

COMMISSION REGULATION (EC) No 1292/2005**of 5 August 2005****amending Annex IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council
as regards animal nutrition****(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 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 on the feeding of proteins derived from animals in order to prevent the dissemination of transmissible spongiform encephalopathies (TSEs) to animals.
- (2) That Regulation prohibited the use of certain animal proteins in the feeding of farmed animals either because such proteins may potentially contain TSE infectivity or because they could jeopardise the detection of small amounts of potentially TSE infected proteins in feedingstuffs. It also established zero-tolerance of prohibited animal constituents in feedingstuffs.
- (3) Commission Directive 2003/126/EC of 23 December 2003 on the analytical method for the determination of constituents of animal origin for the official control of feedingstuffs ⁽²⁾ provides that official analysis of feedingstuffs with a view to officially control the presence, identification or estimation of the amount of constituents of animal origin in feedingstuffs are to be carried out in accordance with that Directive. Proficiency testing of laboratories, carried out in accordance with that Directive by the Commission's Institute for Reference Materials and Measurements (IRMM-JRC), has demonstrated that the performance of laboratories for detecting small amounts of mammalian proteins in feedingstuffs has improved considerably.

(4) That improvement in laboratory performance has resulted in the detection of the adventitious presence of bone spicules, particularly in tuber and root crops. Scientific evidence has demonstrated that contamination of such crops by bone spicules present in the soil cannot be avoided. Consignments of contaminated tuber and root crops are to be disposed of in accordance with Council Directive 95/53/EC of 25 October 1995 fixing the principles governing the organisation of official inspections in the field of animal nutrition ⁽³⁾, and often have to be destroyed as a result. In order to prevent a disproportionate application of that Directive, Member States should be allowed to make a risk assessment on the presence of animal constituents in tuber and root crops before considering a breach of the feed ban.

(5) On 25 and 26 May 2000, the Scientific Steering Committee (SSC) updated its report and opinion on the safety of hydrolysed proteins produced from ruminant hides, adopted during its meeting of 22 and 23 October 1998. The conditions under which hydrolysed proteins may be considered safe according to that opinion are laid down in Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption ⁽⁴⁾. Since 1 May 2004, those conditions have also applied to hydrolysed proteins imported from third countries. Therefore the feeding to ruminants of hydrolysed proteins produced from ruminant hides and skins ruminants should no longer be prohibited.

(6) In its opinion of 17 September 1999 on intra-species recycling, and again in its opinion of 27 and 28 November 2000 on the scientific basis for banning animal protein from feed for all farmed animals, the SSC stated that there is no evidence of the natural occurrence of TSE in non-ruminant farmed animals producing food, such as pigs and poultry. Furthermore, given that controls on the ban on animal proteins are based on the detection of bones and muscles fibres in feedingstuffs, blood products and hydrolysed proteins derived from non-ruminants should not jeopardise controls on the presence of potentially TSE infected proteins. Therefore, the restrictions on feeding to farmed animals of blood products and hydrolysed derived from non-ruminants should be relaxed.

⁽¹⁾ OJ L 147, 31.5.2001, p. 1. Regulation as last amended by Commission Regulation (EC) No 260/2005 (OJ L 46, 17.2.2005, p. 31).

⁽²⁾ OJ L 339, 24.12.2003, p. 78.

⁽³⁾ OJ L 265, 8.11.1995, p. 17. Directive as last amended by Directive 2001/46/EC of the European Parliament and of the Council (OJ L 234, 1.9.2001, p. 55).

⁽⁴⁾ OJ L 273, 10.10.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 416/2005 (OJ L 66, 12.3.2005, p. 10).

- (7) The conditions for transport, storage and packaging of bulk feedingstuffs containing processed animal proteins should be clarified.
- (8) Continuous evaluation of the competence and training of laboratory staff should be provided for to maintain or improve the quality of the official controls.
- (9) Regulation (EC) No 999/2001 should therefore be amended accordingly. For practical reasons and in the interests of clarity, it is appropriate to replace the amended Annex IV in its entirety.
- (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,

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*.

It shall apply from 1 September 2005.

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

Done at Brussels, 5 August 2005.

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX

Annex IV to Regulation (EC) No 999/2001 is replaced by the following:

'ANNEX IV

ANIMAL FEEDING**I. Extension of the prohibition provided for in Article 7(1)**

The prohibition provided for in Article 7(1) shall be extended to the feeding:

- (a) to farmed animals, with the exception of the feeding to carnivorous fur producing animals, of:
 - (i) processed animal protein;
 - (ii) gelatine of ruminant origin;
 - (iii) blood products;
 - (iv) hydrolysed protein;
 - (v) dicalcium phosphate and tricalcium phosphate of animal origin (dicalcium phosphate and tricalcium phosphate);
 - (vi) feedingstuffs containing the proteins listed in points (i) to (v).
- (b) to ruminants, of animal protein and feedingstuffs containing such protein.

II. Derogations from the prohibitions provided for in Article 7(1) and (2), and specific conditions for the application of such derogations.

A. The prohibitions provided for in Article 7(1) and (2) shall not apply to:

- (a) the feeding to farmed animals of the proteins referred to in points (i), (ii), (iii) and (iv) and of feedingstuffs derived from such proteins:
 - (i) milk, milk-based products and colostrum;
 - (ii) eggs and egg products;
 - (iii) gelatine derived from non-ruminants;
 - (iv) hydrolysed proteins derived from parts of non-ruminants and from ruminant hides and skins;
- (b) the feeding to non-ruminant farmed animals of the proteins referred to in points (i), (ii) and (iii), 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;
- (c) the feeding to fish of blood meal derived from non-ruminants in accordance with the conditions laid down in point D;

- (d) the feeding to farmed animals of tuber and root crops and feedingstuffs containing such products following the detection of bone spicules may be permitted by the Member States if there has been a favourable risk assessment. The risk assessment shall take into account at least the amount and possible source of contamination and the final destination of the consignment.
- B. The following conditions shall apply for the use of fishmeal referred to in point A(b)(i) and feedingstuffs containing fishmeal in the feeding of non-ruminant farmed animals (not applicable to the feeding of carnivorous fur producing animals):
- (a) the fishmeal shall be produced in processing plants dedicated exclusively to the production of fish derived products;
 - (b) before release for free circulation in the Community, each consignment of imported fishmeal shall be analysed by microscopy in accordance with Directive 2003/126/EC;
 - (c) feedingstuffs containing fishmeal shall be produced in establishments which do not produce feedingstuffs for ruminants and which are authorised for this purpose by the competent authority.

By way of derogation from point (c):

- (i) a specific authorisation for the production of complete feedingstuffs from feedingstuffs containing fishmeal 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 fishmeal used in the production contain less than 50 % crude protein;
 - (ii) the production of feedingstuffs for ruminants in establishments which also produce feedingstuffs containing fishmeal for other animal species may be authorised by the competent authority subject to the following conditions:
 - bulk and packaged feedingstuffs destined for ruminants are kept in facilities physically separate from those for bulk fishmeal and bulk feedingstuffs containing fishmeal during storage, transport and packaging,
 - feedingstuffs destined for ruminants are manufactured in facilities physically separate from facilities where feedingstuffs containing fishmeal are manufactured,
 - records detailing the purchases and uses of fishmeal and the sales of feedingstuffs containing fishmeal are kept available to the competent authority for at least five years, and
 - routine tests are carried out on feedingstuffs destined for ruminants to ensure that prohibited proteins including fishmeal are not present.
- (d) The label and accompanying document of feedingstuffs containing fishmeal shall clearly indicate the words "contains fishmeal — shall not be fed to ruminants".
- (e) Bulk feedingstuffs containing fishmeal shall be transported by means of vehicles which do not at the same time transport 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 approved by the competent authority to avoid cross-contamination.

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

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

- C. The following conditions shall apply for the use of dicalcium phosphate and tricalcium phosphate referred to in point A(b)(ii) and feedingstuffs containing such proteins in the feeding of non-ruminant farmed animals (not applicable to the feeding of carnivorous fur producing animals):

- (a) Feedingstuffs containing dicalcium phosphate or tricalcium phosphate 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 dicalcium phosphate or tricalcium phosphate 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 dicalcium phosphate or tricalcium phosphate used in the production contain less than 10 % total phosphorus;

- (ii) the production of feedingstuffs for ruminants in establishments which also produce feedingstuffs containing dicalcium phosphate or tricalcium phosphate for other animal species 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 dicalcium phosphate or tricalcium phosphate are manufactured,

— bulk feedingstuffs destined for ruminants are during storage, transport and packaging kept in facilities physically separate from those for bulk dicalcium phosphate, bulk tricalcium phosphate and bulk feedingstuffs containing dicalcium phosphate or tricalcium phosphate,

— records detailing the purchases and uses of dicalcium phosphate or tricalcium phosphate and the sales of feedingstuff containing dicalcium phosphate or tricalcium phosphate are kept available to the competent authority for at least five years.

- (b) The label and accompanying document of the feedingstuffs containing dicalcium phosphate or tricalcium phosphate shall clearly indicate the words “contains dicalcium/tricalcium phosphate of animal origin – shall not be fed to ruminants”.

- (c) Bulk feedingstuffs containing dicalcium phosphate or tricalcium phosphate shall be transported by means of vehicles which do not at the same time transport 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 approved by the competent authority to avoid cross-contamination.

- (d) The use and storage of feedingstuffs containing dicalcium phosphate or tricalcium phosphate shall be prohibited in farms where ruminants are kept.

By way of derogation from that condition, the competent authority may permit the use and storage of feedingstuffs containing dicalcium phosphate or tricalcium phosphate in farms where ruminants are kept, if it is satisfied that on-farm measures are implemented to prevent that feedingstuffs containing dicalcium phosphate or tricalcium phosphate are fed to ruminants.

- D. The following conditions shall apply for the use of blood products referred to in point A(b)(iii) and blood meal referred to in point A(c) and of feedingstuffs containing such proteins, in the feeding of respectively non-ruminant farmed animals and fish:

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

By way of derogation from that condition, the competent authority may permit the slaughter of ruminants in a slaughterhouse collecting non-ruminant blood intended for the production of blood products and blood meal for use in feed for respectively non-ruminant farmed animals and fish if the slaughterhouse has a recognised control system. That control system shall at least include:

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

- (b) The blood products and blood meal 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 and blood meal for use in feed for respectively non-ruminant farmed animals and fish 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 separate from the processing of ruminant blood,
- keeping of bulk raw material and bulk finished products of ruminant origin during storage, transport and packaging in facilities physically separate from those for bulk raw material and bulk finished products of non-ruminant origin, and
- regular sampling and analysis of non-ruminant blood products and blood meal to detect the presence of ruminant proteins.

- (c) Feedingstuffs containing blood products or blood meal shall be produced in establishments which do not prepare feedingstuffs for respectively ruminants or farmed animals other than fish 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 or blood meal shall not be required for home compounders:
 - registered by the competent authority,
 - keeping only non-ruminants in case blood products are used, or only fish in case blood meal is used,
 - producing complete feedingstuffs for use only in the same holding, and
 - provided that the feedingstuffs containing blood products or blood meal used in the production contain less than 50 % total protein.
- (ii) the production of feedingstuffs for ruminants in establishments which also produce feedingstuffs containing blood products or blood meal for respectively non-ruminant farmed animals or fish may be authorised by the competent authority subject to the following conditions:
 - bulk and packaged feedingstuffs destined for ruminants or farmed animals other than fish are manufactured in facilities physically separate from those where feedingstuffs containing respectively blood products or blood meal are manufactured,
 - bulk feedingstuffs kept, during storage transport and packaging, in physically separate facilities as follow:
 - (a) feedingstuff destined for ruminants is kept separate from blood products and from feedingstuffs containing blood products;
 - (b) feedingstuff destined for farmed animals other than fish is kept separate from blood meal and feedingstuffs containing blood meal,
 - records detailing the purchases and uses of blood products and blood meal, 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 or blood meal shall clearly indicate the words “contains blood products – shall not be fed to ruminants” or “contains blood meal – shall only be fed to fish” as appropriate.
- (e) Bulk feedingstuffs containing blood products shall be transported by means of vehicles which do not transport at the same time feedingstuffs for ruminants and bulk feedingstuffs containing blood meal by means of vehicles which do not transport at the same time feedingstuffs for farmed animals other than fish. If the vehicle is subsequently used for the transport of feedingstuffs intended for respectively ruminants or farmed animals other than fish, 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, and that of feedingstuffs containing blood meal shall be prohibited in farms where farmed animals other than fish are kept.

By way of derogation, the competent authority may permit the use and storage of feedingstuffs containing respectively blood products or blood meal in farms where respectively ruminants or farmed animals other than fish are kept, if it is satisfied that on-farm measures are implemented to prevent that feedingstuffs containing respectively blood products or blood meal are fed to respectively ruminants or species other than fish.

III. General implementing conditions

- A. This Annex shall apply without prejudice to the provisions in Regulation (EC) No 1774/2002.
- 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) approved processing plants producing dicalcium phosphate, tricalcium phosphate, blood products or blood meal, and
 - (c) establishments, with the exception of home compounders, authorised for manufacturing feedingstuffs containing fishmeal and the proteins referred to in point (b) which operate in accordance with the conditions laid down in points B(c), C(a) and D(c) of Part II.
- C. (a) Bulk processed animal protein, with the exception of fishmeal, and bulk products, including feedingstuffs, organic fertilisers and soil improvers, containing such proteins, shall be stored and transported in dedicated facilities. The store or vehicle may only be used for other purposes, following cleaning, and after having been inspected by the competent authority.
- (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 and blood meal referred to in point A(c) of Part II shall be stored and transported in stores and vehicles dedicated to that purpose.
- (c) By way of derogation from point (b):
- (i) stores or vehicles may be used for the storage and transport of feedingstuffs containing the same protein;
 - (ii) stores or vehicles, following cleaning, may be used for other purposes after having been inspected by the competent authority; and
 - (iii) stores and vehicles transporting fishmeal may be used for other purposes if the company has a control system in place, recognised by the competent authority, to prevent cross-contamination. The control system shall at least include:
 - records on material transported and cleaning of the vehicle, and
 - regular sampling and analysis of feedingstuffs transported to detect the presence of fishmeal.
- The competent authority shall carry out frequent on-the-spot checks to verify the correct application of the above control system.
- D. Feedingstuffs, including petfood, which contain blood products of ruminant origin or processed animal proteins, other than fishmeal, 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, other than fishmeal, 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. 1. The export to third countries of processed animal proteins derived from ruminants, and of products containing such processed animal proteins, shall be prohibited.
2. The export of processed animal proteins derived from non-ruminants and of products containing such proteins shall only be permitted by the competent authority subject to the following conditions:
- they are destined for uses not prohibited by Article 7,
 - a written agreement with the third country is made prior to exportation, which includes an undertaking from the third country to respect the final use and not to re-export the processed animal protein or products containing such proteins for uses prohibited by Article 7.
3. Member States which permit exports in accordance with point 2 shall for the effective implementation of this Regulation inform the Commission and the other Member States of all terms and conditions as agreed with the third country concerned, in the context of the Standing Committee on the Food Chain and Animal Health.

Points 2 and 3 shall not apply to:

- exports of fishmeal, provided it fulfils the conditions set out in point B of Part II,
 - products containing fishmeal,
 - petfood.
- F. The competent authority shall carry out documentary and physical checks, including tests on feedingstuffs, throughout the production and distribution chain in accordance with Directive 95/53/EC to control compliance with its provisions and with the provisions of this Regulation. Where any presence of prohibited animal protein is detected, Directive 95/53/EC 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 ring trials. If the competence is considered unsatisfactory, a re-training of the laboratory staff shall be undertaken as the minimal corrective measure.'
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