Requirements for processing (rendering) plants

Contents

What is rendering?

Rendering is a process which involves cooking animal by-products at high temperature, sometimes under pressure, allowing water to be removed and tallow to be separated from the proteinaceous material.

Where do I find the Standard Processing Methods?

The relevant EU legislation is:

- Regulation **1069/2009** hereafter referred to as the “Control Regulation”.
- Implementing Regulation **142/2011** hereafter referred to as the “Implementing Regulation”.

Annex IV chapter III of the EU Implementing Regulation provides detail of the seven standard processing methods including times, temperatures and particle size requirements. The method of processing required will depend on the category and nature of the raw material being processed.

How do I become approved?

In order to become registered, you should contact Animal Health and Welfare Department, Triq il-Biccerija, Albertown Marsa on 22925372/76**,** or email abpsection.mafa@gov.mt You can also obtain an application form for your business sending a request to the same email address.

This form must be completed and returned to allow an approval inspection to be arranged. Detailed conditions will need to be complied with and you will need to satisfy the inspecting officer that you are able to operate the facility in compliance with the legislation. If satisfied, the Animal Health and Welfare Department will issue an approval document that will allow you to operate.

Once approved you will be subject to routine inspections, the frequency of which will be based on the risk posed by the operation and how compliant you are in its operation. Currently there are no charges for these approval or routine inspections.

Do I need to carry out validation?

As part of the approval process, the operator must carry out a validation of the process. The purpose of validation is to define the operational parameters of a given process which will achieve the requirements set out in the legislation. It is the responsibility of the operator to carry out this validation but it should be carried out in discussion with the Animal Health and Welfare Department. The validation requirements are described in Annex XVI chapter I section 2 of the EU Implementing Regulations.

Validation only needs to be repeated following a significant change in the process, for example, changes of raw materials, where a change in throughput rate has occurred or where a change in processing machinery has taken place. If a significant change has occurred and the operator has successfully revalidated the new process with the Animal Health and Welfare Department prior to any change.

Method 7 processing may require specific microbiological requirements to be met prior to approval (see below).

What are the specific requirements for method 7 processing?

The EU Implementing Regulation sets out the criteria for authorisation of method 7 processing. Any processing method can be authorised by the competent authority as processing method 7 where the following have been demonstrated by the operator to that authority:

- the identification of relevant hazards in the starting material, in view of the origin of the material, and of the potential risks in view of the animal health status of the Member State or the area or zone where the method is to be used
- the capacity of the processing method to reduce those hazards to a level which does not pose any significant risks to public and animal health
- the sampling of the final product on a daily basis over a period of 30 production days in compliance with the following microbiological standards:

Samples of material taken directly after the treatment:

- Clostridium perfringens absent in 1g

Samples of material taken during or upon withdrawal from storage:

- Salmonella absent in 25g: n=5, c=0, m=0, M=0
- Enterobacteriaceae: n=5, c=2; m=10; M=300 in 1 g

The above parameters are explained in the guidance laboratory requirements for animal by-product **testing.**

All of the final product must either be retained until the end of the 30 day testing period or be disposed of. Disposal must be by a route approved for the disposal of that category of raw animal by-product.

If any of the 30 day test results fail to meet the Salmonella microbiological standards then action, under the control of an officer of the Animal Health and Welfare Department, will be taken. This will involve reprocessing or destruction of the final product. Similar action will be taken in respect of other failures.

The competent authority may authorise any processing method as method 7 if the following have been demonstrated/provided by the operator to that authority:

- full description of process: including details of how the process will operate and a process flow diagram; defined critical control points (temperature, pressure, exposure time, pH, particle size); equipment specification including calibration details and HACCP plan
- full description of raw material: category, sub-category, physical properties (particle size, water content); Pre-treatment (if any)
- identification of biological hazards (human and animal health). These hazards should be identified in view of origin of the raw material, category, sub-category, the animal health status of the Member State or area or zone where method is used and the destination/use of the product
- demonstration of risk reduction: demonstrate the capacity of the method to reduce the identified hazards to a level which does not pose significant risks to public and animal health. This should be done by focusing on the relevant hazard that is most difficult to inactivate

- the mechanism for demonstrating risk reduction will be dependent on the process and the nature of the risk. The onus is on the process operator to demonstrate that risks have been reduced.

This can be achieved by one of the following approaches:

- Demonstrate quantitatively the reduction of endogenous indicator organisms that are consistently present in the raw material in high numbers. This can be achieved by testing the raw material in order to identify what organisms are present, followed by testing the finished product to demonstrate adequate reduction in the number of those organisms. These organisms must not be less resistant to the treatment process than other identified biological hazard present in the raw material
- Established risk reduction. Where factors leading to the reduction of risk are well known (documented), the model of risk reduction is well established and continuous direct measurement of the factors leading to risk reduction are in place then this can be used to confirm the treatment would result in risk reduction.
- Experimental validation: Introduction of a well-characterised test organism, in a suitable test body, into the starting material and subsequent testing of the final product to confirm risk reduction (this approach should always be discussed with the Animal Health and Welfare Department prior to carrying out any such validation exercise).

Approvals for method 7 processing issued prior to the 4th March 2011 under regulation EC/1774/2002 will generally be accepted, unless it is considered that the microbiological hazards had not previously been identified. The approval of processing method 7 issued before and after 4th March 2011 may be suspended (permanently or temporarily) by the the Animal Health and Welfare Department if there is evidence that the relevant microbiological hazards in the starting material or the capacity of the method to reduce the hazards to acceptable health levels, for animal and public, have changed substantially.

Separation: why is it important?

Separation of materials is vital to ensure the risks associated with animal by-products are effectively controlled. This includes keeping raw feedstocks separate from the processed final product and also separation of categories of by-products. For more information contact the Animal Health and Welfare Department.

In order to prevent cross contamination, different categories of animal by-products should ideally be rendered on separate sites. However, this is not always practical and some processing plants will wish to render more than one category of product on the same site. In these cases it is essential that separation is maintained between categories of unprocessed animal by-products and also between the unprocessed and the processed products.

Within each category, separation between lines processing different species may also be required. Currently, the outputs of mammalian, fish and poultry lines may all have different uses if they are guaranteed free of cross-contamination.

What are the separation requirements at processing plants?

Procedures must be in place, and followed to ensure different categories of animal by-products are kept separate from each other at all times. To minimise the risk of cross-contamination, adequate physical separation is needed. This can be broken down into specific areas:

- Design and Structure
- Buildings
- Equipment
- Cleaning and Disinfection
- Storage
- Personnel

Design, equipment, cleaning and staff

The plant must be designed to provide a clearly defined 'unclean' sector where raw material is received and a 'clean' sector where finished product is dispatched. The operation of the plant should be structured to ensure a one-way flow of material from receipt of raw material through the processing stage and on to storage of the final product with no opportunity for by-pass.

Buildings

The reception bay must be covered and constructed in such a way as to allow easy cleansing and disinfection.

Concrete or other durable floor surfaces must be in good condition and layed to facilitate the drainage of liquids. Floors with proper falls will help wash water and effluent to the drains. Walls should be similarly constructed of durable material. A breezeblock is porous and must be sealed either by rendering or the use of other durable coverings e.g. certain paints.

Equipment

Equipment must be dedicated to a single category of animal by-product, ideally this will involve identifying equipment e.g. colour coding.

Equipment movement should be restricted, for example, if the process requires the size of animal by-products to be reduced prior to processing, then the equipment used to do this should be situated and remain in the unprocessed, 'unclean' sector.

If it is necessary to use equipment for a different category then full cleaning and disinfection procedures must be followed (if transferring equipment used for category 1 processing to category 2 or 3 processing then this will require caustic decontamination). Similarly, if it is necessary to move equipment from the unclean to the clean sector then it must undergo full cleaning & disinfection.

Maintenance work should only be carried out by trained and competent staff. They must ensure their routine work does not result in different categories of animal by-products contaminating each other. Procedures for maintaining and service of equipment should be included in the Standard Operating Procedure (SOP) for the plant.

Cleaning and Disinfection

Facilities must be available for cleaning and disinfecting the containers in which animal by-products are received and the vehicles in which they are stored or transported. The type of facilities will depend on the situation for example steam cleaner, hand-held hose or automated cleaning system or chemical disinfection using an approved disinfectant. Facilities must be available to allow for the disinfection of vehicle wheels and other parts of the vehicle when they leave the unclean sectors of site. Splashes or run-off from the cleaning areas must not contaminate the processed product.

Storage

Different categories of unprocessed animal by-products must be stored separately unless they are to be mixed and rendered as the higher risk category. Products from separate lines must be stored separately unless destined for the same disposal route. If processed products derived from different categories or different species are stored together then all of the stored products must be treated as being of the higher risk material.

Personnel

Procedures must be put in place to control the movement of personnel between areas, including disinfection of footwear and changing protective clothing to prevent by-pass of material. Colour coded protective clothing should be used to ensure separation between personnel working in clean and unclean areas. Procedures must also be in place to control by-pass risks in communally used areas such as lavatories, changing rooms and canteens.

All staff working on the premises must be adequately trained for their job(s). The training must include awareness of the SOP and any critical control points within their area of responsibility. A written record of such training should be maintained. It is also recommended that a list of personnel who own livestock is maintained for notifiable disease contingency planning purposes.

What additional hygiene requirements are required?

In addition to the details given above, the following general hygiene requirements are needed for rendering plant approvals:

- Cleaning procedures must be established for all areas of the rendering plant. Regular hygiene inspections of the environment and equipment must be carried out and documented to ensure the cleaning procedures are being followed. Splashes or run-off from the cleaning must not be allowed to come into contact with the final processed product
- Adequate lavatories, changing rooms and washbasins must be provided for staff. These facilities should either be part of the work area or immediately adjacent to it. Portable lavatories are acceptable; however, facilities located in dwelling houses are not acceptable
- The rendering plant must have a waste-water disposal system (see below 'How should waste water be treated')
- The plant must have appropriate arrangements for protection against pests, such as insects, rodents and birds. As far as practicable the premises must be insect, bird and rodent proof, and there should be a rodent control programme. The operator should also take measures to minimise the level of insects in the premises using screens and/or insect control measures e.g. electrical insect killer.

What operational requirements need to be met?

The rendering plant must have control over the operation of the plant in order to ensure separation of materials is achieved, processing conditions are met, and all documentation is in place. Equipment must be checked regularly and kept in a good state of repair.

Where heat or pressure treatment is required, all installations must be equipped with continuous measuring equipment to monitor temperature and, where applicable, pressure at critical points. Measuring equipment i.e. pressure gauges thermocouples and recorders, must be calibrated at least once a year and records of calibration kept.

Any material that has not received the specified heat treatment must be re-circulated through the heat treatment, reprocessed or disposed of in accordance with the ABP Regulations.

If categories of Animal by-products are mixes then the whole consignment will be regarded as the higher risk, for example, if category 1 material is mixed with category 2 material, then the whole consignment should be considered as category 1.

The processing plant must have sufficient production capacity for hot water and steam for the processing of ABPs.

What are the specific requirements for category 1 and 2 materials?

If a rendering plant wishes to process both category 1 and 2 material on a single site the ABP regulation requires total separation of the category 1 material from the category 2 material throughout the whole process i.e. from reception of the raw material through to the dispatch of the final product. Total separation should be taken to mean that the two processing lines operate in separate parts of the building i.e. divided by a wall or partition. Areas with exposed raw and processed material must be completely separated by floor to ceiling wall or partitions.

Note: if categories of Animal by-products are mixed then the whole consignment will be regarded as the higher risk and will require processing as such.

What are the specific requirements for category 3 materials?

Plants processing category 3 materials cannot be located on the same site as plants processing category 1 or 2 animal by-products, unless they are located in completely separate buildings i.e. divided by a wall or partition. Areas with exposed raw and processed material must be completely separated by floor to ceiling wall or partitions.

Approval may be given to handle and process category 3 material on the same site as category 1 and 2 if the following measures are put in place to avoid cross-contamination:

- the layout and management of the premises, in particular the reception area, process lines including equipment, and storage of products must ensure separation of materials and prevent cross contamination
- appropriate procedures for cleaning and disinfection must be in place and enforced, taking into account the increased level of risk.

If the category 3 rendering plant is producing products that are destined to be fed to animals then they must have mechanisms in place to detect and remove foreign bodies such as packing material, plastic or metallic items from either the raw material or the finished product. Such foreign bodies must be removed before or during processing.

How should waste water be treated?

All processing plants must have a waste-water disposal system meeting the requirements set out by the competent authority in accordance with EU legislation.

Category 1 and category 2 rendering plants are required to have wastewater pre-treatment system in place consisting of drain traps or screens with a mesh size of no more than 6mm in the downstream end of the process. The purpose of this system is to ensure that any solid material in the wastewater is less than 6mm in size. Only wastewater that has been filtered through the pre-treatment system can leave the premises.

It is not permitted to grind, macerate or pre-process solid material to allow it to pass through the pre-treatment system.

Any material captured in the pre-treatment system must be collected and disposed of as category 1 or category 2 material according to the ABP Regulations.

It is not permissible to dispose of liquid animal by-products (e.g. blood or milk) or derived products through the wastewater system even if it passes through the pre-treatment system.

What routine microbiological testing is needed?

Operators are required to carry out microbiological testing on finished products. The nature and frequency of testing depends on the source of the raw material and the intended final destination of the processed material.

For validation purposes:

- methods 1 to 6 do not require bacteriology testing, however, method 7 processing does require Clostridium, Salmonella and Enterobacteriacaea testing (see ‘What are the specific requirements for method 7 processing?’).

For routine sampling purposes:

- final product derived from Category 1 material which is going for destruction or to landfill and final product derived from Category 2 material which is going for destruction or to landfill does not require testing
- final product derived from Category 2 and Category 3 material which is going to be used as Organic fertilizer or soil improver, biogas or composting must be sampled for Salmonella and Enterobacteriacea weekly
- final product derived from Category 3 material, which is destined for use in feeding stuffs must be sampled every day that material is consigned from the premises. The samples must be tested for Salmonella and Enterobacteriacea
- final product derived from Category 3 material, which is not intended for use in feeding stuffs must be sampled for Salmonella and Enterobacteriacea weekly unless it is going for destruction or to land fill in which case no testing is required.

The plant must have its own laboratory on site or make use of an external laboratory that is equipped to carry out the necessary testing. The laboratory must be accredited to international standard ISO17025 in order to carry out testing.

Do I need a Standard Operating Procedure?

In addition to a detailed Hazard Analysis and Critical Control Points (HACCP) plan which details the control of the processes within the plant, a standard operating procedure (SOP) is also required. While these are often held as a single document it is essential that the HACCP plan is clearly identified and accompanied by monitoring and corrective action documentation.

As a minimum, the SOP should include the following information:

- management of common and shared areas including the procedures to be followed if cross-contamination occurs:
    - Common areas will include canteens, offices, wastewater treatment plants and boilers. Procedures to avoid cross-contamination in common areas could include a requirement for 'staff must remove their outer clothing and change their footwear before going to the common area'
    - Shared areas include those where animal by-products are handled or transported. For Category 1 and 2 lines, shared areas may include raw material intake and storage within the same airspace; two or more cookers in the same airspace; weighbridge; entrances from the public highway; lorry parking and washing.
- management of spillages of any animal by-products and/or processed products
- equipment management including mobile equipment (e.g. color coding), procedures for dealing with breakdowns, maintenance, etc.
- personnel requirements including training
- storage requirements for raw materials and final products.

What are the requirements regarding permanent marking with glycerol-tri-heptanoate (GTH)?

Annex VIII chapter V of the EU Implementing Regulation lays down the specific requirements for permanently marking category 1 or category 2 derived products with glycerol-tri-heptanoate (GTH).

GTH is a fat that does not occur in nature and that can withstand the extreme sterilization conditions used in rendering plants. When applied to a rendering process, GTH concentrates in the processed fat or in the fat component of meat & bonemeal and can be used to permanently mark the final product. This will allow processed category 1 and 2 materials to be identified post rendering.

There is no requirement to incorporate GTH into processed animal by-products that are destined for immediate direct incineration or co-incineration within the same rendering site if material is moved by a closed conveyer system.