
Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011, Division Section 2. (See end of Document for details)

ANNEX IV

PROCESSING

CHAPTER IV

ALTERNATIVE PROCESSING METHODS

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

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- (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

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

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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:
 - (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 gasifier 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;

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- (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;
- (d) ^[F1]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 850 °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.

Textual Amendments

F1 Substituted by [Commission Regulation \(EU\) 2020/762 of 9 June 2020 amending Regulation \(EU\) No 142/2011 as regards microbiological standards for raw petfood, requirements concerning approved establishments, technical parameters applicable to the alternative method Brookes' gasification process and hydrolysis of rendered fats, and exports of processed manure, certain blood, blood products and intermediate products \(Text with EEA relevance\).](#)

- 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

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- (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;
- (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 [F2retained EU law] 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.

Textual Amendments

F2 Words in Regulation substituted (E.W.S.) (31.12.2020) by [The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1388\)](#), regs. 1(2)(c), **13(2)(a)**

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.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011, Division Section 2. (See end of Document for details)

- (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.

^{F3}H. Hydrolysis with subsequent disposal

1. Member States concerned

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2. Starting materials

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3. Methodology

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Textual Amendments

F3 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).

[^{F4}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 %.

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- (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.

- (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

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- 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

F4 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
 - 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.]

[^{F5}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;

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011, Division Section 2. (See end of Document for details)

- (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.]

Textual Amendments

- F5** 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 \(Text with EEA relevance\).](#)

[^{F6}L. Multiple-step catalytic hydro-treatment for the production of renewable fuels

1. Starting materials

For this process, the following materials may be used:

- (a) rendered fats derived from Category 1 material, which have been processed using processing method 1 (pressure sterilisation);
- (b) rendered fats and fish oil complying with point J(1)(a) of this Section.

2. Processing method

- (a) The rendered fat must be submitted to a pre-treatment which consists at least of bleaching of the starting material, including rendered fats, with acid in the presence of bleaching clay and subsequent removal of the used bleaching clay and insoluble impurities by filtration.

Prior to this treatment rendered fat may be degummed with acid and/or caustic solution in order to remove impurities from the rendered fat by forming gums and subsequently separating those gums by centrifugation.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011, Division Section 2. (See end of Document for details)

- (b) The pre-treated materials must be submitted to a hydro-treatment process which consists of a catalytic hydro-treatment step, a stripping step followed by an isomerisation step.

The materials must be submitted to a pressure of at least 30 bars at a temperature of at least 265 °C for at least 20 minutes.]

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Textual Amendments

- F6** Inserted by [Commission Regulation \(EU\) 2017/1261](#) of 12 July 2017 amending Regulation (EU) No 142/2011 as regards an alternative method for processing certain rendered fats (Text with EEA relevance).

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011, Division Section 2. (See end of Document for details)

- (1) [^{F4}BS EN 12880:2000, Characterization of sludges. Determination of dry residue and water content. European Committee for Standardisation,]
- (2) [^{F4}CEN EN 459-2:2002 method CEN/TC 51 - Cement and building limes. European Committee for Standardisation,]

Textual Amendments

- F4** 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).

Changes to legislation:

There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011, Division Section 2.