# [<sup>F1</sup>ANNEX 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 <sup>F2</sup>... 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.

#### **Textual Amendments**

F2 Words in Annex 7 Ch. A omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, 2(45)(a); 2020 c. 1, Sch. 5 para. 1(1)

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 [<sup>F3</sup>appropriate authority] may decide that other holdings or only the holding of exposure shall be placed under official control, depending on the epidemiological information available.

#### **Textual Amendments**

F3 Words in Annex 7 Ch. A substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, 2(45) (b); 2020 c. 1, Sch. 5 para. 1(1)

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;
- (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 [<sup>F4</sup>appropriate authority] 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

[<sup>F5</sup>If 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).]

**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 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.

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

[<sup>F6</sup>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 [<sup>F7</sup>appropriate authority] 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 ovine animals of the holding and a different option to the caprine animals of the holding:]

(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 [<sup>F8</sup>Great Britain].

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 [<sup>F9</sup>appropriate authority] 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.

By way of derogation from the conditions set out in the first paragraph of option 1, [<sup>F10</sup>nothing in this Regulation prevents the appropriate authority from deciding] 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 [<sup>F11</sup>Great Britain];
  - 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.

[<sup>F6</sup>Movement of animals mentioned in points (i) and (ii) from the holding to the slaughterhouse shall be allowed.]

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) [<sup>F6</sup>Option 2 – killing and complete destruction of the susceptible animals only

The prion protein genotyping of all ovine and caprine animals present in the holding, except 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.

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 [<sup>F12</sup>appropriate authority] 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.

[<sup>F13</sup>Nothing in this Regulation prevents the appropriate authority from deciding] 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 [<sup>F14</sup>appropriate authority] 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 [<sup>F15</sup>action] 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;

to delay the killing and complete destruction or (iii) 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. [F16Such action shall be limited to cases where the appropriate authority] 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 [<sup>F17</sup>appropriate authority] 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. [<sup>F18</sup>Where such action is taken], 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) [<sup>F6</sup>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 [<sup>F19</sup>appropriate authority] 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 [<sup>F20</sup>appropriate authority]. If it is concluded that applying option 3 does not ensure a proper control of the outbreak, the [<sup>F20</sup>appropriate authority] 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.

[<sup>F21</sup>Any appropriate authority] 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.]

2.2.3. In cases where atypical scrapie is confirmed

Where the TSE case confirmed on a holding is an atypical scrapie 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 scrapie 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) [<sup>F22</sup>the appropriate authority] 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, [<sup>F23</sup>the appropriate authority] may decide to limit the application

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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, [<sup>F24</sup>the appropriate authority] 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**

- **F4** Words in Annex 7 Ch. B point 2.1 substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, 2(47); 2020 c. 1, Sch. 5 para. 1(1)
- F5 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).
- **F6** Substituted by Commission Regulation (EU) 2020/772 of 11 June 2020 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 (Text with EEA relevance).
- **F7** Words in Annex 7 Ch. B point 2.2.2 substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, 2(48)(a); 2020 c. 1, Sch. 5 para. 1(1)
- F8 Words in Annex 7 Ch. B point 2.2.2(a) substituted (31.12.2020) by S.I. 2019/170, regs. 1, 2(48)(b)(i) (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), 20(2)(n)(i)); 2020 c. 1, Sch. 5 para. 1(1)
- **F9** Words in Annex 7 Ch. B point 2.2.2(a) substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, 2(48)(b)(ii); 2020 c. 1, Sch. 5 para. 1(1)
- **F10** Words in Annex 7 Ch. B point 2.2.2(b) substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, 2(48)(c)(i); 2020 c. 1, Sch. 5 para. 1(1)
- F11 Words in Annex 7 Ch. B point 2.2.2(b) substituted (31.12.2020) by S.I. 2019/170, regs. 1, 2(48)(c)(ii) (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), 20(2)(n)(i)); 2020 c. 1, Sch. 5 para. 1(1)
- F12 Words in Annex 7 Ch. B point 2.2.2(c) substituted (31.12.2020) by S.I. 2019/170, reg. 2(48)(d)(i) (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), 20(2)(n)(ii))
- **F13** Words in Annex 7 Ch. B point 2.2.2(c) substituted (31.12.2020) by S.I. 2019/170, reg. 2(48)(d)(ii) (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), 20(2)(n)(ii))
- F14 Words in Annex 7 Ch. B point 2.2.2(c)(i) substituted (31.12.2020) by S.I. 2019/170, reg. 2(48)(d)(iii) (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), 20(2)(n)(ii))
- F15 Word in Annex 7 Ch. B point 2.2.2(c)(ii) substituted (31.12.2020) by S.I. 2019/170, reg. 2(48)(d)(iv) (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), 20(2)(n)(ii))

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- F16 Words in Annex 7 Ch. B point 2.2.2(c)(iii) substituted (31.12.2020) by S.I. 2019/170, reg. 2(48)(d)(v) (aa) (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), 20(2)(n) (ii))
- F17 Words in Annex 7 Ch. B point 2.2.2(c)(iii) substituted (31.12.2020) by S.I. 2019/170, reg. 2(48)(d)(v) (bb) (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), 20(2)(n) (ii))
- F18 Words in Annex 7 Ch. B point 2.2.2(c)(iii) substituted (31.12.2020) by S.I. 2019/170, reg. 2(48)(d)(v) (cc) (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), 20(2)(n) (ii))
- **F19** Words in Annex 7 Ch. B point 2.2.2(d) substituted (31.12.2020) by S.I. 2019/170, reg. 2(48)(e)(i) (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), 20(2)(n)(iii))
- **F20** Words in Annex 7 Ch. B point 2.2.2(d) substituted (31.12.2020) by S.I. 2019/170, reg. 2(48)(e)(ii) (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), 20(2)(n)(iii))
- F21 Words in Annex 7 Ch. B point 2.2.2(d) substituted (31.12.2020) by S.I. 2019/170, reg. 2(48)(e)(iii) (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), 20(2)(n)(iii))
- **F22** Words in Annex 7 Ch. B point 2.3(a) substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, 2(49)(a); 2020 c. 1, Sch. 5 para. 1(1)
- **F23** Words in Annex 7 Ch. B point 2.3(b) substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, 2(49)(b); 2020 c. 1, Sch. 5 para. 1(1)
- F24 Words in Annex 7 Ch. B point 2.3(c) substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, 2(49)(b); 2020 c. 1, Sch. 5 para. 1(1)
- [<sup>F6</sup>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) or 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,

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- 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 [<sup>F25</sup>appropriate authority] 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 [<sup>F26</sup>appropriate authority] so decides, lambs and kids less than three months old on the date of slaughter,
    - all animals when the [<sup>F26</sup>appropriate authority] has decided to apply the derogations laid down in points 2.2.2(b)(i) and 2.2.2(c) (i);
  - (c) if the [<sup>F27</sup>appropriate authority] 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 [<sup>F28</sup>Great Britain] 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), 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.]

#### **Textual Amendments**

- **F25** Words in Annex 7 Ch. B point 3.3 substituted (31.12.2020) by S.I. 2019/170, reg. 2(49A) (as inserted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(o)**)
- **F26** Words in Annex 7 Ch. B point 3.4(b) substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(50)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F27 Words in Annex 7 Ch. B point 3.4(c) substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, 2(50)(b)(i); 2020 c. 1, Sch. 5 para. 1(1)
- **F28** Words in Annex 7 Ch. B point 3.4(c) substituted (31.12.2020) by S.I. 2019/170, regs. 1, **2(50)(b)(ii)** (as amended by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(p)**); 2020 c. 1, Sch. 5 para. 1(1)
- [<sup>F6</sup>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 in 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.

 $[^{F29}$ Nothing in this Regulation prevents the appropriate authority from deciding that instead of the measures in points 3.2 and 3.3 the authority may decide to] 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:

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- 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 [<sup>F30</sup>appropriate authority] 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 shall be transported directly to a slaughterhouse located within the [<sup>F31</sup>United Kingdom] to be slaughtered not later than when they are 12 months of age.
- 4.4. The [<sup>F32</sup>appropriate authority] 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.]

# **Textual Amendments**

- **F29** Words in Annex 7 Ch. B point 4.2 substituted (31.12.2020) by S.I. 2019/170, reg. 2(51) (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), 20(2)(q))
- **F30** Words in Annex 7 Ch. B point 4.3(b) substituted (31.12.2020) by S.I. 2019/170, reg. 2(51a)(i) (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), 20(2)(q))

- **F31** Words in Annex 7 Ch. B point 4.3(b) substituted (31.12.2020) by S.I. 2019/170, reg. 2(51a)(ii) (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(q)**)
- **F32** Words in Annex 7 Ch. B point 4.4 substituted (31.12.2020) by S.I. 2019/170, **reg. 2(52)** (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(q)**)

# 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, [<sup>F33</sup>the appropriate authority] 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.

# **Textual Amendments**

- **F33** Words in Annex 7 Ch. C Pt. 1 point 1 substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, 2(54)(a)(i); 2020 c. 1, Sch. 5 para. 1(1)
- 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, 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

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breeding programme, shall be carried out in laboratories that have been approved under the breeding programme.

6. The competent authority <sup>F34</sup>... 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.

#### **Textual Amendments**

- **F34** Words in Annex 7 Ch. C Pt. 1 point 6 omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(54)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- 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.
- [<sup>F35</sup>8. Where the [<sup>F36</sup>appropriate authority] 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 <sup>F37</sup>..., 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 <sup>F38</sup>... 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**

**F38** Words in Annex 7 Ch. C Pt. 1 point 8(b) omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, 2(54)(a)(iii)(bb); 2020 c. 1, Sch. 5 para. 1(1)

#### **Textual Amendments**

**F35** 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).

- Words in Annex 7 Ch. C Pt. 1 point 8 substituted (31.12.2020) by The Transmissible Spongiform F36 Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(54)(a)(iii)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)
- Words in Annex 7 Ch. C Pt. 1 point 8 omitted (31.12.2020) by virtue of The Transmissible Spongiform F37 Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(54)(a)(iii)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

# 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:
- all animals in the flock that are to be genotyped shall be individually identified using (a) secure means;
- all rams intended for breeding within the flock shall be genotyped before being used (b) for breeding:
- any male animal carrying the VRQ allele shall be slaughtered or castrated, within six (c) 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;
- male animals, including semen donors used for artificial insemination, other than those (e) certified under the breeding programme, shall not be used for breeding within the flock.
- 3. [<sup>F39</sup>Nothing in these Regulations prevents the appropriate authority from deciding] 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.

#### **Textual Amendments**

F39 Words in Annex 7 Ch. C Pt. 2 point 3 substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, 2(54)(b)(i); 2020 c. 1, Sch. 5 para. 1(1)

4.

# F40

#### **Textual Amendments**

F40 Annex 7 Ch. C Pt. 2 point 4 omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, 2(54)(b)(ii); 2020 c. 1, Sch. 5 para. 1(1)

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

[<sup>F41</sup>The appropriate authority] may decide to grant recognition on further levels to suit national requirements.

#### **Textual Amendments**

- F41 Words in Annex 7 Ch. C Pt. 4 point 1 substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, 2(54)(c); 2020 c. 1, Sch. 5 para. 1(1)
- 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

<sup>F42</sup>...]

#### **Textual Amendments**

F42 Annex 7 Ch. C Pt. 5 omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, 2(54) (d); 2020 c. 1, Sch. 5 para. 1(1)

**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) [<sup>F1</sup>OJ L 300, 14.11.2009, p. 1.]

#### **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).

# Status:

Point in time view as at 31/12/2020.

#### 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.