://gain.fas.usda.gov/)</u> published for Indonesia for details on this process.

Saudi Arabia

All food products imported into Saudi Arabia are subject to requirements established by the Saudi Food and Drug Authority (SFDA) and expected to comply with Saudi Arabia's hygiene requirements and technical regulations. For certain human food products of animal origin, Saudi Arabia will only accept imports from establishments that appear on lists of establishments that have been certified to comply with applicable food safety requirements by the competent authority in the exporting country. These listing requirements currently apply to fishery products and honey and bee products. For ease of reference, FDA refers to Saudi Arabia's lists for these products as the Saudi Arabia seafood export list and Saudi Arabia honey and bee products export list. Establishments involved in the production of these products for export to Saudi Arabia may apply with FDA to be included on these lists via the Export Listing Module (/food/food-export-lists/online-applications-export-lists). For more information about FDA export lists, please visit Food Export Lists (/food/food-export-lists/seafood-export-lists). To view the U.S. establishments eligible to export honey and bee products and seafood to Saudi Arabia, visit the List of exported food establishments to the Kingdom of Saudi Arabia (https://www.sfda.gov.sa/en/list_countries) C (http://www.fda.gov/about-fda/website-policies/website-disclaimer). Select classification by country and select the United States for all approved U.S establishments.

South Korea

South Korea requires U.S. dairy exporters to register their facilities with Korea's Ministry of Food & Drug Safety (MFDS). Please consult the latest <u>USDA/GAIN Food and Agricultural Import Regulations and Standards (FAIRS) Report (https://gain.fas.usda.gov/#/)</u> published for South Korea for details on how to register.

On July 1, 2021 South Korea implemented a new regulation on HACCP certification that applies to foreign manufacturing facilities producing foods for export to Korea. Only foreign food manufacturers are allowed to apply for the certification. Other entities such as exporters and distributors are not subject to the certification application. Please consult the latest <u>USDA/GAIN Food and Agricultural Import Regulations and Standards (FAIRS)</u> <u>Report (https://gain.fas.usda.gov/#/)</u> published for South Korea for details on the certification process.

Taiwan

All food products exported to Taiwan are subject to requirements established by the Taiwan Food and Drug Administration and expected to comply with Taiwan's hygiene requirements and technical regulations. For certain human food products of animal origin, Taiwan will only accept imports from establishments that appear on lists of establishments that have been certified to comply with applicable food safety requirements by the competent authority in the exporting country. These listing requirements currently apply to fishery product. For ease of reference, FDA refers to Taiwan's lists for these products as the Taiwan seafood export list. Establishments involved in the production of these products for export to Taiwan may apply with FDA to be included on these lists via the Export Listing Module (/food/food-export-lists/online-applications-export-lists). For more information about FDA export lists, please visit Food Export Lists (/food/exporting-food-products-united-states/food-export-lists). To view the U.S. establishments eligible to export fishery products Taiwan, visit the List of exported seafood establishments.

 $\underline{(https://www.fda.gov.tw/TC/siteContent.aspx?sid=2405)} \ \square \underline{(http://www.fda.gov/about-fda/website-policies/website-disclaimer)}$

United Arab Emirates

The United Arab Emirates (UAE) requires certification for all imported food products. UAE accepts the FDA-issued "Certificate to a Foreign Government" for FDA-regulated food products.

Certification Data Elements Required by UAE

Facility Information Section of CFSAN eCATS

 Exporter Name: Applicants should identify the exporter on the CFSAN eCATS application and indicate that the exporter information should appear on the certificate.

Product Details Section of CFSAN eCATS

· Product Name: This is a required field and will always be printed on the certificate.

Additional Information Section of CFSAN eCATS

- Importer Name and Address: Applicants should provide the following information in the Optional Shipment Details section of the application. When provided, this information will be printed on the certificate.
 - a. Consignee/Importer Name
 - b. Consignee/Importer Country / Area
 - c. Consignee/Importer Address Line 1
 - d. Consignee/Importer Address Line 2
 - e. Consignee/Importer Postal Code
 - f. Consignee/Importer City
 - g. Consignee/Importer Province/Territory
- Additional Information for Certificate: Exporters are required to include the commercial invoice number within the certificate that will
 enable UAE port authorities to link the certificate with the corresponding consignment. Along with the mandatory commercial invoice
 number, voluntary information such as bill of lading number, packing list number, and container number may also be included on the
 certificate. While not required, exporters are encouraged to incorporate these supporting details to help facilitate a timely and successful
 release of the consignment.

United Kingdom

On January 1, 2021, the United Kingdom (UK) withdrew from the European Union (EU) and adopted most EU rules as UK law. Thus, the UK has the same three levels of requirements for most imported products containing animal-derived ingredients: country/territory listing, establishment listing, and certificates. Please note that the information below applies to Great Britain (England, Scotland and Wales). Different procedures may apply in Northern Ireland because Northern Ireland remains aligned with the EU's listing and certification requirements.

\checkmark Country/Territory Listing Requirements

For many products of animal origin, the UK will only accept imports that originate in countries or territories that appear on the UK's lists of third countries and territories from which imports of that product are permitted. The U.S. appears on the UK lists of third countries and territories from which imports of dairy, seafood, bivalve molluscan shellfish, collagen, and gelatin products are permitted.

Please note that the UK only allows shellfish imports from U.S. states or territories that are listed in Annex I of Commission Implementing Regulation (EU) 2019/626 (https://www.legislation.gov.uk/eur/2019/626/contents). (http://www.fda.gov/about-fda/website-policies/website-disclaimer).

∨ Establishment Listing Requirements

Like the EU, the UK will only accept imports of products of animal origin that originate from establishments that appear on the <u>UK's list of establishments that are approved to export animal products to the UK (https://data.gov.uk/dataset/4698a65d-1a3b-42d1-981e-df869e04185b/export-of-animals-and-animal-products-to-the-uk) (https://www.fda.gov/about-fda/website-policies/website-disclaimer). The UK will only list establishments that appear on the EU's lists of approved establishments, so FDA does not have a separate application</u>

process for the UK lists. Any establishment that wishes to export FDA-regulated products of animal origin to the UK may apply to be included on the EU lists via the EXPA sends the same listing updates to both the EU and the UK. Currently listed establishments may modify their listing information for both the EU and UK lists via the EXPORT LISTING MODULE (https://www.fda.gov/food/food-export-lists/online-applications-export-lists). For more information about the UK establishment listing requirements for each product type, please visit Food Export Lists (/food/food-export-lists/seafood-export-lists) and the following webpages:

- Dairy Exports to Chile, China, the European Union, and the United Kingdom (/food/food-export-lists/dairy-export-lists)
- Egg and Egg Product Exports to the European Union and the United Kingdom (/food/food-export-lists/egg-and-egg-products-export-lists)
- Collagen and Gelatin Exports to the European Union and the United Kingdom (/food/food-export-lists/collagen-and-gelatin-export-lists)
- Seafood Exports to China, the European Union, and the United Kingdom (/food/food-export-lists/seafood-export-lists)
- Shellfish Exports to the European Union and the United Kingdom (/food/food-export-lists/shellfish-export-lists)

∨ Certificate Requirements

The UK requires health certificates for every shipment of dairy, seafood, shellfish, collagen, or gelatin products. Industry may contact the certifying agencies listed in the <u>EU Certificate Requirements</u> section above to request certificates for the UK.

Vietnam

Vietnam requires product registration for many imported food products, and for certain products, the registration process requires a certificate that provides assurances regarding the safety of the product. Vietnam accepts the FDA-issued "Certificate to a Foreign Government" but does not accept the FDA-issued "Certificate of Free Sale" for dietary supplements, medical foods, and foods for special dietary use. Firms that export these products to Vietnam may be able to obtain the necessary certification from their state authorities.