European Union - Intermediate Products - Chapter 20

Last Modified:

APHIS **does not** endorse any documents for materials exported from the United States as “intermediate products” as defined in Regulation (EU) 142/2011. However, the EU requires facilities exporting intermediate products to the EU to be listed by APHIS. Exporters should contact the Veterinary Services Field Operations Veterinary Export Trade Services serving their State for information on how to obtain these listings.

Regulation (EU) 142/2011 defines an intermediate product as a derived product:

1. which is intended for uses within the **manufacture of medicinal products, veterinary medicinal products, medical devices for medical and veterinary purposes, active implantable medical devices, in vitro diagnostic medical devices for medical and veterinary purposes, laboratory reagents, or cosmetics**; AND
2. whose design, transformation and manufacturing stages have been sufficiently completed in order to be regarded as a derived product and to qualify the material directly or as a component of a product for the purposes referred to in II.B.1; AND
3. which however requires some further manufacturing or transformation, such as mixing, coating, assembling or packaging to make it suitable for placing on the

market or putting into service, as applicable, a medicinal product, veterinary medicinal product, medical device for medical and veterinary purposes, active implantable medical device, in vitro diagnostic medical device for medical and veterinary purposes, laboratory reagent, or cosmetic products.

There is likely to be variation between EU border control posts (BCPs), regarding determination of which consignments qualify as “intermediate products.”

Prior to export, the exporter should complete the following steps:

1. Have their importer confirm with the border inspection post (BCP) through which the product will enter the EU that the product is eligible for import with only the following documentation required: Regulation (EU) 142/2011 CHAPTER 20 Model Declaration *“Declaration for the import from third countries and for the transit through the European Union of intermediate products to be used for the manufacture of medicinal products, veterinary medicinal products, medical devices for medical and veterinary purposes, active implantable medical devices, in vitro diagnostics medical devices for medical and veterinary purposes, laboratory reagents and cosmetic products”*.
2. Contact their local VS Field Office to obtain information on obtaining the relevant APHIS listing.
3. Complete the APHIS listing process.
4. Await final confirmation from the VS Field Office that the facility has been granted the relevant listing.
5. Have the importer confirm again with the BCP that all necessary information is available on Trade Control and Expert System (TRACES) and the consignment will be allowed entry with the Regulation (EU) 142/2011 Chapter 20 Model Declaration

Chapter 20 Importer declaration (1.48 MB) *for the import from third countries and for the transit through the European Union of intermediate products to be used for the manufacture of medicinal products, veterinary medicinal products, medical devices for medical and veterinary purposes, active implantable medical devices, in vitro diagnostics medical devices for medical and veterinary purposes, laboratory reagents and cosmetic products* - Chapter 20 - May 2019 (pdf 208kb)

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