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)

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)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies[(1)], and in particular the first paragraph of Article 23 thereof,

Whereas:

(1) Regulation (EC) No 999/2001 lays down rules for the prevention, control and eradication of transmissible spongiform encephalopathies (TSEs) in bovine, ovine and caprine animals. It applies to the production and placing on the market of live animals and products of animal origin and in certain specific cases to exports thereof.

(2) Annex II to Regulation (EC) No 999/2001 lays down the criteria based on which the BSE status of countries or regions shall be determined in accordance with Article 5(2) of that Regulation. Those criteria are based on the conditions set out in the chapter on bovine spongiform encephalopathy (BSE) of the Terrestrial Animal Health Code of the World Animal Health Organisation (OIE).

(3) In May 2015, the OIE World Assembly of Delegates amended the BSE Chapter of the OIE Terrestrial Animal Health Code, by adding the following sentence in Article 11.4.1 of the Code: ‘For the purpose of official BSE risk status recognition, BSE excludes “atypical BSE” as a condition believed to occur spontaneously in all cattle populations at a very low rate’[(2)]. Atypical BSE should therefore be excluded from the definition of ‘BSE’ for the purpose of Annex II to Regulation (EC) No 999/2001.

(4) Annexes III, V and VII to Regulation (EC) No 999/2001 contain a number of references to Council Directive 64/433/EEC[(3)], Regulation (EC) No 1774/2002 of the European Parliament and of the Council[(4)] and Commission Regulation (EC) No 1974/2006[(5)]. As those three acts have been repealed, references in the Annexes to Regulation (EC) No 999/2001 should be updated.

(5) The specific requirements set out in Annex V to Regulation (EC) No 999/2001, concerning to the removal of specified risk material for bovine animals whose origin is in Member States with a negligible BSE risk, was amended by Commission Regulation (EU) 2015/1162[(6)]. As a consequence of this amendment, certain provisions relating to the removal of specified risk material set out in Annex V and in Annex IX to Regulation (EC) No 999/2001 should also be amended, as developed below.

(6) First, in accordance with the amendment made to the specific requirements for Member States with a negligible BSE risk status set out in Annex V to Regulation (EC) No 999/2001, by Regulation (EU) 2015/1162, tonsils are no longer defined as specified risk material for bovine animals whose origin is in Member States with negligible BSE risk. The transverse cut rostral to the lingual process of the basihyoid bone for tongues of bovine animals, required in accordance with point 7 of Annex V to Regulation (EC) No 999/2001, should therefore only apply to bovine animals whose origin is in Member States with controlled or undetermined BSE risk. Point 7 of that Annex V should therefore be amended accordingly.

(7) Second, in accordance with the amendment made to Annex V to Regulation (EC) No 999/2001, by Regulation (EU) 2015/1162, the vertebral column is defined as specified risk material only for a minority of bovine animals in the Union. Taking into account the evolution of the epidemiological situation in the Union and the need to reduce administrative burden on operators, the requirement set out in point 11.3.(a) of Annex V to Regulation (EC) No 999/2001, to provide information on the label of the carcasses as regards the removal of the vertebral column, should be modified as follows: while so far a blue stripe must be indicated on the label of the carcasses or wholesale cuts of carcasses of bovine animals containing vertebral column when the removal of the vertebral column is not required, after a transitional period, a red stripe should be indicated on the label of the carcases or wholesale cuts of carcasses of bovine animals containing vertebral column when the removal of the vertebral column is required.

(8) The same modification from a requirement to indicate a blue stripe when the removal of the vertebral column is not required to a requirement to indicate a red stripe when the removal of the vertebral column is required, should apply for products of bovine origin imported into the Union. Point 3 of Section C and point 3 of Section D of Chapter C of Annex IX to Regulation (EC) No 999/2001 should therefore be amended accordingly.

(9) In order to give economic operators and competent authorities inside and outside the Union the necessary time to adjust to this new regime of red stripe required when the removal of the vertebral column is required, this provision should enter into force after a transitional period until 30 June 2017.

(10) Article 8(3) of Regulation (EC) No 999/2001 prohibits the practice, in Member States or regions thereof, with a controlled or undetermined BSE risk, of lacerating, after stunning, central nervous tissues by means of an elongated rod-shaped instrument introduced into the cranial cavity, or by means of gas injection into the cranial cavity, of bovine, ovine and caprine animals whose meat is intended for human or animal consumption. Point 6 of Annex V to Regulation (EC) No 999/2001 extends that prohibition to Member States with a negligible BSE risk, until all Member States are

classified as countries with negligible BSE risk. Since atypical BSE is considered a spontaneous disease which occurs at a low prevalence also in countries with a negligible BSE risk, that prohibition should remain applicable after all Member States have been classified as countries with a negligible BSE risk. Point 6 of Annex V to Regulation (EC) No 999/2001 should therefore be amended to remove this time limitation.

(11) Point 2 of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001 sets out the rules relating to the approval of the negligible risk status for classical scrapie of Member States or zones of a Member State. On 25 June 2014 and 24 August 2014, Finland and Sweden respectively submitted an application to the Commission to be recognised as having a negligible risk status for classical scrapie.

(12) On 13 January 2015, the Commission requested the scientific and technical assistance of the European Food Safety Authority (EFSA) to evaluate whether Finland and Sweden, in their respective applications, demonstrated compliance with point 2.1.(c) and point 2.2 of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001.

(13) On 19 November 2015, the EFSA published two scientific reports in response to the Commission's request[7] ('the EFSA reports'). The EFSA reports conclude that, based on the testing sensitivity provided by the past evaluations of screening diagnostic tests by the EFSA and the Joint Research Centre Institute for Reference Materials and Measurement (IRMM), Sweden demonstrated compliance with point 2.1.(c) of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001 for each of the preceding seven years, and Finland demonstrated such compliance for each of the preceding seven years, except for 2010, a year during which the level of confidence of detecting classical scrapie at a prevalence rate exceeding 0,1 per cent was 94,73 per cent. As the difference between a level of confidence of 94,73 per cent and of 95 per cent is negligible when it comes to the risk of missing a case of classical scrapie, and as the criterion of point 2.1.(c) of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001 was fulfilled in all six other years, the criterion can be considered as fulfilled for the past 7 years.

(14) The EFSA reports also conclude that, based on the testing sensitivity provided by the past evaluations of screening diagnostic tests by the EFSA and the IRMM, Sweden and Finland's intentions concerning surveillance of classical scrapie in the future would comply with point 2.2 of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001.

(15) Taking into account the EFSA reports and the favourable outcome of the Commission assessment of those applications with the other criteria set out in point 2.1 of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001, Finland and Sweden should be listed as Member States with a negligible risk of classical scrapie.

(16) Point 3.2 of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001 lists the Member States with an approved national control programme for classical scrapie. As Finland and Sweden should now be listed in point 2.3 of that Section as Member States with a negligible risk of classical scrapie, they should be deleted from the list of Member States with an approved national control programme for classical scrapie in

point 3.2 of that Section, as that status offers guarantees exceeding those provided by an approved national control programme.

(17) Points 1.2 and 1.3 of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001 set out the conditions to be fulfilled for a holding to be recognised as having a negligible risk or a controlled risk of classical scrapie. Point 4 of that Section sets out the scrapie-related conditions to be fulfilled for intra-Union trade in ovine and caprine animals and semen and embryos thereof.

(18) In addition, Article 3(1)(i) of Regulation (EC) No 999/2001 defines a holding as any place in which animals covered by that Regulation are held, kept, bred, handled or shown to the public. Semen collection centres, as well as zoos, must therefore be considered as holdings, and subject to conditions set out in Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001.

(19) Given that the risk of spreading scrapie via male ovine and caprine animals kept at semen collection centres approved and supervised in accordance with the conditions set out in Annex D to Council Directive 92/65/EEC[8] is limited, it is appropriate to establish specific conditions for semen collection centres in Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001.

(20) These specific conditions should provide that a holding with a negligible, respectively controlled, risk of classical scrapie may introduce ovine and caprine animals from a semen collection centre provided that: (i) the semen collection centre is approved and supervised in accordance with Annex D to Directive 92/65/EEC; (ii) the semen collection centre has had no case of classical scrapie for the last seven, respectively three years; (iii) only the following ovine and caprine animals were introduced into the semen collection centre for the last seven, respectively three years: ovine and caprine animals from holdings where ovine and caprine animals are permanently marked and records are maintained, where records of movements of ovine and caprine animals in and out the holding are maintained, where no case of classical scrapie have been detected in the last seven, respectively three years, and which were subjected to regular checks by an official veterinarian or a veterinarian authorised by the competent authority; (iv) the semen collection centre has biosecurity measures in place to ensure that ovine and caprine animals coming from holdings with different scrapie statuses are not in contact in the semen collection centre. Points 1.2.(c) and 1.3.(c) of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001 should be amended accordingly.

(21) In addition, the scrapie-related intra-Union trade conditions for semen and embryos, laid down in point 4.2 of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001, should be amended to take into account the specific conditions for semen collection centres mentioned in the above recital. Furthermore, reference to those specific conditions should also be introduced in the conditions for import of semen and embryos of ovine and caprine animals set out in Chapter H of Annex IX to Regulation (EC) No 999/2001.

(22) The conditions for intra-Union trade in ovine and caprine animals provided for in point 4.1 of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001 are aimed at preventing the spread of classical scrapie in farmed animals kept on holdings.

Since the movement of ovine and caprine animals exclusively between zoos has no impact on the scrapie status of the Union ovine and caprine farmed animals, those specific conditions should not apply to ovine and caprine animals kept in and moved exclusively between zoos as covered by the definition of approved bodies, institutes or centres provided in Article 2(1)(c) to Council Directive 92/65/EEC. Those animals should therefore be exempted from the conditions set out in point 4.1 of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001.

(23) The scrapie requirements for intra-Union trade in live ovine and caprine animals set out in point 4.1 of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001 is difficult to comply with for intra-Union trade in certain rare breeds. In order to avoid inbreeding and to preserve the genetic diversity in rare breed populations, regular exchange of such animals between Member States is necessary. Specific conditions for intra-Union trade in ovine and caprine animals of rare breeds should therefore be laid down. Those specific conditions should allow intra-Union trade in ovine or caprine animals of rare breeds which do not comply with the requirements of point 4.1 of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001.

(24) The term ‘rare breed’ is not specifically defined in the Union legislation. However, Article 7(2) and (3) of Commission Delegated Regulation (EU) No 807/2014[(9)] establish the conditions under which commitments under the agri-environment-climate measure to rear local breeds in danger of being lost to farming can be made. Those conditions notably require that a duly recognised relevant technical body registers and keeps up-to-date the herd or flock book for the breed. In accordance with Council Directive 89/361/EEC[(10)], such a technical body is to be a breeders' organisation or association officially approved by the Member State in which that breeders' organisation or association is established, or an official agency of the Member State in question.

(25) Therefore, for the purpose of Regulation (EC) No 999/2001, local breeds in danger of being lost to farming should be defined as those sheep and goat breeds that fulfil the conditions of Article 7(2) and (3) of Delegated Regulation (EU) No 807/2014, and which are subject to a preservation programme carried out by a breeders' organisation or association approved in accordance with Directive 89/361/EEC or by an official agency of the Member State in question.

(26) Section B of Chapter C of Annex IX to Regulation (EC) No 999/2001 should be amended so as to allow the import into the Union of products of bovine, ovine or caprine origin from third countries with a negligible BSE risk also when these products are derived from raw materials coming, in part or in total, from countries with controlled or undetermined BSE risk, provided that specified risk material has been removed from those raw materials originating from countries with controlled or undetermined BSE risk.

(27) Annexes II, III, V, VII, VIII and IX to Regulation (EC) No 999/2001 should therefore be amended accordingly.

(28) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes II, III, V, VII, VIII and IX to Regulation (EC) No 999/2001 are amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

The amendments made to Annex IX to Regulation (EC) No 999/2001 by point 6 of the Annex to this Regulation shall apply from 1 July 2017.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 18 August 2016.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX

Annexes II, III, V, VII, VIII and IX to Regulation (EC) No 999/2001 are amended as follows:

1. In Annex II, the first paragraph of Chapter A is replaced by the following:

   The BSE status of Member States or third countries or regions thereof (hereinafter referred to as countries or regions), shall be determined on the basis of the criteria set out in points (a) to (e). For the purpose of this Annex, "BSE" excludes "atypical BSE" as a condition believed to occur spontaneously in all cattle populations at a very low rate.

2. In Annex III, Chapter A is amended as follows:

   (a) In Part I, point 6 is replaced by the following:

   6. **Measures following testing**

   6.1. Where an animal slaughtered for human consumption has been selected for testing for BSE, the health marking provided for in Chapter III of Section I of Annex I to Regulation (EC) No 854/2004 shall not be carried out on the carcase of that animal until a negative result to the rapid test has been obtained.

   6.2. Member States may derogate from point 6.1 where an official system is in place in the slaughterhouse ensuring that no parts of examined animals bearing the health mark leave the slaughterhouse until a negative result to the rapid test has been obtained.

   6.3. All parts of the body of an animal tested for BSE including the hide shall be retained under official control until a negative result to the rapid test has been obtained, unless they are disposed of in accordance with Article 12(a) or (b) of Regulation (EC) No 1069/2009, or unless its fats are processed in accordance with Regulation (EU) No 142/2011 and used in accordance with Article 12(e) of Regulation (EC) No 1069/2009 or used for the manufacture of derived products referred to in Article 36 of that Regulation.

   6.4. All parts of the body of an animal found positive or inconclusive to the rapid test including the hide shall be disposed of in accordance with Article 12(a) or (b) of Regulation (EC) No 1069/2009, apart from material to be retained in conjunction with the records provided for in Chapter B, Part III of this Annex, and apart from the fats obtained from such a body, provided that these fats are processed in accordance with Regulation (EU) No 142/2011 and used in accordance with Article 12(e) of Regulation (EC) No 1069/2009 or used for the manufacture of derived products referred to in Article 36 of that Regulation.

   6.5. Where an animal slaughtered for human consumption is found positive or inconclusive to the rapid test, at least the carcase immediately preceding and the two carcases immediately following the animal tested positive or inconclusive on the same slaughter line shall be destroyed in accordance with point 6.4.

By way of derogation from the first paragraph of this point, Member States may decide to destroy the aforementioned carcases only if the result of the rapid test is confirmed to be positive or inconclusive by confirmatory examinations referred to in Annex X, Chapter C, point 3.1(b).

6.6. Member States may derogate from the provisions of point 6.5 where a system is in place in the slaughterhouse preventing contamination between carcases.

(b) In Part II, points 7.3 and 7.4 are replaced by the following:

7.3. All parts of the body of a tested animal, including the hide, shall be retained under official control until a negative result has been obtained to the rapid test, unless they are disposed of in accordance with Article 12(a) or (b) of Regulation (EC) No 1069/2009, or unless its fats are processed in accordance with Regulation (EU) No 142/2011 and used in accordance with Article 12(e) of Regulation (EC) No 1069/2009 or used for the manufacture of derived products referred to in Article 36 of that Regulation.

7.4. All parts of the body of an animal found positive to the rapid test, including the hide, shall be directly disposed of in accordance with Article 12(a) or (b) of Regulation (EC) No 1069/2009, apart from the material to be retained in conjunction with the records provided for in Chapter B, Part III of this Annex, and apart from rendered fats derived from such a body provided that these rendered fats are processed in accordance with Regulation (EU) No 142/2011 and used in accordance with Article 12(e) of Regulation (EC) No 1069/2009 or used for the manufacture of derived products referred to in Article 36 of that Regulation.

3. Annex V is amended as follows:

(a) points 3 and 4 are replaced by the following:

3. **Marking and disposal**

Specified risk material shall be stained with a dye or, as appropriate, otherwise marked, immediately on removal, and disposed of in accordance with the rules laid down in Regulation (EC) No 1069/2009, and in particular in Article 12 thereof.

4. **Removal of specified risk material**

4.1. Specified risk material shall be removed at:

(a) slaughterhouses, or, as appropriate, other places of slaughter;

(b) cutting plants, in the case of vertebral column of bovine animals;

(c) where appropriate, in approved establishments or plants referred to in Article 24(1)(h) of Regulation (EC) No 1069/2009.

4.2. By way of derogation from point 4.1, the use of an alternative test to the removal of specified risk material, referred to in Article 8(2), may be authorised in accordance with the procedure referred to in

Article 24(3) of this Regulation, provided that that alternative test is listed in Annex X, in accordance with the following conditions:

(a) the alternative tests must be carried out in slaughterhouses on all animals eligible for the removal of specified risk material;

(b) no bovine, ovine or caprine product intended for human consumption or animal feed may leave the slaughterhouse before the competent authority has received and accepted the results of the alternative tests on all slaughtered animals potentially contaminated if BSE has been confirmed in one of them;

(c) when an alternative test gives a positive result, all bovine, ovine and caprine material which has been potentially contaminated in the slaughterhouse must be destroyed in accordance with point 3, unless all parts of the body including the hide of the affected animal can be identified and kept separate.

4.3. By way of derogation from point 4.1, Member States may decide to allow:

(a) the removal of the spinal cord of ovine and caprine animals in cutting plants specifically authorised for that purpose;

(b) the removal of the vertebral column of bovine animals from carcasses or parts of carcasses in butcher shops specifically authorised, monitored and registered for that purpose;

(c) the harvesting of head meat from bovine animals in cutting plants specifically authorised for that purpose in accordance with point 9.

4.4. The rules on the removal of specified risk material set out in this Chapter shall not apply to Category 1 material used in accordance with Article 18(2)(a) of Regulation (EC) No 1069/2009 for feeding to zoo animals, as well as to Category 1 material used in accordance with Article 18(2)(b) of that Regulation for feeding to endangered or protected species of necrophagous birds and other species living in their natural habitat, for the promotion of biodiversity.

(b) points 6 and 7 are replaced by the following:

6. **Measures concerning laceration of tissues**

In addition to the prohibition laid down in Article 8(3) against the use, in Member States, or regions thereof, with a controlled or undetermined BSE risk, of laceration, after stunning, of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, or by means of gas injection into the cranial cavity, in bovine, ovine or caprine animals whose meat is intended for human or animal consumption, that prohibition shall also be applicable in Member States with a negligible BSE risk.

7. **Harvesting of tongues from bovine animals**

The tongues of bovine animals of all ages intended for human or animal consumption shall be harvested at the slaughterhouse by a transverse cut

rostral to the lingual process of the basihyoid bone, except for tongues of bovine animals whose origin is in Member States with a negligible BSE risk.

(c) point 11 is replaced by the following:

11. **Controls**

11.1. Member States shall carry out frequent official controls to verify the correct application of this Annex and shall ensure that measures are taken to avoid any contamination, particularly in slaughterhouses, cutting plants or other places where specified risk material is removed, such as butcher shops or establishments referred in point 4.1(c).

11.2. Member States shall in particular set up a system to ensure and check that specified risk material is handled and disposed of in accordance with this Regulation and Regulation (EC) No 1069/2009.

11.3. A control system shall be put in place for the removal of the vertebral column as specified in point 1(a). That control system shall include at least the following measures:

(a) Until 30 June 2017, when removal of the vertebral column is not required, carcasses or wholesale cuts of carcasses of bovine animals containing vertebral column shall be identified by a clearly visible blue stripe on the label referred to in Article 13 of Regulation (EC) No 1760/2000.

From 1 July 2017, when the removal of the vertebral column is required, carcasses or wholesale cuts of carcasses of bovine animals containing vertebral column shall be identified by a clearly visible red stripe on the label referred to in Article 13 of Regulation (EC) No 1760/2000.

(b) Where applicable, specific information on the number of bovine carcasses or wholesale cuts of carcasses, from which the removal of the vertebral column is required, shall be added on the commercial document relating to consignments of meat. Where applicable, that specific information shall be added to the Common Veterinary Entry Document (CVED) referred to in Article 2(1) of Commission Regulation (EC) No 136/2004[(11)] in the case of imports.

(c) Butcher shops shall keep, for at least one year, the commercial documents referred to in (b).

4. In Annex VII, Chapter B, points 4.2, 4.3 and 4.4 are replaced by the following:

4.2. Only the following ovine animals may be introduced into the holding:

(a) male ovine animals of the ARR/ARR genotype;

(b) female ovine animals carrying at least one ARR allele and no VRQ allele.

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

(i) the breed reared in the holding is a local breed in danger of being lost to farming in accordance with Articles 7(2) and 7(3) of Commission Delegated Regulation (EU) No 807/2014[(12)];

(ii) the breed reared in the holding is subject to a preservation programme carried out by a breeders' organisation or association officially approved in accordance with Article 5 of Council Directive 89/361/EEC[(13)], or an official agency; and

(iii) the frequency of the ARR allele within the breed reared in the holding is low;

(c) male ovine animals carrying at least one ARR allele and no VRQ allele;

(d) female ovine animals carrying no VRQ allele.

4.3. Only the following breeding rams and ovine germinal products may be used in the holding:

(a) male ovine animals of the ARR/ARR genotype;

(b) semen from rams of the ARR/ARR genotype;

(c) embryos carrying at least one ARR allele and no VRQ allele.

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

(i) the breed reared in the holding is a local breed in danger of being lost to farming in accordance with Articles 7(2) and 7(3) of Delegated Regulation (EU) No 807/2014;

(ii) the breed reared in the holding is subject to a preservation programme carried out by a breeders' organisation or association officially approved in accordance with Article 5 of Directive 89/361/EEC, or an official agency; and

(iii) the frequency of the ARR allele within the breed reared in the holding is low;

(d) male ovine animals carrying at least one ARR allele and no VRQ allele;

(e) semen from male ovine animals carrying at least one ARR allele and no VRQ allele;

(f) embryos carrying no VRQ allele.

4.4. Movement of animals from the holding shall be allowed for the purposes of destruction or to go directly for slaughter for human consumption, or shall be subject to the following conditions:

(a) rams and ewes of the ARR/ARR genotype may be moved from the holding for all purposes, including breeding, provided that they are moved to other holdings which are subject to the application of measures in accordance with point 2.2.2.(c) or 2.2.2.(d);

(b) if the Member State so decides, lambs and kids may be moved to one other holding located within its territory solely for the purposes of fattening prior to slaughter subject to compliance with the following conditions:

(i) the holding of destination shall not contain any ovine or caprine animals other than those being fattened prior to slaughter;

(ii) at the end of the fattening period, the lambs and kids originating from the holdings subject to the eradication measures referred to in point 2.2.2.(c)(iii) or 2.2.2.(d) shall be transported directly to a slaughterhouse located within the territory of the same Member State to be slaughtered not later than when they are 12 months of age.

5. In Annex VIII, Section A of Chapter A is amended as follows:

(a) point 1 is replaced by the following:

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:

— the semen collection centre is approved in accordance with Chapter I(I) of Annex D to Council Directive 92/65/EEC[(14)] 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:

(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;

(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.

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.

(b) points 2.1(b) and 2.1.(c) are replaced by the following:

(b) 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;

(c) point 2.3 is replaced by the following:

2.3. The Member States or zone of the Member State with a negligible risk for classical scrapie are the following:

— Austria

— Finland
— Sweden.

(d) point 3.2 is replaced by the following:

3.2. The national scrapie control programmes of the following Member States are hereby approved:
— Denmark.

(e) point 4 is replaced by the following:

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:

(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 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.

6. Annex IX is replaced by the following:

‘ANNEX IX

IMPORTATION INTO THE UNION OF LIVE ANIMALS, EMBRYOS, OVA AND PRODUCTS OF ANIMAL ORIGIN

CHAPTER B

Imports of bovine animals

SECTION A

Imports from a country or a region with a negligible BSE risk

Imports of bovine animals from a country or a region with a negligible BSE risk shall be subject to the presentation of an animal health certificate attesting that:

(a) the animals were born and continuously reared in a country or region or countries or regions classified in accordance with Commission Decision 2007/453/EC[15] as countries or regions posing a negligible BSE risk;

(b) the animals are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin, and have not been exposed to the following bovine animals:

  (i) all BSE cases;

  (ii) all bovine animals which, during their first year of life, were reared with the BSE cases during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period; or

  (iii) if the results of the investigation referred to in indent (ii) are inconclusive, all bovine animals born in the same herd as, and within 12 months of the birth of, the BSE cases;

  and

(c) if there have been BSE indigenous cases in the country concerned, the animals were born:

  (i) after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants, as defined in the OIE Terrestrial Animal Health Code, has been effectively enforced; or

  (ii) after the date of birth of the last BSE indigenous case if born after the date of the feed ban referred to in indent (i).

SECTION B

Imports from a country or a region with a controlled BSE risk

Imports of bovine animals from a country or a region with a controlled BSE risk shall be subject to the presentation of an animal health certificate attesting that:

(a) the country or region is classified in accordance with Decision 2007/453/EC as a country or region posing a controlled BSE risk;

(b) the animals are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin, and have not been exposed to the following bovine animals:

  (i) all BSE cases;

  (ii) all bovine animals which, during their first year of life, were reared with the BSE cases during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period; or

  (iii) if the results of the investigation referred to in indent (ii) are inconclusive, all bovine animals born in the same herd as, and within 12 months of the birth of, the BSE cases;

(c) the animals were born:

  (i) after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants, as defined in the OIE Terrestrial Animal Health Code, has been effectively enforced; or

  (ii) after the date of birth of the last BSE indigenous case if born after the date of the feed ban referred to in indent (i).

SECTION C

Imports from a country or a region with undetermined BSE risk

Imports of bovine animals from a country or a region with an undetermined BSE risk shall be subject to the presentation of an animal health certificate attesting that:

(a) the country or region has been categorised in accordance with Decision 2007/453/EC as a country or region with undetermined BSE risk;

(b) the feeding of ruminants with meat-and-bone meal and greaves from ruminants, as defined in the OIE Terrestrial Animal Health Code, has been banned and the ban has been effectively enforced in the country or region;

(c) the animals are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin, and have not been exposed to the following bovine animals:

  (i) all BSE cases;

(ii) all bovine animals which, during their first year of life, were reared with the BSE cases during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period; or

(iii) if the results of the investigation referred to in indent (ii) are inconclusive, all bovine animals born in the same herd as, and within 12 months of the birth of, the BSE cases;

(d) the animals were born:

(i) at least two years after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants, as defined in the OIE Terrestrial Animal Health Code, has been effectively enforced; or

(ii) after the date of birth of the last BSE indigenous case if born after the date of the feed ban referred to in indent (i).

CHAPTER C

Imports of products of animal origin from bovine, ovine or caprine animals

SECTION A

Products

The following products of bovine, ovine and caprine origin, as defined in the following points of Annex I to Regulation (EC) No 853/2004, shall be subject to the conditions set out in Sections B, C or D of this Chapter depending on the BSE risk category of the country of origin:

— fresh meat, as defined in point 1.10 thereof,
— minced meat, as defined in point 1.13 thereof,
— mechanically separated meat, as defined in point 1.14 thereof,
— meat preparations, as defined in point 1.15 thereof,
— meat products, as defined in point 7.1 thereof,
— rendered animal fat, as defined in point 7.5 thereof,
— greaves, as defined in point 7.6 thereof,
— gelatine, as defined in point 7.7 thereof, other than derived from hides and skins,
— collagen, as defined in point 7.8 thereof, other than derived from hides and skins,
— treated stomachs, bladders and intestines, as defined in point 7.9 thereof.

SECTION B

Imports from a country or a region with a negligible BSE risk

Imports of products of bovine, ovine and caprine animal origin referred to in Section A from a country or a region with a negligible BSE risk shall be subject to the presentation of an animal health certificate attesting that:

(a) the country or region is classified in accordance with Decision 2007/453/EC as a country or region posing a negligible BSE risk;

(b) the animals from which the products of bovine, ovine and caprine animal origin were derived passed *ante mortem* and *post mortem* inspections;

(c) the products of bovine, ovine and caprine animal origin do not contain and are not derived from specified risk material as defined in point 1 of Annex V to this Regulation;

(d) if the animals, from which the products of bovine animal origin were derived, originate from a country or region classified in accordance with Decision 2007/453/EC as a country or region posing a controlled or an undetermined BSE risk, by way of derogation from point (c) of this Section, carcasses, half carcasses or half carcasses cut into no more than three wholesale cuts, and quarters containing no specified risk material other than the vertebral column, including dorsal root ganglia, may be imported. In the case of such imports, the carcasses or wholesale cuts of carcasses of bovine animals containing a vertebral column which is defined as specified risk material in accordance with point 1 of Annex V to this Regulation shall be identified by a clearly visible red stripe on the label referred to in Article 13 or 15 of Regulation (EC) No 1760/2000. Furthermore, specific information on the number of bovine carcasses or wholesale cuts of carcasses, from which the removal of the vertebral column is required, shall be added to the Common Veterinary Entry Document (CVED) referred to in Article 2(1) of Regulation (EC) No 136/2004;

(e) the products of bovine, ovine and caprine animal origin do not contain and are not derived from mechanically separated meat obtained from bones of bovine, ovine or caprine animals, except if the animals, from which the products of bovine, ovine and caprine animal origin are derived, were born, continuously reared and slaughtered in a country or region classified in accordance with Decision 2007/453/EC as a country or region posing a negligible BSE risk in which there has been no BSE indigenous cases;

(f) 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, except if the animals from which the products of bovine, ovine and caprine animal origin are derived, were born, continuously reared and slaughtered in a country or region classified in accordance with Decision 2007/453/EC as a country or region posing a negligible BSE risk;

(g) if the animals, from which the products of bovine, ovine and caprine animal origin were derived, originate from a country or region classified in accordance with Decision 2007/453/EC as a country or region posing an undetermined BSE risk, the animals have not been fed with meat-and-bone meal or greaves, as defined in the OIE Terrestrial Animal Health Code;

(h) if the animals, from which the products of bovine, ovine and caprine animal origin were derived, originate from a country or region classified in accordance with Decision 2007/453/EC as a country or region posing an undetermined BSE risk, the products were produced and handled in a manner which ensures that they did not contain and were not contaminated with nervous and lymphatic tissues exposed during the deboning process.

SECTION C

Imports from a country or a region with a controlled BSE risk

1. Imports of products of bovine, ovine and caprine animal origin referred to in Section A from a country or a region with a controlled BSE risk shall be subject to the presentation of an animal health certificate attesting that:

(a) the country or region is classified in accordance with Decision 2007/453/EC as a country or region posing a controlled BSE risk;

(b) the animals from which the products of bovine, ovine and caprine animal origin were derived passed *ante mortem* and *post mortem* inspections;

(c) the animals from which the products of bovine, ovine and caprine animal origin destined for export were derived have not been killed, after stunning, by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, or by means of gas injected into the cranial cavity;

(d) the products of bovine, ovine and caprine animal origin do not contain and are not derived from specified risk material as defined in point 1 of Annex V to this Regulation, or mechanically separated meat obtained from bones of bovine, ovine or caprine animals.

2. For products of bovine animal origin, by way of derogation from point 1(d) carcasses, half carcasses or half carcasses cut into no more than three wholesale cuts, and quarters containing no specified risk material other than the vertebral column, including dorsal root ganglia, may be imported.

3. When the removal of the vertebral column is required, carcasses or wholesale cuts of carcasses of bovine animals containing vertebral column, shall be identified by a clearly visible red stripe on the label referred to in Article 13 or 15 of Regulation (EC) No 1760/2000.

4. The number of bovine carcasses or wholesale cuts of carcasses, from which the removal of the vertebral column is required shall be added to the Common Veterinary Entry Document (CVED) referred to in Article 2(1) of Regulation (EC) No 136/2004 in the case of imports.

5. In the case of intestines originally sourced from a country or a region with a negligible BSE risk, imports of treated intestines shall be subject to the presentation of an animal health certificate attesting that:

(a) the country or region is classified in accordance with Decision 2007/453/EC as a country or region posing a controlled BSE risk;

(b) the animals from which the products of bovine, ovine and caprine animal origin were derived were born, continuously reared and slaughtered in the country or region with a negligible BSE risk and passed *ante mortem* and *post mortem* inspections;

(c) if the intestines are sourced from a country or region where there have been BSE indigenous cases:

(i) the animals were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants has been enforced; or

(ii) the products of bovine, ovine and caprine animal origin do not contain and are not derived from specified risk material as defined in point 1 of Annex V to this Regulation.

SECTION D

Imports from a country or a region with an undetermined BSE risk

1. Imports of products of bovine, ovine and caprine animal origin referred to in Section A from a country or a region with an undetermined BSE risk, shall be subject to the presentation of an animal health certificate attesting that:

(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, as defined in the OIE Terrestrial Animal Health Code, and passed *ante mortem* and *post mortem* inspections;

(b) the animals from which the products of bovine, ovine and caprine animal origin were derived have not been killed, after stunning, by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, or by means of gas injected into the cranial cavity;

(c) the products of bovine, ovine and caprine animal origin do not contain and are not derived from:

(i) specified risk material as defined in point 1 of Annex V to this Regulation;

(ii) nervous and lymphatic tissues exposed during the deboning process;

(iii) mechanically separated meat obtained from bones of bovine, ovine or caprine animals.

2. For products of bovine animal origin, by way of derogation from point 1(c), carcasses, half carcasses or half carcasses cut into no more than three wholesale cuts, and quarters containing no specified risk material other than the vertebral column, including dorsal root ganglia, may be imported.

3. When removal of the vertebral column is required, carcasses or wholesale cuts of carcasses of bovine animals containing vertebral column, shall be identified by a clearly visible red stripe on the label referred to in Article 13 or 15 of Regulation (EC) No 1760/2000.

4. Specific information on the number of bovine carcasses or wholesale cuts of carcasses, from which removal of the vertebral column is required shall be added to the Common Veterinary Entry Document (CVED) referred to in Article 2(1) of Regulation (EC) No 136/2004 in the case of imports.

5. In the case of intestines originally sourced from a country or a region with a negligible BSE risk, imports of treated intestines shall be subject to the presentation of an animal health certificate attesting that:

(a) the country or region is classified in accordance with Decision 2007/453/EC as a country or region posing an undetermined BSE risk;

(b) the animals from which the products of bovine, ovine and caprine animal origin were derived were born, continuously reared and slaughtered in the country or region with a negligible BSE risk and passed *ante mortem* and *post mortem* inspections;

(c) if the intestines are sourced from a country or region where there have been BSE indigenous cases:

(i) the animals were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants had been enforced; or

(ii) the products of bovine, ovine and caprine animal origin do not contain and are not derived from specified risk material as defined in point 1 of Annex V to this Regulation.

CHAPTER D

Imports of animal by-products and derived products from bovine, ovine and caprine origin

SECTION A

Animal by-products

This Chapter shall apply to the following animal by-products, as defined in points (1) of Article 3 of Regulation (EC) No 1069/2009 and the following derived products as defined in point (2) of that Article, provided that those animal by-products and derived products are of bovine, ovine and caprine animal origin:

(a) rendered fats derived from Category 2 material, which are intended to be used as organic fertilisers or soil improvers, as defined in point 22 of Article 3 of Regulation (EC) No 1069/2009;

(b) bones and bone products derived from Category 2 material;

(c) rendered fats derived from Category 3 material which are intended to be used as organic fertilisers or soil improvers or as feed, as defined in points 22 and 25 respectively of Article 3 of Regulation (EC) No 1069/2009, or their starting materials;

(d) pet food including dog chews;

(e) blood products;

(f) processed animal protein;

(g) bones and bone products derived from Category 3 material;

(h) gelatine and collagen derived from materials other than hides and skins;

(i) Category 3 material and derived products other than those referred to in points (c) to (h) excluding:

  (i) fresh hides and skins, treated hides and skins;

  (ii) gelatine and collagen derived from hides and skins;

  (iii) fat derivatives.

SECTION B

Health certificate requirements

Imports of the animal by-products and derived products of bovine, ovine and caprine origin referred to in Section A shall be subject to the presentation of a health certificate which has been completed with the following attestation:

(a) the animal by-product or derived product:

  (i) does not contain and is not derived from specified risk material as defined in point 1 of Annex V to this Regulation; and

  (ii) does not contain and is not derived from mechanically separated meat obtained from bones of bovine, ovine or caprine animals, except if the animals, from which the animal by-product or derived product are derived, were born, continuously reared and slaughtered in a country or region classified in accordance with Decision 2007/453/EC as a country or region posing a negligible BSE risk, in which there has been no BSE indigenous cases; and

  (iii) is derived from animals which have not been killed, after stunning, by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, or by means of gas injected into the cranial cavity, except for animals born, continuously reared and slaughtered in a country or region

classified as posing a negligible BSE risk in accordance with Decision 2007/453/EC; or

(b) the animal by-product or derived product does not contain and is not derived from bovine, ovine and caprine materials other than those derived from animals born, continuously reared and slaughtered in a country or region classified as posing a negligible BSE risk in accordance with Decision 2007/453/EC.

In addition to points (a) and (b) of this Section, imports of the animal by-products and derived products referred to in Section A, containing milk or milk products of ovine or caprine animal origin and intended for feed, shall be subject to the presentation of a health certificate which has been completed with the following attestation:

(c) the ovine and caprine animals from which those animal by-products or derived products have been derived have been kept continuously since birth in a country where the following conditions are fulfilled:

(i) classical scrapie is compulsorily notifiable;

(ii) an awareness, surveillance and monitoring system is in place;

(iii) official restrictions apply to holdings of ovine or caprine animals in case of a suspicion of TSE or a confirmation of classical scrapie;

(iv) ovine and caprine animals affected with classical scrapie are killed and completely destroyed;

(v) the feeding to ovine and caprine animals of meat-and-bone meal or greaves of ruminant origin, as defined in the OIE Terrestrial Animal Health Code, has been banned and effectively enforced in the whole country for a period of at least the preceding seven years;

(d) the milk and milk products of ovine or caprine animals originate from holdings where no official restriction is imposed due to a suspicion of TSE;

(e) the milk and milk products of ovine or caprine animals originate from holdings where no case of classical scrapie has been diagnosed during the preceding seven years or, following the confirmation of a case of classical scrapie:

(i) all ovine and caprine animals on the holding have been killed and destroyed or slaughtered, except for breeding rams of the ARR/ARR genotype, breeding ewes carrying at least one ARR allele and no VRQ allele and other ovine animals carrying at least one ARR allele; or

(ii) all animals in which classical scrapie was confirmed have been killed and destroyed, and the holding has been subjected for two years at least since the confirmation of the last classical scrapie case to intensified TSE monitoring, including testing with negative results for the presence of TSE in accordance with the laboratory methods set out in Annex X, Chapter C, point 3.2, of all of the following animals which are over the age of 18 months, except ovine animals of the ARR/ARR genotype:

— animals which have been slaughtered for human consumption, and

— animals which have died or been killed on the holding but which were not killed in the framework of a disease eradication campaign.

CHAPTER E

Imports of ovine and caprine animals

Ovine and caprine animals imported into the Union shall be subject to the presentation of an animal health certificate attesting that they have been kept continuously since birth in a country where the following conditions are fulfilled:

(1) classical scrapie is compulsorily notifiable;

(2) an awareness, surveillance and monitoring system is in place;

(3) ovine and caprine animals affected with classical scrapie are killed and completely destroyed;

(4) the feeding to ovine and caprine animals of meat-and-bone meal or greaves of ruminant origin, as defined in the OIE Terrestrial Animal Health Code, has been banned and effectively enforced in the whole country for a period of at least the preceding seven years.

In addition to the conditions set out in points 1 to 4, the animal health certificate shall attest that:

(5) For ovine and caprine animals for breeding imported into the Union and intended for Member States other than those with a negligible risk of classical scrapie or those with an approved national scrapie control programme listed in point 3.2 of Section A of Chapter A of Annex VIII, the following conditions have been complied with:

(a) the imported ovine and caprine animals come from a holding or holdings that have complied with the conditions of point 1.3 of Section A of Chapter A of Annex VIII; or

(b) they are ovine animals of the ARR/ARR prion protein genotype and they come from a holding where no official movement restriction has been imposed due to BSE or classical scrapie during the last two years.

(6) For ovine and caprine animals for all uses except immediate slaughter imported into the Union and intended for a Member State with a negligible risk of classical scrapie or with an approved national scrapie control programme listed in point 3.2 of Section A of Chapter A of Annex VIII, the following conditions have been complied with:

(a) they come from a holding or holdings that have complied with the conditions of point 1.2 of Section A of Chapter A of Annex VIII; or

(b) they are ovine animals of the ARR/ARR prion protein genotype and they come from a holding where no official movement restriction has been imposed due to BSE or classical scrapie during the last two years.

CHAPTER F

Imports of products of animal origin from farmed and wild cervid animals

1. When fresh meat, minced meat, meat preparations and meat products as defined in points 1.10, 1.13, 1.15 and 7.1 respectively of Annex I to Regulation (EC) No 853/2004, derived from farmed cervid animals, are imported into the Union from Canada or the United States of America, the health certificates shall be accompanied by a declaration signed by the competent authority of the country of production, worded as follows:

This product contains or is derived exclusively from meat, excluding offal and spinal cord, of farmed cervid animals which have been examined for chronic wasting disease by histopathology, immunohistochemistry or other diagnostic method recognised by the competent authority with negative results and is not derived from animals coming from a herd where chronic wasting disease has been confirmed or is officially suspected.

2. When fresh meat, minced meat, meat preparations and meat products as defined in points 1.10, 1.13, 1.15 and 7.1 respectively of Annex I to Regulation (EC) No 853/2004, derived from wild cervid animals, are imported into the Union from Canada or the United States of America, the health certificates shall be accompanied by a declaration signed by the competent authority of the country of production, worded as follows:

This product contains or is derived exclusively from meat, excluding offal and spinal cord, of wild cervid animals which have been examined for chronic wasting disease by histopathology, immunohistochemistry or other diagnostic method recognised by the competent authority with negative results and is not derived from animals coming from a region where chronic wasting disease has been confirmed in the last three years or is officially suspected.

CHAPTER H

Import of ovine and caprine semen and embryos

Ovine and caprine semen and embryos imported into the Union shall be subject to the presentation of an animal health certificate attesting that:

(1) the donor animals have been kept continuously since birth in a country where the following conditions are fulfilled:

(a) classical scrapie is compulsorily notifiable;

(b) an awareness, surveillance and monitoring system is in place;

(c) ovine and caprine animals affected with classical scrapie are killed and completely destroyed;

(d) the feeding to ovine and caprine animals of meat-and-bone meal, or greaves of ruminant origin, as defined in the OIE Terrestrial Animal Health Code, has been banned and effectively enforced in

the whole country for a period of at least the preceding seven years; and

(2) the donor animals have been kept continuously for a period of three years preceding the date of the collection of the exported semen or embryos in a holding or holdings which have satisfied during that period all the requirements set out in point 1.3.(a) to (f) of Section A of Chapter A of Annex VIII 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) of that Section; or

(a) in the case of semen of animals of the ovine species, the semen has been collected from male animals of the ARR/ARR prion protein genotype; or

(b) in the case of embryos of animals of the ovine species, the embryos carry at least one ARR allele.

(**1**) OJ L 147, 31.5.2001, p. 1.

(**2**) http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_bse.htm

(**3**) Council Directive 64/433/EEC of 26 June 1964 on health conditions for the production and marketing of fresh meat (OJ 121, 29.7.1964, p. 2012).

(**4**) Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption (OJ L 273, 10.10.2002, p. 1).

(**5**) Commission Regulation (EC) No 1974/2006 of 15 December 2006 laying down detailed rules for the application of Council Regulation (EC) No 1698/2005 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD) (OJ L 368, 23.12.2006, p. 15).

(**6**) Commission Regulation (EU) 2015/1162 of 15 July 2015 amending Annex V 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 (OJ L 188, 16.7.2015, p. 3).

(**7**) 'Evaluation of the application of Sweden to be recognised as having a negligible risk of classical scrapie' (*EFSA Journal* 2015;13(11):4292) and 'Evaluation of the application of Finland to be recognised as having a negligible risk of classical scrapie' (*EFSA Journal* 2015;13(11):4293).

(**8**) 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).

(**9**) Commission Delegated Regulation (EU) No 807/2014 of 11 March 2014 supplementing Regulation (EU) No 1305/2013 of the European Parliament and of the Council on support for rural development by the European Agricultural Fund for Rural Development (EAFRD) and introducing transitional provisions (OJ L 227, 31.7.2014, p. 1).

(**10**) Council Directive 89/361/EEC of 30 May 1989 concerning pure-bred breeding sheep and goats (OJ L 153, 6.6.1989, p. 30).

(**11**) Commission Regulation (EC) No 136/2004 of 22 January 2004 laying down procedures for veterinary checks at Community border inspection posts on products imported from third countries (OJ L 21, 28.1.2004, p. 11).'

(**12**) Commission Delegated Regulation (EU) No 807/2014 of 11 March 2014 supplementing Regulation (EU) No 1305/2013 of the European Parliament and of the Council on support for rural development by the European Agricultural Fund for Rural Development (EAFRD) and introducing transitional provisions (OJ L 227, 31.7.2014, p. 1).

(**13**) Council Directive 89/361/EEC of 30 May 1989 concerning pure-bred breeding sheep and goats (OJ L 153, 6.6.1989, p. 30).'

(**14**) 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).'

(**15**) Commission Decision 2007/453/EC of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk (OJ L 172, 30.6.2007, p. 84).'

Changes to legislation:
There are currently no known outstanding effects for the Commission Regulation (EU) 2016/1396.