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CONDITIONS FOR A PLANT INVOLVED IN THE PROCESSING OF CATEGORY 3 ANIMAL BY-PRODUCTS

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 1st December 2014
Milk & Meat Hygiene/ABP/TSE Division

CONDITIONS FOR A PLANT INVOLVED IN THE PROCESSING OF CATEGORY 3 ANIMAL BY-PRODUCTS

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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 animal by-products;

E

'**Establishment**' or '**plan**t' 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.

SECTION 1

GENERAL INFORMATION, REQUIREMENTS AND HACCP

1.1 GENERAL INFORMATION AND REQUIREMENTS

- A plant involved in the production of processing of CATEGORY 3 material 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 (a) of Regulation (EC) No. 1069/2009.

- The operator must comply with all relevant requirements listed in National legislation 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 processing 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 supervision of DAFM.

- All records required in the context of the Animal By-Products (ABP) Regulations must be retained in the plant's office for a period of 3 years. Records must be made available for inspection by DAFM staff.

- 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 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, working effectively and in accordance with Regulation (EC) No. 1069/2009 and Regulation (EU) No. 142/2011. Verification procedures shall be carried out regularly;
g) establish documents and records proportionate to 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.

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, the operator shall review their procedures and make the necessary changes and the HACCP plan should be routinely reviewed at least once yearly.

A DAFM veterinary inspector from the Regional Veterinary Office should sanction any proposed significant changes to the HACCP plan in advance of their implementation and should be provided with an up-to-date copy of the HACCP plan.

- A plan for insoluble impurities testing of final product (whether designated a CCP or not) must be documented in a Standard Operating Procedure (SOP) by the operator.

This operating procedure must be provided to the authorised officer.

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 defined as follows:
  - A tallow tank on the processing plant site or
  - A tallow road tanker or
  - A tallow tank in a tallow storage facility
- 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. Where processing plants are using their own on-site laboratory, verification of testing at this on-site laboratory must take place by comparison with an external ISO accredited independent laboratory);
- defined pre-determined corrective actions in the event of test results being non-compliant.

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

- Microbiological Criteria must be met in end products destined for feed.
  Unless there is separate dedicated storage for end products destined for feed then all end products must be subject to monitoring via final product testing in accordance with legislation in italics below.

  The plant must draw up and implement a written standard operating procedure (SOP) to monitor the microbiological suitability of end-products.

  This operating procedure must be provided to the authorised officer.

  The operating procedure must incorporate the following elements:

  - definition of a batch, lot or storage location to be assessed, which the results (and if appropriate corrective action) will be associated with. (Where storage of end product takes place it is important that the monitoring regime described in the SOP incorporate microbiological assessment of all storage locations);

  - 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 and the laboratory should be accredited to use this test. Where processing plants are using their own on-site laboratory verification of testing at this on-site laboratory must take place by comparison with an external ISO - accredited independent laboratory);

  - defined pre-determined corrective actions in the event of test results being non-compliant.

  Legislation:

  'Microbiological standards for derived products
  The following microbiological standards shall apply to derived products:
  Samples of the final products taken during or on withdrawal from storage at the processing plant must comply with the following standards:
  Salmonella: absence in 25 g: n = 5, c = 0, m = 0, M = 0
  Enterobacteriaceae: n = 5, c = 2, m = 10, M = 300 in 1 g
  where:
  n = number of samples to be tested;
  m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all samples does not exceed m;
  M = maximum value for the number of bacteria; the result is 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 still being considered acceptable if the bacterial count of the other samples is m or less.
  However, the microbiological standards set out in this Chapter shall not apply to rendered fats and fish oil from the processing of animal by-products, when the processed animal protein (PAP), which is obtained during the same processing, is subject to sampling to ensure compliance with those standards.'

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

Below is a link to the list of Private Laboratories approved by DAFM for microbiological testing of Animal By-Products in accordance with Commission Regulation (EU) No 142/2011 implementing Regulation, (EC) No 1069/2009.

https://www.agriculture.gov.ie/agri-foodindustry/animalbyproducts/euapprovedabpplants/

- Specific conditions apply to the production of feed destined for aquaculture. This is in accordance with Section D, Chapter IV, Annex IV of E.U Regulation 999/2001.

  The animal by-products intended to be used for the production of processed animal protein destined for aquaculture must come from:

  (i) slaughterhouses which do not slaughter ruminants and which are registered by the competent authority as not slaughtering ruminants; or

  (ii) cutting plants which do not bone or cut up ruminant meat and which are registered by the competent authority as not boning or cutting up ruminant meat; or

  (iii) other establishments than those referred to in (i) or (ii) which do not handle ruminant products and which are registered by the competent authority as not handling ruminant products.

  Sampling of every batch produced that is destined for aquaculture must be carried out by the operator to detect the presence of ruminant material. The method of detection must be scientifically validated for that purpose and must be carried out in laboratory approved to carry out that test by DAFM. This should be part of the operator's HACCP plan.

- Specific conditions apply to Cat 3 Processing Plants processing insect protein where an inherent activity results in the generation of frass.

  "Frass" is defined as a mixture of excrements derived from farmed insects, the feeding substrate, parts of farmed insects, dead eggs and with a content of dead farmed insects of not more than 5% volume and not more than 3% in weight.

  Frass must meet specific requirements before it can be placed on the market as an organic fertiliser/soil improver. These requirements are set out below.

  - Each batch of Frass must come from a plant for derived products for uses outside the feed chain or from a biogas or composting plant that manufactures organic fertiliser or soil improvers.
  - Each batch of Frass must be heat treated to at least 70 degrees Celsius for a minimum of 60 continuous minutes.

(i) The plant must have received approval by DAFM to operate to these parameters. A validation of the process must be carried out over a 10 week period with a minimum of 6 batches being produced during this period. Applicants must apply to M&MH/ABP Division in Portlaoise via email address AnimalByProducts@agriculture.gov.ie

(ii) The plant must be equipped with equipment that has been validated by DAFM (unless otherwise agreed by DAFM).

(iii) The processing of Frass and related activities must take place in a dedicated area that has been approved by DAFM.

(iv) The processing parameters must be continually monitored using temperature probes that continually record live during the processing time producing thermograph records.

- Each batch of processed Frass must be stored in a way that ensures contamination or secondary infection and dampness is minimised. They must therefore be stored in:

  (i) Well-sealed and insulated silos or properly constructed storage sheds; or

  (ii) Properly sealed packs, such as plastic bags or 'big bags'

- Microbiological Criteria must be met for each batch of Frass as specified below.

  The plant must draw up and implement a written Standard Operating Procedure (SOP) to monitor the microbiological suitability of the Frass.

  This operating procedure must be agreed by a DAFM authorised officer.

  The operating procedure must incorporate the following elements:

- Definition of a batch, lot or storage location to be assessed, which the results (and if appropriate corrective action) will be associated with. (Where storage of end product takes place, it is important that the monitoring regime described in the SOP incorporate microbiological assessment of all storage locations).

- Documented Sampling Apparatus and Sample Taking Procedure.

- Documented Laboratory Testing procedure & the laboratory to be employed to carry out said test. (The testing procedure must be one that is internationally accredited by an accreditation body and the laboratory should be accredited to use this test. Where processing plants are using their own on-site laboratory verification of testing at this on-site laboratory must take place by comparison with an external ISO-accredited independent laboratory).

- Defined Pre-determined Corrective Actions in the event of test results being non-compliant.

Legislation:

'Microbiological standards for derived products

- *The following microbiological standards shall apply to derived products:*

Representative samples of the manure taken during or immediately after processing at the plant in order to monitor the process must comply with the following standards:

Escherichia coli: n = 5, c = 5, m = 0, M = 1 000 in 1 g;

or

Enterococcaceae: n = 5, c = 5, m = 0, M = 1 000 in 1 g;

and

Representative samples of the manure taken during or on withdrawal from storage at the plant of production or the biogas or composting plant must comply with the following standards:

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

where:

n = number of samples to be tested;

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

M = maximum value for the number of bacteria; the result is 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 still being considered acceptable if the bacterial count of the other samples is m or less.

Processed manure or processed manure products not complying with the standards in this point shall be regarded as unprocessed;

- Rendered Fats destined for feed must be monitored for dioxins in accordance with legislation (defined in italics below).

  Unless there is separate dedicated storage for rendered fats destined for feed then all rendered fats must count towards the frequency defined in legislation.

  The plant must draw up and implement a written SOP to fulfill this obligation and in the absence of a testing regime the SOP should prohibit rendered fats from going to feed.

  This operating procedure must be provided to the authorised officer.

  The operating procedure must incorporate the following elements: -

  - definition of a batch, lot or storage location to be assessed, which the results (and if appropriate corrective action) will be associated with. (Where storage of end product takes place it is important that the monitoring regime described in the SOP incorporate microbiological assessment of all storage locations);
  - 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 and the laboratory should be accredited to use this test. Where processing plants are using their own on-site laboratory verification of testing at this on-site laboratory must take place by comparison with an external ISO-accredited independent laboratory);
- defined Pre-determined Corrective Actions in the event of test results being non-compliant.

Legislation:

'DIOXIN MONITORING'

1. *Feed business operators placing on the market fats, oils or products derived thereof intended for use in feed, including compound feed, shall analyse those products in accredited laboratories for the sum of dioxins and dioxin-like PCBs in accordance with Commission Regulation (EC) No 152/2009.*

2. *To supplement the feed business operator's HACCP system, the analyses referred to in point 1 shall be carried out with at least the following frequencies:*
   (b) producers of animal fat:
   one representative analysis per 2 000 tonnes of animal fat and products derived thereof belonging to category 3, as laid down in Article 10 of Regulation (EC) No 1069/2009 of the European Parliament and of the Council.

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

- Operators must take action swiftly following the receipt of results that do not meet the requirements of legislation or safety[1]; this applies to the results of checks the operator has organised and upon presentation of the results of checks that DAFM has organised.

[1] If required the operator should organise an independent external expert to interpret results on its behalf.

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 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.

  In particular, processing plants must not be situated on the same site as slaughterhouses or other establishments which have been approved or registered in accordance with Regulation (EC) No. 852/2004 or Regulation (EC) No. 853/2004, unless the risks to public and animal health resulting from the processing of ABP, which originate from such slaughterhouses or other establishments, are mitigated by compliance with at least the following conditions:

  (i) the processing plant must be physically separated from the slaughterhouse or other establishment, where appropriate by locating the processing plant in a building that is completely separated from the slaughterhouse or other establishment;
  (ii) the following must be installed and operated in the processing plant:
  — a conveyer system which links the processing plant to the slaughterhouse or other establishment and which may not be by-passed,
  — separate entrances, reception bays, equipment and exits for both the processing plant and the slaughterhouse or establishment;
  (iii) measures must be taken to prevent the spreading of risks by personnel who are employed in the processing plant, slaughterhouse or other establishment.

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.

- 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, processing, 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 intake, processing, storage, dispatch and final product sampling and testing;
  - ensure the acquisition and correct completion of documentation so as to contribute to safe intake of ABP and safe dispatch of ABP or final products to suitable safe end-usage or disposal;

  Examples of documentation would include:
    - Health certificates and associated ancillary documentation;
    - Commercial documentation (paper or electronic) for incoming and outgoing consignments 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.

- 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.

  Transport vehicles and containers must be permanently and prominently marked on both sides appropriately, as follows:

  INCOMING MATERIAL:

  Raw ABP (Category 3 ABP)
  - haulier registration code[2] and receptacle number
  - the Category of ABP as well as the applicable ancillary wording
    Examples:
    "CATEGORY 3 MATERIAL not for Human Consumption"

  OUTGOING PRODUCTS:
  - haulier registration code[2] and receptacle number
  - the Category of ABP as well as the applicable ancillary wording
    Examples:
    "CATEGORY 3 MATERIAL Not For animal Consumption"

- Raw 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.

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

- All storage tanks for rendered fat must be labelled appropriately and in accordance with category of ABP:

  "CATEGORY 3 Material Not For Human Consumption" for tanks which store Category 3 tallow.

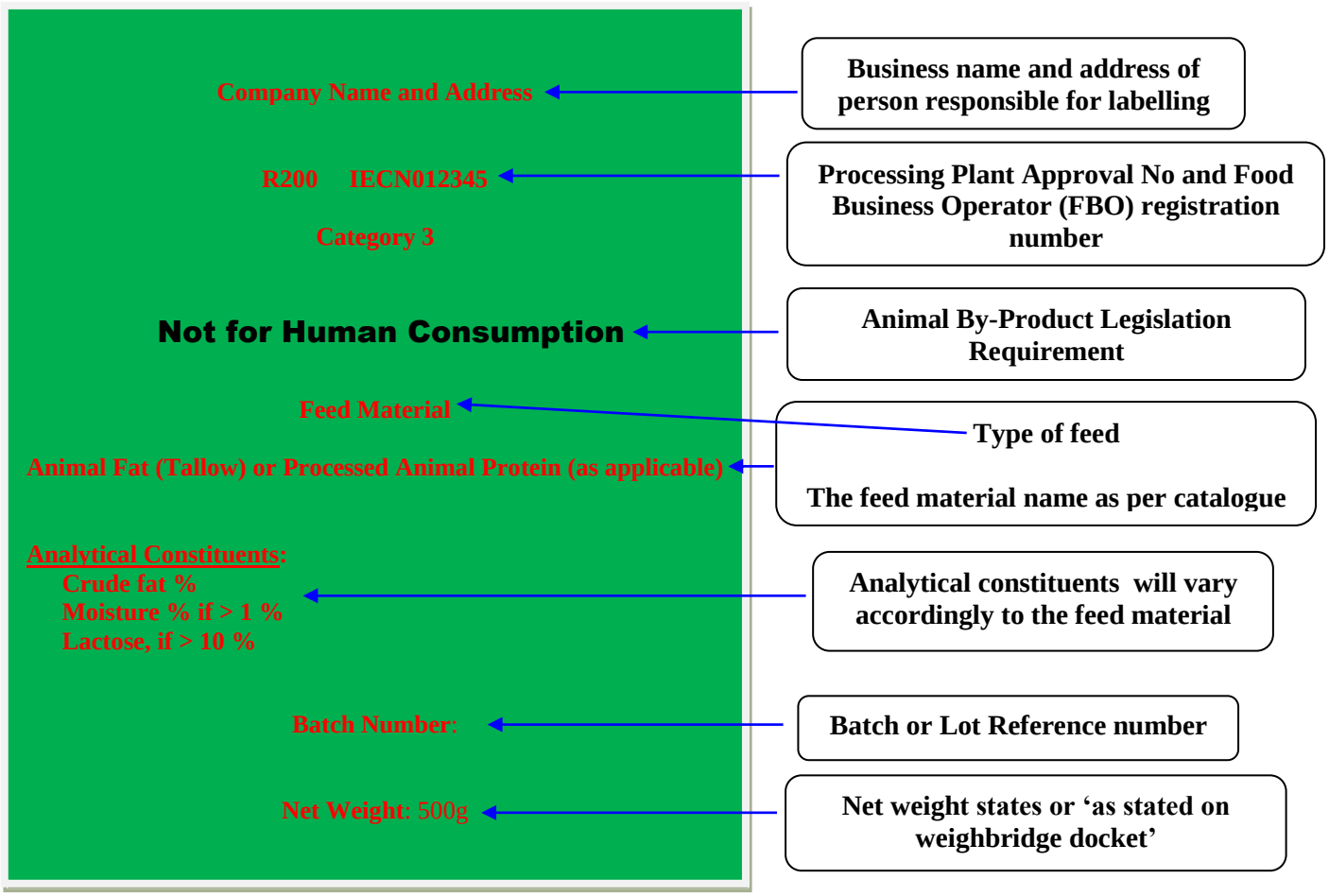
  Upon re-dedicating a storage tank to the storage of lower risk ABP category a full disinfection and decontamination protocol, pre-approved by a DAFM authorised officer, must be implemented and certified upon completion by the DAFM authorised officer.

➢ For rendered fats and processed animal protein destined for feed:
A feed material or compound feed shall not be placed on the market unless the following particulars are indicated by labelling (directly on packaging or for bulk product in documentation accompanying the consignment):

(a) the type of feed: 'feed material', 'complete feed' or 'complementary feed';
(b) the name or business name and the address of the feed business operator responsible for the labelling;
(c) if available, the establishment approval number of the person responsible for the labelling;
(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.

Label for Animal Fat (Tallow) or Processed Animal Protein destined for animal feed – complying with Feedingstuffs Legislation.

Text in Red is required under feedingstuffs legislation.



- For rendered fats and processed animal protein destined for feed:

  The labelling and the presentation of feed shall not mislead the user, in particular:
  - 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;
  - 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 FBO under whose name or business name the feed is marketed.

2.7 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 maintain and implement measures to prohibit the disposal of ABP or derived products via the waste water system. This should 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 (or an equivalent system).

  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 the raw materials described in Article 10 of Regulation (EC) No. 1069/2009, excluding sub points (n), (o) and (p), may be accepted into the plant to be used for processing.

- The operator must organise for documentary and visual checks on raw material consignments to verify that only raw materials allowed in this approval and which are safe will be accepted into the plant and that in particular raw material described in Article 8 (Category 1 material), and Article 9 (Category 2 material), hazardous material and catering waste are not allowed into the plant as raw material for processing.

- Specific conditions apply to the production of feed destined for aquaculture. This is in accordance with Section D, Chapter IV, Annex IV of E.0 Regulation 999/2001.

  The animal by-products intended to be used for the production of processed animal protein destined for feeding to aquaculture animals must come from:

  (i) slaughterhouses which do not slaughter ruminants and which are registered by the competent authority as not slaughtering ruminants; or

  (ii) cutting plants which do not bone or cut up ruminant meat and which are registered bythe competent authority as not boning or cutting up ruminant meat; or

  (iii) other establishments than those referred to in (i) or (ii) which do not handle ruminant products and which are registered by the competent authority as not handling ruminant products.

  For plants handling ruminant material, every batch of non-ruminant PAP destined for aquaculture must be sampled by the operator to verify the absence of ruminant material. The method of detection must be scientifically validated for that purpose and must be carried out in laboratory approved by DAFM for that testing method. This should be part of the operator's HACCP plan.

  Intake bays for lines producing PAP destined for aquaculture must have a system in place that ensures that cross contamination with ruminant material is prevented. The entire line of production must ensure that cross contamination with ruminant material is prevented. This must be documented in an SOP.

3.2 DOCUMENTATION

- All ABP material delivered to the plant must be accompanied by a completed 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.

  Relevant Trader Notices can be found on the DAFM website by using the following link:
  http://www.agriculture.gov.ie/agri-foodindustry/animalbyproducts/animalbyproducts-tradernotices/

  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 transporter 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.

- The operator should fulfill obligations describing to the consignor the proof of arrival of raw material consignments. This may involve return of a plant-stamped commercial document.

- 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 the Competent Authority (Regional Veterinary Officer) if imported[3] ABP/derived products are received on site.

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

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

SECTION 4

PROCESSING/HANDLING

4.1 PROCESSING/HANDLING REQUIREMENTS

- The operator must not engage in activities other than the acceptance, sorting, processing, temporary storage, combustion (of Tallow) and dispatching of ABP and derived products.

- All raw materials must be processed using the equipment used and tested during validation. If equipment is modified or replaced any such modifications or replacements should be notified in writing in advance to a DAFM authorised officer who will determine whether validation should be repeated.

- The minimum process parameters listed below and in additional conditions attached to the approval must be met:
  - All raw materials must undergo processing in accordance with the method, validated at the time of first approval or during re-validation. Allowable methods are described in Chapter III Annex IV of Regulation 142/2011. The critical control points that determine the extent of the heat treatments applied in processing shall include for each processing method as specified in Chapter III:
    a) raw material particle size;
    b) temperature achieved in the heat treatment process;
    c) pressure, if applied to the raw material;
    d) duration of the heat treatment process or feed rate to a continuous system.

  Minimum processing standards must be specified for each applicable critical control point in the HACCP Plan.

  - an adequate safety system must be in place to assure processing of all raw material;

  - at all times while the plant is operational, tamper-proof measuring equipment for critical control point monitoring as well as recording devices to record continuously the results of measurements must be working;

  - checks by the operator upon achievement of minimum process parameters must be documented and must be retained for the purpose of checks and official control for a minimum period of 3 years;

  - the processing plant must retain at all times sufficient production capacity for hot water and steam for the processing of ABP, while operational.

- Rendered Fats must be purified in such a way that the maximum level of remaining total insoluble impurities does not exceed 0.15 % in weight. No consignment of rendered fats must leave the plant or be combusted on site until such time as a check to ensure the level of purification afore-mentioned has been achieved.

4.2 EQUIPMENT

- The operator must ensure that all measuring devices including 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 as follows:
  - disposal as waste by incineration;
  - disposal by co-incineration;
  - used as a fuel for combustion in the case of rendered fats;
  - used for the manufacture of derived products referred to in Articles 33, 34 and 36 of Regulation (EC) No. 1069/2009 and placed on the market in accordance with those Articles. A DAFM authorised officer must be informed in advance of such end-usage and approve such usage prior to dispatching consignments.

- ABP or derived products suspected or discovered not to comply with the legislation or the specific plant approval requirements may not leave the plant until these products have been brought to the attention of a DAFM authorised officer who should agree a plan for them.

5.2 DOCUMENTATION

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

  - 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 incoming material (preferably using a plant's own weighbridge);

- A fully completed commercial document or DOCOM (TRACES) 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 (1 original and 3 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 cases of ABP being dispatched to other EU countries or third countries, the EU commercial document must be used.

  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.

- 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.

CONTACT DETAILS

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