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)

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)

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) On 19 January 2011, the European Food Safety Authority (EFSA) published a joint opinion prepared with the European Centre for Disease Prevention and Control (ECDC) on any possible epidemiological or molecular association between TSEs in animals and humans ('the joint EFSA and ECDC Opinion')[(2)]. In the joint EFSA and ECDC opinion, the EFSA and ECDC confirmed the identification of atypical forms of bovine spongiform encephalopathy (BSE) in cattle and made the distinction between classical BSE, L-type atypical BSE and H-type atypical BSE. It is therefore appropriate to insert definitions for classical BSE cases and atypical BSE cases in Annex I to Regulation (EC) No 999/2001.

(3) Part I of Chapter A of Annex III to Regulation (EC) No 999/2001 lays down rules for monitoring BSE in bovine animals slaughtered for human consumption. It refers to animals slaughtered in accordance with 'special emergency slaughter' as defined in Article 2(n) of Council Directive 64/433/EEC of 26 June 1964 on health conditions for the production and marketing of fresh meat[(3)]. That Directive has since been repealed by Directive 2004/41/EC of the European Parliament and of the Council[(4)]. This has led to legal uncertainty and caused reduced testing in animals that should have been tested. It is therefore necessary to clearly define emergency slaughter in the framework

of the rules for monitoring BSE in bovine animals slaughtered for human consumption in Annex III to Regulation (EC) No 999/2001.

(4) Part II of Chapter A of Annex III to Regulation (EC) No 999/2001 lays down rules for monitoring in ovine and caprine animals. The annual reports carried out by the Member States on the monitoring and testing of ruminants for the presence of Transmissible Spongiform Encephalopathy (TSE) in the Union have shown in recent years that the testing of ovine and caprine animals not slaughtered for human consumption is usually more efficient to identify cases of TSE than the testing of animals slaughtered for human consumption. More flexibility should therefore be given to the Member States to focus a larger part of the limited number of tests required by that Annex in the subpopulations where there is a greater chance to identify such cases.

(5) Annex VII to Regulation (EC) No 999/2001 lays down the eradication measures to be carried out following the confirmation of the presence of TSE in bovine, ovine and caprine animals and the minimum requirements for breeding programmes for resistance to TSEs in sheep. That Annex has been amended several times, including by Commission Regulations (EC) No 727/2007[(5)] and (EC) No 746/2008[(6)].

(6) On 17 July 2007, in Case T-257/07, France brought an action against the Commission before the General Court, applying for the suspension of the operation of point (3) of the Annex to Regulation (EC) No 727/2007 insofar as it introduces point 2.3(b)(iii), point 2.3(d) and point 4 into Chapter A of Annex VII to Regulation (EC) No 999/2001, or alternatively the entire annulment of that Regulation. According to France, those points would authorise less restrictive measures of surveillance and eradication than those earlier prescribed for sheep and goats. In its Order of 28 September 2007[(7)], the Court suspended the application of those provisions until judgment would be given in the main action.

(7) The Commission subsequently asked the EFSA to assist it in clarifying the main premises on which Regulation (EC) No 727/2007 was based. In view of the EFSA clarifications, Regulation (EC) No 999/2001 was amended by Regulation (EC) No 746/2008, which reinstated provisions the application of which had been suspended by the General Court. In its Order of 30 October 2008[(8)], the General Court suspended the application of point 2.3(b)(iii), point 2.3(d) and point 4 of Chapter A of Annex VII to Regulation (EC) No 999/2001, as amended by Regulation (EC) No 746/2008, until judgment would be given in the main action in Case T-257/07.

(8) In its judgment of 9 September 2011 in Case T-257/07[(9)], the General Court dismissed the application by France for the annulment of Regulation (EC) No 746/2008, and lifted the suspension of the application of those provisions of Chapter A of Annex VII to Regulation (EC) No 999/2001.

(9) On 28 November 2011, in Case C-601/11 P[(10)], an appeal was brought by France against the judgment of the General court in Case T-257/07, requesting the Court to set aside the judgment of the General Court in Case T-257/07 and to give final judgment in the dispute by annulling Regulation (EC) No 746/2008 or to refer the case back to the General Court.

(10) It is appropriate to clarify the very complex construct of management options and derogations for the control and eradication of classical scrapie in ovine and caprine animals set out in Annex VII to Regulation (EC) No 999/2001. Annex VII should only provide for three options in infected flocks or herds of ovine and caprine animals, namely: option 1 for the elimination of all animals; option 2 for the elimination of the susceptible animals only; and option 3 for no mandatory elimination of animals.

(11) The measures to be applied in each of those three options should be re-drafted in order to facilitate comparison between the options and improve awareness of the consequences for the individual holding. As option 1 and option 2 include stringent eradication measures which improve disease control, the post-eradication measures enforced under option 1 and option 2 should be more flexible than under option 3.

(12) It is necessary to clarify the conditions under which the elimination measures set out in option 2 may be delayed. It is appropriate to allow for a short term delay not exceeding three months linked to lambing season considerations. However, a long term delay can only be justified by the need of additional time to increase the level of genetic resistance to classical scrapie in a holding. Since genetic resistance to classical scrapie has so far been proven only in ovine animals, the long term delay should not be permitted for herds comprising only caprine animals. When permitted, it should be limited to a period of three years under certain conditions.

(13) Where classical scrapie is confirmed in holdings keeping a local ovine breed in danger of being lost to farming, the post-eradication measures laid down in Annex VII to Regulation (EC) No 999/2001 should take into consideration the difficulty of introducing and using only resistant ovine animals or ovine germinal products of the same endangered breed. In this particular case, Member States should be permitted to apply more flexible rules regarding the genotype of breeders and germinal products introduced and used in the holdings.

(14) The joint EFSA and ECDC Opinion suggests that atypical scrapie could be little or not contagious at all. That finding mainly relies on the lack of statistical difference of the observed Atypical/Nor98 frequencies between the general population and the flocks where a positive case had been identified. Therefore, restriction measures on the movement of ovine and caprine animals where a case of atypical scrapie has been confirmed are no longer justified. Increased surveillance in those flocks or herds should, however, be maintained in order to gather more scientific data on atypical scrapie. This amendment to Annex VII to Regulation (EC) No 999/2001 is in line with the future policy options envisaged by paragraph 2.4.3 of the Communication from the Commission to the European Parliament and the Council — The TSE Road map 2 — A Strategy paper on Transmissible Spongiform Encephalopathies for 2010-2015[(11)].

(15) The participation in breeding programmes has been so far limited to ovine flocks of high genetic merit. Where they have been applied, the breeding programmes have been effective in increasing the resistance to classical scrapie in the high genetic merit sheep population. But the diffusion in the ordinary production population of the hereditary factor (allele) carrying the resistance appears to have been limited so far. Chapter C of Annex VII to Regulation (EC) No 999/2001 should allow the genotyping of

the breeding rams of flocks not participating in the breeding programme in order to facilitate a broader diffusion of the resistance factor to classical scrapie in the production population.

(16) Chapter A of Annex VIII to Regulation (EC) No 999/2001 lays down rules governing intra-Union trade in live animals, semen and embryos. As referred to in recital 14, the joint EFSA and ECDC Opinion suggests that atypical scrapie could be little or not contagious at all. The lifting of all restriction measures on the movement of ovine and caprine animals where a case of atypical scrapie has been confirmed should therefore apply to intra-Union trade. This position is also supported by the fact that the Terrestrial Animal Health Code, as voted in 2010 at the 78th General Session of the World Organisation for Animal Health (OIE), does not recommend any trade restriction with regards to atypical scrapie.

(17) The rules set out in Annex VIII to Regulation (EC) No 999/2001 relating to intra-Union trade in ovine and caprine animals and their semen and embryos should be made as consistent as possible with the OIE standards, so that they do not preclude Member States with an approved national control programme for classical scrapie from claiming the country freedom status for classical scrapie according to the conditions laid out in the OIE code. The amended intra-Union trade provisions should however not adversely impact existing intra-Union trade flows among Member States where no national control programme for classical scrapie has been approved.

(18) For that purpose, and as proposed in paragraph 2.4.3 of the TSE Roadmap 2, a framework enabling the Member States to establish an official scheme for the recognition of classical scrapie status in holdings should be set out in Annex VIII to Regulation (EC) No 999/2001. The possibility for a holding to engage in intra-Union trade of ovine and caprine animals, with regards to classical scrapie, should be determined by its classical scrapie status.

(19) A two tiered system for classical scrapie status in holdings should be established in Annex VIII to Regulation (EC) No 999/2001. A negligible risk status, equivalent in technical terms to the scrapie free status in a holding, as laid down in Article 14.9.5. of the OIE Terrestrial Animal Health code and based on compliance with the full list of the OIE requirements for at least seven years (in line with the rule laid down in article 6a and Annex VII to Regulation (EC) No 999/2001 favouring the development of the resistant genotypes in ovines, the proposal however recognises the ARR/ARR genotype as a valid option), should be required for transporting animals for breeding and rearing to the Member States with an approved national control programme for classical scrapie. Animals for breeding intended to other Member States should only be required to come from holdings with a controlled risk of classical scrapie based on compliance with a shorter list of requirements for at least three years, as is presently the case.

(20) Considering the difficulty to demonstrate freedom in the territory of part of the territory of a Member State for a disease as complex as classical scrapie, which is characterised by a long incubation delay, the absence of any in-vivo diagnostic method and a variable individual susceptibility of the animals depending on their genetic profile, the concept of ‘classical scrapie free Member State’ should be replaced in Annex VIII to Regulation

(EC) No 999/2001 by that of 'Member State or zone of a Member State with a negligible risk of classical scrapie'. The conditions for the recognition of a Member State or zone of a Member State with a negligible risk of classical scrapie should also be updated and largely brought in line with the recommendations laid down in Article 14.9.3 of the OIE Terrestrial Animal Health code.

(21) As Annex VIII to Regulation (EC) No 999/2001 should cover all trade aspects related to classical scrapie, and considering that the proposed creation of an official scheme for the recognition of classical scrapie status in holdings constitutes an appropriate basis for establishing differentiated guarantees for animals to be traded with Member States with an approved national control plan for classical scrapie and with other Member States, that Annex should also include the list of Member States with an approved national control plan for classical scrapie.

(22) Chapter C of Annex IX to Regulation (EC) No 999/2001 lays down rules relating to imports into the Union of products of animal origin from bovine, ovine and caprine animals, in particular gelatine intended for human consumption. Section A of Chapter D of Annex IX to Regulation (EC) No 999/2001 lays down rules related to imports into the Union of animal by-products and derived products from bovine, ovine and caprine origin, in particular gelatine intended to be used as feed ingredient. Since collagen intended to be used for food or feed is produced from the same raw materials as gelatine, import conditions for collagen to be used for food or feed should be aligned with those laid down for gelatine intended for the same usage.

(23) Section B of Chapter D of Annex IX to Regulation (EC) No 999/2001 provides specific attestations which are to accompany imports into the Union of certain animal by-products and derived products of bovine, ovine and caprine origin. Those attestations should be amended in order to also apply to products processed in a third country classified as posing a controlled or undetermined BSE risk and made from mixed material originating from this third country as well as from a third country with a negligible BSE risk. The specific attestation regarding the importation of products containing milk of ovine and caprine origin and intended for feeding farmed animals should also be amended to better reflect the restrictions applicable to intra-Union trade in these products.

(24) Chapters E and H of Annex IX to Regulation (EC) No 999/2001 lay down rules for the importation in the Union of ovine and caprine animals, and ovine and caprine semen and embryos. Those import rules should be updated to reflect the conditions for intra-Union trade laid down in Annex VIII to Regulation (EC) No 999/2001, including the general pre-requisites in terms of monitoring and eradication of classical scrapie laid down in Annexes III and VII to Regulation (EC) No 999/2001, as well as feed ban provisions laid down in Annex IV to Regulation (EC) No 999/2001.

(25) Annex X to Regulation (EC) No 999/2001 lays down the methods of analysis applicable to TSE testing in bovine, ovine and caprine animals. The joint EFSA and ECDC Opinion indicated that the L-type Atypical BSE agent has a significant zoonotic potential (transmission from animals to humans), which appears similar or even higher than that of the Classical BSE agent. L-type and H-type cases of atypical BSE have

been identified in several countries throughout the world and EFSA indicated that the unusually old age of all H-BSE and L-BSE identified cases and their apparent low prevalence in the population could suggest that these Atypical BSE forms are arising spontaneously. In order to gain more knowledge on atypical BSE, more relevant data need to be gathered.

(26) For that purpose, it is necessary to require that material from all future cases of BSE confirmed in the Union is submitted to discriminatory tests that allow the precise identification of the agent, namely classical BSE, L-type atypical BSE and H-type atypical BSE. As certain Member States and third countries have already published details of the phenotype of their recent BSE cases, discriminatory testing of future BSE cases confirmed in the Union should be made mandatory in Chapter C of Annex X to Regulation (EC) No 999/2001.

(27) Point 4 of Chapter C of Annex X to Regulation (EC) No 999/2001 sets out a list of rapid tests approved for the monitoring of TSEs in bovine, ovine and caprine animals.

(28) Considering that the two following rapid test kits for the monitoring of BSE in bovine animals are not manufactured any more, as confirmed in the letters sent by Enfer Scientific on 21 August 2012 and Roche Diagnostics GmbH on 31 August 2012, they should be deleted from the list of rapid tests set out in Point 4 of Chapter C of Annex X: Enfer test & Enfer TSE Kit version 2.0, automated sample preparation; Roche Applied Science PrionScreen.

(29) As Member States need sufficient time to adapt their national instructions to the new requirements introduced by this Regulation, this Regulation should apply on 1 July 2013.

(30) Regulation (EC) No 999/2001 should therefore be amended accordingly.

(31) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council have opposed them,

HAS ADOPTED THIS REGULATION:

Article 1

The Annexes 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*.

It shall apply from 1 July 2013.

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

Done at Brussels, 28 June 2013.

For the Commission

The President

José Manuel BARROSO

ANNEX

The Annexes to Regulation (EC) No 999/2001 are amended as follows:

(1) In Annex I, point 2 is replaced by the following:

2. For the purpose of this Regulation, the following definitions shall also apply:

(a) 'BSE indigenous case' means a case of bovine spongiform encephalopathy which has not been clearly demonstrated to be due to infection prior to importation as a live animal;

(b) 'cohort' means a group of bovine animals which includes both:

(i) animals born in the same herd as the affected bovine animal, and within 12 months preceding or following the date of birth of the affected bovine animal; and

(ii) animals which at any time during the first year of their lives were reared together with the affected bovine animal during the first year of its life;

(c) 'index case' means the first animal on a holding, or in an epidemiologically defined group, in which a TSE infection is confirmed;

(d) 'TSE in small ruminants' means a transmissible spongiform encephalopathy case detected in an ovine or caprine animal following a confirmatory test for abnormal PrP protein;

(e) 'scrapie case' means a transmissible spongiform encephalopathy confirmed case in an ovine or caprine animal where a diagnosis of BSE has been excluded in accordance with the criteria laid down in the European Union reference laboratory's technical handbook on TSE strain characterisation in small ruminants[(12)];

(f) 'classical scrapie case' means a scrapie confirmed case classified as classical in accordance with the criteria laid down in the European Union reference laboratory's technical handbook on TSE strain characterisation in small ruminants;

(g) 'atypical scrapie case' means a scrapie confirmed case which is distinguishable from classical scrapie in accordance with the criteria laid down in the European Union reference laboratory's technical handbook on TSE strain characterisation in small ruminants;

(h) 'Prion protein genotype' in ovine animals means a combination of two alleles as described in point 1 of Annex I to Commission Decision 2002/1003/EC[(13)];

(i) 'BSE case' means a case of BSE confirmed in a national reference laboratory according to the methods and protocols in point 3.1.(a) and (b) of Chapter C of Annex X;

(j) 'classical BSE case' means a BSE case classified as such in accordance with the criteria laid down in the European Union reference laboratory's method for the classification of bovine TSE isolates[(14)];

(k) 'atypical BSE case' means a BSE case which cannot be classified as a classical BSE case in accordance with the criteria laid down in the European Union reference laboratory's method for the classification of bovine TSE isolates;

(l) 'ovine and caprine animals over 18 months of age' means ovine and caprine animals:

(i) whose age is confirmed by the registers or movement documents referred to in point 1(b), (c) and (d) of Article 3 of Council Regulation (EC) No 21/2004[15], or

(ii) which have more than two permanent incisors erupted through the gum.

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

(a) In Part I, point 2 is replaced by the following:

2. **Monitoring in animals slaughtered for human consumption**

2.1. All bovine animals over 24 months of age shall be tested for BSE where they have undergone:

— emergency slaughter in accordance with point 1 of Chapter VI of Section I of Annex III to Regulation (EC) No 853/2004[16], or

— an ante mortem inspection with observations concerning accidents, or serious physiological and functional problems, or signs in accordance with point 2 of Part B of Chapter II of Section I of Annex I to Regulation (EC) No 854/2004[17].

2.2. All healthy bovine animals over 30 months of age slaughtered normally for human consumption shall be tested for BSE.

(b) Part II is amended as follows:

(i) Point 2 is replaced by the following:

2. **Monitoring in ovine and caprine animals slaughtered for human consumption**

(a) Member States in which the population of ewes and ewe lambs put to the ram exceeds 750 000 animals shall test, in accordance with the sampling rules set out in point 4, a minimum annual sample of 10 000 ovine animals slaughtered for human consumption;

(b) Member States in which the population of goats which have already kidded and goats mated exceeds 750 000 animals shall test, in accordance with the sampling rules set out in point 4, a minimum annual sample of 10 000 caprine animals slaughtered for human consumption;

(c) A Member State may choose to replace a maximum of:

— 50 % of its minimum sample size of ovine and caprine animals slaughtered for human consumption set out in points (a) and (b) by testing dead ovine or caprine animals

over the age of 18 months at the ratio of one to one and in addition to the minimum sample size set out in point 3;

— 10 % of its minimum sample size set out in points (a) and (b) by testing ovine or caprine animals killed in the framework of a disease eradication campaign over the age of 18 months at the ratio of one to one.

(ii) Point 5 is replaced by the following:

5. **Monitoring in holdings under TSE control and eradication measures**

Animals over 18 months of age which are killed for destruction in accordance with Annex VII, Chapter B, Part 2, point 2.2.1. and point 2.2.2.(b) or (c), shall be tested for the presence of TSE in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2.(b), based on the selection of a simple random sample, in accordance with the sample size set out in the following table.

Number of animals over 18 months of age killed for destruction in the herd or flock	**Minimum sample size**
70 or less	All eligible animals
80	68
90	73
100	78
120	86
140	92
160	97
180	101
200	105
250	112
300	117
350	121
400	124
450	127
500 or more	150

(3) Annex VII is replaced by the following:

‘ANNEX VII

CONTROL AND ERADICATION OF TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES

CHAPTER A

Measures following the suspicion of the presence of a TSE in ovine and caprine animals

If a TSE is suspected in an ovine or caprine animal on a holding in a Member State and until the results of the confirmatory examinations are available, all other ovine and caprine animals on that holding shall be placed under an official movement restriction.

If there is evidence that the holding where the animal was present when the TSE was suspected is unlikely to be the holding where the animal could have been exposed to the TSE, the Member State may decide that other holdings or only the holding of exposure shall be placed under official control, depending on the epidemiological information available.

The milk and the milk products derived from the ovine and caprine animals of a holding placed under official control, which are present on that holding from the date when the presence of the TSE is suspected until the results of the confirmatory examinations are available, shall only be used within that holding.

CHAPTER B

Measures following confirmation of the presence of a TSE in bovine, ovine and caprine animals

1. The inquiry referred to in Article 13(1)(b) must identify:

(a) in the case of bovine animals:
- all other ruminants on the holding of the animal in which the disease was confirmed,
- where the disease was confirmed in a female animal, its progeny born within a period of two years prior to, or after, the clinical onset of the disease,
- all animals of the cohort of the animal in which the disease was confirmed,
- the possible origin of the disease,
- other animals on the holding of the animal in which the disease was confirmed or on other holdings which may have become infected by the TSE agent or been exposed to the same feed or contamination source,
- the movement of potentially contaminated feedingstuffs, of other material or any other means of transmission, which may have transmitted the TSE agent to or from the holding in question;

(b) in the case of ovine and caprine animals:

— all ruminants other than ovine and caprine animals on the holding of the animal in which the disease was confirmed,
— insofar as they are identifiable, the parents, and in the case of females all embryos, ova and the last progeny of the female animal in which the disease was confirmed,
— all other ovine and caprine animals on the holding of the animal in which the disease was confirmed in addition to those referred to in the second indent,
— the possible origin of the disease and the identification of other holdings on which there are animals, embryos or ova which may have become infected by the TSE agent or been exposed to the same feed or contamination source,
— the movement of potentially contaminated feedingstuffs, other material or any other means of transmission, which may have transmitted the TSE agent to or from the holding in question.

2. The measures laid down in Article 13(1)(c) shall comprise at least the following:

2.1. In the case of confirmation of BSE in a bovine animal, the killing and complete destruction of bovine animals identified by the inquiry referred to in the second and third indents of point 1(a); however, the Member State may decide:
— not to kill and destroy animals of the cohort referred to in the third indent of point 1(a) if evidence has been provided that such animals did not have access to the same feed as the affected animal,
— to defer the killing and destruction of animals of the cohort referred to in the third indent of point 1(a) until the end of their productive life, provided that they are bulls continuously kept at a semen collection centre and it can be ensured that they are completely destroyed following death.

2.2. In the case of confirmation of TSE in an ovine or caprine animal:

2.2.1. In cases where BSE cannot be excluded

If BSE cannot be excluded after the results of a ring trial carried out in accordance with the methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2(c), the killing and complete destruction, without delay, of all animals, embryos and ova identified by the inquiry referred to in the second to fifth indents of point 1(b).

The animals over 18 months of age killed for destruction shall be tested for the presence of TSE in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2, as laid down in Annex III, Chapter A, Part II, point 5.

The prion protein genotype of all ovine animals, up to a maximum of 50, shall be determined.

The milk and the milk products derived from the animals to be destroyed, which were present on the holding between the date of confirmation that BSE cannot be excluded and the date of complete

destruction of the animals, shall be disposed of in accordance with Article 12 of Regulation (EC) No 1069/2009 of the European Parliament and of the Council[19].

Following the killing and complete destruction of all animals, the conditions set out in point 3 shall apply to the holding.

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

If BSE and atypical scrapie are excluded in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2(c), the holding shall be subject to the conditions set out in point (a) and, pursuant to the decision of the Member State responsible for the holding, to the conditions of either option 1 set out at point (b), or option 2 set out at point (c), or option 3 set out at point (d):

(a) The milk and milk products derived from the animals to be destroyed or slaughtered and which were present on the holding between the date of confirmation of the case of TSE and the date of the completion of the measures to be applied in the holding as laid down in point (b) and (c), or derived from the infected flock/herd until all the restrictions laid down in point (d) and point 4 are lifted, shall not be used for the feeding of ruminants, except for the feeding of ruminants within that holding.

The placing on the market of such milk and milk products as feed for non-ruminants shall be limited to the territory of the Member State responsible for the holding.

The commercial document accompanying consignments of such milk and milk products and any packaging containing such consignments shall be clearly marked with the words: ‘shall not be fed to ruminants’.

The use and the storage of feedingstuffs containing such milk and milk products shall be prohibited on holdings where ruminants are kept.

Bulk feedingstuffs containing such milk and milk products shall be transported by means of vehicles which do not transport feedingstuffs for ruminants at the same time.

If those vehicles are subsequently used for the transport of feedingstuffs intended for ruminants, they shall be thoroughly cleaned in order to avoid cross-contamination, in accordance with a procedure approved by the Member State responsible for the holding.

(b) Option 1 — killing and complete destruction of all animals

The killing and complete destruction, without delay, of all animals, embryos and ova identified by the inquiry referred to in the second and third indents of point 1(b).

The animals over 18 months of age killed for destruction shall be tested for the presence of TSE in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2, as laid down in Annex III, Chapter A, Part II, point 5.

The prion protein genotype of all ovine animals, up to a maximum of 50, shall be determined.

By way of derogation from the conditions set out in the first paragraph of option 1, Member States may decide instead to carry out the measures listed in (i) or (ii):

(i) to replace the killing and complete destruction of all animals, without delay, by their slaughtering for human consumption, without delay, provided that:

— the animals are slaughtered for human consumption within the territory of the Member State responsible for the holding;

— all animals which are over 18 months of age slaughtered for human consumption shall be tested for the presence of TSE in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2.

(ii) to exempt the lambs and kids less than three months old from killing and complete destruction without delay, provided that they are slaughtered for human consumption not later than when they are three months of age.

Pending the killing and complete destruction or slaughtering for human consumption of all animals, the measures set out in point 2.2.2.(a) and point 3.4.(b) third and fourth indents shall apply on the holding where it has been decided to apply option 1.

Following the killing and complete destruction or slaughtering for human consumption of all animals the conditions set out in point 3 shall apply to the holding where it has been decided to apply option 1.

(c) Option 2 — killing and complete destruction of the susceptible animals only

The prion protein genotyping of all ovine animals present on the holding followed by the killing and complete

destruction, without delay, of all animals, embryos and ova identified by the inquiry referred to in the second and third indents of point 1(b), with the exception of:

— breeding rams of the ARR/ARR genotype,

— breeding ewes carrying at least one ARR allele and no VRQ allele and, where such breeding ewes are pregnant at the time of the inquiry, the lambs subsequently born, if their genotype meets the requirements of this subparagraph,

— ovine animals carrying at least one ARR allele which are intended solely for slaughter for human consumption,

— if the Member State responsible for the holding so decides, lambs and kids less than three months old provided that they are slaughtered for human consumption not later than when they are three months of age. These lambs and kids shall be exempted from the genotyping.

The animals over 18 months of age killed for destruction shall be tested for the presence of TSE in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2, as laid down in Annex III, Chapter A, Part II, point 5.

By way of derogation from the conditions set out in the first paragraph of option 2, Member States may decide instead to carry out the measures listed in (i), (ii) and (iii):

(i) to replace the killing and complete destruction of the animals referred to in the first paragraph of option 2 by their slaughtering for human consumption, provided that:

— the animals are slaughtered for human consumption within the territory of the Member State responsible for the holding;

— all animals which are over 18 months of age slaughtered for human consumption shall be tested for the presence of TSE in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2.

(ii) to delay the genotyping and subsequent killing and complete destruction or slaughtering for human consumption of the animals referred to in the first paragraph of option 2 for a period not exceeding three months in situations where the index case is confirmed close to the commencement of the lambing season, provided that the ewes, goats and their new-

born are kept isolated from ovine and caprine animals of other holdings during the whole period;

(iii) to delay the killing and complete destruction or slaughtering for human consumption of the animals referred to in the first paragraph of option 2 for a maximum period of three years from the date of confirmation of the index case, in ovine flocks and holdings where ovine and caprine animals are kept together. The application of the derogation set out in the present paragraph shall be limited to cases where the Member State responsible for the holding considers that the epidemiological situation cannot be handled without killing the relevant animals, but that this cannot be carried out immediately due to the low level of resistance in the ovine population of the holding coupled with other considerations, including economic factors. Breeding rams other than those of the ARR/ARR genotype shall be killed or castrated without delay and all possible measures to quickly build up genetic resistance in the ovine population of the holding, including by reasoned breeding and culling of ewes to increase the frequency of the ARR allele and eliminate the VRQ allele, shall be implemented. The Member State responsible for the holding shall ensure that the number of animals to be killed at the end of the period of delay is not greater than immediately after the index case was confirmed.

Pending the killing and complete destruction or slaughtering for human consumption of the animals referred to in the first paragraph of option 2, the following measures shall apply on the holding where it has been decided to apply option 2: point 2.2.2.(a), point 3.1., point 3.2.(a) and (b), point 3.3. and point 3.4.(a) first and second indents, (b) first, third and fourth indents, and (c). However, where the Member State responsible for the holding decides to delay the killing and complete destruction or slaughtering for human consumption of the animals in accordance with point (iii), the following measures shall instead apply on the holding: point 2.2.2. (a) and points 4.1. to 4.6.

Following the killing and complete destruction, or slaughtering for human consumption of the animals referred to in the first paragraph of option 2 the conditions set out in point 3 shall apply to the holding where it has been decided to apply option 2.

(d) Option 3 — no mandatory killing and complete destruction of animals

A Member State may decide not to kill and completely destroy the animals identified by the inquiry referred to in the second and third indents of point 1(b) where the criteria laid down in at least one of the following four indents are met:

— it is difficult to obtain replacement ovine animals of genotypes allowed under point 3.2. (a) and (b),

— the frequency of the ARR allele within the breed or holding is low,

— it is deemed necessary in order to avoid inbreeding,

— it is deemed necessary by the Member State based on a reasoned consideration of all the epidemiological factors.

The Member States allowing recourse to option 3 in the management of classical scrapie outbreaks shall keep records of the reasons and criteria founding each individual application decision.

When additional classical scrapie cases are detected in a holding where option 3 is being applied, the relevance of the reasons and criteria founding the decision to apply option 3 to this holding shall be reassessed by the Member State. If it is concluded that applying option 3 does not ensure a proper control of the outbreak, the Member State shall switch the management of this holding from option 3 to either option 1 or option 2, as laid down in points (b) and (c).

The prion protein genotype of all ovine animals, up to a maximum of 50, shall be determined within a period of three months from the date of confirmation of the index case of classical scrapie.

The conditions set out in point 2.2.2.(a) and point 4 shall immediately apply to a holding where it has been decided to apply option 3.

2.2.3. In cases where atypical scrapie is confirmed

Where the TSE case confirmed on a holding is an atypical scrapie case, the holding shall be subject to the following intensified TSE monitoring protocol for a period of two years from the date of the detection of the last atypical scrapie case: all ovine and caprine animals which are over the age of 18 months and slaughtered for human consumption and all ovine and caprine animals over the age of 18 months which have died or been killed on the holding shall be tested for the presence of TSE in accordance with the laboratory

methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2.

If a case of TSE other than atypical scrapie is confirmed during the intensified TSE monitoring period of two years referred to in the first paragraph, the holding shall be subject to the measures referred to in point 2.2.1 or point 2.2.2.

2.3. If an animal infected with TSE has been introduced from another holding:

(a) a Member State may decide, based on the history of the infected animal, to apply eradication measures in the holding of origin in addition to, or instead of, the holding in which the infection was confirmed;

(b) in the case of land used for common grazing by more than one flock or herd, Member States may decide to limit the application of eradication measures to a single flock or herd, based on a reasoned consideration of all the epidemiological factors;

(c) where more than one flock or herd is kept on a single holding, Member States may decide to limit the application of the eradication measures to the flock or herd in which the TSE has been confirmed, provided it has been verified that the flocks or herds have been kept isolated from each other and that the spread of infection between the flocks or herds through either direct or indirect contact is unlikely.

3. Following the killing and complete destruction or slaughtering for human consumption of all animals identified on a holding, in accordance with point 2.2.1., point 2.2.2.(b) or point 2.2.2.(c):

3.1. The holding shall be subjected to an intensified TSE monitoring protocol including the testing for the presence of TSE, in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2, of all of the following animals which are over the age of 18 months, except ovine animals of the ARR/ARR genotype:

(a) animals which were kept in the holding at the time when the TSE case was confirmed, in accordance with point 2.2.2.(c), and which have been slaughtered for human consumption;

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

3.2. Only the following animals may be introduced to 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;

(c) caprine animals, provided that a cleaning and disinfection of all animal housing on the premises has been carried out following destocking.

3.3. Only the following breeding rams 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.

3.4. Movement of animals from the holding shall either be allowed for the purposes of destruction, or shall be subject to the following conditions:

(a) the following animals may be moved from the holding for all purposes, including breeding:
- ARR/ARR ovine animals;
- ewes carrying one ARR allele and no VRQ allele, provided that they are moved to other holdings which are restricted following the application of measures in accordance with point 2.2.2.(c) or 2.2.2.(d);
- caprine animals, provided that they are moved to other holdings which are restricted following the application of measures in accordance with point 2.2.2.(c) or 2.2.2.(d);

(b) the following animals may be moved from the holding to go directly for slaughter for human consumption:
- ovine animals carrying at least one ARR allele;
- caprine animals;
- if the Member State so decides, lambs and kids less than three months old on the date of slaughter;
- all animals when the Member State has decided to apply the derogations laid down in point 2.2.2.(b)(i) and point 2.2.2.(c)(i);

(c) 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:
- the holding of destination does not contain any ovine or caprine animals other than those being fattened prior to slaughter;
- at the end of the fattening period, the lambs and kids originating from the holdings subject to the eradication measures shall be transported directly to a slaughterhouse located within the territory of the same Member State to be slaughtered not later than when they are 12 months of age.

3.5. The restrictions set out in points 3.1 to 3.4 shall continue to apply to the holding:

(a) until the date of attainment of ARR/ARR status by all ovine animals on the holding, provided that no caprine animals are kept on the holding; or

(b) for a period of two years from the date when all the measures referred to in point 2.2.1., point 2.2.2.(b) or point 2.2.2.(c) have been completed, provided that no TSE case other than atypical scrapie is detected during this two-year period. If a case of atypical scrapie is confirmed during this two-year period the holding shall also be subject to the measures referred to in point 2.2.3.

4. Following the decision to implement option 3 laid down in point 2.2.2.(d) or the derogation provided for in point 2.2.2.(c)(iii), the following measures shall immediately apply to the holding:

4.1. The holding shall be subjected to an intensified TSE monitoring protocol including the testing for the presence of TSE in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2, of all of the following animals which are over the age of 18 months, except ovine animals of the ARR/ARR genotype:

(a) animals which have been slaughtered for human consumption;

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

4.2. Only the following ovine animals may be introduced to 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 animals referred to in points (c) and (d) to be introduced to the holding where the breed reared in the holding is listed by the Member State as a local breed in danger of being lost to farming in accordance with Annex IV to Commission Regulation (EC) No 1974/2006[20], and where the frequency of the ARR allele within the breed 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 where the breed reared in the holding is listed by the Member State as a local breed in danger of being lost to farming in accordance with Annex IV to Commission Regulation (EC) No

1974/2006, and where the frequency of the ARR allele within the breed 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 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) the following animals may be moved from the holding to go directly for slaughter for human consumption:

— either ovine animals carrying at least one ARR allele and, if the Member State so decides, lambs and kids less than three months old on the date of slaughter;

— or all animals when the Member State has decided to apply the derogation from option 2 laid down in point 2.2.2.(c)(iii) or option 3 laid down in point 2.2.2.(d).

(c) 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:

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

— at the end of the fattening period, the lambs and kids originating from the holdings subject to the eradication measures shall be transported directly to a slaughterhouse located within the territory of the same Member State to be slaughtered not later than when they are 12 months of age.

4.5. Movement of germinal products from the holding shall be subject to the following conditions: the Member State shall ensure that no semen, embryo and ova are dispatched from the holding.

4.6. Common grazing of all ovine and caprine animals in the holding with ovine and caprine animals of other holdings shall be prohibited during the lambing and kidding period.

Outside of the lambing and kidding period, common grazing shall be subject to restrictions to be determined by the Member State, based on a reasoned consideration of all the epidemiological factors.

4.7. The restrictions set out in point 2.2.2.(a) and in points 4.1 to 4.6 shall continue to apply for a period of two years following the detection of the last

TSE case, other than atypical scrapie, on the holdings where option 3 laid down in point 2.2.2.(d) has been implemented. If a case of atypical scrapie is confirmed during this two-year period the holding shall also be subject to the measures referred to in point 2.2.3.

In holdings where the derogation from option 2 provided for in point 2.2.2.(c)(iii) has been implemented, the restrictions set out in point 2.2.2.(a) and in points 4.1 to 4.6 shall apply until the complete destruction or slaughtering for human consumption of the animals identified for killing in accordance with point 2.2.2.(c), after which the restrictions laid out in point 3 shall be applicable.

CHAPTER C

Minimum requirements for a breeding programme for resistance to TSEs in ovine animals in accordance with article 6A

PART 1

General requirements

1. The breeding programme shall concentrate on flocks of high genetic merit, as defined in point 3 of Annex I of Commission Decision 2002/1003/EC.

However, Member States where a breeding programme is in place may decide to allow sampling and genotyping of breeding rams only, in flocks not participating in the breeding programme.

2. A database shall be established containing at least the following information:

(a) the identity, breed and number of animals in all flocks participating in the breeding programme;

(b) the identification of the individual animals sampled under the breeding programme, including breeding rams sampled in flocks not participating in the breeding programme;

(c) the results of any genotyping tests.

3. A system of uniform certification shall be established in which the genotype of each animal sampled under the breeding programme, including breeding rams sampled in flocks not participating in the breeding programme, is certified by reference to its individual identification number.

4. A system for the identification of animals and samples, the processing of samples and the delivery of results shall be established which minimises the possibility of human error. The effectiveness of that system shall be subject to regular random checking.

5. Genotyping of blood or other tissues collected for the purposes of the breeding programme, including from breeding rams sampled in flocks not participating in the breeding programme, shall be carried out in laboratories that have been approved under the breeding programme.

6. The competent authority of the Member State may assist breed societies, to establish genetic banks consisting of semen, ova and embryos representative of prion protein genotypes which are likely to become rare as a result of the breeding programme.

7. Breeding programmes shall be drawn up for each breed, taking account of:

(a) frequencies of the different alleles within the breed;

(b) rarity of the breed;

(c) avoidance of inbreeding or genetic drift.

PART 2

Specific rules for participating flocks

1. The breeding programme shall be aimed at increasing the frequency of the ARR allele within the flock, while reducing the prevalence of those alleles which have been shown to contribute to susceptibility to TSEs.

2. The minimum requirements for participating flocks shall be the following:

(a) all animals in the flock that are to be genotyped shall be individually identified using secure means;

(b) all rams intended for breeding within the flock shall be genotyped before being used for breeding;

(c) any male animal carrying the VRQ allele shall be slaughtered or castrated, within six months following the determination of its genotype; any such animal shall not leave the holding except for slaughter;

(d) female animals that are known to carry the VRQ allele shall not leave the holding except for slaughter;

(e) male animals, including semen donors used for artificial insemination, other than those certified under the breeding programme, shall not be used for breeding within the flock.

3. Member States may decide to grant derogations from the requirements set out in point 2(c) and (d) for the purposes of the protection of breeds and production traits.

4. Member States shall inform the Commission of any derogation granted under point 3 and of the criteria used.

PART 3

Specific rules for breeding rams sampled in flocks not participating in the breeding programme

1. Rams to be sampled shall be individually identified using secure means.

2. Any ram found to carry the VRQ allele shall not leave the holding except for slaughter.

PART 4

The framework for the recognition of the TSE-resistant status of flocks of ovine animals

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

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

(a) level I flocks shall be flocks composed entirely of ovine animals of the ARR/ARR genotype;

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

Member States may decide to grant recognition on further levels to suit national requirements.

2. Regular random sampling of ovine animals from TSE-resistant flocks shall be carried out:

(a) on the holding or at the slaughterhouse to verify their genotype;

(b) in the case of level I flocks, in animals over 18 months of age at the slaughterhouse, for TSE testing in accordance with Annex III.

PART 5

Reports to be provided to the Commission by the Member States

Member States introducing national breeding programmes to select for resistance to TSE in their ovine populations shall:

1. notify to the Commission the requirements for such programmes;

2. submit to the Commission an annual report on their progress.

The report for each calendar year shall be submitted at the latest by 31 March of the following year.

(4) In Annex VIII, Chapter A is replaced by the following:

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

1. Holdings with a negligible risk of classical scrapie and a controlled risk of classical scrapie:

1.1. Member States may establish or 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.

When they do so, they shall maintain a list 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 at least 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 at least 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 may be introduced:

  (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 laid down in points (a) to (i) for a minimum of seven years or for at least the same period of time as the holding where they are to be introduced;

  (iii) ovine animals of the ARR/ARR prion protein genotype.

(d) the holding is subject to regular checks to verify compliance with the provisions set out in point (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) all ovine and caprine animals over 18 months of age slaughtered for human consumption are inspected by an official veterinarian, and all those exhibiting wasting signs, neurological signs or sent for emergency slaughter are tested in a laboratory for classical scrapie in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2.

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, Part 3, 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 shall be tested in a laboratory for classical scrapie in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2.

By way of derogation from the conditions set out in the second and third paragraphs of point (f), Member States may decide to apply the provisions of the first paragraph of point (f) to 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.

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 ovine and caprine embryos/oocytes may be introduced:

(i) embryos/oocytes 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 meet the following requirements:

— they are permanently identified to enable trace 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 embryo/oocyte collection;

(ii) ovine embryos/oocytes of the ARR/ARR prion protein genotype.

(h) only the following ovine and caprine semen may be introduced:

(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 meet the following requirements:

— they are permanently identified to enable trace back to their holding of birth;

— they showed no clinical sign of classical scrapie at the time of semen collection;

(ii) ovine semen from a ram of the ARR/ARR prion protein genotype;

(i) ovine and caprine animals on the holding have no direct or indirect contact, including sharing grazing, with ovine and caprine animals from holdings of a lower status.

1.3. A holding of ovine and/or 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 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 may be introduced:

(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 laid down in points (a) to (i) for a minimum of three years or for at least the same period of time as the holding where they are to be introduced;

(iii) ovine animals of the ARR/ARR prion protein genotype.

(d) the holding is subject to regular checks to verify compliance with the provisions set out in point (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) all ovine and caprine animals over 18 months of age slaughtered for human consumption are inspected by an official veterinarian, and all those exhibiting wasting signs, neurological signs or sent for emergency slaughter are tested in a laboratory for classical scrapie in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2.

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, Part 3, 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 shall be tested in a laboratory for classical scrapie in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2.

By way of derogation from the conditions set out in the second and third paragraphs of point (f), Member States may decide to apply the provisions of the first paragraph of point (f) to 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.

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 ovine and caprine embryos/oocytes may be introduced:

(i) embryos/oocytes 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 meet the following requirements:

— they are permanently identified to enable trace 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 embryo/oocyte collection;

(ii) ovine embryos/oocytes of the ARR/ARR prion protein genotype.

(h) only the following ovine and caprine semen may be introduced:

(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 meet the following requirements:

— they are permanently identified to enable trace back to their holding of birth;

— they showed no clinical sign of classical scrapie at the time of semen collection;

(ii) ovine semen from a ram of the ARR/ARR prion protein genotype;

(i) ovine and caprine animals of the holding have no direct or indirect contact, including sharing grazing, with ovine and caprine animals from holdings of lower 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.

The Member State shall immediately inform the other Member States which have imported ovine and caprine animals originating from, or semen or embryos collected from ovine and caprine animals kept in that holding during the last seven years in the case of a holding with a negligible risk or during the last three years in the case of a holding with a controlled risk.

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) for a period of at least seven years, ovine and caprine animals displaying clinical signs compatible with classical scrapie have been tested;

(c) for a period of at least seven years, a sufficient number of ovine and caprine animals over 18 months of age, representative of slaughtered, culled or found dead on farm, have been tested annually, to provide a 95 percent level of confidence of detecting classical scrapie if it is present in that population at a prevalence rate exceeding 0,1 percent 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).

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).

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 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).

3.2. The national scrapie control programmes of following Member States are hereby approved:
- Denmark
- Austria
- Finland
- Sweden.

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 intended for 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; however ovine and caprine animals for breeding coming from a holding or holdings which have complied with all the requirements laid down in point 1.3. (a) to (f), for a period of at least three years may be subject to intra-Union trade until 31 December 2014; 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 laid down in Annex VII, Chapter B, points 3 and 4.

(b) ovine and caprine animals for all intended use except immediate slaughter intended for the 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; however ovine and caprine animals coming from a holding or holdings which have complied with all the requirements laid down in point 1.2. (a) to (i), for a period of at least seven years may be subject to intra-Union trade until 31 December 2014; 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 laid down in Annex VII, Chapter B, points 3 and 4.

4.2. semen and embryos of ovine and caprine animals 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; 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 requirements laid down in Part 1, point 1.3. (a) to (f) for three years; 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 ovine semen, be collected from male animals of the ARR/ARR prion protein genotype; or

(e) in the case of ovine embryos, be of the ARR/ARR prion protein genotype.

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.

(5) Annex IX is amended as follows:

(a) In Chapter C, Section A is replaced by the following:

SECTION A

Products

The following products of bovine, ovine and caprine origin, as defined by points 1.10, 1.13, 1.15, 7.1, 7.5, 7.6, 7.7, 7.8 and 7.9 of Annex I to Regulation (EC) No 853/2004 of the European Parliament and of the Council, shall be subject to the conditions laid down in Sections B, C or D of this Chapter depending on the BSE risk category of the country of origin:

— fresh meat,
— minced meat,
— meat preparations,
— meat products,
— rendered animal fat,
— greaves,
— gelatine and collagen other than derived from hides and skins,
— treated intestines.

(b) Chapters D and E are replaced by the following:

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 and derived products, as defined in points (1) and (2) of Article 3 of Regulation (EC) No 1069/2009 of the European Parliament and of the Council, provided that those 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, or their starting materials or intermediate products;

(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 of Article 3 of Regulation (EC) No 1069/2009, or their starting materials or intermediate products;

(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 does not contain and is not derived from specified risk material or mechanically separated meat obtained from bones of bovine, ovine or caprine animals and, except for animals born, continuously reared and slaughtered in a country or region classified as posing a negligible BSE risk by a decision in accordance with Article 5(2), the animals from which this animal by-product or derived product is 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 of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity; 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 by a decision in accordance with Article 5(2).

In addition to points (a) and (b), 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 products are 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 has been banned and effectively enforced in the whole country for a period at least seven years;

(d) the milk and milk products of ovine or caprine animals derive 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 derive from holdings where no case of classical scrapie has been diagnosed for the last 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 are to 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 has been banned and effectively enforced in the whole country for a period of at least 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 shall be complied with:
   — 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
   — 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 shall be complied with:
   — 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
   — 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.

(c) Chapter H is replaced by the following:

CHAPTER H

Import of ovine and caprine semen and embryos

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

1. 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) ovine and caprine animals affected with classical scrapie are killed and completely destroyed;

   (iv) 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 country for a period of at least seven years;

2. have been kept continuously for the last three years before the collection of the exported semen or embryos in a holding or holdings which have been satisfying for the last three years at least all the requirements laid down in point 1.3. (a) to (f) of Section A of Chapter A of Annex VIII, or:

   (i) in the case of ovine semen, the semen has been collected from male animals of the ARR/ARR prion protein genotype.

   (ii) in the case of ovine embryos, the embryos are of the ARR/ARR prion protein genotype.

(6) Annex X is amended as follows

(a) In Chapter C, in Part 3, in point 3.1, the following point 3.1(c) is added:

‘(c) Further examination of positive BSE cases

Samples from all positive BSE cases shall be forwarded to a laboratory, appointed by the competent authority, which has participated successfully in proficiency testing organised by the European Union reference laboratory for discriminatory testing of confirmed BSE cases, where they shall be further tested in accordance with the methods and protocols laid down in the European Union reference laboratory’s method for the classification of bovine TSE isolates[18].

(b) Part 4 of Chapter C of Annex X is replaced by the following:

4. Rapid tests

For the purposes of carrying out the rapid tests in accordance with Articles 5(3) and 6(1), only the following methods shall be used as rapid tests for the monitoring of BSE in bovine animals:

— the immuno-blotting test based on a Western blotting procedure for the detection of the Proteinase K-resistant fragment PrPRes (Prionics-Check Western test),

— the microplate-based immunoassay for the detection of PrPSc (Enfer TSE Version 3),

— the sandwich immunoassay for PrPRes detection (short assay protocol) carried out following denaturation and concentration steps (Bio-Rad TeSeE SAP rapid test),

— the microplate-based immunoassay (ELISA) which detects Proteinase K-resistant PrPRes with monoclonal antibodies (Prionics-Check LIA test),

— the immunoassay using a chemical polymer for selective PrP Sc capture and a monoclonal detection antibody directed against conserved regions of the PrP molecule (IDEXX HerdChek BSE Antigen Test Kit, EIA & IDEXX HerdChek BSE-Scrapie Antigen Test Kit, EIA),

— the lateral-flow immunoassay using two different monoclonal antibodies to detect Proteinase K-resistant PrP fractions (Prionics Check PrioSTRIP),

— the two-sided immunoassay using two different monoclonal antibodies directed against two epitopes presented in a highly unfolded state of bovine PrP Sc (Roboscreen Beta Prion BSE EIA Test Kit),

For the purposes of carrying out the rapid tests in accordance with Articles 5(3) and 6(1), only the following methods shall be used as rapid tests for the monitoring of TSE in ovine and caprine animals:

— the sandwich immunoassay for PrPRes detection (short assay protocol) carried out following denaturation and concentration steps (Bio-Rad TeSeE SAP rapid test),

— the sandwich immunoassay for PrPRes detection with the TeSeE Sheep/Goat Detection kit carried out following denaturation and concentration steps with the TeSeE Sheep/Goat Purification kit (Bio-Rad TeSeE Sheep/Goat rapid test),

— the immunoassay using a chemical polymer for selective PrP Sc capture and a monoclonal detection antibody directed against conserved regions of the PrP molecule (IDEXX HerdChek BSE-Scrapie Antigen Test Kit, EIA),

— the lateral-flow immunoassay using two different monoclonal antibodies to detect Proteinase K-resistant PrP fractions (rapid test Prionics — Check PrioSTRIP SR, visual reading protocol).

In all rapid tests, sample tissue on which the test must be applied must comply with the manufacturer’s instructions for use.

Producers of rapid tests must have a quality assurance system in place that has been approved by the European Union Reference Laboratory and

ensures that the test performance does not change. Producers must provide the European Union Reference Laboratory with the test protocols.

Changes to rapid tests and to test protocols may only be made after prior notification to the European Union Reference Laboratory and provided that the European Union Reference Laboratory finds that the change does not alter the sensitivity, specificity or reliability of the rapid test. That finding shall be communicated to the Commission and to the national reference laboratories.

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

(**2**) *EFSA Journal 2011*;9(1):1945

(**3**) OJ 121, 29.7.1964, p. 2012.

(**4**) OJ L 157, 30.4.2004, p. 33.

(**5**) OJ L 165, 27.6.2007, p. 8.

(**6**) OJ L 202, 31.7.2008, p. 11.

(**7**) OJ C 283, 24.11.2007, p. 28.

(**8**) OJ C 327, 20.12.2008, p. 26.

(**9**) OJ C 311, 22.10.2011, p. 33.

(**10**) OJ C 80, 17.3.2012, p. 5.

(**11**) COM(2010)384 final.

(**12**) http://vla.defra.gov.uk/science/docs/sci_tse_rl_handbookv4jan10.pdf

(**13**) OJ L 349, 24.12.2002, p. 105.

(**14**) http://vla.defra.gov.uk/science/docs/sci_tse_rl_2blot.pdf

(**15**) OJ L 5, 9.1.2004, p. 8.'

(**16**) OJ L 139, 30.4.2004, p. 55.

(**17**) OJ L 139, 30.4.2004, p. 206.'

(**18**) http://vla.defra.gov.uk/science/docs/sci_tse_rl_2blot.pdf'

(**19**) OJ L 300, 14.11.2009, p. 1.

(**20**) OJ L 368, 23.12.2006, p. 15.'

Changes to legislation:
There are currently no known outstanding effects for the Commission Regulation (EU) No 630/2013.