

COMMISSION REGULATION (EU) No 189/2011**of 25 February 2011****amending Annexes VII and IX 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) Chapter A of Annex VII to Regulation (EC) No 999/2001 lays down the eradication measures to be carried out following the confirmation of TSE in ovine and caprine animals. In the case of confirmation of TSE other than bovine spongiform encephalopathy (BSE) in an ovine or caprine animal, the eradication measures consist in either the killing and complete destruction of all animals on the holding or the killing and complete destruction of ovine animals genetically susceptible to scrapie on the holding and in the killing and the complete destruction of all caprine animals on the holding insofar as no genetic resistance to scrapie has been demonstrated in caprine animals.
- (3) Chapter A of Annex VII to Regulation (EC) No 999/2001 also provides that the Member States may decide to delay the destruction of the animals by up to 5 breeding years subject to certain conditions. However, in the case of ovine or caprine animals kept for the production of milk with a view to placing it on the market, the killing and destruction of the animals may only be delayed for a maximum of 18 months. Regulation (EC) No 999/2001 does not define the starting date for that

deferred period of 18 months. In the interests of certainty of Union legislation, it is appropriate to amend Annex VII to that Regulation so that the deferral period begins from the date of confirmation of the index case.

- (4) In addition, in July 2010, the preliminary results of a scientific study ⁽²⁾ conducted by the Cypriot authorities under the supervision of the European Union Reference Laboratory (EURL) for TSEs showed that a genetic resistance to scrapie in caprine animals could exist. However, the definitive results of that study are not expected to be available before the second semester of 2012.
- (5) If that study confirms the existence of a resistance to scrapie, it may be considered appropriate, from January 2013, to amend Regulation (EC) No 999/2001, in order to exempt scrapie resistant caprine animals from the requirements for killing and complete destruction laid down in Chapter A of Annex VII to that Regulation. In order to avoid the unnecessary killing and complete destruction of caprine animals that may be considered as scrapie resistant in the near future, on holdings where animals are kept for the production of milk with a view to placing it on the market, it is appropriate to prolong the deferral period for the killing and complete destruction of those animals for a period ending on 31 December 2012, where the index case was confirmed before 1 July 2011.
- (6) Annex IX to Regulation (EC) No 999/2001 sets out rules for the importation into the Union of live animals, embryos, ova and products of animal origin. Chapter C of that Annex sets out the rules for imports of products of animal origin from bovine, ovine and caprine animals, and in particular gelatine.
- (7) Article 16 of Regulation (EC) No 999/2001 provides that gelatine derived from hides and skins from healthy ruminants is not to be subject to restrictions on placing on the market pursuant to certain provisions of that Regulation. Therefore, imports into the Union of gelatine derived from hides and skins from healthy ruminants should also not be subject to those restrictions.

⁽¹⁾ OJ L 147, 31.5.2001, p. 1.

⁽²⁾ <http://www.efsa.europa.eu/en/scdocs/scdoc/1371.htm>

- (8) Chapter D of Annex IX to Regulation (EC) No 999/2001 lays down the rules for imports of animal by-products and processed products derived therefrom from bovine, ovine and caprine animals.
- (9) Certain animal by-products and derived products, as defined in 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) ⁽¹⁾, do not present any risk of TSE transmission to humans or animals. Therefore, the health certification requirements laid down in Chapter D of Annex IX to Regulation (EC) No 999/2001 should not apply to imports of such products.
- (10) Annexes VII and IX to Regulation (EC) No 999/2001 should therefore be amended accordingly.
- (11) Regulation (EC) No 1069/2009 applies from 4 March 2011. In the interests of clarity and coherency of
- Union legislation, the amendments made to Chapter D of Annex IX to Regulation (EC) No 999/2001 by this Regulation should also apply from that date.
- (12) 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 VII and IX 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 20th day following its publication in the *Official Journal of the European Union*.

Point 2(b) of the Annex to this Regulation shall apply from 4 March 2011.

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

Done at Brussels, 25 February 2011.

For the Commission
The President
José Manuel BARROSO

⁽¹⁾ OJ L 300, 14.11.2009, p. 1.

ANNEX

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

(1) In Annex VII, Chapter A is amended as follows:

(a) point 2.3(f) is replaced by the following:

‘(f) where the frequency of the ARR allele within the breed or holding is low or absent, or where it is deemed necessary in order to avoid inbreeding, a Member State may decide to delay the killing and complete destruction of the animals referred to in point 2.3(b)(i) and (ii) for a period not exceeding 5 breeding years from the date of confirmation of the index case provided that no breeding rams other than those of the ARR/ARR genotype are present on the holding.

However, in the case of ovine and caprine animals kept for the production of milk with a view to placing it on the market, the killing and complete destruction of the animals may only be delayed for a maximum period of 18 months from the date of confirmation of the index case, except for caprine animals where the killing and complete destruction may be delayed until 31 December 2012 if the index case is confirmed before 1 July 2011.’

(b) the following point is inserted after point 2.4:

‘2.5 Pending the killing and complete destruction of the animals referred to in points 2.3(b) (i) and (ii), including animals for which the killing and complete destruction has been delayed as provided for in point 2.3(f), the measures set out in point 3.1(a) and (b), point 3.2 and point 3.3(a), (b) first indent and (d) shall apply on the holding(s).’

(2) Annex IX is amended as follows:

(a) in Chapter C, Section A is replaced by the following:

‘SECTION A

Products

The following products of bovine, ovine and caprine origin, as defined by points 1.10, 1.13, 1.15, 7.1, 7.5, 7.6, 7.7 and 7.9 of Annex I to Regulation (EC) No 853/2004 of the European Parliament and of the Council (*), shall be subject to the conditions laid down in Sections B, C and D of this Chapter depending on the BSE risk category of the country of origin:

- fresh meat,
- minced meat,
- meat preparations,
- meat products,
- rendered animal fat,
- greaves,
- gelatine other than gelatine derived from hides and skins,
- treated intestines.

(*) OJ L 139, 30.4.2004, p. 55.’

(b) Chapter D is replaced by the following:

‘CHAPTER D

Imports of animal by-products and processed products derived therefrom from bovine, ovine and caprine animal origin

SECTION A

Animal by-products

This Chapter shall apply to the following animal by-products and derived products, as defined in points (1) and (2) of Article 3 of Regulation (EC) No 1069/2009 of the European Parliament and of the Council (*), provided that those products are of bovine, ovine and caprine animal origin:

- (a) rendered fats derived from Category 2 material, which are intended to be used as organic fertilisers or soil improvers, as defined in point 22 of Article 3 of Regulation (EC) No 1069/2009, or their starting materials or intermediate products;
- (b) bones and bone products derived from Category 2 material;
- (c) rendered fats derived from Category 3 material which are intended to be used as organic fertilisers or soil improvers or as feed, as defined in points 22 and 25 of Article 3 of Regulation (EC) No 1069/2009, or their starting materials or intermediate products;
- (d) pet food including dog chews;
- (e) blood products;
- (f) processed animal protein;
- (g) bones and bone products derived from Category 3 material;
- (h) gelatine derived from materials other than hides and skins;
- (i) category 3 material and derived products other than those referred to in points (c) to (h) excluding:
 - (i) fresh hides and skins, treated hides and skins;
 - (ii) gelatine derived from hides and skins;
 - (iii) fat derivatives;
 - (iv) collagen.

SECTION B

Health certificate requirements

Imports of the animal by-products and derived products of bovine, ovine and caprine animal origin referred to in Section A shall be subject to the presentation of a health certificate which has been completed with the following attestation:

- (a) the animal by-product or derived product does not contain and is not derived from specified risk material or mechanically separated meat obtained from bones of bovine, ovine or caprine animals and the animals from which this animal by-product or derived product is derived, have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity; or
- (b) the animal by-product or derived product does not contain and is not derived from bovine, ovine and caprine materials other than those derived from animals born, continuously reared and slaughtered in a country or region classified as posing a negligible BSE risk by a decision in accordance with Article 5(2).

In addition to points (a) and (b), imports of the animal by-products and derived products referred to in Section A, containing milk or milk products of ovine or caprine animal origin and intended for feeding ruminants, shall be subject to the presentation of a health certificate which has been completed with the following attestation:

(c) the ovine and caprine animals from which those products are derived must have been kept continuously since birth or for the last 3 years on a holding where no official movement restriction is imposed due to a suspicion of TSE and which has satisfied the following requirements for the last 3 years:

- (i) it has been subject to regular official veterinary checks;
- (ii) no classical scrapie case has been diagnosed or, following the confirmation of a classical scrapie case:
 - all animals in which classical scrapie was confirmed have been killed and destroyed, and
 - all ovine and caprine animals on the holding have been killed and destroyed, except for breeding rams of the ARR/ARR genotype and breeding ewes carrying at least one ARR allele and no VRQ allele;
- (iii) ovine and caprine animals, with the exception of sheep of the ARR/ARR prion protein genotype, are introduced into the holding only if they come from a holding which complies with the requirements set out in points (i) and (ii);

or

(d) for animal by-products or derived products destined for a Member State listed in the Annex to Commission Regulation (EC) No 546/2006 (**), the ovine and caprine animals from which these products are derived must have been kept continuously since birth or for the last 7 years on a holding where no official movement restriction is imposed due to a suspicion of TSE and which has satisfied the following requirements for the last 7 years:

- (i) it has been subject to regular official veterinary checks;
- (ii) no classical scrapie case has been diagnosed or, following the confirmation of a classical scrapie case:
 - all animals in which classical scrapie was confirmed have been killed and destroyed, and
 - all ovine and caprine animals on the holding have been killed and destroyed, except for breeding rams of the ARR/ARR genotype and breeding ewes carrying at least one ARR allele and no VRQ allele;
- (iii) ovine and caprine animals, with the exception of sheep of the ARR/ARR prion protein genotype, are introduced into the holding only if they come from a holding which complies with the requirements set out in points (i) and (ii).

(*) OJ L 300, 14.11.2009, p. 1.

(**) OJ L 94, 1.4.2006, p. 28.