

HOW TO EXPORT FOOD AND ALCOHOLIC BEVERAGES FROM ITALY TO THE UNITED STATES OF AMERICA

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For Italians living abroad it is always nice to find a product from Italy in a corner of the United States of America. Whether it is a wine or food product, it makes no difference as the important thing is that it is Italian. They are happy to find a piece of Italy, but no one wonders what was needed for that piece of Italy to land on a shelf in an American store.

Those who wish to export food products or alcoholic beverages² in the United States of America must follow the procedure established immediately after the events of September 11, 2001.

This brief article describes, in general terms, the procedure for the import of food products and alcoholic beverages to the United States for commercial purposes.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002

The events of September 11, 2001, have reinforced the need to improve the security of the United States of America. Since then, Congress has passed several laws to better prepare the nation. One of these laws is the *Public Health Security and Bioterrorism Preparedness and Response Act* del 2002 (“BTA”)³, which provides specific rules to protect the American people from a potential or real terrorist attack that can be done through the import of food products and alcoholic beverages. The *Food and Drug Administration* (“FDA”), the administrative agency that ensures that food products and alcoholic beverages imported into the United States of America are safe and pose no danger to the nation, applies the procedure established by the BTA. In fact, it controls both domestic and foreign products when they arrive at any port of entry.

To give effect to the provisions of the BTA, the FDA has established certain regulations that require domestic and foreign facilities that manufacture, process, pack food products and alcoholic beverages for consumption in the United States of America Stati Uniti be (i) registered with the FDA, (ii) have an agent in the United States of America, and (iii) notify the FDA before the food products and alcoholic beverages enter the United States of America.

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² Wine, beer, and liquors.

³The BTA is a federal law. Each single State may have different state laws that may require additional steps, such as permits or certifications.

Registering with the FDA

Registering with the FDA may be accomplished electronically at <https://www.access.fda.gov/oa/>. The interested party creates its own account with a password. The FDA registration indicates only that the company is in compliance with the BTA, and not that the imported food products or alcoholic beverages are in compliance with FDA standards. The FDA reserves the right to inspect at the time of arrival at the port of entry. If any of the registration information changes at some point in the future, it is mandatory to update the account⁴.

Agent Designation

In addition to being registered with the FDA, foreign facilities must designate an American agent that will keep the communications with the FDA. It is not necessary that the agents are legal entities. An agent can be an individual, having a residence or business address in the United States, therefore, physically present in this country. A foreign facility may have only one agent for purposes of the registration with the FDA.

If the foreign entity does not designate an agent and exports anyway to the United States of America, the FDA will not allow the goods to clear Customs and enter the country. Those goods will not be delivered to the importer or the recipient in the United States of America, but will be held at the port of entry. Costs associated with the storage are at the exporter's expenses.

The agent communicates with the FDA and is the bridge between the exporter and the FDA.

Prior Notice to the FDA.

Whenever the foreign company is ready to ship food products or alcoholic beverages to the United States of America, it must submit prior notice to the FDA no more than five (5) calendar days before the anticipated date of arrival. Such prior notice may be submitted electronically, providing, among other things, the description of the goods and the port of entry. Once prior notice is received, the FDA assigns a reference number that must accompany the goods to the United States of America.

Inspection

The FDA reserves the right to inspect the goods that reach the port of entry and to analyze samples. If the analyzed samples do not comply with the FDA standards, the FDA may issue

⁴ Foreign facilities that manufacture, package, or hold food in the United States of America are required to register with the FDA. Even foreign facilities responsible for the packaging only, such as putting on a label, before the products are exported to the United States, are required to register.

pecuniary sanctions, detain the imported goods, and, if the violation is a serious one, may obtain an injunction.

Products subject to inspection are food products, in general, medicines, and drugs⁵. As far as meat, white or red, and eggs are concerned, they may be exempt from FDA inspection because subject to inspection of the *United States Department of Agriculture*.

Importing Alcoholic Beverages

Pursuant to the *Federal Alcohol Administration Act*, the foreign exporting entity of alcoholic beverages, such as wine, beer, and liquors, must apply for an additional basic import permit with the *Alcohol and Tobacco Tax and Trade Bureau* (“TTB”). The form, *TTB Form 5100.24*⁶, can be filed electronically.

COLA

The same requirements discussed above, meaning the registration with the FDA, the designation of an agent in the United States of America, and prior notice to the FDA, apply to the import of alcoholic beverages as well. Further, the importer must apply and obtain a Certification of Approved Label or “COLA”⁷. COLA ensures that goods are labeled according to federal law with respect to, among other things, health warnings, sulfites, and alcoholic volume.

To obtain COLA, the importer must submit an *Application for and Certification/Exemption of Label/Bottle Approval*, *TTB Form 5100.31*⁸ to the *Advertising, Labeling, and Formulation Division* (“ALFD”) at the TTB. The process may start electronically, through [COLA Online](#), or by mailing a paper copy. For additional information about COLA approval, please contact [ALFD](#).

The standard language for the health warnings is as follows:

GOVERNMENT WARNING: (1) ACCORDING TO THE SURGEON GENERAL, WOMEN SHOULD NOT DRINK ALCOHOLIC BEVERAGES DURING PREGNANCY BECAUSE OF THE RISK OF BIRTH DEFECTS, (2) CONSUMPTION OF ALCOHOLIC BEVERAGES IMPAIRS YOUR ABILITY TO DRIVE A CAR OR OPERATE MACHINERY, AND MAY CAUSE HEALTH PROBLEMS.

CONTAINS SULFITE

⁵ Milk and cheese may be subject to a different procedure that may require an import permit or license.

⁶ www.ttb.gov/forms/f510024.pdf

⁷ *Certificate of Label Approval*. Please note that the importer of samples may request, in some cases, an exemption from TTB through a letter.

⁸ <http://www.ttb.gov/forms/index.shtml>



Certification of Proper Cellar Treatment

Importers of natural wine⁹ must comply with certification requirements established by the *Miscellaneous Trade and Technical Corrections Act* of 2004. The scope of this law is to ensure that the production practices and procedures of the imported wine are in accordance with proper cellar treatment. Some foreign countries are exempted from such certification because of agreements signed on oenological practices with the United States of America.

According to the oenological agreement in force between the United States of America and the European Union, natural grape wines with alcoholic content between 0.5% and 22%, imported from various European countries, including Italy, are not subject to the certification. However, wines from berries and other fruits are excluded from such agreements, and, therefore, subject to certification.

Setting up a Wine Company in the United States of America

The foreign importer cannot conduct its business from its country of origin, but must have a business establishment with employees in the United States of America,. Further, it must obtain an Employer Identification Number (similar to the *partita IVA*) with the American fiscal agency, *Internal Revenue Service*. The foreign company unable to be directly present in this country must find a local importer, generally a distributor, with a permit.

⁹ Natural wine is the product of juice or must, ripe grape, ripe fruit (including berries) made with proper cellar treatment according to chapters "F" and "L" 27 *CFR*, part 24, not containing more than 24% alcohol and 21% in weight.

Taxes

Every importer must pay the *Federal Alcohol Excise Tax* for the alcoholic beverages at the time of their removal from the port of entry.

The applicable procedure and the various permits and certifications to obtain for FDA purposes are quite complex. Our Firm may assist you in the registration process with the FDA and the submittal of the prior notice to the FDA. Further, we may advise and help you to set up an American entity, generally, a *limited liability company* or *corporation*. Questions or requests for additional information may be sent to daniela.morrison@vallalaw.com

This article covers, in general terms, the FDA procedures with respect to the import of food products and alcoholic beverages into the United States of America, and is not intended, in any way, to constitute legal advice. Depending on the type of investment you wish to realize in the United States of America, legal consultation is advisable to discuss the procedure and identify the permits applicable to the specific case.