Commission Regulation (EU) No 56/2013 of 16 January 2013 amending Annexes I and IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance)

COMMISSION REGULATION (EU) No 56/2013

of 16 January 2013

amending Annexes I and IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies

(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 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies[(1)], and in particular the first paragraph of Article 23 thereof,

Whereas:

(1) Regulation (EC) No 999/2001 lays down rules for the prevention, control and eradication of transmissible spongiform encephalopathies (TSEs) in animals. It applies to the production and placing on the market of live animals and products of animal origin and in certain specific cases to exports thereof.

(2) Article 7(1) of Regulation (EC) No 999/2001 provides that the feeding to ruminants of protein derived from animals is prohibited. Article 7(2) of that Regulation extends that prohibition to animals other than ruminants and restricts that prohibition, as regards the feeding of those animals with products of animal origin, in accordance with Annex IV to that Regulation.

(3) Annex IV to Regulation (EC) No 999/2001 extends the prohibition provided for in Article 7(1) to the feeding to non-ruminant farmed animals, with the exception of the feeding to carnivorous fur-producing animals, of, inter alia, processed animal protein (PAP). By way of derogation, and under specific conditions, Annex IV authorises certain PAP to be fed to non-ruminant farmed animals.

(4) Article 11 of 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 (Animal by-products Regulation)[(2)] prohibits the feeding of terrestrial animals of a given species other than fur animals with PAP derived from the bodies or parts of bodies of animals of the same species. That Article also prohibits the feeding

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of farmed fish with PAP derived from the bodies or parts of bodies of farmed fish of the same species.

(5) The Communication from the Commission to the European Parliament and the Council — The TSE Road Map 2 — A Strategy paper on Transmissible Spongiform Encephalopathies for 2010-2015[3] was adopted on 16 July 2010. It outlines areas where future possible changes to Union legislation on TSEs could be made. It also emphasises that any review of the TSE rules should be primarily driven by scientific advice and technical issues related to the control and enforcement of the new measures.

(6) That Communication, inter alia, addresses the revision of the current feed ban rules laid down in Union legislation. Based on the contents of two scientific opinions issued by the Panel on Biological Hazards (BIOHAZ) of the European Food Safety Authority (EFSA) on 24 January 2007[4] and on 17 November 2007[5] respectively, the Communication acknowledges that no TSE have been identified as occurring in non-ruminant farmed animals under natural conditions and that the transmission risk of bovine spongiform encephalopathy (BSE) from non-ruminants to non-ruminants is negligible as long as intra-species recycling is avoided. Consequently, the Communication concludes that a lifting of the ban on the use of PAP from non-ruminants in non-ruminant feed could be considered, but without lifting the existing prohibition on intra-species recycling and only if validated analytical techniques to determine the species origin of PAP are available and a correct channelling of PAP from different species is in place.

(7) On 29 November 2010, the Council adopted conclusions on that Communication[6]. Those conclusions recognise the fundamental importance of the ban on using PAP in feed for farmed animals in preventing the circulation of BSE via the feed chain and thus playing a key role in the reduction of the incidence of that disease in the bovine population. Furthermore, those conclusions consider that it should be a prerequisite of any possible reintroduction of the use of non-ruminant PAPs to feed for other non-ruminant species that effective and validated tests are available to distinguish between PAP originating from different species and also that there has been a careful analysis of the risks of relaxation, regarding animal and public health.

(8) On 9 December 2010, the BIOHAZ Panel of EFSA adopted a scientific opinion on the revision of the quantitative risk assessment (QRA) of the BSE risk posed by processed animal proteins (PAPs)[7]. It concluded that ‘on the basis of 2009 BSE surveillance data in the Union, assuming a 0,1 % contamination (the limit of detection for PAP in feed) with non-ruminant PAP and according to EFSA’s QRA PAP model, the estimated mean total BSE infectivity load that could enter in cattle feed per year in the Union would be equivalent to 0,2 cattle oral infectious dose 50 %’. It estimated that ‘this would mean that less than one additional BSE infected animal could be expected in the Union cattle population per year with an upper 95 % confidence’.

(9) European Parliament resolution of 8 March 2011 on the EU protein deficit: what solution for a long-standing problem[8], calls on the Commission to submit a legislative proposal to the Parliament and the Council authorising the use of PAP from slaughtered offal for the production of feed for monogastric animals (pigs and poultry), provided that the ingredients stem from meat which was approved for human consumption, and

that the ban on intra-species recycling and forced cannibalism is fully implemented and controlled.

(10) European Parliament resolution of 6 July 2011 on EU legislation on Transmissible Spongiform Encephalopathies (TSE) and on related feed and food controls — implementation and outlook[9] supports, particularly in the light of the existing protein deficit in the Union, the Commission intention to remove the feed ban provisions in Union legislation banning the feeding of PAP to non-ruminants, provided that it applies to non-herbivores, and under certain conditions.

(11) That resolution calls for the production and sterilisation methods used for processed animal protein to comply with highest safety standards and with the rules laid down in Regulation (EC) No 1069/2009 and the use of the latest and safest technology available. It calls for the existing prohibitions on intra-species recycling to remain in place, that production channels of PAP derived from different species be completely separated, and that the separation of such production channels be controlled by the competent authorities in the Member States and audited by the Commission. In addition, it states that before the lifting of the feed ban is implemented, a reliable species specific method is in place to identify the species origin of the proteins in animal feed containing PAP so that intra-species recycling and the presence of PAP can be excluded, that the production of PAP from category 1 or category 2 material be prohibited and that only category 3 material fit for human consumption be used for the production of PAP. That resolution rejects the use of PAP derived from non-ruminants or ruminants in feed for ruminants.

(12) On 9 March 2012, the European Union Reference Laboratory for Animal Proteins in feedingstuffs (EURL-AP) validated a new diagnostic DNA-based method which is able to detect very low level of ruminant material that may be present in feed[10]. That method can be used for performing routine controls on PAP and compound feed containing PAP in order to verify the absence of proteins of ruminant origin.

(13) There is currently no diagnostic method validated which is able to detect the presence of porcine or poultry material in feed. Therefore, it would not be possible to control the correct implementation of the prohibition on intra-species recycling should the use of PAP of porcine origin in poultry feed and the use of poultry PAPs in pig feed be reauthorised.

(14) Aquaculture production does not present any concern regarding compliance with the intra-species recycling ban as current channelling requirements for the use of fishmeal in feed for aquaculture animals have already proven to be effective.

(15) With the exception of fishmeal and compound feed containing fishmeal, which are already permitted for feeding non-ruminant animals, PAP from non-ruminant animals and feedingstuffs containing such PAP should therefore be reauthorised for feeding aquaculture animals. Strict requirements during the collection, transport and processing of those products should apply in order to avoid any risk of cross-contamination with ruminant protein. In addition, regular sampling and analysis of the PAP and the compound feed containing this PAP should be performed in order to verify the absence of cross-contamination with ruminant proteins.

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(16) The prohibition to feed aquaculture animals with PAP from non-ruminant animals as laid down in Annex IV to Regulation (EC) No 999/2001 should therefore be deleted. In the interests of clarity of Union legislation, it is appropriate to replace the whole Annex IV by the Annex IV set out in the Annex to this Regulation.

(17) Point 1 of Annex I to Regulation (EC) No 999/2001 refers to definitions of feedingstuffs and animal by-products not intended for human consumption set out in Union legal acts that have since been repealed. For the sake of clarity of Union legislation, those references should be replaced by references to the respective definitions contained in legal acts in force. Annex I to Regulation (EC) No 999/2001 should therefore be amended in accordance with the Annex to this Regulation.

(18) As Member States and the economic operators of the feeding sector need sufficient time to adapt their control procedures to the new requirements introduced by this Regulation, this Regulation should not apply immediately after its entry into force.

(19) Regulation (EC) No 999/2001 should therefore be amended accordingly.

(20) 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

Annexes I and IV to Regulation (EC) No 999/2001 are amended in accordance with the Annex to this Regulation.

Article 2

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

It shall apply from 1 June 2013.

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

Done at Brussels, 16 January 2013.

For the Commission

The President

José Manuel BARROSO

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ANNEX

Annexes I and IV to Regulation (EC) No 999/2001 are amended as follows:

(1) Annex I, point 1 is replaced by the following:

1. For the purpose of this Regulation, the following definitions set out in Regulation (EC) No 1069/2009 of the European Parliament and of the Council[(11)], Commission Regulation (EU) No 142/2011[(12)], Regulation (EC) No 178/2002 of the European Parliament and of the Council[(13)], Regulation (EC) No 767/2009 of the European Parliament and of the Council[(14)] and Council Directive 2006/88/EC[(15)] shall apply:

   (a) the definition of "farmed animal" in Article 3(6) of Regulation (EC) No 1069/2009;

   (b) the following definitions in Annex I to Regulation (EU) No 142/2011:

      (i) "fur animals" in point 1;

      (ii) "blood products" in point 4;

      (iii) "processed animal protein" in point 5;

      (iv) "fishmeal" in point 7;

      (v) "collagen" in point 11;

      (vi) "gelatine" in point 12;

      (vii) "hydrolysed proteins" in point 14;

      (viii) "canned petfood" in point 16;

      (ix) "petfood" in point 19;

      (x) "processed petfood" in point 20;

   (c) the definition of "feed" in Article 3(4) of Regulation (EC) No 178/2002;

   (d) Regulation (EC) No 767/2009:

      (i) "feed materials" in Article 3(2)(g);

      (ii) "compound feed" in Article 3(2)(h);

      (iii) "complete feed" in Article 3(2)(i);

   (e) Directive 2006/88/EC:

      (i) "aquaculture animal" in Article 3(1)(b);

      (ii) "aquatic animal" in Article 3(1)(e).;

(2) Annex IV is replaced by the following: