Commission Regulation (EC) No 727/2007 of 26 June 2007 amending Annexes I, III, VII and X to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance)

COMMISSION REGULATION (EC) No 727/2007

of 26 June 2007

amending Annexes I, III, VII and X to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 Article 6a(2) and Article 23 thereof,

Whereas:

(1) Regulation (EC) No 999/2001 lays down rules for the monitoring of transmissible spongiform encephalopathies in bovine, ovine and caprine animals and for eradication measures to be carried out following the confirmation of a transmissible spongiform encephalopathy (TSE) in ovine and caprine animals.

(2) In October 2005 the European Food Safety Authority (EFSA) adopted an opinion on the classification of atypical TSE cases in small ruminants. In its opinion EFSA concludes that an operational definition of atypical scrapie is possible and provides the elements for a classification of scrapie cases. EFSA also recommends that surveillance programmes, including tests and sampling arrangements, be used so as to enable detection of all forms of TSE in small ruminants.

(3) It appears appropriate, therefore, to introduce definitions for TSE in small ruminants, scrapie cases, classical scrapie cases and atypical scrapie cases.

(4) Where an animal slaughtered for human consumption is found positive to a rapid test under the current rules, namely Annex III to Regulation (EC) No 999/2001, at least the carcase immediately preceding the test-positive carcase and two carcases immediately following the test-positive carcase on the same slaughter line have to be destroyed, in addition to the test-positive carcase.

(5) The complete destruction, on the same slaughter line, of the three carcases adjacent to a rapid test-positive one is disproportionate with regard to the risk. These carcases should

only be destroyed if the result of a rapid test is confirmed positive or inconclusive after examination by the reference methods.

(6) Regulation (EC) No 999/2001, as amended by Commission Regulations (EC) No 214/2005[(2)] and (EC) No 1041/2006[(3)] provide for increased monitoring programmes in caprine and ovine animals, following the detection of bovine spongiform encephalopathies (BSE) in a goat in 2005 and three unusual TSE cases in sheep where BSE could not be excluded. Those monitoring programmes should be reviewed in the light of the results of two years of intensified testing which have not led to the detection of any additional BSE case in ovine or caprine animals. In order to ensure an efficient implementation of the programmes the reviewed monitoring requirements should apply from 1 July 2007.

(7) The monitoring programmes in ovine and caprine animals should be assessed and reviewed in the light of new scientific data.

(8) In view of the results of the increased monitoring in ovine and caprine animals, the current strict culling and repopulation policy in TSE affected flocks appears to be disproportionate. In addition, several difficulties, in particular regarding repopulation of infected flocks, hamper the effective implementation of measures following the detection of a TSE in a flock.

(9) On 8 March 2007 EFSA adopted an opinion on certain aspects related to the risk of TSEs in ovine and caprine animals. In its opinion, the Authority considers that there is no evidence for an epidemiological or molecular link between classical and/or atypical scrapie and TSEs in humans and that the BSE agent is the only TSE agent identified as zoonotic. In addition, the Authority considers that Current discriminatory tests as described in the EC legislation to be used for discrimination between scrapie and BSE are reliable for the differentiation of BSE from classical and atypical scrapie.

(10) Additional factors which confirm the need to reappraise TSE eradication measures in small ruminants include the absence of scientific evidence to indicate that scrapie is transmissible to humans, the ruling out of BSE in cases of TSE in small ruminants and the detection of atypical TSE cases having a limited spread of infection within a flock but also emerging in sheep with genotypes considered resistant to BSE and classical scrapie.

(11) The structure of the sheep and goat sector is notoriously different across the Community, Member States should therefore have the possibility to apply alternative policies, provided that harmonised rules are established.

(12) The Commission's TSE roadmap, adopted on 15 July 2005, establishes as one of the strategic goals the review of the eradication measures for small ruminants taking into account the new diagnostic tools available but ensuring the current level of consumer protection.

(13) On 13 July 2006 EFSA adopted an opinion on the Breeding Programmes for TSE resistance in sheep. In its opinion EFSA concludes that the breeding programmes increase the robustness of sheep populations against the currently known TSEs and

therefore contributes to both improved animal health and consumer protection. EFSA also made recommendations on the determination of the prion protein genotype.

(14) Article 6a of Regulation (EC) No 999/2001 provides that Member States may introduce breeding programmes to select for resistance to TSEs in their ovine populations. It is necessary to introduce harmonised minimum requirements for those breeding programmes.

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

(16) Commission Decision 2003/100/EC of 13 February 2003 laying down minimum requirements for the establishment of breeding programmes for resistance to transmissible spongiform encephalopathies in sheep[(4)] is obsolete as the provisions provided for therein are now to be replaced by provisions laid down in this Regulation. In the interests of clarity and legal certainty that Decision should be repealed.

(17) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1 U.K.

Annexes I, III, VII and X to Regulation (EC) No 999/2001 are amended in accordance with the Annex to this Regulation.

Article 2 U.K.

Decision 2003/100/EC is repealed.

Article 3 U.K.

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Point (2)(b) of the Annex to this Regulation shall apply from 1 July 2007.

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

Done at Brussels, 26 June 2007.

For the Commission

Markos KYPRIANOU

Member of the Commission

ANNEX U.K.

Annexes I, III, VII and X 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) "indigenous case of BSE" 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) "discrete adipose tissue" means internal and external body fat removed during the slaughter and cutting process, in particular fresh fat from the heart, caul and kidney of bovine animals, and fat from cutting rooms;

(c) "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;

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

(e) "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;

(f) "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 Community reference laboratory's technical handbook on TSE strain characterisation in small ruminants[(5)];

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

(h) "atypical scrapie case" means a scrapie confirmed case which is distinguishable from classical Scrapie in accordance with the criteria laid down in the Community reference laboratory's technical handbook on TSE strain characterisation in small ruminants.

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

(a) In part I, points 6.4 and 6.5 are replaced by the following:

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 4(2)(a) and (b) of Regulation (EC) No 1774/2002, apart from material to be retained in conjunction with the records provided for in Chapter B(III).

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 tested positive or inconclusive animal on the same slaughter line shall be destroyed in accordance with point 6.4. By way of derogation, 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).

(b) Part II is replaced by the following:

II. MONITORING IN OVINE AND CAPRINE ANIMALS

1. General

Monitoring in ovine and caprine animals shall be carried out in accordance with the laboratory methods laid down in Annex X, Chapter C, point 3.2(b).

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) Where a Member State experiences difficulty in collecting sufficient numbers of healthy slaughtered ovine or caprine animals to reach its allotted minimum sample size established in points (a) and (b), it may choose to replace a maximum of 50 % of its minimum sample size 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. In addition a Member State may choose to replace a maximum of 10 % of its minimum sample size 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.

3. Monitoring in ovine and caprine animals not slaughtered for human consumption

Member States shall test, in accordance with the sampling rules set out in point 4 and the minimum sample sizes indicated in Table A and Table B, ovine and caprine animals which have died or been killed, but which were not:

— killed in the framework of a disease eradication campaign, or

— slaughtered for human consumption.

TABLE A

Member State population of ewes and ewe lambs put to the ram	Minimum sample size of dead ovine animals[a]
> 750 000	10 000
100 000-750 000	1 500
40 000-100 000	100 % up to 500
< 40 000	100 % up to 100

a Minimum sample sizes are set to take account of the size of the ovine populations in the individual Member States and are intended to provide achievable targets.

TABLE B

Member State population of goats which have already kidded and goats mated	Minimum sample size of dead caprine animals[a]
> 750 000	10 000
250 000-750 000	1 500
40 000-250 000	100 % up to 500
< 40 000	100 % up to 100

a Minimum sample sizes are set to take account of the size of the caprine population in the individual Member States and are intended to provide achievable targets.

4. Sampling rules applicable to the animals referred to in points 2 and 3

The animals shall be over 18 months of age or have more than two permanent incisors erupted through the gum.

The age of the animals shall be estimated on the basis of dentition, obvious signs of maturity, or any other reliable information.

The sample selection shall be designed with a view to avoid the over-representation of any group as regards the origin, age, breed, production type or any other characteristic.

The sampling shall be representative for each region and season. Multiple sampling in the same flock shall be avoided, wherever possible. Member States shall aim their monitoring programmes to achieve, wherever possible, that in successive sampling years all officially registered holdings with more than 100 animals and where TSE cases have never been detected are subject to TSE testing.

The Member States shall put in place a system to check, on a targeted or other basis, that animals are not being diverted from sampling.

However, Member States may decide to exclude from the sampling remote areas with a low animal density, where no collection of dead animals is organised. Member States making use of this derogation shall inform the Commission thereof, and shall submit a list of those remote areas where the derogation applies. The derogation shall not cover more than 10 % of the ovine and caprine population in the Member State concerned.

5. Monitoring in infected flocks

Animals over 18 months of age or have more than two permanent incisors erupted through the gum, and which are killed for destruction in accordance with Annex VII, point 2.3(b)(i) or (ii) or point 5(a), shall be tested based on the selection of a simple random sample, in accordance with the sample size indicated in the following table.

Number of animals over 18 months of age or which have more than two permanent incisors erupted through the gum, 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

6. Monitoring in other animals

In addition to the monitoring programmes set out in points 2, 3 and 4, Member States may on a voluntary basis carry out monitoring in other animals, in particular:

— animals used for dairy production,

— animals originating from countries with indigenous TSEs,

— animals which have consumed potentially contaminated feedingstuffs,

— animals born or derived from TSE infected dams.

7. Measures following testing of ovine and caprine animals

7.1. Where an ovine or caprine animal slaughtered for human consumption has been selected for TSE testing in accordance with point 2, its carcase shall not be marked with the health marking provided for in Section I, Chapter III of Annex I to Regulation (EC) No 854/2004 until a negative result to the rapid test has been obtained.

7.2. Member States may derogate from point 7.1. where a system approved by the competent authority is in place in the slaughterhouse ensuring that all parts of an animal can be traced and that no parts of the animals tested bearing the health mark can leave the slaughterhouse until a negative result to the rapid test has been obtained.

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, except for animal by-products directly disposed of in accordance with Article 4(2)(a), (b) or (e) of Regulation (EC) No 1774/2002.

7.4. Except for the material to be retained in conjunction with the records provided for in Chapter B, Part III of this Annex, 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 4(2)(a), (b) or (e) of Regulation (EC) No 1774/2002.

8. Genotyping

8.1. The prion protein genotype for the codons 136, 154 and 171 shall be determined for each positive TSE case in sheep. TSE cases found in sheep of genotypes which encode alanine on both alleles at codon 136, arginine on both alleles at codon 154 and arginine on both alleles at codon 171 shall immediately be reported to the Commission. Where the positive TSE case is an atypical scrapie case the prion protein genotype for the codon 141 shall be determined.

8.2. In addition to the animals genotyped in accordance with point 8.1, the prion protein genotype for the codons 136, 141, 154 and 171 of a minimum sample of ovine animals shall be determined. In the case of Member States with an adult sheep population of more than 750 000 animals, this minimum sample shall consist of at least 600 animals. In the case of other Member States the minimum sample shall consist of at least 100 animals. The samples may be chosen from animals slaughtered for human consumption, from animals dead-on-farm or from live animals. The sampling should be representative of the entire ovine population.

(3) Annex VII is replaced by the following:

ANNEX VII U.K.

ERADICATION OF TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY

CHAPTER A U.K.

Measures following confirmation of the presence of a TSE

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

(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 two years prior to, or after, 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,

— in so far 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: U.K.

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 in 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. If a TSE is suspected in an ovine or caprine animal on a holding in a Member State, all other ovine and caprine animals from that holding shall be placed under official movement restriction until the results of the examination are available. If there is evidence that the holding where the animal was present when the TSE was suspected is not likely to be the holding where the animal could have been exposed to a TSE, the competent authority may decide that other holdings or only the holding of exposure shall be placed under official control depending on the epidemiological information available.

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

(a) if BSE cannot be excluded after the results of a ring trial carried out in accordance with the procedure set out in Annex X, Chapter C, point 3.2(c), the killing and complete destruction of all animals, embryos and ova identified by the inquiry referred to in the second to fifth indents of point 1(b);

(b) if BSE is excluded in accordance with the procedure set out in Annex X, Chapter C, point 3.2(c), pursuant to the decision of the competent authority:

either

(i) the killing and complete destruction of all animals, embryos and ova identified by the inquiry referred to in the second and third indents of point 1(b). The conditions set out in point 3 shall apply to the holding;

or

(ii) the killing and complete destruction 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,

— sheep carrying at least one ARR allele which are intended solely for slaughter,

— if the competent authority so decides, sheep and goats less than three months old which are intended solely for slaughter.

The conditions set out in point 3 shall apply to the holding;

or

(iii) a Member State may decide not to kill and destroy the animals, identified by the inquiry referred to in the second and third indents of point 1(b) where it is difficult to obtain replacement ovine animals of a known genotype or where the frequency of the ARR allele within the breed or holding is low, or where it is deemed necessary in order to avoid inbreeding, or based on a reasoned consideration of all the epidemiological factors. The conditions set out in point 4 shall apply to the holding;

(c) by way of derogation from the measures set out in point (b), and only where the TSE case confirmed on a holding is an atypical scrapie case, the Member State may decide to apply the measures laid down in point 5.

(d) Member States may decide:

(i) to replace the killing and complete destruction of all animals referred to in b(i) by slaughtering for human consumption;

(ii) to replace the killing and complete destruction of animals referred to in b(ii) by slaughtering for human consumption;

provided that:

— the animals are slaughtered within the territory of the concerned Member State,

— all animals which are over 18 months of age or have more than two permanent incisors erupted through the gum and are slaughtered for human consumption shall be tested for the presence of TSE in accordance with the laboratory methods set out in Annex X, Chapter C, point 3.2(b);

(e) the prion protein genotype of ovine animals, up to a maximum of 50, killed and destroyed or slaughtered for human consumption in accordance with points (b)(i) and (iii) shall be determined.

2.4. If the infected animal has been introduced from another holding, a Member State may decide, based on the history of the case, to apply eradication measures in the holding of origin in addition to, or instead of, the holding in which the infection was confirmed; in the case of land used for common grazing by more than one flock, Member States may decide to limit the application of those measures to a single flock, based on a reasoned consideration of all the epidemiological factors; where more than one flock is kept on a single holding, Member States may decide to limit the application of the measures to the flock in which the TSE has been confirmed, provided it has been verified that the flocks have been kept isolated from each other and that the spread of infection between the flocks through either direct or indirect contact is unlikely.

3. Following the application on a holding of the measures referred to in point 2.3(a) and (b)(i) and (ii): U.K.

3.1. Only the following animals may be introduced to the holding(s):

(a) male sheep of the ARR/ARR genotype;

(b) female sheep carrying at least one ARR allele and no VRQ allele;

(c) caprine animals, provided that:

(i) no ovine animals for breeding other than those of the genotypes referred to in points (a) and (b) are present on the holding;

(ii) thorough cleaning and disinfection of all animal housing on the premises has been carried out following destocking.

3.2. Only the following ovine germinal products may be used in the holding(s):

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

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

3.3. Movement of the animals from the holding shall be subject to the following conditions:

(a) movement of ARR/ARR sheep from the holding shall not be subject to any restriction;

(b) sheep carrying only one ARR allele may be moved from the holding only to go directly for slaughter for human consumption or for the purposes of destruction; however,

— ewes carrying one ARR allele and no VRQ allele may be moved to other holdings which are restricted following the application of measures in accordance with point 2.3(b)(ii) or 4,

— if the competent authority so decides, lambs and kids may be moved to one other holding solely for the purposes of fattening prior to slaughter; the holding of destination shall not contain any ovine or caprine animals other than those being fattened prior to slaughter, and shall not dispatch live ovine or caprine animals to other holdings, except for direct slaughter;

(c) caprine animals may be moved provided that the holding is subjected to intensified TSE monitoring, including the testing of all caprine animals which are over the age of 18 months and:

(i) are slaughtered for human consumption at the end of their productive lives; or

(ii) have died or been killed on the holding, and meet the conditions set out to in Annex III, Chapter A, Part II, point 3;

(d) if the Member State so decides, lambs and kids less than three months old may be moved from the holding to go directly for slaughter for human consumption.

3.4. The restrictions set out in points 3.1, 3.2 and 3.3 shall continue to apply to the holding for a period of two years from:

(a) the date of attainment of ARR/ARR status by all ovine animals on the holding; or

(b) the last date when any ovine or caprine animal was kept on the premises; or

(c) the date when the intensified TSE monitoring set out in 3.3(c) commenced; or

(d) the date when all breeding rams on the holding are of ARR/ARR genotype and all breeding ewes carry at least one ARR allele and no VRQ allele, provided that during the two-year period, negative results are obtained from TSE testing of the following animals over the age of 18 months:

— an annual sample of ovine animals slaughtered for human consumption at the end of their productive lives in accordance with the sample size referred to in the Table in Annex III, Chapter A, Part II, point 5, and

— all ovine animals referred to in Annex III, Chapter A, Part II, point 3 which have died or been killed on the holding.

4. Following the application on a holding of the measures set out in point 2.3(b)(iii) and for a period of two breeding years following the detection of the last TSE case: U.K.

(a) all ovine and caprine animals on the holding shall be identified;

(b) all ovine and caprine animals on the holding may be moved only within the territory of the concerned Member State for slaughter for human consumption or for the purposes of destruction; all animals over the age of 18 months slaughtered for human consumption shall be tested for the presence of TSE in accordance with the laboratory methods laid down in Annex X, Chapter C, point 3.2(b);

(c) the competent authority shall ensure that embryos and ova are not dispatched from the holding;

(d) only the semen from rams of the ARR/ARR genotype and embryos carrying at least one ARR allele and no VRQ allele may be used in the holding;

(e) all ovine and caprine animals which are over the age of 18 months which have died or been killed on the holding shall be subject to TSE testing;

(f) only male sheep of the ARR/ARR genotype and female ovine animals from holdings where no TSE cases have been detected or from flocks fulfilling the conditions set out in point 3.4 may be introduced in the holding;

(g) only caprine animals from holdings where no TSE cases have been detected or from flocks fulfilling the conditions of point 3.4 may be introduced in the holding;

(h) All ovine and caprine animals in the holding shall be subject to common grazing restrictions to be determined by the competent authority, based on a reasoned consideration of all the epidemiological factors;

(i) by way of derogation of point (b) if the competent authority so decides, lambs and kids may be moved to another holding within the same Member State solely for the purposes of fattening prior to slaughter; provided that the holding of destination shall not contain any ovine or caprine animals other than those being fattened prior to slaughter, and shall not dispatch live ovine or caprine animals to other holdings, except for direct slaughter.

5. Following the application of the derogation provided for in point 2.3(c) the following measures shall apply: U.K.

(a) either the killing and complete destruction of all animals, embryos and ova identified by the inquiry referred to in the second and third indents of point 1(b). Member States may decide to determine the prion protein genotype of ovine animals which have been killed and destroyed;

(b) or, for a period of two breeding years following the detection of the last TSE case, at least the following measures:

(i) all ovine and caprine animals in the holding shall be identified;

(ii) the holding must be subject to intensified TSE monitoring for a two years period, including the testing of 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 which have died or been killed on the holding;

(iii) the competent authority shall ensure that live ovine and caprine animals, embryos and ova from the holding are not dispatched to other Member States or third countries.

6. Member States applying the measures set out in point 2.3(b)(iii) or the derogations provided for in points 2.3(c) and (d) shall notify to the Commission an account of the conditions and criteria used for granting them. Where additional TSE cases are detected in flocks where derogations are applied, the conditions for granting such derogations shall be reassessed.

CHAPTER B U.K.

Minimum requirements for a breeding programme for resistance to TSEs in sheep in accordance with Article 6a

PART 1 U.K.

General requirements

1. The breeding programme shall concentrate on flocks of high genetic merit.

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

(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;

(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 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 shall be carried out in laboratories that have been approved under that programme.

6. The competent authority of the Member State may assist breed societies, to establish genetic banks consisting of semen, ova and/or 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: U.K.

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

(b) rarity of the breed;

(c) avoidance of inbreeding or genetic drift.

PART 2 U.K.

Specific rules for participating flocks

1. The breeding programme shall be aimed at increasing the frequency of the ARR allele within the sheep 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: U.K.

(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 to 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 protection of breeds and production traits.

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

PART 3 U.K.

The framework for the recognition of the TSE-resistant status of flocks of sheep

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

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

(a) level I flocks shall be flocks composed entirely of sheep 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 sheep from TSE-resistant flocks shall be carried out: U.K.

(a) on the farm 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 4 U.K.

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 notify to the Commission the requirements for such programmes and shall provide 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 X, Chapter C is amended as follows:

(a) Point 1 is replaced by the following:

1. Sampling

Any samples intended to be examined for the presence of a TSE shall be collected using the methods and protocols laid down in the latest edition of the Manual for diagnostic tests and vaccines for Terrestrial Animals of the International Office for Epizooties (IOE/OIE) (the Manual). In addition, or in the absence, of OIE methods and protocols, and to ensure that sufficient material is available, the competent authority shall ensure the use of sampling methods and protocols in accordance with guidelines issued by the Community Reference Laboratory. In particular the competent authority shall collect the appropriate tissues, according to the available scientific advice and the guidelines of the Community Reference Laboratory, in order to ensure the detection of all known strains of TSE in small ruminants and shall keep at least half of the collected tissues fresh but not frozen until the result of the rapid test is negative. Where the result is positive or inconclusive the residual tissues must be processed in accordance with the Community reference laboratory guidelines.

The samples shall be correctly marked as to the identity of the sampled animal.

(b) Point 3.2(b) is replaced by the following:

(b) TSE monitoring

Samples from ovine and caprine animals sent for laboratory testing pursuant to the provisions of Annex III, Chapter A, Part II (Monitoring in ovine and caprine animals) shall be examined by a rapid test using the appropriate methods and protocols, according to the available scientific advice and the guidelines of the Community Reference Laboratory, in order to ensure the detection of all known strains of TSE.

When the result of the rapid test is inconclusive or positive, the sampled tissues shall immediately be sent to an official laboratory for confirmatory

examinations by immunocytochemistry, immuno-blotting or demonstration of characteristic fibrils by electron microscopy, as referred to in (a). If the result of the confirmatory examination is negative or inconclusive, additional confirmatory testing shall be carried out according the guidelines of the Community reference laboratory.

If the result of one of the confirmatory examination is positive, the animal shall be regarded a positive TSE case.

(c) In point 3.2(c)(ii), the third paragraph is replaced by the following:

Further testing of positive TSE samples detected in infected flocks on the same holding shall be carried out at least on the first two positive TSE cases detected every year following the index case.

(**1**) OJ L 147, 31.5.2001, p. 1. Regulation as last amended by Regulation (EC) No 1923/2006 (OJ L 404, 30.12.2006, p. 1).

(**2**) OJ L 37, 10.2.2005, p. 9.

(**3**) OJ L 187, 8.7.2006, p. 10.

(**4**) OJ L 41, 14.2.2003, p. 41.

(**5**) http://www.defra.gov.uk/corporate/vla/science/science-tse-rl-confirm.htm’

Changes to legislation:
There are currently no known outstanding effects for the Commission Regulation (EC) No 727/2007.