Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council, ANNEX VII. (See end of Document for details)

# [F1ANNEX VII

# CONTROL AND ERADICATION OF TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES

#### **Textual Amendments**

**F1** Substituted by Commission Regulation (EU) No 630/2013 of 28 June 2013 amending the Annexes 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).

### CHAPTER A

## Measures following the suspicion of the presence of a TSE in ovine and caprine animals

If a TSE is suspected in an ovine or caprine animal on a holding in a Member State and until the results of the confirmatory examinations are available, all other ovine and caprine animals on that holding shall be placed under an official movement restriction.

If there is evidence that the holding where the animal was present when the TSE was suspected is unlikely to be the holding where the animal could have been exposed to the TSE, the Member State may decide that other holdings or only the holding of exposure shall be placed under official control, depending on the epidemiological information available.

The milk and the milk products derived from the ovine and caprine animals of a holding placed under official control, which are present on that holding from the date when the presence of the TSE is suspected until the results of the confirmatory examinations are available, shall only be used within that holding.

## CHAPTER B

# Measures following confirmation of the presence of a TSE in bovine, ovine and caprine animals

- 1. The inquiry referred to in Article 13(1)(b) must identify:
- (a) in the case of bovine animals:
  - all other ruminants on the holding of the animal in which the disease was confirmed,
  - where the disease was confirmed in a female animal, its progeny born within a period of two years prior to, or after, the clinical onset of the disease,
  - all animals of the cohort of the animal in which the disease was confirmed,
  - the possible origin of the disease,
  - other animals on the holding of the animal in which the disease was confirmed or on other holdings which may have become infected by the TSE agent or been exposed to the same feed or contamination source,
  - the movement of potentially contaminated feedingstuffs, of other material or any other means of transmission, which may have transmitted the TSE agent to or from the holding in question;

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council, ANNEX VII. (See end of Document for details)

- (b) in the case of ovine and caprine animals:
  - all ruminants other than ovine and caprine animals on the holding of the animal in which the disease was confirmed.
  - insofar as they are identifiable, the parents, and in the case of females all embryos, ova and the last progeny of the female animal in which the disease was confirmed.
  - all other ovine and caprine animals on the holding of the animal in which the disease was confirmed in addition to those referred to in the second indent,
  - the possible origin of the disease and the identification of other holdings on which there are animals, embryos or ova which may have become infected by the TSE agent or been exposed to the same feed or contamination source,
  - the movement of potentially contaminated feedingstuffs, other material or any other means of transmission, which may have transmitted the TSE agent to or from the holding in question.
- 2. The measures laid down in Article 13(1)(c) shall comprise at least the following:
- 2.1. In the case of confirmation of BSE in a bovine animal, the killing and complete destruction of bovine animals identified by the inquiry referred to in the second and third indents of point 1(a); however, the Member State may decide:
  - not to kill and destroy animals of the cohort referred to in the third indent of point 1(a) if evidence has been provided that such animals did not have access to the same feed as the affected animal,
  - to defer the killing and destruction of animals of the cohort referred to in the third indent of point 1(a) until the end of their productive life, provided that they are bulls continuously kept at a semen collection centre and it can be ensured that they are completely destroyed following death.
- 2.2. In the case of confirmation of TSE in an ovine or caprine animal:
  - 2.2.1. In cases where BSE cannot be excluded

[F2If BSE cannot be excluded after the results of the secondary molecular testing carried out in accordance with the methods and protocols set out in Annex X, Chapter C, point 3.2(c) (ii), the killing and complete destruction, without delay, of all animals, embryos and ova identified by the inquiry referred to in the second to fifth 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.

The milk and the milk products derived from the animals to be destroyed, which were present on the holding between the date of confirmation that BSE cannot be excluded and the date of complete destruction of the animals, shall be disposed of in accordance with Article 12 of Regulation (EC) No 1069/2009 of the European Parliament and of the Council<sup>(1)</sup>.

Following the killing and complete destruction of all animals, the conditions set out in point 3 shall apply to the holding.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council, ANNEX VII. (See end of Document for details)

## 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):

(a) The milk and milk products derived from the animals to be destroyed or slaughtered and which were present on the holding between the date of confirmation of the case of TSE and the date of the completion of the measures to be applied in the holding as laid down in point (b) and (c), or derived from the infected flock/herd until all the restrictions laid down in point (d) and point 4 are lifted, shall not be used for the feeding of ruminants, except for the feeding of ruminants within that holding.

The placing on the market of such milk and milk products as feed for non-ruminants shall be limited to the territory of the Member State responsible for the holding.

The commercial document accompanying consignments of such milk and milk products and any packaging containing such consignments shall be clearly marked with the words: 'shall not be fed to ruminants'.

The use and the storage of feedingstuffs containing such milk and milk products shall be prohibited on holdings where ruminants are kept.

Bulk feedingstuffs containing such milk and milk products shall be transported by means of vehicles which do not transport feedingstuffs for ruminants at the same time.

If those vehicles are subsequently used for the transport of feedingstuffs intended for ruminants, they shall be thoroughly cleaned in order to avoid cross-contamination, in accordance with a procedure approved by the Member State responsible for the holding.

(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.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council, ANNEX VII. (See end of Document for details)

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.

Pending the killing and complete destruction or slaughtering for human consumption of all animals, the measures set out in point 2.2.2.(a) and point 3.4.(b) third and fourth indents shall apply on the holding where it has been decided to apply option 1.

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

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

The prion protein genotyping of all ovine animals present on the holding followed by 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), 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 slaughter for human consumption,
- 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

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council, ANNEX VII. (See end of Document for details)

of age. These lambs and kids shall be exempted from the genotyping.

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 paragraph of option 2, Member States may decide instead to carry out the measures listed in (i), (ii) and (iii):

- (i) to replace the killing and complete destruction of the animals referred to in the first 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 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 delay the genotyping and subsequent killing and complete destruction or slaughtering for human consumption of the animals referred to in the first 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 season, provided that the ewes, goats and their new-born are kept isolated from ovine and caprine animals of other holdings during the whole period;
- to delay the killing and complete destruction or (iii) slaughtering for human consumption of the animals referred to in the first paragraph of option 2 for a maximum period of three years from the date of confirmation of the index case, in ovine 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 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 and all possible measures to quickly build up genetic resistance in the ovine population of the holding, including by reasoned breeding and culling of ewes to increase the frequency of the ARR allele and eliminate the VRQ allele, shall

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council, ANNEX VII. (See end of Document for details)

be implemented. 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.

Pending the killing and complete destruction or slaughtering for human consumption of the animals referred to in the first paragraph of option 2, the following measures shall apply on the holding where it has been decided to apply option 2: point 2.2.2.(a), point 3.1., point 3.2.(a) and (b), point 3.3. and point 3.4.(a) first and second indents, (b) first, third and fourth indents, and (c). However, where the Member State responsible for the holding decides to delay the killing and complete destruction or slaughtering for human consumption of the animals in accordance with point (iii), the following measures shall instead apply on the holding: point 2.2.2.(a) and points 4.1. to 4.6.

Following the killing and complete destruction, or slaughtering for human consumption of the animals referred to in the first paragraph of option 2 the conditions set out in point 3 shall apply to the holding where it has been decided to apply option 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 genotypes allowed under point 3.2.(a) and (b),
- the frequency of the ARR allele within the 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 animals, up to a maximum of 50, shall be determined within a period of three months from the date of confirmation of the index case of classical scrapie.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council, ANNEX VII. (See end of Document for details)

The conditions set out in point 2.2.2.(a) and point 4 shall immediately apply to a holding where it has been decided to apply option 3.

## 2.2.3. In cases where atypical scrapie is confirmed

Where the TSE case confirmed on a holding is an atypical scrapic case, the holding shall be subject to the following intensified TSE monitoring protocol for a period of two years from the date of the detection of the last atypical scrapic case: all ovine and caprine animals which are over the age of 18 months and slaughtered for human consumption and all ovine and caprine animals over the age of 18 months which have died or been killed on the holding 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.

If a case of TSE other than atypical scrapie is confirmed during the intensified TSE monitoring period of two years referred to in the first paragraph, the holding shall be subject to the measures referred to in point 2.2.1 or point 2.2.2.

- 2.3. If an animal infected with TSE has been introduced from another holding:
  - (a) a Member State may decide, based on the history of the infected animal, to apply eradication measures in the holding of origin in addition to, or instead of, the holding in which the infection was confirmed;
  - (b) in the case of land used for common grazing by more than one flock or herd, Member States may decide to limit the application of eradication measures to a single flock or herd, based on a reasoned consideration of all the epidemiological factors;
  - (c) where more than one flock or herd is kept on a single holding, Member States may decide to limit the application of the eradication measures to the flock or herd in which the TSE has been confirmed, provided it has been verified that the flocks or herds have been kept isolated from each other and that the spread of infection between the flocks or herds through either direct or indirect contact is unlikely.

#### **Textual Amendments**

- **F2** Substituted by Commission Regulation (EU) No 1148/2014 of 28 October 2014 amending Annexes II, VII, VIII, IX 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).
- 3. Following the killing and complete destruction or slaughtering for human consumption of all animals identified on a holding, in accordance with point 2.2.1., point 2.2.2.(b) or point 2.2.2.(c):
- 3.1. The holding shall 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 of the following

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council, ANNEX VII. (See end of Document for details)

animals which are over the age of 18 months, except ovine animals of the ARR/ARR genotype:

- (a) animals which were kept in the holding at the time when the TSE case was confirmed, in accordance with point 2.2.2.(c), and which have been slaughtered for human consumption;
- (b) animals which have died or been killed on the holding but which were not killed in the framework of a disease eradication campaign.
- 3.2. Only the following animals may be introduced to the holding:
  - (a) male ovine animals of the ARR/ARR genotype;
  - (b) female ovine animals carrying at least one ARR allele and no VRQ allele;
  - (c) 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 and ovine germinal products may be used in the holding:
  - (a) male ovine animals of the ARR/ARR genotype;
  - (b) semen from rams of the ARR/ARR genotype;
  - (c) embryos carrying at least one ARR allele and no VRQ allele.
- 3.4. Movement 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.(c) or 2.2.2.(d);
    - 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.(c) or 2.2.2.(d);
  - (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;

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council, ANNEX VII. (See end of Document for details)

- 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.
- 3.5. 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 on the holding, provided that no caprine animals are kept on the holding; or
  - (b) 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) or 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.
- 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 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 of the following animals which are over the age of 18 months, except ovine animals of the ARR/ARR genotype:
  - (a) animals which have been slaughtered for human consumption;
  - (b) 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. | F<sup>3</sup>Only the following ovine animals may be introduced into the holding:
  - (a) male ovine animals of the ARR/ARR genotype;
  - (b) female ovine animals carrying at least one ARR allele and no VRQ allele.

However, by way of derogation from points (a) and (b), a Member State may allow the ovine animals referred to in points (c) and (d) to be introduced into the holding, subject to compliance with the following conditions:

- (i) the breed reared in the holding is a local breed in danger of being lost to farming in accordance with Articles 7(2) and 7(3) of Commission Delegated Regulation (EU) No 807/2014<sup>(2)</sup>;
- (ii) the breed reared in the holding is subject to a preservation programme carried out by a breeders' organisation or association officially approved in accordance with Article 5 of Council Directive 89/361/EEC<sup>(3)</sup>, or an official agency; and
- (iii) the frequency of the ARR allele within the breed reared in the holding is low;
- (c) male ovine animals carrying at least one ARR allele and no VRQ allele;
- (d) female ovine animals carrying no VRQ allele.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council, ANNEX VII. (See end of Document for details)

- 4.3. Only the following breeding rams and ovine germinal products may be used in the holding:
  - (a) male ovine animals of the ARR/ARR genotype;
  - (b) semen from rams of the ARR/ARR genotype;
  - (c) embryos carrying at least one ARR allele and no VRQ allele.

However, by way of derogation from points (a), (b) and (c), a Member State may allow the breeding rams and ovine germinal products referred to in points (d), (e) and (f) to be used in the holding, subject to compliance with the following conditions:

- (i) the breed reared in the holding is a local breed in danger of being lost to farming in accordance with Articles 7(2) and 7(3) of Delegated Regulation (EU) No 807/2014;
- (ii) the breed reared in the holding is subject to a preservation programme carried out by a breeders' organisation or association officially approved in accordance with Article 5 of Directive 89/361/EEC, or an official agency; and
- (iii) the frequency of the ARR allele within the breed reared in the holding is low;
- (d) male ovine animals carrying at least one ARR allele and no VRQ allele;
- (e) semen from male ovine animals carrying at least one ARR allele and no VRQ allele;
- (f) embryos carrying no VRQ allele.
- 4.4. 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 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 point 2.2.2.(c) or 2.2.2.(d);
  - (b) 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:
    - (i) the holding of destination shall not contain any ovine or caprine animals other than those being fattened prior to slaughter;
    - (ii) at the end of the fattening period, the lambs and kids originating from the holdings subject to the eradication measures referred to in point 2.2.2.(c)(iii) or 2.2.2.(d) 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.]

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council, ANNEX VII. (See end of Document for details)

- 4.5. Movement of germinal products from the holding shall be subject to the following conditions: 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 point 2.2.2.(a) and in points 4.1 to 4.6 shall continue to 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.

#### **Textual Amendments**

**F3** Substituted by Commission Regulation (EU) 2016/1396 of 18 August 2016 amending certain Annexes to Regulation (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).

## CHAPTER C

Minimum requirements for a breeding programme for resistance to TSEs in ovine animals in accordance with article 6A

## PART 1

## General requirements

1. The breeding programme shall concentrate on flocks of high genetic merit, as defined in point 3 of Annex I of Commission Decision 2002/1003/EC.

However, Member States where a breeding programme is in place may decide to allow sampling and genotyping of breeding rams only, in flocks not participating in the breeding programme.

- 2. A database shall be established containing at least the following information:
- (a) the identity, breed and number of animals in all flocks participating in the breeding programme;

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council, ANNEX VII. (See end of Document for details)

- (b) the identification of the individual animals sampled under the breeding programme, including breeding rams sampled in flocks not participating in the breeding programme;
- (c) the results of any genotyping tests.
- 3. A system of uniform certification shall be established in which the genotype of each animal sampled under the breeding programme, including breeding rams sampled in flocks not participating in the breeding programme, is certified by reference to its individual identification number.
- 4. A system for the identification of animals and samples, the processing of samples and the delivery of results shall be established which minimises the possibility of human error. The effectiveness of that system shall be subject to regular random checking.
- 5. Genotyping of blood or other tissues collected for the purposes of the breeding programme, including from breeding rams sampled in flocks not participating in the breeding programme, shall be carried out in laboratories that have been approved under the breeding programme.
- 6. The competent authority of the Member State may assist breed societies, to establish genetic banks consisting of semen, ova and embryos representative of prion protein genotypes which are likely to become rare as a result of the breeding programme.
- 7. Breeding programmes shall be drawn up for each breed, taking account of:
- (a) frequencies of the different alleles within the breed;
- (b) rarity of the breed;
- (c) avoidance of inbreeding or genetic drift.
- [F48. Where the Member State allows, in accordance with the second paragraph of point 1, the sampling and genotyping of breeding rams in flocks not participating in the breeding programme, the prion protein genotype for the codons 136, 141, 154 and 171 shall be determined for a minimum sample representative of the entire ovine population of the Member State, either:
- (a) once every 3 years with a minimum sample of at least 1 560 ovine animals; or
- (b) at a frequency and with a sample size determined by the Member State based on compliance with the following criteria:
  - (i) the sampling design takes into account relevant epidemiological data collected during previous surveys, including data concerning the prion protein genotype of sheep for the codons 136, 141, 154 and 171 by breed, region, age, sex and flock type;
  - (ii) the sampling design allows at a minimum to detect a change of 5 % in genotype prevalence over a 3-year period, with a 80 % power and 95 % confidence level.]

# **Textual Amendments**

**F4** Inserted by Commission Regulation (EU) 2017/894 of 24 May 2017 amending Annexes III and VII to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the genotyping of ovine animals (Text with EEA relevance).

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council, ANNEX VII. (See end of Document for details)

#### PART 2

## Specific rules for participating flocks

- 1. The breeding programme shall be aimed at increasing the frequency of the ARR allele within the flock, while reducing the prevalence of those alleles which have been shown to contribute to susceptibility to TSEs.
- 2. The minimum requirements for participating flocks shall be the following:
- (a) all animals in the flock that are to be genotyped shall be individually identified using secure means;
- (b) all rams intended for breeding within the flock shall be genotyped before being used for breeding;
- (c) any male animal carrying the VRQ allele shall be slaughtered or castrated, within six months following the determination of its genotype; any such animal shall not leave the holding except for slaughter;
- (d) female animals that are known to carry the VRQ allele shall not leave the holding except for slaughter;
- (e) male animals, including semen donors used for artificial insemination, other than those certified under the breeding programme, shall not be used for breeding within the flock.
- 3. Member States may decide to grant derogations from the requirements set out in point 2(c) and (d) for the purposes of the protection of breeds and production traits.
- 4. Member States shall inform the Commission of any derogation granted under point 3 and of the criteria used.

### PART 3

# Specific rules for breeding rams sampled in flocks not participating in the breeding programme

- 1. Rams to be sampled shall be individually identified using secure means.
- 2. Any ram found to carry the VRQ allele shall not leave the holding except for slaughter.

### PART 4

## The framework for the recognition of the TSE-resistant status of flocks of ovine animals

1. The framework for the recognition of the TSE-resistant status of flocks of ovine animals shall recognise the TSE-resistant status of flocks of ovine animals that as a result of participation in the breeding programme as provided for in Article 6a, satisfy the criteria required in that programme.

That recognition shall be granted on at least the following two levels:

(a) level I flocks shall be flocks composed entirely of ovine animals of the ARR/ARR genotype;

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council, ANNEX VII. (See end of Document for details)

(b) level II flocks shall be flocks whose progeny have been sired exclusively by rams of the ARR/ARR genotype.

Member States may decide to grant recognition on further levels to suit national requirements.

- 2. Regular random sampling of ovine animals from TSE-resistant flocks shall be carried out:
- (a) on the holding or at the slaughterhouse to verify their genotype;
- (b) in the case of level I flocks, in animals over 18 months of age at the slaughterhouse, for TSE testing in accordance with Annex III.

### PART 5

# Reports to be provided to the Commission by the Member States

Member States introducing national breeding programmes to select for resistance to TSE in their ovine populations shall:

- 1. notify to the Commission the requirements for such programmes;
- 2. submit to the Commission an annual report on their progress.

The report for each calendar year shall be submitted at the latest by 31 March of the following year.]

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council, ANNEX VII. (See end of Document for details)

- (1) [F1OJ L 300, 14.11.2009, p. 1.]
- (2) [F1[F3Commission Delegated Regulation (EU) No 807/2014 of 11 March 2014 supplementing Regulation (EU) No 1305/2013 of the European Parliament and of the Council on support for rural development by the European Agricultural Fund for Rural Development (EAFRD) and introducing transitional provisions (OJ L 227, 31.7.2014, p. 1).]]
- (3) [F1[F3Council Directive 89/361/EEC of 30 May 1989 concerning pure-bred breeding sheep and goats (OJ L 153, 6.6.1989, p. 30).]]

### **Textual Amendments**

- **F1** Substituted by Commission Regulation (EU) No 630/2013 of 28 June 2013 amending the Annexes 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).
- F3 Substituted by Commission Regulation (EU) 2016/1396 of 18 August 2016 amending certain Annexes to Regulation (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).

## **Status:**

Point in time view as at 01/01/2018.

# **Changes to legislation:**

There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council, ANNEX VII.