

## [<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 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>F2</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

- F2** 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.

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**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, Division CHAPTER C. (See end of Document for details)

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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 <sup>F3</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**

**F3** 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>F4</sup>8. Where the [<sup>F5</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>F6</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>F7</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**

**F7** 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)

**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, Division CHAPTER C. (See end of Document for details)

#### 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).
- F5** Words in Annex 7 Ch. C Pt. 1 point 8 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)(iii)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)
- F6** Words in Annex 7 Ch. C Pt. 1 point 8 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)(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:
  - (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. [<sup>F8</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

- F8** 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. **F9** ...

*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, Division CHAPTER C. (See end of Document for details)*

#### Textual Amendments

- F9** 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)

### 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>F10</sup>The appropriate authority] may decide to grant recognition on further levels to suit national requirements.

#### Textual Amendments

- F10** 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.

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**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, Division CHAPTER C. (See end of Document for details)

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## PART 5

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

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#### **Textual Amendments**

**F11** 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, Division CHAPTER C.