

CONDITIONS FOR APPROVAL AND OPERATION OF BIOGAS PLANTS TREATING ANIMAL BY-PRODUCTS IN IRELAND

GOVERNING EU LEGISLATION:

REGULATION (EC) No. 1774/2002 laying down health rules concerning animal by-products not intended for human consumption.

GOVERNING NATIONAL LEGISLATION:

S.I. No. 252 of 2008 and S.I. No. 253 of 2008

27 March 2009 DAFF Animal By-Products Section

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GLOSSARY OF TERMS PERTAINING TO BIOGAS PLANTS IN IRELAND

'A Plant transforming 'own ABP'' only, means an on-farm Plant transforming/processing manure and or milk derived from animals on the same premises as the Plant is located, as the only animal byproducts;

ABP means animal by-product;

'Biogas Plant': Under EU Regulation No. 1774/2002, a biogas plant means a plant in which biological degradation of products of animal origin is undertaken under anaerobic conditions for the production and collection of biogas.

For the purposes of these conditions for the approval and operation of a biogas plant treating animal by-products in Ireland, a 'biogas plant' shall include:

The site on which the plant is located, all services and facilities used in any way thereon for, or in connection with the plant and any buildings erected, located, or to be erected and located on the site, hereinafter referred to as a 'Plant';

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

DAFF shall mean the Department of Agriculture, Fisheries and Food;

Digestion Residues means residues resulting from the transformation of animal by-products in a Plant;

Digestive tract content means the contents of the digestive tract of mammals and ratites, separated from the digestive tract;

EU means the European Union;

'Fishmeal' means processed animal protein derived from sea animals, except sea mammals;

'Manure' means any excrement and or urine of farmed animals, with or without litter, or guano;

MDM refers to category 2 manure and or category 2 digestive tract content and or category 2 milk and or category 3 milk;

'Organic Fertilizers' and 'Soil Improvers' mean materials of animal origin used to maintain or improve plant nutrition and the physical and chemical properties and biological activity of soils, either separately or together; they may include digestion residues;

'Own ABP' refers to manure and or milk derived from animals on the same farm premises as the Plant is located;

Placing on the market is defined as any operation the purpose of which is to sell animal by-products, or products derived therefrom covered by EU Regulation No. 1774/2002 to a third party in the Community or any other form of supply against payment or free of charge to such a third party or storage with a view to supply to such a third party;

Plant: Refer to Biogas Plant definition;

Processed ABP: The term processed ABP refers to ABP material that has been processed to the EU, National or an authorised alternative processing standard. (Ref. Section 5);

'Processed Animal Protein' means animal proteins derived entirely from Category 3 material, which have been treated in accordance with Chapter II of Annex V of EU Regulation 1774/2002 so as to render them suitable for direct use as feed material or other use in feedingstuffs, including petfood, or use in organic fertilisers or soil improvers; however, it does not include blood products, milk, milk-based products, colostrum, gelatine, hydrolysed proteins and dicalcium phosphate, eggs and egg-products, tricalcium phosphate and collagen;

Processing means treatment to either the EU, National or an authorised alternative processing standard. (Ref. Section 5);

The "Minister" shall mean the Minister for Agriculture, Fisheries and Food;

Transformed ABP: This refers to ABP that has undergone an anaerobic digestion procedure for the production and collection of biogas without necessarily being processed to the EU, National Standard or an authorised alternative processing standard. (Ref. section 5);

Transformation: The term transformation refers to an anaerobic digestion procedure for the production and collection of biogas;

1. INTRODUCTION

The purpose of this document is to set out the approval and operating conditions required by DAFF for a Plant involved in the transformation of animal by-products in Ireland. The requirements apply to a Plant involved in the transformation of any feedstock referred to in Section 2, unless otherwise specified. These conditions do not apply to those plants involved in the transformation of animal by-products which are authorised as an alternative system in accordance with EU Regulation No.197 of 2006 as amended. Such plants to be the subject of a separate DAFF Conditions document.

1) Governing EU legislation

Regulation (EC) No. 1774/2002 of the European Parliament and of the Council of 3 October 2002 lays down health rules concerning animal by-products not intended for human consumption. This regulation defines animal by-products as "entire bodies or parts of animals or products of animal origin... not intended for human consumption". The purpose of the legislation is to safeguard human and animal health by providing controls for the safe use and disposal of animal by-products.

2) Governing National Legislation

S.I. No. 252 of 2008 (European Communities (Transmissable Spongiform Encephalopathies and Animal By-Products) Regulations 2008, transposes EU Regulation No. 1774/2002 into Irish law.

S.I. No. 253 of 2008 (Diseases of Animals Act 1966 (Transmissable Spongiform Encephalopathies) (Fertilisers and Soil improvers) Order 2008 lays down national rules for organic fertilisers and soil improvers and transposes EU Regulation No. 181 of 2006 into Irish law.

Article 15 of Regulation (EC) No. 1774/2002 requires that a biogas plant (Plant) shall be subject to approval by the competent authority.

Under Part 4 of S.I. No. 252 of 2008, the Minister for Agriculture, Fisheries and Food may grant an approval, attach conditions to an approval, revoke or vary a condition, insert a new condition, suspend or withdraw an approval or refuse an application in respect of a Plant.

Where an approval has issued for a Plant, any additional buildings, services or facilities installed, or erected thereon (additional buildings), shall be subject to a separate and additional approval in respect of any additional buildings being made to and granted by the Minister.

Re-validation of the Plant technology may be required in certain circumstances.

In certain situations, e.g. in the event of a Class A Disease outbreak, the Competent Authority may restrict movement of animal by-products to and or from a Plant under relevant national legislation implementing the relevant EU Control Directives for the disease in question and or may require additional controls and measures to be implemented in a Plant.

The objective of the legislation pertaining to biogas plants is to ensure that all products of animal origin which are treated by anaerobic digestion meet the treatment standards required by Regulation (EC) No. 1774/2002 to ensure sufficient pathogen reduction and recontamination is prevented, so that the treated material may be safely applied to land. Specific requirements for the operation of a Plant are set out in Annex VI of this Regulation.

These conditions may be subject to review and amendment by the Minister from time to time to ensure compliance by an owner, operator or person in charge of a Plant as a consequence of changes to the EU or National legislation. The Minister may from time to time inter alia introduce new trader, or general notices relating to these conditions, which shall be published on the DAFF's web site and or published in local or national press. It is the responsibility of an owner, operator, or person in charge of a Plant to ensure that a Plant operates in full compliance with all current legislation and other requirements governing the operation of a Plant.

Operators should also refer to the EPA Best Available Technique (BAT) documents relating to anaerobic digestion when available.

2. FEEDSTOCK

The term feedstock in this document refers to any animal by-product material which is permitted to be transformed in a Plant in Ireland (see Section 2.2.)

2.1. GENERAL

As part of the approval process, an application for a Plant must list all intended feedstock and its animal by-product classification as defined in Section 2.2. The processing parameters adopted and approved in a particular Plant will determine the type of animal by-product that may be transformed in the Plant.

2.2. PERMITTED FEEDSTOCKS

The following animal by-product (ABP) materials may be used as feedstock in a Plant in Ireland; (animal by-product classification as set out in EU Regulation No. 1774/2002 in italics)

- Category 2 Material comprising the following:
 - o Manure (Article 5, 1 (a))
 - o Digestive tract content separated from the digestive tract, (Article 5, I(a))
 - o Milk (*Article 5, 1 (c)*)
- Category 3 Material comprising the following:
 - \circ Feathers (Article 6, 1(c))
 - o Former foodstuffs of animal origin, or former foodstuffs containing products of animal origin, other than catering waste, which are no longer intended for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects, which do not present any risk to humans or animals, (*Article 6, 1 (f)*)
 - o Raw milk, originating from animals that do not show clinical signs of any disease communicable through that product to humans or animals (*Article 6*, 1 (g))
 - Fish or other sea animals, except sea mammals, caught in the open sea for the purposes of fishmeal production (Article 6, 1 (h))
 - Fresh by-products from fish from plants manufacturing fish products for human consumption (Article 6,1 (i))
 - Shells, hatchery by-products and cracked eggs by-products originating from animals which did not show clinical signs of any disease communicable through that product to humans or animals (Article 6, 1 (j))
 - O Catering waste which is defined as 'all waste food including used cooking oil originating in restaurants, catering facilities and kitchens, including central kitchens and household kitchens.' (Article 6, 1(1))

Other acceptable feedstocks:

o Processed animal protein, as defined in Annex 1 of EU Regulation No. 1774/2002.

A person must not transform processed animal protein in a Plant, except in accordance with these conditions and additionally in accordance with an 'animal protein fertiliser licence' and conditions attached to same, as provided by S.I. 253 of 2008. Further details are available from the Animal By-Products Section of DAFF.

Animal by-products must not be accepted from any agricultural holding or other holding or premises restricted under the Disease of Animals Act without specific authorisation by DAFF.

2.3. FEEDSTOCK ACCEPTANCE PROCEDURES

- It is the responsibility of the Plant owner, operator or person in charge to ensure that feedstock received at a Plant is in compliance with the Plant's approval.
- A new animal by-product supplier must complete a feedstock acceptance agreement in advance of commencement to supply animal by-products to the Plant. Completed 'feedstock acceptance agreements' from all animal by-product suppliers must be available for inspection on site and updated as necessary. (See Appendix 2, sample feedstock acceptance document.)
- Intake records for all animal by-products delivered to or collected by a Plant must be maintained.
- In the case of feedstocks other than catering waste and manure, commercial documents for each delivery consignment must be received and retained by the Plant.
- In the case of catering waste and manure, intake dockets for each delivery consignment must be received and retained by the Plant.
- The intake records must include the date of delivery, the source of the material, the quantity, description and animal by-product categorisation of the material, the name of the haulier, and the receptacle number where applicable.
- Plant procedures to verify that only the permitted ABP feedstocks for the Plant are received must be documented in the Plant HACCP Plan. Verification checks must also be documented, signed and dated.
- Waste or any other material not directly used in the biogas process cannot be accepted or stored at a Plant unless otherwise agreed by DAFF.

3. PLANTS

3.1. LOCATION

- A Plant, with the exception of a Plant processing 'own ABP' as the only ABP, must be separated from other premises and surrounded on all sides by permanent and effective animal-proof closemeshed fencing in accordance with the fencing specifications set out in Appendix 1 stock proof fencing, subject to the bullet point immediately below.
- In addition to the general separation requirement immediately above, if a Plant is located on, or adjacent to premises, or land where farmed animals are kept or have access, and uses animal byproducts other than 'own ABP', the Plant shall be located at an adequate distance from the area where such animals are kept or have access, and there must be no access whatsoever to the Plant from the place where farmed animals, or other animals are kept.

 In such circumstances, there must be total physical separation between the Plant and the premises

In such circumstances, there must be total physical separation between the Plant and the premises or land where farmed animals and any feed and bedding for such animals are kept. Further, a double fencing system with a minimum distance of two metres between each fence is required if a Plant transforms animal by-products other than only MDM animal by-products. The outside fence must be of a permanent nature and be stock proof. (See Appendix 1, stock proof fencing)

NB: The biosecurity achieved through distance and separation can also be achieved by the use of pre-pasteurisation of the input material before it reaches the farm location. This may be used as an alternative measure for certain locations.

Assessment of other equivalent separation measures shall be made on a risk basis for individual plants.

- A lockable gate of minimum height of 1.8 m must be present at the entrance to the Plant with the exception of a Plant where fencing is not required as detailed above. (See Appendix 1, stock proof fencing)
- The access route from the public road to the Plant must be laid out in a manner that ensures that there is no contact between livestock and the access route to the Plant. Generally, this will mean a separate entrance from the public road to the Plant, located some distance away from the main farm entrance.

In addition, a double stock proof fence with a minimum distance of 2 meters between both fences is required either side of the access route. Alternatively, a stock proof fence located a minimum of 5 meters from either side of the access route is required.

However, exceptions may be made for a Plant based on equivalent biosecurity standards being agreed with DAFF and fully implemented by the Plant e.g.

- > exemptions from the requirement of a separate entrance from the public road to the Plant may apply to a Plant processing/transforming MDM ABP feedstocks only.
- ➤ In the case of a Plant processing/transforming MDM ABP feedstocks only, the access route from the public road to the Plant must be stock-proof and is not required to be double fenced.
- Fencing and gates must be adequately maintained.
- Additional entrances/exits anywhere from a Plant to surrounding land/premises are not permitted unless otherwise agreed by DAFF.
- In order to prevent the possibility of contact of animal by-product with farmed animals either directly or indirectly (via vermin, birds, or other pests etc), all untransformed/unprocessed ABPs must be stored and or retained in a fully enclosed area at the Plant until after transformation/processing has been achieved. Manure however, may be otherwise stored prior to processing/transformation, subject to compliance with relevant legislation and or EPA/ local authority directions.
- No animals including farmed and pet animals and poultry must have access to the Plant.
- Office facilities must be available on site and shall be maintained in a manner suitable for the processing and storing of documentation.

3.2. EQUIPMENT REQUIRED AT A PLANT

- (a) A Plant transforming animal by-products must be equipped with a pasteurisation/hygienisation unit, which cannot be by-passed, with:
 - (i) installations for monitoring temperature against time;
 - (ii) recording devices to record continuously the results of the monitoring measurements referred to in (i); and
 - (iii) an adequate safety system to prevent insufficient heating;
- (b) However, subject to requirements set out in Section 5, a pasteurisation/hygienisation unit shall not be mandatory for a Plant that transforms only:
 - (i) permitted animal by-products that have undergone processing Method 1¹
 - (ii) permitted Category 3 material that has undergone pasteurisation/hygienisation elsewhere; or
 - (iii) animal by-products which may be used as raw material without processing;

Method 1 processing method refers to processing at 133 °C for at least 20 minutes at 3 bar pressure, at a particle size of 50mm or less.

3.3. LABORATORY REQUIREMENTS

Each Plant must have its own laboratory or make use of an external laboratory for microbiological testing with the exception of a Plant not required to process ABPs to a processing standard. A laboratory must be equipped to carry out the necessary analyses and be approved by DAFF. A list of laboratories approved by DAFF for microbiological testing is attached in Appendix 3.

3.4. COMPLIANCE WITH OTHER LEGISLATION

Applicants seeking approval to treat animal by-products in a Plant under S.I. No. 252 of 2008 must also be compliant with all other applicable legislation.

A Plant must maintain all permits, licences and approvals, (authorisations), attached to it at all times and in good standing. Failure to maintain any one of these authorisations may lead to the DAFF approval being revoked and the Plant will no longer be entitled to accept or transform animal by-products at that Plant.

4. HYGIENE REQUIREMENTS

4.1. GENERAL

The processing premises or buildings should be separated into distinct 'clean' and 'dirty' areas and shall operate on a simple one-way flow basis i.e., material flows from the dirty area to the clean area. All untransformed and or unprocessed material must enter the Plant via the dirty area. The transformed/processed material must be stored in the clean area at all times prior to being removed from the Plant. Dirty material must not be allowed to contaminate clean material.

4.2. FEEDSTOCK ACCEPTANCE AND RECEPTION AREAS

- External environmental contamination of a Plant or any part of it with untransformed/unprocessed animal by-products must be avoided and the Plant must be kept clean and tidy at all times.
- All animal by-products must be transported in sealed new packaging or in covered leak-proof containers or vehicles.
- There must be a covered, fully enclosed area (reception building) in the Plant, within which all animal by-products must be received.
 Unloading systems which can be demonstrated to achieve equivalent effect may be considered on a case-by-case basis. The unloading area in such cases must be designed in such a way as to allow easy and adequate cleaning and disinfection of the delivery area and delivery vehicle and to allow collection and containment of any spillages as well as all waste water generated.

The following exceptions to the above bullet point apply;

- (i) In the case of a Plant transforming MDM ABP feedstocks, these feedstocks may be received in a designated area that is not required to be enclosed within a reception building provided the feedstocks are delivered and received by means of a closed, piped or equivalent system and subject to compliance with other authority requirements. The designated area must be designed in such a way as to allow easy and adequate cleaning and disinfection of the delivery area and delivery vehicle and to allow collection and containment of any spillages as well as all waste water generated.
- (ii) In the case of a Plant which is not located on, or adjacent to a farm and which transforms ABPs other than or including MDM to the Plant, feedstock may be received in a designated area which is not required to be enclosed within a reception building, provided

the feedstocks are delivered and received by means of a closed, piped or equivalent system and subject to compliance with other authority requirements. This reception area must be designed in such a way as to allow easy and adequate cleaning and disinfection of the delivery area and delivery vehicle and to allow collection and containment of any spillages as well as all waste water generated.

- (iii) As an alternative to points (i) and (ii), in a Plant transforming manure feedstocks, this feedstock may be received in a designated area that is not required to be enclosed subject to compliance with relevant legislation and or EPA/local authority directions. The designated area must be designed in such a way as to allow easy and adequate cleaning and disinfection of the delivery area and delivery vehicle and to allow collection and containment of any spillages as well as all waste water generated. The area must be contained so as to prevent environmental contamination.
- The reception building must be kept closed at all times other than during feedstock delivery, or when other essential tasks require.
- In the case of a Plant accepting both ABP which requires processing as well as ABP which does not require processing, the reception areas for both feedstocks must be located in distinctly separate areas within the Plant and effective measures to ensure avoidance of delivery of feedstocks to the wrong reception areas must be demonstrated, implemented and maintained at all times.
- In the case of a Plant located on, or adjacent to a farm and which takes in ABPs other than MDM to the Plant, then any manure derived from animals on the same premises on which the Plant is located, must be transported by pipeline from the place where the manure is stored on the farm to the Plant, unless the ABPs are pasteurised prior to delivery to the Plant, or unless otherwise agreed by DAFF.

4.3. VEHICLES USED TO TRANSPORT FEEDSTOCK

- Vehicles, during the time of transportation of animal by-products other than manure or poultry litter must not enter any place where farm animals are kept.
- Vehicles and receptacles used for transporting ABP material to the Plant shall be maintained in a clean condition and must be clean and dry before use.
- Containers, receptacles and vehicles used for transporting untreated material must be cleaned, washed and disinfected both internally and externally in the designated area within the Plant after each use with the following exceptions:
 - In the case of vehicles transporting only untreated catering waste, only the wheels of the vehicle need be cleaned and disinfected as well as any gross external contamination of the vehicle.
 - ➤ Vehicles transporting MDM only to a Plant, must be subjected to thorough external cleaning and disinfection procedures before leaving the Plant. This is particularly important in the case of vehicles transporting manure where the vehicle is returning to a place where farm animals are kept.
- Documented cleaning and hygiene procedures must be in place.
- The designated vehicle/receptacle cleaning area in a Plant shall be situated, or designed so as to prevent risk of contamination of any transformed/processed products and shall be located indoors within the waste reception building, or externally, in close proximity to the waste reception exit

door, so as to avoid environmental contamination with untreated material and to ensure that no waste water, leachate or ABP is carried off site. In a Plant with no reception building, the designated cleaning area shall be located in proximity to the feedstock delivery area and in a location situated or designed so as to prevent contamination of transformed/processed products.

- Wheel-wash facilities must be designed, operated and maintained in a manner which works properly.
- In the case of manually operated cleaning and disinfection facilities for containers/receptacles/ vehicles, or if specified by DAFF, the cleaning procedures must be recorded and signed off by the transporter. Records must be retained at the Plant.

4.4. PROCESSING/TRANSFORMATION

- A one-way production system of material flow shall be operated in a Plant, in order to prevent contamination of transformed/processed feedstock by untransformed/unprocessed feedstock.
- All initial handling and treatment of raw material (e.g. macerating, screening and mixing) must be carried out in an enclosed space.
- In a Plant requiring a reception building, the internal walls must be constructed with smooth walls and floors. Floors must be designed and laid in such a way to ensure adequate drainage of fluids and ease of cleaning and disinfection.
- The Plant shall commence the transformation of animal by-products received as soon as possible after arrival, and preferably within 24 hours of arrival at the Plant.
- All animal by-products must be stored indoors until after processing parameters/transformation have been achieved. Manure may be otherwise stored subject to compliance with relevant legislation and or EPA/local authority directions. If stored outside, the storage area must be contained so as to prevent environmental contamination.
- In a Plant where feedstock is taken in and transformed/processed and stored in the same building, the clean and unclean areas shall be physically separated by a wall or some other such substantial physical barrier, to prevent untransformed/unprocessed feedstock or leachate contaminating transformed/processed feedstock in the clean end.
- In a Plant where non-ABP feedstock is mixed or contaminated with unprocessed ABP feedstock which is required to be processed, <u>all</u> feedstock, must be processed to the relevant processing standard (See Section 5), unless otherwise agreed by DAFF.
- Digestion residues must be handled and stored at the Plant in such a way as to prevent recontamination and suitable operating procedures must be in place and documented in the HACCP Plan to ensure that cross-contamination is avoided. The storage facility and or storage area for material that has been transformed/processed must be located so as to ensure that no cross-contamination from the intake area occurs from untransformed/unprocessed material.
- In the event that any feedstock fails to meet processing parameter requirements (where applicable) and or in the event that any processed feedstock becomes cross-contaminated with unprocessed feedstock and or fails microbiological testing, it, along with all in-contact feedstock shall be;
 - o re-processed, or,
 - o disposed of by burial in an EPA licenced non-inert landfill, subject to EPA and the landfill site management agreement, or,

o disposed of by another approved disposal option subject to compliance with all applicable legislation.

The contaminated area must be thoroughly cleaned and disinfected. This procedure must be documented in the Plant HACCP. The cleaning and disinfection procedure must be signed off by Plant management.

4.5. PERSONNEL

- All personnel in a Plant must observe strict biosecurity precautions when entering and or leaving the Plant or when moving from dirty areas to the clean areas.
- In a Plant other than a 'Plant transforming own ABP' as the only ABP, the following applies:

Personnel changing and washing facilities must be in situ on the Plant. Boot washes, footbaths and hand-washing facilities must be used by operatives and located in appropriate locations on the Plant, i.e. between clean and dirty areas and at all entrances/exits to the reception, processing and storage buildings. It is recommended that boot washes and footbaths should be located at the entrance to the Plant.

- Plant dedicated clothing and footwear which is clearly identifiable shall be worn by all operatives on site.
- Appropriate protective equipment should be provided for use by all visitors while at the Plant.
- Personnel hygiene Standard Operating Procedures must be documented in the Plant's HACCP Plan.

4.6. PLANT VEHICLES, MACHINERY AND EQUIPMENT

- Vehicles, machinery and or equipment used on a Plant shall be Plant dedicated and shall not enter any place where animals are kept. They must be clearly marked by permanent marking/wording/signage to indicate Plant dedication. The following exception applies; a Plant transforming 'own ABP' only, is not required to have Plant dedicated machinery.
- Digestion residues must be handled and stored in such a way as to prevent recontamination. Plant procedures detailing how this is achieved must be included in the Plant HACCP.
- Machines and equipment used in the dirty area (handling untransformed/unprocessed feedstock) shall not be used in the clean area (handling transformed/processed feedstock) with the following exception;
 - In Plants processing MDM ABP feedstocks only, it is recommended that separate machinery is used in the dirty and clean areas of the Plant. In the absence of separate machinery being used, procedures to prevent cross-contamination occurring, must be documented, implemented and recorded.
- Installations as well as equipment/technology used to achieve, measure, monitor and verify
 processing parameters (time/temperature/particle size equipment) must be kept in a good state of
 repair and must be checked and maintained on a regular basis so as to ensure optimum function.
 Plant service records and installation/equipment checks and maintenance records must be
 maintained.
- Equipment used to achieve and verify particle size, as well as measuring equipment for time/temperature parameters must be inspected and calibrated at least once every 6 months by an appropriate, competent independent agency and calibration certificates maintained for same.

Manual/hand-held particle size verification equipment however may not be required to be calibrated by an independent agency. Own Plant documented checks as outlined in previous bullet point are required.

4.7. CLEANING AND HYGIENE PROCEDURES

- Cleaning procedures and their frequency of implementation must be established, documented and applied for all parts of a Plant. Suitable equipment and cleaning agents must be provided for cleaning. Cleaning measures must be effective and thorough.
- The reception building/area shall be cleaned at least once daily on days of operation and disinfected, post cleaning, at least once weekly.
- Saturated steam cleaning may be used as an alternative to disinfectants.
- In the case of a microbiological non-compliance being identified, all parts of a Plant contaminated by the microbiological failed material shall be thoroughly cleaned and disinfected. See Section 6.3, microbiological non-compliances.
- Footbaths and permanent wheel wash facilities using disinfectant must be replenished and changed as required to ensure disinfection efficacy.
- Hygiene control measures must include regular inspections of the environment and equipment. Visual inspections of a Plant must be carried out on a daily basis and all results and corrective actions taken must be recorded and signed off. A Plant's HACCP plan must set out the frequency of monitoring and inspection for identified control points and critical control points.

4.8. VERMIN AND PEST CONTROL

Preventive measures shall be taken against birds, rodents, insects and other vermin. A fully documented pest-control programme shall be implemented throughout the whole Plant. The operator must be able to demonstrate that effective pest control measures are taken on an ongoing basis and at intervals of no more than 6 weeks. A baiting point map must be kept on site. Bait points must be visibly and clearly numbered. Results of inspections carried out on bait points as well as corrective actions taken must be recorded and signed off.

4.9. LEACHATE/WASTE WATER

- Drainage must be constructed to ensure that there is no possibility of leachate contamination of fully, or partially processed material. Leachate may be used in the anaerobic digestion process prior to the commencement of processing.
- For Plants located on or adjacent to farms, leachate and waste water generated within a Plant must not be collected, stored or treated in any farm waste collection system, for example, a drainage system used by an adjoining farm premises.
- A Plant shall ensure that adequate measures are taken to contain wastewater and or leachate generated thus avoiding environmental contamination.

4.10. CLEANING AND HYGIENE SOPS

Standard Operating Procedures (SOPs) detailing cleaning and hygiene procedures for all parts of a Plant, equipment and vehicles/receptacles, inspection schedules, as well as recording documentation which will form part of the Plant HACCP Plan shall be maintained.

5. PROCESSING/TREATMENT STANDARDS

5.1. EU STANDARD

Animal by-products used as raw material in a Plant must be submitted to the following minimum requirements:

- ➤ Maximum particle size before entering the unit: 12 mm;
- ➤ Minimum temperature in all material in the unit: 70 °C; and
- > Minimum time in the unit without interruption: 60 minutes.

All feedstocks with the exception of catering waste and or category 2 milk and or category 3 milk and or manure and or digestive tract content, must be processed to the EU processing standard or an alternative processing standard, (See Section 5.3).

5.2. NATIONAL PROCESSING STANDARD:

As an alternative to processing to the EU standard, a national processing standard has been adopted. This standard applies to the following feedstocks only:

- catering waste alone, or if mixed with
- manure and or digestive tract content and or milk and or colostrum, provided that the resulting material is considered as if it were from catering waste.

DAFF has approved the following biogas processing parameter conditions as a national standard for this category of waste. The following minimum requirements must be met:

- Maximum particle size before entering the unit: 400 mm;
- Minimum temperature in all material in the unit: 60 °C; and
- Minimum time in the unit: 48 continuous hours.

These processing parameters must be met twice, i.e. a twin barrier method.

- The standard comprises of two separate stages. The first stage shall take place in a closed unit at a temperature of 60 degrees celcius for 48 continuous hours with a maximum particle size of 400 mm
- The second stage shall achieve time, temperature and particle size parameters similar to the first stage.
- All material within the unit shall achieve temperatures of 60 degrees celcius or above, simultaneously, for each 48 hour processing period.
- Processing parameters shall be automatically recorded on a thermograph in both stages.

Material must be mixed thoroughly between processing stages. We would normally expect that the second stage would take place in a separate and distinct vessel/area (i.e. the feedstock is treated in one vessel, then moved to a second vessel for the second stage.) However, some systems where the material is mixed may be able to achieve both stages in a single vessel. It would need to be clearly demonstrated to DAFF that the material within such a vessel achieves the two time/temperature treatment stages separately, and that mixing of material should occur between the first and second stage (e.g. by an auger or other turning device.)

Note that the introduction of national treatment standards for catering waste does not mean that catering waste must only be treated to the national standard. It may also be treated to the EU standard. Alternatively, processing as outlined in Section 5.3 can apply to this category of feedstock also.

Notwithstanding 5.1 and 5.2:

- a) Specific processing standards are not required in a 'Plant transforming 'own ABP'' as the only ABP feedstock. The resultant digestate is considered unprocessed material.
- b) In a Plant taking in <u>less than</u> 5000 tonnes per annum of ABP (including MDM ABP feedstocks, but excluding 'own ABP'), only the ABP, other than MDM and 'own ABP', is required to be processed to a processing standard. ('< 5000tpa Plant')

 The digestate in such instances is considered unprocessed and as such, must be used for local landspread only, subject to the grazing restrictions outlined in Section 10.

In a Plant taking in greater than 5000 tonnes per annum of ABP (including MDM but excluding 'own ABP'), <u>all ABP</u> including 'own ABP' is required to be processed to a processing standard. ('>5000tpa Plant')

A '<5000tpa Plant' must submit a revised application for approval if they intend to operate as a '>5000tpa Plant', and obtain a 2nd stage approval in principle from DAFF in advance of accepting additional feedstocks. Such Plants will be required to undergo a re-validation process.

Processed manure and processed manure products which are 'placed on the market' as defined in EU Regulation No.1774/2002 must be processed to the EU standard or to an alternative processing standard in accordance with Section 5.3. Ref. Article 2 and Annex VIII of EU Regulation No. 1774/2002.

In a Plant where MDM feedstocks are mixed or contaminated with other unprocessed animal by-products, the MDM must also be processed to the relevant processing standard.

Non-animal by-product feedstocks, are not required to be reduced to a specified particle size prior to processing. Once mixed with animal by-product feedstocks however, <u>all</u> feedstock must achieve the required processing temperature standard for the required time.

5.3. ALTERNATIVE PROCESSING STANDARDS

DAFF may authorise the use of other standardised processing parameters (alternative processing standards) for processing animal by-products, provided the applicant demonstrates that such parameters ensure minimising of biological risks. The operator must produce documentary evidence in support of the system, including an independent risk assessment of the system as part of a Plant application process. A validation must be carried out in accordance with the following points:

- a) Identification and analysis of possible hazards, including the impact of input material, based on a full definition of the processing conditions.
- b) A risk assessment which evaluates how the specific processing conditions referred to in a) are achieved in practice under normal and atypical situations.
- c) Validation of the intended process by measuring the reduction of viability/infectivity of:
 - Endogenous indicator organisms during the process, where the indicator is:
 - Consistently present in the raw material in high numbers,
 - Not less heat resistant to the lethal aspects of the treatment process, but also not significantly more resistant than the pathogens for which it is being used to monitor,
 - relatively easy to quantify and relatively easy to identify and to confirm;

- a well characterised test organism or virus, during exposure, introduced in a suitable test body into the starting material.
- d) The validation of the intended process referred to in c) must demonstrate that the process achieves the following overall risk reduction:
 - For thermal and chemical processes by:
 - reduction of 5 log10 of Enterococcus faecalis or Salmonella Senftenberg (775W, H2S negative),
 - reduction of infectivity titre of thermo resistant viruses such as *parvovirus* by at least 3 log10, whenever they are identified as a relevant hazard;

and

- as regards chemical processes also by:
 - reduction of resistant parasites such as eggs of *ascaris sp*. by at least 99,9%(3 log10) of viable stages.
- e) Designing a complete control programme including procedures for monitoring the functioning of the process referred to in (c).
- f) Measures ensuring continuous monitoring and supervision of the relevant process parameters fixed in the control programme when operating a Plant.
- g) Records on the relevant process parameters as well as other critical control points must be recorded and maintained so that the owner, operator or the person in charge can monitor the operation of a Plant.

5.4. GENERAL REQUIREMENTS AND VALIDATION

Application and approval:

New Plants at the design and planning stages must submit plans and other relevant details to DAFF as part of the application process. This is to ensure that a Plant design and processing procedures are in accordance with the Regulations, and to help identify and correct potential problems prior to capital expenditure.

A Plant must notify DAFF of the intended feedstock types and estimated quantities as part of the application. Alterations to feedstock types subsequent to approval being issued may not be permitted for reasons such as Plant location, Plant layout etc.

Approved Plants intending to use a new process and or if modification to existing processes or process management procedures are intended, must submit a revised application detailing the proposed changes for approval by DAFF. These Plants may be required to carry out a re-validation.

A final approval is issued following satisfactory Plant validation.

Operation requirements for a Plant in which the animal by-products are required to be processed to a processing standard.

The operator of a Plant must be able to demonstrate that all the material in the system that requires processing has reached the required particle size and temperature standard for the required time during the process, without interruption. For the processing phase, the material must be batched.

All the material within a batch must achieve the required particle size <u>prior</u> to entry into the processing unit and prior to the commencement of the processing phase. The Plant applicant must be able to demonstrate and provide documentary evidence to verify that the particle sizing

equipment is capable of reliably and consistently achieving correct particle size and that a system is in place to verify this. This must be submitted as part of the application. In the absence of permanent in-line verification equipment (e.g. 12mm or 400mm grids as applicable) which verifies particle size achievement, other proposed methods of verification will be considered by DAFF. Alternatively, a Plant operator must be able to manually verify particle size for random samples from every batch and record results of same. In a Plant with permanent in-line verification equipment, regular documented checks must be carried out to ensure effective functionality.

All material within a batch must simultaneously achieve the required temperature standard during the processing phase.

In the case of a 'wet anaerobic digestion' Plant, the processing unit must contain a mixing system that ensures that temperatures recorded by the temperature probe(s) are representative of temperatures of material throughout the processing unit and this must be verifiable and supported with documentary evidence. A minimum of one temperature probe must be located at the bottom of each processing unit.

In the case of a 'dry anaerobic digestion' Plant, recording temperature probes must be positioned in locations which represent the coldest temperature locations within the processing unit. This must be verifiable and supported with documentary evidence. Multi sensory probes may be used provided the plant has the software to support it.

Post validation, the Plant owner, operator or person in charge must have procedures in place to verify, on a regular basis, that the permanent temperature probes are recording temperatures which continuously represent the coldest temperature locations within the processing units. The results of these checks must be documented. These procedures must be included in the HACCP plan.

Material which has not achieved the required particle size, time and temperature parameters is considered to be unprocessed and must not be permitted to mix with processed materials. If there is a failure at any of the critical control points during the treatment of a batch, the operator must be able to isolate that batch as well as all in-contact material and material that may have become contaminated by the failed batch, and re-process it or dispose of it as detailed in Section 4.4. The operator must be able to demonstrate that the system will be operated in such a way that this standard will be maintained and cross contamination is prevented.

A Plant must maintain a documentary system to provide evidence that all batches of feedstock have been processed satisfactorily (if applicable) and that all batches sampled have achieved the microbiological standards.

Records for every batch must include:

- a) The dates of treatment, along with the processing unit number within which each batch has been processed,
- b) Particle size verification checks,
- c) In the case of a Plant processing material to the EU standard, temperature recordings must be logged at intervals not greater than every 5 minutes and automatically recorded on a thermograph. In the case of a Plant processing material to the national standard, temperature recordings must be taken at intervals not greater than every 30 minutes and automatically recorded on a thermograph.

Time and temperature measuring and recording devices must be tamperproof. Hard copy thermographs must be maintained including expanded thermographs of the critical processing stage to ensure that no temperature fluctuations occur below the minimum temperature requirements. The thermograph must be signed off and dated by Plant management or a nominated, suitably qualified and experienced deputy.

In the case of an equipment/machine malfunction, an alert system should be in place which informs the operator of same.

Validation requirements for a Plant in which the animal by-products are required to be processed to processing standards:

During the Plant validation period and prior to approval being granted, DAFF will inspect the following:

- Plant compliance with conditions and legislation. (During the validation period, a Plant operator must be able to demonstrate the consistent and competent management of the Plant and that the system is capable of being operated satisfactorily in compliance with conditions and legislative requirements on an on-going basis.)
- ➤ Plant processing validation procedures (as outlined below)
- ➤ <u>Plant operation of the HACCP Plan.</u> A Plant operator must be able to demonstrate satisfactory operation of the Plant HACCP Plan and standard operation procedures.

In the case of a 'wet anaerobic digestion' Plant, the validation time period will comprise of the following:

- A) A one month time period from the date of commencement of transformation of ABPs, provided, a minimum of 10 batches are processed in the Plant during this time, or
- B) In a Plant in which less than 10 batches are processed in a one month time period, the validation time will extend for the period of time required to process 10 batches, whichever is applicable to a particular Plant.

In the case of a 'dry anaerobic digestion' Plant, the validation time period will comprise of the following:

- A) A three month time period from the date of commencement of transformation of ABPs, provided, a minimum of 6 batches are processed in the Plant during this time, or
- B) In a Plant in which less than 6 batches are processed in a three month time period, the validation time will extend for the period of time required to process 6 batches, whichever is applicable to a particular Plant.

Processing in this context refers to material which has achieved processing parameters, e.g. EU standards, national standards or authorised alternative standards <u>and</u> which has subsequently undergone E.Coli sampling.

No digestate/end-product is permitted to move off site until validation is completed and the plant approved, unless otherwise agreed by DAFF.

DAFF must be notified on completion of the validation period.

Plant processing validation procedures:

During the validation period, the Plant operator must be able to demonstrate, that the technology is capable of achieving processing parameter requirements consistently and reliably, and in compliance with conditions and legislative requirements.

During the validation phase, the processing unit must contain volumes of feedstock equivalent to volumes of feedstock that will be processed post validation. Feedstock types processed during the validation period must be representative of feedstock types that will be used in the Plant.

In a Plant with multiple identical processing units, it may not be necessary to operate each one during the validation process. The processing units to be used should be detailed in the Plant validation proposal.

A Plant that has processing parameter and or microbiological sample failures during the validation period and or who fail to comply with DAFF agreed validation procedures may have to restart the validation process.

<u>In the case of 'dry anaerobic digestion' Plants, the following processing validation procedures also apply:</u>

As part of a Plant's 2nd stage application, the applicant must submit a detailed proposal, drawn up by an independent person with technical expertise, detailing how the Plant processing stage will be validated.

During the validation period, the Plant operator must also be able to identify and determine which areas are the slowest to reach the required temperature within the processing unit and which areas tend to be colder than others, so that the positions of the permanent temperature probes can be reliably determined.

In order to do this, a number of temperature recording devices which log temperatures, time and date automatically ('trd's) are required throughout the processing unit to draw up a temperature profile both longitudinally and in cross section.

The proposed number and location of 'trd's to be used during the validation must be submitted as part of the validation proposal referred to above. A minimum of 1 validation temperature probe per 30 cubic meters of material with a minimum number of 5 probes per processing unit is required during the validation period. Probes must be located at varying positions and depths throughout the piles. The depths and distances from surfaces must be chosen to best represent the coldest areas. At least one 'trd' must be located in each of the following locations, i.e. 15cm or less from the top, side and bottom pile surfaces.

The number and location of permanent temperature probes required should be determined from information gathered, as well as the temperature profile developed, during the validation period. A proposal regarding same, along with supporting documentation must be submitted to DAFF within 3 weeks of completion of the validation process by an independent person with technical expertise. This proposal must indicate why the proposed locations of the permanent probes are considered to provide adequate assurance of representative temperature recording throughout the mass of material on an on-going basis. A meeting may be arranged with DAFF to discuss same. Ultimately DAFF needs to be satisfied by the Plant applicant that there are a sufficient number of probes in sufficient locations to show that all the material in the processing unit is achieving the required temperature standard for the required time simultaneously.

Operation and validation requirements for a Plant in which the animal by-products are not required to be processed:

During the validation period (which will comprise of a one month time period), and prior to approval being granted, DAFF will inspect the following:

- ➤ <u>Plant compliance with conditions and legislation</u> (A Plant operator must be able to demonstrate the consistent and competent management of the Plant in compliance with conditions and legislative requirements both during the validation period and on an on-going basis.)
- ➤ <u>Plant operation of HACCP Plan</u> (A Plant operator must be able to demonstrate satisfactory operation of the Plant HACCP Plan and standard operation procedures.)

6. SAMPLING OF DIGESTION RESIDUES

6.1. GENERAL REQUIREMENTS

In a Plant accepting MDM ABP feedstocks only and which are not required to be processed, or in a 'Plant transforming own ABP' as the only ABP, there is no requirement to microbiologically sample digestate.

In a Plant in which sampling is required, a sampling SOP, detailing sampling procedures, representative sampling locations for both E.Coli and Salmonella, acceptable microbiological levels, a clear definition of what constitutes a 'batch' for sampling purposes, as well as procedures to be followed in the event of a microbiological non-compliance for the Plant in question must be documented and submitted to DAFF as part of the application.

The sampling frequency schedule must also be documented in the SOP and shall be specified by DAFF. During the validation stage of a Plant, every batch must be sampled unless otherwise agreed by DAFF. The frequency of sampling may be reduced over time and this will be specified by DAFF.

A batch is defined as a unit of production produced in a single Plant using uniform production parameters-or a number of such units, when stored together- and that can be identified for the purposes of recall and re-treatment or disposal should tests show that to be necessary.

Samples taken by the Plant operator should be sent to a DAFF approved laboratory. (See Appendix 3, DAFF approved laboratories.) All testing will be at the operator's expense.

Sampling shall be undertaken by competent staff in accordance with documented operating procedures.

Sampling must be carried out on digestive residue during or immediately after processing (i.e. immediately after processing parameters have been achieved) in the case of E.Coli, and during or on withdrawal from storage for Salmonella.

Clean and sterile containers must be used and hygienic practices employed in the sampling procedure. Five separate samples must be taken per batch. In large batches, subsampling is recommended to achieve representative sampling.

DAFF officials will, as part of the approval process and ongoing monitoring take samples for microbiological analysis.

It should be noted that using end-product monitoring or microbiological sampling alone to validate a process is not acceptable. (Ref. EFSA Journal (2005) 264,1-21)

6.2. MICROBIOLOGICAL STANDARDS

Representative samples of the digestion residues taken during or immediately after processing (after the time/temperature parameters have been met) at the Plant must comply with the following standards:

Escherichia coli: n = 5, c = 1, m = 1000cfu, M = 5000cfu in 1 g;

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Enterococaceae: n = 5, c = 1, m = 1000cfu, M = 5000cfu in 1 g;

<u>and</u>

Representative samples of the digestion residues taken during or on withdrawal from storage at the Plant must comply with the following standards:

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

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.

In the case of processed manure and processed manure products which will be placed on the market, the sampling procedures outlined above apply. However the following bacteriological standards, which differ from those above, must be achieved:

Escherichia coli: n = 5, c = 1, m = 0cfu, M = 1000cfu in 1 g;

or

Enterococaceae: n = 5, c = 1, m = 0cfu, M = 1000cfu in 1 g;

and

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

A reduction in spore-forming bacteria and toxin formation must also be demonstrated.

6.3. MICROBIOLOGICAL NON-COMPLIANCES

In a situation where microbiological sample results do not comply with these standards, the following procedure must be adhered to:

- DAFF must be notified immediately.
- The operator of a Plant must investigate and establish the cause of the failure and document results of same.
- The operator of a Plant must take appropriate corrective actions and record results of same.
- The contaminated batch and any in-contact material must be re-processed or disposed of as detailed in Section 4.4.
- Appropriate decontamination, cleaning and disinfection procedures must be followed.
- The frequency of sampling and testing may be increased as specified by DAFF officials.

Procedures to be followed in the event of a microbiological non-compliance must be documented as part of the sampling SOP and must be submitted as part of the application.

Where appropriate, further recommendations will be issued by DAFF for these cases.

7. RECORD KEEPING

All records relating to all aspects of a Plant's procedures must be kept on site for a minimum period of 2 years. These records must be available for inspection on request by an authorised officer from the DAFF and must include:

- Feedstock acceptance agreements
- ➤ Intake records
- > Batch processing records e.g. particle size records, thermographs
- Dispatch records
- > Pest/vermin control records
- Cleaning and Hygiene procedure records
- > Plant checks, service records and equipment repair records
- Calibration records
- > Sampling records
- ➤ HACCP plan and records pertaining to same
- Commercial Documents

All records shall be certified accurate and representative by the Plant manager or a nominated, suitably qualified and experienced deputy.

8. PLANT HACCP PLANS

8.1. GENERAL

A Plant must have a HACCP Plan in place which must be kept on site. This Plan must identify the critical control points (CCPs) and control points (CPs) and establish and implement methods for monitoring and checking these points. All checks of the Critical Control Points and Control Points must be documented and non-compliances and the corrective actions taken in each instance must also be recorded.

8.2. HACCP REQUIREMENTS

The HACCP plan must include provision for a full audit trail of all materials that passes through the Plant. (An audit trail is not required in Plants transforming MDM only, unless this feedstock is required to be processed.)

Standard operating procedures (SOPs) describe the practical procedures which any operative working in a Plant must follow to ensure the HACCP Plan is adhered to and these must be documented in the Plants HACCP Plan.

The HACCP Plan must:

- ➤ Identify any hazards that must be prevented, eliminated or reduced
- > Identify the critical control points (CCPs) at the steps at which control is essential
- > Establish critical limits at CCPs
- > Establish procedures to monitor the CCPs
- Establish corrective actions to be taken when a CCP is not under control
- Establish procedures to verify whether the above procedures are working effectively, and
- Establish documents and records to demonstrate the effective application of the above measures

The following points must be addressed in the HACCP Plan:

Plant biosecurity

- > Feedstock acceptance procedures
- Clean/Dirty separation (in terms of Plant layout, product flow and by-pass avoidance measures)
- ➤ Handling of untreated material
- ➤ Handling, storage and disposal of waste water and leachate
- Movement of personnel and equipment (including by-pass avoidance measures)
- Personnel hygiene procedures (including by-pass avoidance measures)
- ➤ Delivery and on-site vehicle cleaning and disinfection (including by-pass avoidance measures)
- > Rodent and pest prevention and control
- ➤ Clean-down procedures and hygiene controls for the Plant including buildings, equipment, external environment etc.
- ➤ Monitoring equipment repair and calibration
- > Temperature monitoring and recording
- > Sampling SOP
- Action in the event of a processing failure and microbiological failure.

All operatives must be familiar with all aspects of the HACCP Plan and the SOPs. Plant managers and Plant operatives must be provided with Plant specific HACCP training.

It is the responsibility of Plant management to ensure that the HACCP Plan is reviewed at regular intervals, updated as necessary and compliant with current conditions and legislative requirements.

9. COLLECTION AND TRANSPORT OF ABPS

Hygiene requirements for the transport of animal by-products are laid down in Article 7, Article 9 and Annex II of Regulation (EC) No. 1774/2002 and must be complied with.

In the case of catering waste, the requirements in Article 7 and Annex II do not apply and waste management controls apply. Catering waste must be collected and transported in such a way as to ensure that it does not cause a human or animal health risk, or environmental risk. In particular, all external surfaces of vehicles transporting catering waste must be kept clean and equipment must be available for this purpose. The wheels of these vehicles must be cleaned and disinfected or steam cleaned prior to the vehicle leaving the Plant.

9.1. IDENTIFICATION OF VEHICLES USED TO TRANSPORT ABPS

- Different categories of animal by-products (e.g. category 2, category 3) must be kept separate and identifiable during collection and transportation. In the case of category 3 catering waste, this must be transported separately to other category 3 animal by-products if it is destined for a Plant approved to operate to national processing standards only.
- Reusable containers must be dedicated to the carriage of one particular category of animal byproduct in order to prevent cross-contamination.
- Signage with wording detailed below must be permanently attached on both sides of the container in such a way that they are clearly legible and visible. The letters should be at least 15cms high.
 - For Category 3 Material: <u>Category 3 Material Not for Human Consumption</u>
 - For Category 2 manure and digestive tract content: 'Manure'
- All signs must be permanently attached to the trailer, i.e. bolted, welded or riveted. It will not suffice to have the signs attached with glue, magnets or slide in slots.
- All hauliers transporting animal by-products shall be registered on the Animal By-Products transport register with the following exceptions:

- A farmer or his or her employee is permitted to transport manure from his or her farm to an approved Plant,
- ➤ A person can transport Category 3 former foodstuff and Category 3 catering waste to an approved Plant.
- Animal By-Products Section of DAFF, Pavilion B, Grattan Business Park, Portlaoise, Co. Laois should be contacted for ABP transport register application forms.
- A sign depicting the haulier registration code as well as a DAFF allocated receptacle number, must also be permanently affixed to the haulier receptacles.

9.2. COMMERCIAL DOCUMENTS IN RELATION TO FEEDSTOCKS

A Commercial Document must accompany all consignments of animal by-products with the
exception of catering waste and manure transported between two points located on the same
farm, or between farms and users located in the same Member State.

Commercial Documents must be produced in quadruplicate with the original being retained by the consignee and copies to be kept by the consignor and the haulier. The fourth copy must be returned by the consignee to the consignor. The consignor should implement a system of correlating receipt of the returned copy with their retained document (e.g. stapled together and filed.)

- Information contained on Commercial Documents must include:
 - a) The name and address of the premises of origin, and its approval number (if appropriate);
 - b) The name and address of the haulier;
 - c) A description of the material;
 - d) The category of ABP;
 - e) The quantity of material;
 - f) The date of dispatch from the premises;
 - g) The receptacle number where applicable;
 - h) The signature of the consignor of the premises of origin and its official stamp;
 - i) The name and address of the receiver (Plant) and its approval number.

All of the above requirements (Sections 9.1 and 9.2) are detailed in the Animal By-Products Trader Notice 01/2008 issued by DAFF. Copies of this notice are available on the DAFF website, www.agriculture.gov.ie

10. ORGANIC FERTILISERS AND SOIL IMPROVERS (OF/SI) DERIVED FROM DIGESTION RESIDUES

10.1. STORAGE

Organic fertilisers/soil improvers derived from digestion residues, with the exception of OF/SI derived or part derived from 'processed animal protein', must be stored at the Plant of origin or at the end-users premises only, subject to requirements detailed in Section 10.2 and relevant legislative requirements being met.

Alternative storage options under the control of the Plant operator may be permitted by DAFF on a case-by-case basis.

All OF/SI derived or part derived from 'processed animal protein', must be stored at the Plant of origin.

10.2. END-USES FOR ORGANIC FERTILISERS, SOIL IMPROVERS

Regulation (EC) No. 1774/2002 as amended, provides for the use of organic fertilisers and soil improvers on land. S.I. No. 253 of 2008 regulates the use of organic fertilisers and soil improvers in Irish Law.

Organic fertilisers/soil improvers referred to below are those consisting of or derived from digestion residues.

All organic fertiliser/soil improver produced in a Plant from permitted feedstocks, as detailed in Section 2, can be spread on land subject to the following conditions:

- Farmed animals (apart from pigs) must not be allowed access to the land for at least 21 days following application to the land.
- In the case of pigs, this period is extended to 60 days.

Notwithstanding the above, in the case of an organic fertiliser/soil improver derived from processed animal protein, it is not permitted to spread or otherwise use this material on land that, at the time of spreading, is covered with grass or other herbage grazed by or used as a feeding stuff for farmed animals.

In the case of an organic fertiliser/soil improver produced from manure only, the above restrictions do not apply.

Farmed animals must not have access to the organic fertiliser/soil improver.

The organic fertiliser/soil improver must not come into contact with a feeding stuff.

Ensiled crops or hay should not be made from a crop grown on land on which an organic fertiliser/soil improver has been spread during the previous 21days.

10.3. TRANSPORT AND LABELLING OF ORGANIC FERTILISERS AND SOIL IMPROVERS

Republic of Ireland.

- 1. After processing the organic fertiliser/soil improver must be stored so as to prevent recontamination.
- 2. Labelling of organic fertilisers/soil improvers derived from permitted feedstocks other than 'processed animal protein':
 - Organic fertilisers and soil improvers must be transported and supplied packaged and labelled to final users. The packaging shall be clearly and legibly labelled with the name and address of the Plant and shall bear the words 'organic fertilisers and soil improvers-farmed animals must not be allowed access to the land for at least 21 days following application to the land and 60 days in the case of pigs'.
 The following exception applies: organic fertilisers/soil improvers produced in the Republic of Ireland may be transported and supplied unpackaged and unlabelled within the
- 3. Commercial documents relating to organic fertilisers/soil improvers derived from permitted feedstocks other than 'processed animal protein':
 - A Commercial Documents must accompany all organic fertilisers/soil improvers supplied unless retailed to final users other than business operators, and must bear the wording detailed in italics above. (see also ABP Trader Notice 01/2008),

• In the case of an end-user collecting and transporting organic fertilisers/soil improvers in a single day to the same end-destination in several loads, a single commercial document for the entire consignment is sufficient provided it documents the quantity of material transported and the number of loads.

Labelling requirements for organic fertilisers/soil improvers derived or part derived from 'processed animal protein' as well as details regarding commercial documents for same, will be as detailed in the 'animal protein fertiliser licence conditions' document.

4. Plant management must retain all relevant copies of the commercial documents for a minimum period of two years and they must be available for inspection by DAFF at all times.

10.4. REGISTER OF END- USERS OF ORGANIC FERTILISERS/SOIL IMPROVERS ON AGRICULTURAL LAND

Any person who supplies ('supplier') organic fertiliser/soil improver shall only supply to:

- a person ('customer') who will use and or intends to use OF/SI on land to which farmed animals have or may have access, and or
- a person ('customer') who will use and or intends to use OF/SI on land which is cropped for feedingstuffs,

provided that the customer;

- has completed a DAFF 'Notification form for users of Organic Fertiliser and Soil Improvers' in order to be registered as an 'organic fertiliser/soil improver end-user' with DAFF, or
- is registered, as 'organic fertiliser/soil improver end-user' with the Animal By-Products Section of DAFF, and
- has acknowledged the requirements of the 'Code of Good Agricultural Practice'

The supplier shall carry out verification checks, which must be documented, to ensure that a customer is registered prior to supplying OF/SI and if not registered, to assess which customers are required to be registered.

Any customer who is not already registered as an 'organic fertiliser/soil improver end-user', must complete a 'Notification Form for users of Organic Fertilisers and Soil Improvers' which may be obtained from the Plant from which they wish to source the OF/SI.

Completed notification forms must be forwarded to DAFF within 5 working days to:

Animal By-Products Section,
Department of Agriculture, Fisheries and Food,
Pavilion B,
Grattan Business Centre,
Portlaoise,
Co. Laois.

APPENDIX 1

STOCK PROOF FENCING.

a) A Plant shall be separated from adjoining premises and surrounded on all sides by permanent animal-proof fencing of a minimum height of 1.8 metres or as otherwise specified by DAFF.

Posts must be 2.3 m long minimum of either: -

- i) Reinforced concrete 125mm x 125mm at butt end (to IS 177: 1980)
- ii) Galvanised angle iron 60mm x 60mm x 6mm thick
- iii) Galvanised tubular steel, 75mm outside diameter, and 3.2 mm thick

Uprights and strainers shall be embedded in 0.5m square concrete bases, not more than 3.0m apart. Four strands of 3.2 mm plain wire shall be strained, and stapled or tied to the uprights with tying wire. Chain link fencing, 2.5mm, (to IS 130:1980), 1.8m high, shall be secured to the outside of the line wires over entire fence. One strand of 1.5mm barbed wire shall be placed along the top of the fence.

- b) Plants surrounded by land to which farmed animals have, or may have access must be surrounded by double fencing, the inside fence of which must be constructed to the specifications detailed above or equivalent, subject to DAFF agreement. The outside fence must be of a permanent nature and be stock proof. A minimum distance of two metres between each fence is required.
- c) A gate 1.8m high, of galvanised steel, or preservative treated timber, with closing bolts and locks, shall be fitted at the entrance to the Plant. The only horizontal bars shall be at the top and bottom of the gates. Chain-link fencing shall be fitted to the outside of the gates. The gates shall be designed such that neither people nor animals can get through or under when closed.
- d) Other equivalent fencing systems to those referred to above may be acceptable and full details should be submitted to DAFF for consideration and approval as part of the first stage application.

DAFF reserves the right to introduce additional fencing, or separation measures, which shall be complied with by the Plant owner.

APPENDIX 2

Sample feedstock acceptance form

A FEEDSTOCK ACCEPTANCE FORM MUST INCLUDE AT LEAST THE FOLLOWING INFORMATION:

Name and address of Plant

Name, address and telephone number of feedstock supplier

List of ABP feedstocks acceptable at the Plant, e.g. catering waste, manure etc

Definitions of the feedstock (as detailed in EU Regulation No. 1774 of 2002)

Description of feedstock

Estimated volume of feedstock supplied per annum

Statement of conformity e.g. ABP feedstock supplied to the above named Plant will only contain permitted ABPs detailed above.

Signature and capacity of person signing on behalf of feedstock supplier.

Date

Plant management signature and date.

Appendix 3

List of non-Departmental Laboratories Approved for Microbiological testing by the Department of Agriculture, Fisheries and Food

Advanced Micro Services, South Ring Business Park,

Tramore Rd, Co Cork

Anser Laboratories Ltd. 69A Killyman Street, Moy, Co Tyrone BT71 7ED.

Aqua Lab. Donegal Road, Killybegs, Co. Donegal.

Biosearch (NI) Ltd Dufferin Road

Belfast BT3 9AA

Complete Laboratory Solutions

Ros Muc, Connemara, Co. Galway.

Consult-Us Ltd.

Glanmire Industrial Estate,

Glanmire, Co. Cork.

Enfer Micro Laboratories Ltd, Carrigeen Business Park,

Clonmel,
Co. Tipperary

Envirolab Ltd.

Christendom Enterprise Centre

Christendom Ferrybank Waterford

Eurofins Scientific Ireland Ltd. Finnabair Industrial Estate, Science Services Centre, Dundalk, Co. Louth.

Foodtech Consultants Ltd.

Rocklawn, West Village, Ballincollig, Co Cork. Food Safety Laboratory, Veterinary Department Cork County Council,

County Hall, Cork.

Independent Micro Lab Ltd. Lismard Business Park,

Timahoe Road, Portlaoise, Co. Laois.

Irish Equine Centre

Johnstown, Naas,

Co. Kildare.

Mercury Analytical Ltd, Raheen Industrial Estate,

Limerick.

Microchem Laboratories

Clogherane, Dungarvan, Co. Waterford

Microlab Ltd. Drumillard Little, Monaghan Road, Castleblayney, Co. Monaghan.

Mid Antrim Laboratory

Services

42A Broughshane Road,

Ballymena, Co. Antrim.

Monaghan Veterinary

Laboratory Clones Road, Monaghan.

Oldcastle Laboratories Ltd.

Cogan Street, Oldcastle, Co. Meath. Q Lab Ltd. P.O. Box 27,

Kerlogue Industrial Estate,

Drinagh, Wexford.

Southern Scientific Services Ltd.

Dunrine, Killarney Co. Kerry.