

**CN20: CONDITIONS FOR REGISTERED PLANTS HANDLING
INTERMEDIATE PRODUCTS (SECTION XIII)**



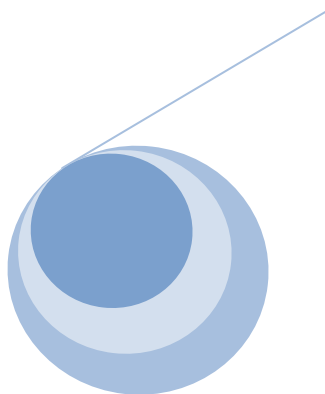
Department of
**Agriculture,
Food and the Marine**
An Roinn
**Talmhaíochta,
Bia agus Mara**

**CONDITIONS FOR REGISTERED PLANTS HANDLING
INTERMEDIATE PRODUCTS FOR THE PURPOSE OF
MANUFACTURING MEDICINAL PRODUCTS, VETERINARY
MEDICINAL PRODUCTS, MEDICAL DEVICES, ACTIVE
IMPLANTABLE MEDICAL DEVICES, IN VITRO DIAGNOSTIC
MEDICAL DEVICES, LABORATORY REAGENTS OR COSMETICS
(SECTION XIII)**



GOVERNING EU AND NATIONAL LEGISLATION:

The European Union (Animal By-Products) Regulation 2014 (S.I. No. 187 of 2014) and in accordance with Regulation (EC) No. 1069 of 2009 and Regulation (EU) No. 142 of 2011.



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Milk & Meat Hygiene/ABP/TSE Division**

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GLOSSARY OF TERMS

A

‘**Animal By-Products**’ (**ABP**) means entire bodies or parts of animals, products of animal origin or other products obtained from animals, which are not intended for human consumption, including oocytes, embryos and semen.

D

‘**DAFM**’ means the Department of Agriculture, Food and the Marine.

‘**Derived products**’ means products obtained from one or more treatments, transformations or steps of processing of animal by-products.

E

‘**Establishment**’ or ‘**plant**’ means any place where any operation involving the handling of animal by-products or derived products is carried out, other than a fishing vessel.

‘**EU**’ means the European Union.

O

‘**Operator**’ means the natural or legal persons having an animal by-product or derived product under their actual control, including carriers, traders and users.

SECTION 1

GENERAL INFORMATION AND REQUIREMENTS

- 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.
- A plant receiving intermediate products for the purpose of manufacturing medicinal products, veterinary medicinal products, medical devices for medical and veterinary purposes, active implantable medical devices, in vitro diagnostic medical devices for medical devices for medical and veterinary purposes, laboratory reagents or cosmetic products must be registered by the (DAFM) and the registration must be in date. (Article 23 of Regulation (EC) No 1069/2009).
- The operator must be authorised by the relevant competent authority, to manufacture a finished product under the relevant legislation referred to in Article 33 of Regulation (EC) No 1069/2009. A copy of the licence or authorisation to manufacture a finished product referred to in Article 33 must be provided to DAFM. All licenses and authorisations required from competent authorities must be valid while the plant is operational.

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- The operator must abide by all relevant requirements detailed in national legislation European Union (Animal By-Products) Regulations 2014 (S.I. No. 187 of 2014) and EU Legislation Regulation (EC) No. 1069/2009 and Commission Regulation (EU) No. 142/2011.
- The operator must put in place, implement and maintain a system of checks to monitor compliance with the legislation (Article 28 of Regulation (EC) No. 1069/2009).
- The operator must notify DAFM immediately if the plant no longer handles derived products or intermediate products or is no longer manufacturing the products details in the plant registration application. The plant must be decommissioned at this time and prior to use for any other activity. The operator will organise the decommissioning of the plant and clean up of the site and buildings as well as safe disposal of all ABP contaminated equipment in a reasonable time-period, under the direction of DAFM.
- The operator must make available for inspection stocks of intermediate products and records, and provide data and statistics as and when required by a DAFM officer.
- Any inspection report on the plant by a state or international agency containing a negative finding must be notified to DAFM without delay.

SECTION 2

BIOSECURITY, PLANT STRUCTURE, HYGIENE AND TRANSPORT

2.1 BUILDING/STRUCTURAL

- The plant must have adequate facilities for the receipt and storage of the intermediate products, which prevents the risk of transmission of diseases communicable to humans or animals.

2.2 ABP TRANSPORT AND SIGNAGE

- Intermediate products must be transported directly to the plant and under conditions which prevent the risk of transmission of any diseases communicable to humans or animals.
- Intermediate products accepted into the plant must be labelled on the outer packaging, and bear the words “*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*”

2.3 PLANT WASTE DISPOSAL

- Intermediate products or products derived from them must not be disposed of via the waste water stream.
(See also 5.1 Dispatch Procedures on page 7)

SECTION 3

INTAKE

3.1 INTAKE PROCEDURES

- The plant must only accept intermediate products for the purposes of manufacturing the finished product listed in the plant certificate of registration to be used:
 - 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.
- Consignments of intermediate products imported from a third country must be in compliance with import conditions and controls. A responsible and competent employee of the plant of destination must accurately and fully complete a Chapter 20 model declaration (Annex XV of Commission Regulation (EU) No. 142/2011) for each consignment of intermediate products to be imported from third countries. The declaration and consignment must be presented to the EU Border Inspection Post (BIP) on arrival for veterinary checks.
- Following veterinary checks at the BIP each consignment must be transported directly from the BIP to the plant of destination which completed the Chapter 20 model declaration.
- There must be appropriate and effective checks (documentary, identity and, if necessary, physical) on each consignment received into the plant to verify that intermediate products accepted into the plant are those permitted and/or declared in the Chapter 20 declaration.

3.2 DOCUMENTATION

- Each consignment of intermediate products from third countries accepted into the plant must be accompanied by a copy of the Chapter 20 declaration submitted by the plant, a copy of the commercial document completed by the plant of dispatch, and an original fully completed Common Veterinary Entry Document (CVED) from the BIP of importation.
- An ABP commercial document must specify the following information as a minimum:
 - a description of the material and the animal species of origin;
 - the category of the material as defined in Articles 8, 9 or 10 of Regulation (EC) No. 1069/2009;
 - the quantity of the material;
 - the place of origin and the place of destination of the material;
 - the name and the address of the consignor;
 - the name and the address of the consignee and/or user.

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Operators must keep all commercial documents filed and in date order.

The commercial document template for national use can be found on the DAFM website by using the following link:

<http://www.agriculture.gov.ie/media/migration/agri-foodindustry/animalby-products/animalby-products-tradernotices/TN012015CommercialDocumentsRev2250315.pdf>

The commercial document template for use within the EU may be found on the DAFM website by accessing Page 58 of Regulation (EU) No. 142/2011 using the following link:

<http://www.agriculture.gov.ie/media/migration/agri-foodindustry/animalby-products/legislation/eulegislation/ECReg142of2011.pdf>

- An intake register must be maintained for all intermediate products received into the plant. This register must include the following:
 - i) a description of the intermediate product
 - ii) the category of the material as defined in Articles 8, 9 or 10 of Regulation (EC) No. 1069/2009
 - iii) the quantity of the material
 - iv) the name and the address of the plant of origin, and approval number,
 - v) the date of intake
 - vi) the commercial document and CVED reference number where appropriate
 - vii) the name and address of the transporter

SECTION 4

PROCESSING

4.1 PROCESSING REQUIREMENTS

- Intermediate products may only be used as material in a manufacturing process or in the final production of the finished product detailed in the plant certificate of registration or in validation or verification during a manufacturing process or in quality control of a finished product.
- Intermediate products must not pose any risk of transmission of diseases communicable to humans or animals, due to their purification or to other treatments used during their production, due to the concentration of ABP in the intermediate product, or due to the provision of bio-security measures for the handling of intermediate products.
- The manufacturing of finished products using intermediate products must be carried out in accordance with the relevant legislation for the finished product concerned.
- If potential public or animal health risks, other than those already identified in the plant registration application arise, the operator must suspend operations and DAFM should be notified immediately.

4.2 CROSS-CONTAMINATION/BY-PASS

- All necessary measures must be taken to prevent contamination and the spreading of diseases communicable to humans or animals during the handling of the materials.

SECTION 5

STORAGE, DISPATCH AND TRACEABILITY/RECALL

5.1 DISPATCH PROCEDURES

- The plant operator must have appropriate and effective controls and checks in place to ensure disposal of unused intermediate product or products derived from intermediate product is carried out safely and in compliance with relevant legislation.

5.2 DOCUMENTATION

- Operators must keep a dispatch register for each consignment dispatched from the plant including sales and disposal. This register must include the following:
 - i) a description of the material,
 - ii) the category of the material as defined in Articles 8, 9 or 10 of Regulation (EC) No. 1069/2009 (if applicable)
 - iii) the quantity of the material,
 - iv) the name and the address of the place of destination (and approval/registration number where applicable,
 - v) the date of dispatch,
 - vi) the date and method of disposal where applicable,
 - vii) CN code for the material.
- The operator must maintain detailed records (Article 22 of Regulation (EC) No. 1069/2009) of purchases, sales, uses, stocks and disposals of surplus or waste products for the purpose of reconciliation of the quantities of intermediate products introduced on the one hand, and stocked, used, dispatched or disposed of on the other to permit DAFM officers check compliance with Commission Regulation (EU) No. 142/2011.
- All records must be easily accessible to DAFM and must be kept for a minimum of 3 years.

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CONTACT DETAILS

For Further Information contact:

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