CN3: Conditions for approval of a plant involved in the production of raw petfood

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Bia agus Mara
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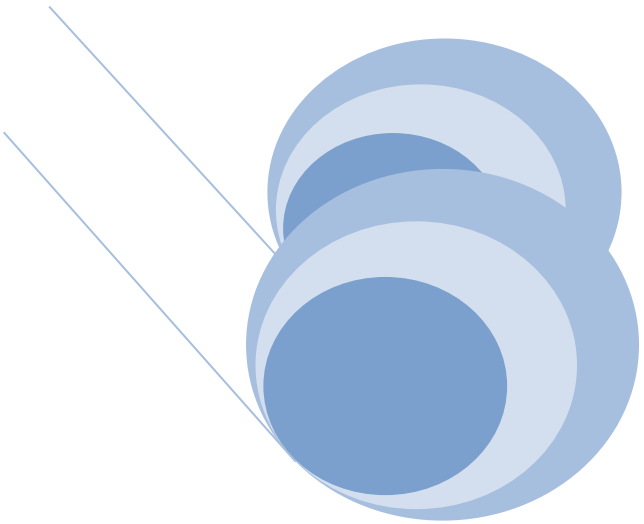
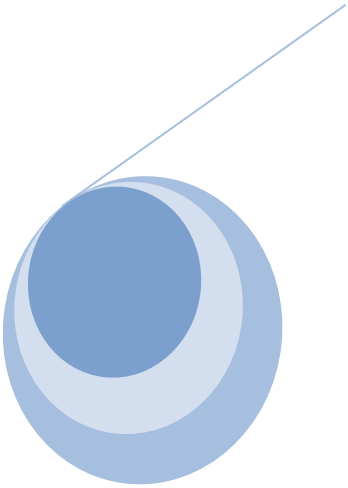
CONDITIONS FOR APPROVAL OF A PLANT INVOLVED IN THE PRODUCTION OF RAW PETFOOD



GOVERNING EU AND NATIONAL LEGISLATION:

The European Communities (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

CONDITIONS FOR APPROVAL OF A PLANT INVOLVED IN THE PRODUCTION OF RAW PETFOOD

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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

'Catering Waste' means all waste food, including used cooking oil originating in restaurants, catering facilities and kitchens, including central kitchens and household kitchens

'**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 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.

'**Export**' means movement from the Community to a third country

F

'Feed Material' means those feed materials, as defined in Article 3(2)(g) of Regulation (EC) No 767/2009, that are of animal origin, including processed animal proteins, blood products, rendered fats, egg products, fish oil, fat derivatives, collagen, gelatine and hydrolysed proteins, dicalcium phosphate, tricalcium phosphate, milk, milk- based products, milk-derived products, colostrum, colostrum products and centrifuge or separator sludge;

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.

R

'Raw petfood' means petfood containing certain Category 3 material which has not undergone any preserving process other than chilling or freezing

U

'**User**' means the natural or legal persons using animal by-products and derived products for special feeding purposes, for research or for other specific purposes;

SECTION 1

GENERAL INFORMATION, REQUIREMENTS AND HACCP

1.1 GENERAL INFORMATION, REQUIREMENTS AND HACCP

- A plant involved in the production of raw petfood Animal By-Product (ABP) must be approved by the Department of Agriculture, Food and the Marine (DAFM) and hold a valid certificate of approval in accordance with (Article 24 (e) of Regulation (EC) No. 1069/2009.

- The operator must comply with all relevant requirements listed in the European Union (Animal By-Products) Regulations 2014 (S.I. No. 187 of 2014) and in accordance with EU Legislation (Regulation (EC) No. 1069/2009 and Regulation (EU) No. 142/2011).

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

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

- The operator must notify DAFM immediately if the plant is no longer to be used for handling ABP. 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 equipment in a reasonable time period, under the direction of DAFM.

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

1.2 HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP)

- The operator must design, document and implement a Hazard Analysis and Critical Control Points (HACCP) plan, incorporating all the following elements:
  a) identify any hazards that must be prevented, eliminated or reduced to acceptable levels;
  b) identify the critical control points (CCPs) at the step or steps at which control is essential to prevent or eliminate a hazard or reduce it to acceptable levels;
  c) establish critical limits at (CCPs) which separate acceptability from unacceptability, for the prevention, elimination or reduction of identified hazards;
  d) establish and implement effective monitoring procedures at (CCPs);
  e) establish corrective action when monitoring indicates that a (CCP) is not under control;

f) establish procedures to verify that the measures outlined in points (a) to (e) are complete and working effectively. Verification procedures shall be carried out regularly;

g) establish documents and records commensurate with the nature and size of the businesses to demonstrate the effective application of the measures set out in points (a) to (f).

This HACCP plan should also describe and document:

- clear responsibilities for all previous points and actions;
- the HACCP team and frequency of routine HACCP review;
- HACCP training;
- detailed process flow diagrams;
- detailed product descriptions and end-usages, including labelling of product storage conditions, ingredients and warnings.

The HACCP should be underpinned by a good set of pre-requisite programme procedures (for example hygiene, maintenance, traceability, calibration, final product testing).

When any modification is made to a product, process or any stage of production, processing, storage or distribution, operators shall review their procedures and make the necessary changes.

1.3 MICROBIOLOGICAL TESTING, CORRECTIVE ACTION AND RECALL

- A plan for Microbiological Testing of Final Product must be documented in a Standard Operating Procedure by the plant. Microbiological testing is considered a CCP for raw petfood plants and every batch must be tested to ensure it complies with legislative requirements.

  This operating procedure must be provided to the veterinary inspector who should agree it.

  The operating procedure must incorporate the following elements: -

  - Definition of a batch. A batch is taken as a volumetric measurement. It will not suffice for a batch to be defined in general terms as a week's production or any given period of time. A batch should be the final product deriving from raw material processed during a specific process cycle.
  - The prescribed frequency at which testing will take place (every batch).
  - Documented Sampling Apparatus and Sample Taking Procedure.
  - Documented Laboratory Testing procedure and the laboratory to be employed to carry out said test. The testing procedure must be one that is internationally accredited by an accreditation body (e.g. INAB accredited in Ireland). Laboratories used must be on the DAFM approval list: http://www.agriculture.gov.ie/agri-foodindustry/animalbyproducts/euapprovedabpplants/
  - A Corrective Actions and Recall Plan must be in situ and implemented in the event of test results being non-compliant.

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- *Random samples must be taken from raw petfood during storage (before dispatch) to verify compliance with the following standards:*

  Salmonella: absence in 25 g, n = 5, c = 0, m = 0, M = 0.

  The process of production of raw petfood shall meet the following process hygiene criterion:

  Enterobacteriaceae: n = 5, c = 2, m = 500 in 1 g, M = 5 000 in 1 g

  Where:

  n = number of samples to be tested;

  m = threshold value for the number of bacteria; the result shall be considered satisfactory if the number of bacteria in all samples does not exceed m;

  M = maximum value for the number of bacteria; the result shall be considered unsatisfactory if the number of bacteria in one or more samples is M or more; and

  c = number of samples the bacterial count of which may be between m and M, the sample shall still be considered acceptable if the bacterial count of the other samples is m or less.

- The records of tests and associated results must be suitably organised, retained on site and available to authorised officers of the Department.

SECTION 2

BIOSECURITY, PLANT STRUCTURE, HYGIENE AND TRANSPORT

2.1 PERIMETER

- The premises must be located so that it is adequately separated from public highways, slaughterhouses 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.

2.2 BUILDINGS/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 layout of plants must ensure the total separation of Category 3 material from all other materials from reception until dispatch.
- The plant 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 where incoming material for handling is unloaded and the areas set aside for the handling and the storage of products.
- Suitable office facilities where an examination of records can take place must be provided on site.

2.3 PLANT HYGIENE

- The operator must ensure that a hygiene plan has been designed and implemented effectively for all areas of the plant.
- 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

- The operator must implement effective procedures and training plans for all operatives employed or subcontracted, ensuring to focus the procedures and training on:
  - safe handling of ABP and derived products;
  - supervision of processing, storage and transport temperature controls;
  - 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 would include:
    - Health certificates and associated ancillary documentation;
    - Commercial documentation and proof or arrival at destination for documentation going with outgoing consignments.

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

- Footbaths/bootwashes must be provided at all entrances and exits to the plant.

- 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

- Operators transporting ABP to the plant or from the plant must be registered ABP hauliers and listed on DAFM's Animal By-Products transport register.

- The operator must maintain receptacle registers for each ABP haulier used. Each haulier must provide each ABP plant they service with a copy of the receptacle register which should contain the following information:
  - container number;
  - receptacle chassis number;
  - authorised ABP or derived product category;
  - registered owner;
  - date of listing/commission;
  - date of delisting/decommission;
  - date of cleaning and disinfection as indicated on cleaning certificate at time of delisting.

- ABP transport vehicles must be designed so as to prevent any accidental discharge of organic material or liquids to the environment.

- The operator must have a system for cleaning and disinfecting the vehicles or reusable containers or receptacles in which ABP are transported.

- ABP must not be stored overnight in transport vehicles or transferred between vehicles (this constitutes handling) or stored at premises other than those approved by DAFM.

- Transport vehicles or containers must be dedicated to the carriage of a single Category of ABP or derived (final) product. Raw and processed product should not be transported in the same vehicle or container unless transport takes place in sealed packaging in both instances (preventing cross-contamination). Transport vehicles and containers must be permanently and prominently marked on both sides appropriately, as follows:

  Raw ABP or Waste (Category 3 ABP)

  - Haulier registration code[1] and receptacle number.
  - The Category of ABP as well as the applicable ancillary wording
    Examples:
    "CATEGORY 3 MATERIAL Not For Human Consumption"

  In the case of Raw Petfood

  - Haulier registration code[1] and receptacle number.
  - The Category of ABP as well as the applicable ancillary wording
    "CATEGORY 3 MATERIAL As Pet Food Only"

2.7 LABELLING

- The labelling and the presentation of feed shall not mislead the user, in particular:

  (a) as to the intended use or characteristics of the feed, in particular, the nature, method of manufacture or production, properties, composition, quantity, durability, species or categories of animals for which it is intended;

  (b) by attributing to the feed effects or characteristics that it does not possess or by suggesting that it possesses special characteristics when in fact all similar feeds possess such characteristics.

- The person responsible for the labelling shall ensure the presence and substantive accuracy of the labelling particulars. The person responsible for the labelling shall be the feed business operator who first places feed on the market or, where applicable, the feed business operator under whose name or business name the feed is marketed.

- A feed material or compound feed shall not be placed on the market unless the following particulars are indicated by labelling:

  a) the type of feed: 'feed material', 'complete feed' or 'complementary feed'

[1] The haulier must be officially registered with the Department of Agriculture, Food and the Marine.

- For 'complete feed', the designation 'complete milk replacer feed' may be used, if appropriate,
- For 'complementary feed', the following designations may be used if appropriate: 'mineral feed' or 'complementary milk replacer feed',
- For pets other than cats and dogs, 'complete feed' or complementary feed' may be replaced by 'compound feed'

b) the name or business name and the address of the feed business operator responsible for the labelling;

c) the establishment ABP and Feed approval number;

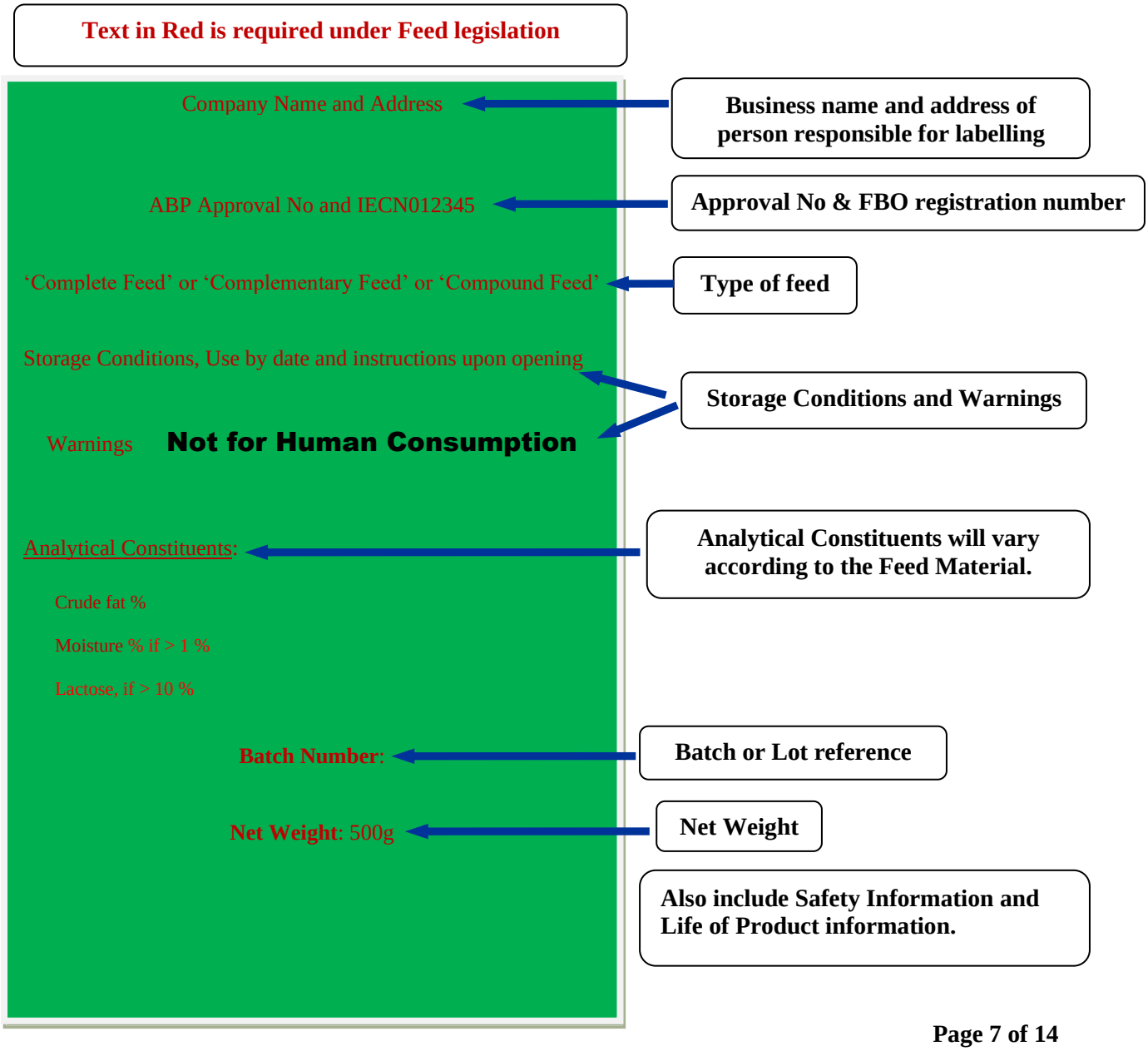
d) the batch or lot reference number;

e) the net quantity expressed in units of mass in the case of solid products, and in units of mass or volume in the case of liquid products;

f) the list of feed additives preceded by the heading 'additives';

g) safety information.

EXAMPLE



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- The operator must retain documentation on file to justify and support assertions, nutritional claims or labelling instructions.

  This justification should include good support for claims in relation to minimum durability of product at different storage conditions i.e. support for use by dates for example.

  Research in relation to allergens or ingredients that may pose risks to humans or animals should also be documented and retained.

2.8 PLANT WASTE DISPOSAL

- All waste ABP from the plant 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 may 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 Community environmental legislation. See Trader Notice 02/2011 which can be found on the DAFM website by using the following link: http://www.agriculture.gov.ie/agri-foodindustry/animalbyproducts/animalbyproducts-tradernotices/

SECTION 3

INTAKE

3.1 RAW MATERIAL INTAKE PROCEDURES

- Only Category 3 ABP material as defined in Article 10 (a) and 10 (b)(i) and (ii) of Regulation (EC) No. 1069/2009 may be accepted into the plant. Fish is not permitted for use in raw petfood.

  The operator must ensure to advise consignors of raw material for use in feed or pet-food production that materials referred to in Regulation (EC) No. 1069/2009 Article 10 (b)(iii)-(p), and in particular catering waste and fish, are not dispatched as raw material and the operator must take steps to ensure these are excluded from the premises.
  Other raw materials (non ABP) accepted into the plant, to be incorporated in final product must be safe for animals and humans.

- Packaging must be leakproof and sealed. It shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, packaging does not transfer their constituents to food in quantities which could:
  (a) endanger human or animal health; or
  (b) bring about an unacceptable change in the composition of the product; or
  (c) bring about a deterioration in the organoleptic characteristics thereof.

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

- The transport of ABP destined for the production of feed material or raw petfood must take place at an appropriate temperature. Short distances should be transported at a maximum temperature of 7 °C, (unless the premises is approved as a Collection Centre and the ABP are exclusively used for feeding purposes in accordance with Chapter I of Annex II of Regulation (EU) No. 142/2011) in order to avoid any risk to animal or public health. Longer journeys will require the ABP to be refrigerated.

  Operators must communicate with suppliers ensuring in contracts and implemented procedures, including intake checks, that the cold-chain at the supplier premises and during transport has been maintained.

- Should Category 3 material at any stage become contaminated with Category 1 material or adulterated or contaminated with material that may be hazardous to humans or animals then it should not be accepted into the plant i.e. all of that material must be treated as Category 1 for the purposes of disposal.

3.2 DOCUMENTATION

- All Category 3 material delivered to the plant must be accompanied by a commercial document which meets the requirements as laid down in Annex VIII Chapter III of Regulation (EU) No. 142/2011, and, when required by the legislation, a health certificate.

  Commercial documents must specify:
  - the name and address of the consignor and approval number of the plant (if applicable);
  - the name and address of the consignee and plant approval number (if applicable);
  - the name and address of the carrier (haulier) and the registration number of the vehicle;
  - the quantity/weight of the material;
  - the date of dispatch;
  - the container number (if applicable);
  - the seal number (if applicable);
  - a description of the material;
  - signature of the consignor;
  - signature of carrier (haulier).

  Four copies of the commercial document must be produced.

  See relevant Trader Notices on the DAFM website.

  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 and sign and return the copy to the producer as proof of arrival of the consignment.

- The operator must keep an up-to-date intake register completed appropriately, in chronological order and should include:
  - a description of the material including species of animal(s) 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 of origin (and approval number if applicable);
  - the name and address of the carrier/haulier and the receptacle registration number (if applicable);

- date of notification of the Regional Veterinary Officer of intake of material (if relevant);
- weights of consignments of incoming material (preferably using a plant's own weighbridge).

- The operator must establish a system to notify DAFM (Regional Veterinary Inspector) when imported[2] ABP/derived products are received on site.

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

[2] Imported products are products received from non-EU countries.

SECTION 4

PROCESSING/HANDLING

4.1 PROCESSING/HANDLING REQUIREMENTS

- Procedures on site should ensure the safe handling and temporary storage of ABP. ABP should be stored in temperature conditions that should be appropriate both in terms of mitigating public and animal health risks and preventing odours. The operator must be able to justify temperature control systems, on the basis of documented research.

- All the time during storage the Category 3 material must be handled and stored separately from other goods and in such a way as to prevent the spread of disease. In the case of mixed loads (mixed categories), Category 3 material must be dispatched for lawful disposal within a reasonable timeframe.

- The operator must not engage in activities other than the acceptance, collection, sorting, treatment, temporary storage and dispatching of the Category 3 ABP specified in the plants approval.

4.2 EQUIPMENT

- The operator must ensure that all measuring devices including thermometers and weighbridges are calibrated and confirmed to be working effectively at least once every 12 months.

- If any significant changes to equipment or buildings are intended, the operator should contact Milk and Meat Hygiene/ABP/TSE Division to describe the changes. These changes must be sanctioned by an authorised officer prior to taking place.

4.3 CROSS-CONTAMINATION/BY-PASS

- All necessary measures must be taken to prevent contamination and the spreading of diseases communicable to humans or animals, throughout the production chain.

SECTION 5

STORAGE, DISPATCH AND TRACEABILITY/RECALL

5.1 DISPATCH PROCEDURES

- The operator must ensure that ABP or products manufactured or derived from ABP, dispatched from the plant, are traceable and must be disposed of safely and in compliance with national and EU legislation. The prescribed end-usages are set out in the conditions attached to the certificate of approval.

- ABP suspected or discovered not to comply with the legislation or the specific plant approval requirements may not leave the plant unless destined for legal waste disposal.

5.2 DOCUMENTATION

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

  The following final destinations are permitted for raw petfood:-
  - supply of product directly to end-users (pet owners);
  - supply of product directly to shops selling directly to end-users.

- The operator must keep an up-to-date dispatch register completed appropriately, in chronological order and must include:

  - a description of the ABP (including waste), intermediate products or derived products dispatched- including quantities;
  - 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 carrier/haulier and the receptacle registration number (if applicable);
  - date of notification of the Regional Veterinary Office of dispatch (if relevant e.g. for exportation);
  - weights of consignments of outgoing material (preferably using a plant's own weighbridge).

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

  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 of origin, the transporter must retain one copy and the premises of destination the other. The fourth copy is signed by the premises of destination and returned to the plant of origin.

  In the case of ABP being dispatched to other EU countries or third countries, the EU commercial document must be used.

  The operator 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.

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

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

- A corrective action plan detailing the steps to be taken in the event a recall is required, must be available.

- The operator must implement procedures to ensure continuity of the cold-chain during transport to customers and take steps to ensure that customers are made aware of correct storage conditions for products.

CONTACT DETAILS

For further information contact:

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