International Business Certificates

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Prepared by the Hawaii Export Assistance Center

Export certificates are often required by an importing country when an exporting company is engaging in international trade. The certificates required vary depending on the particular importing country and the good that is being exported.

This guide includes information on the following types of certificates:

Certificates of Origin

Certificate of Free Sale

Good Manufacturing Practices

Phytosanitary Certificate

Zoosanitary Certificate

Certificates of Origin

A Certificate of Origin is a document certifying that goods being exported were manufactured in a particular country. It usually accompanies the exporter's/shipper's invoice or the bill of lading and is required by most countries.

The Chamber of Commerce of Hawaii will provide the following certification only, on a Certificate of Origin:

"The Chamber of Commerce of Hawaii states that, based solely on the attached exporter's affidavit, the Chamber believes that the goods described in the attached affidavit are products of the United States of America. The Chamber assumes no responsibility beyond obtaining sworn statements in the attached affidavit. It makes no warranty, expressed or implied, concerning the goods, affidavit, or any documents relating thereto, and assumes no responsibility for the truth or accuracy of any statements contained in said affidavit or any of the documents mentioned therein."

Hawaii Chamber of Commerce
1132 Bishop Street
Honolulu, HI 96813
(808) 545-4300

To obtain certification from The Chamber of Commerce of Hawaii, the following is required in all cases:

1. Certificate of Origin form and the original invoice that includes:
    a) the description of the goods being shipped;
    b) statement by the manufacturing company that the goods are of U.S. origin;
    c) destination of shipment;
    d) an original signature on form or document i.e. original bill of lading, manufacturer's certificate of origin (we will not certify a fax or photocopy signature); and
    e) signed and notarized indemnification AFFIDAVIT.
2. Effective May 1, 2007, fees for the execution of each Certificate of Origin are as follows:
    a) Chamber MEMBERS are charged the following rate schedule per each Certificate of Origin:
        - Up to $1,000.00 in export value: $30.00
        - From $1,000.01 to $5,000.00 in export value: $40.00
        - Over $5,000.01 in export value: $50.00

b) All NON-MEMBERS are charged the following rate schedule per each Certificate of Origin:

- Up to $1,000.00 in export value: $45.00
- From $1,000.01 to $5,000.00 in export value: $55.00
- Over $5,000.01 in export value: $75.00

3. Certificates of Origin may be obtained from The Chamber of Commerce of Hawaii by appointment ONLY. Please call Melody Maon at 808-545-4300 x300 for this service and an appointment.

4. For access to all necessary directions and forms for this certificate please click here

NAFTA Certificate of Origin can be used only for Canada and Mexico.

a. Once an exporter determines that the exported good will meet the NAFTA rules of origin, a NAFTA Certificate of Origin must be completed accurately and legibly. The exporter must then send the Certificate to the importer.
b. While the Certificate does not have to accompany the shipment, the importer must have a copy of the Certificate in hand before claiming the NAFTA tariff preference at customs.
c. Certificates of Origin may, at the discretion of the exporter, cover a single importation of goods or multiple importations of identical goods.
d. For a link to the NAFTA Certificate of origin, click here.
e. For more information on the NAFTA Certificate of Origin, click here.

Certificate of Free Sale

A Certificate of Free Sale, sometimes called a "Certificate for Export" or "Certificate to Foreign Governments", is required by some foreign governments when exporting a U.S product. The certificate states that the product is under the jurisdiction of the U.S. Food and Drug Administration and is acceptable for sale in the United States, and that the particular manufacturer has no unresolved enforcement actions pending before or taken by FDA. These certificates may be issued by FDA-CFSAN (Center for Food Safety and Applied Nutrition) or by a State governmental authority.

Products covered: The FDA provides Certificates of Free Sale (also called Export Certificates) for cosmetics, dietary supplements, infant formulas, medical foods (includes vitamins, minerals, amino acids, herbals), food additives, plant and dairy foods and beverages, seafood, EU Animal Health and specified risk (Specified Risk Materials of Bovine, Ovine and Caprine Origin Certificate), human or animal drugs, biologics, and medical devices

Certificates issued by CFSAN for food, food additives; seafood, dietary supplements, and cosmetics cost $10. You will receive a bill along with the completed certificates.

Approximate wait time for certificates of food, dietary supplements, cosmetics, and food additives may take up to 3-8 weeks, depending on work load and regulatory status of the products and /or the company. Processing of a certificate cannot begin until all requested documents have been received.

For export certificates for human or animal drugs, biologics and devices issued under section 801(e)(4) of the Act, the agency may charge a fee of up to $175 if the certificate is issued within 20 government working days from the time a complete request is received. This fee may vary depending on the product type, but will not exceed $175.

There is an e-application available; you can create a login at this site.

Export of Legally Marketed Medical Devices (FDA):

While FDA does not place any restrictions on the export of Legally Marketed Devices, certain countries may require written certification that a firm or its devices are in compliance with U.S. law. In such instances FDA will accommodate U.S. firms by providing a Certificate for Foreign Government (CFG). These export certifications were formerly referred to as a Certificate for Products for Export or Certificate of Free Sale. The CFG is a self-certification process that is used to speed the processing of requests. Original certificates will be provided on special counterfeit resistant paper with an embossed gold foil seal.

Cost: CDRH requires an initial fee of **$175** per certificate and **$15** per certificate for additional certificate(s) issued for the same product(s) in the same letter of request. Original certificates will be provided on special counterfeit resistant paper with an embossed gold foil seal.

Export of Unapproved Medical Devices:

The FDA implemented a new certification process referred to as a Certificate of Exportability (COE) to facilitate export of an unapproved medical device. Exporters applying for a COE are required to sign a statement indicating that they meet four criteria (see link below).

Cost: CDRH requires an initial fee of**$175** per certificate and **$15** per certificate for additional certificate(s) issued for the same product(s) in the same letter of request. Original certificates will be provided on special counterfeit resistant paper with an embossed gold foil seal. CDRH should to issue the certification within 20 days upon the firm's showing that the product meets the applicable requirements.

For products NOT regulated by the U.S. Food and Drug Administration or U.S. Department of Agriculture:

Fees are as follows; please note that fees are **per individual Certificate per country**.

1. You must purchase a separate Certificate for each country to which you wish to export.
2. Original copies of certificates (to have two on file) will be the same cost ($75)
3. **$75** for all non-member companies (located in or outside of Colorado); The $75 fee covers up to 25 products listed on the Certificate. If you would like more than 25 products listed on a certificate, please add $25 for each additional 25 products
4. Prepayment is required. We accept AMEX, Visa, MasterCard, check or cash.
5. Once all of the above has been submitted, the Certificate takes 7 business days to process. *Please note, if any of the requirements are missing in the form or invoices, it will significantly prolong the processing time.*

To download the certificate application and obtain a list of requirements, please visit the WTCD website here.

Your certificate application and accompanying invoices should be sent by either email to Ms. Azahar Aguilar at certificate@wtcdenver.org, **or** by mail to:

World Trade Center Denver
1625 Broadway, Ste. 680
Denver, Colorado 80202
Please include an account number and method of shipment if your Certificate needs to be returned via FedEx, UPS or USPS.

Please allow 7 business days for certificates to be processed and returned by mail. For more information, please email us at certificate@wtcdenver.org or call us at 303-592-5760.

Good Manufacturing Practices (GMP)

Good Manufacturing Practices (GMPs) refer to establishing manufacturing procedures, documenting and following these procedures, the training of operators to follow these procedures, and processes for the investigation and corrective actions following deviations from these procedures. The purpose is to ensure the products are manufactured safely and that quality is assured.

GMP refers to the Good Manufacturing Practice Regulations promulgated by the US Food and Drug Administration under the authority of the Federal Food, Drug, and Cosmetic Act (See Chapter IV for food, and Chapter V, Subchapters A, B, C, D, and E for drugs and devices.) These regulations, which have the force of law, require that manufacturers, processors, and packagers of drugs, medical devices, some food, and blood take proactive steps to ensure that their products are safe, pure, and effective. GMP regulations require a quality approach to manufacturing, enabling companies to minimize or eliminate instances of contamination, mixups, and errors. This in turn, protects the consumer from purchasing a product which is not effective or even dangerous. Failure of firms to comply with GMP regulations can result in very serious consequences including recall, seizure, fines, and jail time.

GMP regulations address issues including recordkeeping, personnel qualifications, sanitation, cleanliness, equipment verification, process validation, and complaint handling. Most GMP requirements are very general and open-ended, allowing each manufacturer to decide individually how to best implement the necessary controls. This provides much flexibility, but also requires that the manufacturer interpret the requirements in a manner which makes sense for each individual business.

For a complete list of guidelines for obtaining GMP Certificate, go to Good Manufacturing Practice (GMP) Guidelines/Inspection Checklist.

GMPs are enforced in the United States by the U.S. Food and Drug Administration (FDA), under Section 501(B) of the 1938 Food, Drug, and Cosmetic Act (21 USCS § 351). The regulations use the phrase "current good manufacturing practices" (cGMP) to describe these guidelines.

For questions, you can contact the FDA by phone at 800-216-7331 or 301-575-0156 or though the mail at:

Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

You can receive GMP certification though third party certifies such as NSF. You can begin the registration process online though NSF here.

Phytosanitary Certificate

A Phytosanitary Certificate is an official document that states that plants and plant material exporting are free from pests and diseases, its purpose is to prevent induction and spread of diseases to the importing countries. Phytosanitary Certificates are issued by the National Plant Protection Agency (NPPO) or equivalent in a country. They certify that a good meets the requirements of a country.

Information on exports please call (808) 861-8494

Area of specialty ranges from agricultural plants, cuttings, vegetables, and flowers. Many countries have different rules pertaining to the Phytonsanitary Certificate. The USDA will help clients with procedures for each type of agricultural product and each country. The USDA can help with a foreign Import permit as well.

FEES (depend on value of shipment):

$1250 of value or less: $61

$1250 of value or more: $106

*Inspection of offer and treatments require additional fees

Territorial Shipping:
Hawaii Department of Agriculture (HDOA)
Plant Quarantine Branch
1849 Auiki Street
Phone: (808) 832-0566
For additional information contact: Sharon Hurd (808) 973-9465

International Shipping:
U.S. Department of Agriculture (USDA)
Animal and Plant Health Inspection Service
Plant Protection and Quarantine
Honolulu International Airport
300 Rodgers Blvd., #57
Honolulu, HI 96819-1987

Zoosanitary Certificate

A Zoosanitary certificate is issued by a body in the country of origin that attests to the good sanitary conditions of the good of the animal origin. It is sometimes required by the importing country of the exported products. The exporter should obtain any required certificates prior to shipping any product.

If you have any questions or concerns regarding the procedures and requirements to obtain a Zoosanitary certificate for an animal product being exported, you should contact the VS Area Office covering the area from where the product will be exported (or the area in which your office is located).

For Hawaii, contact:

10365 Old Placerville Road Suite 210
Sacramento, CA 95827-2518
Phone: (916) 854-3950
Fax (916) 363-3919

Adobe Forms

Exporters are advised that the forms linked below are to be submitted to the endorsing office electronically by email after preparation consistent with the Special instructions for exporters regarding the preparation of the new VS forms. Exporters should contact the endorsing office officials regarding the correct email address to use and the proper formatting of emails so that the process flows well. If submission by email is not possible, exporters should contact endorsing office officials to discuss alternatives. Prior to endorsement, APHIS prints the forms on special VS Security Paper.

VS Form 16-4

VS Form 16-4A

Combined VS form 16-4 and VS form 16-4A

Special instructions for exporters regarding the preparation of the new VS forms – Sept. 2011

Prior to utilizing these forms, users should ensure Adobe Reader Version 9.0 (or above) is installed on their computer. Version 9.0 (or above) is necessary to ensure that the forms open and function optimally. Any Adobe software (Reader, Standard, or Professional) may be utilized as long as it is version 9.0 or above.

The U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) has created the International Animal Product Export Regulations (IREGS) to provide exporters with our best understanding of importing countries requirements for certain animal-origin products.

Countries may change their import requirements without notice. In all cases, the exporter has the responsibility of having their importer confirm with the Ministry of Animal Health in the importing country the certification requirements prior to shipping. The exporter should obtain any required certificates prior to shipping. Most countries will not accept certificates issued after consignments have shipped. The availability of APHIS endorsement of certificates should not be assumed until after consultation with the pertinent VS Area Office.

For Canada, when the product in question is entered into the Canadian Automated Import Reference System (AIRS), it shows that a zoo-sanitary certificate is needed. SIP will issue that document online. There is no physical inspection needed and documents can be overnighted to the exporter so that they can accompany the consignment for arrival at the Canadian BIP. The use of the online service entities the SIP to audit the facility, processes and product to determine compliance to international standards for aqua-cultured products, at no cost to the exporter.

The US exporter will need to set up an account online and the process will take several days. The exporter then must use the AIRS system to determine if a animal health certificate will be needed, and request one from the SIP online system prior to export for each consignment.

For a detailed explanation of the new Canadian aquatic animal regulations and the services SIP provides to help industry meet those requirements - http://www.seafood.nmfs.noaa.gov/.

If you have any questions or require further assistance, please contact the Hawaii Export Assistance Center, at (808) 522.8041.