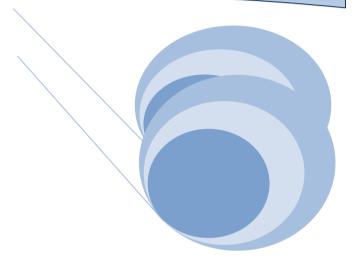


CONDITIONS FOR REGISTERED PLANTS MANUFACTURING DERIVED PRODUCTS FOR PURPOSES OUTSIDE THE FEED CHAIN (SECTION IX)



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.



Issued 12th February 2016 Milk & Meat Hygiene/ABP/TSE Division

CONDITIONS FOR REGISTERED PLANTS MANUFACTURING DERIVED PRODUCTS FOR PURPOSES OUTSIDE THE FEED CHAIN (SECTION IX)

CONTENTS	PAG:
Glossary of terms	
Section 1: General Information and Requirements	1
Section 2: Biosecurity, Plant Structure, Hygiene and Transport	2-3
2.1 Building/Structural	2
2.2 Plant Hygiene	2
2.3 Personnel and Workflows	2
2.4 Pests and Birds	2
2.5 ABP Transport and Signage	3
2.6 Plant Waste Disposal	3
Section 3: Intake	4-5
3.1 Intake Procedures	4
3.2 Documentation	4&5
Section 4: Processing/Handling	6
4.1 Processing/Handling Requirements	6
4.2 Cross-Contamination/By-Pass	6
Section 5: Storage, Dispatch and Traceability/Recall	7
5.1 Dispatch Procedures	7
5.2 Documentation	7
Contact Details	8

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.

0

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

Final version Rev0: 20160212

SECTION 1

GENERAL INFORMATION AND REQUIREMENTS

- An plant receiving animal by products (ABP) and/or derived products for manufacturing derived products for purposes outside the feed chain 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).
- A senior member of management at the plant must have provided a written guarantee that the animal by-products shall be used only for the purpose of producing the products for which the plant has been registered and shall not leave the plant untreated other than for direct disposal.
- Where an operator is authorised or approved to manufacture derived products by a competent authority for which the animal by-products are introduced such authorisation must be valid while the plant is operational. A copy of any such authorisation to manufacture must be provided to DAFM.
- 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.
- The operator must notify DAFM immediately if the plant no longer handles ABP or derived products. 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 ABP or derived 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 operator must ensure that there is no access to the plant 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.

2.2 PLANT HYGIENE

• The plant, its installations and equipment must be kept in a clean and hygienic condition.

2.3 PERSONNEL HYGIENE AND WORKFLOWS

The operator of the plant 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.

- Access to the plant 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.

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

- ABP or derived products must be transported in sealed packaging or in bulk covered leak-proof containers or vehicles.
- Vehicles or reusable containers used to transport bulk ABP must be cleaned washed and disinfected after each use and must be decommissioned before being used for other purposes.
- ABP or derived products accepted into the plant must be labelled on the outer packaging; "Animal by-products only for the manufacture of derived products for uses outside the feed chain" or in the case of blood products "Not for human or animal consumption".

2.6 PLANT WASTE DISPOSAL

• ABP or derived products may 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

- Only ABPs or derived products listed in the plant certificate of registration may be accepted into the plant for the purposes of manufacturing the derived products for which the plant is registered.
- There must be appropriate and effective checks (documentary, identity and, if necessary, physical) on each consignment received into the plant to verify that ABPs or derived products accepted into the plant are those permitted.
- For consignments monitored from the border inspection post (BIP) in Ireland to the plant (channelled consignments) the form BIP F5 which accompanying the consignment must, within 12 hours of arrival, be completed, scanned & e-mailed or faxed to the BIP by a person responsible for intake procedures at the registered plant.
- The operator of a plant receiving products requiring monitoring to destination (channelled consignments) must collaborate with DAFM in putting in place and implementing a procedure to enable verification of arrival of each consignment in accordance with TSE SOP/04/2014.

3.2 DOCUMENTATION

- ABP or derived products within the EU may only be accepted into an plant provided each consignment is accompanied by an ABP commercial document specifying:
 - 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.

A copy of the commercial document must be signed and dated and returned by the plant operator to the place of origin.

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

In the case of ABPs or derived products imported from a third country each consignment must be accompanied by an original CVED (Common Veterinary Entry Document) and an authenticated copy of the original Health Certificate.

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

- An intake register 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 place of origin of the material;
 - e) the name and the address of the plant of origin, and approval number where applicable;
 - f) the date of intake;
 - g) the commercial document or CVED reference number;
 - h) the name and address of the transporter;
 - i) CN code for the material.
- Intake records format must expedite verification of intake of products requiring monitoring to destination (channelled consignments) by a DAFM officer.

SECTION 4

PROCESSING/HANDLING

4.1 PROCESSING REQUIREMENTS

- If potential public or animal health risks, other than those already identified in the plant registration application arise, the operator should suspend work and DAFM should be notified immediately.
- ABP or derived products may only be used for the activities and purposes detailed in the plant certificate of registration.

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 checks in place to ensure disposal of and ABP or derived product material is carried out safely and in compliance with legislation and the plant certificate of registration.
- ABPs or derived products which are not used must be disposed of in accordance with the relevant Article of Regulation (EC) No 1069/2009.

5.2 DOCUMENTATION

- A dispatch register for each consignment of ABP or derived products dispatched from the plant 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 and approval number (where applicable);
 - e) the date of dispatch;
 - f) the date and method of disposal;
 - g) the commercial document reference number;
 - h) the transporter name and address.
- A separate commercial document must be completed for each batch of material
 collected in the case of mixed loads. The consignor should send the original plus two
 copies with the ABP and retain the final copy. The carrier retains one copy and hands
 the original plus a copy to the receiver. The receiver should keep the original, sign and
 return the copy to the producer as proof of arrival of the consignment.

A link to the commercial document template can be found on page 4.

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

Page 7 of 8

CONTACT DETAILS

For Further Information contact:

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

Phone Number: 0761 064440

Fax Number: 057-8694386

Email Address: <u>AnimalByProducts@agriculture.gov.ie</u>