# 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)

## 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.

(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[(4)] (the bunker system project); a scientific opinion adopted on 8 July 2010 on Lime Treatment of Solid Pig and Poultry Manure[(5)]; 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[(6)].

(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.

(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[7]. 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.

*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