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

Application form for establishments registered to use Animal By-Products (ABP) and/or derived products for diagnostic, educational or research purposes (Section X)

Information Note

Please note the following:

- An establishment using animal by-products (ABP) and/or derived products for research, or diagnostic purposes must comply with the European Communities (Animal By-Products) Regulations 2014 (S.I. No. 187 of 2014) and in accordance with Regulation (EC) No. 1069/2009 and Regulation (EU) No. 142/2011.
- *'CN21 - Conditions for establishments registered to use Animal By-Products (ABP) and/or derived products for diagnostic, educational or research purposes (Section X)'* can be found here and 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'. 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, e.g., Director or Company Secretary.
- 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), Room 220, Eir Building, Old Knockmay Road, Portlaoise, Co. Laois, R32 YK81.
- ***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 2nd February 2016
Milk & Meat Hygiene/ABP/TSE Division

AP21: Application form for establishments registered to use Animal By-Products (ABP) and/or derived products for diagnostic, educational or research purposes (Section X)

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

Application form for establishments registered to use Animal By-Products (ABP) and/or derived products for diagnostic, educational or research purposes (Section X) 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, e.g., Director or Company Secretary.*

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

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 material being used for diagnostic, educational or research purposes:

Describe the material (e.g. blood sample):

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

Is it intended to introduce material from other Member States?

Is it intended to introduce material from third countries?

Average quantity of material per consignment:

4. Details of material being used for diagnostic, educational or research purposes contd..

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

(a) Is the laboratory compliant with the requirements of the Safety, Health and Welfare at work (Biological Agents) Regulations S.I. 572/2013, see Annex 1?

(b) What is the accreditation status of the laboratory (e.g. ISO, GLP, GMP, DFA Licence)?

(c) Does the applicant laboratory contain more than one building or premises (details of each must be provided)?

(d) Are standard operating procedures and good laboratory practice principles in place and being applied?

5. Details of use

Describe how you intend to use the material (diagnostic, research or educational purposes):

Describe the activities, processes and procedures in the laboratory (e.g. in vitro/in vivo testing etc.):

Describe how will the material be stored?

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

5. Details of use contd..

Disposal (complete A, B or C only and provide details as requested:

A. As waste by incineration: **Yes** ☐ **No** ☐

If yes, provide details of disposal (including details of authorised disposal plant)

B. By pressure sterilisation and subsequent disposal or use: **Yes** ☐ **No** ☐

If yes, provide details of subsequent disposal or use in accordance with Articles 12 to 14 of Regulation (EC) No. 1069/2009 (including details of authorised plant)

C. Equivalent to steam autoclave validated to standard CEN TC/102: **Yes** ☐ **No** ☐

If yes, provide the following details:

Quantity of material being imported per consignment (in Millilitres):

Countries or part thereof of production:

Countries or part thereof of export:

Indicate whether cell cultures, laboratory kits or laboratory samples:

5. Details of use contd..

Describe waste water system and treatment:

Give the full postal address of the premises where any remaining material, residues or packaging will be disposed off:

6. Details of ABP Source

Species of origin:

Country of origin:

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. Containment and Bio-Security

Has a risk assessment been performed for the laboratory in accordance with Regulation 7 of the Health and Safety and Welfare at work Regulations 2013 (S.I. No. 572/2013 to determine the containment level measures necessary?

Yes ☐ **No** ☐

If yes, describe what containment level measures have been adopted:

8. Containment and Bio-Security contd..

If No, describe the containment level in which the laboratory will operate and provide justification:

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

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

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),
Room 220,
Eir Building,
Old Knockmay Road,
Portlaoise,
Co. Laois,
R32 YK81.

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