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CONDITIONS FOR A PLANT/ESTABLISHMENT APPROVED TO CARRY OUT INTERMEDIATE ACTIVITIES AND STORE HORSE PLACENTA

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 and 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.

B

'**Batch**' means a unit of production produced in a single plant using uniform production parameters, such as the origin of the materials, or a number of such units, when produced in continuous order in a single plant and stored together as a shipping unit.

C

'**Competent Authority**' means the central authority of a member state competent to ensure compliance with the requirements of EU ABP Regulations or any authority to which that competence has been delegated; it also includes, where appropriate, the corresponding authority of a third country.

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 ABP.

E

'**Establishment**' or '**plant**' means any place where any operation involving the handling of ABP or derived products is carried out, other than a fishing vessel.

'EU' means the European Union.

I

'Intermediate product' means a derived product: (a) which is intended for the manufacture of medicinal products, veterinary medicinal products, medical devices, active implantable medical devices, in vitro diagnostic medical devices or laboratory reagents; (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 that purpose; (c) which however requires some further handling or transformation, such as mixing, coating, assembling, packaging or labeling to make it suitable for placing the product on the market or putting it into service, as applicable, as a medicinal product, veterinary medicinal product, medical device, active implantable medical device, in vitro diagnostic medical device or laboratory reagent.

O

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

SECTION 1

GENERAL INFORMATION, REQUIREMENTS AND HACCP

1.1 GENERAL INFORMATION, REQUIREMENTS AND HACCP

- A plant/establishment involved in handling ABP or carrying out intermediate operations (as defined in Article 2 of Regulation 142/2011) following their collection must be approved and the approval must be in date. (EU Regulation 1069/2009, Article 24 (h)),(i) and (j)).

- The operator must comply with all relevant requirements set out in Regulation (EC) No. 1069/2009 and Commission Regulation (EU) No.142/2011 and all other relevant EU and National Legislation, in particular S.I No. 187 of 2014.

- Plants/establishments must comply with Articles 28 and 29 on Own Checks and HACCP in Regulation (EC) 1069/2009.

- Licenses and authorisations required to operate must be valid from all relevant licensing authorities while the plant/establishment is operational.

- The plant/establishment operator must notify DAFM immediately if significant changes are proposed to plant/establishment activities.

- The operator must notify DAFM immediately if the plant/establishment is no longer to be used for handling ABP. The plant/establishment must be decommissioned at this time and prior to use for any other activity. The operator must organise the decommissioning of the plant/establishment and clean up of the site and buildings as well as safe disposal of all equipment in a reasonable time period, under the supervision of DAFM.

- The operator must provide data and statistics to DAFM as and when required and in whichever format requested.

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

- The operator should sufficiently equip the plant/establishment in relation to fire safety and health and safety, seeking expert advice if necessary.

SECTION 2

BIOSECURITY, PLANT/ESTABLISHMENT STRUCTURE, HYGIENE AND TRANSPORT

2.1 PERIMETER

- The premises must be located so that it is adequately separated from public highways, and other appropriate premises sufficient to prevent cross-contamination of food and feed for humans and animals respectively. Animals must not be allowed access to the plant/establishment.

2.2 BUILDING/STRUCTURAL

- There must be a sufficiently large covered space to receive, handle and store the ABP. All ABP must be under cover.
- All buildings must be maintained clean and in good condition and any necessary repairs must be made on a regular basis.
- The floors must be smooth and sloped to facilitate the drainage of liquids. The inner walls must be smooth, clean and well maintained.
- The plant/establishment must be designed and personnel must work so as to assure adequate separation of the handling of materials for different end-usage destinations.
- There must be adequate separation between the area of the plant/establishment where incoming material for handling is unloaded and the areas set aside for the storage of products.
- Suitable office facilities where an examination of records can take place must be provided on site and be made available to DAFM staff.

2.3 PLANT/ESTABLISHMENT HYGIENE

- The operator must ensure that a hygiene plan has been designed and implemented effectively for all areas of the plant/establishment.
- All handling and storage locations and equipment must be emptied and cleaned regularly to the extent necessary to ensure hygienic practice.

2.4 PERSONNEL AND WORKFLOWS

- Management at the plant/establishment must implement effective procedures and training plans for all operatives employed or subcontracted, ensuring to focus the procedures and training (including training records) on:

  - Safe handling of ABP and derived products.

  - Ensuring the acquisition and correct completion of documentation so as to contribute to safe intake of ABP, safe dispatch of ABP to suitable safe end-usage and safe dispatch of ABP 'waste' to suitable, legal disposal.

  Examples of documentation include:

    - Identification documents.
    - Commercial documentation and proof of arrival at destination for documentation going with outgoing consignments.

- Operatives must use suitable dedicated protective clothing when handling ABP. This must be removed/cleaned/disinfected or discarded before leaving the plant/establishment.

- Footbaths/boot washes must be provided at all entrances and exits to the plant/establishment. These must be signposted and replenished regularly so as to provide adequate disinfection.

- There must be access to adequate facilities for personal hygiene including lavatories, changing rooms and washbasins for staff. The washing facilities must be equipped with hot water, soap and paper towels.

2.5 PESTS AND BIRDS

- The operator must have a documented rodent control program in place which includes the following:-

  - A bait map.
  - Service schedule for bait points.
  - Service records for bait points.

2.6 ABP TRANSPORT AND SIGNAGE

- Horse placentas must be transported in plastic, leak-proof containers with labelling **"CATEGORY 3 MATERIAL Not for Human Consumption"**.
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- Vehicles must be well maintained to prevent any accidental discharge of material or liquids to the environment.

- The operator must have a system for cleaning and disinfecting the vehicles and containers and must include a wheel wash, with disinfectant, at the entrance and exit to the plant/establishment.

- Horse placentas must not be stored overnight in transport vehicles or transferred between vehicles or stored at premises other than those approved by the DAFM.

- Containers must be dedicated to the carriage of a single category of ABP or derived product.

2.7 PLANT/ESTABLISHMENT WASTE DISPOSAL

- All waste ABP from the plant/establishment must be disposed of appropriately in compliance with national and EU legislation and in a way that mitigates risk. Traceability of waste disposal must be ensured.

- The operator must ensure to maintain and implement measures to prohibit the disposal of ABP, intermediate or derived products via the waste water stream. This must be achieved by the use of drain traps or screens with apertures with a filter pore or a mesh size of no more than 6 mm. Waste water that has passed through the screen is no longer regarded as ABP. However, the operator has a responsibility to ensure that waste water is treated in accordance with relevant EU and national environmental legislation.

2.8 INTAKE

Raw Material Intake Procedures

- Only horse placentas may be accepted into the plant/establishment.

- The operator must organise for documentary and visual checks on raw material consignments to verify that only raw material allowed in the approval and which are safe are accepted into the plant/establishment.

Documentation

- All horse placenta delivered to the plant/establishment must be accompanied by a commercial document which meets the requirements as laid down in Annex VIII Chapter III of Regulation 142/2011.

- The plant/establishment must keep an up to date electronic intake register completed appropriately, in chronological order and including:

    - A description of the material (including species of animal(s)) or type of materials, age and quantities.
    - Dates of intake.
    - A batch reference or consignment number if appropriate.
    - A health certificate or commercial document reference number.
    - The name and address (and country) of the premises/holding of origin (and approval number if applicable).
    - The name and address of the haulier and the receptacle registration number (if applicable).
    - Date of notification of the RVO of intake of material (if relevant).

2.9 PROCESSING/HANDLING

Processing/Handling Requirements

- The plant/establishment must not engage in activities other than those provided for in the plant/establishment conditions of approval.
- Procedures on site should ensure the safe handling and storage of ABP.
- All necessary measures must be taken to prevent contamination and the spreading of diseases communicable to humans or animals.

2.10 STORAGE, DISPATCH AND TRACEABILITY/RECALL

Dispatch Procedures

- The operator must ensure that ABP and intermediate or derived products manufactured or derived from ABP, dispatched from the plant/establishment, are traceable and must be disposed of safely and in compliance with national and EU legislation.
- All ABP, intermediate or derived products must be disposed directly, in a manner that is safe, legal and in accordance with the end-usage applied for in the operator application and agreed by DAFM as described in the plant/establishment conditions document. If the operator seeks to dispose of end-product or waste in a fashion other than provided for in the conditions document then the operator should complete an application that will be assessed by DAFM in the normal manner.
- Management must organise for documentary and visual checks on consignments from the plant/establishment to verify that waste and products, will be disposed of safely and in compliance with legislation and conditions.
- All ABP, intermediate or derived products to be dispatched from the plant/establishment must be suitably packaged so as to mitigate risk and must be labelled appropriately in accordance with legislation and safety.
- The operator dispatching the product must verify that the plant/establishment of destination is actively licensed by the relevant competent authority (authorised, approved or registered in accordance with ABP Regulations) in advance of dispatch if:
    - the ABP or material derived from ABP must undergo further manufacturing.
    - The ABP or intermediate product must be disposed as waste.
- ABP, intermediate products or derived products suspected or discovered not to comply with the legislation or the specific plant/establishment conditions may not leave the plant/establishment unless destined for legal waste disposal.

Documentation

- The operator must ensure that ABP consignments or consignments of products manufactured or derived from ABP, dispatched from the plant/establishment are traceable and disposed of safely.

- The plant/establishment must keep and up to date dispatch register completed appropriately, in chronological order and up to date including:

  - A description of the ABP.
  - Dates of dispatch.
  - A batch reference or consignment number if appropriate.
  - A health certificate or commercial document reference number.
  - The name and address and country of the premises of dispatch (and approval number if applicable).
  - The name and address of the haulier and the receptacle registration number (if applicable).
  - Date of notification of the RVO of dispatch (if relevant e.g. for export).
  - Weights of consignments of outgoing material (preferably using the plant/establishment weighbridge).

- A fully completed commercial document must accompany each load of ABP leaving the plant/establishment.

- Operators must use A3 EU commercial documents for trade of material outside the state and within the European Union whereas an A4 commercial document may be used for trade within the state.

- The commercial document must be assigned a unique identifiable number. The commercial document must be produced in quadruplicate (one original and three copies). The original must remain at the plant/establishment of origin, the transporter must retain one copy and the premises of destination the other. The fourth copy is signed or stamped by the premises of destination and returned to the plant/establishment of origin. Operators must keep the copies of commercial documents for all outgoing loads filed and in date order.

- Copies of all health certificates issued must be retained. Health certificates may only be drawn up and signed by DAFM officials and operators should provide ample time for the process of drawing up health certificates.

- The operator must retain proof of arrival destination for all ABP consignments or consignments of products manufactured or derived from ABP dispatched from the plant/establishment. This proof of destination would typically be the signed or stamped copy of the commercial document returned by the customer (consignee).

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