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IMPORTS AND EU POLICY TEAM

OVS Note 2015/10 **Date: 26th February 2015**

AMENDMENTS TO REGULATION (EU) NO 142/2011 AS REGARDS THE DEFINATION AND USE OF INTERMEDIATE PRODUCTS FROM 23RD FEBRUARY 2015

Purpose

1. To advise you of changes to the import requirements of intermediate products not for human consumption which come into force on 23rd February 2015.

Background

2. Commission Regulation (EU) 2015/9 of the 6th January 2015 amends Commission Regulation (EU) No 142/2011 with regards certain animal by-products and derived products not intended for human consumption.

3. These amendments include changes to the definition and usage of intermediate products imported from non EU countries.

4. As from 23rd February 2015 the definition of intermediate products in Annex 1 point 35 will be as follows:

   "**intermediate product**" means a derived product:

   (a) which is intended for uses within the manufacturing 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 cosmetic products as follows:

(i) as material in a manufacturing process or in the final production of a finished product;
(ii) in validation or verification during a manufacturing process; or
(iii) in quality control of a finished product;

(b) 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 point (a);

(c) 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 devices for medical and veterinary purposes, laboratory reagent or cosmetic products;'.

5. New uses for Intermediate products have also been introduced and will now be able to be imported for the manufacture of the following products:

- Medical devices for medical and veterinary purposes.
- In vitro diagnostic medical devices for medical and veterinary purposes.
- Cosmetic products

6. The use of an intermediate product will now be defined as the following:

(i) as material in a manufacturing process or in the final production of a finished product;
(ii) in validation or verification during a manufacturing process; or
(iii) in quality control of a finished product.

7. Importers should note that in point 4(c) above the word "labelling" has been removed from the definition. If a product requires some further manufacturing or transformation such as labelling it will no longer be defined as an intermediate product as per the requirements of Regulation (EU) No 2015/9 from 23rd February 2015.

NOTE

Importers of animal by-products used in the manufacture of products mentioned in points 5 and point 6 above may now be required to import under the intermediate product requirements. It is the responsibility of the importer to ensure they comply with the correct import requirements.

8. The outer packaging must be labelled applicable for the products usage in line with the following wording: "FOR 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/ COSMETIC PRODUCTS ONLY"

9. There is no change to the requirement that an intermediate product must be a derived product and used directly or as a component of a product for the purposes referred to above.

10. If a product cannot meet the above criteria (i.e. the product to be imported is **not** for the manufacture of one of the products referred to above or the product to be imported requires further processing to extract a product which will be then be used to manufacture the above mentioned devices) then it cannot be classed as an intermediate product and cannot be imported under such conditions.

11. Annex XII, point 3(a) of Regulation (EU) No 142/2011 will be replaced by the following wording:

    The intermediate products imported into the Union shall be checked at the border inspection post in accordance with Article 4 of Directive 97/78/EC and transported directly from the border inspection post either to:

    (a) a registered establishment or plant for the production of laboratory reagents, medical devices and in vitro diagnostic medical devices for veterinary purposes or the derived products referred to in Article 33 of Regulation (EC) No 1069/2009, where the intermediate products must be further mixed, used for coating, assembled or packaged before they are placed on the market or put into services in accordance with the Union legislation applicable to the derived product;'.

12. An amended Chapter 20 model declaration (as per (11) of Regulation (EU) No 2015/9) will be available for use on 23rd February 2015. However, for a transitional period until 27th September 2015, consignments of animal by-products and of derived products accompanied by a model declaration, which has been completed and signed in accordance with the model set out in chapter 20 of Annex XV to Regulation (EU) No 142/2011 prior to amendedment by Regulation (EU) No 2015/9, will be accepted provided that such model declarations were completed and signed before 27th July 2015.

Action for OVSs

- To note the changes to the definitions and new uses of intermediate products as defined in Regulation (EU) No 2015/9 and when they come into effect.

- The note changes to the labelling requirements.

- To note the changes to the types of registered premises intermediates products can now be shipped directly to.

- To be aware of the transitional period for use of the model set out in Chapter 20 of Annex XV to Regulation (EU) No 142/2011 prior to the amended version in Regulation (EU) No 2015/9 as per point 10 above.

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