

*Status: Point in time view as at 31/01/2020.*

*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 VIII. (See end of Document for details)*

## ANNEX VIII

### PLACING ON THE MARKET AND EXPORT

#### [<sup>F1</sup>CHAPTER A

#### **Conditions for intra-Union trade in live animals, semen and embryos**

##### *SECTION A*

##### ***Conditions which apply to ovine and caprine animals and semen and embryos thereof***

- [<sup>F2</sup>1. Holdings with a negligible risk of classical scrapie and a controlled risk of classical scrapie:
- 1.1. For the purpose of intra-Union trade, Member States shall, where applicable, establish and supervise an official scheme for the recognition of holdings with a negligible risk of classical scrapie and holdings with a controlled risk of classical scrapie. Based on that official scheme, they shall, where applicable, establish and maintain lists of holdings of ovine and caprine animals with a negligible risk and holdings with a controlled risk of classical scrapie.
  - 1.2. A holding of ovine animals having the TSE-resistance level I status, as laid down in Annex VII, Chapter C, Part 4, point 1.(a), and where no case of classical scrapie has been confirmed for a period of at least the preceding seven years, may be recognised as having a negligible risk of classical scrapie.

A holding of ovine animals, caprine animals, or ovine and caprine animals may also be recognised as having a negligible risk of classical scrapie provided that it has complied with the following conditions for a period of at least the preceding seven years:

- (a) ovine and caprine animals are permanently identified and records are maintained, to enable them to be traced back to their holding of birth;
- (b) records of movements of ovine and caprine animals in and out of the holding are maintained;
- (c) only the following ovine and caprine animals are introduced into the holding:
  - (i) ovine and caprine animals from holdings with a negligible risk of classical scrapie;
  - (ii) ovine and caprine animals from holdings which have met the conditions set out in points (a) to (i) for a minimum period of the preceding seven years or for at least the same period of time as the period of time during which the holding, where they are to be introduced, has met the conditions set out in those points;
  - (iii) ovine animals of the ARR/ARR prion protein genotype;
  - (iv) ovine or caprine animals that comply with the conditions set out in point (i) or (ii) except during the period when they were kept at a semen collection centre, provided that the semen collection centre complies with the following conditions:

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- the semen collection centre is approved in accordance with Chapter I(I) of Annex D to Council Directive 92/65/EEC<sup>(1)</sup> and supervised in accordance with Chapter I(II) of that Annex,
  - for a period of the preceding seven years, only those ovine or caprine animals from holdings which have fulfilled during that period the conditions set out in points (a), (b) and (e), and which were subject to regular checks by an official veterinarian or a veterinarian authorised by the competent authority, were introduced into the semen collection centre,
  - no case of classical scrapie has been confirmed at the semen collection centre for a period of the preceding seven years,
  - biosecurity measures are in place at the semen collection centre to ensure that ovine and caprine animals kept at that centre and coming from holdings with a negligible or a controlled risk status for classical scrapie have no direct or indirect contact with ovine and caprine animals coming from holdings of a lower classical scrapie status;
- (d) the holding is subject to regular checks to verify compliance with the conditions set out in points (a) to (i) by an official veterinarian or a veterinarian authorised for that purpose by the competent authority, to be conducted at least on an annual basis from 1 January 2014;
- (e) no case of classical scrapie has been confirmed;
- (f) until 31 December 2013, all ovine and caprine animals referred to in Annex III, Chapter A, Part II, point 3, over 18 months of age, that have died or have been killed for reasons other than slaughter for human consumption are tested in a laboratory for classical scrapie in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, point 3.2.

From 1 January 2014, all ovine and caprine animals over 18 months of age that have died or have been killed for reasons other than slaughter for human consumption are tested in a laboratory for classical scrapie in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, point 3.2.

By way of derogation from the conditions set out in the first and second paragraphs of point (f), Member States may decide that all ovine and caprine animals over 18 months of age with no commercial value, culled at the end of their productive life instead of being slaughtered for human consumption, are inspected by an official veterinarian, and all those exhibiting wasting signs or neurological signs are tested in a laboratory for classical scrapie in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, point 3.2.

In addition to the conditions set out in points (a) to (f), the following conditions shall be complied with from 1 January 2014:

- (g) only the following ova and embryos of animals of the ovine and caprine species are introduced into the holding:

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- (i) ova and embryos from donor animals which have been kept since birth in a Member State with a negligible risk of classical scrapie, or in a holding with a negligible or a controlled risk of classical scrapie, or which comply with the following requirements:
      - they are permanently identified to enable them to be traced back to their holding of birth,
      - they have been kept since birth in holdings in which no case of classical scrapie has been confirmed during their residency,
      - they showed no clinical sign of classical scrapie at the time of collection of the ova or embryos;
    - (ii) ova and embryos of animals of the ovine species carrying at least one ARR allele;
  - (h) only the following semen of animals of the ovine and caprine species are introduced into the holding:
    - (i) semen from donor animals which have been kept since birth in a Member State with a negligible risk of classical scrapie, or in a holding with a negligible risk or a controlled risk of classical scrapie, or which comply with the following requirements:
      - they are permanently identified to enable them to be traced back to their holding of birth,
      - they showed no clinical sign of classical scrapie at the time of semen collection;
    - (ii) semen from rams of the ARR/ARR prion protein genotype;
  - (i) ovine and caprine animals on the holding have no direct or indirect contact, including shared grazing, with ovine and caprine animals from holdings of a lower classical scrapie status.
- 1.3. A holding of ovine animals, caprine animals or ovine and caprine animals may be recognised as having a controlled risk of classical scrapie provided that it has complied with the following conditions for a period of at least the preceding three years:
  - (a) ovine and caprine animals are permanently identified and records are maintained, to enable them to be traced back to their holding of birth;
  - (b) records of movements of ovine and caprine animals in and out of the holding are maintained;
  - (c) only the following ovine and caprine animals are introduced into the holding:
    - (i) ovine and caprine animals from holdings with a negligible or a controlled risk of classical scrapie;
    - (ii) ovine and caprine animals from holdings which have met the conditions set out in points (a) to (i) for a minimum period of the preceding three years or for at least the same period of time as the period of time during which the holding, where they are to be introduced, has met the conditions set out in those points;
    - (iii) ovine animals of the ARR/ARR prion protein genotype;

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- (iv) ovine or caprine animals that comply with the conditions set out in point (i) or (ii) except during the period when they were kept at a semen collection centre, provided that the semen collection centre complies with the following conditions:
- the semen collection centre is approved in accordance with Chapter I(I) of Annex D to Directive 92/65/EEC and supervised in accordance with Chapter I(II) of that Annex,
  - for a period of the preceding three years, only those ovine or caprine animals from holdings which have fulfilled during that period the conditions set out in points (a), (b) and (e), and which were subject to regular checks by an official veterinarian or a veterinarian authorised by the competent authority, were introduced into the semen collection centre,
  - no case of classical scrapie has been confirmed at the semen collection centre during the period of the preceding three years,
  - biosecurity measures are in place at the semen collection centre to ensure that ovine and caprine animals kept at that centre and coming from holdings with a negligible or a controlled risk status for classical scrapie have no direct or indirect contact with ovine and caprine animals coming from holdings of a lower classical scrapie status;
- (d) the holding is subject to regular checks to verify compliance with the conditions set out in points (a) to (i) by an official veterinarian or a veterinarian authorised for that purpose by the competent authority, to be conducted at least on an annual basis from 1 January 2014;
- (e) no case of classical scrapie has been confirmed;
- (f) Until 31 December 2013, all ovine and caprine animals referred to in Annex III, Chapter A, Part II, point 3 over 18 months of age that have died or have been killed for reasons other than slaughter for human consumption are tested in a laboratory for classical scrapie in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, point 3.2.

From 1 January 2014, all ovine and caprine animals over 18 months of age that have died or have been killed for reasons other than slaughter for human consumption are tested in a laboratory for classical scrapie in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, point 3.2.

By way of derogation from the conditions set out in the first and second paragraphs of point (f), Member States may decide that all the ovine and caprine animals over 18 months of age with no commercial value culled at the end of their productive life instead of being slaughtered for human consumption, are inspected by an official veterinarian, and all those exhibiting wasting signs or neurological signs are tested in a laboratory for classical scrapie in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, point 3.2.

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In addition to the conditions set out in points (a) to (f), the following conditions shall be complied with from 1 January 2014:

- (g) only the following ova and embryos of animals of the ovine and caprine species are introduced into the holding:
  - (i) ova and embryos from donor animals which have been kept since birth in a Member State with a negligible risk of classical scrapie, or in a holding with a negligible or a controlled risk of classical scrapie, or which comply with the following requirements:
    - they are permanently identified to enable them to be traced back to their holding of birth,
    - they have been kept since birth in holdings in which no case of classical scrapie has been confirmed during their residency,
    - they showed no clinical sign of classical scrapie at the time of collection of the ova or embryos,
  - (ii) ova and embryos of animals of the ovine species carrying at least one ARR allele;
- (h) only the following semen of animals of the ovine and caprine species are introduced into the holding:
  - (i) semen from donor animals which have been kept since birth in a Member State with a negligible risk of classical scrapie, or in a holding with a negligible risk or with a controlled risk of classical scrapie, or which comply with the following requirements:
    - they are permanently identified to enable them to be traced back to their holding of birth,
    - they showed no clinical sign of classical scrapie at the time of semen collection;
  - (ii) semen from rams of the ARR/ARR prion protein genotype;
- (i) ovine and caprine animals of the holding have no direct or indirect contact, including shared grazing, with ovine and caprine animals from holdings of a lower classical scrapie status.

- 1.4. If a case of classical scrapie is confirmed in a holding with a negligible risk or a controlled risk of classical scrapie, or in a holding found to have an epidemiological link to a holding with a negligible risk or a controlled risk of classical scrapie as a result of an inquiry referred to in Part 1 of Chapter B of Annex VII, the holding with a negligible risk or a controlled risk of classical scrapie shall be immediately deleted from the list referred to in point 1.1 of this Section.

The Member State shall immediately inform the other Member States which have introduced ovine and caprine animals originating from, or semen or embryos collected from ovine and caprine animals kept in the infected holding during a period of the preceding seven years in the case of a holding with a negligible risk of classical scrapie or during the period of the preceding three years in the case of a holding with a controlled risk of classical scrapie.]

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### Textual Amendments

**F2** 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 \(Text with EEA relevance\)](#).

2. Member States or zones of a Member State with a negligible risk of classical scrapie
  - 2.1. Where a Member State considers that its territory or part of its territory poses a negligible risk of classical scrapie, it shall submit to the Commission appropriate supporting documentation, setting out in particular that:
    - (a) a risk assessment has been conducted, and it has demonstrated that appropriate measures are currently in place and have been taken for the relevant period of time to manage any risk identified. This risk assessment shall identify all potential factors for classical scrapie occurrence and their historic perspective, in particular the:
      - (i) importation or introduction of ovine and caprine animals or their semen and embryos potentially infected with classical scrapie;
      - (ii) extent of knowledge of the population structure and husbandry practices of ovine and caprine animals;
      - (iii) feeding practices, including consumption of meat-and-bone meal or greaves derived from ruminants;
      - (iv) importation of milk and milk products of ovine and caprine animals origin intended for use in feeding of ovine and caprine animals;
    - (b) [F2 for a period of at least the preceding seven years, ovine and caprine animals displaying clinical signs compatible with classical scrapie have been tested;
    - (c) for a period of at least the preceding seven years, a sufficient number of ovine and caprine animals over 18 months of age, representative of ovine and caprine animals slaughtered, that have died or have been killed for reasons other than slaughter for human consumption, have been tested annually, to provide a 95 per cent level of confidence of detecting classical scrapie if it is present in that population at a prevalence rate exceeding 0,1 per cent and no case of classical scrapie has been reported during that period;]
    - (d) the feeding to ovine and caprine animals of meat-and-bone meal or greaves of ruminant origin has been banned and effectively enforced in the whole Member State for a period of at least seven years;
    - (e) introductions from other Member States of ovine and caprine animals and semen and embryos thereof are carried out in accordance with point 4.1.(b) or point 4.2.;
    - (f) introductions from third countries of ovine and caprine animals and semen and embryos thereof are carried out in accordance with Chapter E or Chapter H of Annex IX.
  - 2.2. The negligible risk status for classical scrapie of the Member State or of the zone of the Member State may be approved in accordance with the procedure referred to in Article 24(2).

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The Member State is to notify the Commission of any change in the information submitted according to point 2.1. relating to the disease.

The negligible risk status approved in accordance with point 2.2. may, in the light of such notification, be withdrawn in accordance with the procedure referred to in Article 24(2).

[<sup>F2</sup>2.3. The Member States or zone of the Member State with a negligible risk for classical scrapie are the following:

- Austria
- Finland
- Sweden.]

3. National control programme for classical scrapie:

3.1. a Member State which has a national control programme for classical scrapie covering all of its territory:

(a) may submit its national control programme to the Commission, outlining in particular:

- the distribution of classical scrapie in the Member State,
- the reasons for national control programme, taking into consideration the importance of the disease and the cost/benefit ratio,
- the status categories defined for holdings and the standards which must be attained in each such category,
- the test procedures to be used,
- the national control programme monitoring procedures,
- the action to be taken if, for any reason, a holding loses its status,
- the measures to be taken if the results of checks carried out in accordance with the national control programme are positive,

(b) the programme referred to in point (a) may be approved if it complies with the criteria laid down in that point, in accordance with the procedure referred to in Article 24(2); amendments or additions to the programmes submitted by Member States may be approved in accordance with the procedure referred to in Article 24(2).

[<sup>F3</sup>3.2. The national scrapie control programmes of the following Member States are hereby approved:

- Denmark,
- Slovenia.]

#### Textual Amendments

**F3** Substituted by [Commission Implementing Regulation \(EU\) 2017/736 of 26 April 2017 amending Annex VIII to Regulation \(EC\) No 999/2001 of the European Parliament and of the Council as regards the approval of Slovenia's national control programme for classical scrapie \(Text with EEA relevance\).](#)

[<sup>F2</sup>4. Intra-Union trade in ovine and caprine animals and semen and embryos thereof

The following conditions shall apply:

4.1. Ovine and caprine animals:

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- (a) ovine and caprine animals for breeding destined to Member States other than those with a negligible risk of classical scrapie or with an approved national scrapie control programme shall:
  - (i) come from a holding or holdings with a negligible risk or a controlled risk of classical scrapie; or
  - (ii) come from a Member State or zone of a Member State with a negligible risk of classical scrapie; or
  - (iii) in the case of ovine animals, be of the ARR/ARR prion protein genotype, provided they do not come from a holding subject to the restrictions set out in Annex VII, Chapter B, points 3 and 4.
- (b) ovine and caprine animals for all intended uses except immediate slaughter destined to Member States with a negligible risk of classical scrapie or with an approved national scrapie control programme shall:
  - (i) come from a holding or holdings with a negligible risk of classical scrapie; or
  - (ii) come from a Member State or zone of a Member State with a negligible risk of classical scrapie; or
  - (iii) in the case of ovine animals, be of the ARR/ARR prion protein genotype, provided they do not come from a holding subject to the restrictions set out in Annex VII, Chapter B, points 3 and 4.
- (c) By way of derogation from points (a) and (b), the requirements set out in those points shall not apply to ovine and caprine animals which are kept in and moved exclusively between approved bodies, institutes or centres as defined in Article 2(1)(c) of Directive 92/65/EEC.
- (d) By way of derogation from points (a) and (b), the competent authority of a Member State may authorise intra-Union trade in animals that do not comply with the requirements set out in those points, provided that it has received prior consent from the competent authority of the Member States of destination of those animals, and provided that the animals comply with the following conditions:
  - (i) the animals belong to a local breed in danger of being lost to farming, as referred to in Articles 7(2) and (3) of Delegated Regulation (EU) No 807/2014;
  - (ii) the animals are entered in a flock book established and maintained by a breeders' organisation or association officially approved in accordance with Article 5 of Directive 89/361/EEC in the Member State of dispatch, or by an official agency of that Member State, and the animals are to be entered in a flock book for that breed established and maintained by a breeders' organisation or association officially approved in accordance with Article 5 of Directive 89/361/EEC in the Member State of destination, or by an official agency of that Member State;
  - (iii) in the Member State of dispatch and in the Member State of destination, the breeders' organisations or associations or official



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agency referred to in point (ii) carry out a preservation programme for that breed;

- (iv) the animals do not come from a holding subject to the restrictions set out in Annex VII, Chapter B, points 3 and 4;
- (v) following the entry of the animals not fulfilling the requirements set out in point (a) or (b) into the recipient holding in the Member State of destination, the movement of all ovine and caprine animals on that holding shall be restricted in accordance with point 3.4. of Chapter B of Annex VII, for a period of three years, or for a period of seven years when the Member State of destination is a Member State with a negligible risk of classical scrapie or with an approved national scrapie control programme.

By way of derogation from the first paragraph of this point, such restriction on movement shall not apply to intra-Union trade in animals carried out in accordance with the conditions laid down in point 4.1.(d) of this Section nor to domestic movements of animals destined to a holding where a local breed in danger of being lost to farming, as referred to in Articles 7(2) and (3) of Delegated Regulation (EU) No 807/2014, is bred, provided that the breed is subject to a preservation programme carried out by a breeders' organisation or association officially approved or recognised in accordance with Article 5 of Directive 89/361/EEC or by an official agency.

Following the intra-Union trade or domestic movement referred to in the second paragraph of point (v), the movement of all ovine and caprine animals on the holding or holdings receiving animals moved under that derogation shall be restricted in accordance with the first and second paragraphs of point (v).

4.2. Semen and embryos of animals of the ovine and caprine species shall:

- (a) be collected from animals which have been kept continuously since birth on a holding or holdings with a negligible risk or a controlled risk of classical scrapie, except where the holding is a semen collection centre, provided that the semen collection centre complies with the conditions set out in point 1.3. (c)(iv); or
- (b) be collected from animals which have been kept continuously for the last three years before the collection on a holding or holdings which have complied with all the conditions set out in point 1.3. (a) to (f) for three years, except where the holding is a semen collection centre, provided that the semen collection centre complies with the conditions set out in point 1.3. (c)(iv); or
- (c) be collected from animals which have been kept continuously since birth in a country or zone with a negligible risk of classical scrapie; or
- (d) in the case of semen of animals of the ovine species, be collected from male animals of the ARR/ARR prion protein genotype; or
- (e) in the case of embryos of animals of the ovine species, be carrying at least one ARR allele.]

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## SECTION B

### **Conditions which apply to bovine animals**

The United Kingdom shall ensure that bovine animals born or reared on its territory before 1 August 1996 are not dispatched from its territory to other Member States or third countries.]

#### **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 B

Conditions relating to progeny of TSE suspect or confirmed animals referred to in Article 15(2)

It shall be prohibited to place on the market the last-born progeny to which female bovine animals infected with a TSE or BSE-confirmed ovine or caprine animals gave birth during the preceding two-year period or during the period that followed the appearance of the first clinical signs of the onset of the disease.

## [<sup>F4</sup>CHAPTER C

### **Conditions for intra-Community trade in certain products of animal origin**

#### SECTION A

##### **Products**

The following products of animal origin are exempt from the prohibition referred to in Article 16(3), provided that they are derived from bovine, ovine and caprine animals that satisfy the requirements of Section B:

- fresh meat,
- minced meat,
- meat preparations,
- meat products.

#### SECTION B

##### **Requirements**

The products referred to in Section A must satisfy the following requirements:

- (a) the animals from which the products of bovine, ovine and caprine animal origin were derived have not been fed meat-and-bone meal or greaves derived from ruminants and passed ante-mortem and post-mortem inspections;

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- (b) the animals from which the products of bovine, ovine and caprine animal origin were derived have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity;
- (c) the products of bovine, ovine and caprine animal origin are not derived from:
  - (i) specified risk material as defined in Annex V;
  - (ii) nervous and lymphatic tissues exposed during the deboning process; and
  - (iii) mechanically separated meat obtained from bones of bovine, ovine or caprine animals.]

#### **Textual Amendments**

- F4** Substituted by [Commission Regulation \(EC\) No 722/2007 of 25 June 2007 amending Annexes II, V, VI, VIII, IX and XI 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 D

### Conditions applicable to exports

Live bovine animals and products of animal origin derived therefrom are to be subject — as regards exports to third countries — to the rules laid down in this Regulation for intra-Community trade.

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- (1) [<sup>F1</sup>][<sup>F2</sup>Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 90/425/EEC (OJ L 268, 14.9.1992, p. 54).]]

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#### 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 \(Text with EEA relevance\).](#)
- F2** 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 \(Text with EEA relevance\).](#)

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