



Council of the
European Union

Brussels, 11 October 2016
(OR. en)

13182/16

AGRILEG 147
VETER 97

COVER NOTE

From:	European Commission
date of receipt:	11 October 2016
To:	General Secretariat of the Council

No. Cion doc.:	D045867/03
Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Annexes IV and X 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

Delegations will find attached document D045867/03.

Encl.: D045867/03



EUROPEAN
COMMISSION

Brussels, **XXX**
SANTE/10540/2016
(POOL/G4/2016/10540/10540-EN.doc)
D045867/03
[...](2016) **XXX** draft

COMMISSION REGULATION (EU) .../...

of **XXX**

**amending Annexes IV and X 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) .../...

of **XXX**

amending Annexes IV and X 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 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 prohibits the feeding to ruminants of protein derived from animals and Chapter I of Annex IV to that Regulation extends that prohibition. Chapter II of that Annex sets out a number of derogations from that prohibition. Point (b)(ii) of Chapter II of Annex IV to Regulation (EC) No 999/2001 provides that the prohibition is not to apply to the feeding to non-ruminant farmed animals of fishmeal and compound feed containing fishmeal which are produced, placed on the market and used in accordance with Chapter III of Annex IV and the specific conditions laid down in Section A of Chapter IV of that Annex. In addition, point (d) of Chapter II of Annex IV to Regulation (EC) No 999/2001 provides that the prohibition is not to apply to the feeding to unweaned ruminants of milk replacers containing fishmeal which are produced, placed on the market and used in accordance with the specific conditions laid down in Section E of Chapter IV of that Annex.
- (3) Point (a) of Section A of Chapter IV of Annex IV to Regulation (EC) No 999/2001 requires that the fishmeal must be produced in processing plants dedicated exclusively to the production of products derived from aquatic animals, except sea mammals. Point (a) of Section E of that Chapter requires that the fishmeal used in milk replacers for the feeding of unweaned ruminants must be produced in processing plants

¹ OJ L 147, 31.5.2001, p. 1.

dedicated exclusively to the production of products derived from aquatic animals, and it must comply with general conditions laid set out in Chapter III.

- (4) Point 1(e)(ii) of Annex I to Regulation (EC) No 999/2001 defines 'aquatic animals' by reference to the definition laid down in Article 3(1)(e) of Council Directive 2006/88/EC² as (i) fish belonging to the superclass *Agnatha* and to the classes *Chondrichthyes* and *Osteichthyes*, (ii) mollusc belonging to the Phylum *Mollusca*, and (iii) crustacean belonging to the Subphylum *Crustacea*.
- (5) Therefore, since the definition of 'aquatic animals' laid down in Annex I to Regulation (EC) No 999/2001 does not cover invertebrates other than molluscs and crustaceans, the requirements of point (a) of Section A and of point (a) of Section E of Chapter IV of Annex IV to that Regulation do not allow the use of wild starfish and farmed aquatic invertebrates, other than molluscs and crustaceans, for the production of fishmeal. As the use of meal produced from wild starfish and farmed aquatic invertebrates, other than molluscs and crustaceans, in feed for non-ruminant animals does not represent a higher risk for the transmission of TSEs than the use of fishmeal in such feed, the requirements of point (a) of Section A and of point (a) of Section E of Chapter IV of Annex IV to Regulation (EC) No 999/2001 should be amended in order to add the possibility of using starfish or farmed aquatic invertebrates, other than molluscs and crustaceans, for the production of fishmeal.
- (6) In order to protect the environment, the use of wild starfish for the production of fishmeal should be restricted to cases where starfish are multiplying and represent a threat to an aquaculture production area. Therefore, the requirements of point (a) of Section A and of point (a) of Section E of Chapter IV of Annex IV to Regulation (EC) No 999/2001 should only include starfish that are harvested in a mollusc production area.
- (7) Annex IV of Regulation (EC) No 999/2001 should therefore be amended accordingly.
- (8) Point 4 of Chapter C of Annex X to Regulation (EC) No 999/2001 sets out the lists of rapid tests approved for the monitoring of TSEs in bovine, ovine and caprine animals. On 8 April 2016, the Prionics group informed the Commission that it would cease the manufacture of the Prionics Check PrioSTRIP SR diagnostic kit as of 15 April 2016. This diagnostic kit should therefore be deleted from the list of approved TSE rapid tests in ovine and caprine animals. The fourth indent of the second paragraph of point 4 of Chapter C of Annex X should therefore be deleted.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

² Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals (OJ L 328, 24.11.2006, p.14).

HAS ADOPTED THIS REGULATION:

Article 1

Annexes IV and X 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*.

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

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER