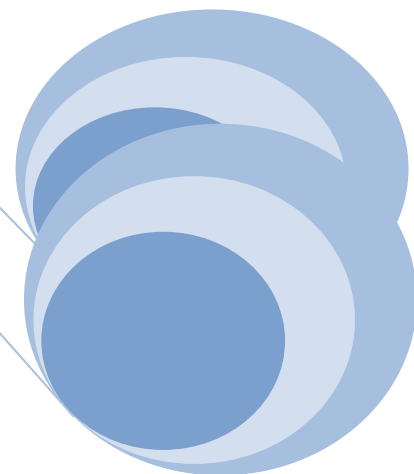


**CONDITIONS FOR ESTABLISHMENTS REGISTERED  
TO USE ANIMAL BY-PRODUCTS (ABPS)  
AND/OR DERIVED PRODUCTS FOR DIAGNOSTIC,  
EDUCATIONAL OR RESEARCH PURPOSES.  
(SECTION X)**



**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**

**CN21: Conditions for establishments registered to use Animal By-Products (ABP) and/or derived products for diagnostic, educational or research purposes (Section X)**

**CONDITIONS FOR ESTABLISHMENTS REGISTERED TO USE  
ANIMAL BY-PRODUCTS (ABPS) AND/OR DERIVED PRODUCTS  
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(SECTION X)**

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## **GLOSSARY OF TERMS**

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### **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.

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## **SECTION 1**

### **GENERAL INFORMATION AND REQUIREMENTS**

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#### **1.1 GENERAL INFORMATION AND REQUIREMENTS**

- An establishment using animal by products (ABP) and/or derived products for research or diagnostic purposes must be registered by the Department of Agriculture, Food and the Marine (DAFM) and the registration must be in date. (Article 23 of Regulation (EC) No 1069/2009).

DAFM may exempt an establishment handling or disposing of research and diagnostic samples for educational purposes from registration, provided there are no unacceptable risks for public and animal health.

- ‘Research and diagnostic samples’ means ABP and derived products intended for the following purposes: examination in the context of diagnostic activities or analysis for the promotion of progress in science and technology, in the context of educational or research activities. (Commission Regulation (EU) No. 142/2011).
- 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.
- All licenses and authorisations required to operate must be valid from relevant authorities while the establishment is operational.
- The operator must notify DAFM immediately if the establishment is no longer handling ABP or derived products. The establishment must be decommissioned at this time and prior to use for any other activity. The operator is required to organise the decommissioning of the establishment 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 establishment must also inform DAFM if any substantive changes are made to the facilities activities.

- The operator must make available for inspection stocks of samples of ABP or derived products and records, and provide data and statistics as and when required by a DAFM officer.
- Any inspection report on the establishment by a state or international agency containing a negative finding must be notified to DAFM without delay.

## **SECTION 2**

### **BIOSECURITY, ESTABLISHMENTS STRUCTURE, HYGIENE AND TRANSPORT**

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#### **2.1 BUILDING/STRUCTURAL**

- The operator must ensure that there is no access to the establishment by any animals.
- Floors and walls must be constructed of a material that is easy to clean and disinfect and must be kept in a satisfactory state of repair.
- The establishment must have appropriate hazard signage which must be highly visible e.g. hazard identification, name and phone number of the bio-security or safety officer etc.

#### **2.2 ESTABLISHMENT HYGIENE**

- The establishment, its installations and equipment must be kept in a clean and hygienic condition.

#### **2.3 PERSONNEL HYGIENE AND WORKFLOWS**

- A bio-security officer must be appointed for the establishment.

The operator of the establishment must implement effective bio-security procedures and train all relevant staff in relation to same.

In particular, there must be procedures for:

- the safe handling of ABP and derived products;
- the safe disposal of ABP and derived products.

Bio-security training records must be maintained and available for inspection.

DAFM must be notified of any change in bio-security personnel.

- Access to the facility must be restricted to authorised personnel only.
- Operatives must use suitable dedicated protective clothing when handling ABP or derived products.
- There must be adequate facilities and equipment for personnel hygiene and safety.

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### **2.4 PESTS AND BIRDS**

- The operator must have a documented pest control program (insects, rodents) in place which includes the following:
  - a bait map;
  - a service schedule for bait points;
  - a service records for bait points.

### **2.5 ABP TRANSPORT AND SIGNAGE**

- Research or diagnostic samples must be transported in appropriate UN approved packaging and in accordance with ADR (the European Agreement concerning the International Carriage of Dangerous Goods by Road) and IATA (International Air Transport Association) Regulations.
- Research and diagnostic samples must be transported directly from the point of dispatch or import to the destination facility.
- During transport, each consignment must bear a label with the following words visibly and legibly displayed “**for research and diagnostic purposes**”

### **2.6 ESTABLISHMENT WASTE DISPOSAL**

- ABP or derived products may not be disposed of via the waste water stream. (See also 5.1 Dispatch Procedures on pages 7 and 8)

## **SECTION 3**

### **INTAKE**

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#### **3.1 RAW MATERIAL INTAKE PROCEDURES**

- Only research and diagnostic samples as defined in Section 1, 2<sup>nd</sup> bullet point on page and the type and category as listed in the establishment certificate of registration may be accepted into the establishment.
- There must be appropriate and effective checks (documentary and visual) of each consignment received into the establishment to verify that only permitted products are accepted into the establishment.

#### **3.2 DOCUMENTATION**

- ABP or derived products may only be accepted into an establishment for research and diagnostic purposes provided each consignment is accompanied by an ABP commercial document specifying 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.
  - CN code for the material

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:

<https://www.agriculture.gov.ie/media/migration/foodindustrydevelopmenttrademarket/s/animalby-products/animalby-products-tradernotices/TN012015CommercialDocumentsRev2261016.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:

<https://www.agriculture.gov.ie/media/migration/foodindustrydevelopmenttrademarket/s/animalby-products/legislation/eulegislation/ECReg142of2011.pdf>

Derogation from the requirement for a commercial document may be granted to an establishment handling research and diagnostic samples for educational purposes provided no unacceptable risks for public or animal health arise, and subject to DAFM agreement.

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- Research and diagnostic samples from third countries must be authorised in advance of dispatch or importation by a licence granted by the DAFM. Importation must be in compliance with relevant legislation and conditions detailed in the import licence.

Samples from a third country must be accompanied by a copy of the import licence during transport.

Import licences must be retained for a minimum of 3 years.

- An intake register must be maintained at the establishment. This register must include the following:
  - a) a description of the material and the animal species of origin accepted into the establishment;
  - b) the category of the material as defined in Articles 8, 9 or 10 of Regulation (EC) No. 1069/2009;
  - c) the quantity of the material;
  - d) the place of origin of the material;
  - e) the name and the address (including country) of the establishment of origin, and approval number where applicable;
  - f) the date of intake;
  - g) the commercial document reference number;
  - h) the import licence reference number where ABP or derived products have originated from third countries;
  - i) the name and address of the transporter.

Derogation may be granted to an establishment handling research and diagnostic samples for educational purposes from keeping intake records provided no unacceptable risks for public or animal health arise, and subject to DAFM agreement.

- All records must be accessible to DAFM and must be kept for a minimum of 3 years.

## **SECTION 4**

### **PROCESSING/HANDLING**

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#### **4.1 PROCESSING REQUIREMENTS**

- If potential public or animal health risks, other than those already identified in the establishment registration application arise, the operator should suspend work and DAFM should be notified immediately.
- Research or diagnostic samples may not be used in a manufacturing process or in the production of a finished product; in validation or verification during a manufacturing process; or in quality control of a finished product.

Samples may only be used for the activities and purposes as detailed in the establishment certificate of registration for:

- examination in the context of diagnostic activities;
- analysis for the promotion of progress in science and technology;
- educational or research activities.

Sale, supply or dispatch to any other establishment or person for any purposes other than for immediate destruction is strictly prohibited.

- Adequate quarantine, where appropriate, and storage facilities must be in place for ABP or derived products and its packaging so as to prevent cross-contamination, in particular of food and feed for humans and animals, and to prevent any contact that might present a risk to public or animal health. Storage with products of either a higher or lower public or animal health status is strictly prohibited.
- An inventory of stock of ABP or derived product must be maintained in the establishment.

#### **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.

Standard operating procedures and good laboratory practice must be applied.

In the case of diagnostic and research laboratory establishments, a risk assessment in accordance with the Safety, Health and Welfare at Work (Biological Agents) Regulations, 2013 (SI 572/2013) shall be carried out.

In the case of samples imported from third countries, the relevant containment for the product concerned as set out in Schedule 2 of the Code of Practice for the Safety, Health and Welfare at Work (Biological Agents) Regulations, 2013 (SI 572/2013) must be applied as a minimum for animal health purposes.

*(Public health and safety considerations should be dealt with separately and in accordance with the legislation.)*

## **SECTION 5**

### **STORAGE, DISPATCH AND TRACEABILITY/RECALL**

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#### **5.1 DISPATCH PROCEDURES**

- Unless research, diagnostic or educational samples are kept for reference purposes or re-dispatched to the third country of origin all samples and any products derived from the use of those samples must be disposed of as detailed in the establishment certificate of registration and in accordance with ABP legislation.

The disposal method must be agreed and authorised by DAFM and will depend primarily on the type and ABP categorisation of the material and the place of origin.

***Disposal options for research and diagnostic samples are as follows:***

- (a) incineration or co-incineration;
- (b) pressure sterilization and subsequent disposal or use in accordance with Articles 12, 13 and 14 of Regulation (EC) No. 1069/2009;
- or
- (c) in the case of ABP or derived products referred to in Article 8(a) (iv), Article 8(c) and (d) and Article 9 and Article 10 of Regulation (EC) No. 1069/2009, which are part of cell cultures, laboratory kits or laboratory samples, by a treatment under conditions which are at least equivalent to the validated method for steam autoclaves and subsequent disposal as waste or waste water in accordance with relevant Union legislation.

***Disposal options for research and diagnostic samples imported from third countries are as follows:***

- (a) incineration;
- (b) pressure sterilization and subsequent disposal or use in accordance with Articles 12, 13 and 14 of Regulation (EC) No. 1069/2009; or
- (c) in the case of imports of research and diagnostic samples which are derived from ABP or derived products referred to in Article 8(a)(iv), Article 8(c) and (d) and Article 9 and Article 10 of Regulation (EC) No. 1069/2009, which are part of cell cultures, laboratory kits or laboratory samples, by a treatment under conditions which are at least equivalent to the validated method for steam autoclaves and subsequent disposal as waste or waste water in accordance with relevant Union legislation provided:
  - (i) the quantities do not exceed 2 000 ml; and
  - (ii) the samples or derived products have been produced in and dispatched from third countries or parts of third countries, from which Member States authorise imports of fresh meat of domestic bovine animals, which are listed in Part I of Annex II to Regulation (EU) No. 206/2010.

Where a steam autoclave is being used, it must be equipped with a cycle log recorder (to record time, temperature and pressure). The records of this log must be kept available for inspection.)

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*A registered establishment handling research and diagnostic samples for educational purposes may dispose of the material;*

- (a) by an alternative safe method other than those listed above, provided no unacceptable risks for public or animal health arise, subject to agreement by DAFM
- (b) in some cases, where appropriate, by re-dispatching the ABP or derived products to their place of origin.

- The establishment operator must have appropriate and effective procedures in place to ensure disposal of diagnostic and research samples, products derived from them, waste products including any material that may be contaminated is carried out safely and in compliance with legislation and the establishment certificate of registration.
- The establishment operator must have appropriate and effective checks in place to ensure disposal is carried out in accordance with procedures safely and as required.

### **5.2 DOCUMENTATION**

- A dispatch register for material dispatched from the establishment must be maintained. This register must include the following:
  - a) a description of the material and the animal species of origin;
  - b) the category of the material as defined in Articles 8, 9 or 10 of Regulation (EC) No. 1069/2009;
  - c) the quantity of the material;
  - d) the name and the address of the place of destination for destruction (unless re-dispatched) and approval number (where applicable);
  - e) the date of dispatch;
  - f) the method of disposal (unless re-dispatched);
  - g) the commercial document reference number;
  - h) name and address of the transporter.

Derogation may be granted to an establishment handling research and diagnostic samples for educational purposes from keeping dispatch records provided no unacceptable risks for public or animal health arise, and subject to DAFM agreement.

- All records must be easily accessible to DAFM and must be kept for a minimum of 3 years.

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**CONTACT DETAILS**

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