

ANNEX
Non-paper
in view of a
possible revision of
Regulation (EC) No 999/2001 as
regards TSE eradication measures in
goats and endangered breeds

Revision dated 10 December 2018

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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 subpoint (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) the introductory paragraph of point 2.2.2 is replaced by the following:

2.2.2. In cases where BSE and atypical scrapie can be excluded

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(c), the holding shall be subject to the conditions set out in point (a) and, pursuant to the decision of the Member State responsible for the holding, to the conditions of either option 1 set out at point (b), or option 2 set out at point (c), or option 3 set out at 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 ovine animals of the holding and a different option to the caprine animals of the holding.'
 - (b) the point 2.2.2 (b) is replaced by the following:

2.2.2.(b) Option 1 — killing and complete destruction of all animals

The killing and complete destruction, without delay, of all animals, embryos and ova identified by the inquiry referred to in the second and third indents of point 1(b).

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.

The prion protein genotype of all ovine animals, up to a maximum of 50, shall be determined.

¹ OJ L 300, 14.11.2009, p. 1.

² OJ L 54, 26.2.2011, p. 1.

³ OJ L 31, 1.2.2002, p. 1.

⁴ OJ L 229, 1.9.2009, p. 1.

⁵ OJ L 328, 24.11.2006, p. 14.

⁶ OJ L 171, 29.6.2016, p. 66.

By way of derogation from the conditions set out in the first paragraph of option 1, Member States may decide instead to carry out the measures listed in (i) or (ii):

- (i) to replace the killing and complete destruction of all animals, without delay, by their slaughtering for human consumption, without delay, provided that:
 - the animals are slaughtered for human consumption within the territory of the Member State responsible for the holding;
 - all animals which are 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 exempt the lambs and kids less than three months old from killing and complete destruction without delay, provided that they are slaughtered for human consumption not later than when they are three months of age.

Movement of animals mentioned in points (i) and (ii) from the holding to go directly for slaughter for human consumption shall be allowed.

Following the killing and complete destruction or slaughtering for human consumption of all animals the conditions set up in point 3 shall apply to the holding where it has been decided to apply option 1.

- (b) the point 2.2.2.(c) is replaced by the following:

2.2.2.(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 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.

In addition, the holding must be subjected to an intensified TSE monitoring protocol, including the testing for the presence of TSE of animals over the age of 18 months, which have died or been killed on the holding, except ovine animals of the ARR/ARR genotype and caprine animals carrying at least one of the following alleles: K222, D146 and S146.

By way of derogation from the conditions set out in the 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, in situations where the index case is confirmed close to the commencement of the lambing and 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. 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.

Pending and 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 up in point 3 shall apply to the holding.

- (c) the point 2.2.2.(d) is replaced by the following:

2.2.2.(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 ovine animals of the ARR/ARR genotype and caprine animals carrying at least one of the following alleles: K222, D146 and S146.
- the frequency of the ARR allele within the ovine breed and 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 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.

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 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.

The conditions set out in point 3.3.(c) and point 4 shall immediately apply to a holding where it has been decided to apply option 3.

- (d) the point 3 is replaced by the following:

3. After 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 2.2.2.(c), the following restrictions shall apply:

3.1. 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.

3.2. 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.

3.3. 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 point 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 point 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 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 point 2.2.2. (b)(i) and point 2.2.2. (c)(i).
- (c) if the Member State so decides, lambs and 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 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.

3.4. The restrictions set out in points 3.1 to 3.3 shall continue to apply to the holding:

- (a) until the date of attainment of ARR/ARR status by all ovine animals on 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 following alleles: K222, D146 and S146, 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 following alleles: K222, D146 and S146; 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.'

(e) the 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 must be subjected to an intensified TSE monitoring protocol including the testing 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, of all the following animals which are over the age of 18 months, except ovine animals of the ARR/ARR genotype and caprine animals carrying at least one of the following alleles: K222, D146 and S146:

- animals which have been slaughtered for human consumption;
- animals which have died or been killed on the holding but which were not killed in the framework of a disease eradication campaign.

4.2 The conditions set out in points 3.1 and 3.2 shall apply.

However, by way of derogation from points 3.1 and 3.2, a Member State may allow the introduction into the holding of male ovine animals carrying at least one ARR allele and no VRQ allele, and female ovine animals carrying no VRQ allele; and the use in the holding for breeding of male ovine animals and their semen carrying at least one ARR allele and no VRQ allele and 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.

4.4. Rams and ewes of the ARR/ARR genotype and caprine animals carrying at least one of the following alleles: K222, D146 and S146, may be moved from the holding for all purposes, including breeding.

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

4.6. 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 kidding period.

Outside of the lambing and 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.

4.7. The restrictions set out in points 4.1 to 4.6 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.

In holdings where the derogation from option 2 provided for in point 2.2.2.(c)(iii) has been implemented, the restrictions set out in point 2.2.2.(a) and in points 4.1 to 4.6 shall apply until the complete destruction or slaughtering for human consumption of the animals identified for killing in accordance with point 2.2.2.(c), after which the restrictions laid out in point 3 shall be applicable.

(3) In Annex VIII, points 4.1 of Section A of Chapter A is amended as follows:

(a) point (a)(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 following alleles: K222, D146 and S146'

(b) point (b)(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 following alleles: K222, D146 and S146'

(c) points (d)(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 established and maintained by a breed society, recognised in accordance with Article 4(3) of Regulation (EU) 2016/1012, in the Member State of dispatch or by a competent authority of the that Member State in accordance with Article 38 of that Regulation and the animals are to be entered in a breeding book for that breed established and maintained by a breed society, recognised in accordance with Article 4(3) of Regulation (EU) 2016/1012 in the

Member State of destination, 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 aiming at the preservation of that breed;'

(d) the first and second paragraph of point (d)(v) are replaced by the following:

'following the entry of the animals not fulfilling the requirements set out in point (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 3.3 of Chapter B of Annex VII, for a period of three years, or for a period of seven years when the Member State of destination has negligible risk of classical scrapie or has an approved national scrapie control programme.

By way of derogation from the first paragraph of this point, when the animals to be moved belong to an endangered breed and are destined to a holding where this endangered breed is bred, provided that the breed 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, such restriction on movement shall not apply to intra-Union trade nor to movements of animals within the Member State.'