

AP20: Application form for registered plants handling Intermediate Products (Section XIII)

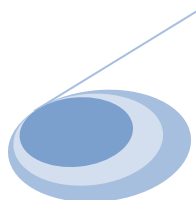


Application Form for registered plants handling intermediate products for the purpose of manufacturing medicinal products, veterinary medicinal products, medical devices, active implantable medical devices, in vitro diagnostic medical devices, laboratory reagents or cosmetics (Section XIII)

Information Note

Please note the following:

- In order to be registered as a plant 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), the applicant must comply with the European Communities (Animal By-Products) Regulations 2014 (S.I. No. 187 of 2014) and operate in accordance with Regulation (EC) No. 1069/2009 and Regulation (EU) No. 142/2011.
- ‘CN20 - 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)’ which is attached for your convenience, should be read before completing this application form.
- **Please note:** The application form must be completed by the ‘operator’. The operator is defined as ‘the natural or legal persons having an animal by-product or derived product under their actual control, including carriers, traders and users’.
- The completed application form and supporting documentation should be sent to Department of Agriculture Food and the Marine (DAFM), Milk and Meat Hygiene/ABP/TSE Division, (Animal By-Products Section), Grattan House, Grattan Business Centre, Dublin Road, Portlaoise, Co Laois, R32 RY6V.
- ***Applications that are incomplete, that contain insufficient or unsatisfactory information or that do not comply with conditions or legislative requirements will be returned to the applicant and a revised, fully completed application must be re-submitted.***



Issued 10th February 2016
Milk & Meat Hygiene/ABP/TSE Division

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Application form for registered plants handling intermediate products (Section XIII) under the requirements of Article 23 of Regulation (EC) No. 1069/2009

Please complete the application form in block capitals in black or blue ink. Please do not leave any section blank, or it may be returned to you for completion.

1. Company Details

Registered Company Name:

Registered Company Address:

Eircode:

Company Registration Number:

VAT Number:

2. Plant Details

Plant Name:

Plant Address:

Eircode:

Signature of Applicant (operator):

The applicant must be the operator. 'Operator' means the natural or legal person having an animal by-product or derived product under their actual control, including carriers, traders and users. Where the Operator is a corporate entity the person signing the application must be in a position of authority that he/she can bind the company.

Print Name:

Position within the plant:

Phone Number (Landline):

Phone Number (Mobile):

Email Address:

Date:

DAFM SHOULD BE NOTIFIED IMMEDIATELY OF ANY CHANGES TO THE ABOVE INFORMATION

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3. Plant Biosecurity Officer (if this person changes, please notify DAFM)

Name:
Phone Number (Landline):
Phone Number (Mobile):
Email Address:

DAFM SHOULD BE NOTIFIED IMMEDIATELY TO ANY CHANGE TO BIOSECURITY OFFICER

4. Details of product:

Describe the type of material used in this product:

Category of the material (Category 1,2,3):

Quantity of material used:

Could the material present a risk to animal or public health? If yes, describe how the risk will be mitigated:

5. Details of use

Describe how you intend to use the material, include significant information e.g. manufacturing or processing involving said Animal By-Products (ABP). Please attached any relevant documentation:

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5. Details of use contd..

Describe how the material will be transported to your plant (including if compliant with IATA and or ADR regulations):

Describe how will the material be stored:

Provide details of inventory and record keeping (including whether manual or electronic):

Describe how you intend to dispose of any unused material: *Provide information on how and where waste material will be collected, stored, transported and reused/disposed of. Please provide details of the company who wil lbe collecting/transporting/disposing of the waste material. If being destroyed after use, please indicate the method of destruction used by the company. Detail in this section for efficient processing of your application.*

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6. Details of ABP Source

Species of origin:

Country(s) of origin:

Address and status of the premises from which the material has been sourced:

Is there a certificate available stating that the source of the ABP was TSE free?

Has the Border Inspection Post (BIP) been contacted in relation to the importation of ABP?
Contact with the BIP should be made to ensure a licence to import has been obtained and that any imported ABP are accompanied by the relevant documentation, e.g. Health Cert or Commercial Veterinary Entry Document (CVED).

7. Other Information

Please provide any other relevant information including details of any other non-ABP stored or to be stored:

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DECLARATION

I, the undersigned declare that the information provided here is correct to my knowledge. The material will be used only as stated in this application form and will not be used for human consumption. I understand that I must comply with the conditions of any licence that may be granted to me.

Signature:

Date:

Block Letters:

Title:

CONTACT DETAILS

For further information contact:

**Department of Agriculture, Food and the Marine,
Milk and Meat Hygiene/ABP/TSE Division,
(Animal By-Products Section),
Grattan House,
Grattan Business Centre,
Dublin Road, Portlaoise, Co. Laois
R32 RY6V**

Phone Number: 0761 064440

Fax Number: 057-8694386

Email Address: AnimalByProducts@agriculture.gov.ie