

COMMISSION REGULATION (EC) No 92/2005**of 19 January 2005****implementing Regulation (EC) No 1774/2002 of the European Parliament and of the Council as regards means of disposal or uses of animal by-products and amending its Annex VI as regards biogas transformation and processing of rendered fats****(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal-by-products not intended for human consumption⁽¹⁾, and in particular Article 4(2)(e), Article 5(2)(g), Article 6(2)(i) and Article 32(1) thereof,

Whereas:

- (1) Regulation (EC) No 1774/2002 provides for rules concerning the means of disposal and uses of animal by-products. It also provides for the possibility for additional means of disposal and uses of animal by-products to be approved following consultation of the appropriate scientific committee.
- (2) The Scientific Steering Committee (SSC) issued an opinion on 10 and 11 April 2003 on six alternative processing methods for safe treatment and disposal of animal by-products. According to that opinion five processes are considered as safe for the disposal of and/or uses of Categories 2 and 3 material under certain conditions.
- (3) The SSC issued a final opinion and report on 10 and 11 April 2003 on a treatment of animal waste by means of high temperature and high pressure alkaline hydrolysis, providing guidance on the possibilities to use alkaline hydrolysis and on its risks for the disposal of Categories 1, 2 and 3 material.
- (4) The European Food Safety Authority (EFSA) issued an opinion on 26 and 27 November 2003 on the process of High Pressure Hydrolysis Biogas (HPHB) providing guidance on the possibilities to use this process and on its risks for the disposal of Category 1 material.
- (5) Five processes may, therefore, be approved as alternative means for the disposal and/or uses of animal by-products in line with the SSC opinions, in addition to those processing methods already provided for by Regulation (EC) No 1774/2002. It is also appropriate to lay down the conditions for the use of those processes.
- (6) The Commission has asked some of the applicants for approval of the processes to submit further information regarding the safety of their processes for the treatment and disposal of Category 1 material. That information is to be forwarded to the European Food Safety Authority for evaluation in due course.
- (7) Pending that evaluation, and considering current SSC opinions that tallow is safe as regards TSE, especially if it is pressure-cooked and filtered to remove insoluble impurities, it is appropriate to approve one of the processes, which processes animal fat into biodiesel, also for treatment and disposal, under strict conditions, of most Category 1 material, except for the most risky. In that case, it should be made clear that the treatment and disposal may include the recovery of bioenergy.
- (8) The approval and the operation of such alternative means should be without prejudice to other applicable EU legislation, in particular environmental legislation, and therefore the operating conditions established in this Regulation should, where applicable, be implemented according to Article 6 paragraph 4 of Directive 2000/76/EC of the European Parliament and of the Council of 4 December 2000⁽²⁾ on the incineration of waste.
- (9) For processes approved for the treatment of Category 1 animal by-products, and as a surveillance measure complementary to the regular monitoring of processing parameters, the efficacy of the process, together with its safety with regard to animal and public health, should be demonstrated to the competent authorities by testing in a pilot plant during the first two years following the implementation of the process within each Member State concerned.
- (10) It is appropriate to amend Annex VI, Chapters II and III of Regulation (EC) No 1774/2002 as a consequence of approving the transformation of Category 1 animal by-products.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

⁽¹⁾ OJ L 273, 10.10.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 668/2004 (OJ L 112, 19.4.2004, p. 1).

⁽²⁾ OJ L 332, 28.12.2000, p. 91.

HAS ADOPTED THIS REGULATION:

Article 1

Treatment and disposal of Category 1 material

1. The processes of alkaline hydrolysis as defined in Annex I and of high pressure hydrolysis biogas as defined in Annex III are approved and may be authorised by the competent authority for the treatment and disposal of Category 1 material.

2. The process of biodiesel production as defined in Annex IV is approved and may be authorised by the competent authority for the treatment and disposal of Category 1 material, except for material referred to in Article 4(1)(a)(i) and (ii) of Regulation (EC) No 1774/2002.

However, material derived from animals referred to in Article 4(1)(a)(ii) may be used for this process provided that:

- (a) the animals were below 24 months of age at the time they were killed; or
- (b) the animals were subjected to laboratory testing for the presence of a TSE pursuant to Regulation (EC) No 999/2001 of the European Parliament and of the Council⁽¹⁾ and the result of the testing was negative.

The competent authority may also authorise this process for the treatment and disposal of any Category 1 processed animal fat.

Article 2

Treatment and use or disposal of Categories 2 or 3 material

The processes of alkaline hydrolysis, high pressure high temperature hydrolysis, high pressure hydrolysis biogas, biodiesel production and Brookes gasification as defined in Annexes I to V respectively are approved and may be authorised by the competent authority for the treatment and use or disposal of Categories 2 or 3 material.

Article 3

Conditions for implementing the processes defined in Annexes I to V

The competent authority shall approve the plants which use one of the processes described in Annexes I to V once it has authorised the process, if the plant complies with the technical specifications and parameters in the relevant Annex,

⁽¹⁾ OJ L 147, 31.5.2001, p. 1.

and with the conditions laid down in Regulation (EC) No 1774/2002, except for the technical specifications and parameters laid down in that Regulation for other processes. For this purpose the person responsible for the plant shall demonstrate to the competent authority that all technical specifications and parameters established in the relevant Annex are met.

Article 4

Marking and further disposal or use of resulting materials

1. Resulting materials shall be permanently marked, where technically possible with smell in accordance with Annex VI, Chapter I, point 8 of Regulation (EC) No 1774/2002.

However, in the case where the by-products being processed are exclusively Category 3 material, and where the resulting materials are not intended for disposal as waste, no such marking shall be required.

2. Materials resulting from the treatment of Category 1 material shall be disposed of as waste by:

- (a) incineration or co-incineration in accordance with the provisions of Directive 2000/76/EC on the incineration of waste;
- (b) burial in a landfill approved under Council Directive 1999/31/EC⁽²⁾ on the landfill of waste; or
- (c) further transformation in a biogas plant and disposal of the digestion residues as provided for in points (a) or (b).

3. Materials resulting from the treatment of Category 2 or 3 materials shall be:

- (a) disposed of as waste as provided for in paragraph 2;
- (b) further processed into fat derivatives for the uses mentioned in Article 5(2)(b)(ii) of Regulation (EC) No 1774/2002, without the prior use of processing methods 1 to 5; or
- (c) used, transformed or disposed of directly as provided for in Article 5(2)(c)(i), (ii) and (iii) of Regulation (EC) No 1774/2002, without the prior use of processing method 1.

4. Any resulting waste, such as sludge, filter contents, ash and digestion residues, derived from the production process, shall be disposed of as provided for in paragraph 2, points (a) or (b).

⁽²⁾ OJ L 182, 16.7.1999, p. 1.

*Article 5***Additional surveillance on initial implementation**

1. The following provisions shall apply for the first two years of implementation of the following processes in each Member State, for the treatment of animal by-products referred to in Article 4 of Regulation (EC) No 1774/2002:

- (a) alkaline hydrolysis as defined in Annex I;
- (b) high pressure hydrolysis biogas as defined in Annex III; and
- (c) biodiesel production as defined in Annex IV.

2. The operator or supplier of the process shall designate a pilot plant in each Member State where, at least annually, tests shall be undertaken to reconfirm the efficacy of the process with regard to animal and public health.

3. The competent authority shall ensure that:

- (a) suitable tests are applied in the pilot plant to the materials derived from the treatment steps, such as the liquid and solid residues, and any gas generated during the process; and
- (b) the official control of the pilot plant include a monthly inspection of the plant and a verification of the processing parameters and conditions applied.

At the end of each of the two years the competent authority shall report to the Commission the results of the surveillance, and any practical operating difficulties encountered.

*Article 6***Amendment of Annex VI of Regulation (EC) No 1774/2002**

Chapters II and III of Annex VI of Regulation (EC) No 1774/2002 shall be amended as follows:

1. In Chapter II, point B, at the end of number 4, the following sentence is added:

'However, resulting materials from the processing of Category 1 material may be transformed in a biogas plant, provided that the processing was done pursuant to an alternative method approved in accordance with Article 4(2)(e) and, except as otherwise specified, the biogas production is part of that alternative method and the resulting material is disposed of in accordance with the conditions laid down for the alternative method.'

2. At the end of Chapter III, the following sentence is added:

'However, other processes may be used for further processing of animal fats derived from Category 1 material, provided these processes are approved as alternative method in accordance with Article 4(2)(e).'

*Article 7***Entry into force and applicability**

This Regulation shall enter into force on the third day following that of its publication in the *Official Journal of the European Union*.

It shall apply no later than 1 January 2005.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 19 January 2005.

For the Commission

Markos KYPRIANOU

Member of the Commission

ANNEX I

ALKALINE HYDROLYSIS PROCESS

1. Alkaline hydrolysis means treatment of animal by-products under the following conditions:

- (a) Either a sodium hydroxide (NaOH) or potassium hydroxide (KOH) solution (or a combination thereof) is 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 is adjusted to the current fat content of the material.

- (b) The animal by-products and alkali mixture are 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 4(1)(a)(i) and (ii) of Regulation (EC) No 1774/2002. However, material derived from animals referred to in Article 4(1)(a)(ii) may be processed in accordance with point 1(b)(i) provided that:

— the animals were below 24 months of age at the time they were killed, or

— the animals were subjected to laboratory testing for the presence of a TSE pursuant to Regulation (EC) No 999/2001 and the result of the testing was negative, or

- (iii) one hour without interruption in case of animal by-products consisting exclusively of fish or of poultry materials.

- (c) The process is carried out in a batch and the material in the vessel is constantly mixed; and

- (d) The animal by-products are treated in such a manner that the time-temperature-pressure requirements are achieved at the same time.

2. Animal by-products are placed in a steel alloy container. The measured amount of alkali is added either in solid form or as a solution as referred to in point 1(a). The vessel is closed and the content heated in accordance with point 1(b). The physical energy generated by a constant pumping action continually circulates the liquid material present in the vessel thereby aiding the digestion process until the tissues are dissolved and bones and teeth softened.

3. Following the treatment described above, resulting materials may be transformed in a biogas plant provided that:

- (a) Transformation in a biogas plant of material referred to in Article 4(1)(a) and (b) of Regulation (EC) No 1774/2002 and products derived therefrom takes place on the same site and in a closed system as the process described under points 1 and 2 above;

- (b) An appropriate gas clean-up system is in place to exclude contamination of the biogas with protein residues;

- (c) The biogas is combusted rapidly at a minimum of 900 °C, and followed by rapid chilling ('quenching').
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ANNEX II**HIGH PRESSURE HIGH TEMPERATURE HYDROLYSIS PROCESS**

1. High pressure high temperature hydrolysis process means treatment of animal by-products under the following conditions:
 - (a) The animal by-products are 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 is carried out in a batch and the material in the vessel is constantly mixed; and
 - (c) The animal by-products are treated in such a manner that the time-temperature-pressure requirements are achieved at the same time.
2. The basis of the technology is a high pressure, high temperature steam reactor. At these elevated pressures and temperatures the phenomena of hydrolysis occurs which fractures long chain molecules of the organic material into smaller fragments.

Animal by-products, including whole animal carcasses are placed in a container ('biolytic reactor'). The vessel is closed and the content heated in accordance with point 1(a). In the dehydration cycle the steam water is condensed and may be used for other purposes or may be discarded. Each cycle for one reactor takes approximately four hours.

ANNEX III**HIGH PRESSURE HYDROLYSIS BIOGAS PROCESS**

1. High pressure hydrolysis biogas process means treatment of animal by-products under the following conditions:
 - (a) The animal by-products are first processed using processing method 1 in a processing plant approved in accordance with Regulation (EC) No 1774/2002;
 - (b) Following the above process, the defatted materials are 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 is carried out in a batch or continuous system and the material is constantly mixed;
 - (d) The animal by-products are treated in such a manner that the time-temperature-pressure requirements are achieved at the same time; and
 - (e) The resulting material is then mixed with water and anaerobically fermented (biogas transformation) in a biogas reactor.
2. In case of treatment of Category 1 animal by-products:
 - (a) The entire process takes place on the same site and in a closed system;
 - (b) The biogas produced during the process is combusted rapidly in the same plant at a minimum of 900 °C followed by rapid chilling ('quenching'), and an appropriate gas clean-up system is in place to exclude contamination with protein residues of the biogas or the gases derived from its burning.
3. The process is designed to process material coming out of a conventional rendering plant using processing method 1. This material is treated in accordance with point (1) (b), subsequently mixed with water and submitted to biogas fermentation.

ANNEX IV

BIODIESEL PRODUCTION PROCESS

1. Biodiesel production means treatment of the fat fraction of animal by-products (animal fat) under the following conditions:
 - (a) The fat fraction of animal by-products is first processed using:
 - (i) processing method 1 as referred to in Annex V, Chapter III of Regulation (EC) No 1774/2002 in case of Category 1 or 2 materials; and
 - (ii) any of the processing methods 1 to 5 or 7 or, in the case of material derived from fish, method 6 as referred to in Annex V, Chapter III of Regulation (EC) No 1774/2002 in case of Category 3 materials;
 - (b) The processed fat is separated from the protein and insoluble impurities are removed to a level not exceeding 0,15 % in weight, and subsequently submitted to esterification and transesterification. However, esterification is not required for Category 3 processed fat. For esterification the pH is reduced to less than 1 by adding sulphuric acid (H_2SO_4 ; 1,2-2 molar) or an equivalent acid and the mixture is heated to 72 °C for 2 hours during which it is intensely mixed. Transesterification shall be carried out by increasing the pH to about 14 with 15 % potassium hydroxide (KOH; 1-3 molar) or with an equivalent base at 35 °C to 50 °C for at least 15 to 30 minutes. Transesterification shall be carried out twice under the conditions described above using a new base solution. This process is followed by refinement of the products including vacuum distillation at 150 °C, leading to biodiesel;
 - (c) In case of biodiesel resulting from the treatment of Category 1 material an appropriate gas clean-up system shall be in place to exclude emission of possible non-combusted protein residues when the biodiesel is combusted.
 2. Animal fat is processed for the production of biodiesel consisting of methyl esters of fatty acids. This is achieved by submitting the fat to esterification and/or transesterification. Subsequent refinement of the products including vacuum distillation leads to biodiesel, which is used as fuel for combustion.
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ANNEX V

BROOKES GASIFICATION PROCESS

1. Brookes gasification process means treatment of animal by-products under the following conditions:
 - (a) The afterburner chamber is warmed up using natural gas.
 - (b) The animal by-products are loaded into the primary chamber of the gasifier and the door is closed. The primary chamber has no burners and is heated instead by the transfer of heat by conduction from the afterburner, which is underneath the primary chamber. The only air admitted to the primary chamber is via three inlet valves mounted on the main door to enhance the efficiency of the process.
 - (c) The animal by-products are volatilised into complex hydrocarbons and the resultant gases pass from the primary chamber via a narrow opening at the top of the back wall to the mixing and cracking zones, where they are broken down into their constituent elements. Finally the gases pass into the afterburner chamber where they are burned in the flame of a natural gas fired burner in the presence of excess air.
 - (d) Each process unit has two burners and two secondary air fans for back-up in case of burner or fan failure. The secondary chamber is 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 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 is 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 is removed from the primary chamber by a vacuum extraction system into enclosed bags, which are then sealed before being transported off-site for disposal.
 2. The process employs high temperature combustion in excess oxygen to oxidise organic matter to CO₂, NO₂ and H₂O. A batch process is used with a prolonged residence time for the animal by-products of around 24hrs. The source of heat is a secondary chamber fired by natural gas, which is underneath the primary chamber (in which the tissue to be processed is placed). The gases produced as a result of the combustion process enter the secondary chamber where they are further oxidised. The gas stream has a minimum residence time of two seconds at a recommended temperature of 950 degrees centigrade. Subsequently the gases pass through a 'barometric damper' where they are mixed with ambient air.
 3. The gasification of other material than animal by-products is not permitted.
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