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ANNEX IV

PROCESSING

CHAPTER I

REQUIREMENTS FOR PROCESSING PLANTS AND CERTAIN OTHER PLANTS AND ESTABLISHMENTS

Section 1

General conditions

1. Processing plants shall meet the following requirements, for processing by pressure sterilisation or in accordance with the processing methods referred to in Article 15(1) (b) of Regulation (EC) No 1069/2009:
 - (a) Processing plants must not be situated on the same site as slaughterhouses or other establishments which have been approved or registered in accordance with Regulation (EC) No 852/2004 or Regulation (EC) No 853/2004, unless the risks to public and animal health resulting from the processing of animal by-products, which originate from such slaughterhouses or other establishments, are mitigated by compliance with at least the following conditions:
 - (i) the processing plant must be physically separated from the slaughterhouse or other establishment, where appropriate by locating the processing plant in a building that is completely separated from the slaughterhouse or other establishment;
 - (ii) the following must be installed and operated in the processing plant:
 - a conveyer system which links the processing plant to the slaughterhouse or other establishment and which may not be by-passed,
 - separate entrances, reception bays, equipment and exits for both the processing plant and the slaughterhouse or establishment;
 - (iii) measures must be taken to prevent the spreading of risks through the operation of personnel which is employed in the processing plant and in the slaughterhouse or other establishment;
 - (iv) unauthorised persons and animals must not have access to the processing plant.

By way of derogation from points (i) to (iv), in the case of processing plants processing Category 3 material, the competent authority may authorise other conditions instead of those set out in those points, aimed at mitigating the risks to public and animal health, including the risks arising from the processing of Category 3 material, which originates from off-site establishments approved or registered in accordance with Regulation (EC) No 852/2004 or Regulation (EC) No 853/2004.

Member States shall inform the Commission and the other Member States in the framework of the Standing Committee on the Food Chain and Animal Health referred

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- to in Article 52(1) of Regulation (EC) No 1069/2009 of the use made of this derogation by their competent authorities;
- (b) The processing plant must have a clean and unclean sector, adequately separated. The unclean sector must have a covered place to receive animal by-products and must be constructed in such a way that it is easy to clean and disinfect. Floors must be laid in such a way as to facilitate the draining of liquids;
 - (c) The processing plant must have adequate facilities including lavatories, changing rooms and washbasins for staff;
 - (d) The processing plant must have sufficient production capacity for hot water and steam for the processing of animal by-products;
 - (e) The unclean sector must, if appropriate, contain equipment to reduce the size of animal by-products and equipment for loading the crushed animal by-products into the processing unit;
 - (f) Where heat treatment is required, all installations must be equipped with:
 - (i) measuring equipment to monitor temperature against time and, if applicable for the processing method used, pressure at critical points;
 - (ii) recording devices to record continuously the results of these measurements in a way so that they remain accessible for the purpose of checks and official controls;
 - (iii) an adequate safety system to prevent insufficient heating;
 - (g) To prevent recontamination of the derived product by the introduction of animal by-products, there must be a clear separation between the area of the plant where incoming material for processing is unloaded and the areas set aside for the processing of that product and the storage of the derived product.
2. The processing plant must have adequate facilities for cleaning and disinfecting the containers or receptacles in which animal by-products are received and the means of transport, other than ships, in which they are transported.
 3. Adequate facilities must be provided for the disinfecting of vehicle wheels and the other parts of the vehicle, as appropriate, on leaving the unclean sector of the processing plant.
 4. All processing plants must have a waste-water disposal system meeting the requirements set out by the competent authority in accordance with Union legislation.
 5. The processing plant must have its own laboratory or make use of the services of an external laboratory. The laboratory must be equipped to carry out necessary analyses and be approved by the competent authority on the basis of an assessment of the capacity of the laboratory to carry out those analyses, be accredited according to internationally recognised standards or be subject to regular controls by the competent authority, to assess the capacity of the laboratory to carry out those analyses.
 6. If on the basis of a risk assessment, the volume of products treated requires the regular or permanent presence of the competent authority, the processing plants must have an adequately equipped lockable room for the exclusive use of the inspection service.

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Section 2

Wastewater treatment

1. Processing plants processing Category 1 material and other premises where specified risk material is removed, slaughterhouses and processing plants processing Category 2 material shall have a pre-treatment process for the retention and collection of animal material as an initial step in the treatment of wastewater.

The equipment used in the pre-treatment process shall consist of drain traps or screens with apertures with a filter pore or a mesh size of no more than 6 mm in the downstream end of the process or equivalent systems that ensure that the solid particles in the wastewater passing through them are no more than 6 mm.

2. Wastewater from the premises as referred to in point 1 must enter a pre-treatment process which shall ensure that all wastewater has been filtered through the process before being drained off the premises. No grinding, maceration or any other processing or application of pressure shall be carried out which could facilitate the passage of solid animal material through the pre-treatment process.
3. All animal material retained in the pre-treatment process in premises as referred to in point 1 shall be collected and transported as Category 1 or Category 2 material, as appropriate, and disposed of in accordance with Regulation (EC) No 1069/2009.
4. Wastewater having passed the pre-treatment process in premises referred to in point 1 and wastewater from other premises handling or processing animal by-products shall be treated in accordance with Union legislation, without restrictions in accordance with this Regulation.
5. In addition to the requirements laid down in point 4, the competent authority may oblige operators to treat wastewater originating in the unclean sector of processing plants and in plants or establishments carrying out intermediate operations with Category 1 material or Category 2 material or storing Category 1 material or Category 2 material, in accordance with conditions which ensure that risks from pathogens are mitigated.
6. Without prejudice to points 1 to 5, the disposal of animal by-products, including blood and milk, or derived products through the wastewater stream shall be prohibited.

However, Category 3 material comprising of centrifuge or separator sludge may be disposed of through the wastewater stream, provided that it has been subject to one of the treatments for centrifuge or separator sludge set out in Part III of Section 4 of Chapter II of Annex X hereto.

Section 3

Specific requirements for the processing of Category 1 and Category 2 materials

The layout of processing plants processing Category 1 and Category 2 materials must ensure the total separation of Category 1 material from Category 2 material from reception of the raw material until dispatch of the resulting derived product, unless a mixture of Category 1 material and Category 2 material is processed as Category 1 material.

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Section 4

Specific requirements for the processing of Category 3 materials

The following requirements shall apply in addition to the general conditions set out in Section 1:

1. Processing plants processing Category 3 materials shall not be located at the same site as processing plants processing Category 1 or Category 2 materials, unless located in a completely separate building.
2. However, the competent authority may authorise the processing of Category 3 material on a site where handling or processing of Category 1 or Category 2 material takes place, if cross-contamination is prevented due to:
 - (a) the layout of the premises, in particular the arrangements for the reception, and by way of the further handling of raw materials;
 - (b) the layout and the management of the equipment used for processing, including the layout and the management of separate processing lines or of cleaning procedures which are excluding the propagation of any possible risks to public and animal health; and
 - (c) the layout and the management of the areas for the temporary storage of the end products.
3. Processing plants processing Category 3 material shall have in place an installation to check the presence of foreign bodies, such as packaging material or metallic pieces, in the animal by-products or derived products, if they are processing materials which are destined for feeding. Such foreign bodies shall be removed before or during processing.

CHAPTER II

HYGIENE AND PROCESSING REQUIREMENTS

Section 1

General hygiene requirements

In addition to the general hygiene requirements provided for in Article 25 of Regulation (EC) No 1069/2009, processing plants shall have a documented pest control programme in place for the implementation of the arrangements for protection against pests, such as insects, rodents and birds, referred to in Article 25(1)(c) of that Regulation.

Section 2

General processing requirements

1. Accurately calibrated gauges/recorders must be used to monitor continuously the processing conditions. Records must be kept to show the date of calibration of gauges/recorders.

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2. Material that may not have received the specified heat treatment, such as material discharged at start up or leakage from cookers, must be recirculated through the heat treatment or collected and reprocessed or disposed of in accordance with Regulation (EC) No 1069/2009.

Section 3

Processing methods for Category 1 and Category 2 material

Unless the competent authority requires the application of pressure sterilisation (method 1), Category 1 and Category 2 material shall be processed in accordance with processing methods 2, 3, 4 or 5 as referred to in Chapter III.

Section 4

Processing of Category 3 material

1. The critical control points that determine the extent of the heat treatments applied in processing shall include for each processing method as specified in Chapter III:
 - (a) raw material particle size;
 - (b) temperature achieved in the heat treatment process;
 - (c) pressure, if applied to the raw material;
 - (d) duration of the heat treatment process or feed rate to a continuous system. Minimum processing standards must be specified for each applicable critical control point.
2. In the case of chemical treatments which have been authorised by the competent authority as processing method 7 in accordance with point G of Chapter III, the critical control points that determine the extent of the chemical treatments applied shall include the pH adjustment achieved.
3. Records shall be maintained for at least two years to show that the minimum process values for each critical control point are applied.
4. Category 3 material shall be processed in accordance with any of the processing methods 1 to 5 or processing method 7, or, in the case of material originating from aquatic animals, with any of the processing methods 1 to 7, as referred to in Chapter III.

CHAPTER III

STANDARD PROCESSING METHODS

A. Processing method 1 (pressure sterilisation) Reduction

1. If the particle size of the animal by-products to be processed is more than 50 millimetres, the animal by-products must be reduced in size using appropriate equipment, set so that the particle size after reduction is no greater than 50 millimetres. The effectiveness of the equipment must be checked daily and its condition recorded.

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If checks disclose the existence of particles larger than 50 millimetres, the process must be stopped and repairs made before the process is resumed.

Time, temperature and pressure

2. The animal by-products with the particle size of no greater than 50 millimetres must be heated to a core temperature of more than 133 °C for at least 20 minutes without interruption at a pressure (absolute) of at least 3 bars. The pressure must be produced by the evacuation of all air in the sterilisation chamber and the replacement of the air by steam ('saturated steam'); the heat treatment may be applied as the sole process or as a pre- or post-process sterilisation phase.
3. The processing may be carried out in batch or continuous systems.

B. Processing method 2

Reduction

1. If the particle size of the animal by-products to be processed is more than 150 millimetres, the animal by-products must be reduced in size using appropriate equipment, set so that the particle size after reduction is no greater than 150 millimetres. The effectiveness of the equipment must be checked daily and its condition recorded. If checks disclose the existence of particles larger than 150 millimetres, the process must be stopped and repairs made before the process is resumed.

Time, temperature and pressure

2. After reduction the animal by-products must be heated in a manner which ensures that a core temperature greater than 100 °C is achieved for at least 125 minutes, a core temperature greater than 110 °C is achieved for at least 120 minutes and a core temperature greater than 120 °C is achieved for at least 50 minutes.

The core temperatures may be achieved consecutively or through a coincidental combination of the time periods indicated.

3. The processing must be carried out in a batch system.

C. Processing method 3

Reduction

1. If the particle size of the animal by-products to be processed is more than 30 millimetres, the animal by-products must be reduced in size using appropriate equipment, set so that the particle size after reduction is no greater than 30 millimetres. The effectiveness of the equipment must be checked daily and its condition recorded. If checks disclose the existence of particles larger than 30 millimetres, the process must be stopped and repairs made before the process is resumed.

Time, temperature and pressure

2. After reduction the animal by-products must be heated in a manner which ensures that a core temperature greater than 100 °C is achieved for at least 95 minutes, a core temperature greater than 110 °C is achieved for at least 55 minutes and a core temperature greater than 120 °C is achieved for at least 13 minutes.

The core temperatures may be achieved consecutively or through a coincidental combination of the time periods indicated.

3. The processing may be carried out in batch or continuous systems.

D. Processing method 4

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Reduction

1. If the particle size of the animal by-products to be processed is more than 30 millimetres, the animal by-products must be reduced in size using appropriate equipment, set so that the particle size after reduction is no greater than 30 millimetres. The effectiveness of the equipment must be checked daily and its condition recorded. If checks disclose the existence of particles larger than 30 millimetres, the process must be stopped and repairs made before the process is resumed.

Time, temperature and pressure

2. After reduction the animal by-products must be placed in a vessel with added fat and heated in a manner which ensures that a core temperature greater than 100 °C is achieved for at least 16 minutes, a core temperature greater than 110 °C is achieved for at least 13 minutes, a core temperature greater than 120 °C is achieved for at least eight minutes and a core temperature greater than 130 °C is achieved for at least three minutes.

The core temperatures may be achieved consecutively or through a coincidental combination of the time periods indicated.

3. The processing may be carried out in batch or continuous systems.

E. Processing method 5

Reduction

1. If the particle size of the animal by-products to be processed is more than 20 millimetres, the animal by-products must be reduced in size using appropriate equipment, set so that the particle size after reduction is no greater than 20 millimetres. The effectiveness of the equipment must be checked daily and its condition recorded. If checks disclose the existence of particles larger than 20 millimetres, the process must be stopped and repairs made before the process is resumed.

Time, temperature and pressure

2. After reduction the animal by-products must be heated until they coagulate and then pressed so that fat and water are removed from the proteinaceous material. The proteinaceous material must then be heated in a manner which ensures that a core temperature greater than 80 °C is achieved for at least 120 minutes and a core temperature greater than 100 °C is achieved for at least 60 minutes.

The core temperatures may be achieved consecutively or through a coincidental combination of the time periods indicated.

3. The processing may be carried out in batch or continuous systems.

F. Processing method 6 (for Category 3 animal by-products originating from aquatic animal or aquatic invertebrates only)

Reduction

1. The animal by-products must be reduced to a particle size which is no greater than:
 - (a) 50 mm, in case of heat treatment in accordance with point 2(a); or
 - (b) 30 mm, in case of heat treatment in accordance with point 2(b).

They must then be mixed with formic acid to reduce and maintain the pH to 4,0 or lower. The mixture must be stored for at least 24 hours pending further treatment.

Time, temperature and pressure

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2. After reduction, the mixture must be heated to:
 - (a) a core temperature of at least 90 °C for at least 60 minutes; or
 - (b) a core temperature of at least 70 °C for at least 60 minutes.

When using a continuous flow system, the progression of the product through the heat converter must be controlled by means of mechanical commands limiting its displacement in such way that at the end of the heat treatment operation the product has undergone a cycle which is sufficient in both time and temperature.

3. The processing may be carried out in batch or continuous systems.

G. Processing method 7

1. Any processing method authorised by the competent authority where the following have been demonstrated by the operator to that authority:
 - (a) 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;
 - (b) 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;
 - (c) the sampling of the final product on a daily basis over a period of 30 production days in compliance with the following microbiological standards:
 - (i) Samples of material taken directly after the treatment:
Clostridium perfringens absent in 1 g of the products
 - (ii) Samples of material taken during or upon withdrawal from storage:
Salmonella: absence in 25g: n=5, c=0, m=0, M=0
Enterobacteriaceae: n=5, c=2; m=10; M=300 in 1 g

where:

n	=	number of samples to be tested;
m	=	threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all samples does not exceed m;
M	=	maximum value for the number of bacteria; the result is considered unsatisfactory if the number of bacteria in one or more samples is M or more; and
c	=	number of samples the bacterial count of which may be between m and M, the samples still being considered acceptable if the bacterial count of the other samples is m or less.

2. Details of the critical control points under which each processing plant satisfactorily complies with the microbiological standards must be recorded and maintained so that the operator and the competent authority can monitor the operation of the processing

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plant. The information to be recorded and monitored must include the particle size, and, as appropriate, the critical temperature, the absolute time, pressure profile, raw material feed rate and fat recycling rate.

3. By way of derogation from point 1, the competent authority may authorise the use of processing methods which have been approved prior to the date of entry into application of this Regulation, in accordance with Chapter III of Annex V to Regulation (EC) No 1774/2002.
4. The competent authority shall permanently or temporarily suspend the application of processing methods referred to in points 1 and 3, if it obtains evidence that any of the circumstances specified in point 1(a) or (b) have substantially changed.
5. The competent authority shall inform the competent authority of another Member State upon request about the information at its disposal under points 1 and 2 in relation to an authorised processing method.

CHAPTER IV

ALTERNATIVE PROCESSING METHODS

Section 1

General provisions

[^{F1}1. Materials resulting from the processing of Category 1 and 2 materials shall be permanently marked in accordance with the requirements for the marking of certain derived products set out in Chapter V of Annex VIII.

However, such marking shall not be required for the following materials referred to in Section 2:

- (a) biodiesel produced in accordance with point D;
- (b) hydrolysed materials referred to in point H;
- (c) mixtures of pig and poultry manure with quick lime produced in accordance with point I;
- (d) renewable fuels produced from rendered fats, which are derived from Category 2 materials, in accordance with point J.]

Textual Amendments

F1 Substituted by [Commission Regulation \(EU\) No 749/2011 of 29 July 2011 amending Regulation \(EU\) No 142/2011 implementing Regulation \(EC\) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive \(Text with EEA relevance\).](#)

2. The competent authority of a Member State shall make the results of official controls available to the competent authority of another Member State upon request, when an alternative method is used for the first time in that Member State, in order to facilitate the introduction of the new alternative method.

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Section 2

Processing standards

A. Alkaline hydrolysis process

1. Starting material

For this process, animal by-products of all categories may be used.

2. Processing method

Alkaline hydrolysis shall be carried out according to the following processing standards:

- (a) Either a sodium hydroxide (NaOH) or potassium hydroxide (KOH) solution (or a combination thereof) must be used in an amount that assures approximate molar equivalency to the weight, type and composition of the animal by-products to be digested.

In the case of high fat in the animal by-products that neutralises the base, the added base must be adjusted so that the molar equivalency referred to is achieved.

- (b) Animal by-products must be placed in a steel alloy container. The measured amount of alkali must be added either in solid form or as a solution as referred to in point (a).
- (c) The container must be closed and the animal by-products and alkali mixture must be heated to a core temperature of at least 150 °C and at a pressure (absolute) of at least 4 bars for at least:
- (i) three hours without interruption;
 - (ii) six hours without interruption in case of treatment of animal by-products referred to in Article 8(a)(i) and (ii) of Regulation (EC) No 1069/2009.

However, materials derived from Category 1 materials comprising of animals killed in the context of TSE eradication measures which are either ruminants not requiring TSE testing or ruminants which have been tested with a negative result in accordance with Article 6(1) of Regulation (EC) No 999/2001 may be processed in accordance with point 2(c)(i) of this Section;
or

- (iii) one hour without interruption in the case of animal by-products consisting of fish or of poultry materials.
- (d) The process must be carried out in a batch system and the material in the vessel must be constantly mixed in order to facilitate the digestion process until the tissues are dissolved and bones and teeth are softened; and
- (e) The animal by-products must be treated in such way that the requirements regarding time, temperature and pressure are achieved at the same time.

B. High pressure high temperature hydrolysis process

1. Starting material

For this process, Category 2 and Category 3 materials may be used.

2. Processing method

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High pressure high temperature hydrolysis shall be carried out according to the following processing standards:

- (a) The animal by-products must be heated to a core temperature of at least 180 °C for at least 40 minutes without interruption at a pressure (absolute) of at least 12 bar, heated by indirect steam application to the biolytic reactor;
 - (b) The process must be carried out in a batch and the material in the vessel must be constantly mixed; and
 - (c) The animal by-products must be treated in such a manner that the requirements regarding time, temperature and pressure are achieved at the same time.
- C. High pressure hydrolysis biogas process

1. Starting material

For this process, animal by-products of all categories may be used.

2. Processing method

The high pressure hydrolysis biogas process shall be carried out according to the following processing standards:

- (a) The animal by-products must be first processed using processing method 1 (pressure sterilisation) as set out in Chapter III in an approved processing plant;
- (b) Following the process referred to in point (a), the defatted materials must be treated at a temperature of at least 220 °C for at least 20 minutes at a pressure (absolute) of at least 25 bar, heated in a two-step procedure, first by direct steam injection, secondly indirect in a coaxial heat exchanger;
- (c) The process must be carried out in a batch or continuous system and the material is constantly mixed;
- (d) The animal by-products must be treated in such a manner that the requirements regarding time, temperature and pressure are achieved at the same time;
- (e) The resulting material must then be mixed with water and anaerobically fermented (biogas transformation) in a biogas reactor;
- (f) In the case of starting material of Category 1, the entire process must take place on the same site and in a closed system and the biogas produced during the process must be combusted rapidly in the same plant at a minimum of 900 °C followed by rapid chilling ('quenching').

D. Biodiesel production process

1. Starting material

For this process, a fat fraction derived from animal by-products of all categories may be used.

2. Processing method

Biodiesel production shall be carried out according to the following processing standards:

- (a) Unless fish oil or rendered fat are used which have been produced in accordance with Sections VIII or XII of Annex III to Regulation (EC) No 853/2004, respectively, the fat fraction derived from animal by-products must be first processed using:

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- (i) in the case of Category 1 or 2 materials, processing method 1 (pressure sterilisation) as set out in Chapter III; and
 - (ii) in the case of Category 3 materials, any of the processing methods 1 to 5 or processing method 7 or, in the case of material derived from fish, processing methods 1 to 7 as set out in Chapter III;
- (b) The processed fat must then be processed further using one of the following methods:
- (i) a process whereby the processed fat must be separated from the protein and in the case of fat from ruminant origin, insoluble impurities in excess of 0,15 % by weight must be removed, and the processed fat must be subsequently submitted to esterification and transesterification.

 However, esterification is not required for processed fat derived from Category 3 material. For esterification the pH must be reduced to less than 1 by adding sulphuric acid (H₂SO₄) or an equivalent acid and the mixture must be heated to 72 °C for at least two hours during which it must be intensely mixed.

 Transesterification must be carried out by increasing the pH to about 14 with potassium hydroxide or with an equivalent base at 35 °C to 50 °C for at least 15 minutes. Transesterification shall be carried out twice under the conditions described in this point using a new base solution. This process must be followed by refinement of the products including vacuum distillation at 150 °C, leading to biodiesel;
 - (ii) a process using equivalent process parameters authorised by the competent authority.

E. Brookes' gasification process

1. Starting material

For this process, Category 2 and Category 3 material may be used.

2. Processing method

Brookes' gasification shall be carried out according to the following processing standards:

- (a) The afterburner chamber must be warmed up using natural gas;
- (b) The animal by-products must be loaded into the primary chamber of the gasificator and the door must be closed. The primary chamber must have no burners and must be heated instead by the transfer of heat by conduction from the afterburner, which must be underneath the primary chamber. The only air admitted to the primary chamber must be via three inlet valves mounted on the main door to enhance the efficiency of the process;
- (c) The animal by-products must be volatilised into complex hydrocarbons and the resultant gases must pass from the primary chamber via a narrow opening at the top of the back wall to the mixing and cracking zones, where they must be broken down into their constituent elements. Finally the gases must pass into the afterburner chamber where they must be burned in the flame of a natural gas fired burner in the presence of excess air;

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- (d) Each process unit must have two burners and two secondary air fans for back-up in case of burner or fan failure. The secondary chamber must be designed to give a minimum residence time of two seconds at a temperature of at least 950 °C under all conditions of combustion;
- (e) On leaving the secondary chamber the exhaust gases must pass through a barometric damper at the base of the stack, which cools and dilutes them with ambient air, maintaining a constant pressure in the primary and secondary chambers;
- (f) The process must be carried out over a 24-hour cycle, which includes loading, processing, cool down and ash removal. At the end of the cycle the residual ash must be removed from the primary chamber by a vacuum extraction system into enclosed bags and sealed before transporting;
- (g) The gasification of material other than animal by-products must not be permitted.

F. Combustion of animal fat in a thermal boiler process

1. Starting material

For this process, a fat fraction derived from animal by-products of all categories may be used.

2. Processing method

Combustion of animal fat in a thermal boiler shall be carried out according to the following processing standards:

- (a) Unless fish oil or rendered fat are used which has been produced in accordance with Sections VIII or XII of Annex III to Regulation (EC) No 853/2004, respectively, the fat fraction derived from animal by-products must first be processed using:
 - (i) in the case of fat fraction of Category 1 and 2 materials which is intended to be combusted in another plant,
 - for the fat fraction from the processing of ruminants which have been tested with a negative result in accordance with Article 6(1) of Regulation (EC) No 999/2001 and from the processing of animals, other than ruminants which require TSE testing, any of the processing methods 1 to 5 as set out in Chapter III of this Annex.
 - for the fat fraction from the processing of other ruminants, processing method 1 as referred in Chapter III; and
 - (ii) in the case of Category 1 and 2 materials intended for combustion within the same plant and in the case of Category 3 material, any of the processing methods 1 to 5 or processing method 7; in the case the materials are derived from fish, processing methods 1 to 7 as set out in Chapter III;
- (b) The fat fraction must be separated from the protein and in the case of fat from ruminant origin which is intended to be combusted in another plant, insoluble impurities in excess of 0,15 % by weight must be removed;
- (c) Following the process referred to in points (a) and (b), the fat must be:
 - (i) vaporised in a steam-raising boiler and combusted at a temperature of at least 1 100 °C for at least 0,2 seconds; or
 - (ii) processed using equivalent process parameters authorised by the competent authority;

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- (d) The combustion of material of animal origin other than animal fat must not be permitted;
- (e) The combustion of the fat derived from Category 1 and Category 2 materials shall take place in the same plant where the fat is rendered with the aim of utilising the energy generated for the rendering processes. However, the competent authority may authorise the movement of that fat to other plants for combustion provided that:
 - (i) the plant of destination is authorised for the combustion;
 - (ii) the processing of food or feed in an approved plant on the same premises takes place under strict conditions of separation;
- (f) The combustion must be carried out in accordance with Union legislation for the protection of the environment, in particular, with reference to the standards of that legislation regarding best available techniques for the control and monitoring of emissions.

G. Thermomechanical biofuel production process

1. Starting material

For this process, manure and digestive tract content and Category 3 material may be used.

2. Processing method

Thermomechanical biofuel production shall be carried out according to the following processing standards:

- (a) The animal by-products must be loaded into a converter and subsequently treated at a temperature of 80 °C for a period of eight hours. During this period, the material must be constantly reduced in size using appropriate mechanical abrasion equipment.
- (b) The material must be subsequently treated at a temperature of 100 °C for at least two hours.
- (c) The particle size of the resulting material must not be larger than 20 millimetres;
- (d) The animal by-products must be treated in such a manner that the requirements regarding time, temperature and pressure set out in points (a) and (b) are achieved at the same time;
- (e) During the heat treatment of the material, evaporated water must be continually extracted from the air-space above the biofuel and must be passed through a stainless steel condenser. The condensate must be kept at a temperature of at least 70 °C for at least one hour before being discharged as wastewater;
- (f) After the heat treatment of the material, the resulting biofuel from the converter must then be discharged and automatically conveyed by a fully covered and interlocked conveyor to incineration or co-incineration on the same site;
- (g) The process must be carried out in a batch mode.

²H. Hydrolysis with subsequent disposal

1. Member States concerned

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Status: Point in time view as at 23/02/2015.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011, ANNEX IV. (See end of Document for details)

2. Starting materials

.....

3. Methodology

.....

Textual Amendments

F2 Deleted by Commission Regulation (EU) 2015/9 of 6 January 2015 amending Regulation (EU) No 142/2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (Text with EEA relevance).

[^{F3}I. Lime treatment for pig and poultry manure

1. Starting materials

For this process, manure, as referred to in Article 9(a) of Regulation (EC) No 1069/2009, of pig and poultry origin may be used.

2. Processing method

(a) The dry matter content of the manure must be determined by using the CEN EN 12880:2000⁽¹⁾ method 'Characterization of sludges. Determination of dry residue and water content'.

For this process, the dry matter content must be between 15 % and 70 %.

(b) The amount of lime which has to be added must be determined in such way that one of the combinations of time and temperature set out in point (f) is achieved.

(c) The particle size of the animal by-products to be processed must be no greater than 12 mm.

If necessary, the particles of the manure must be reduced in size in such a way that that maximum particle size is achieved.

(d) The manure must be mixed with quick lime (CaO) which has a medium to high reactivity of less than six minutes to achieve a 40 °C rise in temperature as per the criteria in the reactivity test 5.10 in the CEN EN 459-2:2002 method⁽²⁾.

The mixing must be carried out with two mixers which are operating in line, with two screws per mixer.

Both mixers must:

- (i) have a screw diameter of 0,55 m and a screw length of 3,5 m;
- (ii) operate with a power of 30 kW and a rotation speed of the screw of 156 rpm;
- (iii) have a treatment capacity of 10 tonnes per hour.

The mean blending duration must be approximately two minutes.

Status: Point in time view as at 23/02/2015.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011, ANNEX IV. (See end of Document for details)

- (e) The mixture must be mixed for a period of at least six hours into a stockpile with a minimum size of two tonnes.
- (f) At monitoring points which must be introduced into the stockpile, continuous measurements must be carried out to demonstrate that the mixture in the stockpile reaches a pH of at least 12 during one of the following periods of time, during which period one of the corresponding following temperatures must be achieved:
 - (i) 60 °C for 60 minutes; or
 - (ii) 70 °C for 30 minutes.
- (g) The process must be carried out in a batch mode.
- (h) A permanent written procedure based on the HACCP principles must be put in place.
- (i) Operators may demonstrate to the competent authority, by way of a validation according to the following requirements, that a process using a mixing device which is different from the mixing device referred to in point (d) or using dolime (CaOMgO) instead of quick lime is at least as efficient as the process set out in points (a) to (h):

That validation must:

- demonstrate that by using the different mixing device to that referred to in point (d) or the dolime, as applicable, a mixture with manure can be produced which achieves the parameters for pH, time and temperature referred to in point (f);
- be based on monitoring of time and temperature at the base, the middle and at the top of the stockpile, with a representative number of monitoring points (at least four monitoring points in the basal zone, which are located at a maximum of 10 cm above the base and at a maximum of 10 cm below the top, one monitoring point in the middle half way between base and the top of stockpile, and four monitoring points in the marginal zone at the top of the pile, which are located at a maximum of 10 cm below the surface and at a maximum of 10 cm below the top of the stockpile);
- be carried out during two periods of at least 30 days, of which one must be in the cold season of the year at the geographical place where the mixing device is to be used.

Textual Amendments

F3 Inserted by [Commission Regulation \(EU\) No 749/2011 of 29 July 2011 amending Regulation \(EU\) No 142/2011 implementing Regulation \(EC\) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive \(Text with EEA relevance\).](#)

- J. Multi-step catalytic process for the production of renewable fuels
 - 1. Starting materials
 - (a) For this process, the following materials may be used:
 - (i) rendered fats derived from Category 2 material, which have been processed using processing method 1 (pressure sterilisation);
 - (ii) fish oil or rendered fats derived from Category 3 material, which have been processed using:
 - any of the processing methods 1 to 5 or processing method 7; or

Status: Point in time view as at 23/02/2015.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011, ANNEX IV. (See end of Document for details)

- in the case of material derived from fish oil, any of the processing methods 1 to 7;
 - (iii) fish oil or rendered fat which have been produced in accordance with Sections VIII or XII of Annex III to Regulation (EC) No 853/2004, respectively.
 - (b) The use of rendered fats derived from Category 1 material for this process shall be prohibited.
2. Processing method
- (a) The rendered fat must be submitted to a pre-treatment which consists of:
 - (i) the bleaching of the centrifuged materials by passing them through a clay filter;
 - (ii) the removal of remaining insoluble impurities by filtration.
 - (b) The pre-treated materials must be submitted to a multi-step catalytic process which consists of a hydro-deoxygenisation step, followed by an isomerisation step.

The materials must be submitted to a pressure of at least 20 bars at a temperature of at least 250 °C for at least 20 minutes.]

[^{F4}K. Ensilage of fish material

1. Starting materials

For this process, only the following by-products obtained from aquatic animals may be used:

- (a) Category 2 materials referred to in Article 9(f)(i) and (iii) of Regulation (EC) No 1069/2009;
- (b) Category 3 materials.

2. Processing method

- 2.1. The materials to be treated shall be collected at aquaculture farms and food processing establishments on a daily basis and without undue delays, ground or chopped, and thereafter subjected to ensiling at a pH of 4 or below, with formic acid or other organic acid authorised in accordance with the feed legislation. The resulting fish silage must be a suspension of parts of aquatic animals liquefied by the action of endogenous enzymes in the presence of the added acid. The proteins of aquatic animals must be reduced into smaller soluble units, by the enzymes and the acid, in order to prevent microbial spoilage. The ensiled material is transported to the processing plant.
- 2.2. At the processing plant the ensiled material of aquatic animals must be piped into closed storage tanks. The incubation time must be at least 24 hours at a pH of 4 or below before heat treatment can be conducted. Before the heat treatment the ensilage of aquatic animals must have a pH of 4 or below and have a particle size of less than 10 mm following a filtration or maceration at the plant. During processing it must be subjected to preheating to a temperature above 85 °C, followed by incubation in an insulated container to obtain 85 °C throughout the fish material for 25 minutes. The process must take place in a closed production line with tanks and pipelines.
- 2.3. Before authorisation is given, the operator's permanent written procedure referred to in Article 29(1) to (3) of Regulation (EC) No 1069/2009 must be assessed by the competent authority.]

Status: Point in time view as at 23/02/2015.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011, ANNEX IV. (See end of Document for details)

Textual Amendments

- F4** Inserted by Commission Regulation (EU) 2015/9 of 6 January 2015 amending Regulation (EU) No 142/2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (Text with EEA relevance).

Section 3

Disposal and use of derived products

1. Products derived from the processing of:
 - (a) Category 1 material shall be:
 - (i) disposed of in accordance with Article 12(a) or (b) of Regulation (EC) No 1069/2009;
 - (ii) disposed of by burial in an authorised landfill;
 - (iii) [^{F5}transformed into biogas. In such case the digestion residues must be disposed of in accordance with point (i) or (ii), except where the material results from processing in accordance with point 2(a) or (b) where the residues can be used in accordance with the conditions set out in point 2(a) or point 2(b)(iii) as appropriate; or]
 - (iv) further processed into fat derivatives for uses other than feeding.
 - (b) Category 2 or Category 3 material shall be:
 - (i) [^{F5}disposed of as provided for in point 1(a)(i) or (ii), with or without prior processing as provided for in Article 13(a) and (b) and Article 14(a) and (b) of Regulation (EC) No 1069/2009;]
 - (ii) further processed into fat derivatives for uses other than feeding;
 - (iii) used as an organic fertiliser or soil improver; or
 - (iv) composted or transformed into biogas.

Textual Amendments

- F5** Substituted by Commission Regulation (EU) No 294/2013 of 14 March 2013 amending and correcting Regulation (EU) No 142/2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (Text with EEA relevance).

2. Materials resulting from processing in accordance with:
 - (a) the alkaline hydrolysis process defined in point A of Section 2 may be transformed in a biogas plant and subsequently combusted rapidly at a minimum of 900 °C, followed

Status: Point in time view as at 23/02/2015.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011, ANNEX IV. (See end of Document for details)

- by rapid chilling ('quenching'); where material referred to in Article 8(a) and (b) of Regulation (EC) No 1069/2009 has been used as starting material, the transformation into biogas shall take place on the same site as the processing and in a closed system;
- (b) the biodiesel production process may be:
- (i) in the case of biodiesel and of residues from the distillation of biodiesel, used as a fuel without restrictions under this Regulation (end point);
 - (ii) [^{F5}in the case of potassium sulphate, used for direct application to land or for the production of derived products for application to land;
 - (iii) in the case of glycerine derived from Categories 1 and 2 material which has been processed in accordance with processing method 1 as set out in Chapter III:
 - used for technical purposes,
 - transformed into biogas, in which case the digestion residues may be applied to land within the national territory of the producing Member State, subject to the decision of the competent authority, or
 - used for denitrification in a waste water treatment plant, in which case the residues of the denitrification may be applied to land in accordance with Council Directive 91/271/EEC⁽³⁾;
 - (iv) in the case of glycerine derived from Category 3 material:
 - used for technical purposes,
 - transformed into biogas, in which case the digestion residues may be applied to land, or
 - used for feeding, provided that the glycerine is not derived from Category 3 material referred to in Article 10(n), (o) and (p) of Regulation (EC) No 1069/2009;]
- (c) [^{F3}the multi-step catalytic process for the production of renewable fuels may be:
- (i) in the case of gasoline and the other fuels resulting from the process, used as a fuel without restrictions under this Regulation (end point);
 - (ii) in the case of used clay from bleaching and sludge from the pre-treatment process referred to in point J(2)(a) of Section 2:
 - disposed of by incineration or co-incineration,
 - transformed into biogas,
 - composted or used for the manufacture of derived products referred to in Article 36(a)(i) of Regulation (EC) No 1069/2009;]
- (d) [^{F6}the lime-treated mixture of pig and poultry manure may be applied to land as processed manure;]
- (e) [^{F4}The final product derived from the ensilaging of fish material may:
- (i) for Category 2 materials, be used for purposes referred to in Article 13(a) to (d) and (g) to (i) of Regulation (EC) No 1069/2009 without further processing or as feed for animals referred to in Article 18 or Article 36(a)(ii) of that Regulation; or

Status: Point in time view as at 23/02/2015.

*Changes to legislation: There are currently no known outstanding effects for the
Commission Regulation (EU) No 142/2011, ANNEX IV. (See end of Document for details)*

- (ii) for Category 3 materials, be used for purposes referred to in Article 14 of Regulation (EC) No 1069/2009.]

Textual Amendments

- F6** Substituted by [Commission Regulation \(EU\) 2015/9 of 6 January 2015 amending Regulation \(EU\) No 142/2011 implementing Regulation \(EC\) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive \(Text with EEA relevance\).](#)

- [^{F53}. Any waste other than animal by-products and derived products provided for in point 2, resulting from the processing of animal by-products in accordance with this Section, such as sludge, filter contents, ash and digestion residues, shall be disposed of in accordance with Regulation (EC) No 1069/2009 and with this Regulation.]

Status: Point in time view as at 23/02/2015.

Changes to legislation: There are currently no known outstanding effects for the
Commission Regulation (EU) No 142/2011, ANNEX IV. (See end of Document for details)

- (1) [^{F3}BS EN 12880:2000, Characterization of sludges. Determination of dry residue and water content. European Committee for Standardisation,]
- (2) [^{F3}CEN EN 459-2:2002 method CEN/TC 51 - Cement and building limes. European Committee for Standardisation,]
- (3) [^{F5}OJ L 135, 30.5.1991, p. 40.]

Textual Amendments

- F3** Inserted by Commission Regulation (EU) No 749/2011 of 29 July 2011 amending Regulation (EU) No 142/2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (Text with EEA relevance).
- F5** Substituted by Commission Regulation (EU) No 294/2013 of 14 March 2013 amending and correcting Regulation (EU) No 142/2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (Text with EEA relevance).

Status:

Point in time view as at 23/02/2015.

Changes to legislation:

There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011, ANNEX IV.