

Guidance notes for Validation of Plants Processing ABP Feedstocks to a Processing Standard.

Validation:

In plants where processing of the feedstock to a processing standard is required, the technology for achieving same must be validated.

Validation means *"establishing documented evidence that provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality attributes."*

Validation in the composting/ biogas plant context means demonstrating that the particle sizing equipment (where present) , particle size verification equipment, and the composting reactor/ pasteurisation unit (where time/ temperatures will be achieved), will reliably and consistently lead to the required processing standards being met and having documentary evidence to prove same.

Validation Plan

As part of the second stage application, a validation plan detailing how the processing technology will be validated must be submitted to DAFM .

In composting plants, wet biogas plants and dry biogas plants, the validation plan must be drawn up by an independent expert who has expertise in composting/ biogas processing technology and knowledge of the composting/ biogas process. Exceptions to this requirement will be considered by DAFM for wet biogas plants in certain situations. At the end of the technology validation period, a validation report must be submitted by the same expert, and so it is essential that the Plant seeks the commitment of the company/expert/consultant to see the process through. In order to understand and assess the technology, it would be essential that the expert visits the plant when operational as a minimum.

The validation plan must contain the following as a minimum;

1. a) A description of (i) the particle sizing equipment (where present) , (ii) the particle size verification equipment, and (iii) the composting reactor/ pasteurisation unit
- b) A description of how the technology operates and will be operated in order to achieve the required processing standard.

Where there are different types and/ or sizes of composting reactors/ pasteurisation units on site, each type/ size must be validated separately. In a Plant with multiple identical composting reactors/ pasteurisation units, it will not be necessary to validate each one. In such cases, the composting reactors/ pasteurisation units to be used should be detailed in the Plant validation plan.
- c) A description of the temperature recording system (live and real time thermographs must be produced. Data recording and subsequent thermograph production is not accepted)
2. Variables which may affect temperatures from batch to batch must be detailed and explanation provided as to how they will be controlled and managed in normal production ,e.g.,
 - feedstock homogeneity, use of extrinsic heat , airflow direction etc in composting plants;
 - mixing systems, heating systems etc in ‘wet’ system biogas plants;
 - feedstock homogeneity, use of extrinsic heat etc in ‘dry’ system biogas plants
3. Detailed information on how the i) the particle sizing equipment (where present) , (ii) the particle size verification equipment, and (iii) the composting reactor/ pasteurisation unit will be validated in order to provide a high degree of assurance that the required processing standards will be met reliably and consistently.

The information for the **composting reactor and pasteurisation unit in ‘dry’ system biogas plants**, must include a plan of the composting reactor / pasteurisation unit detailing precise locations of proposed temperature probe locations (top and side views). The plan must detail the volume of feedstock within the composting reactor/ pasteurisation unit as well as the pile height and shape. The temperature probes must be located at varying positions and depths throughout the piles ensuring that some of the probes are positioned in locations which best represent a) areas which will be slowest to reach temperatures potentially, b) areas which will be coldest potentially, and c) areas which may have difficulty retaining temperatures. A minimum of 5 temperature probes must be used to test each composting reactor/ pasteurisation unit with at least one located in each of the following locations; 15cm or less from the top of the pile , 15cm or less from the side of the composting reactor/ pasteurisation unit and 15cm or less from the bottom of the composting reactor/ pasteurisation unit. The variables referred to in point 2 must also be considered when selecting temperature probe locations. The reason for selecting each of the proposed temperature probe locations must be detailed. However, exceptions to the above temperature probe requirements will be considered on a case by case basis by DAFM.

For wet biogas plants:

There must be at least 2 temperature recording probes in the biogas pasteurisation unit, one located in the top third of the vessel & one located in the bottom third of the pasteurisation vessel.

The probes must be located in such a position that they record accurately the temperature of the digestate being processed and are not directly influenced by an extrinsic heat source e.g. circulating hot water in water jackets of pasteuriser.

Once a satisfactory application has been received by DAFM, DAFM will notify the operator of same. The operator must then notify the inspector when the plant is ready to commence operations in order to arrange a site inspection. The inspector will assess if the plant meets the necessary infrastructure and equipment requirements and has a HACCP system, plant procedures and recording systems in place to ensure that the required operational requirements can be met in compliance with the conditions and legislation requirements. The operator will need to demonstrate that they know how to operate the system properly and that the site management techniques will ensure that the plant will comply with the Regulations.

Conditional Approval to Operate

A Conditional Approval is granted for a period of 3 months subject to:

- (a) A satisfactory 2nd stage application being submitted, and,
- (b) A satisfactory plant site inspection by DAFM officials.

No compost/ digestate is permitted to move off site during the conditional approval period unless otherwise agreed by DAFM.

A plant which is issued with conditional approval is subject to DAFM inspections. The purpose of these inspections is to assess the following:

1. The plant technology validation procedure and compliance with the agreed validation plan (in plants which are required to process the feedstock to specified processing standards).
2. Plant compliance with the conditions and legislation:
 - The plant operator must be able to demonstrate the consistent and competent management of the plant in line with conditions and legislative requirements.
3. The implementation of the HACCP plan and plant procedures:
 - The plant operator must be able to demonstrate good understanding and effective implementation of the plant HACCP and standard operation procedures/plant pre-requisite programmes.

During the conditional approval period, plants which are required to process their

feedstock to a processing standard must validate the plant technology in accordance with the agreed validation plan.

Validation Periods

For composting plants and ‘dry’ system biogas plants:

The technology validation period will comprise of a 10 week period from the date conditional approval is granted. At least 6 batches must be processed in the plant during this time. Where the composting reactor/pasteurisation unit is located towards the end of the process, this time period may be extended by DAFM on a case by case basis.

For ‘wet’ system biogas plants:

The technology validation period will comprise of a 10 week period from the date conditional approval is granted. At least 10 batches must be processed in the plant during this time. Where the pasteurisation unit is located post digester, the 10 week period may be extended by DAFM on a case by case basis to enable the plant to validate the processing technology.

As specified in the plant conditional approval certificate, the independent expert must submit a validation report within one week of completion of the validation period. This validation report must be based on all processing which occurred during the validation period. In the case where a plant has not been able to process the required minimum number of batches during the validation period, the plant operator must inform DAFM in writing at least one week before the end of the validation period, detailing the reasons for same. DAFM may extend the validation period to facilitate the processing of the required number of batches in certain case, such as for plants with very low throughput or with back end processing systems.

VALIDATION REPORT

The following information must be included in the validation report:

1. A statement from the independent expert giving his/her opinion as to whether the processing technology has and can achieve the processing *requirements consistently and reliably, and in compliance with conditions and legislative requirements.*
2. The documented supporting evidence to prove that the processing technology can and will, reliably and consistently, achieve the processing standards..
This evidence must include:

- Evidence that **all** feedstock taken into the plant and which is required to be processed, has been processed e.g. intake records, batch traceability records etc;
- Particle size verification records for every batch;
- Thermographs for **all** batches (not only the minimum number of batches) which have been put into the composting reactor/pasteurisation unit, including batches which have failed to meet the required processing standards . In the case of ‘failed batches’, there must be documentary evidence that an investigation has been carried out to determine the cause, and that appropriate corrective actions were taken. There must also be evidence that processing standards were subsequently achieved for those batches.
- E.Coli sample results for every batch processed and Salmonella results from end-product at the frequency specified in the conditional approval document.

Final Approval

A DAFM inspector will carry out an approval inspection at the end of the three month conditional approval period.

The plant may be granted a full approval based on:

- (i) the findings of the approval inspection, and of inspections carried out during the conditional approval period;
- (ii) the validation report where applicable.

OR

The plant may be refused approval **or** in some circumstances DAFM may extend the conditional approval in accordance with Article 44 of Regulation (EU) No. 1069/2009 for a period of up to 3 months where clear progress has been made but the plant still does not meet all of the relevant requirements.

However, Conditional Approval cannot exceed a total of 6 months. Where plants cannot comply with the conditions and legislative requirements, conditional approval will not be extended and the plant must cease operating. The ABP material and compost/ digestate on site must be dealt with in accordance with DAFM instructions.

Once a premises is fully approved, relaxation of the microbiological testing requirements will be considered by DAFM, provided that the testing and monitoring of control points set out in the HACCP demonstrate that the site continues to comply with the requirements of the Regulations.