

Status: Point in time view as at 18/03/2011.

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)

[^{F1}ANNEX VII

ERADICATION OF TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY

Textual Amendments

- F1** Substituted by [Commission Regulation \(EC\) No 727/2007 of 26 June 2007 amending Annexes I, III, VII 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 \(Text with EEA relevance\).](#)

[^{F2}CHAPTER A

Measures following confirmation of the presence of a TSE

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 two years prior to, or after, 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;
 - (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:
 - 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:

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- 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 in 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. [F3If 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 from 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 competent authority 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 the 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.]
- 2.3. In the case of confirmation of TSE in an ovine or caprine animal:
- (a) [F3if BSE cannot be excluded after the results of a ring trial carried out in accordance with the procedure set out in Annex X, Chapter C, point 3.2(c), the killing and complete destruction of all animals, embryos and ova identified by the inquiry referred to in the second to fifth indents of point 1(b). 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 destroyed.]
 - (b) if BSE is excluded in accordance with the procedure set out in Annex X, Chapter C, point 3.2(c), pursuant to the decision of the competent authority:
 - either
 - (i) [F3the killing and complete destruction of all animals, embryos and ova identified by the inquiry referred to in the second and third indents of point 1(b). In case the confirmed TSE is classical scrapie, the milk and milk products derived from the animals to be destroyed and which were present on the holding between the date of confirmation of the classical scrapie case and the date of the complete destruction of the animals 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 products as feed for non-ruminants shall be limited to the territory of the Member State concerned. The commercial document accompanying consignments of such products and any packaging containing such consignments must be clearly marked with the words: ‘shall not be fed to ruminants’. The use and the storage of feedingstuffs containing such products shall be prohibited on farms where ruminants are kept. Bulk feedingstuffs containing such products shall be transported by means of vehicles

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which do not transport feedingstuffs for ruminants at the same time. If such 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 competent authority.

The conditions set out in point 3 shall apply to the holding;

or

- (ii) the killing and complete destruction 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,
 - sheep carrying at least one ARR allele which are intended solely for slaughter,
 - if the competent authority so decides, sheep and goats less than three months old which are intended solely for slaughter.

In case the confirmed TSE is classical scrapie, the milk and milk products derived from the animals to be destroyed and which were present on the holding between the date of confirmation of the classical scrapie case and the date of the complete destruction of the animals 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 products as feed for non-ruminants shall be limited to the territory of the Member State concerned. The commercial document accompanying consignments of such products and any packaging containing such consignments must be clearly marked with the words: 'shall not be fed to ruminants'. The use and the storage of feedingstuffs containing such products shall be prohibited on farms where ruminants are kept. Bulk feedingstuffs containing such products shall be transported by means of vehicles which do not transport feedingstuffs for ruminants at the same time. If such 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 competent authority.

The conditions set out in point 3 shall apply to the holding;]

- (iii) a Member State may decide not to kill and destroy the animals, identified by the inquiry referred to in the second and third indents of point 1(b) where it is difficult to obtain replacement ovine animals of a known genotype or where the frequency of the ARR allele within the breed or holding is low, or where it is deemed necessary in order to avoid inbreeding, or based on a reasoned

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consideration of all the epidemiological factors. The conditions set out in point 4 shall apply to the holding;

- (c) by way of derogation from the measures set out in point (b), and only where the TSE case confirmed on a holding is an atypical scrapie case, the Member State may decide to apply the measures laid down in point 5;
- (d) Member States may decide:
 - (i) to replace the killing and complete destruction of all animals referred to in b(i) by slaughtering for human consumption;
 - (ii) to replace the killing and complete destruction of animals referred to in b(ii) by slaughtering for human consumption provided that:
 - the animals are slaughtered within the territory of the concerned Member State,
 - all animals which are over 18 months of age or have more than two permanent incisors erupted through the gum and are slaughtered for human consumption shall be tested for the presence of TSE in accordance with the laboratory methods set out in Annex X, Chapter C, point 3.2 (b);
- (e) the prion protein genotype of ovine animals, up to a maximum of 50, killed and destroyed or slaughtered for human consumption in accordance with points (b)(i) and (ii) shall be determined;
- (f) [^{F4}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.]

- 2.4. If the infected animal has been introduced from another holding, a Member State may decide, based on the history of the case, to apply eradication measures in the holding of origin in addition to, or instead of, the holding in which the infection was confirmed; in the case of land used for common grazing by more than one flock, Member States may decide to limit the application of those measures to a single flock, based on a reasoned consideration of all the epidemiological factors; where more than one flock is kept on a single holding, Member States may decide to limit the application of the measures to the flock in which the TSE has been confirmed, provided it has been verified that the flocks have been kept isolated from each other and that the spread of infection between the flocks through either direct or indirect contact is unlikely.
- 2.5. [^{F5}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

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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).]

Textual Amendments

- F3** Substituted by Commission Regulation (EC) No 103/2009 of 3 February 2009 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).
- F4** Substituted by 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).
- F5** Inserted by 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).

3. Following the application on a holding of the measures referred to in point 2.3 (a) and (b)(i) and (ii):
- 3.1. Only the following animals may be introduced to the holding(s):
- (a) male sheep of the ARR/ARR genotype;
 - (b) female sheep carrying at least one ARR allele and no VRQ allele;
 - (c) caprine animals, provided that:
 - (i) no ovine animals for breeding other than those of the genotypes referred to in points (a) and (b) are present on the holding;
 - (ii) thorough cleaning and disinfection of all animal housing on the premises has been carried out following destocking.
- 3.2. Only the following ovine germinal products may be used in the holding(s):
- (a) semen from rams of the ARR/ARR genotype;
 - (b) embryos carrying at least one ARR allele and no VRQ allele.
- 3.3. Movement of the animals from the holding shall be subject to the following conditions:
- (a) movement of ARR/ARR sheep from the holding shall not be subject to any restriction;
 - (b) sheep carrying only one ARR allele may be moved from the holding only to go directly for slaughter for human consumption or for the purposes of destruction; however,
 - ewes carrying one ARR allele and no VRQ allele may be moved to other holdings which are restricted following the application of measures in accordance with point 2.3 (b)(ii) or 4,
 - if the competent authority so decides, lambs and kids may be moved to one other holding solely for the purposes of fattening prior to slaughter; the holding of destination shall not contain any ovine or caprine animals other than those being fattened prior to

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- slaughter, and shall not dispatch live ovine or caprine animals to other holdings, except for direct slaughter within the territory of the concerned Member State;
- (c) caprine animals may be moved provided that the holding is subjected to intensified TSE monitoring, including the testing of all caprine animals which are over the age of 18 months and:
- (i) are slaughtered for human consumption at the end of their productive lives; or
- (ii) have died or been killed on the holding, and meet the conditions set out to in Annex III, Chapter A, Part II, point 3;
- (d) if the Member State so decides, lambs and kids less than three months old may be moved from the holding to go directly for slaughter for human consumption.
- 3.4. The restrictions set out in points 3.1, 3.2 and 3.3 shall continue to apply to the holding for a period of two years from:
- (a) the date of attainment of ARR/ARR status by all ovine animals on the holding; or
- (b) the last date when any ovine or caprine animal was kept on the premises; or
- (c) the date when the intensified TSE monitoring set out in 3.3 (c) commenced; or
- (d) the date when all breeding rams on the holding are of ARR/ARR genotype and all breeding ewes carry at least one ARR allele and no VRQ allele, provided that during the two-year period, negative results are obtained from TSE testing of the following animals over the age of 18 months:
- an annual sample of ovine animals slaughtered for human consumption at the end of their productive lives in accordance with the sample size referred to in the Table in Annex III, Chapter A, Part II, point 5, and
 - all ovine animals referred to in Annex III, Chapter A, Part II, point 3 which have died or been killed on the holding.
4. Following the application on a holding of the measures set out in point 2.3 (b)(iii) and for a period of two breeding years following the detection of the last TSE case:
- (a) all ovine and caprine animals on the holding shall be identified;
- (b) all ovine and caprine animals on the holding, may be moved only within the territory of the concerned Member State for slaughter for human consumption or for the purposes of destruction; all animals over the age of 18 months slaughtered for human consumption shall be tested for the presence of TSE in accordance with the laboratory methods laid down in Annex X, Chapter C, point 3.2(b);
- (c) the competent authority shall ensure that embryos and ova are not dispatched from the holding;
- (d) only the semen from rams of the ARR/ARR genotype and embryos carrying at least one ARR allele and no VRQ allele may be used in the holding;

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- (e) all ovine and caprine animals which are over the age of 18 months which have died or been killed on the holding shall be subject to TSE testing;
 - (f) only male sheep of the ARR/ARR genotype and female ovine animals from holdings where no TSE cases have been detected or from flocks fulfilling the conditions set out in point 3.4 may be introduced in the holding;
 - (g) only caprine animals from holdings where no TSE cases have been detected or from flocks fulfilling the conditions of point 3.4 may be introduced in the holding;
 - (h) all ovine and caprine animals in the holding shall be subject to common grazing restrictions to be determined by the competent authority, based on a reasoned consideration of all the epidemiological factors;
 - (i) by way of derogation of point (b) if the competent authority so decides, lambs and kids may be moved to another holding within the same Member State solely for the purposes of fattening prior to slaughter; provided that the holding of destination shall not contain any ovine or caprine animals other than those being fattened prior to slaughter, and shall not dispatch live ovine or caprine animals to other holdings, except for direct slaughter within the territory of the concerned Member State.
5. Following the application of the derogation provided for in point 2.3 (c) the following measures shall apply:
- (a) either the killing and complete destruction of all animals, embryos and ova identified by the inquiry referred to in the second and third indents of point 1(b). Member States may decide to determine the prion protein genotype of ovine animals which have been killed and destroyed;
 - (b) or, for a period of two breeding years following the detection of the last TSE case, at least the following measures:
 - (i) all ovine and caprine animals in the holding shall be identified;
 - (ii) the holding must be subject to intensified TSE monitoring for a period of two years, including the testing of 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 which have died or been killed on the holding;
 - (iii) the competent authority shall ensure that live ovine and caprine animals, embryos and ova from the holding are not dispatched to other Member States or third countries.
6. Member States applying the measures set out in point 2.3(b)(iii) or the derogations provided for in points 2.3(c) and (d) shall notify to the Commission an account of the conditions and criteria used for granting them. Where additional TSE cases are detected in flocks where derogations are applied, the conditions for granting such derogations shall be reassessed.]

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CHAPTER B

Minimum requirements for a breeding programme for resistance to TSEs in sheep in accordance with Article 6a

PART 1

General requirements

1. The breeding programme shall concentrate on flocks of high genetic merit.
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;
 - (b) the identification of the individual animals sampled under 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 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 shall be carried out in laboratories that have been approved under that programme.
6. The competent authority of the Member State may assist breed societies, to establish genetic banks consisting of semen, ova and/or 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.

PART 2

Specific rules for participating flocks

1. The breeding programme shall be aimed at increasing the frequency of the ARR allele within the sheep 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;

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- (b) all rams intended for breeding within the flock to 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 protection of breeds and production traits.
 4. Member States shall inform the Commission of derogations granted under point 3 and of the criteria used.

PART 3

The framework for the recognition of the TSE-resistant status of flocks of sheep

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

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

- (a) level I flocks shall be flocks composed entirely of sheep of the ARR/ARR genotype;
- (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 sheep from TSE-resistant flocks shall be carried out:
 - (a) on the farm 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 4

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 notify to the Commission the requirements for such programmes and shall provide 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.]

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