



Council of the
European Union

071562/EU XXVI. GP
Eingelangt am 12/07/19

Brussels, 12 July 2019
(OR. en)

11214/19
ADD 1

AGRILEG 123
VETER 54

COVER NOTE

From:	European Commission
date of receipt:	11 July 2019
To:	General Secretariat of the Council
No. Cion doc.:	D060710/03 ANNEX
Subject:	ANNEX to the COMMISSION REGULATION (EU) .../... amending Annexes I, VII and VIII to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards eradication measures for transmissible spongiform encephalopathies in goats and endangered breeds

Delegations will find attached document D060710/03 ANNEX.

Encl.: D060710/03 ANNEX



EUROPEAN
COMMISSION

Brussels, **XXX**
SANTE/11882/2017 ANNEX Rev. 1
(POOL/G4/2017/11882/11882R1-EN
ANNEX.docx) D060710/03
[...](2019) **XXX** draft

ANNEX

ANNEX

to the

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

**amending Annexes I, VII and VIII to Regulation (EC) No 999/2001 of the European
Parliament and of the Council as regards eradication measures for transmissible
spongiform encephalopathies in goats and endangered breeds**

ANNEX

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

- (1) in Annex I, point 1 is amended as follows:
 - (a) the introductory sentence 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 Council¹, Commission Regulation (EU) No 142/2011², Regulation (EC) No 178/2002 of the European Parliament and of the Council³, Regulation (EC) No 767/2009 of the European Parliament and of the Council⁴, Council Directive 2006/88/EC⁵ and Regulation (EU) 2016/1012 of the European Parliament and of the Council⁶ shall apply.’;
 - (b) the following point (f) is added:

‘(f) the definition of “endangered breed” in Article 2(24) of Regulation (EU) 2016/1012.’;
- (2) in Annex VII, Chapter B is amended as follows:
 - (a) in point 2.2.2, the introductory paragraph is replaced by the following:

‘If BSE and atypical scrapie are excluded in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2, the holding shall be subject to the conditions set out in point (a). In addition, pursuant to the decision of the Member State responsible for the holding, the holding shall be subject to the conditions of either option 1 set out in point (b), or option 2 set out in point (c), or option 3 set out in point (d). In case of a holding with a mixed ovine and caprine flock, the Member State responsible for the holding may decide to apply the conditions of one of the options to the

¹ 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) (OJ L 300, 14.11.2009, p. 1).

² 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 Directive (OJ L 54, 26.2.2011, p. 1).

³ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

⁴ Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC (OJ L 229, 1.9.2009, p. 1).

⁵ 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).

⁶ Regulation (EU) 2016/1012 of the European Parliament and of the Council of 8 June 2016 on zootechnical and genealogical conditions for the breeding, trade in and entry into the Union of purebred breeding animals, hybrid breeding pigs and the germinal products thereof and amending Regulation (EU) No 652/2014, Council Directives 89/608/EEC and 90/425/EEC and repealing certain acts in the area of animal breeding (‘Animal Breeding Regulation’) (OJ L 171, 29.6.2016, p. 66).

ovine animals of the holding and a different option to the caprine animals of the holding:’;

- (b) in point 2.2.2, the penultimate paragraph of point (b) is replaced by the following:

‘Movement of animals mentioned in point (i) and (ii) from the holding to the slaughterhouse shall be allowed.’

- (c) in point 2.2.2, point (c) is replaced by the following:

- ‘(c) Option 2 — killing and complete destruction of the susceptible animals only

The prion protein genotyping of all ovine and/or caprine animals present on the holding, except lambs and/or kids less than three months old provided that they are slaughtered for human consumption not later than when they are three months of age.

Killing and complete destruction, without delay, of all ovine and/or caprine animals, embryos and ova identified by the inquiry referred to in the second and third indents of point 1(b), with the exception of:

- breeding rams of the ARR/ARR genotype,
- breeding ewes carrying at least one ARR allele and no VRQ allele and, where such breeding ewes are pregnant at the time of the inquiry, the lambs subsequently born, if their genotype meets the requirements of this subparagraph,
- ovine animals carrying at least one ARR allele which are intended solely for human consumption,
- caprine animals carrying at least one of the following alleles: K222, D146 and S146,
- if the Member State responsible for the holding so decides, lambs and/or kids less than three months old provided that they are slaughtered for human consumption not later than when they are three months of age.

The animals over 18 months of age killed for destruction, shall be tested for the presence of TSE in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2, as laid down in Annex III, Chapter A, Part II, point 5.

By way of derogation from the conditions set out in the first and second paragraph of option 2, Member States may decide instead to carry out the measures listed in (i), (ii) or (iii):

- (i) to replace the killing and complete destruction of the animals referred to in the second paragraph of option 2 by their slaughtering for human consumption, provided that:
- the animals are slaughtered for human consumption within the territory of the Member State responsible for the holding;
 - all animals over 18 months of age slaughtered for human consumption shall be tested for the presence of TSE in

accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2.

- (ii) to delay the genotyping and subsequent killing and complete destruction or slaughtering for human consumption of the animals referred to in the second paragraph of option 2, for a period not exceeding three months. This derogation can be applied in situations where the index case is confirmed close to the commencement of the lambing and/or kidding season, provided that the ewes and/or goats and their new-born are kept isolated from ovine and/or caprine animals of other holdings during the whole period.
- (iii) to delay the killing and complete destruction or slaughtering for human consumption of the animals referred to in the second paragraph of option 2 for a maximum period of three years from the date of confirmation of the index case, in ovine or caprine flocks and holdings where ovine and caprine animals are kept together. The application of the derogation set out in the present paragraph shall be limited to cases where the Member State responsible for the holding considers that the epidemiological situation cannot be handled without killing the relevant animals, but that this cannot be carried out immediately due to the low level of resistance in the ovine and caprine population of the holding, coupled with other considerations, including economic factors. Breeding rams other than those of the ARR/ARR genotype shall be killed or castrated without delay. All possible measures to quickly build up genetic resistance in the ovine and/or caprine population of the holding shall be implemented, including reasoned breeding and culling of ewes to increase the frequency of the ARR allele and eliminate the VRQ allele, and the breeding of bucks carrying the K222, D146 or S146 alleles. The Member State responsible for the holding shall ensure that the number of animals to be killed at the end of the period of delay is not greater than immediately after the index case was confirmed. In the case of the application of the derogation set out in the present paragraph, the measures set out in point 4 shall apply to the holding until the complete destruction or slaughtering for human consumption of the animals referred to in the second paragraph of option 2, after which the restrictions laid down in point 3 shall be applicable.

Following the killing and complete destruction or slaughtering for human consumption of the animals referred to in the second paragraph of option 2, the conditions set out in point 3 shall apply to the holding.’;

- (d) in point 2.2.2, point (d) is replaced by the following:

‘(d) Option 3 - no mandatory killing and complete destruction of animals

A Member State may decide not to kill and completely destroy the animals identified by the inquiry referred to in the second and third indents of point 1(b) where the criteria laid down in at least one of the following four indents are met:

- it is difficult to obtain replacement male ovine animals of the ARR/ARR genotype and female ovine animals carrying at least one ARR allele and no VRQ allele, or caprine animals carrying at least one of the following alleles: K222, D146 and S146,
- the frequency of the ARR allele within the ovine breed or holding or the K222, D146 or S146 alleles within the caprine breed or holding is low,
- it is deemed necessary in order to avoid inbreeding,
- it is deemed necessary by the Member State based on a reasoned consideration of all the epidemiological factors.

The prion protein genotype of all ovine and caprine animals, up to a maximum of 50 of each species, shall be determined within a period of three months from the date of confirmation of the index case of classical scrapie.

When additional classical scrapie cases are detected in a holding where option 3 is being applied, the relevance of the reasons and criteria founding the decision to apply option 3 to this holding shall be reassessed by the Member State. If it is concluded that applying option 3 does not ensure a proper control of the outbreak, the Member State shall switch the management of this holding from option 3 to either option 1 or option 2 as laid down in points (b) and (c).

The conditions set out in point 4 shall immediately apply to a holding where it has been decided to apply option 3.

The Member States allowing recourse to option 3 in the management of classical scrapie outbreaks shall keep records of the reasons and criteria founding each individual application decision.’;

(e) point 3 is replaced by the following:

- ‘3. Following the killing and complete destruction or slaughtering for human consumption of all animals identified in a holding in accordance with point 2.2.1, point 2.2.2(b) and point 2.2.2(c), the following restrictions shall apply:
 - 3.1. The holding shall be subject to an intensified TSE monitoring protocol. This shall include the testing for the presence of TSE in animals over the age of 18 months, which have died or have been killed in the holding but not in the framework of a disease eradication campaign. Ovine animals of the ARR/ARR genotype and caprine animals carrying at least one of the K222, D146 or S146 alleles are exempt. Testing shall be carried out in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2.
 - 3.2. Only the following animals may be introduced to the holding:
 - male ovine animals of the ARR/ARR genotype;
 - female ovine animals carrying at least one ARR allele and no VRQ allele;

- caprine animals provided that a cleaning and disinfection of all animal housing on the premises has been carried out following destocking.
- 3.3. Only the following breeding rams, breeding bucks and ovine and caprine germinal products may be used in the holding:
- male ovine animals of the ARR/ARR genotype;
 - semen from rams of the ARR/ARR genotype;
 - embryos carrying at least one ARR allele and no VRQ allele;
 - breeding bucks and caprine germinal products as defined in the measures decided by the Member State to build up genetic resistance in the caprine population of the holding.
- 3.4. Movements of animals from the holding shall either be allowed for the purposes of destruction or shall be subject to the following conditions:
- (a) the following animals may be moved from the holding for all purposes, including breeding:
- ARR/ARR ovine animals;
 - ewes carrying one ARR allele and no VRQ allele, provided that they are moved to other holdings which are restricted following the application of measures in accordance with points 2.2.2(b) (option 1), 2.2.2(c) (option 2), or 2.2.2(d) (option 3);
 - caprine animals carrying at least one of the following alleles: K222, D146 and S146;
 - caprine animals provided that they are moved to other holdings which are restricted following the application of measures in accordance with points 2.2.2(b) (option 1), 2.2.2(c) (option 2) or 2.2.2(d) (option 3);
- (b) the following animals may be moved from the holding to go directly for slaughter for human consumption:
- ovine animals carrying at least one ARR allele;
 - caprine animals;
 - if the Member State so decides, lambs and/or kids less than three months old on the date of slaughter;
 - all animals when the Member State has decided to apply the derogations laid down in points 2.2.2(b)(i) and 2.2.2(c)(i);
- (c) if the Member State so decides, lambs and/or kids may be moved to one other holding located within its territory solely for the purposes of fattening prior to slaughter subject to compliance with the following conditions:
- the holding of destination does not contain any ovine or caprine animals other than those being fattened prior to slaughter;

- at the end of the fattening period, the lambs and/or kids originating from the holdings subject to the eradication measures shall be transported directly to a slaughterhouse located within the territory of the same Member State to be slaughtered not later than when they are 12 months of age.
- 3.5. The restrictions set out in points 3.1 to 3.4 shall continue to apply to the holding:
- (a) until the date of attainment of ARR/ARR status by all ovine animals in the holding, provided that no caprine animals are kept on the holding; or
 - (b) until the date all caprine animals on the holding carry at least one of the K222, D146 or S146 alleles, provided that no ovine animals are kept on the holding; or
 - (c) until the date of attainment of ARR/ARR status by all ovine animals on the holding and all caprine animals on the holding carry at least one of the K222, D146 or S146 alleles; or
 - (d) for a period of two years from the date when all the measures referred to in point 2.2.1, point 2.2.2(b), and point 2.2.2(c) have been completed, provided that no TSE case other than atypical scrapie is detected during this two-year period. If a case of atypical scrapie is confirmed during this two-year period the holding shall also be subject to the measures referred to in point 2.2.3.’;
- (f) point 4 is replaced by the following:
- ‘4. Following the decision to implement option 3 laid down in point 2.2.2(d) or the derogation provided for in point 2.2.2(c)(iii) the following measures shall immediately apply to the holding:
- 4.1. The holding shall be subject to an intensified TSE monitoring protocol. This shall include the testing for the presence of TSE of animals over the age of 18 months which:
- have been slaughtered for human consumption;
 - have died or been killed on the holding but not in the framework of a disease eradication campaign.
- Ovine animals of the ARR/ARR genotype and caprine animals carrying at least one of the K222, D146 or S146 alleles are exempt. Testing shall be carried out in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2.
- 4.2. The conditions set out in points 3.2 and 3.3 shall apply.
- However, by way of derogation from points 3.2 and 3.3, a Member State may allow the introduction and use in the holding of
- male ovine animals and their semen carrying at least one ARR allele and no VRQ allele including for breeding;
 - female ovine animals carrying no VRQ allele;
 - embryos carrying no VRQ allele;

subject to compliance with the following conditions:

- the breed of the animal kept on the holding is an endangered breed;
- the breed of the animal kept on the holding is subject to a breeding programme aiming at the preservation of the breed carried out by a breed society as defined in Article 2(5) of Regulation (EU) 2016/1012 or a competent authority in accordance with Article 38 of that Regulation; and
- the frequency of the ARR allele within that breed is low.

4.3. Movement of animals from the holding shall be allowed for the purposes of destruction or to go directly for slaughter for human consumption or shall be subject to the following conditions:

- (a) rams and ewes of the ARR/ARR genotype and caprine animals carrying at least one of the K222, D146 or S146 alleles, may be moved from the holding for all purposes, including breeding, provided that they are moved to other holdings which are subject to the application of measures in accordance with points 2.2.2(c) (option 2) or 2.2.2(d) (option 3);
- (b) if the Member State so decides, lambs and/or kids may be moved to one other holding located within its territory solely for the purposes of fattening prior to slaughter subject to compliance with the following conditions:
 - the holding of destination does not contain any ovine or caprine animals other than those being fattened prior to slaughter;
 - at the end of the fattening period, the lambs and/or kids shall be transported directly to a slaughterhouse located within the territory of the same Member State to be slaughtered not later than when they are 12 months of age.

4.4. The Member State shall ensure that no semen, embryo and ova are dispatched from the holding.

4.5. Common grazing of all ovine and caprine animals in the holding with ovine and caprine animals of other holdings shall be prohibited during the lambing and/or kidding period.

Outside of the lambing and/or kidding period, common grazing shall be subject to restrictions to be determined by the Member State, based on a reasoned consideration of all the epidemiological factors.

4.6. The restrictions set out in points 4.1 to 4.5 shall apply for a period of two years following the detection of the last TSE case, other than atypical scrapie, on the holdings where option 3 laid down in point 2.2.2(d) has been implemented. If a case of atypical scrapie is confirmed during this two-year period the holding shall also be subject to the measures referred to in point 2.2.3.;

- (3) In Annex VIII, point 4.1 of Section A of Chapter A is amended as follows:
- (a) in point (a), point (iii) is replaced by the following:

‘(iii) in the case of ovine animals, be of the ARR/ARR prion protein genotype and in the case of caprine animals, carry at least one of the K222, D146 or S146 alleles, provided they do not come from a holding subject to the restrictions set out in Annex VII, Chapter B, points 3 and 4.’;
 - (b) in point (b), point (iii) is replaced by the following:

‘(iii) in the case of ovine animals, be of the ARR/ARR prion protein genotype and in the case of caprine animals, carry at least one of the K222, D146 or S146 alleles, provided they do not come from a holding subject to the restrictions set out in Annex VII, Chapter B, points 3 and 4.’;
 - (c) in point (d), points (i), (ii) and (iii) are replaced by the following:
 - ‘(i) the breed of the animals is an endangered breed;
 - (ii) the animals are entered in a breeding book for that breed in the Member State of dispatch. This breeding book is established and maintained by a breed society, recognised in accordance with Article 4(3) of Regulation (EU) 2016/1012, or by a competent authority of that Member State, in accordance with Article 38 of that Regulation. The animals are also to be entered in a breeding book for that breed in the Member State of destination. This breeding book is also established and maintained by a breed society, recognised in accordance with Article 4(3) of Regulation (EU) 2016/1012, or by a competent authority of that Member State in accordance with Article 38 of that Regulation;
 - (iii) in the Member State of dispatch and in the Member State of destination, the breed societies or competent authorities referred to in point (ii) carry out a breeding programme aimed at the preservation of that breed;’;
 - (d) in point (d), the first and second paragraphs of point (v) are replaced by the following:

‘following the entry of the animals not fulfilling the requirements set out in points (a) or (b) into the recipient holding in the Member State of destination, the movement of all ovine and caprine animals on that holding shall be restricted in accordance with point 3.4 of Chapter B of Annex VII, for a period of three years. When the Member State of destination has negligible risk of classical scrapie or has an approved national scrapie control programme this restriction shall be maintained for a period of seven years.

By way of derogation from the first paragraph of this point, such restriction on intra-Union trade or to movements of animals within the Member State shall not apply to animals belonging to an endangered breed, which are destined to a holding where this endangered breed is bred. The breed shall be subject to a breeding programme aiming at the preservation of the breed and carried out by a breed society as defined in Article 2(5) of Regulation (EU) 2016/1012 or a competent authority in accordance with Article 38 of that Regulation.’