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Certification and Labeling for EU Whey Protein Supplements

Report Categories:

Food and Agricultural Import Regulations and Standards - Certification

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Report Highlights:

Exporters shipping whey protein food supplements to the EU should be aware that EU Importing Countries' Inspectors at EU Border Inspection Posts (BIPs) will check if the consignment is shipped with certification and labeling conform with European Union requirements. This report provides guides exporters through the requirements.

General Information:

Exporters shipping whey protein food supplements to the EU should be aware that EU Importing Countries' Inspectors at EU Border Inspection Posts (BIPs) will check if the consignment is shipped with proper certification and labeling.

What will Border Inspectors check?

- Is the product sourced from an EU-approved establishment?
- Is the proper certification available and accurate?
- Does the consignment correspond with the health certificate?
- Does the product labeling meet the EU Labeling requirements?

If the answer to one of these questions is 'NO' goods will not be allowed to enter the European Union.

Exporters should make sure they provide consistent information in the certificate and on the product labels and that traceability is not lost due to inconsistent use of the different U.S. establishment numbering systems. Next, exporters should determine if their product will be treated upon arrival at an EU port as: a) a processed dairy product; b) a composite product; or c) a product exempt from veterinary inspection. It is important to work with your importer to confirm which type of product you are shipping to the EU as this determination has implications for the required certificates and product labels.

Please follow the instructions below for the scenario that applies to you.

Scenario A: Food Supplement is considered a processed dairy product in the EU

When: The food supplement is manufactured in the establishment performing the processing of the raw milk product, irrespective of the addition of other ingredients.

Required Certificate: EU HTB Dairy Health Certificate.

In order to obtain an EU HTB Dairy Health Certificate, the manufacturer must have their final production, blending, and/or packing facility listed on the [FDA Dairy Plant Reference List \(pdf\)](#) of EU-approved raw milk and dairy product facilities. These facility approval numbers must be included on the EU HTB Dairy Health Certificate as indicated in the USDA/AMS EU Request Form Instructions (see <http://www.ams.usda.gov/services/imports-exports/dairy-exports>).

(I.11) PLACE OF ORIGIN:

Enter the following information for the approved facility from which the finished product is being dispatched (shipped). This is the place of production if the product is direct shipped to the EU or the warehouse where the product was stored in the United States from which the products were dispatched. For example: Establishment NAME (35), ADDRESS (city and state) (225), and EU APPROVAL NUMBER (35).

(I.28) IDENTIFICATION OF COMMODITIES:

APPROVAL NUMBER OF ESTABLISHMENT MANUFACTURING PLANT

Provide the approval number of the treatment and/or processing establishment approved to export to the EU. A maximum of three plants may be included on one certificate.

EU Label Requirements for Products shipped with an EU HTB Dairy Health Certificate:

All regular EU label requirements apply. Additionally, an identification/health mark **must be applied to each individual consumer package**. The identification/health mark must contain the following information and must be clearly legible.

- The name of the country in which the establishment is located
- The EU approval number of the establishment as published on the [FDA Dairy Plant Reference List \(pdf\)](#).

****Warning: Do not use an establishment's State or USDA number if different from the listed FDA number as your shipment will be rejected.****

Scenario B: Food Supplement is considered a composite product in the EU

When: Composite products contain ingredients of both animal and plant (e.g. soy flour, sugar, pea protein, etc) origin. A Composite Product Health Certificate is required for whey protein food supplements if: the whey protein is combined with a meat product; if the combined processed dairy, fishery and egg, meat product (e.g. liver) content is above 50%; or if the product is not shelf stable at room temperature. Some products may require additional composite certificates for other animal origin ingredients i.e. egg proteins, issued by other U.S. Government agencies.

Required Certificate: EU Composite Certificate.

In order to obtain an EU Composite Certificate, USDA/AMS requires that the manufacturers list their final production, blending, and/or packing facility on the [FDA Dairy Plant Reference List \(pdf\)](#) of EU-approved raw milk and dairy products facilities. Those facility approval numbers must be mentioned on the composite certificate as indicated in the USDA/AMS EU Request Form Instructions (see <http://www.ams.usda.gov/services/imports-exports/dairy-exports>).

(I.11) PLACE OF ORIGIN:

Enter the following information for the approved facility from which the finished product is being dispatched (shipped). This is the place of production if the product is direct shipped to the EU or the warehouse where the product was stored in the United States from which the products were dispatched. For example: Establishment NAME (35), ADDRESS (city and state) (225), and EU APPROVAL NUMBER (35).

(I.28) IDENTIFICATION OF COMMODITIES:

APPROVAL NUMBER OF ESTABLISHMENT MANUFACTURING PLANT

Provide the approval number of the treatment and/or processing establishment approved to export to the EU. A maximum of three plants may be included on one certificate.

Note: Also fill in section II.2.B on the certificate

EU Label Requirements for Products shipped with an EU Composite Certificate:

Label requirements for these goods are less stringent than for goods that are shipped as a dairy product as EU regulations on composite products **DO NOT** require an identification/health mark on **individual consumer packages**. All other regular EU label requirements apply.

Is it possible to use the EU HTB dairy certificate instead of an EU Composite Certificate?

Yes, provided that the composite product contains no other animal origin ingredients than dairy and that the establishment identification mark and country of origin is applied to each individual consumer package.

Scenario C: Food Supplement is exempt from veterinary inspection

When: A composite product certificate is NOT required for whey protein food supplements if the dairy content is below 50%, there are no other animal and plant origin ingredients, and the product is shelf stable at room temperature.

Please be advised that these are the requirements of the European Union and your shipments will be at risk if you do not comply with their labeling requirements. It is the exporter's responsibility to discuss all European Union requirements with importing customers to verify that you meet all of the packaging and labeling requirements of the importing country.

For more information, contact:

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