CN29: Conditions for approval of a plant involved in the processing of Category 1 (Biodiesel) ABP

Department of Agriculture, Food and the Marine
An Roinn Talmhaíochta, Bia agus Mara

CONDITIONS FOR APPROVAL OF A PLANT INVOLVED IN PROCESSING OF CATEGORY 1 (BIODIESEL) 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.

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Milk & 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 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.

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SECTION 1

GENERAL INFORMATION, REQUIREMENTS AND HACCP

1.1 GENERAL INFORMATION AND REQUIREMENTS

- A plant involved in the processing of Category1 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 the European Union (Animal By-Products) Regulations 2014 (S.I. No. 187 of 2014) and 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 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 Implementing Regulation (EU) No. 142/2011. 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.

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

When any modification is made to a raw material (type or source), product (including end-usage), process or any stage of production, processing, storage or distribution, operators 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 District 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 checks on raw material prior to esterification (whether designated a CCP or not) must be documented in a Standard Operating Procedure (SOP) by the operator to provide for compliance with legislation as follows:

"*processed fat must be separated from the protein and in the case of fat from ruminant origin, insoluble impurities in excess of 0,15 % by weight must be removed, and the processed fat must be subsequently submitted to esterfication and transesterfication"*

This operating procedure must be provided to the authorised officer who should agree it.

The operating procedure must incorporate the following elements:

- checks on documentation and paperwork accompanying consignments if purification has taken place in advance of arrival at the plant, as well as specification for suppliers contacts/agreements;

- verification checks on raw material to ensure that this requirement is met including:
  - the frequency at which these checks will take place;

- 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 plant site or
  - A tallow road tanker
- 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.

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SECTION 2

BIOSECURITY, PLANT STRUCTURE, HYGIENE AND TRANSPORT

2.1 PERIMETER

- The premises must be located so that it is adequately separated from public highway 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 through the operation of personnel which is employed in the processing plant and in the 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 material and derived products.
- Suitable office facilities where an examination of records can take place must be provided on site.

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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.

- Operatives must use suitable dedicated protective clothing, when handling ABP which must be removed/cleaned/disinfected or discarded before leaving 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 and must not enter the plant unless registered.

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- 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 (where applicable);
  - 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, the reusable containers or receptacles in which ABP are transported.

- Receptacles 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 the ABP or derived product is packaged in sealed, leakproof packaging in both instances (preventing cross-contamination). Transport vehicles, receptacles and containers must be covered and leak proof and permanently and prominently marked on both sides appropriately, as follows:

  INCOMING MATERIAL:

  Raw ABP (Category 1 ABP)
  - haulier registration code[1] and receptacle number
  - the Category of ABP as well as the applicable ancillary wording
    Examples:
    "CATEGORY 1 MATERIAL For Disposal Only"

  Raw ABP (Category 3 ABP only)
  - haulier registration code[1] and receptacle number
  - the Category of ABP as well as the applicable ancillary wording
    Examples:
    "CATEGORY 3 MATERIAL Not For animal Consumption"

  OUTGOING PRODUCTS:

  - haulier registration code[1] and receptacle number
  - the Category of ABP as well as the applicable ancillary wording
    Examples:
    "CATEGORY 1 MATERIAL FOR DISPOSAL ONLY"

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

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- 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.

- All storage tanks for rendered fat and ABP catering waste must be labelled appropriately and in accordance with category of ABP.
  "CATEGORY 1 MATERIAL For Disposal Only" (unless there are dedicated tanks and lines for Category 3 material)

  Upon re-dedicating a storage tank to the storage of lower risk ABP category a full disinfection and decontamination protocol, preapproved by a DAFM authorised officer, must be implemented and under the supervision of DAFM.

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 ensure to 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/

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SECTION 3

INTAKE

3.1 RAW MATERIAL INTAKE PROCEDURES

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

- Intake Official Control documentation (Health certificates or commercial documentation) for ABP raw materials must list all operators where ABP raw material is handled or stored, i.e. material must move directly from a consignor to a consignee on official documentation.

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);
  - the category of material;
  - 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/media/migration/agri-foodindustry/animalby-products/animalby-products-tradernotices/TN012015CommercialDocumentsRev2250315.pdf

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A separate commercial document must be completed for each consignment 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 fulfil legal obligations describing the proof of arrival of raw material consignments. This may involve return of a plant-stamped commercial document or TRACES message by the Competent Authority to the consignor of the material if from another Member State.

- 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;
  - the category of incoming material;
  - 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[2] ABP/derived products are received on site.

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

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SECTION 4

PROCESSING/HANDLING

4.1 PROCESSING/HANDLING REQUIREMENTS

- The operator must not engage in activities other than the acceptance, sorting, processing (in accordance with the biodiesel process described in Chapter IV, Annex IV of Regulation (EU) No. 142/2011), temporary storage, and dispatching of ABP and derived products.

- All raw material 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 following minimum process parameters must be met:
  - "(a) Unless fish oil or rendered fat are used which have been produced in accordance with Sections VIII or XII of Annex III to Regulation (EC) No 853/2004, respectively, the fat fraction derived from animal by-products must be first processed using:
    (i) in the case of Category 1 or 2 materials, processing method 1 (pressure sterilisation) as set out in Chapter III; and
    (ii) in the case of Category 3 materials, any of the processing methods 1 to 5 or processing method 7 or, in the case of material derived from fish, processing methods 1 to 7 as set out in Chapter III". Discrimination between "Category 3 Material" and "Category 1 Material" may only take place where storage tanks for each category are entirely dedicated with no adjoining pipe work or facility for these materials to mix on site.

  - The ABP material must undergo a process whereby it must be submitted to esterfication and transesterfication. However, esterfication is not required for processed fat derived from Category 3 material (*this derogation only applies if a process line is present that is solely dedicated to handling Category 3 material away from Category 1 or Category 2 material)*
    - For esterfication the pH must be reduced to less than 1 by adding sulphuric acid (H2SO4) or an equivalent acid and the mixture must be heated to 72 °C for at least two hours during which it must be intensely mixed.
    - Transesterfication must be carried out by increasing the pH to about 14 with potassium hydroxide or with an equivalent base at 35 °C to 50 °C for at least 15 minutes. (*Plant should* specify a definite pH figure here rather than 'about 14' to provide for corrective action taking place)
    - Transesterfication shall be carried out twice under the conditions described in the previous bullet point using a new base solution.

    This process (esterification and transesterifcation) must be followed by refinement of the products including vacuum distillation at 150 °C, leading to biodiesel;

- At all times while the plant is operational tamper-proof measuring equipment as well as recording devices to record continuously the results of these measurements must be working, measuring the parameters outlined in the previous bullets and must do so in a way that they remain accessible for the purpose of checks and official controls.

- The plant must implement monitoring routines and checks to ensure that the afore-mentioned legal parameters are being met and so that if required, corrective action (which should be defined and documented in advance) can be taken in real-time. Verification checks should be implemented to ensure that this system is working.

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:
  - Biodiesel and residues from the distillation of biodiesel may be used as a fuel and will have moved beyond the scope of ABP legislation
  - Potassium sulphate may be used for direct application to land or for the production of derived products for application to land
  - Glycerine:
    - derived from Categories 1 and 2 material which has been processed (rendered) in accordance with processing method 1 (pressure sterilization) as set out in Chapter III of Regulation (EU) No. 142/2011 may be, used for technical purposes; transformed into biogas, in which case the digestion residues may be applied to land within the national territory of Ireland; subject to the or used for denitrification in a waste water treatment plant, in which case the residues of the denitrification may be applied to land;
    - derived from Category 3 material, if the process line has been authorized by an authorised officer in whose opinion material may be handled and processed separately to other categories of material may be used for technical purposes; transformed into biogas, in which case the digestion residues may be applied to land; or used for feeding, provided that the glycerine is not derived from Category 3 material referred to in Article 10(n) (hides skins hooves, feathers, wool, horns, hair and fur originating from dead animals), (o) and (p) (Catering Waste including Used Cooking Oil derived within Ireland) of Regulation (EC) No. 1069/2009.
    - Derived from Used Cooking Oil (Category 3 (Within Ireland) or Category 1 (From an International Destination)) which has not been processed (rendered) in accordance with processing method 1 must be disposed of in accordance with Article 12 of Regulation (EC) No. 1069/2009 (see relevant legislation)

- 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 with plant management.

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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;
  - a health certificate or commercial document reference number;
  - the name and address and country of the premises of dispatch (and approval number);
  - 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 export or trade);
  - weights of consignments of outgoing material (preferably using a plant's own weighbridge);
  - seal numbers of consignments (if applicable);
  - a reference to indicate proof of arrival at destination.

- A fully completed commercial document must accompany each load of ABP, potassium polysulphate or glycerine leaving the plant. The commercial document must be assigned a unique identifiable number.

  Paper commercial documents 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 or derived product being dispatched to other EU countries or third countries, the EU commercial document must be used and a DOCOM message generated by the business operator or the Competent Authority.

  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.

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CONTACT DETAILS

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