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EUROPEAN COMMISSION

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Draft

COMMISSION REGULATION

of

amending Annex IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards prohibitions concerning animal feeding of processed animal proteins derived from non-ruminant animals

(Text with EEA relevance)

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(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 encephalopathies¹, 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) extends this prohibition to animals other than ruminants and restricts feeding of those animals with products of animal origin in accordance with provisions laid down in Annex IV to Regulation (EC) No 999/2001.
- (3) Annex IV to Regulation (EC) No 999/2001 prohibits the feeding to non-ruminant farmed animals, with the exception of the feeding to carnivorous fur producing animals, of processed animal proteins (PAP) as defined in Annex I to 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 Directive². By way of derogation, and under specific conditions, Annex IV authorizes certain PAP to be fed to non-ruminant farmed animals.
- (4) Article 11 of Regulation 1069/2009 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. This Article prohibits also the feeding of

¹ OJ L 147, 31.5.2001, p. 1.

² OJ L 54, 26.2.2011, p.1

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

- (5) On 16 July 2010 the Commission adopted the TSE Road Map 2³, a Communication to the European Parliament and the Council which outlines areas where future possible changes to EU legislation on TSEs could be made. This Communication 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. One of the topics addressed in this Communication is the revision of the current feed ban provisions. Considering that the transmission risk of BSE from non ruminants to non-ruminants is very unlikely, the Communication acknowledges 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.
- (6) The European Union Reference Laboratory for Animal Proteins (EURL-AP) has achieved the development and the validation of new diagnostic methods which are able identify the species origin of PAP found in feed. These methods can therefore be used by Member States for performing routine controls on PAP and feedingstuffs containing PAP.
- (7) On 17 November 2007, the Panel on Biological Hazards (BIOHAZ) of the European Food Safety Authority (EFSA) adopted a scientific opinion on certain aspects related to the feeding of animal proteins to farmed animals⁴. This opinion concluded that to date, no TSEs have been identified as occurring in pigs or poultry under natural conditions. Taking account of the epidemiological situation of BSE in cattle in the EU, which indicates a decreasing trend, together with the current control measures in place to avoid exposure of pigs and poultry to BSE contaminated material, the BIOHAZ Panel of EFSA concluded that the risk of transmitting BSE to pigs utilizing poultry PAP and vice versa is negligible and that, in this scenario, any increase in the exposure risk of BSE to humans would be negligible.
- (8) PAP from non-ruminant animals and feedingstuffs containing such PAP should therefore be reauthorized for feeding non-ruminant animals provided that strict requirements during the collection, transport and processing of these products apply in order to avoid any cross-contamination which could lead to feed animals from a given species with PAP derived from the same species.
- (9) Annex IV to the Regulation (EC) No 999/2001 should therefore be amended accordingly.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

³ http://ec.europa.eu/food/food/biosafety/tse_bse/docs/roadmap_2_en.pdf

⁴ Opinion of the Scientific Panel on Biological Hazards on a request from the European Parliament on Certain Aspects related to the Feeding of Animal Proteins to Farm Animals, The EFSA Journal (2007) Journal number 576, 1-41

HAS ADOPTED THIS REGULATION:

Article 1

Annex IV to Regulation (EC) No 999/2001 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the 20th day following 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, [...]

For the Commission
José Manuel BARROSO
The President

ANNEX

1. Part II of Annex IV to the Regulation (EC) 999/2001 is amended as follows:

a. Point A (b) is replaced by the following:

- “(b) the feeding to non-ruminant farmed animals of the proteins referred to in points (i), (ii), (iii) and (iv), and of products derived from such proteins:
- (i) fishmeal, in accordance with the conditions laid down in point B;
 - (ii) dicalcium phosphate and tricalcium phosphate, in accordance with the conditions laid down in point C;
 - (iii) blood products derived from non-ruminants in accordance with the conditions laid down in point D
 - (iv) processed animal proteins, other than fishmeal, derived from non-ruminants in accordance with the conditions laid down in point E”

b. Point A (c) is deleted.

c. Point D is replaced by the following:

"D. The following conditions shall apply for the use of blood products derived from non-ruminants referred to in point A (b) (iii) and of feedingstuffs containing such proteins, in the feeding of non-ruminant farmed animals.

- (a) The blood intended to be used for the production of blood products shall be derived from approved slaughterhouses which do not slaughter ruminants and which are registered as not slaughtering ruminants, and shall be transported directly to a processing plant in vehicles dedicated exclusively for the transport of non-ruminant blood. If the vehicle was used for the transport of blood derived from ruminants it shall be, following cleaning, inspected by the competent authority before the transport of non-ruminant blood.

By way of derogation, the competent authority may permit the slaughter of ruminants in a slaughterhouse producing non-ruminant blood intended for the production of blood products for use in feed for non-ruminant farmed animals if the slaughterhouse has a recognised control system including at least:

- keeping the slaughtering of non-ruminants physically separate from the slaughtering of ruminants,
- keeping collection, storage, transport and packaging facilities for blood of non-ruminant origin separate from those for blood of ruminant origin,
- regular sampling and analysis of blood of non ruminant origin to detect the presence of ruminant proteins.

- (b) The blood products shall be produced in an establishment exclusively processing non-ruminant blood.

By way of derogation from that condition, the competent authority may permit the production of blood products for use in feed for non-ruminant farmed animals in establishments processing ruminant blood, which have a recognised control system in place preventing cross-contamination.

That control system shall at least include:

- processing of non-ruminant blood in a closed system physically separated from the processing of the ruminant blood,
 - keeping of bulk raw material and bulk finished products of non-ruminant origin during storage, transport and packaging in facilities physically separated from those for bulk raw material and bulk finished of ruminant origin,
 - regular sampling and analysis of the blood to detect the presence of ruminant proteins.
- (c) Feedingstuffs containing blood products derived from non-ruminants shall be produced in establishments which do not prepare feedingstuffs for ruminants and which are authorised for this purpose by the competent authority.

By way of derogation from that condition:

(i) a specific authorisation for the production of complete feedingstuffs from feedingstuffs containing blood products derived from non-ruminants shall not be required for home compounders:

- registered by the competent authority,
- keeping only non-ruminants,
- producing complete feedingstuffs for use only in the same holding, and
- provided that the feedingstuffs containing blood products derived from non-ruminants contain less than 50 % total protein.

(ii) the production of feedingstuffs for ruminants in establishments which also produce feedingstuffs containing blood products derived from non-ruminants may be authorised by the competent authority subject to the following conditions:

- bulk and packaged feedingstuffs destined for ruminants are manufactured in facilities physically separate from those where

feedingstuffs containing respectively blood products derived from non-ruminants are manufactured,

- bulk feedingstuffs destined for ruminants are kept, during storage, transport and packaging, in facilities physically separated from those for used for non ruminants.
- records detailing the purchases and uses of blood products derived from non-ruminants, and the sales of feedingstuffs containing such products, are kept available to the competent authority for at least five years.

(d) The label, accompanying commercial document or health certificate, as appropriate, of the feedingstuffs containing blood products shall clearly indicate the words ‘contains blood products – shall not be fed to ruminants’.

(e) Bulk feedingstuffs containing blood products shall be transported by means of vehicles which do not transport at the same time feedingstuffs for ruminants. If the vehicle is subsequently used for the transport of feedingstuffs intended for ruminants, it shall be thoroughly cleaned in accordance with a procedure to avoid cross-contamination approved by the competent authority.

(f) The use and storage of feedingstuffs containing blood products shall be prohibited in farms where ruminants are kept.

By way of derogation, the competent authority may permit the use and storage of feedingstuffs containing blood products in farms where ruminants are kept, if it is satisfied that on-farm measures are implemented to prevent that feedingstuffs containing blood products are fed to ruminants."

d. The following Point E is inserted:

"E. The following conditions shall apply for the use of processed animal proteins, other than fishmeal, derived from non-ruminants referred to in point A (b) (iv) and of feedingstuffs containing such proteins, in the feeding of non-ruminant farmed animals.

- (a) The raw materials intended to be used for the production of processed animal proteins shall be derived from approved slaughterhouses which do not slaughter ruminants and which are registered as not slaughtering ruminants, and shall be transported directly to a processing plant in vehicles dedicated exclusively for the transport of non-ruminant raw materials. If the vehicle was used for the transport of non ruminant raw material derived from different animal species, a control system shall be in place to avoid any cross-contamination during transport. If the vehicle was used for the transport of raw material derived from ruminants it shall be, following cleaning, inspected by the competent authority before the transport of non-ruminant raw materials.

By way of derogation, the competent authority may permit the slaughter of ruminants in a slaughterhouse producing non-ruminant raw material

intended for the production of processed animal proteins for use in feed for non-ruminant farmed animals if the slaughterhouse has a recognised control system including at least:

- keeping the slaughtering of non-ruminants physically separate from the slaughtering of ruminants,
- keeping collection, storage, transport and packaging facilities for raw material of non-ruminant origin separate from those for raw material of ruminant origin,
- regular sampling and analysis of raw material of non ruminant origin to detect the presence of ruminant proteins.

- (b) The processed animal proteins shall be produced in establishments exclusively processing raw materials derived from one single animal species.

By way of derogation, the competent authority may permit the production of processed animal proteins for use in feed for non-ruminant farmed animals in establishments processing raw materials derived from different animal species, which have a recognised control system in place preventing cross-contamination.

That control system shall at least include:

- production of processed animal proteins derived from one given animal species in a closed system physically separated from the production of the processed animal proteins derived from another animal species,
- keeping of bulk raw material and bulk finished products derived from one given animal species origin during storage, transport and packaging in facilities physically separated from those for bulk raw material and bulk finished products derived from another animal species,
- regular sampling and analysis of the processed animal proteins produced derived from one given animal species to detect the presence of processed animal proteins derived from another animal species.

- (c) Feedingstuffs containing processed animal proteins derived from non ruminants shall be produced in establishments which do not produce feedingstuffs intended to be fed to more than one animal species and which are authorised for this purpose by the competent authority.

By way of derogation:

(i) a specific authorisation for the production of complete feedingstuffs from feedingstuffs containing processed animal proteins derived from non ruminants shall not be required for home compounders:

- registered by the competent authority,
- keeping only animal species different from those of which the processed animal proteins contained in the feedingstuffs are derived from,
- producing complete feedingstuffs for use only in the same holding, and
- provided that the feedingstuffs containing processed animal proteins derived from non-ruminants contain less than 50 % total protein.

(ii) the production of feedingstuffs containing processed animal proteins derived from non ruminants in establishments which produce feedingstuffs for different animal species may be authorised by the competent authority subject to the following conditions:

- bulk and packaged feedingstuffs destined for one given animal species are manufactured in facilities physically separate from those where feedingstuffs destined for another animal species are manufactured,
- bulk feedingstuffs destined for one given animal species are kept, during storage, transport and packaging, in facilities physically separated from those for used for another animal species.
- records detailing the purchases and uses processed animal proteins derived from non ruminants, and the sales of feedingstuffs containing such products, are kept available to the competent authority for at least five years.

(d) The label, accompanying commercial document or health certificate, as appropriate, of the feedingstuffs containing processed animal proteins derived from non-ruminants shall clearly indicate the animal species for which the feedingstuffs are intended for and the words "contains processed animal proteins derived from *non-ruminants* (specify species) – shall not be fed to ruminants or *to animal species from which the processed animal proteins contained in the feedingstuffs are derived from* (specify species)"

(e) Bulk feedingstuffs containing processed animal proteins derived from non-ruminants shall be transported by means of vehicles which do not transport at the same time feedingstuffs intended to feed more than one animal species. If the vehicle is subsequently used for the transport of feedingstuffs intended for another animal species, it shall be thoroughly cleaned in accordance with a procedure to avoid cross-contamination approved by the competent authority.

(f) The use and storage of feedingstuffs containing processed animal proteins derived from non-ruminants shall be prohibited in farms keeping animals species for which the feedingstuffs are not intended for.

By way of derogation, the competent authority may permit the use and storage of feedingstuffs containing processed animal proteins derived from non-ruminants in farms keeping the animal species for which the feedingstuffs are not intended for if on-farm measures are implemented to prevent that such feedingstuffs are fed to an unauthorised animal species.

(2) Part III of Annex IV to the Regulation (EC) 999/2001 is amended as follows:

a. Point A is replaced by the following:

“A. This Annex shall apply without prejudice to the provisions of Regulation (EC) No 1069/2009.”

b. Point B is replaced by the following:

“B. Member States shall keep up-to-date lists of:

- (a) slaughterhouses approved for the collection of blood in accordance with point D(a) of Part II;
- (b) slaughterhouses approved for the collection of raw materials intended to be used for the production of processed animal proteins in accordance with point E(a) of Part II;
- (c) approved processing plants producing dicalcium phosphate, tricalcium phosphate or blood products,
- (d) approved processing plants producing processed animal proteins derived from non-ruminants which operate in accordance with point E(b) of Part II;
- (e) establishments, with the exception of home compounders, authorised for manufacturing feedingstuffs containing processed animal proteins derived from non ruminants, including fishmeal, and the proteins referred to in point (b) which operate in accordance with the conditions laid down in points B(c), BA(d), C(a), D(c) and E(c) of Part II.”

c. Point C. (b) is replaced by the following:

"C. (b) Bulk fishmeal referred to in point A(b)(i) of Part II, bulk dicalcium phosphate and bulk tricalcium phosphate referred to in point A(b)(ii) of Part II, blood products referred to in point A(b)(iii) of Part II shall be stored and transported in stores and vehicles dedicated to that purpose."

d. Points D is replaced by the following:

"D. Feedingstuffs, including petfood, which contain blood products of ruminant origin or processed animal proteins of ruminant origin shall not be manufactured in establishments which produce feedingstuffs for farmed animals, with the exception of feedingstuffs for carnivorous fur producing animals.

Bulk feedingstuffs, including petfood, which contain blood products of ruminant origin or processed animal proteins of ruminant origin shall during storage, transport and packaging be kept in facilities physically separate from facilities for bulk feedingstuffs for farmed animals, with the exception of feedingstuffs for carnivorous fur producing animals.

Petfood and feedingstuffs intended for carnivorous fur producing animals containing dicalcium phosphate or tricalcium phosphate referred to in point A(b)(ii) of Part II, and blood products referred to in point A(b)(iii) of Part II shall be manufactured and transported in accordance with points C(a) and (c) and points D(c) and (e), respectively of Part II."

e. Points F is replaced by the following:

"F. The competent authority shall carry out documentary and physical checks throughout the production and distribution chain in accordance with Regulation (EC) No 882/2004 to control compliance with its provisions and with the provisions of this Regulation. These checks shall include tests on processed animal proteins and feedingstuffs in compliance with protocols and methods of analysis laid down in Annex VI to Regulation (EC) No 152/2009. Where any presence of prohibited animal protein is detected, Regulation (EC) No 882/2004 shall apply. The competent authority shall verify on a regular basis the competence of laboratories carrying out analyses for such official controls, in particular by evaluating the results of inter-proficiency tests. If the competence is considered unsatisfactory, a re-training of the laboratory staff shall be undertaken as the minimal corrective measure."