

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)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002⁽¹⁾, and in particular Article 5(2), Article 15(1)(c), the second subparagraph of Article 15(1), Article 20(10) and (11), the first and third subparagraphs of Article 41(3), Article 42(2) and Article 45(4) thereof,

Whereas:

- (1) Regulation (EC) No 1069/2009 lays down public and animal health rules for animal by-products and derived products, in order to prevent and minimise risks to public and animal health arising from those products. It also provides for the determination of an end point in the manufacturing chain for certain derived products beyond which they are no longer subject to the requirements of that Regulation.
- (2) Commission Regulation (EU) No 142/2011 of 25 February 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⁽²⁾, lays down implementing rules for Regulation (EC) No 1069/2009, including rules on the determination of end points for certain derived products.
- (3) Denmark has submitted a request for the determination of an end point for fish oil which is used for the

production of medicinal products. Since such fish oil is derived from Category 3 material and is processed under strict conditions, an end point for that oil should be determined. Article 3 of Regulation (EU) No 142/2011 and Annex XIII thereto should therefore be amended accordingly.

- (4) Regulation (EU) No 142/2011 carried on provisions introduced to implement Regulation (EC) No 1774/2002 and Commission Decision 2003/324/EC⁽³⁾ in particular allowing Estonia, Latvia and Finland the feeding of certain fur animals with processed animal protein derived from the bodies or parts of bodies of animals of the same species, in particular foxes. Annex II should be amended to allow feeding of such material to both commonly kept species, the Red fox (*Vulpes vulpes*), currently listed, and the Arctic fox (*Alopex lagopus*), as Decision 2003/324/EC has been repealed by Regulation (EU) No 142/2011.
- (5) Regulation (EC) No 1069/2009 lays down certain rules for pressure sterilisation and provides for implementing measures to be adopted for other processing methods, which have to be applied to animal by-products or derived products, so that no unacceptable risks to public and animal health arise when such products are used or disposed of. Accordingly, Annex IV to Regulation (EU) No 142/2011 sets out standard processing methods for processing plants and certain other plants and establishments.
- (6) Regulation (EC) No 1069/2009 allows for the disposal or use of animal by-products or derived products by way of alternative methods, provided that such methods have been authorised on the basis of an assessment of the capacity of those methods to reduce risks to public and animal health to a degree which is at least equivalent, for the relevant category of animal by-products, to the standard processing methods. Regulation (EC) No 1069/2009 also provides for a standard format for applications for alternative methods to be adopted. Accordingly, Annex IV to Regulation (EU) No 142/2011 sets out alternative processing methods for processing plants and certain other plants and establishments.

⁽¹⁾ OJ L 300, 14.11.2009, p. 1.

⁽²⁾ OJ L 54, 26.2.2011, p. 1.

⁽³⁾ OJ L 117, 13.5.2003, p. 37.

- (7) The European Food Safety Authority (EFSA) has adopted three opinions in relation to such alternative methods: a scientific opinion adopted on 21 January 2009 on the Project to study alternatives to carcass destruction systems using the bunker system ⁽¹⁾ (the bunker system project); a scientific opinion adopted on 8 July 2010 on Lime Treatment of Solid Pig and Poultry Manure ⁽²⁾; and a scientific opinion adopted 22 September 2010 on the Neste Oil Application for a new alternative method of disposal or use of Animal By-Products ⁽³⁾.
- (8) The bunker system project proposes the hydrolysis of pig cadavers and of other animal by-products from farmed pigs in a closed container on the site of a farm. After a defined period of time, the hydrolysed materials obtained are to be disposed of by incineration or by processing, in accordance with the health rules on animal by-products as a first option.
- (9) The bunker system project also proposes the crushing and the subsequent pasteurization of pig cadavers and of other animal by-products from farmed pigs as a second option, prior to their disposal.
- (10) In its opinion of 21 January 2009 on the bunker system project, EFSA concluded that the information provided was not a sufficient basis for considering the second option as a safe means of disposal of animal by-products from pigs. Regarding the first option, based on hydrolysis, EFSA was also not able to deliver a final assessment. However, EFSA indicated that the hydrolysed material would not pose an additional risk, provided it was further processed according to the health rules for Category 2 materials.
- (11) Therefore, the hydrolysis of animal by-products on the site of a holding should be permitted under conditions which prevent the transmission of diseases communicable to humans or animals and which avoid adverse effects to the environment. In particular, the hydrolysis should take place in a closed, leak-proof container which is separated from any farmed animals on the same site as a third option. However, since the hydrolysis methodology does not constitute a processing method, the specific conditions for the processing of animal by-products in such plants should not apply. The container should be regularly checked for the absence of corrosion, under official supervision, so that leakage of materials into the ground is prevented.
- (12) The ability of the hydrolysis methodology to reduce potential health risks has not yet been demonstrated. Therefore, any handling or use of the hydrolysed material, other than incineration or co-incineration, with or without prior processing, or disposal in an authorised landfill, composting or transformation into biogas, where the latter three options are each to be preceded by pressure sterilisation, should be prohibited.
- (13) Spain, Ireland, Latvia, Portugal and the United Kingdom have indicated an interest to allow their operators to use of the hydrolysis methodology. The competent authorities of those Member States have confirmed that strict controls over such operators are to be carried out in order to prevent potential health risks.
- (14) In its opinion of 8 July 2010 on a Lime Treatment of Solid Pig and Poultry Manure, EFSA concluded that the proposed mixing of lime with manure could be considered as a safe process for the inactivation of relevant bacterial and viral pathogens, in view of the intended application of the derived product, namely the mixture of lime with manure, to land. Since the application demonstrated the efficiency of the process only for a particular mixing device, EFSA recommended that when a different mixing device is to be used for the process, a validation should be carried out, on the basis of measurements of pH, time and temperature, to demonstrate that by using the different mixing device, an equivalent inactivation of pathogens is achieved.
- (15) A validation according to those principles should be carried out when quick lime (CaO), which was used for the process assessed by EFSA, is replaced by dolime (CaOMgO).
- (16) In its opinion of 22 September 2010 concerning a multi-step catalytic process for the production of renewable fuels, EFSA concluded that the process can be considered as safe, when rendered fats derived from Category 2 and Category 3 materials are used as starting materials and those rendered fats have been processed in accordance with the standard processing methods for animal by-products. However, the evidence presented did not allow a conclusion that the process is also capable of mitigating potential TSE risks which may be present in rendered fats derived from Category 1 materials. Therefore, the multi-step catalytic process should be authorised for rendered fats derived from Category 2 and Category 3 materials, while it should be rejected for rendered fats derived from Category 1 material. While such rejection does not prevent the applicant from submitting further evidence to EFSA for a new assessment, the use of rendered fats derived from Category 1 material for the process should be prohibited, pending such assessment.
- (17) Annex IV to Regulation (EU) No 142/2011 should be amended to take account of the conclusions of the three scientific opinions of the EFSA.

⁽¹⁾ EFSA Journal (2009) 971, 1-12.

⁽²⁾ EFSA Journal (2010); 8(7):1681.

⁽³⁾ EFSA Journal (2010); 8(10):1825.

- (18) Regulation (EC) No 1069/2009 provides for the adoption of implementing measures for the transformation of animal by-products into biogas or compost. When animal by-products are mixed in a biogas plant or in a composting plant with materials of non-animal origin or with other materials which are not covered by that Regulation, the competent authority should be allowed to authorise the taking of representative samples after pasteurisation and before the mixing takes place, in order to test their compliance with microbiological criteria. The taking of such samples should demonstrate whether the pasteurisation of animal by-products has mitigated microbiological risks in the animal by-products to be transformed.
- (19) Annex V of Regulation (EU) No 142/2011 should therefore be amended accordingly.
- (20) Regulation (EC) No 1069/2009 provides for the adoption of a standard format for applications for alternative methods of use or disposal of animal by-products or derived products. That format is to be used by interested parties when they submit an application for the authorisation of such methods.
- (21) On request of the Commission, EFSA adopted a scientific opinion on 7 July 2010 on a statement on technical assistance on the format for applications for new alternative methods for animal by-products⁽¹⁾. In that statement, EFSA recommends, in particular, further clarifications regarding the information which interested parties should supply when they submit an application for the authorisation of a new alternative method.
- (22) Taking account of the recommendations of that scientific opinion, the standard format for applications for new alternative methods set out in Annex VII to Regulation (EU) No 142/2011 should be amended.
- (23) Since renewable fuels from the multi-step catalytic process may also be produced from imported rendered fats, the import requirements for such fats and the conditions set out in the health certificate which must accompany consignments of rendered fats at the point of entry into the Union where the veterinary checks take place should be clarified. Annexes XIV and XV to Regulation (EU) No 142/2011 should therefore be amended accordingly.
- (24) Accordingly, Article 3 and Annexes II, IV, V, VII, VIII, XI and Annexes XIII to XVI should therefore be amended.
- (25) A transitional period should be provided for after the entry into force of this Regulation, in order to allow for the continued importation into the Union of rendered fats not intended for human consumption for certain purposes outside the feed chain, as provided for in Regulation (EU) No 142/2011 before the amendments introduced by this Regulation.
- (26) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EU) No 142/2011 is amended as follows:

(1) In Article 3, point (g) is replaced by the following:

- ‘(g) fur which fulfils the special requirements for the end point for that product set out in Chapter VIII of Annex XIII;
- (h) fish oil for the production of medicinal products which fulfils the special requirements for the end point for that product set out in Chapter XIII of Annex XIII;
- (i) gasoline and fuels which fulfil the specific requirements for products from the multi-step catalytic process for the production of renewable fuels set out in point 2(c) of Section 3 of Chapter IV of Annex IV.’

(2) Annexes II, IV, V, VII, VIII, XI and Annexes XIII to XVI are amended in accordance with the Annex to this Regulation.

Article 2

For a transitional period until 31 January 2012, consignments of rendered fats not intended for human consumption to be used for certain purposes outside the feed chain which are accompanied by a health certificate which has been signed and completed in accordance with the model set out in Chapter 10(B) of Annex XV to Regulation (EU) No 142/2011 before the date of entry into force of this Regulation, shall continue to be accepted for importation into the Union, provided that such certificates were completed and signed before 30 November 2011.

⁽¹⁾ EFSA Journal 2010; 8(7):1680.

Article 3

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

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

Done at Brussels, 29 July 2011.

For the Commission
The President
José Manuel BARROSO

ANNEX

Regulation (EU) No 142/2011 is amended as follows:

(1) In Annex II, Chapter I, point 1(a) is replaced by the following:

‘(a) foxes (*Vulpes vulpes* and *Alopex lagopus*);’

(2) In Annex IV, Chapter IV is amended as follows:

(a) In Section 1, point 1 is replaced by the following:

‘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.’

(b) In Section 2, the following points are added:

‘H. Hydrolysis with subsequent disposal

1. Member States concerned

The process of hydrolysis with subsequent disposal may be used in Spain, Ireland, Latvia, Portugal and the United Kingdom.

Following hydrolysis, the authorising competent authority must ensure that the materials are collected and disposed of within the same Member State referred to above.

2. Starting materials

For this process, only the following materials may be used:

- (a) Category 2 materials referred to in Article 9(f)(i), (ii) and (iii) of Regulation (EC) No 1069/2009 which are of porcine origin;
- (b) Category 3 materials referred to in Article 10(h) of that Regulation which are of porcine origin.

However, bodies or parts of bodies of animals that have died due to the presence of, or in order to eradicate an epizootic disease, may not be used

3. Methodology

Hydrolysis with subsequent disposal is a temporary storage on the spot. It shall be carried out according to the following standards:

- (a) Following their collection on a holding for which the competent authority has authorised the use of the processing method, based on an assessment of the animal density of the holding, the likely mortality rate and the potential risks for public and animal health which may arise, the animal by-products must be placed into a container which has been constructed in accordance with point (b) (“the container”) and which has been placed at a dedicated site in accordance with points (c) and (d) (“the dedicated site”).

- (b) The container must:
 - (i) have a device to close it;
 - (ii) be water-proof, leak-proof and hermetically sealed;
 - (iii) be coated in a way which prevents corrosion;
 - (iv) be equipped with a device for controlling emissions in accordance with point (e).
- (c) The container must be placed in a dedicated site which is physically separate from the holding.
That site must have dedicated access routes for the movement of materials and for collection vehicles.
- (d) The container and the site must be constructed and laid out in accordance with Union legislation for the protection of the environment, in order to prevent odours and risks to soil and groundwater.
- (e) The container must be linked to a pipe for gaseous emissions, which must be equipped with appropriate filters to prevent the transmission of diseases communicable to humans and animals.
- (f) The container must be closed for the process of hydrolysis for a period of at least three months, in such a way that any unauthorised opening is prevented.
- (g) The operator must put in place procedures to prevent the transmission of diseases communicable to humans or animals by movements of personnel.
- (h) The operator must:
 - (i) take preventive measures against birds, rodents, insects and other vermin;
 - (ii) put in place a documented pest control programme.
- (i) The operator must keep records of:
 - (i) any placing of material into the container;
 - (ii) any collection of hydrolysed material from the container.
- (j) The operator must empty the container at regular intervals for a check:
 - (i) for the absence of corrosion;
 - (ii) to detect and prevent possible leakage of liquid materials into the ground.
- (k) Following hydrolysis, the materials must be collected, used and disposed of in accordance with Article 13(a), (b), (c) or Article 13(e)(i) of Regulation (EC) No 1069/2009.
- (l) The process must be carried out in a batch mode.
- (m) Any other handling or use of the hydrolysed materials, including their application to land, shall be prohibited.

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 (*) 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 (**).

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 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.

- 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-deoxygenation 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.

(*) BS EN 12880:2000, Characterization of sludges. Determination of dry residue and water content. European Committee for Standardisation,

(**) CEN EN 459-2:2002 method CEN/TC 51 - Cement and building limes. European Committee for Standardisation,

- (c) In Section 3, point 2 is amended as follows:
- (i) The second indent of point (b)(iii) is replaced by the following:
 - ‘— derived from Category 3 material other than materials referred to in Article 10(p) of Regulation (EC) No 1069/2009, used for feeding;’
 - (ii) The following points are added:
 - ‘(c) 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) the lime treated mixture of pig and poultry manure may be applied to land as processed manure.’

(3) In Annex V, in Chapter III, in Section 3, the following point 3 is added:

'3. When animal by-products are transformed into biogas or composted together with materials which are not of animal origin, the competent authority may authorise operators to take representative samples after the pasteurisation referred to in point 1(a) of Section 1 of Chapter I or after composting referred to in point 1 of Section 2, as applicable, and before the mixing with materials which are not of animal origin takes place, in order to monitor the efficiency of the transformation or composting of the animal by-products, as applicable.'

(4) In Annex VII, in Chapter II, points 1, 2 and 3 are replaced by the following:

'1. Applications shall contain all the necessary information to allow EFSA to assess the safety of the proposed alternative method, and in particular describe:

- the categories of animal by-products intended to be submitted to the method,
- the entire process,
- the biological hazards for human and animal health involved, and
- the degree of risk reduction to be achieved by the process.

2. The application referred to in paragraph 1 shall moreover:

- (a) indicate the applicable points in Articles 8, 9 and 10 of Regulation (EC) No 1069/2009 including the physical status of those materials and, if applicable, any pre-treatment to which those materials have been submitted and indicating any materials other than animal by-products which are to be used in the process.
- (b) include a HACCP protocol and a flow diagram which clearly indicates the individual steps of the process, identifies the parameters critical for the inactivation of relevant pathogens such as temperature, pressure, exposure time, adjustment of the pH value and particle size and is complemented by technical data sheets of the equipment used during the process;
- (c) identify and characterize biological hazards for human and animal health represented by the categories of animal by-products intended to be submitted to the method;
- (d) show that the most resistant biological hazards associated with the category of materials to be processed are reduced in any products generated during the process, including the waste water, at least to the degree achieved by the processing standards laid down in this Regulation for the same category of animal by-products. The degree of risk reduction must be determined with validated direct measurements, unless modelling or comparisons with other processes are acceptable.

3. Validated direct measurements as referred to in paragraph 2(d) above shall mean:

- (a) measuring the reduction of viability/infectivity of: endogenous indicator organisms during the process, where the indicator is:
 - consistently present in the raw material in high numbers;
 - not less resistant to the lethal aspects of the treatment process, but also not significantly more resistant than the pathogens for which it is being used to monitor;
 - relatively easy to quantify, to identify and to confirm; or
- (b) using a well-characterised test organism or virus introduced in a suitable test body into the starting material.

If several treatment steps are involved, an assessment must be performed on the degree to which individual titre reduction steps are additive, or whether early steps in the process may compromise the efficacy of subsequent steps;

(c) reporting complete results by

- (i) describing in detail the used methodology;

- (ii) describing the nature of samples which have been analysed;
 - (iii) showing that the number of samples analysed is representative;
 - (iv) justifying the number of tests performed and the selection of measuring points;
 - (v) indicating the sensitivity and the specificity of the detection methods used;
 - (vi) providing data on the repeatability and statistical variability of the measurements obtained during the experiments;
 - (vii) justifying, if used the significance of prion surrogates;
 - (viii) showing, where in absence of direct measurements, models or comparisons with other processes are used, that the factors leading to risk reduction are well known and the model of risk reduction is well established;
 - (ix) providing data for the entire process on direct measurements of all factors leading to the risk reduction which demonstrate that these factors are homogeneously applied throughout the treated batch.
4. The HACCP plan referred to in paragraph 2(b) must be based on the critical parameters which are used to obtain the risk reduction, in particular:
- temperature,
 - pressure,
 - time, and
 - microbiological criteria.

The critical limits retained in the HACCP plan must be defined, based on the results of the experimental validation and/ or of the model provided.

If the successful functioning of the process can only be demonstrated with reference to technical parameters which are specifically related to the equipment used in the process, the HACCP plan must also include the technical limits which must be met, in particular energy uptake, number of pump strokes or dosage of chemicals.

Information must be given on the critical and technical parameters that are to be monitored and recorded in a continuous manner or after defined intervals and on the methods used for measuring and monitoring.

The variability of parameters under typical production conditions must be taken into account.

The HACCP plan must reflect normal and abnormal/ emergency operating conditions including a breakdown of the process and it must specify possible corrective actions which are to be applied in the case of abnormal/ emergency operating conditions.

5. The applications shall also contain sufficient information on:
- (a) the risks associated with interdependent processes, and in particular on the outcome of an evaluation of possible indirect impacts, which may:
 - (i) influence the level of risk reduction of a particular process;
 - (ii) arise from transport or storage of any products generated during the process and from the safe disposal of such products, including waste water.

- (b) the risks associated with the intended end use of the products, in particular:
- (i) the intended end use of any products generated during the process must be specified;
 - (ii) the likely risks for human health and animal health and possible impacts on the environment must be assessed on the basis of the risk reduction estimated in accordance with point 2(d).
6. Applications shall be submitted with documentary evidence, in particular:
- (a) a flow diagram showing the functioning of the process;
 - (b) the evidence referred to in point 2(d), as well as other evidence aiming to substantiate the information provided in the framework of the application as set out in point 2.
7. Applications shall include a contact address for the interested party, which shall include the name and full address, telephone and/or fax number and/or the electronic mail address of a particular person that is responsible as or on behalf of the interested party.'
- (5) Annex VIII is amended as follows:
- (a) In Chapter II, in point 2(b), (xvii) is replaced by the following:
 - '(xvii) in the case of display items, the words "display item not for human consumption", instead of the label text laid down in point (a);
 - (xviii) in the case of fish oil for the production of medicinal products referred to in Chapter XIII of Annex XIII, the words "fish oil for the production of medicinal products", instead of the label text laid down in point (a);
 - (xix) in the case of manure which has been subject to the lime treatment set out in point I of Section 2 of Chapter IV of Annex IV, the words "manure-lime-mixture".'
 - (b) In Chapter V, in point 3(d), (ii) is replaced by the following:
 - '(ii) intended for research and other specific purposes as referred to in Article 17 of Regulation (EC) No 1069/2009 which have been authorised by the competent authority;
 - (e) renewable fuels produced from rendered fats, which are derived from Category 2 materials, in accordance with point J of Section 2 of Chapter IV of Annex IV.'
- (6) In Annex XI, in Chapter I, in Section 2, the introductory phrase is replaced by the following:
- 'The placing on the market of processed manure, derived products from processed manure and guano from bats shall be subject to the following conditions. In addition, in the case of guano from bats the consent of the Member State of destination is required as referred to in Article 48(1) of Regulation (EC) No 1069/2009.'
- (7) In Annex XIII, the following Chapter XIII is added:

CHAPTER XIII

Specific requirements for fish oil for the production of medicinal products

End point for fish oil for the production of medicinal products

Fish oil derived from the materials referred to in point A.2 of Section 3 of Chapter II of Annex X, which has been de-acidified with a NaOH solution at a temperature of 80 °C or more and which has subsequently been purified by distillation at a temperature of 200 °C or more, may be placed on the market for the production of medicinal products without restrictions in accordance with this Regulation.'

(8) Annex XIV is amended as follows:

(a) Chapter I is amended as follows:

(i) Section 1 is amended as follows:

— in the introductory paragraph, point (e) is replaced by the following:

‘(e) they shall be presented at the point of entry into the Union where the veterinary checks take place accompanied by a document corresponding to the model referred to in the column “certificates/model documents” of Table 1;

(f) they must come from an establishment or plant which is registered or approved by the competent authority of the third country, as applicable, and which is on the list of such establishments and plants referred to in Article 30.’

— in Table 1, in row no 1, the product description in the second column is replaced by the following:

‘processed animal protein, including mixtures and products other than petfood containing such protein, and compound feeds containing such proteins as defined in Article 3(2)(h) of Regulation (EC) No 767/2009’.

(ii) In Section 2, the title is replaced by the following:

‘Imports of processed animal protein, including mixtures and products other than petfood containing such protein, and compound feeds containing such protein as defined in Article 3(2)(h) of Regulation (EC) No 767/2009’.

(b) Chapter II is amended as follows:

(i) Section 1 is amended as follows:

— in the introductory paragraph, point (d) and (e) are replaced by the following:

‘(d) they must come from an establishment or plant which is registered or approved by the competent authority of the third country, as applicable, and which is on the list of such establishments and plants referred to in Article 30; and

(e) they shall be accompanied during transportation to the point of entry into the Union where the veterinary checks take place by the health certificate referred to in the column “certificates/model documents” of Table 1; or

(f) they shall be presented at the point of entry into the Union where the veterinary checks take place accompanied by a document corresponding to the model referred to in the column “certificates/model documents” of Table 2.’

— in Table 2, row no 17 is replaced by the following:

<p>'17</p>	<p>Rendered fats for certain purposes outside the feed chain for farmed animals</p>	<p>(a) In the case of materials destined to the production of biodiesel: Category 1, 2 and 3 materials referred to in Articles 8, 9 and 10.</p> <p>(b) In the case of materials destined to the production of renewable fuels referred to in point J of Section 2 of Chapter IV of Annex IV: Category 2 and 3 materials referred to in Articles 9 and 10.</p> <p>(c) In the case of materials destined to organic fertilisers and soil improvers: Category 2 materials referred to in Article 9, points (c) and (d) and Article 9, point (f)(i) and Category 3 materials referred to in Article 10, other than in points (c) and (p).</p> <p>(d) In the case of materials destined to other purposes: Category 1 materials referred to in Article 8, points (b), (c) and (d), Category 2 materials referred to in Article 9, points (c), (d) and Article 9, point (f)(i) and Category 3 materials referred to in Article 10, other than in points (c) and (p).</p>	<p>The rendered fats shall comply with the requirements set out in Section 9.</p>	<p>Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010 and, in the case of fish materials, third countries listed in Annex II to Decision 2006/766/EC.</p>	<p>Chapter 10(B) of Annex XV.'</p>
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(ii) In Section 9, point (a)(iii) is replaced by the following:

‘(iii) in the case of materials destined to the production of renewable fuels referred to in point J of Section 2 of Chapter IV of Annex IV of this Regulation, Category 2 materials referred to in Article 9 of Regulation (EC) No 1069/2009 and Category 3 materials referred to in Article 10 of that Regulation;

(iv) in the case of other materials Category 1 materials referred to in points (b), (c) and (d) of Article 8 of Regulation (EC) No 1069/2009, Category 2 materials referred to in points (c) and (d) and point (f)(i) of Article 9 of Regulation (EC) No 1069/2009 or Category 3 materials, other than the materials referred to in points (c) and (p) of Article 10 of that Regulation;’

(9) In Annex XV, Chapter 10(B) is replaced by the following:

'CHAPTER 10(B)

Health certificate

For rendered fats not intended for human consumption to be used for certain purposes outside the feed chain, intended for dispatch to or for transit through ⁽²⁾ the European Union

COUNTRY:**Veterinary certificate to EU**

Part I: Details of dispatched consignment	I.1. Consignor Name Address Tel.		I.2. Certificate reference No		I.2.a.			
			I.3. Central competent authority					
			I.4. Local competent authority					
	I.5. Consignee Name Address Postal code Tel.		I.6. Person responsible for the load in EU Name Address Postal code Tel.					
	I.7. Country of origin ISO code		I.8. Region of origin Code		I.9. Country of destination ISO code		I.10. Region of destination Code	
	I.11. Place of origin Name Address Name Address Name Address		Approval number Approval number Approval number		I.12. Place of destination Name Address Postal code		Custom warehouse <input type="checkbox"/> Approval number	
	I.13. Place of loading		I.14. Date of departure					
	I.15. Means of transport Aeroplane <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/> Road vehicle <input type="checkbox"/> Other <input type="checkbox"/> Identification Documentation references		I.16. Entry BIP in EU		I.17.			
	I.18. Description of commodity				I.19. Commodity code (HS code)			
							I.20. Quantity	
	I.21. Temperature of product Ambient <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/>				I.22. Number of packages			
	I.23. Seal/Container No				I.24. Type of packaging			
	I.25. Commodities certified for: Technical use <input type="checkbox"/>							
I.26. For transit through EU to third country <input type="checkbox"/>		Third country		ISO code		I.27. For import or admission into EU <input type="checkbox"/>		
I.28. Identification of the commodities								
Species (Scientific name)		Nature of commodity		Approval number of establishments Manufacturing plant		Number of packages		
						Net weight		
						Batch number		

COUNTRY		Rendered fats not intended for human consumption for certain purposes outside the feed chain	
Part II: Certification	II. Health information	II.a. Certificate reference No	II.b.
		I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 ^(1a) and in particular Articles 8, 9 and 10 thereof, and Regulation (EU) No 142/2011 ^(1b) , and in particular Annex XIV, Chapter II thereof, and certify that the rendered fats described above:	
	II.1.	consist of rendered fats not intended for human consumption that satisfy the health requirements below;	
	II.2.	have been prepared exclusively with the following animal by-products:	
	II.2.1.	in the case of materials destined for the production of biodiesel, animal by-products referred to in Articles 8, 9 and 10 of Regulation (EC) No 1069/2009;	
	II.2.2.	in the case of materials destined for the production of renewable fuels referred to in point J of Section 2 of Chapter IV of Annex IV of Regulation (EU) No 142/2011, animal by-products referred to in Articles 9 and 10 of Regulation (EC) No 1069/2009;	
	II.2.3.	in the case of materials destined for other purposes:	
	(2)either	[- animal by-products containing residues of authorised substances or contaminants exceeding the permitted levels referred to in Article 15(3) of Directive 96/23/EC;]	
	(2)and/or	[- products of animal origin which have been declared unfit for human consumption due to the presence of foreign bodies in those products;]	
	(2)and/or	[- animals and parts of animals, other than those referred to in Articles 8 and 10 of Regulation (EC) No 1069/2009, that died other than being slaughtered or killed for human consumption, including animals killed for disease control purposes;]	
(2)and/or	[- carcasses and parts of animals slaughtered or, in the case of game, bodies or parts of animals killed, and which are fit for human consumption in accordance with Union legislation, but are not intended for human consumption for commercial reasons;]		
(2)and/or	[- carcasses and the following parts originating either from animals that have been slaughtered in a slaughterhouse and were considered fit for slaughter for human consumption following an ante-mortem inspection or bodies and the following parts of animals from game killed for human consumption in accordance with Union legislation:		
	(i) carcasses or bodies and parts of animals which are rejected as unfit for human consumption in accordance with Union legislation, but which did not show any signs of disease communicable to humans or animals;		
	(ii) heads of poultry;		
	(iii) hides and skins, including trimmings and splitting thereof, horns and feet, including the phalanges and the carpus and metacarpus bones, tarsus and metatarsus bones, of animals, other than ruminants;		
	(iv) pig bristles;		
	(v) feathers;]		
(2)and/or	[- blood of animals which did not show any signs of disease communicable through blood to humans or animals obtained from animals other than ruminants that have been slaughtered in a slaughterhouse after having been considered fit for slaughter for human consumption following an ante-mortem inspection in accordance with Union legislation;]		

COUNTRY **Rendered fats not intended for human consumption for certain purposes outside the feed chain**

II. Health attestation	II.a. Certificate reference No	II.b.
<p>(2)and/or [- animal by-products arising from the production of products intended for human consumption, including degreased bone, greaves and centrifuge or separator sludge from milk processing;]</p> <p>(2)and/or [- products of animal origin, or foodstuffs containing products of animal origin, which are no longer intended for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arise;]</p> <p>(2)and/or [- petfood and feeding stuffs of animal origin, or feeding stuffs containing animal by-products or derived products, which are no longer intended for feeding for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arises;]</p> <p>(2)and/or [- blood, placenta, wool, feathers, hair, horns, hoof cuts and raw milk originating from live animals that did not show signs of any disease communicable through that product to humans or animals;]</p> <p>(2)and/or [- aquatic animals, and parts of such animals, except sea mammals, which did not show any signs of diseases communicable to humans or animals;]</p> <p>(2)and/or [- animal by-products from aquatic animals originating from plants or establishments manufacturing products for human consumption;]</p> <p>(2)and/or [- the following material originating from animals which did not show any signs of disease communicable through that material to humans or animals:</p> <p style="padding-left: 40px;">(i) shells from shellfish with soft tissue or flesh;</p> <p style="padding-left: 40px;">(ii) the following originating from terrestrial animals:</p> <p style="padding-left: 80px;">— hatchery by-products,</p> <p style="padding-left: 80px;">— eggs,</p> <p style="padding-left: 80px;">— egg by-products, including egg shells,</p> <p style="padding-left: 40px;">(iii) day-old chicks killed for commercial reasons;]</p> <p>(2)and/or [- aquatic and terrestrial invertebrates other than species pathogenic to humans or animals;]</p> <p>(2)and/or [- animals and parts thereof of the zoological orders of Rodentia and Lagomorpha, except Category 1 material as referred to in Article 8(a)(iii), (iv) and (v) and Category 2 material as referred to in Article 9(a) to (g) of Regulation (EC) No 1069/2009;]</p> <p>(2)and/or [- hides and skins, hooves, feathers, wool, horns, hair and fur originating from dead animals that did not show any signs of disease communicable through that product to humans or animals;]</p> <p>(2)and/or [- adipose tissue from animals which did not show any signs of disease communicable through that material to humans or animals, which were slaughtered in a slaughterhouse and which were considered fit for slaughter for human consumption following an ante-mortem inspection in accordance with Union legislation;]</p>		
II.2.4.	in the case of materials destined for purposes other than the production of organic fertilisers or soil improvers or renewable fuels referred to in point J of Section 2 of Chapter IV of Annex IV of Regulation (EU) No 142/2011:	
(2)either	[- specified risk material as defined in Article 3(1)(g) of Regulation (EC) No 999/2001;]	

Rendered fats not intended for human consumption for certain purposes outside the feed chain

COUNTRY

II. Health information	II.a. Certificate reference No	II.b.
(2)and/or [- entire bodies or parts of dead animals containing specified risk material as defined in Article 3(1)(g) of Regulation (EC) No 999/2001 at the time of disposal;]		
(2)and/or [- animal by-products which have been derived from animals which have been submitted to illegal treatment as defined in Article 1(2)(d) of Directive 96/22/EC or Article 2(b) of Directive 96/23/EC;]		
(2)and/or [- animal by-products containing residues of other substances and environmental contaminants listed in Group B(3) of Annex I to Directive 96/23/EC, if such residues exceed the permitted levels laid down by Union legislation or, in the absence thereof, by legislation of the Member State of importation;]		
<p>II.3. the rendered fats:</p> <p>(a) have been subjected to processing in accordance with method as laid down in Chapter III of Annex IV to Regulation (EU) No 142/2011, in order to kill pathogenic agents,</p> <p>(b) have been marked before shipment to the European Union with glyceroltriheptanoate (GTH), so that a homogenous minimum concentration of at least 250 mg GTH per kilogram fat is achieved,</p> <p>(c) in the case of rendered fats of ruminant origin, insoluble impurities in excess of 0.15% in weight have been removed,</p> <p>(d) have been transported under conditions which prevent their contamination, and</p> <p>(e) bear labels on the packaging or container indicating 'NOT FOR HUMAN OR ANIMAL CONSUMPTION';</p>		
<p>II.4. in the case of materials destined for organic fertilisers or soil improvers or renewable fuels referred to in point J of Section 2 of Chapter IV of Annex IV to Regulation (EU) No 142/2011:</p> <p>(2)either [the product does not contain and is not derived from specified risk material as defined in Annex V to Regulation (EC) No 999/2001(3) or mechanically separated meat obtained from bones of bovine, ovine or caprine animals; and the animals from which this product is derived have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity.]</p> <p>(2)or [the product does not contain and is not derived from bovine, ovine or caprine materials other than those derived from animals born, continuously reared and slaughtered in a country or region classified as posing a negligible BSE risk by a decision in accordance with Article 5(2) of Regulation (EC) No 999/2001.]</p>		
<i>Notes</i>		
Part I:		
— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.		
— Box reference I.11 and I.12: Approval number: the registration number of the establishment or plant, which has been issued by the competent authority.		
— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for a transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.		
— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in case of unloading and reloading.		
— Box reference I.19: use the appropriate HS code: 15.02; 15.03; 15.04; 15.05; 15.06; 15.16.10; 15.17 or 15.18.		

COUNTRY **Rendered fats not intended for human consumption for certain purposes outside the feed chain**

II. Health information	II.a. Certificate reference No	II.b.
<p>— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be included.</p> <p>— Box reference I.25: technical use: any use other than for animal consumption.</p> <p>— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.</p> <p>— Box reference I.28: Manufacturing plant: provide the registration number of the treatment/processing establishment.</p> <p>Part II:</p> <p>(^{1a}) OJ L 300, 14.11.2009, p. 1.</p> <p>(^{1b}) OJ L 54, 26.2.2011, p. 1.</p> <p>(²) Delete as appropriate.</p> <p>(³) OJ L 147, 31.5.2001, p. 1.</p> <p>— The signature and the stamp must be in a different colour to that of the printing.</p> <p>— Note for the person responsible for the consignment in EU: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.</p>		
<p>Official veterinarian/Official inspector</p> <p>Name (in capital letters):</p> <p>Date:</p> <p>Stamp:</p> <p>Qualification and title:</p> <p>Signature:*</p>		

(10) In Annex XVI, in Chapter III, the following Section 11 is added:

'Section 11

Official controls regarding hydrolysis with subsequent disposal

The competent authority shall carry out controls at sites where hydrolysis with subsequent disposal is carried out in accordance with point H of Section 2 of Chapter IV of Annex IV.

Such controls shall, for the purpose of reconciliation of the quantities of hydrolysed materials dispatched and disposed of, include documentary checks:

- (a) of the amount of materials which are hydrolysed at the site;
- (b) in the establishments or plants where the hydrolysed materials are disposed of.

Controls shall be carried out regularly on the basis of a risk assessment.

During the period of the first twelve months of operation, a control visit to a site, where a container for the hydrolysis is located, shall be carried out every time hydrolysed material is collected from the container.

Following the period of the first twelve months of operation, a control visit to such sites shall be carried out every time the container is emptied and checked for the absence of corrosion and leaking in accordance with point H(j) of Section 2 of Chapter IV of Annex IV.'
