[F1ANNEX I

SPECIFIC DEFINITIONS

Textual Amendments

F1 Substituted by Commission Regulation (EC) No 1234/2003 of 10 July 2003 amending Annexes I, IV and XI to Regulation (EC) No 999/2001 of the European Parliament and of the Council and Regulation (EC) No 1326/2001 as regards transmissible spongiform encephalopathies and animal feeding (Text with EEA relevance).

[F2[F3]1. For the purpose of this Regulation, the following definitions set out in Regulation (EC) No 1069/2009 of the European Parliament and of the Council[(1)], Commission Regulation (EU) No 142/2011[(2)], Regulation (EC) No 178/2002 of the European Parliament and of the Council[(3)], Regulation (EC) No 767/2009 of the European Parliament and of the Council[(4)], Council Directive 2006/88/EC[(5)] and Regulation (EU) 2016/1012 of the European Parliament and of the Council[(6)] shall apply:]

(a) the definition of 'farmed animal' in Article 3(6) of Regulation (EC) No 1069/2009;

(b) the following definitions in Annex I to Regulation (EU) No 142/2011:

- (i) 'fur animals' in point 1;
- (ii) 'blood products' in point 4;
- (iii) 'processed animal protein' in point 5;
- (iv) 'fishmeal' in point 7;
- (v) 'collagen' in point 11;
- (vi) 'gelatine' in point 12;
- (vii) 'hydrolysed proteins' in point 14;
- (viii) 'canned petfood' in point 16;
- (ix) 'petfood' in point 19;
- (x) 'processed petfood' in point 20;

(c) the definition of 'feed' in Article 3(4) of Regulation (EC) No 178/2002;

(d) Regulation (EC) No 767/2009:

- (i) 'feed materials' in Article 3(2)(g);
- (ii) 'compound feed' in Article 3(2)(h);
- (iii) 'complete feed' in Article 3(2)(i);
- (iv) [F4'label' in Article 3(2)(t);]

(e) Directive 2006/88/EC:

- (i) 'aquaculture animal' in Article 3(1)(b);

(ii) 'aquatic animal' in Article 3(1)(e)**[**[F3];**]**

(f) **[**[F5]the definition of 'endangered breed' in Article 2(24) of Regulation (EU) 2016/1012.**]]**

Textual Amendments

F4 Inserted by Commission Regulation (EU) 2017/893 of 24 May 2017 amending Annexes I and IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council and Annexes X, XIV and XV to Commission Regulation (EU) No 142/2011 as regards the provisions on processed animal protein (Text with EEA relevance).

F5 Inserted by Commission Regulation (EU) 2020/772 of 11 June 2020 amending Annexes I, VII and VIII to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards eradication measures for transmissible spongiform encephalopathies in goats and endangered breeds (Text with EEA relevance).

Textual Amendments

F2 Substituted by Commission Regulation (EU) No 56/2013 of 16 January 2013 amending Annexes I and IV 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).

F3 Substituted by Commission Regulation (EU) 2020/772 of 11 June 2020 amending Annexes I, VII and VIII to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards eradication measures for transmissible spongiform encephalopathies in goats and endangered breeds (Text with EEA relevance).

[[F6]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 **[**[F7]national**]** reference laboratory's technical handbook on TSE strain characterisation in small ruminants [(7)] ;

(f) ‘ classical scrapie case ’ means a scrapie confirmed case classified as classical in accordance with the criteria laid down in the **[**F8national**]** 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 **[**F9national**]** 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 (8) ;

(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 **[**F10national**]** reference laboratory’s method for the classification of bovine TSE isolates (9) ;

(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 **[**F11national**]** 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 (10) , or

(ii) which have more than two permanent incisors erupted through the gum **[**F12;**]**

(m) **[**F4‘ farmed insects ’ means farmed animals, as defined in Article 3(6)(a) of Regulation (EC) No 1069/2009, of those insect species which are authorised for the production of processed animal protein in accordance with point 2 of Part A of Section 1 of Chapter II of Annex X to Regulation (EU) No 142/2011;

(n) ‘home compounders’ means livestock farmers who mix compound feed for the exclusive use on their own holding **[**F13;**]]**

(o) ‘**[**F14farmed and captive cervids’ means animals of the family *Cervidae* which are kept by humans in an enclosed territory;

(p) ‘wild cervids’ means animals of the family *Cervidae* which are not kept by humans;

(q) ‘semi-domesticated cervids’ means animals of the family *Cervidae* which are kept by humans although not in an enclosed territory.**]]]**

Textual Amendments

F7 Word in Annex 1 para. 2(e) substituted (13.12.2022) by The Animals and Animal Health, Feed and Food, Plants and Plant Health (Amendment) Regulations 2022 (S.I. 2022/1315), regs. 1(1), **14(2)(a)**

F8 Word in Annex 1 para. 2(f) substituted (13.12.2022) by The Animals and Animal Health, Feed and Food, Plants and Plant Health (Amendment) Regulations 2022 (S.I. 2022/1315), regs. 1(1), **14(2)(b)**

F9 Word in Annex 1 para. 2(g) substituted (13.12.2022) by The Animals and Animal Health, Feed and Food, Plants and Plant Health (Amendment) Regulations 2022 (S.I. 2022/1315), regs. 1(1), **14(2)(c)**

F10 Word in Annex 1 para. 2(j) substituted (13.12.2022) by The Animals and Animal Health, Feed and Food, Plants and Plant Health (Amendment) Regulations 2022 (S.I. 2022/1315), regs. 1(1), **14(2)(d)**

F11 Word in Annex 1 para. 2(k) substituted (13.12.2022) by The Animals and Animal Health, Feed and Food, Plants and Plant Health (Amendment) Regulations 2022 (S.I. 2022/1315), regs. 1(1), **14(2)(e)**

F12 Substituted by Commission Regulation (EU) 2017/893 of 24 May 2017 amending Annexes I and IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council and Annexes X, XIV and XV to Commission Regulation (EU) No 142/2011 as regards the provisions on processed animal protein (Text with EEA relevance).

F13 Substituted by Commission Regulation (EU) 2017/1972 of 30 October 2017 amending Annexes I and III to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards a surveillance programme for chronic wasting disease in cervids in Estonia, Finland, Latvia, Lithuania, Poland and Sweden and repealing Commission Decision 2007/182/EC (Text with EEA relevance).

F14 Inserted by Commission Regulation (EU) 2017/1972 of 30 October 2017 amending Annexes I and III to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards a surveillance programme for chronic wasting disease in cervids in Estonia, Finland, Latvia, Lithuania, Poland and Sweden and repealing Commission Decision 2007/182/EC (Text with EEA relevance).

Textual Amendments

F6 Substituted by Commission Regulation (EU) No 630/2013 of 28 June 2013 amending the Annexes to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

[F15ANNEX II

DETERMINATION OF BSE STATUS

Textual Amendments

F15 Substituted by Commission Regulation (EC) No 722/2007 of 25 June 2007 amending Annexes II, V, VI, VIII, IX and XI to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

CHAPTER A

Criteria

[F16The BSE status of F17... countries or regions thereof (hereinafter referred to as countries or regions), shall be determined on the basis of the criteria set out in points (a) to (e). For the purpose of this Annex, ‘ BSE ’ excludes ‘ atypical BSE ’ as a condition believed to occur spontaneously in all cattle populations at a very low rate.]

Textual Amendments

F16 Substituted by Commission Regulation (EU) 2016/1396 of 18 August 2016 amending certain Annexes to Regulation (No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

F17 Words in Annex 2 Ch. A omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(18)**; 2020 c. 1, Sch. 5 para. 1(1)

In the country or region:

(a) a risk analysis in accordance with the provisions of Chapter B, identifying all the potential factors for BSE occurrence and their historic perspective in the country or region, is carried out;

(b) a system of continuous surveillance and monitoring of BSE relating in particular to the risks described in Chapter B and complying with the minimal surveillance requirements laid down in Chapter D is in place;

(c) an on-going awareness programme for veterinarians, farmers, and workers involved in transportation, marketing and slaughter of bovine animals, to encourage reporting of all cases showing clinical signs consistent with BSE in target sub-populations as defined in Chapter D of this Annex is in place;

(d) an obligation to notify and investigate all bovine animals showing clinical signs consistent with BSE is in force;

(e) the examination of brain or other tissues collected within the framework of the surveillance and monitoring system referred to in point (b) is carried out in an approved laboratory.

CHAPTER B

Risk analysis

[F18 1. Structure of the risk analysis

The risk analyses shall comprise an entry assessment and an exposure assessment.

Textual Amendments

F18 Substituted by Commission Regulation (EU) No 1148/2014 of 28 October 2014 amending Annexes II, VII, VIII, IX 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).

2. Entry assessment (external challenge)

2.1. The entry assessment shall consist of assessing the likelihood that the BSE agent has either been introduced into the country or region via commodities potentially contaminated with a BSE agent, or is already present in the country or region.

The following risk factors shall be taken into account:

(a) the presence or absence of the BSE agent in the country or region and, if the agent is present, its prevalence based on the outcome of surveillance activities;

(b) the production of meat-and-bone meal or greaves from the BSE indigenous ruminant population;

(c) imported meat-and-bone meal or greaves;

(d) imported bovine and ovine and caprine animals;

(e) imported animal feed and feed ingredients;

(f) imported products of ruminant origin for human consumption, which may have contained tissues listed in point 1 of Annex V and may have been fed to bovine animals;

(g) imported products of ruminant origin for *in vivo* use in bovine animals.

2.2. Special eradication schemes, surveillance and other epidemiological investigations (especially surveillance for BSE conducted on the bovine animals population) relevant to the risk factors listed in point 2.1 should be taken into ac-count in carrying out the entry assessment.**]**

3. Exposure assessment

The exposure assessment shall consist of assessing the likelihood of exposure of bovine animals to the BSE agent, through a consideration of the following:

(a) recycling and amplification of the BSE agent through consumption by bovine animals of meat-and-bone meal or greaves of ruminant origin, or other feed or feed ingredients contaminated with these;

(b) the use of ruminant carcasses (including from fallen stock), by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of animal feed manufacture;

(c) the feeding or not of ruminants with meat-and-bone meal and greaves derived from ruminants, including measures to prevent cross-contamination of animal feed;

(d) the level of surveillance for BSE conducted on the bovine animals population to that time and the results of that surveillance.

CHAPTER C

Definition of categories

I. COUNTRY OR REGION WITH A NEGLIGIBLE BSE RISK

A country or region:

(1) where a risk analysis in accordance with Chapter B has been conducted in order to identify the historical and existing risk factors;

(2) which has demonstrated that appropriate specific measures have been taken for the relevant period of time defined below to manage each identified risk;

(3) which has demonstrated that Type B surveillance, in accordance with Chapter D, is in place, and the relevant points target, in accordance with Table 2 thereof, has been met; and

(4) which is:

(a) either in the following situation:

(i) in the country or region there has been no case of BSE, or, any case of BSE has been demonstrated to have been imported and has been completely destroyed;

(ii) the criteria in points (c), (d) and (e) of Chapter A of this Annex have been complied with for at least seven years; and

(iii) it has been demonstrated through an appropriate level of control and audit that for at least eight years neither meat-and-bone meal nor greaves derived from ruminants has been fed to ruminants;

(b) or in the following situation:

(i) there has been one or more BSE indigenous cases in the country or region but every BSE indigenous case was born more than 11 years ago;

(ii) the criteria in points (c), (d) and (e) of Chapter A have been complied with for at least seven years;

(iii) it has been demonstrated through an appropriate level of control and audit that for at least eight years neither meat-and-bone meal nor greaves derived from ruminants has been fed to ruminants;

(iv) the following animals, if alive in the country or region, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed:

— all BSE cases,

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

— if the results of the investigation referred to in the second indent are inconclusive, all bovine animals born in the same herd as, and within 12 months of the birth of, the BSE cases.

II. COUNTRY OR REGION WITH A CONTROLLED BSE RISK

A country or region

(1) where a risk analysis based on the information laid down in Chapter B has been conducted in order to identify the historical and existing risk factors;

(2) which has demonstrated that appropriate measures are been taken to manage all identified risks, but those measures have not been taken for the relevant period of time;

(3) which has demonstrated that Type A surveillance, in accordance with Chapter D, is in place and the relevant points target, in accordance with Table 2, has been met. Type B

surveillance may replace Type A surveillance once the relevant points target is met; and

(4) which is:

(a) either in the following situation:

(i) in the country or region there has been no case of BSE, or, any case of BSE has been demonstrated to have been imported and has been completely destroyed, the criteria in points (c), (d) and (e) of Chapter A are complied with, and it can be demonstrated through an appropriate level of control and audit that neither meat-and-bone meal nor greaves derived from ruminants has been fed to ruminants;

(ii) the criteria in points (c), (d) and (e) of Chapter A have been complied with for a period shorter than seven years; and/or

(iii) it cannot be demonstrated that controls over the feeding of meat-and-bone meal or greaves derived from ruminants to ruminants have been in place for eight years;

(b) or in the following situation:

(i) in the country or region there has been a BSE indigenous case, the criteria in points (c), (d) and (e) of Chapter A are complied with, and it can be demonstrated through an appropriate level of control and audit that neither meat-and-bone meal nor greaves derived from ruminants has been fed to ruminants;

(ii) the criteria in points (c) to (e) of Chapter A of this Annex have been complied with for a period shorter than seven years; and/or

(iii) it cannot be demonstrated that controls over the feeding of meat-and-bone meal or greaves derived from ruminants to ruminants have been in place for at least eight years;

(iv) the following animals, if alive in the country or region, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed: and

— all BSE cases, and

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

— if the results of the investigation referred to in the second indent are inconclusive, all bovine animals born in the same herd as, and within 12 months of the birth of, the BSE cases.

III. COUNTRY OR REGION WITH UNDETERMINED BSE RISK

A country or region for which the determination of BSE status has not been concluded, or which does not meet the conditions to be fulfilled by the country or region to be classified in one of the other categories.

CHAPTER D

Minimal surveillance requirements

1. Surveillance types

For the purpose of this Annex, the following definitions shall apply:

(a) *Type A surveillance*

The application of Type A surveillance will allow the detection of BSE at a design prevalence[11] of at least one case per 100 000 in the adult bovine animals population in the country or region of concern, at a confidence level of 95 %;

(b) *Type B surveillance*

The application of Type B surveillance will allow the detection of BSE at a design prevalence of at least one case per 50 000 in the adult bovine animals population in the country or region of concern, at a confidence level of 95 %.

Type B surveillance may be carried out by countries or region of negligible BSE risk status to confirm the conclusions of the risk analysis, for example by demonstrating the effectiveness of the measures mitigating any risk factors identified, through surveillance targeted to maximise the likelihood of identifying failures of such measures.

Type B surveillance may also be carried out by countries or regions of controlled BSE risk status, following the achievement of the relevant points target using Type A surveillance, to maintain confidence in the knowledge gained through Type A surveillance.

For the purpose of this Annex, the following four sub-populations of bovine animals have been identified for surveillance purposes:

(a) bovine animals over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects);

(b) bovine animals over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; bovine animals over 30 months of age sent for emergency slaughter or with abnormal observations at ante-mortem inspection (casualty or emergency slaughter);

(c) bovine animals over 30 months of age which are found dead or killed on farm, during transport or at an abattoir (fallen stock);

(d) bovine animals over 36 months of age at routine slaughter.

2. Surveillance strategy

2.1. The surveillance strategy shall be designed to ensure that samples are representative of the herd of the country or region, and include consideration of demographic factors such as production type and geographic location, and the potential influence of culturally unique husbandry practices. The approach used and the assumptions made shall be fully documented, and the documentation retained for seven years.

2.2. In order to implement the surveillance strategy for BSE, a country shall use documented records or reliable estimates of the age distribution of the adult bovine

animals population and the number of bovine animals tested for BSE stratified by age and by sub-population within the country or region.

3. Points values and point targets

Surveillance samples must meet the point targets set out in Table 2, on the basis of 'point values' fixed in Table 1. All clinical suspects shall be investigated, regardless of the number of points accumulated. A country shall sample at least three out of the four sub-populations. The total points for samples collected shall be accumulated over a period of a maximum of seven consecutive years to achieve the target number of points. The total points accumulation shall be periodically compared to the target number of points for a country or region.

TABLE 1

Surveillance point values for samples collected from animals in the given sub-population and age category

Surveillance sub-population			
Routine slaughter[a]	**Fallen stock**[b]	**Casualty slaughter**[c]	**Clinical suspect**[d]
Age ≥ 1 year and < 2 years			
0,01	0,2	0,4	N/A
Age ≥ 2 years and < 4 years (young adult)			
0,1	0,2	0,4	260
Age ≥ 4 years and < 7 years (middle adult)			
0,2	0,9	1,6	750
Age ≥ 7 years and < 9 years (older adult)			
0,1	0,4	0,7	220
Age ≥ 9 years (aged)			
0,0	0,1	0,2	45

a Bovine animals over 36 months of age at routine slaughter.

b Bovine animals over 30 months of age which are found dead or killed on farm, during transport or at an abattoir (fallen stock).

c Bovine animals over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; bovine animals over 30 months of age sent for emergency slaughter or with abnormal observations at ante-mortem inspection (casualty or emergency slaughter).

d Bovine animals over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects).

[F18 TABLE 2

Points targets for different adult bovine animals population sizes in a country or region

Points targets for country or region		
Adult bovine animals population size(24 months and older)	**Type A surveillance**	**Type B surveillance**
> 1 000 000	300 000	150 000
900 0011 000 000	214 600	107 300

800 001900 000	190 700	95 350
700 001800 000	166 900	83 450
600 001700 000	143 000	71 500
500 001600 000	119 200	59 600
400 001500 000	95 400	47 700
300 001400 000	71 500	35 750
200 001300 000	47 700	23 850
100 001200 000	22 100	11 500
90 001100 000	19 900	9 950
80 00190 000	17 700	8 850
70 00180 000	15 500	7 750
60 00170 000	13 000	6 650
50 00160 000	11 000	5 500
40 00150 000	8 800	4 400
30 00140 000	6 600	3 300
20 00130 000	4 400	2 200
10 00120 000	2 100	1 050
9 00110 000	1 900	950
8 0019 000	1 600	800
7 0018 000	1 400	700
6 0017 000	1 200	600
5 0016 000	1 000	500
4 0015 000	800	400
3 0014 000	600	300
2 0013 000	400	200
1 0012 000	200	100**]**

4. Specific targeting

Within each of the sub-populations above in a country or region, a country may target bovine animals identifiable as imported from countries or regions where BSE has been detected and bovine animals which have consumed potentially contaminated feedstuffs from countries or regions where BSE has been detected.

5. BSE surveillance model

A country may choose to use the full BSurvE model or an alternative method based on the BSurvE model to estimate its BSE presence/prevalence.

6. Maintenance surveillance

Once the points target has been achieved, and in order to continue to designate the status of a country or region as controlled BSE risk or negligible risk, surveillance can be reduced to Type B surveillance (provided all other indicators remain positive). However, to continue to comply with the requirements laid down in this Chapter, ongoing annual surveillance must continue to include at least three of the four prescribed sub-populations. In addition all bovine animals clinically suspected of being infected with BSE shall be investigated regardless of the number of points accumulated. The annual surveillance in a country or region following the achievement of the required points target, shall be no less than the amount required for one-seventh of its total Type B surveillancetarget.**]**

[F19 ANNEX III

MONITORING SYSTEM

Textual Amendments

F19 Substituted by Commission Regulation (EC) No 2245/2003 of 19 December 2003 amending Annex III to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards monitoring of transmissible spongiform encephalopathies in ovine and caprine animals.

CHAPTER A

I. MONITORING IN BOVINE ANIMALS

1. General

Monitoring in bovine animals shall be carried out in accordance with the laboratory methods laid down in Annex X, Chapter C, point 3(1)(b).

[F6 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 [(12)] , 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 [(13)] .

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

3. Monitoring in animals not slaughtered for human consumption

3.1. All bovine animals over 24 months of age which have died or been killed but which were not:

— killed for destruction pursuant to Commission Regulation (EC) No 716/96 [(14)] ,

— killed in the framework of an epidemic, such as foot-and-mouth disease,

— slaughtered for human consumption,

shall be tested for BSE.

[F20 3.2. Point 3.1 does not prevent the exercise by the appropriate authority of any power to disapply the requirement for testing under that point in remote areas with a low animal density, where no collection of dead animals takes place, provided that when taken with other such exclusions not more than 10% of the bovine population in the United Kingdom is excluded from that requirement.]

Textual Amendments

F20 Annex 3 Ch. A Pt. 1 point 3.2 substituted (31.12.2020) by The Animals (Legislative Functions) (EU Exit) Regulations 2019 (S.I. 2019/588), regs. 1, **4(20)(a)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)

[F21 4. Monitoring in animals purchased for destruction pursuant to Regulation (EC) No 716/96

All animals born between 1 August 1995 and 1 August 1996 killed for destruction pursuant Regulation (EC) No 716/96 shall be tested for BSE.]

Textual Amendments

F21 Substituted by Commission Regulation (EC) No 657/2006 of 10 April 2006 amending Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the United Kingdom and repealing Council Decision 98/256/EC and Decisions 98/351/EC and 1999/514/EC (Text with EEA relevance).

5. Monitoring in other animals

In addition to the testing referred to in points 2 to 4, [F22 the appropriate authority may test other bovine animals], in particular where those animals originate from countries with indigenous BSE, have consumed potentially contaminated feedingstuffs or were born or derived from BSE infected dams.

Textual Amendments

F22 Words in Annex 3 Ch. A Pt. 1 point 5 substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(21)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

[F16 6. Measures following testing

6.1. Where an animal slaughtered for human consumption has been selected for testing for BSE, the health marking provided for in [F23 Article 18(4) of Regulation (EU) No 2017/625] shall not be carried out on the carcase of that animal until a negative result to the rapid test has been obtained.

Textual Amendments

F23 Words in Annex 3 Ch. A Pt. 1 point 6.1 substituted (31.12.2020) by S.I. 2019/170, **reg. 2(21)(aa)** (as inserted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant

Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(i)**)

6.2. **[**F24The appropriate authority need not comply with**]** point 6.1 where an official system is in place in the slaughterhouse ensuring that no parts of examined animals bearing the health mark leave the slaughterhouse until a negative result to the rapid test has been obtained.

Textual Amendments

F24 Words in Annex 3 Ch. A Pt. 1 point 6.2 substituted (31.12.2020) by The Animals (Legislative Functions) (EU Exit) Regulations 2019 (S.I. 2019/588), regs. 1, **4(20)(b)(i)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)

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

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

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

By way of derogation from the first paragraph of this point, **[**F25The appropriate authority may decide not to destroy the carcases mentioned in the first paragraph unless**]** 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).

Textual Amendments

F25 Words in Annex 3 Ch. A Pt. 1 point 6.5 substituted (31.12.2020) by The Animals (Legislative Functions) (EU Exit) Regulations 2019 (S.I. 2019/588), regs. 1, **4(20)(b)(ii)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)

6.6. **[**F26The appropriate authority may decide not to destroy the carcases mentioned in**]** point 6.5 where a system is in place in the slaughterhouse preventing contamination between carcases.**]**

Textual Amendments

F26 Words in Annex 3 Ch. A Pt. 1 point 6.6 substituted (31.12.2020) by The Animals (Legislative Functions) (EU Exit) Regulations 2019 (S.I. 2019/588), regs. 1, **4(20)(b)(iii)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)

7. Revision of the annual monitoring programmes concerning BSE (BSE monitoring programmes), as provided for in Article 6(1b)

. . . . . .

F27...

Textual Amendments

F27 Annex 3 Ch. A Pt. 1 point 7 omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(21)(b)**; 2020 c. 1, **Sch. 5 para. 1(1)**

[F28[F29]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).

[F6]2. Monitoring in ovine and caprine animals slaughtered for human consumption

(a) **[**F30The appropriate authorities shall test**]** a minimum annual sample of 10 000 ovine animals slaughtered for human consumption **[**F31within Great Britain**]**;

Textual Amendments

F30 Words in Annex 3 Ch. A Pt. 2 point 2(a) substituted (31.12.2020) by S.I. 2019/170), regs. 1, **2(22)(a)(i)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F31 Words in Annex 3 Ch. A Pt. 2 point 2(a) inserted (31.12.2020) by S.I. 2019/170, regs. 1, **2(22)(a)(i)(bb)** (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(j)(i)**); 2020 c. 1, Sch. 5 para. 1(1)

(b) F32...

Textual Amendments

F32 Annex 3 Ch. A Pt. 2 point 2(b) omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(22)(a)(ii)**; 2020 c. 1, **Sch. 5 para. 1(1)**

(c) **[**F33The Secretary of State, with the consent of the other appropriate authorities,**]** 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.**]**

Textual Amendments

F33 Words in Annex 3 Ch. A Pt. 2 point 2(c) substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(22)(a)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)

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

[F34The appropriate authorities**]** 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:

Textual Amendments

F34 Words in Annex 3 Ch. A Pt. 2 point 3 substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(22)(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

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

— slaughtered for human consumption.

TABLE A

F36 **...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 F35... and are intended to provide achievable targets.

Textual Amendments

F35 Words in Annex 3 Ch. A Pt. 2 point 3 Table A omitted (31.12.2020) by virtue of S.I. 2019/170, **reg. 2(22)(b)(iii)** (as inserted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(j)(ii)**)

F36 Words in Annex 3 Ch. A Pt. 2 point 3 Table A substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(22)(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

TABLE B

F38 **...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 [F37]... and are intended to provide achievable targets.

Textual Amendments

F37 Words in Annex 3 Ch. A Pt. 2 point 3 Table B omitted (31.12.2020) by virtue of S.I. 2019/170, **reg. 2(22)(b)(iii)** (as inserted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(j)(ii)**)

F38 Words in Annex 3 Ch. A Pt. 2 point 3 Table B substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(22)(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

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. **[**[F39]The monitoring programmes must be designed by the Secretary of State, with the consent of each other authority which, in relation to any part of Great Britain, is the appropriate authority so as**]** 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.

Textual Amendments

F39 Words in Annex 3 Ch. A Pt. 2 point 4 substituted (31.12.2020) by S.I. 2019/588, **reg. 4(21)(a)(i)** (as substituted by The Aquatic Animal Health and Alien Species in Aquaculture, Animals, and

Marketing of Seed, Plant and Propagating Material (Legislative Functions and Miscellaneous Provisions) (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1463), regs. 1(2)(a), **6(3)(g)**)

The **[**F40appropriate authority**]** shall put in place a system to check, on a targeted or other basis, that animals are not being diverted from sampling.

Textual Amendments

F40 Words in Annex 3 Ch. A Pt. 2 point 4 substituted (31.12.2020) by The Animals (Legislative Functions) (EU Exit) Regulations 2019 (S.I. 2019/588), regs. 1, **4(21)(a)(ii)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)

[F41However, an appropriate authority may exclude from the sampling any remote areas with a low animal density and where no collection of dead animals takes place, provided that when taken with other such exclusions not more than 10% of the ovine and caprine population in the United Kingdom is excluded.**]**

Textual Amendments

F41 Words in Annex 3 Ch. A Pt. 2 point 4 substituted (31.12.2020) by The Animals (Legislative Functions) (EU Exit) Regulations 2019 (S.I. 2019/588), regs. 1, **4(21)(a)(iii)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)

[F6 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**]**

6. Monitoring in other animals

In addition to the monitoring programmes set out in points 2, 3 and 4, **[**[F42]the appropriate authority**]** may on a voluntary basis carry out monitoring in other animals, in particular:

Textual Amendments

F42 Words in Annex 3 Ch. A Pt. 2 point 6 substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(22)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

— 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. **[**[F43]The appropriate authority may decide not to comply with 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.

Textual Amendments

F43 Words in Annex 3 Ch. A Pt. 2 point 7.2 substituted (31.12.2020) by The Animals (Legislative Functions) (EU Exit) Regulations 2019 (S.I. 2019/588), regs. 1, **4(21)(b)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)

[[F16]7.3. All parts of the body of a tested animal, including the hide, shall be retained under official control until a negative result has been obtained to the rapid test, unless they are disposed of in accordance with Article 12(a) or (b) of Regulation (EC) No 1069/2009, or unless its fats are processed in accordance with Regulation (EU) No 142/2011 and used in accordance with Article 12(e) of Regulation (EC) No 1069/2009 or used for the manufacture of derived products referred to in Article 36 of that Regulation.

7.4. All parts of the body of an animal found positive to the rapid test, including the hide, shall be directly disposed of in accordance with Article 12(a) or (b) of Regulation (EC) No 1069/2009, apart from the material to be retained in conjunction with the records

provided for in Chapter B, Part III of this Annex, and apart from rendered fats derived from such a body provided that these rendered fats are processed in accordance with Regulation (EU) No 142/2011 and used in accordance with Article 12(e) of Regulation (EC) No 1069/2009 or used for the manufacture of derived products referred to in Article 36 of that Regulation.**]**

[F44 8. Genotyping

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 **[**F45 appropriate authority, which must immediately notify the other appropriate authorities**]**. Where the positive TSE case is an atypical scrapie case the prion protein genotype for the codon 141 shall also be determined.**]]**

Textual Amendments

F45 Words in Annex 3 Ch. A Pt. 2 point 8 substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(22)(d)**; 2020 c. 1, Sch. 5 para. 1(1)

Textual Amendments

F44 Substituted by Commission Regulation (EU) 2017/894 of 24 May 2017 amending Annexes III and VII to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the genotyping of ovine animals (Text with EEA relevance).

Textual Amendments

F28 Substituted by Commission Regulation (EC) No 36/2005 of 12 January 2005 amending Annexes III and X to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards epidemio-surveillance for transmissible spongiform encephalopathies in bovine, ovine and caprine animals (Text with EEA relevance).

F29 Substituted by 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).

[F13 III. MONITORING IN CERVIDS

A. **Three-year monitoring programme for chronic wasting disease (CWD)**

F46 ...

. . . . . .

Textual Amendments

F46 Annex 3 Ch. A Pt. 3 Ch. A omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(23)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

[F47B. Monitoring in cervids

The appropriate authority may carry out monitoring for TSEs in cervids.]]

Textual Amendments

F47 Annex 3 Ch. A Pt. 3 Ch. B substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(23)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

[F14IV. MONITORING IN OTHER ANIMAL SPECIES

[F48The appropriate authority] may on a voluntary basis carry out monitoring for TSE in animal species other than bovine, ovine, caprine and cervid animals.]]

Textual Amendments

F48 Words in Annex 3 Ch. A Pt. 4 substituted (13.12.2022) by The Animals and Animal Health, Feed and Food, Plants and Plant Health (Amendment) Regulations 2022 (S.I. 2022/1315), regs. 1(1), **14(3)**

[F49CHAPTER B

REPORTING AND RECORDING REQUIREMENTS

I. REQUIREMENTS ON [F50APPROPRIATE AUTHORITIES]

A. Information to be presented by [F51appropriate authorities in their annual report]

1. The number of suspected cases placed under official movement restrictions in accordance with Article 12(1), per animal species.

2. The number of suspected cases subject to laboratory examination in accordance with [F52Article 12], per animal species, including the results of the rapid and confirmatory tests (number of positives and negatives) and, with regard to bovine animals, the age distribution of all tested animals. The age distribution should be grouped as follows: ‘ below 24 months ’ , distribution per 12 months between 24 and 155 months, and ‘ above 155 months ’ of age.

Textual Amendments

F52 Words in Annex 3 Ch. B Pt. 1 s. A point 2 substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(25)(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

3. The number of flocks where suspected cases in ovine and caprine animals have been reported and investigated pursuant to [F53Article 12].

Textual Amendments

F53 Words in Annex 3 Ch. B Pt. 1 s. A point 3 substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(25)(b)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)

4. The number of bovine animals tested within each subpopulation referred to in Chapter A, Part I, points 2.1, 2.2, 3.1 and 5. The method of the sample selection, the results of the rapid and confirmatory tests and the age distribution of the tested animals grouped as set out in point 2 shall be provided.

5. The number of ovine and caprine animals and flocks tested within each subpopulation referred to in Chapter A, Part II, points 2, 3, 5 and 6 together with the method for sample selection and the results of the rapid and confirmatory tests.

6. The geographical distribution, including the country of origin if not the same as the reporting country, of positive cases of BSE and scrapie. The year, and where possible the month of birth shall be given for each TSE case in bovine, ovine and caprine animals. TSE cases which have been considered atypical shall be indicated. For scrapie cases, the results of the primary and secondary molecular testing, referred to in Annex X, Chapter C, point 3.2(c), shall be reported, where appropriate.

[F13 7. In animals other than bovine, ovine and caprine animals, as well as in cervids other than those covered by the three-year CWD monitoring programme referred to in Part III.A of Chapter A of this Annex, the number of samples and confirmed TSE cases per species.]

[F44 8. The genotype, and, where possible, the breed, of each ovine animal found positive to TSE and sampled in accordance with Chapter A, Part II, point 8.]

9. F54 ...

. . . . . .

Textual Amendments

F54 Annex 3 Ch. B Pt. 1 s. A point 9 omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(25)(b)(iv)**; 2020 c. 1, Sch. 5 para. 1(1)

Textual Amendments

F51 Words in Annex 3 Ch. B Pt. 1 s. A heading substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(25)(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

B. Reporting periods

F55 ...

Textual Amendments

F55 Annex 3 Ch. B Pt. 1 s. B omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(25)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

Textual Amendments

F50 Words in Annex 3 Ch. B Pt. 1 heading substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(25)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

II. INFORMATION TO BE PRESENTED IN THE UNION SUMMARY REPORT

F56 …

Textual Amendments

F56 Annex 3 Ch. B Pt. 2 omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(26)**; 2020 c. 1, Sch. 5 para. 1(1)

III. RECORDS

1. The competent authority shall keep, for 7 years, records of the information referred to in Part I.A.

2. The investigating laboratory shall keep, for 7 years, all records of testing, in particular laboratory workbooks and, where appropriate, paraffin blocks and photographs of western blots.**]]**

Textual Amendments

F49 Substituted by Commission Regulation (EU) 2016/27 of 13 January 2016 amending Annexes III and IV 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.

[F2ANNEX IV

ANIMAL FEEDING

CHAPTER I

Extensions of the prohibition provided for in Article 7(1)

In accordance with Article 7(2), the prohibition provided for in Article 7(1) shall be extended to the feeding:

(a) to ruminants of dicalcium phosphate and tricalcium phosphate of animal origin and compound feed containing these products;

(b) to non-ruminant farmed animals, other than fur animals, of:

(i) processed animal protein;

(ii) collagen and gelatine of ruminant origin;

(iii) blood products;

(iv) hydrolysed protein of animal origin;

(v) dicalcium phosphate and tricalcium phosphate of animal origin;

(vi) feed containing the products listed in (i) to (v).

CHAPTER II

Derogations from the prohibitions provided for in Article 7(1) and in Chapter I

In accordance with the first subparagraph of Article 7(3), the prohibitions provided for in Article 7(1) and in Chapter I shall not apply to the feeding to:

(a) ruminants of:

(i) milk, milk-based products, milk-derived products, colostrum and colostrum products;

(ii) eggs and egg products;

(iii) collagen and gelatine derived from non-ruminants;

(iv) hydrolysed proteins derived from:
— parts of non-ruminants, or
— ruminant hides and skins;

(v) compound feed containing the products listed in points (i) to (iv) above;

(b) non-ruminant farmed animals of the following feed materials and compound feed:

(i) hydrolysed proteins derived from parts of non-ruminants or from ruminant hides and skins;

(ii) fishmeal and compound feed containing fishmeal which are produced, placed on the market and used in accordance with the general conditions laid down in Chapter III and the specific conditions laid down in Section A of Chapter IV;

(iii) dicalcium phosphate and tricalcium phosphate of animal origin and compound feed containing such phosphates which are produced, placed on the market and used in accordance with the general conditions laid down in Chapter III and the specific conditions laid down in Section B of Chapter IV;

(iv) blood products derived from non-ruminants and compound feed containing such blood products which are produced, placed on the market and used in accordance with the general conditions laid down in Chapter III and the specific conditions laid down in Section C of Chapter IV;

(c) **[**[F12]aquaculture animals of the following feed materials and compound feed:

(i) processed animal protein derived from non-ruminants, other than fishmeal and other than processed animal protein derived from farmed insects, and compound feed containing such processed animal protein, which are produced, placed on the market and used in accordance with the general conditions laid down in Chapter III and the specific conditions laid down in Section D of Chapter IV;

(ii) processed animal protein derived from farmed insects, and compound feed containing such processed animal protein, which are produced, placed on the market and used in accordance with the general conditions laid down in Chapter III and the specific conditions laid down in Section F of Chapter IV;**]**

(d) unweaned ruminants of milk replacers containing fishmeal and which are produced, placed on the market and used in accordance with specific conditions laid down in Section E of Chapter IV;

(e) farmed animals of feed materials of plant origin and compound feed containing such feed materials contaminated with insignificant amount of bone spicules derived from unauthorised animal species. **[**[F57]The appropriate authority**]** may only use this derogation if **[**[F58]it has**]** carried out a risk assessment beforehand which has confirmed there is a negligible risk for animal health. That risk assessment must take into account at least the following:

(i) the level of the contamination;

(ii) the nature and the source of the contamination;

(iii) the intended use of the contaminated feed.

Textual Amendments

F57 Words in Annex 4 Ch. 2 point (e) substituted (13.12.2022) by The Animals and Animal Health, Feed and Food, Plants and Plant Health (Amendment) Regulations 2022 (S.I. 2022/1315), regs. 1(1), **14(4)(a)**

F58 Words in Annex 4 Ch. 2 point (e) substituted (13.12.2022) by The Animals and Animal Health, Feed and Food, Plants and Plant Health (Amendment) Regulations 2022 (S.I. 2022/1315), regs. 1(1), **14(4)(b)**

CHAPTER III

General conditions for the application of certain derogations provided for in Chapter II

[F12SECTION A

Transport and storage of feed materials and compound feed intended to be used for feeding non-ruminant farmed animals

1. The following products intended to be used for feeding non-ruminant farmed animals shall be transported in vehicles and containers and stored in storage facilities which are not used, respectively, for the transport or storage of feed intended for ruminants:

(a) bulk processed animal protein derived from non-ruminants, including fishmeal and processed animal protein derived from farmed insects;

(b) bulk dicalcium and tricalcium phosphate of animal origin;

(c) bulk blood products derived from non-ruminants;

(d) bulk compound feed containing the feed materials listed in (a), (b) and (c).

Records detailing the type of products that were transported or stored in a storage plant shall be kept available to the competent authority for a period of at least two years.

2. By way of derogation from point 1, vehicles, containers and storage facilities which have been previously used for the transport or storage of the products listed in that point, may be subsequently used for the transport or storage of feed intended for ruminants provided that they are cleaned beforehand in order to avoid cross-contamination, in accordance with a documented procedure which has been given prior authorisation by the competent authority.

Whenever such a procedure is used, a documented record of such use shall be kept available to the competent authority for a period of at least two years.

3. Storage plants storing in accordance with point 2 feed materials and compound feed listed in point 1 shall be authorised by the competent authority based on verification of their compliance with the requirements listed in point 2.

4. Bulk processed animal protein derived from non-ruminants, including processed animal protein derived from farmed insects but excluding fishmeal, and bulk compound feed containing such processed animal protein, shall be transported in vehicles and containers and stored in storage facilities which are not used, respectively, for the transport or storage of feed intended for non-ruminant farmed animals other than aquaculture animals.

5. By way of derogation from point 4, vehicles, containers and storage facilities which have been previously used for the transport or storage of the products referred to in that point may be subsequently used for the transport or storage of feed intended for non-ruminant farmed animals other than aquaculture animals provided that they are cleaned beforehand in order to avoid cross-contamination, in accordance with a documented procedure which has been given prior authorisation by the competent authority.

Whenever such a procedure is used, a documented record of such use shall be kept available to the competent authority for a period of at least two years.**]**

SECTION B

Production of compound feed intended to be used for feeding non-ruminant farmed animals

1. Compound feed intended to be used for feeding non-ruminant farmed animals and which contain the following feed materials, shall be produced in establishments which do not produce compound feed for ruminants, and which are authorised by the competent authority:

(a) fishmeal;

(b) dicalcium and tricalcium phosphate of animal origin;

(c) blood products derived from non-ruminants.

2. By way of derogation from point 1, the production of compound feed for ruminants, in establishments which also produce compound feed for non-ruminant farmed animals which contains the products listed in that point, may be authorised by the competent authority, following an on-site inspection by it, subject to compliance with the following conditions:

(a) compound feed intended for ruminants must be manufactured and kept, during storage, transport and packaging, in facilities that are physically separate from those facilities where compound feed for non-ruminants are manufactured and kept;

(b) records detailing the purchases and uses of the products listed in point 1 and the sales of compound feed containing those products must be kept available to the competent authority for a period of at least five years;

(c) regular sampling and analysis of the compound feed intended for ruminants must be carried out in order to verify the absence of unauthorised constituents of animal origin using the methods of analysis for the determination of constituents of animal origin for the control of feed set out in Annex VI to Commission Regulation (EC) No 152/2009[(15)]; the frequency of sampling and analysis shall be determined on the basis of a risk assessment carried out by the operator as part of its procedures based on hazard analysis and critical control points (HACCP) principles; the results of such sampling and analysis shall be kept available to the competent authority for a period of at least five years.

[[F12]3. By way of derogation from point 1, a specific authorisation for the production of complete feed from compound feed containing the products listed in that point, shall not be required for home compounders subject to their compliance with the following conditions:

(a) they must be registered by the competent authority as producing complete feed from compound feed containing the products listed in point 1;

(b) they must keep only non-ruminant animals;

(c) any compound feed containing fishmeal used in the production of the complete feed must contain less than 50 % crude protein;

(d) any compound feed containing dicalcium and tricalcium phosphate of animal origin used in the production of the complete feed must contain less than 10 % total phosphorus;

(e) any compound feed containing blood products derived from non-ruminants used in the production of the complete feed must contain less than 50 % crude protein.**]**

SECTION C

Import of feed materials and compound feed intended to be used for feeding non-ruminant farmed animals other than fur animals

Before release [F59]..., importers shall ensure that each of the consignment of the following feed materials and compound feed, which are intended to be used for the feeding of non-ruminant farmed animals, other than fur animals, in accordance with Chapter II of this Annex, is analysed

in accordance with the methods of analysis for the determination of constituents of animal origin for the control of feed set out Annex VI to Regulation (EC) No 152/2009 in order to verify the absence of unauthorised constituents of animal origin:

Textual Amendments

F59 Words in Annex 4 Ch. 3 s. C omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(28)**; 2020 c. 1, Sch. 5 para. 1(1)

(a) **[**F12processed animal protein derived from non-ruminants, including fishmeal and processed animal protein derived from farmed insects;**]**

(b) blood products derived from non-ruminants;

(c) compound feed containing the feed materials listed in (a) and (b).

SECTION D

Use and storage on farms of feed intended to be used for feeding non-ruminant farmed animals

1. The use and storage of the following feed shall be prohibited on farms keeping farmed animal species for which such feed is not intended:

(a) **[**F12processed animal protein derived from non-ruminants, including fishmeal and processed animal protein derived from farmed insects;**]**

(b) dicalcium and tricalcium phosphate of animal origin;

(c) blood products derived from non-ruminants;

(d) compound feed containing the feed materials listed in (a) to (c).

2. By way of derogation from point 1, the competent authority may authorise the use and storage of compound feed referred to in point 1(d) in farms keeping farmed animal species for which the compound feed is not intended provided that on-farm measures are implemented to prevent such compound feed being fed to an animal species for which it is not intended.

CHAPTER IV

Specific conditions for the application of derogations provided for in Chapter II

SECTION A

Specific conditions applicable to the production and the use of fishmeal and compound feed containing fishmeal intended to be used for feeding non-ruminant farmed animals other than fur animals

The following specific conditions shall apply to the production and use of fishmeal and compound feed containing fishmeal intended to be used for the feeding of non-ruminant farmed animals other than fur animals:

(a) **[**[F60]the fishmeal must be produced in processing plants dedicated exclusively to the production of products derived from:

(i) aquatic animals, except sea mammals;

(ii) farmed aquatic invertebrates other than those that fall within the definition of 'aquatic animals' provided for in Article 3(1)(e) of Directive 2006/88/EC; or

(iii) starfish of the species *Asterias rubens* which are harvested in a production area as defined in Annex I point 2.5 of Regulation (EC) No 853/2004 and classified accordingly;**]**

(b) **[**[F12]The words 'fishmeal — shall not be used in feed for ruminants except unweaned ruminants' shall be clearly indicated on the accompanying commercial document or health certificate referred to in Article 21(2) of Regulation (EC) No 1069/2009, as appropriate, as well as on the label of fishmeal;

The words 'contains fishmeal — shall not be fed to ruminants' shall be clearly indicated on the label of compound feed containing fishmeal intended for non-ruminant farmed animals other than fur animals.**]**

Textual Amendments

F60 Substituted by Commission Regulation (EU) 2017/110 of 23 January 2017 amending Annexes IV 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).

[F12SECTION B

Specific conditions applicable to the use of dicalcium phosphate and tricalcium phosphate of animal origin and compound feed containing such phosphates intended to be used for feeding non-ruminant farmed animals other than fur animals

(a) The words 'di-/tricalcium phosphate of animal origin — shall not be used in feed for ruminants' shall be clearly indicated on the accompanying commercial document or health certificate referred to in Article 21(2) of Regulation (EC) No 1069/2009, as appropriate, as well as on the label of dicalcium/tricalcium phosphate of animal origin;

(b) The words ‘contains dicalcium/tricalcium phosphate of animal origin — shall not be fed to ruminants’ shall be clearly indicated on the label of compound feed containing dicalcium/tricalcium phosphate of animal origin.**]**

SECTION C

Specific conditions applicable to the production and use of blood products derived from non-ruminants and compound feed containing those products intended to be used for feeding non-ruminant farmed animals other than fur animals

The following specific conditions shall apply to the production and use of blood products derived from non-ruminants and to compound feed containing such blood products, intended to be used for the feeding of non-ruminant farmed animals other than fur animals:

(a) The blood intended to be used for the production of blood products shall be derived from slaughterhouses which do not slaughter ruminants and which are registered by the competent authority as not slaughtering ruminants.

By way of derogation from that specific condition, the competent authority may authorise the slaughter of ruminants in a slaughterhouse producing non-ruminant blood intended for the production of blood products for use in feed for non-ruminant farmed animals.

That authorisation may be granted only where the competent authority is satisfied, following an inspection, concerning the effectiveness of measures aimed to prevent cross-contamination between ruminant and non-ruminant blood.

Those measures shall include the following minimum requirements:

(i) the slaughtering of non-ruminants must be carried out in lines that are physically separate from lines used for the slaughtering of ruminants;

(ii) the collection, storage, transport and packaging facilities for blood of non-ruminant origin must be kept separate from those used for blood of ruminant origin;

(iii) a regular sampling and analysis of blood of non-ruminant origin must be carried out to detect the presence of ruminant proteins. The method of analysis used must be scientifically validated for that purpose. The frequency of sampling and analysis must be determined on the basis of a risk assessment carried out by the operator as part of its procedures based on the HACCP principles.

(b) The blood intended to be used for the production of blood products for non-ruminants shall be transported to a processing plant in vehicles and containers dedicated exclusively for the transport of non-ruminant blood.

By way of derogation from that specific condition, vehicles and containers which have been previously used for the transport of blood derived from ruminants may be used for the transport of non-ruminant blood provided that they have been thoroughly cleaned beforehand in order to avoid cross-contamination in accordance with a documented procedure which has been given prior authorisation by the competent authority. Whenever such a procedure is used, a documented trace of such use shall be kept available to the competent authority for a period of at least two years.

(c) **[**[F12]The blood products shall be produced in processing plants exclusively processing non-ruminant blood, and registered by the competent authority as processing exclusively non-ruminant blood.**]**

By way of derogation from that specific condition, the competent authority may authorise the production of blood products for use in feed for non-ruminant farmed animals in processing plants processing ruminant blood.

That authorisation may be granted only where the competent authority is satisfied, following an inspection, concerning the effectiveness of measures aimed to prevent cross-contamination.

Those measures shall include the following minimum requirements:

(i) the production of non-ruminant blood products must be carried out in a closed system that is kept physically separated from that used for the production of ruminant blood products;

(ii) the collection, storage, transport and packaging facilities for bulk raw material and bulk finished products of non-ruminant origin must be kept separate from those for bulk raw material and bulk finished of ruminant origin;

(iii) an ongoing reconciliation process between the incoming blood respectively derived from ruminants and non-ruminants and the corresponding blood products must be applied;

(iv) a regular sampling and analysis of blood products of non ruminant origin must be carried out to verify the absence of cross-contamination with blood products of ruminant origin using the methods of analysis for the determination of constituents of animal origin for the control of feed set out in Annex VI to Regulation (EC) No 152/2009; the frequency of sampling and analysis shall be determined on the basis of a risk assessment carried out by the operator as part of its procedures based on hazard analysis and critical control points (HACCP) principles; the results of such sampling and analysis shall be kept available to the competent authority for a period of at least five years.

(d) **[**[F12]The words ‘non-ruminant blood products — shall not be used in feed for ruminants’ shall be clearly indicated on the accompanying commercial document or health certificate referred to in Article 21(2) of Regulation (EC) No 1069/2009, as appropriate, as well as on the label of blood products derived from non-ruminants.

The words ‘contains non-ruminant blood products — shall not be fed to ruminants’ shall be clearly indicated on the label of compound feed containing blood products derived from non-ruminants.**]**

[F12SECTION D

Specific conditions applicable to the production and use of processed animal protein derived from non-ruminants, other than fishmeal and other than

processed animal protein derived from farmed insects, and compound feed containing such protein, intended to be used for feeding aquaculture animals

The following specific conditions shall apply to the production and use of processed animal protein derived from non-ruminants, other than fishmeal and other than processed animal protein derived from farmed insects, and compound feed containing such protein, intended to be used for feeding aquaculture animals:

(a) The animal by-products intended to be used for the production of processed animal protein referred to in this Section shall come from:

(i) slaughterhouses which do not slaughter ruminants and which are registered by the competent authority as not slaughtering ruminants; or

(ii) cutting plants which do not bone or cut up ruminant meat and which are registered by the competent authority as not boning or cutting up ruminant meat; or

(iii) other establishments than those referred to in (i) or (ii) which do not handle ruminant products and which are registered by the competent authority as not handling ruminant products.

By way of derogation from that specific condition, the competent authority may authorise the slaughter of ruminants in a slaughterhouse producing non-ruminant animal by-products intended for the production of processed animal protein referred to in this Section, and the handling of ruminant products in a cutting plant or another establishment producing non-ruminant animal by-products intended for the production of processed animal protein referred to in this Section.

That authorisation may be granted only where the competent authority is satisfied, following an on-site inspection, of the effectiveness of measures aimed to prevent cross-contamination between ruminant and non-ruminant by-products.

Those measures shall include the following minimum requirements:

(i) the slaughtering of non-ruminants must be carried out in lines that are physically separate from those used for the slaughtering of ruminants;

(ii) non-ruminant products must be handled on production lines that are physically separate from those used for the handling of ruminant products;

(iii) the collection, storage, transport and packaging facilities for animal by-products of non-ruminant origin must be kept separate from those for animal by-products of ruminant origin;

(iv) a regular sampling and analysis of animal by-products of non-ruminant origin must be carried out to detect the presence of ruminant proteins. The method of analysis used must be scientifically validated for that purpose. The frequency of sampling and analysis shall be determined on the basis of a risk assessment carried out by the operator as part of its procedures based on the HACCP principles.**]**

(b) The animal by-products of non-ruminant origin intended to be used for the production of processed animal protein referred to in this Section shall be transported to a processing plant in vehicles and containers which are not used for the transport of animal by-products of ruminant origin.

By way of derogation from that specific condition, they may be transported in vehicles and containers which have been previously used for the transport of animal by-products derived from ruminants, provided that those vehicles and containers have been cleaned beforehand in order to avoid cross-contamination in accordance with a documented procedure which has been given prior authorisation by the competent authority.

Whenever such a procedure is used, a documented trace of such use shall be kept available to the competent authority for a period of at least two years.

(c) **[**[F12]The processed animal protein referred to in this Section shall be produced in processing plants that are dedicated exclusively to processing non-ruminant animal by-products sourced from slaughterhouses, cutting plants or other establishments referred to in point (a). Those processing plants shall be registered by the competent authority as processing exclusively non-ruminant animal by-products.**]**

By way of derogation from that specific condition, the competent authority may authorise the production of processed animal protein referred to in this Section in processing plants processing ruminant animal by-products.

That authorisation may be granted only where the competent authority is satisfied, following an inspection, concerning the effectiveness of the measures aimed to prevent cross-contamination between processed animal protein of ruminant origin and processed animal protein of non-ruminant origin.

Those preventive measures shall include the following minimum requirements:

(i) the production of processed animal protein derived from ruminants must be carried out in a closed system that is physically separated from that used for the production of the processed animal protein referred to in this Section;

(ii) the keeping of animal by-products derived from ruminants during storage and transport in facilities that are physically separated from those for animal by-products derived from non-ruminants;

(iii) the keeping of processed animal protein derived from ruminants during storage and packaging in facilities that are physically separated from those used for finished products derived from non-ruminants;

(iv) regular sampling and analysis of the processed animal protein referred to in this Section must be carried out to verify the absence of cross-contamination with ruminant processed animal protein using the methods of analysis for the determination of constituents of animal origin for the control of feed set out in Annex VI to Regulation (EC) No 152/2009; the frequency of sampling and analysis shall be determined on the basis of a risk assessment carried out by the operator as part of its procedures based on hazard analysis and critical control points (HACCP) principles; the results of such sampling and analysis shall be kept available to the competent authority for a period of at least five years.

(d) Compound feed containing processed animal protein referred to in this Section shall be produced in establishments authorised for that purpose by the competent authority and which are dedicated exclusively to the production of feed for aquaculture animals.

By way of derogation from that specific condition:

(i) **[**F12the production of compound feed, containing processed animal protein referred to in this Section, for aquaculture animals in establishments which also produce compound feed intended for other farmed animals, other than fur animals, may be authorised by the competent authority, following an on-site inspection, subject to compliance with the following conditions:**]**

— compound feed destined for ruminants must be manufactured and kept, during storage, transport and packaging, in facilities that are physically separate from those facilities where compound feed for non-ruminant animals are manufactured and kept;

— compound feed destined for aquaculture animals must be manufactured and kept, during storage, transport and packaging, in facilities that are physically separate from those facilities where compound feed for other non-ruminant animals are manufactured and kept;

— records detailing the purchases and uses of processed animal protein referred to in this Section and the sales of compound feed containing such protein must be kept available to the competent authority for a period of at least five years;

— regular sampling and analysis of the compound feed destined for farmed animals other than aquaculture animals in order to verify the absence of unauthorised constituents of animal origin using the methods of analysis for the determination of constituents of animal origin for the control of feed set out in Annex VI to Regulation (EC) No 152/2009; the frequency of such sampling and analysis shall be determined on the basis of a risk assessment carried out by the operator as part of its procedures based on the HACCP principles; the results must be kept available to the competent authority for a period of at least five years;

(ii) **[**F12a specific authorisation for the production of complete feed from compound feed containing processed animal protein referred to in this Section shall not be required for home compounders that comply with the following conditions:

— they are registered by the competent authority as producing complete feed from compound feed containing processed animal protein derived from non-ruminants, other than fishmeal and other than processed animal protein derived from farmed insects,

— they keep only aquaculture animals, and

— the compound feed containing processed animal protein referred to in this Section used in their production contains less than 50 % crude protein.**]**

(e) **[**F12The accompanying commercial document or health certificate referred to in Article 21(2) of Regulation (EC) No 1069/2009, as appropriate, of processed animal protein referred to in this Section and the label thereof shall be clearly marked with the following words: ‘non-ruminant processed animal protein — shall not be used in feed for farmed animals except aquaculture and fur animals’.

The following words shall be clearly indicated on the label of compound feed containing processed animal protein referred to in this Section:

contains non-ruminant processed animal protein — shall not be fed to farmed animals except aquaculture and fur animals.**]**

SECTION E

Specific conditions applicable to the production, placing on the market and use of milk replacers containing fishmeal for the feeding of unweaned ruminants

The following specific conditions shall apply to the production, placing on the market and use of milk replacers containing fishmeal in the feeding of unweaned farmed animals of the ruminant species:

(a) **[**[F60]the fishmeal used in milk replacers shall be produced in processing plants dedicated exclusively to the production of products derived from:

(i) aquatic animals, except sea mammals;

(ii) farmed aquatic invertebrates other than those that fall within the definition of ‘ aquatic animals ’ provided for in Article 3(1)(e) of Directive 2006/88/EC; or

(iii) starfish of the species *Asterias rubens* which are harvested in a production area as defined in Annex I point 2.5 of Regulation (EC) No 853/2004 and classified accordingly.

The fishmeal used in milk replacers shall comply with general conditions laid set out in Chapter III.**]**

(b) **[**[F12]the words ‘ fishmeal — shall not be used in feed for ruminants except unweaned ruminants ’ shall be clearly indicated on the accompanying commercial document or health certificate referred to in Article 21(2) of Regulation (EC) No 1069/2009, as appropriate, as well as the label of fishmeal intended to be used in milk replacers;

(c) the use of fishmeal for unweaned farmed animals of the ruminant species shall only be authorised for the production of milk replacers, distributed in dry form and administered after dilution in a given quantity of liquid, intended for the feeding of unweaned ruminants as a supplement to, or substitute for, post-colostral milk before weaning is complete;

(d) milk replacers containing fishmeal intended for unweaned farmed animals of the ruminant species shall be produced in establishments which do not produce other compound feed for ruminants and which are authorised for this purpose by the competent authority.

By way of derogation from that special condition, the production of other compound feed for ruminants in establishments which also produce milk replacers containing fishmeal intended for unweaned farmed animals of the ruminant species may be authorised by the competent authority, following an on-site inspection, subject to compliance with the following conditions:

(i) other compound feed destined for ruminants must be kept in facilities that are physically separate from those used for bulk fishmeal and bulk milk replacers containing fishmeal during storage, transport and packaging;

(ii) other compound feed destined for ruminants must be manufactured in facilities that are physically separate from facilities where milk replacers containing fishmeal are manufactured;

(iii) records detailing the purchases and uses of fishmeal and the sales of milk replacers containing fishmeal must be kept available to the competent authority for a period of at least five years;

(iv) regular sampling and analysis of the other compound feed destined for ruminants must be carried out in order to verify the absence of unauthorised constituents of animal origin using the methods of analysis for the determination of constituents of animal origin for the control of feed set out in Annex VI to Regulation (EC) No 152/2009; the frequency of such sampling and analysis shall be determined on the basis of a risk assessment carried out by the operator as part of its procedures based on the HACCP principles; the results must be kept available to the competent authority for a period of at least five years;

(e) before release [F61]..., importers shall ensure that each consignment of imported milk replacers containing fishmeal is analysed in accordance with methods of analysis for the determination of constituents of animal origin for the control of feed set out in Annex VI to Regulation (EC) No 152/2009 in order to verify the absence of unauthorised constituents of animal origin;

(f) The label of milk replacers containing fishmeal, intended for unweaned farmed animals of the ruminant species, must be clearly marked with the words ‘ contains fishmeal — shall not be fed to ruminants except unweaned ruminants ’ ;

(g) bulk milk replacers containing fishmeal intended for unweaned farmed animals of the ruminant species shall be transported in vehicles and containers and stored in storage facilities which are not used, respectively for the transport or storage of other feed intended for ruminants.

By way of derogation from that special condition, vehicles, containers and storage facilities which will be subsequently used for the transport or storage of other bulk feed intended for ruminants may be used for the transport or storage of bulk milk replacers containing fishmeal intended for unweaned farmed animals of the ruminant species provided that they have been cleaned beforehand in order to avoid cross-contamination in accordance with a documented procedure which has been given prior authorisation by the competent authority. Whenever such a procedure is used, a documented record of such use shall be kept available to the competent authority for a period of at least two years;

(h) on farms where ruminants are kept, on-farm measures shall be in place to prevent milk replacers containing fishmeal being fed to other ruminants than unweaned ruminants. The competent authority shall establish a list of farms where milk replacers containing fishmeal are used through a system of prior notification by the farm or another system thereby ensuring compliance with this specific condition.**]**

Textual Amendments

F61 Words in Annex 4 Ch. 4 s. E point (e) omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(29)**; 2020 c. 1, Sch. 5 para. 1(1)

[F4 SECTION F

Specific conditions applicable to the production and use of processed animal protein derived from farmed insects and compound feed containing such protein intended to be used for feeding aquaculture animals

The following specific conditions shall apply to the production and use of processed animal protein derived from farmed insects and compound feed containing such processed animal protein intended to be used for feeding aquaculture animals:

(a) Processed animal protein derived from farmed insects must:

(i) be produced in processing plants approved in accordance with Article 24(1)(a) of Regulation (EC) No 1069/2009 and dedicated exclusively to the production of products derived from farmed insects; and

(ii) be produced in accordance with the requirements laid down in Section 1 of Chapter II of Annex X to Regulation (EU) No 142/2011.

(b) Compound feed containing processed animal protein derived from farmed insects must be produced in establishments authorised for that purpose by the competent authority and which are dedicated exclusively to the production of feed for aquaculture animals.

By way of derogation from that specific condition:

(i) the production of compound feed, containing processed animal protein derived from farmed insects, for aquaculture animals in establishments which also produce compound feed intended for other farmed animals, except fur animals, may be authorised by the competent authority, following an on-site inspection, subject to compliance with the following conditions:

— compound feed destined for ruminants must be manufactured and kept, during storage, transport and packaging, in facilities that are physically separate from those facilities where compound feed for non-ruminant animals are manufactured and kept,

— compound feed destined for aquaculture animals must be manufactured and kept, during storage, transport and packaging, in facilities that are physically separate from those facilities where compound feed for other non-ruminant animals are manufactured and kept,

— records detailing the purchases and uses of processed animal protein derived from farmed insects and the sales of compound feed containing such protein must be kept available to the competent authority for a period of at least five years,

— regular sampling and analysis of the compound feed destined for farmed animals other than aquaculture animals in order to verify

the absence of unauthorised constituents of animal origin using the methods of analysis for the determination of constituents of animal origin for the control of feed set out in Annex VI to Regulation (EC) No 152/2009; the frequency of such sampling and analysis shall be determined on the basis of a risk assessment carried out by the operator as part of its procedures based on the HACCP principles; the results must be kept available to the competent authority for a period of at least five years;

(ii) a specific authorisation for the production of complete feed from compound feed containing processed animal protein derived from farmed insects shall not be required for home compounders that comply with the following conditions:

— they are registered by the competent authority as producing complete feed from compound feed containing processed animal protein derived from farmed insects,

— they keep only aquaculture animals, and

— the compound feed containing processed animal protein derived from farmed insects used in their production contains less than 50 % crude protein.

(c) The accompanying commercial document or health certificate referred to in Article 21(2) of Regulation (EC) No 1069/2009, as appropriate, of processed animal protein derived from farmed insects and the label thereof shall be clearly marked with the following words: ‘processed insect protein — shall not be used in feed for farmed animals except aquaculture and fur animals’.

The following words shall be clearly indicated on the label of compound feed containing processed animal protein derived from insects:

contains non-ruminant processed animal protein — shall not be fed to farmed animals except aquaculture and fur animals.**]**

CHAPTER V

General requirements

[F12SECTION A

Listing

1. **[**F62The appropriate authority**]** shall keep up-to-date and make publicly available lists of:

(a) slaughterhouses registered as not slaughtering ruminants in accordance with the first paragraph of point (a) of Section C of Chapter IV, as well as authorised slaughterhouses from which blood produced in accordance with the second, third and fourth paragraphs of point (a) of Section C of Chapter IV can be sourced;

(b) processing plants registered as processing exclusively non-ruminant blood in accordance with the first paragraph of point (c) of Section C of Chapter IV, as well as

authorised processing plants producing blood products in accordance with the second, third and fourth paragraph of point (c) of Section C of Chapter IV;

(c) slaughterhouses, cutting plants and other establishments registered as, respectively, not slaughtering ruminants, boning or cutting up ruminant meat, and not handling ruminant products, from which animal by-products intended to be used for the production of processed animal protein derived from non-ruminants in accordance with the first paragraph of point (a) of Section D of Chapter IV can be sourced, as well as authorised slaughterhouses, cutting plants and other establishments, from which animal by-products intended to be used for the production of processed animal protein derived from non-ruminants in accordance with the second, third and fourth paragraphs of point (a) of Section D of Chapter IV can be sourced;

(d) processing plants registered as not processing ruminant animal by-products in accordance with the first paragraph of point (c) of Section D of Chapter IV, as well as authorised processing plants producing processed animal protein derived from non-ruminants which operate in accordance with the second, third and fourth paragraphs of point (c) of Section D of Chapter IV;

(e) authorised compound feed establishments producing, in accordance with Section B of Chapter III, compound feed containing fishmeal, dicalcium and tricalcium phosphate of animal origin, or blood products derived from non-ruminants;

(f) authorised compound feed establishments producing, in accordance with point (d) of Section D of Chapter IV, compound feed containing processed animal protein derived from non-ruminants; as well as authorised compound feed establishments producing, in accordance with point 3(b)(ii) of Section E of Chapter V, exclusively compound feed for export from the Union or compound feed for export from the Union and compound feed for aquaculture animals to be placed on the market;

(g) authorised compound feed establishments producing, in accordance with point (d) of Section E of Chapter IV, milk replacers containing fishmeal intended for unweaned farmed animals of the ruminant species;

(h) authorised compound feed establishments producing, in accordance with point (b) of Section F of Chapter IV, compound feed containing processed animal protein derived from farmed insects;

(i) storage plants authorised in accordance with point 3 of Section A of Chapter III or in accordance with the third paragraph of point 3(d) of Section E of Chapter V.

Textual Amendments

F62 Words in Annex 4 Ch. 5 s. A substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(31)**; 2020 c. 1, Sch. 5 para. 1(1)

2. Member States shall keep up-to-date lists of home compounders registered in accordance with point 3 of Section B of Chapter III, point (d)(ii) of Section D of Chapter IV, and point (b)(ii) of Section F of Chapter IV.

SECTION B

Transport and storage of feed materials and compound feed containing products derived from ruminants

1. Bulk feed materials and bulk compound feed containing products derived from ruminants other than those listed in the following points (a) to (d) shall be transported in vehicles and containers and stored in storage facilities which are not used, respectively, for the transport or storage of feed intended for farmed animals other than fur animals:

(a) milk, milk-based products, milk-derived products, colostrum and colostrum products;

(b) dicalcium and tricalcium phosphate of animal origin;

(c) hydrolysed proteins derived from ruminant hides and skins;

(d) rendered fat from ruminants with a maximum level of insoluble impurities of 0,15 % in weight and derivatives made from such fat.

2. By way of derogation from point 1, vehicles, containers and storage facilities which have been previously used for the transport or storage of bulk feed materials and bulk compound feed listed in that point, may be used for the transport or storage of feedingstuffs intended for farmed animals other than fur animals provided that they have been cleaned beforehand in order to avoid cross-contamination in accordance with a documented procedure which has been given prior authorisation by the competent authority.

Whenever such a procedure is used, a documented record of this use shall be kept available to the competent authority for a period of at least two years.

SECTION C

Production of compound feed intended for fur animals or for pet animals containing products derived from ruminants or from non-ruminants

1. Compound feed intended for fur animals or for pet animals which contains products derived from ruminants other than those listed in the following points (a) to (d) shall not be produced in establishments which produce feed for farmed animals other than fur animals:

(a) milk, milk-based products, milk-derived products, colostrum and colostrum products;

(b) dicalcium and tricalcium phosphate of animal origin;

(c) hydrolysed proteins derived from ruminant hides and skins;

(d) rendered fat from ruminants with a maximum level of insoluble impurities of 0,15 % in weight and derivatives made from such fat.

2. Compound feed intended for fur animals or for pet animals, which contains processed animal protein derived from non-ruminants, other than fishmeal, shall not be produced in establishments which produce feed for farmed animals other than fur animals or aquaculture animals.**]**

[F12SECTION D

Use and storage on farms of feed materials and compound feed for farmed animals containing products derived from ruminants

The use and storage of feed materials and compound feed for farmed animals containing products derived from ruminants other than those listed in points (a) to (d) shall be prohibited in farms keeping farmed animals other than fur animals:

(a) milk, milk-based products, milk-derived products, colostrum and colostrum products;

(b) dicalcium and tricalcium phosphate of animal origin;

(c) hydrolysed proteins derived from ruminant hides and skins;

(d) rendered fat from ruminants with a maximum level of insoluble impurities of 0,15 % in weight and derivatives made from such fat.**]**

[F12SECTION E

Export of processed animal protein and products containing such protein

1. The export of processed animal protein derived from ruminants, or of processed animal protein derived from both ruminants and non-ruminants, shall be subject to compliance with the following conditions:

(a) The processed animal protein shall be transported in sealed containers, directly from the processing plant of production to the point of exit [F63]....

(b) **[**[F64]The consignment must be accompanied by a duly completed commercial document made available for the time being by the appropriate authority, and the border inspection post of exit must be indicated as the exit point in that document.**]**

(c) When the consignment arrives at the point of exit, the competent authority at the border inspection post shall verify the seal of each of the containers presented at the border inspection post.

By way of derogation, based on an analysis of the risk, the competent authority at the border inspection post may decide to verify the seal of the container on a random basis.

If the seal verification is not satisfactory, the consignment must either be destroyed or must be re-dispatched to the establishment of origin.

The competent authority at the border inspection post shall inform, via **[**[F65]the appropriate computerised information management system**][**[F66]or any replacement system in operation in Great Britain**]**, the competent authority responsible for the establishment of origin of the arrival of the consignment at the point of exit and, where applicable, of the outcome of the verification of the seal and of any corrective action taken.

(d) The competent authority responsible for the establishment of origin shall carry out regular official controls to verify the correct implementation of points (a) and (b) and to verify that, for each consignment of processed animal protein of ruminant origin intended for export, the confirmation of the control carried out at the exit point was

received from the competent authority of the border inspection post, through TRACES **[**F67or any replacement system in operation in Great Britain**]**.

Textual Amendments

F63 Words in Annex 4 Ch. 5 s. E point 1(a) omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(32)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F64 Annex 4 Ch. 5 s. E point 1(b) substituted (31.12.2020) by The Animals (Legislative Functions) (EU Exit) Regulations 2019 (S.I. 2019/588), regs. 1, **4(22)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)

F65 Words in Annex 4 Ch. 5 s. E point 1(c) substituted (31.12.2020) by S.I. 2019/170, reg. 2(32)(a)(ii) (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(k)(i)**)

F66 Words in Annex 4 Ch. 5 s. E point 1(c) inserted (31.12.2020) by S.I. 2019/170, reg. 2(32)(a)(ii) (as substituted by The Animal Health, Invasive Alien Species, Plant Breeders' Rights and Seeds (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/1220), regs. 1(2)(b), **5(2)(d)(i)(aa)** (as amended by S.I. 2020/1388, regs. 1(2)(a), **22(2)(a)(ii)**)); 2020 c. 1, Sch. 5 para. 1(1))

F67 Words in Annex 4 Ch. 5 s. E point 1(d) inserted (31.12.2020) by S.I. 2019/170, reg. 2(32)(a)(iii) (as substituted by The Animal Health, Invasive Alien Species, Plant Breeders' Rights and Seeds (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/1220), regs. 1(2)(b), **5(2)(d)(i)(bb)** (as amended by S.I. 2020/1388, regs. 1(2)(a), **22(2)(a)(ii)**)); 2020 c. 1, Sch. 5 para. 1(1))

[F68**2.** Without prejudice to point 1, the export of products containing processed animal protein derived from ruminants shall be prohibited.

By way of derogation, that prohibition shall not apply to:

(a) processed petfood containing processed animal protein derived from ruminants which:

(i) has been processed in establishments or plants approved in accordance with Article 24(1)(e) of Regulation (EC) No 1069/2009; and

(ii) is packaged and labelled in accordance with **[**F69EU-derived domestic**]** legislation.

(b) organic fertilisers or soil improvers, as defined in point 22 of Article 3 of Regulation (EC) No 1069/2009, that contain in their composition processed animal proteins derived from ruminants or a mixture of processed animal proteins from ruminants and non-ruminants provided that:

(i) they do not contain Category 1 material and products derived therefrom or Category 2 material and products derived therefrom, other than manure, as defined in point 20 of Article 3 of Regulation (EC) No 1069/2009, processed in accordance with the rules for placing on the market of processed manure, laid down in Section 2(a), (b), (d) and (e) of Chapter I of Annex XI to Commission Regulation (EU) No 142/2011;

(ii) the processed animal proteins contained in the organic fertilisers or soil improvers are in compliance with the specific requirements described in Section 1 of Chapter II of Annex X to Regulation (EU) No 142/2011;

(iii) the organic fertilisers or soil improvers may contain other category 3 materials, that have been processed in accordance to:

— any of the processing methods 1 to 7 set out in Chapter III of Annex IV to Regulation (EU) No 142/2011, or

— the requirements laid down in Section 1 Chapter III of Annex V to Regulation (EU) No 142/2011 in the case of compost or digestion residues from the transformation of animal by-products into biogas, or;

— the specific requirements set out in Annex XIII to Regulation (EU) No 142/2011, where such materials may be used for organic fertilisers and soil improvers in accordance to that Regulation.

(iv) they have been produced in establishments or plants approved in accordance with Article 24(1)(f) of Regulation (EC) No 1069/2009;

(v) are mixed with a sufficient proportion of a component, authorised by the **[**F70appropriate authority of the relevant constituent nation**]** where the organic fertilisers or soil improvers are produced, which renders the product unpalatable to animals or is otherwise effective to prevent misuse of the mixture for feeding purposes. This component is to be mixed with the organic fertilizers or soil improvers in the plant manufacturing them or in a plant registered for this purpose in accordance with point 2 of Section 1 of Chapter II of Annex XI to Regulation (EU) No 142/2011.

If required by the competent authority of the third country of destination, the **[**F70appropriate authority of the relevant constituent nation**]** where the organic fertilisers or soil improvers are produced may accept the use of other components or other methods to prevent the use of the organic fertilisers or soil improvers as feed, different than those authorised in **[**F71the relevant constituent nation**]**, provided that these are not in contradiction with the rules laid down in point 3 of Article 22 and point 3 of Section 1 of Chapter II of Annex XI to Regulation (EU) No 142/2011;

(vi) they have been processed to ensure decontamination of pathogens in accordance with point 5 of Section 1 of Chapter II of Annex XI to Regulation (EU) No 142/2011;

(vii) they have a label attached to the packaging or container bearing the words ' organic fertilisers or soil improvers/no grazing of farmed animals or use of crops as herbage during at least 21 days following application ' ;

(viii) they are exported in compliance with the following conditions:

— they shall be transported in sealed containers, directly from the plant manufacturing the organic fertilisers or soil improvers or the registered plant where the component which renders the product unpalatable to animals is added, to the point of exit from the **[**F72United Kingdom**]**, which shall be a border control post listed in Annex I to Commission Decision 2009/821/EC. Before leaving the **[**F72United Kingdom**]**, the operator responsible for arranging the transport of the organic fertilisers or soil improvers shall inform the competent authority at that border control post of the arrival of the consignment at the point of exit;

— the consignment shall be accompanied by a duly completed commercial document produced according to the model set out in point 6 of Chapter III of Annex VIII to Regulation (EU) No

142/2011 and issued from the integrated computerised veterinary system (TRACES) **[**[F73]or any replacement system in place in the United Kingdom, and the border inspection post of exit must be indicated in the relevant Box**]**;

— when the consignment arrives at the point of exit, the competent authority at the border control post shall, on a risk basis, verify the seal of the containers presented at the border control post. If the seal is verified and the verification is not satisfactory, the consignment must either be destroyed or must be re-dispatched to the establishment of origin, indicated in box I.12 of the commercial document;

— the competent authority at the border control post shall inform, via TRACES **[**[F74]or any replacement system in operation in the United Kingdom**]**, the competent authority indicated in box I.4 of the commercial document of the arrival of the consignment at the point of exit and, where applicable, of the outcome of the verification of the seal and of any corrective action taken;

— The competent authority responsible for the manufacturing plant of origin or the registered plant where the component which renders the product unpalatable to animals is added shall carry out risk based official controls to verify compliance with the first and second indents and to verify that, for each consignment of organic fertilisers and soil improvers that contain in their composition processed animal proteins derived from ruminants or a mixture of processed animal proteins from ruminants and non-ruminants exported, the confirmation of the control carried out at the exit point was received from the competent authority of the border control post, through TRACES **[**[F74]or any replacement system in operation in the United Kingdom**]**.

The conditions set out in points (v), (vii) and (viii) of point 2(b) shall not apply to organic fertilisers or soil improvers which are in ready-to-sell packages of not more than 50 kg in weight for use by the final consumer.**]**

Textual Amendments

F69 Words in Annex 4 Ch. 5 s. E point 2(a)(ii) substituted (31.12.2020) by The Animal Health and Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/1229), regs. 1(3), **2(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F70 Words in Annex 4 Ch. 5 s. E point 2(b)(v) substituted (31.12.2020) by The Animal Health and Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/1229), regs. 1(3), **2(3)(b)(i)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F71 Words in Annex 4 Ch. 5 s. E point 2(b)(v) substituted (31.12.2020) by The Animal Health and Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/1229), regs. 1(3), **2(3)(b)(i)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

F72 Words in Annex 4 Ch. 5 s. E point 2(viii) substituted (31.12.2020) by The Animal Health and Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/1229), regs. 1(3), **2(3)(b)(ii)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F73 Words in Annex 4 Ch. 5 s. E point 2(viii) substituted (31.12.2020) by The Animal Health and Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/1229), regs. 1(3), **2(3)(b)(ii)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

F74 Words in Annex 4 Ch. 5 s. E point 2(viii) inserted (31.12.2020) by The Animal Health and Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/1229), regs. 1(3), **2(3)(b)(ii)(cc)**; 2020 c. 1, Sch. 5 para. 1(1)

Textual Amendments

F68 Substituted by Commission Regulation (EU) 2019/1091 of 26 June 2019 amending Annex IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the requirements for export of products containing processed animal protein derived from ruminants and non-ruminants (Text with EEA relevance).

3. The export of processed animal protein derived from non-ruminants, or compound feed containing such protein, shall be subject to compliance with the following conditions:

(a) The processed animal protein derived from non-ruminants shall be produced in processing plants which fulfil the requirements of point (c) of Section D of Chapter IV.

(b) The compound feed containing processed animal protein derived from non-ruminants shall be produced in compound feed establishments which:

(i) produce in accordance with point (d) of Section D of Chapter IV; or

(ii) source the processed animal protein used in compound feed destined for export in processing plants that comply with point (a) and, either:

— are dedicated exclusively to the production of compound feed for export [F75]... and are authorised for that purpose by the competent authority, or

— are dedicated exclusively to the production of compound feed for export [F75]... and to the production of compound feed for aquaculture animals to be placed on the market [F76]..., and authorised for that purpose by the competent authority.

(c) The compound feed containing processed animal protein derived from non-ruminants shall be packaged and labelled in accordance with **[**[F77]retained EU law**]** or with the legal requirements of the importing country. Where the compound feed containing processed animal protein derived from non-ruminants is not labelled in accordance with **[**[F77]retained EU law**]**, the following words shall be indicated on the labelling: ‘ contains non-ruminant processed animal protein ’ .

(d) Bulk processed animal protein derived from non-ruminants and bulk compound feed containing such protein, and intended for export [F78]..., shall be transported in vehicles and containers and stored in storage facilities which are not used, respectively, for the transport or storage of feed for placing on market and intended for feeding to ruminants or non-ruminant farmed animals other than aquaculture animals. Records detailing the type of products that were transported or stored shall be kept available to the competent authority for a period of at least two years.

By way of derogation from the first paragraph, vehicles, containers and storage facilities which have been previously used for the transport or storage of bulk processed animal protein derived from non-ruminants and bulk compound feed containing such protein, and intended for export [F78]..., may be subsequently used for the transport or storage of feed for placing on the market and intended for

feeding to ruminants or non-ruminant farmed animals other than aquaculture animals, provided that they are cleaned beforehand in order to avoid cross-contamination, in accordance with a documented procedure which has been given prior authorisation by the competent authority. Whenever such a procedure is used, a documented record of such use shall be kept available to the competent authority for a period of at least two years.

Storage plants storing bulk processed animal protein derived from non-ruminants and bulk compound feed containing such protein under the conditions set out in the second paragraph of point (d) shall be authorised by the competent authority based on verification of their compliance with the requirements listed in that paragraph.

Textual Amendments

F75 Words in Annex 4 Ch. 5 s. E point 3(b)(ii) omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(32)(b)(i)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F76 Words in Annex 4 Ch. V s. E point 3(b)(ii) omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(32)(b)(i)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

F77 Words in Annex 4 Ch. 5 s. E point 3(c) substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(32)(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F78 Words in Annex 4 Ch. 5 s. E point 3(d) omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(32)(b)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)

4. By way of derogation from point 3, the conditions laid down in that point shall not apply to:

(a) petfood which contains processed animal protein derived from non-ruminants and which has been processed in petfood establishments approved in accordance with Article 24 of Regulation (EC) No 1069/2009 and which is packaged and labelled in accordance with Union legislation;

(b) fishmeal, provided that it is produced in accordance with this Annex;

(c) processed animal protein derived from farmed insects, provided that it is produced in accordance with this Annex;

(d) compound feed containing no other processed animal protein than fishmeal and processed animal protein derived from farmed insects, provided that it is produced in accordance with this Annex;

(e) processed animal protein derived from non-ruminants destined for the manufacturing of petfood or of organic fertilisers and soil improvers in the [F79]... country of destination, provided that, before export, the exporter ensures that each consignment of processed animal protein is analysed in accordance with the method of analysis set out in point 2.2 of Annex VI to Regulation (EC) No 152/2009 in order to verify the absence of constituents of ruminant origin.

Textual Amendments

F79 Word in Annex 4 Ch. 5 s. E point 4(e) omitted (31.12.2020) by S.I. 2019/170, reg. 2(32)(c) (as substituted by The Animal Health, Invasive Alien Species, Plant Breeders' Rights and Seeds (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/1220), regs. 1(2)(b), **5(2)(d)(ii)**; 2020 c. 1, Sch. 5 para. 1(1))

[F80 5. The export of organic fertilisers or soil improvers that contain in their composition processed animal proteins derived only from non-ruminants and do not contain any materials of ruminant origin, shall be subject to compliance with the following conditions:

(a) the requirements set out in points 2(b)(i), (ii), (iii), (iv), (v), (vi) and (vii) of this section shall apply. The conditions set out in points 2(b)(v) and (vii) shall not apply to organic fertilisers or soil improvers which are in ready-to-sell packages of not more than 50 kg in weight for use by the final consumer.

(b) the processed animal protein derived from non-ruminants contained in them shall be produced in processing plants which fulfil the requirements point (c) of Section D of Chapter IV, and are listed in accordance with point 1(d) of Section A of Chapter V.

(c) they have been produced in establishments or plants that are dedicated exclusively to processing non-ruminant organic fertilisers or soil improvers.

By way of derogation from this specific condition, the competent authority may authorise the export of organic fertilisers or soil improvers referred to in this point produced in establishments or plants processing organic fertilisers or soil improvers containing ruminant material, if effective measures to prevent cross contamination between organic fertilisers or soil improvers containing only non-ruminant material and organic fertilisers or soil improvers containing ruminant material are implemented;

(d) they are transported to the point of exit from the **[**F81United Kingdom**]** in new packaging material, or in bulk containers which are not used for the transport of materials of ruminant origin or that have been cleaned beforehand in order to avoid cross-contamination in accordance with a documented procedure which has been given prior authorisation by the competent authority.

The conditions set out in points (c) and (d) of point 5 shall not apply to organic fertilisers or soil improvers which are in ready-to-sell packages of not more than 50 kg in weight for use by the final consumer.**]]**

Textual Amendments

F81 Words in Annex 4 Ch. 5 s. E point 5(d) substituted (31.12.2020) by The Animal Health and Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/1229), regs. 1(3), **2(4)**; 2020 c. 1, Sch. 5 para. 1(1)

Textual Amendments

F80 Inserted by Commission Regulation (EU) 2019/1091 of 26 June 2019 amending Annex IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the requirements for export

of products containing processed animal protein derived from ruminants and non-ruminants (Text with EEA relevance).

SECTION F

Official controls

1. Official controls carried out by the competent authority in order to verify compliance with the rules laid down set out in this Annex shall include inspections and sampling for analysis on processed animal protein and feed in compliance with the methods of analysis for the determination of constituents of animal origin for the control of feed set out in Annex VI to Regulation (EC) No 152/2009.

2. The competent authority shall verify on a regular basis the competence of laboratories carrying out analyses for such official controls, in particular by evaluating the results of inter-proficiency tests.

If the competence is considered unsatisfactory, a retraining of the laboratory staff shall be undertaken by the laboratory as the minimal corrective measure, prior to carrying out further analyses.**]**

[F15ANNEX V

SPECIFIED RISK MATERIAL

1. Definition of specified risk material

The following tissues shall be designated as specified risk material if they come from animals whose origin is in a **[**F82country or a**]** region with a controlled or undetermined BSE risk:

Textual Amendments

F82 Words in Annex 5 point 1(b) substituted (31.12.2020) by S.I. 2019/170, **reg. 2(34)(a)** (as substituted by The Animal Health, Invasive Alien Species, Plant Breeders' Rights and Seeds (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/1220), regs. 1(2)(b), **5(2)(e)**; 2020 c. 1, **Sch. 5 para. 1(1)**)

(a) as regards bovine animals:

(i) the skull excluding the mandible and including the brain and eyes, and the spinal cord of animals aged over 12 months;

(ii) **[**F83the vertebral column excluding the vertebrae of the tail, the spinous and transverse processes of the cervical, thoracic and lumbar vertebrae and the median sacral crest and wings of the sacrum, but including the dorsal root ganglia, of animals aged over 30 months; and**]**

(iii) **[**F84the tonsils, the last four meters of the small intestine, the caecum and the mesentery of animals of all ages.**]**

(b) **[**F85as regards ovine and caprine animals: the skull, including the brain and eyes, and the spinal cord of animals aged over 12 months or which have a permanent incisor

erupted through the gum, or aged over 12 months as estimated by a method approved by the **[**[F86]appropriate authority**].]**

Textual Amendments

F83 Substituted by Commission Regulation (EC) No 357/2008 of 22 April 2008 amending Annex V to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

F84 Substituted by Commission Regulation (EU) 2015/728 of 6 May 2015 amending the definition of specified risk material set out in Annex V to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

F85 Substituted by Commission Regulation (EU) 2018/969 of 9 July 2018 amending Annex V to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the requirements for the removal of specified risk materials from small ruminants (Text with EEA relevance).

F86 Words in Annex 5 point 1 substituted (31.12.2020) by S.I. 2019/170, **reg. 2(34)(b)** (as substituted by The Animal Health, Invasive Alien Species, Plant Breeders' Rights and Seeds (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/1220), regs. 1(2)(b), **5(2)(e)**; 2020 c. 1, **Sch. 5 para. 1(1)**)

[[F87]2. **Specific requirements for [**[F88]**countries] with negligible BSE risk status**

Tissues listed in point 1.(a)(i) and 1.(b), which are derived from animals whose origin is in **[**[F89]a country**]** with a negligible BSE risk, shall be considered as specified risk material.**]**

Textual Amendments

F89 Words in Annex 5 point 2 substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(35)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

Textual Amendments

F87 Substituted by Commission Regulation (EU) 2015/1162 of 15 July 2015 amending Annex V to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

F88 Words in Annex 5 point 2 heading substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(35)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

[[F16]3. Marking and disposal

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

4. Removal of specified risk material

4.1. Specified risk material shall be removed at:

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

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

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

4.2. By way of derogation from point 4.1, the use of an alternative test to the removal of specified risk material, referred to in Article 8(2), may be authorised in accordance with the procedure referred to in Article 24(3) of this Regulation, provided that that alternative test is listed in Annex X, in accordance with the following conditions:

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

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

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

4.3. By way of derogation from point 4.1, **[**[F90]the appropriate authority**]** may decide to allow:

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

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

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

Textual Amendments

F90 Words in Annex 5 point 4.3 substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(36)**; 2020 c. 1, Sch. 5 para. 1(1)

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

5. Measures concerning mechanically separated meat

[F91]... By way of derogation from Article 9(3), it shall be prohibited [F92]... to use bones or bone-in cuts of bovine, ovine and caprine animals for the production of mechanically separated meat.

Textual Amendments

F91 Words in Annex 5 point 5 omitted (31.12.2020) by virtue of S.I. 2019/170, **reg. 2(37)(a)** (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(l)**)

F92 Words in Annex 5 point 5 omitted (31.12.2020) by virtue of S.I. 2019/170, **reg. 2(37)(b)** (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(l)**)

[F16 6. Measures concerning laceration of tissues

In addition to the prohibition laid down in Article 8(3) against the use, in **[**F93 parts of the United Kingdom**]** with a controlled or undetermined BSE risk, of laceration, after stunning, of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, or by means of gas injection into the cranial cavity, in bovine, ovine or caprine animals whose meat is intended for human or animal consumption, that prohibition shall also be applicable in **[**F94 parts of the United Kingdom**]** with a negligible BSE risk.

Textual Amendments

F93 Words in Annex 5 point 6 substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(38)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F94 Words in Annex 5 point 6 substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(38)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

7. Harvesting of tongues from bovine animals

The tongues of bovine animals of all ages intended for human or animal consumption shall be harvested at the slaughterhouse by a transverse cut rostral to the lingual process of the basihyoid bone, except for tongues of bovine animals whose origin is in **[**F95 parts of the United Kingdom**]** with a negligible BSE risk.**]**

Textual Amendments

F95 Words in Annex 5 point 7 substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(39)**; 2020 c. 1, Sch. 5 para. 1(1)

8. Harvesting of bovine head meat

8.1. Head meat of bovine animals above 12 months of age shall be harvested at slaughterhouses, in accordance with a control system, recognised by the competent authority, to ensure the prevention of possible contamination of head meat with central nervous system tissue. The system shall include at least the following provisions:

(a) harvesting shall take place in a dedicated area, physically separated from the other parts of the slaughterline;

(b) where the heads are removed from the conveyor or hooks before harvesting the head meat, the frontal shot hole and foramen magnum shall be sealed with an impermeable

and durable stopper. Where the brainstem is sampled for laboratory testing for BSE, the foramen magnum shall be sealed immediately after that sampling;

(c) head meat shall not be harvested from heads where the eyes are damaged or lost immediately prior to, or after slaughter, or which are otherwise damaged in a way which might result in contamination of the head with central nervous tissue;

(d) head meat shall not be harvested from heads which have not been properly sealed in accordance with the second indent;

(e) without prejudice to general rules on hygiene, specific working instructions shall be in place to prevent contamination of the head meat during the harvesting, in particular in the case when the seal referred to in the second indent is lost or the eyes damaged during the activity:

(f) a sampling plan using an appropriate laboratory test to detect central nervous system tissue shall be in place to verify that the measures to reduce contamination are properly implemented.

8.2. By way of derogation from the requirements of point 8.1, **[**F96nothing in this Regulation prevents the appropriate authority from deciding**]** to apply at the slaughterhouse an alternative control system for the harvesting of bovine head meat, leading to an equivalent reduction in the level of contamination of head meat with central nervous system tissue. A sampling plan using an appropriate laboratory test to detect central nervous system tissue shall be in place to verify that the measures to reduce contamination are properly implemented. F97...

Textual Amendments

F96 Words in Annex 5 point 8.2 substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(40)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F97 Words in Annex 5 point 8.2 omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(40)(b)** (as amended by S.I. 2019/1220, regs. 1(2)(b), 5(2)(f)); 2020 c. 1, Sch. 5 para. 1(1)

8.3. If the harvesting is performed without removing the bovine head from the conveyor or hooks, points 8.1 and 8.2 shall not apply.

9. Harvesting of bovine head meat in authorised cutting plants

By way of derogation from point 8, **[**F98nothing in this Regulation prevents the appropriate authority from deciding**]** to allow the harvesting of head meat from bovine in cutting plants specifically authorised for this purpose and provided that the following conditions are complied with:

Textual Amendments

F98 Words in Annex 5 point 9 substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(41)**; 2020 c. 1, Sch. 5 para. 1(1)

(a) the heads intended for transport to the cutting plant shall be suspended on a rack during the storing period and the transport from the slaughterhouse to the cutting plant;

(b) the frontal shot hole and the foramen magnum shall be properly sealed with an impermeable and durable stopper before being moved from the conveyor or hooks to the racks. Where the brainstem is sampled for laboratory testing for BSE, the foramen magnum shall be sealed immediately after that sampling;

(c) the heads which have not been properly sealed in accordance with point (b), where the eyes are damaged or lost immediately prior to or after slaughter or which were otherwise damaged in a way which might result in contamination of the head meat with central nervous tissue shall be excluded from transport to the specifically authorised cutting plants;

(d) a sampling plan for the slaughterhouse using an appropriate laboratory test to detect central nervous system tissue shall be in place to verify the proper implementation of the measures to reduce contamination;

(e) the harvesting of head meat shall be carried out in accordance with a control system, recognized by the competent authority, to ensure the prevention of possible contamination of head meat. The system shall include at least:

(i) all heads shall be visually checked for signs of contamination or damage and proper sealing before the harvesting of the head meat begins;

(ii) head meat shall not be harvested from heads which have not been properly sealed, where the eyes are damaged or which were otherwise damaged in a way which might result in contamination of the head meat with central nervous tissue. Head meat shall also not be harvested from any head where contamination from such heads is suspected;

(iii) without prejudice to general rules on hygiene, specific working instructions shall be in place to prevent contamination of the head meat during transport and harvesting, in particular where the seal is lost or the eyes damaged during the activity;

(f) a sampling plan for the cutting plant using an appropriate laboratory test to detect central nervous system tissue shall be in place to verify that the measures to reduce contamination are properly implemented.

10. Rules on trade and export

10.1. **[**[F99]The appropriate authority**]** may allow dispatch of heads or of un-split carcasses containing specified risk material to **[**[F100]a**]** Member State only after that Member State has agreed to receive the material and has approved the conditions of dispatch and transport.

Textual Amendments

F99 Words in Annex 5 point 10.1 substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(42)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F100 Word in Annex 5 point 10.1 substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(42)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

10.2. By way of derogation from point 10.1, carcasses, half carcasses or half carcasses cut into no more than three wholesale cuts, and quarters containing no specified risk material other than the vertebral column, including dorsal root ganglia, may be dispatched **[**F101unless prior approval has been provided by the relevant authority in the receiving country**]**.

Textual Amendments

F101 Words in Annex 5 point 10.2 substituted (31.12.2020) by S.I. 2019/170, regs. 1, **2(42)(b)** (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(m)**); 2020 c. 1, Sch. 5 para. 1(1)

10.3. Exports outside the **[**F102European Union**]** of heads and of fresh meat of bovine, ovine or caprine animals containing specified risk materials shall be prohibited.

Textual Amendments

F102 Words in Annex 5 point 10.3 substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(42)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

[F16 11. Controls

11.1. **[**F103The appropriate authority**]** shall carry out frequent official controls to verify the correct application of this Annex and shall ensure that measures are taken to avoid any contamination, particularly in slaughterhouses, cutting plants or other places where specified risk material is removed, such as butcher shops or establishments referred in point 4.1(c).

Textual Amendments

F103 Words in Annex 5 point 11.1 substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(43)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

11.2. **[**F104The appropriate authority**]** shall in particular set up a system to ensure and check that specified risk material is handled and disposed of in accordance with this Regulation and Regulation (EC) No 1069/2009.

Textual Amendments

F104 Words in Annex 5 point 11.2 substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(43)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

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

(a) [F105]...

From 1 July 2017 , when the removal of the vertebral column is required, carcasses or wholesale cuts of carcasses of bovine animals containing vertebral column shall be identified by a clearly visible red stripe on the label **[**[F106]made available or published for the time being by the appropriate authority.**]**

(b) Where applicable, specific information on the number of bovine carcasses or wholesale cuts of carcasses, from which the removal of the vertebral column is required, shall be added on the commercial document relating to consignments of meat. Where applicable, that specific information shall be added to the Common Veterinary Entry Document (CVED) referred to in Article 2(1) of Commission Regulation (EC) No 136/2004 [(16)] in the case of imports.

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

Textual Amendments

F105 Words in Annex 5 point 11.3(a) omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(43)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F106 Words in Annex 5 point 11.3 substituted (31.12.2020) by The Animals (Legislative Functions) (EU Exit) Regulations 2019 (S.I. 2019/588), regs. 1, **4(23)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)

ANNEX VI

PRODUCTS OF ANIMAL ORIGIN DERIVED FROM OR CONTAINING RUMINANT MATERIAL, AS REFERRED TO IN ARTICLE 9(1)

[[F6]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 [F107]... 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.

Textual Amendments

F107 Words in Annex 7 Ch. A omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(45)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

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 **[**[F108]appropriate authority**]** may decide that other holdings or only the holding of exposure shall be placed under official control, depending on the epidemiological information available.

Textual Amendments

F108 Words in Annex 7 Ch. A substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(45)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

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 **[**F109appropriate authority**]** 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

[F18If BSE cannot be excluded after the results of the secondary molecular testing carried out in accordance with the methods and protocols set out in Annex X, Chapter C, point 3.2(c) (ii), 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 [(17)] .

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

[F3If 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, the holding shall be subject to the conditions set out in point (a). In addition, pursuant to the decision of the **[**F110appropriate authority**]** responsible for the

holding, the holding shall be subject to the conditions of either option 1 set out in point (b), or option 2 set out in point (c), or option 3 set out in point (d). In case of a holding with a mixed ovine and caprine flock, the **[**F111appropriate authority**]** responsible for the holding may decide to apply the conditions of one of the options to the ovine animals of the holding and a different option to the caprine animals of the holding:**]**

(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 **[**F112Great Britain**]**.

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 **[**F113appropriate authority**]** 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, **[**F114nothing in this Regulation prevents the appropriate authority from deciding**]** 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 **[**[F115]Great Britain**]**;

— 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.

[[F3]Movement of animals mentioned in points (i) and (ii) from the holding to the slaughterhouse shall be allowed.**]**

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) **[**[F3]Option 2 – killing and complete destruction of the susceptible animals only

The prion protein genotyping of all ovine and caprine animals present in the holding, except 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.

Killing and complete destruction, without delay, of all ovine and/or caprine 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 human consumption,

— caprine animals carrying at least one of the following alleles: K222, D146 and S146,

— if the **[**[F116]appropriate authority**]** 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.

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.

[F117Nothing in this Regulation prevents the appropriate authority from deciding**]** instead to carry out the measures listed in (i), (ii) or (iii):

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

— the animals are slaughtered for human consumption within the territory of the **[**F118appropriate authority**]** responsible for the holding,

— all animals 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 second paragraph of option 2, for a period not exceeding three months. This **[**F119action**]** can be applied in situations where the index case is confirmed close to the commencement of the lambing and/or kidding season, provided that the ewes and/or goats and their new-born are kept isolated from ovine and/or 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 second paragraph of option 2 for a maximum period of three years from the date of confirmation of the index case, in ovine or caprine flocks and holdings where ovine and caprine animals are kept together. **[**F120Such action shall be limited to cases where the appropriate authority**]** 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 and caprine 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. All possible measures to quickly build up genetic resistance in the ovine and/or caprine population of the holding shall be implemented, including reasoned breeding and culling of ewes to increase the frequency

of the ARR allele and eliminate the VRQ allele, and the breeding of bucks carrying the K222, D146 or S146 alleles. The **[**F121appropriate authority**]** 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. **[**F122Where such action is taken**]**, the measures set out in point 4 shall apply to the holding until the complete destruction or slaughtering for human consumption of the animals referred to in the second paragraph of option 2, after which the restrictions laid down in point 3 shall be applicable.

Following the killing and complete destruction or slaughtering for human consumption of the animals referred to in the second paragraph of option 2, the conditions set out in point 3 shall apply to the holding.**]**

(d) **[**F3Option 3 – no mandatory killing and complete destruction of animals

[F123The appropriate authority**]** 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 male ovine animals of the ARR/ARR genotype and female ovine animals carrying at least one ARR allele and no VRQ allele, or caprine animals carrying at least one of the following alleles: K222, D146 and S146,

— the frequency of the ARR allele within the ovine breed or holding or the K222, D146 or S146 alleles within the caprine breed or holding is low,

— it is deemed necessary in order to avoid inbreeding,

— it is deemed necessary by the **[**F124appropriate authority**]** based on a reasoned consideration of all the epidemiological factors.

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

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 **[**F125appropriate authority**]**. If it is concluded that applying option 3 does not ensure a proper control of the outbreak, the **[**F125appropriate authority**]** 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 conditions set out in point 4 shall immediately apply to a holding where it has been decided to apply option 3.

[[F126]Any appropriate authority**]** 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.**]**

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) **[**[F127]the appropriate authority**]** 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, **[**[F128]the appropriate authority**]** 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, **[**[F129]the appropriate authority**]** 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.

Textual Amendments

F109 Words in Annex 7 Ch. B point 2.1 substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(47)**; 2020 c. 1, Sch. 5 para. 1(1)

F110 Words in Annex 7 Ch. B point 2.2.2 substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(48)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F111 Words in Annex 7 Ch. B point 2.2.2 substituted (13.12.2022) by The Animals and Animal Health, Feed and Food, Plants and Plant Health (Amendment) Regulations 2022 (S.I. 2022/1315), regs. 1(1), **14(5)(a)(i)**

F112 Words in Annex 7 Ch. B point 2.2.2(a) substituted (31.12.2020) by S.I. 2019/170, regs. 1, **2(48)(b)(i)** (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(n)(i)**); 2020 c. 1, Sch. 5 para. 1(1)

F113 Words in Annex 7 Ch. B point 2.2.2(a) substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(48)(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F114 Words in Annex 7 Ch. B point 2.2.2(b) substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(48)(c)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F115 Words in Annex 7 Ch. B point 2.2.2(b) substituted (31.12.2020) by S.I. 2019/170, regs. 1, **2(48)(c)(ii)** (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(n)(i)**); 2020 c. 1, Sch. 5 para. 1(1)

F116 Words in Annex 7 Ch. B point 2.2.2(c) substituted (31.12.2020) by S.I. 2019/170, **reg. 2(48)(d)(i)** (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(n)(ii)**)

F117 Words in Annex 7 Ch. B point 2.2.2(c) substituted (31.12.2020) by S.I. 2019/170, **reg. 2(48)(d)(ii)** (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(n)(ii)**)

F118 Words in Annex 7 Ch. B point 2.2.2(c)(i) substituted (31.12.2020) by S.I. 2019/170, **reg. 2(48)(d)(iii)** (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(n)(ii)**)

F119 Word in Annex 7 Ch. B point 2.2.2(c)(ii) substituted (31.12.2020) by S.I. 2019/170, **reg. 2(48)(d)(iv)** (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(n)(ii)**)

F120 Words in Annex 7 Ch. B point 2.2.2(c)(iii) substituted (31.12.2020) by S.I. 2019/170, **reg. 2(48)(d)(v)(aa)** (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(n)(ii)**)

F121 Words in Annex 7 Ch. B point 2.2.2(c)(iii) substituted (31.12.2020) by S.I. 2019/170, **reg. 2(48)(d)(v)(bb)** (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(n)(ii)**)

F122 Words in Annex 7 Ch. B point 2.2.2(c)(iii) substituted (31.12.2020) by S.I. 2019/170, **reg. 2(48)(d)(v)(cc)** (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(n)(ii)**)

F123 Words in Annex 7 Ch. B point 2.2.2(d) substituted (13.12.2022) by The Animals and Animal Health, Feed and Food, Plants and Plant Health (Amendment) Regulations 2022 (S.I. 2022/1315), regs. 1(1), **14(5)(a)(ii)**

F124 Words in Annex 7 Ch. B point 2.2.2(d) substituted (31.12.2020) by S.I. 2019/170, **reg. 2(48)(e)(i)** (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(n)(iii)**)

F125 Words in Annex 7 Ch. B point 2.2.2(d) substituted (31.12.2020) by S.I. 2019/170, **reg. 2(48)(e)(ii)** (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(n)(iii)**)

F126 Words in Annex 7 Ch. B point 2.2.2(d) substituted (31.12.2020) by S.I. 2019/170, **reg. 2(48)(e)(iii)** (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(n)(iii)**)

F127 Words in Annex 7 Ch. B point 2.3(a) substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(49)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F128 Words in Annex 7 Ch. B point 2.3(b) substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(49)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F129 Words in Annex 7 Ch. B point 2.3(c) substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(49)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

[F3 3. Following the killing and complete destruction or slaughtering for human consumption of all animals identified in a holding in accordance with point 2.2.1, point 2.2.2(b) or point 2.2.2(c), the following restrictions shall apply:

3.1. The holding shall be subject to an intensified TSE monitoring protocol. This shall include the testing for the presence of TSE in animals over the age of 18 months, which have died or have been killed in the holding but not in the framework of a disease eradication campaign. Ovine animals of the ARR/ARR genotype and caprine animals carrying at least one of the K222, D146 or S146 alleles are exempt. Testing shall be carried out in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2.

3.2. Only the following animals may be introduced to the holding:

— male ovine animals of the ARR/ARR genotype,

— female ovine animals carrying at least one ARR allele and no VRQ allele,

— 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, breeding bucks and ovine and caprine germinal products may be used in the holding:

— male ovine animals of the ARR/ARR genotype,

— semen from rams of the ARR/ARR genotype,

— embryos carrying at least one ARR allele and no VRQ allele,

— breeding bucks and caprine germinal products as defined in the measures decided by the **[**F130 appropriate authority **]** to build up genetic resistance in the caprine population of the holding.

3.4. Movements 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 points 2.2.2(b) (option 1), 2.2.2(c) (option 2), or 2.2.2(d) (option 3),

— caprine animals carrying at least one of the following alleles: K222, D146 and S146,

— caprine animals provided that they are moved to other holdings which are restricted following the application of measures in accordance with points 2.2.2(b) (option 1), 2.2.2(c) (option 2) or 2.2.2(d) (option 3);

(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 **[**F131appropriate authority**]** so decides, lambs and kids less than three months old on the date of slaughter,

— all animals when the **[**F131appropriate authority**]** has decided to apply the derogations laid down in points 2.2.2(b)(i) and 2.2.2(c)(i);

(c) if the **[**F132appropriate authority**]** 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 **[**F133Great Britain**]** 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 in the holding, provided that no caprine animals are kept on the holding; or

(b) until the date all caprine animals on the holding carry at least one of the K222, D146 or S146 alleles, provided that no ovine animals are kept on the holding; or

(c) until the date of attainment of ARR/ARR status by all ovine animals on the holding and all caprine animals on the holding carry at least one of the K222, D146 or S146 alleles; or

(d) 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.**]**

Textual Amendments

F130 Words in Annex 7 Ch. B point 3.3 substituted (31.12.2020) by S.I. 2019/170, reg. 2(49A) (as inserted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(o)**)

F131 Words in Annex 7 Ch. B point 3.4(b) substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(50)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F132 Words in Annex 7 Ch. B point 3.4(c) substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(50)(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F133 Words in Annex 7 Ch. B point 3.4(c) substituted (31.12.2020) by S.I. 2019/170, regs. 1, **2(50)(b)(ii)** (as amended by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material

and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(p)**); 2020 c. 1, Sch. 5 para. 1(1)

[F3 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 subject to an intensified TSE monitoring protocol. This shall include the testing for the presence of TSE in animals over the age of 18 months which:

— have been slaughtered for human consumption,

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

Ovine animals of the ARR/ARR genotype and caprine animals carrying at least one of the K222, D146 or S146 alleles are exempt. Testing shall be carried out in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2.

4.2. The conditions set out in points 3.2 and 3.3 shall apply.

[F134 Nothing in this Regulation prevents the appropriate authority from deciding that instead of the measures in points 3.2 and 3.3 the authority may decide to**]** allow the introduction and use in the holding of

— male ovine animals and their semen carrying at least one ARR allele and no VRQ allele including for breeding,

— female ovine animals carrying no VRQ allele,

— embryos carrying no VRQ allele,

subject to compliance with the following conditions:

— the breed of the animal kept on the holding is an endangered breed,

— the breed of the animal kept on the holding is subject to a breeding programme aiming at the preservation of the breed carried out by a breed society as defined in Article 2(5) of Regulation (EU) 2016/1012 or a competent authority in accordance with Article 38 of that Regulation, and

— the frequency of the ARR allele within that breed is low.

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

(a) rams and ewes of the ARR/ARR genotype and caprine animals carrying at least one of the K222, D146 or S146 alleles, 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 points 2.2.2(c) (option 2) or 2.2.2(d) (option 3);

(b) if the **[**F135 appropriate authority**]** 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 shall be transported directly to a slaughterhouse located within the **[**F136United Kingdom**]** to be slaughtered not later than when they are 12 months of age.

4.4. The **[**F137appropriate authority**]** shall ensure that no semen, embryo and ova are dispatched from the holding.

4.5. 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/or kidding period.

Outside of the lambing and/or kidding period, common grazing shall be subject to restrictions to be determined by the **[**F138appropriate authority**]**, based on a reasoned consideration of all the epidemiological factors.

4.6. The restrictions set out in points 4.1 to 4.5 shall 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.**]**

Textual Amendments

F134 Words in Annex 7 Ch. B point 4.2 substituted (31.12.2020) by S.I. 2019/170, **reg. 2(51)** (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(q)**)

F135 Words in Annex 7 Ch. B point 4.3(b) substituted (31.12.2020) by S.I. 2019/170, **reg. 2(51a)(i)** (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(q)**)

F136 Words in Annex 7 Ch. B point 4.3(b) substituted (31.12.2020) by S.I. 2019/170, reg. 2(51a)(ii) (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(q)**)

F137 Words in Annex 7 Ch. B point 4.4 substituted (31.12.2020) by S.I. 2019/170, **reg. 2(52)** (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(q)**)

F138 Words in Annex 7 Ch. B point 4.5 substituted (13.12.2022) by The Animals and Animal Health, Feed and Food, Plants and Plant Health (Amendment) Regulations 2022 (S.I. 2022/1315), regs. 1(1), **14(5)(b)**

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, **[**F139the appropriate authority**]** where a breeding programme is in place may decide to allow sampling and genotyping of breeding rams only, in flocks not participating in the breeding programme.

Textual Amendments

F139 Words in Annex 7 Ch. C Pt. 1 point 1 substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(54)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

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

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

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

(c) the results of any genotyping tests.

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

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 F140... may assist breed societies, to establish genetic banks consisting of semen, ova and embryos representative of prion protein genotypes which are likely to become rare as a result of the breeding programme.

Textual Amendments

F140 Words in Annex 7 Ch. C Pt. 1 point 6 omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(54)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

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

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

(b) rarity of the breed;

(c) avoidance of inbreeding or genetic drift.

[F141**8.** Where the **[**F142appropriate authority**]** allows, in accordance with the second paragraph of point 1, the sampling and genotyping of breeding rams in flocks not participating

in the breeding programme, the prion protein genotype for the codons 136, 141, 154 and 171 shall be determined for a minimum sample representative of the entire ovine population [F143]..., either:

(a) once every 3 years with a minimum sample of at least 1 560 ovine animals; or

(b) at a frequency and with a sample size [F144]... based on compliance with the following criteria:

(i) the sampling design takes into account relevant epidemiological data collected during previous surveys, including data concerning the prion protein genotype of sheep for the codons 136, 141, 154 and 171 by breed, region, age, sex and flock type;

(ii) the sampling design allows at a minimum to detect a change of 5 % in genotype prevalence over a 3-year period, with a 80 % power and 95 % confidence level.**]**

Textual Amendments

F144 Words in Annex 7 Ch. C Pt. 1 point 8(b) omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(54)(a)(iii)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

Textual Amendments

F141 Inserted by Commission Regulation (EU) 2017/894 of 24 May 2017 amending Annexes III and VII to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the genotyping of ovine animals (Text with EEA relevance).

F142 Words in Annex 7 Ch. C Pt. 1 point 8 substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(54)(a)(iii)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F143 Words in Annex 7 Ch. C Pt. 1 point 8 omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(54)(a)(iii)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

PART 2

Specific rules for participating flocks

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

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

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

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

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

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

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

3. **[**F145Nothing in these Regulations prevents the appropriate authority from deciding**]** to grant derogations from the requirements set out in point 2(c) and (d) for the purposes of the protection of breeds and production traits.

Textual Amendments

F145 Words in Annex 7 Ch. C Pt. 2 point 3 substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(54)(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

4. F146...

Textual Amendments

F146 Annex 7 Ch. C Pt. 2 point 4 omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(54)(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

PART 3

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

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

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

PART 4

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

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

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

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

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

[[F147]The appropriate authority**]** may decide to grant recognition on further levels to suit national requirements.

Textual Amendments

F147 Words in Annex 7 Ch. C Pt. 4 point 1 substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(54)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

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

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

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

PART 5

Reports to be provided to the Commission by the Member States

[[F148]...**]**

Textual Amendments

F148 Annex 7 Ch. C Pt. 5 omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(54)(d)**; 2020 c. 1, Sch. 5 para. 1(1)

ANNEX VIII

PLACING ON THE MARKET AND EXPORT

[[F6]CHAPTER A

Conditions for [F149]... trade in live animals, semen and embryos

SECTION A

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

[[F16]1. Holdings with a negligible risk of classical scrapie and a controlled risk of classical scrapie:

1.1. For the purpose of [F150]... trade, **[**[F151]the appropriate authority**]** shall, where applicable, establish and supervise an official scheme for the recognition of holdings with a negligible risk of classical scrapie and holdings with a controlled risk of classical scrapie. Based on that official scheme, they shall, where applicable, establish and maintain lists of holdings of ovine and caprine animals with a negligible risk and holdings with a controlled risk of classical scrapie.

1.2. A holding of ovine animals having the TSE-resistance level I status, as laid down in Annex VII, Chapter C, Part 4, point 1.(a), and where no case of classical scrapie has been confirmed for a period of at least the preceding seven years, may be recognised as having a negligible risk of classical scrapie.

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

(a) ovine and caprine animals are permanently identified and records are maintained, to enable them to be traced back to their holding of birth;

(b) records of movements of ovine and caprine animals in and out of the holding are maintained;

(c) only the following ovine and caprine animals are introduced into the holding:

(i) ovine and caprine animals from holdings with a negligible risk of classical scrapie;

(ii) ovine and caprine animals from holdings which have met the conditions set out in points (a) to (i) for a minimum period of the preceding seven years or for at least the same period of time as the period of time during which the holding, where they are to be introduced, has met the conditions set out in those points;

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

(iv) ovine or caprine animals that comply with the conditions set out in point (i) or (ii) except during the period when they were kept at a semen collection centre, provided that the semen collection centre complies with the following conditions:

— the semen collection centre is approved **[**[F152]and supervised**]**,

— for a period of the preceding seven years, only those ovine or caprine animals from holdings which have fulfilled during that period the conditions set out in points (a), (b) and (e), and which were subject to regular checks by an official veterinarian or a veterinarian authorised by the competent authority, were introduced into the semen collection centre,

— no case of classical scrapie has been confirmed at the semen collection centre for a period of the preceding seven years,

— biosecurity measures are in place at the semen collection centre to ensure that ovine and caprine animals kept at that centre and coming from holdings with a negligible

or a controlled risk status for classical scrapie have no direct or indirect contact with ovine and caprine animals coming from holdings of a lower classical scrapie status;

(d) the holding is subject to regular checks to verify compliance with the conditions set out in points (a) to (i) by an official veterinarian or a veterinarian authorised for that purpose by the competent authority, to be conducted at least on an annual basis F153...;

(e) no case of classical scrapie has been confirmed;

(f) F154...

F155... All ovine and caprine animals over 18 months of age that have died or have been killed for reasons other than slaughter for human consumption are tested in a laboratory for classical scrapie in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, point 3.2.

By way of derogation from the conditions set out in the **[**F156second paragraph of point (f), nothing in this Regulation prevents the appropriate authority from deciding**]** that all ovine and caprine animals over 18 months of age with no commercial value, culled at the end of their productive life instead of being slaughtered for human consumption, are inspected by an official veterinarian, and all those exhibiting wasting signs or neurological signs are tested in a laboratory for classical scrapie in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, point 3.2.

In addition to the conditions set out in points (a) to (f), the following conditions shall be complied with F157...:

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

(i) ova and embryos from donor animals which have been kept since birth in a **[**F158country or region**]** with a negligible risk of classical scrapie, or in a holding with a negligible or a controlled risk of classical scrapie, or which comply with the following requirements:

— they are permanently identified to enable them to be traced back to their holding of birth,

— they have been kept since birth in holdings in which no case of classical scrapie has been confirmed during their residency,

— they showed no clinical sign of classical scrapie at the time of collection of the ova or embryos;

(ii) ova and embryos of animals of the ovine species carrying at least one ARR allele;

(h) only the following semen of animals of the ovine and caprine species are introduced into the holding:

(i) semen from donor animals which have been kept since birth in a **[**F159country or region**]** with a negligible risk of classical scrapie, or

in a holding with a negligible risk or a controlled risk of classical scrapie, or which comply with the following requirements:

— they are permanently identified to enable them to be traced back to their holding of birth,

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

(ii) semen from rams of the ARR/ARR prion protein genotype;

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

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

(a) ovine and caprine animals are permanently identified and records are maintained, to enable them to be traced back to their holding of birth;

(b) records of movements of ovine and caprine animals in and out of the holding are maintained;

(c) only the following ovine and caprine animals are introduced into the holding:

(i) ovine and caprine animals from holdings with a negligible or a controlled risk of classical scrapie;

(ii) ovine and caprine animals from holdings which have met the conditions set out in points (a) to (i) for a minimum period of the preceding three years or for at least the same period of time as the period of time during which the holding, where they are to be introduced, has met the conditions set out in those points;

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

(iv) ovine or caprine animals that comply with the conditions set out in point (i) or (ii) except during the period when they were kept at a semen collection centre, provided that the semen collection centre complies with the following conditions:

— the semen collection centre is approved **[**[F160]and supervised**]**,

— for a period of the preceding three years, only those ovine or caprine animals from holdings which have fulfilled during that period the conditions set out in points (a), (b) and (e), and which were subject to regular checks by an official veterinarian or a veterinarian authorised by the competent authority, were introduced into the semen collection centre,

— no case of classical scrapie has been confirmed at the semen collection centre during the period of the preceding three years,

— biosecurity measures are in place at the semen collection centre to ensure that ovine and caprine animals kept at

that centre and coming from holdings with a negligible or a controlled risk status for classical scrapie have no direct or indirect contact with ovine and caprine animals coming from holdings of a lower classical scrapie status;

(d) the holding is subject to regular checks to verify compliance with the conditions set out in points (a) to (i) by an official veterinarian or a veterinarian authorised for that purpose by the competent authority, to be conducted at least on an annual basis [F161]...;

(e) no case of classical scrapie has been confirmed;

(f) [F162]...

[F163]... All ovine and caprine animals over 18 months of age that have died or have been killed for reasons other than slaughter for human consumption are tested in a laboratory for classical scrapie in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, point 3.2.

By way of derogation from the conditions set out in the **[**[F164]second paragraph of point (f), nothing in this Regulation prevents the appropriate authority from deciding**]** that all the ovine and caprine animals over 18 months of age with no commercial value culled at the end of their productive life instead of being slaughtered for human consumption, are inspected by an official veterinarian, and all those exhibiting wasting signs or neurological signs are tested in a laboratory for classical scrapie in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, point 3.2.

In addition to the conditions set out in points (a) to (f), the following conditions shall be complied with [F165]...:

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

(i) ova and embryos from donor animals which have been kept since birth in a **[**[F166]country or region**]** with a negligible risk of classical scrapie, or in a holding with a negligible or a controlled risk of classical scrapie, or which comply with the following requirements:

— they are permanently identified to enable them to be traced back to their holding of birth,

— they have been kept since birth in holdings in which no case of classical scrapie has been confirmed during their residency,

— they showed no clinical sign of classical scrapie at the time of collection of the ova or embryos,

(ii) ova and embryos of animals of the ovine species carrying at least one ARR allele;

(h) only the following semen of animals of the ovine and caprine species are introduced into the holding:

(i) semen from donor animals which have been kept since birth in a **[**[F167]country or region**]** with a negligible risk of classical

scrapie, or in a holding with a negligible risk or with a controlled risk of classical scrapie, or which comply with the following requirements:

— they are permanently identified to enable them to be traced back to their holding of birth,

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

(ii) semen from rams of the ARR/ARR prion protein genotype;

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

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

The **[**[F168]appropriate authority**]** shall immediately inform **[**[F169]other countries**]** which have introduced ovine and caprine animals originating from, or semen or embryos collected from ovine and caprine animals kept in the infected holding during a period of the preceding seven years in the case of a holding with a negligible risk of classical scrapie or during the period of the preceding three years in the case of a holding with a controlled risk of classical scrapie.**]**

Textual Amendments

F150 Words in Annex 8 Ch. A s. A point 1.1 omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(59)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F151 Words in Annex 8 Ch. A s. A point 1.1 substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(59)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F152 Words in Annex 8 Ch. A s. A point 1.2(c)(iv) substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(59)(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F153 Words in Annex 8 Ch. A s. A point 1.2(d) omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(59)(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F154 Words in Annex 8 Ch. A s. A point 1.2(f) omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(59)(b)(iii)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F155 Words in Annex 8 Ch. A s. A point 1.2(f) omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(59)(b)(iii)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

F156 Words in Annex 8 Ch. A s. A point 1.2(f) substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(59)(b)(iii)(cc)**; 2020 c. 1, Sch. 5 para. 1(1)

F157 Words in Annex 8 Ch. A s. A point 1.2 substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(59)(b)(iv)**; 2020 c. 1, Sch. 5 para. 1(1)

F158 Words in Annex 8 Ch. A s. A point 1.2(g)(i) substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(59)(b)(v)**; 2020 c. 1, Sch. 5 para. 1(1)

F159 Words in Annex 8 Ch. A s. A point 1.2(h)(i) substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(59)(b)(v)**; 2020 c. 1, Sch. 5 para. 1(1)

F160 Words in Annex 8 Ch. A s. A point 1.3(c)(iv) substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(59)(c)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F161 Words in Annex 8 Ch. A s. A point 1.3(d) omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(59)(c)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F162 Words in Annex 8 Ch. A s. A point 1.3(f) omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(59)(c)(iii)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F163 Words in Annex 8 Ch. A s. A point 1.3(f) omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(59)(c)(iii)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

F164 Words in Annex 8 Ch. A s. A point 1.3(f) substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(59)(c)(iii)(cc)**; 2020 c. 1, Sch. 5 para. 1(1)

F165 Words in Annex 8 Ch. A s. A point 1.3 omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(59)(c)(iv)**; 2020 c. 1, Sch. 5 para. 1(1)

F166 Words in Annex 8 Ch. A s. A point 1.3(g)(i) substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(59)(c)(v)**; 2020 c. 1, Sch. 5 para. 1(1)

F167 Words in Annex 8 Ch. A s. A point 1.3(h)(i) substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(59)(c)(v)**; 2020 c. 1, Sch. 5 para. 1(1)

F168 Words in Annex 8 Ch. A s. A point 1.4 substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(59)(d)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F169 Words in Annex 8 Ch. A s. A point 1.4 substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(59)(d)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

2. **[**[F170]A constituent nation [F171]... or a zone within a constituent nation**]** with a negligible risk of classical scrapie

2.1. Where **[**[F172]an appropriate authority**]** considers that its territory or part of its territory poses a negligible risk of classical scrapie, it **[**[F173]must have clear and presentable evidence**]** 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) **[**F16for a period of at least the preceding seven years, ovine and caprine animals displaying clinical signs compatible with classical scrapie have been tested;

(c) for a period of at least the preceding seven years, a sufficient number of ovine and caprine animals over 18 months of age, representative of ovine and caprine animals slaughtered, that have died or have been killed for reasons other than slaughter for human consumption, have been tested annually, to provide a 95 per cent level of confidence of detecting classical scrapie if it is present in that population at a prevalence rate exceeding 0,1 per cent and no case of classical scrapie has been reported during that period;**]**

(d) the feeding to ovine and caprine animals of meat-and-bone meal or greaves of ruminant origin has been banned and effectively enforced in **[**F174its whole territory**]** for a period of at least seven years;

(e) F175...

(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.

Textual Amendments

F174 Words in Annex 8 Ch. A s. A point 2.1(d) substituted (13.12.2022) by The Animals and Animal Health, Feed and Food, Plants and Plant Health (Amendment) Regulations 2022 (S.I. 2022/1315), regs. 1(1), **14(6)(b)**

F175 Annex 8 Ch. A s. A point 2.1(e) omitted (26.11.2021) by virtue of The Animal Health, Plant Health, Seeds and Seed Potatoes (Miscellaneous Amendments) Regulations 2021 (S.I. 2021/1229), regs. 1, **3**

Textual Amendments

F172 Words in Annex 8 Ch. A s. A point 2.1 substituted (31.12.2020) by S.I. 2019/170, **reg. 2(60)(b)(i)(aa)** (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(s)**)

F173 Words in Annex 8 Ch. A s. A point 2.1 substituted (31.12.2020) by S.I. 2019/170, **reg. 2(60)(b)(i)(bb)** (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(s)**)

2.2. F176...

Textual Amendments

F176 Annex 8 Ch. A s. A point 2.2 omitted (31.12.2020) by virtue of S.I. 2019/170, **reg. 2(60)(c)** (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(s)**)

2.3. F177...

. . . . . .

Textual Amendments

F177 Annex 8 Ch. A s. A point 2.3 omitted (31.12.2020) by virtue of S.I. 2019/170, reg. 2(60)(d) (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(s)**)

Textual Amendments

F170 Words in Annex 8 Ch. A s. A point 2 substituted (31.12.2020) by S.I. 2019/170, **reg. 2(60)(a)** (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(s)**)

F171 Words in Annex 8 Ch. A s. A point 2 heading omitted (13.12.2022) by virtue of The Animals and Animal Health, Feed and Food, Plants and Plant Health (Amendment) Regulations 2022 (S.I. 2022/1315), regs. 1(1), **14(6)(a)**

3. National control programme for classical scrapie:

3.1. **[**F178each constituent nation must have**]** a national control programme for classical scrapie covering all of its territory:

(a) **[**F179which outlines**]** in particular:

— the distribution of classical scrapie in the **[**F180constituent nation**]**,

— 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) F181...

Textual Amendments

F179 Words in Annex 8 Ch. A s. A point 3.1(a) substituted (31.12.2020) by S.I. 2019/170, **reg. 2(60)(e)(ii)** (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(s)**)

F180 Words in Annex 8 Ch. A s. A point 3.1(a) substituted (31.12.2020) by S.I. 2019/170, **reg. 2(60)(e)(iii)** (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(s)**)

F181 Annex 8 Ch. A s. A point 3.1(b) omitted (31.12.2020) by virtue of S.I. 2019/170, **reg. 2(60)(e)(iv)** (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(s)**)

Textual Amendments

F178 Words in Annex 8 Ch. A s. A point 3.1 substituted (31.12.2020) by S.I. 2019/170, **reg. 2(60)(e)(i)** (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(s)**)

[F182**3.2. [**F183**Within the European Union the national scrapie control programmes for the following Member States have been approved by the European Commission:]**

— Denmark,

— Slovenia.**]**

Textual Amendments

F182 Substituted by Commission Implementing Regulation (EU) 2017/736 of 26 April 2017 amending Annex VIII to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the approval of Slovenia's national control programme for classical scrapie (Text with EEA relevance).

F183 Words in Annex 8 Ch. A s. A point 3.2 substituted (31.12.2020) by S.I. 2019/170, reg. 2(60)(f) (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(s)**)

4. **F184**...

. . . . . .

Textual Amendments

F184 Annex 8 Ch. A s. A point 4 omitted (31.12.2020) by virtue of S.I. 2019/170, **reg. 2(60)(g)** (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(s)**)

SECTION B

Conditions which apply to bovine animals

The **[**F185appropriate authority**]** shall ensure that bovine animals born or reared on its territory before 1 August 1996 are not dispatched from its territory to F186... Member States or third countries.**]**

Textual Amendments

F185 Words in Annex 8 Ch. A s. B substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(61)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F186 Word in Annex 8 Ch. A s. B omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(61)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

Textual Amendments

F149 Words in Annex 8 Ch. A heading omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(57)**; 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER B

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

. . . . . .

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

[F15CHAPTER C

Conditions for F187... trade in certain products of animal origin

SECTION A

Products

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

— fresh meat,
— minced meat,
— meat preparations,
— meat products.

SECTION B

Requirements

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

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

(b) the animals from which the products of bovine, ovine and caprine animal origin were derived have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning

of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity;

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

(i) specified risk material as defined in Annex V;

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

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

Textual Amendments

F187 Words in Annex 8 Ch. C heading omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(62)**; 2020 c. 1, Sch. 5 para. 1(1)

[F188 CHAPTER D

Conditions applicable to exports

. . . . . .

Textual Amendments

F188 Annex 8 Ch. D omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(63)**; 2020 c. 1, Sch. 5 para. 1(1)

[F16ANNEX IX

IMPORTATION INTO [F189GREAT BRITAIN] OF LIVE ANIMALS, EMBRYOS, OVA AND PRODUCTS OF ANIMAL ORIGIN

Textual Amendments

F189 Words in Annex 9 heading substituted (16.11.2022) by The Animals, Food, Plant Health, Plant Propagating Material and Seeds (Miscellaneous Amendments etc.) Regulations 2022 (S.I. 2022/1090), regs. 1(1), **5(4)**

CHAPTER B

Imports of bovine animals

SECTION A

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

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

(a) the animals were born and continuously reared in a country or region or countries or regions classified in accordance with **[**F190this Regulation**]** as countries or regions posing a negligible BSE risk;

(b) **[**F191the animals are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin, and are not the following bovine animals:**]**

(i) all BSE cases;

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

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

and

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

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

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

Textual Amendments

F190 Words in Annex 9 Ch. B s. A point (a) substituted (1.7.2022) by The Import of Animals and Animal Products and Approved Countries (Amendment) Regulations 2022 (S.I. 2022/735), regs. 1(2), **2(3)(a)(i)**

F191 Substituted by Commission Regulation (EU) 2019/319 of 6 February 2019 amending Annex IX to Regulation (EC) No 999/2001 of the European Parliament and of the Council and Annex XV to Commission Regulation (EU) No 142/2011 as regards health certification at import into the Union concerning transmissible spongiform encephalopathies (Text with EEA relevance).

SECTION B

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

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

(a) the country or region is classified in accordance with **[**F192this Regulation**]** as a country or region posing a controlled BSE risk;

(b) **[**F191the animals are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin, and are not the following bovine animals:**]**

(i) all BSE cases;

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

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

(c) the animals were born:

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

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

Textual Amendments

F192 Words in Annex 9 Ch. B s. B point (a) substituted (1.7.2022) by The Import of Animals and Animal Products and Approved Countries (Amendment) Regulations 2022 (S.I. 2022/735), regs. 1(2), **2(3)(a)(ii)**

SECTION C

Imports from a country or a region with undetermined BSE risk

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

(a) the country or region has been categorised in accordance with **[**F193this Regulation**]** as a country or region with undetermined BSE risk;

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

(c) **[**F191the animals are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin, and are not the following bovine animals:**]**

(i) all BSE cases;

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

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

(d) the animals were born:

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

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

Textual Amendments

F193 Words in Annex 9 Ch. B s. C point (a) substituted (1.7.2022) by The Import of Animals and Animal Products and Approved Countries (Amendment) Regulations 2022 (S.I. 2022/735), regs. 1(2), **2(3)(a)(iii)**

CHAPTER C

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

SECTION A

Products

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

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

SECTION B

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

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

(a) the country or region is classified in accordance with **[**F194this Regulation**]** as a country or region posing a negligible BSE risk;

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

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

(d) if the animals, from which the products of bovine animal origin were derived, originate from a country or region classified in accordance with **[**F195this Regulation**]** as a country or region posing a controlled or an undetermined BSE risk, by way of derogation from point (c) of this Section, carcasses, half carcasses or half carcasses cut into no more than three wholesale cuts, and quarters containing no specified risk material other than the vertebral column, including dorsal root ganglia, may be imported. In the case of such imports, the carcasses or wholesale cuts of carcasses of bovine animals containing a vertebral column which is defined as specified risk material in accordance with point 1 of Annex V to this Regulation shall be identified by a clearly visible red stripe on the label referred to in Article 13 or 15 of Regulation (EC) No 1760/2000. Furthermore, specific information on the number of bovine carcasses or wholesale cuts of carcasses, from which the removal of the vertebral column is required, shall be added to the Common Veterinary Entry Document (CVED) **[**F196made available or published for the time being by the appropriate authority**]**;

(e) the products of bovine, ovine and caprine animal origin do not contain and are not derived from mechanically separated meat obtained from bones of bovine, ovine or caprine animals, except if the animals, from which the products of bovine, ovine and caprine animal origin are derived, were born, continuously reared and slaughtered in a country or region classified in accordance with **[**F197this Regulation**]** as a country or region posing a negligible BSE risk in which there has been no BSE indigenous cases;

(f) the animals from which the products of bovine, ovine and caprine animal origin were derived have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, except if the animals from which the products of bovine, ovine and caprine animal origin are derived, were born, continuously reared and slaughtered in a country or region classified in accordance with **[**F198this Regulation**]** as a country or region posing a negligible BSE risk;

(g) if the animals, from which the products of bovine, ovine and caprine animal origin were derived, originate from a country or region classified in accordance with **[**F199this Regulation**]** as a country or region posing an undetermined BSE risk, the animals have not been fed with meat-and-bone meal or greaves, as defined in the OIE Terrestrial Animal Health Code;

(h) if the animals, from which the products of bovine, ovine and caprine animal origin were derived, originate from a country or region classified in accordance with **[**[F200]this Regulation**]** as a country or region posing an undetermined BSE risk, the products were produced and handled in a manner which ensures that they did not contain and were not contaminated with nervous and lymphatic tissues exposed during the deboning process.

Textual Amendments

F194 Words in Annex 9 Ch. C s. B point (a) substituted (1.7.2022) by The Import of Animals and Animal Products and Approved Countries (Amendment) Regulations 2022 (S.I. 2022/735), regs. 1(2), **2(3)(b)(i)**

F195 Words in Annex 9 Ch. C s. B point (d) substituted (1.7.2022) by The Import of Animals and Animal Products and Approved Countries (Amendment) Regulations 2022 (S.I. 2022/735), regs. 1(2), **2(3)(b)(i)**

F196 Words in Annex 9 Ch. C s. B point (d) substituted (31.12.2020) by The Animals (Legislative Functions) (EU Exit) Regulations 2019 (S.I. 2019/588), regs. 1, **4(24)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)

F197 Words in Annex 9 Ch. C s. B point (e) substituted (1.7.2022) by The Import of Animals and Animal Products and Approved Countries (Amendment) Regulations 2022 (S.I. 2022/735), regs. 1(2), **2(3)(b)(i)**

F198 Words in Annex 9 Ch. C s. B point (f) substituted (1.7.2022) by The Import of Animals and Animal Products and Approved Countries (Amendment) Regulations 2022 (S.I. 2022/735), regs. 1(2), **2(3)(b)(i)**

F199 Words in Annex 9 Ch. C s. B point (g) substituted (1.7.2022) by The Import of Animals and Animal Products and Approved Countries (Amendment) Regulations 2022 (S.I. 2022/735), regs. 1(2), **2(3)(b)(i)**

F200 Words in Annex 9 Ch. C s. B point (h) substituted (1.7.2022) by The Import of Animals and Animal Products and Approved Countries (Amendment) Regulations 2022 (S.I. 2022/735), regs. 1(2), **2(3)(b)(i)**

SECTION C

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

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

(a) the country or region is classified in accordance with **[**[F201]this Regulation**]** as a country or region posing a controlled BSE risk;

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

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

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

Textual Amendments

F201 Words in Annex 9 Ch. C s. C para. 1(a) substituted (1.7.2022) by The Import of Animals and Animal Products and Approved Countries (Amendment) Regulations 2022 (S.I. 2022/735), regs. 1(2), **2(3)(b)(ii)**

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

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

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

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

(a) the country or region is classified in accordance with **[**F202this Regulation**]** as a country or region posing a controlled BSE risk;

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

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

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

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

Textual Amendments

F202 Words in Annex 9 Ch. C s. C para. 5(a) substituted (1.7.2022) by The Import of Animals and Animal Products and Approved Countries (Amendment) Regulations 2022 (S.I. 2022/735), regs. 1(2), **2(3)(b)(ii)**

SECTION D

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

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

(a) the animals from which the products of bovine, ovine and caprine animal origin were derived have not been fed meat-and-bone meal or greaves derived from ruminants, as defined in the OIE Terrestrial Animal Health Code, and passed *ante mortem* and *post mortem* inspections;

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

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

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

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

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

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

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

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

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

(a) the country or region is classified in accordance with **[**[F203]this Regulation**]** as a country or region posing an undetermined BSE risk;

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

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

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

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

Textual Amendments

F203 Words in Annex 9 Ch. C s. D para. 5(a) substituted (1.7.2022) by The Import of Animals and Animal Products and Approved Countries (Amendment) Regulations 2022 (S.I. 2022/735), regs. 1(2), **2(3)(b)(iii)**

CHAPTER D

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

SECTION A

Animal by-products

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

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

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

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

(d) pet food including dog chews;

(e) blood products;

(f) processed animal protein;

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

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

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

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

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

(iii) fat derivatives.

[F191 SECTION B

Health certificate requirements

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

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

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

      (ii) does not contain and is not derived from mechanically separated meat obtained from bones of bovine, ovine or caprine animals, except if the animals, from which the animal by-product or derived product are derived, were born, continuously reared and slaughtered in a country or region classified in accordance with **[**F204this Regulation**]** as a country or region posing a negligible BSE risk, in which there has been no BSE indigenous cases; and

      (iii) is derived from animals which have not been killed, after stunning, by laceration of the central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, or by means of gas injected into the cranial cavity, except for animals born, continuously reared and slaughtered in a country or region classified as posing a negligible BSE risk in accordance with **[**F205this Regulation**]**;

   or

   (b) the animal by-product or derived product does not contain and is not derived from bovine, ovine and caprine materials other than those derived from animals born, continuously reared and slaughtered in a country or region classified as posing a negligible BSE risk in accordance with **[**F206this Regulation**]**.

2. In addition to the requirements of point 1 of this Section, imports of the animal by-products and derived products referred to in points (d) and (f) of 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 originates from a country or region, which is classified as posing a negligible BSE risk in accordance with **[**F207this Regulation**]**, and in which there has been no BSE indigenous case;

   or

   (b) the animal by-product or derived product originates from a country or region classified as posing a negligible BSE risk in accordance with **[**F208this Regulation**]** in which there has been a BSE indigenous case, and the animal by-product or derived product was derived from animals born after the date

from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants, as defined in the OIE Terrestrial Animal Health Code, has been effectively enforced in that country or region.

By way of derogation from the preceding paragraph, the attestation referred to in points (a) and (b) shall not be required for the importation of processed petfood, which is packaged and labelled in accordance with **[**F209retained direct EU**]** legislation.

3. In addition to the requirements of points 1 and 2 of this Section, imports of the animal by-products and derived products referred to in Section A, containing milk or milk products of ovine or caprine animal origin and intended for feed, shall be subject to the presentation of a health certificate which has been completed with the following attestation:

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

(i) classical scrapie is compulsorily notifiable;

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

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

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

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

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

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

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

or

(ii) all animals in which classical scrapie was confirmed have been killed and destroyed, and the holding has been subjected for a period of at least two years since the date of 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 point 3.2 of Chapter C of

Annex X, 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.**]**

Textual Amendments

F204 Words in Annex 9 Ch. D s. B para. 1(a)(ii) substituted (1.7.2022) by The Import of Animals and Animal Products and Approved Countries (Amendment) Regulations 2022 (S.I. 2022/735), regs. 1(2), **2(3)(c)**

F205 Words in Annex 9 Ch. D s. B para. 1(a)(iii) substituted (1.7.2022) by The Import of Animals and Animal Products and Approved Countries (Amendment) Regulations 2022 (S.I. 2022/735), regs. 1(2), **2(3)(c)**

F206 Words in Annex 9 Ch. D s. B para. 1(b) substituted (1.7.2022) by The Import of Animals and Animal Products and Approved Countries (Amendment) Regulations 2022 (S.I. 2022/735), regs. 1(2), **2(3)(c)**

F207 Words in Annex 9 Ch. D s. B para. 2(a) substituted (1.7.2022) by The Import of Animals and Animal Products and Approved Countries (Amendment) Regulations 2022 (S.I. 2022/735), regs. 1(2), **2(3)(c)**

F208 Words in Annex 9 Ch. D s. B para. 2(b) substituted (1.7.2022) by The Import of Animals and Animal Products and Approved Countries (Amendment) Regulations 2022 (S.I. 2022/735), regs. 1(2), **2(3)(c)**

F209 Words in Annex 9 Ch. D s. B point 2 substituted (31.12.2020) by S.I. 2019/170, reg. 2(64)(a) (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(t)**)

CHAPTER E

Imports of ovine and caprine animals

Ovine and caprine animals imported into **[**[F210]Great Britain**]** shall be subject to the presentation of an animal health certificate attesting that they have been kept continuously since birth in a country where the following conditions are fulfilled:

Textual Amendments

F210 Words in Annex 9 Ch. E substituted (31.12.2020) by S.I. 2019/170, **reg. 2(64)(b)(i)** (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(t)**)

(1) classical scrapie is compulsorily notifiable;

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

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

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

F211 …

Textual Amendments

F211 Words in Annex 9 Ch. E omitted (31.12.2020) by virtue of S.I. 2019/170, **reg. 2(64)(b)(ii)** (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(t)**)

(5) For ovine and caprine animals for breeding imported into **[**F212parts of Great Britain**]** other than those with a negligible risk of classical scrapie or those with an approved national scrapie control programme listed in point 3.2 of Section A of Chapter A of Annex VIII, the following conditions have been complied with:

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

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

(6) For ovine and caprine animals for all uses except immediate slaughter imported into **[**F213parts of Great Britain**]** with a negligible risk of classical scrapie or with an approved national scrapie control programme listed in point 3.2 of Section A of Chapter A of Annex VIII, the following conditions have been complied with:

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

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

Textual Amendments

F212 Words in Annex 9 Ch. E point (5) substituted (31.12.2020) by S.I. 2019/170, **reg. 2(64)(b)(iii)** (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(t)**)

F213 Words in Annex 9 Ch. E point (6) substituted (31.12.2020) by S.I. 2019/170, **reg. 2(64)(b)(iv)** (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(t)**)

CHAPTER F

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

1. When fresh meat, minced meat, meat preparations and meat products as defined in points 1.10, 1.13, 1.15 and 7.1 respectively of Annex I to Regulation (EC) No 853/2004, derived from farmed cervid animals, are imported into **[**F214Great Britain**]** from Canada or the United States of America, the health certificates shall be accompanied by a declaration signed by the competent authority of the country of production, worded as follows:

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

Textual Amendments

F214 Words in Annex 9 Ch. F point 1 substituted (31.12.2020) by S.I. 2019/170, **reg. 2(64)(c)** (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(t)**)

2. When fresh meat, minced meat, meat preparations and meat products as defined in points 1.10, 1.13, 1.15 and 7.1 respectively of Annex I to Regulation (EC) No 853/2004, derived from wild cervid animals, are imported into **[**F215Great Britain**]** from Canada or the United States of America, the health certificates shall be accompanied by a declaration signed by the competent authority of the country of production, worded as follows:

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

Textual Amendments

F215 Words in Annex 9 Ch. F point 2 substituted (31.12.2020) by S.I. 2019/170, **reg. 2(64)(c)** (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(t)**)

CHAPTER H

Import of ovine and caprine semen and embryos

Ovine and caprine semen and embryos imported into **[**F216Great Britain**]** shall be subject to the presentation of an animal health certificate attesting that:

Textual Amendments

F216 Words in Annex 9 Ch. H substituted (31.12.2020) by S.I. 2019/170, **reg. 2(64)(d)** (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(t)**)

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

(a) classical scrapie is compulsorily notifiable;

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

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

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

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

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

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

[F18ANNEX X

REFERENCE LABORATORIES, SAMPLING AND LABORATORY ANALYSIS METHODS

F217CHAPTER A

[F217National reference laboratories

F217**No commentary item could be found for this reference** ...

Textual Amendments

F217 Deleted by Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (Text with EEA relevance).

F217

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F217

CHAPTER C

Sampling and laboratory testing

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 World Organisation for Animal Health (OIE) (the Manual). In addition to, 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 **[**F218national reference laboratory**]**.

Textual Amendments

F218 Words in Annex 10 Ch. C point 1 substituted (16.11.2022) by The Animals, Food, Plant Health, Plant Propagating Material and Seeds (Miscellaneous Amendments etc.) Regulations 2022 (S.I. 2022/1090), regs. 1(1), **5(5)**

In particular the competent authority shall collect the appropriate tissues, according to the available scientific advice F219..., 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 subject to confirmatory testing F220....

Textual Amendments

F219 Words in Annex 10 Ch. C point 1 omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(69)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F220 Words in Annex 10 Ch. C point 1 omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(69)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

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

2. **Laboratories**

Any laboratory examination for TSE shall be carried out in official diagnostic laboratories designated for that purpose by the competent authority.

3. **Methods and protocols**

3.1. *Laboratory testing for the presence of BSE in bovine animals*

(a) *Suspect cases*

Samples from bovine animals sent for laboratory testing pursuant to the provisions of Article 12(2) shall immediately be subjected to confirmatory examinations using at least one of the following methods and protocols laid down in the latest edition of the Manual:

(i) the immunohistochemical (IHC) method;

(ii) Western blot;

(iii) the demonstration of characteristic fibrils by electron microscopy;

(iv) histopathological examination;

(v) the combination of rapid tests as laid down in the third subparagraph.

If the histopathological examination is inconclusive or negative, the tissues shall be submitted to a further examination by one of the other confirmatory methods and protocols.

Rapid tests may be used for both primary screening of suspect cases and, if inconclusive or positive, for subsequent confirmation, [F221]... by using a second rapid test ' , and provided that:

Textual Amendments

F221 Words in Annex 10 Ch. C point 3.1(a) omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(71)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

(i) the confirmation is carried out in a national reference laboratory for TSEs; and

(ii) one of the two rapid tests is a Western blot; and

(iii) the second rapid test used:
- — includes a negative tissue control and a bovine BSE sample as positive tissue control,
- — is of a different type than the test used for the primary screening; and

(iv) if a rapid Western blot is used as the first test, the result of that test must be documented and the blot image submitted to the national reference laboratory for TSEs; and

(v) where the result of the primary screening is not confirmed by the subsequent rapid test, the sample must be subjected to an examination by one of the other confirmatory methods; where the histopathological examination is used for that purpose, but proves to be inconclusive or negative, the tissues must be submitted to a further examination by one of the other confirmatory methods and protocols.

If the result of one of the confirmatory examinations referred to in points (i) to (v) of the first subparagraph is positive, the animal shall be regarded as a positive BSE case.

(b) *BSE monitoring*

Samples from bovine animals sent for laboratory testing pursuant to the provisions of Annex III, Chapter A, Part I shall be examined by a rapid test.

When the result of the rapid test is inconclusive or positive, the sample shall immediately be subjected to confirmatory examinations using at least one of the following methods and protocols laid down in the latest edition of the Manual:

(i) the immunohistochemical (IHC) method;

(ii) Western blot;

(iii) the demonstration of characteristic fibrils by electron microscopy;

(iv) histopathological examination;

(v) the combination of rapid tests as laid down in the fourth subparagraph.

Where the histopathological examination is inconclusive or negative, the tissues shall be submitted to a further examination by one of the other confirmatory methods and protocols.

Rapid tests may be used for both primary screening and, if inconclusive or positive, for subsequent confirmation, [F222]... by using a second rapid test, and provided that ' :

Textual Amendments

F222 Words in Annex 10 Ch. C point 3.1(b) omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(71)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

(i) the confirmation is carried out in a national reference laboratory for TSEs; and

(ii) one of the two rapid tests is a Western blot; and

(iii) the second rapid test used:
— includes a negative tissue control and a bovine BSE sample as positive tissue control,
— is of a different type than the test used for the primary screening; and

(iv) if a rapid Western blot is used as the first test, the result of that test must be documented and the blot image submitted to the national reference laboratory for TSEs; and

(v) where the result of the primary screening is not confirmed by the subsequent rapid test, the sample must be subjected to an examination by one of the other confirmatory methods; where the histopathological examination is used for that purpose, but proves to be inconclusive or negative, the tissues must be submitted to a further examination by one of the other confirmatory methods and protocols.

An animal shall be regarded a positive BSE case if the result of the rapid test is inconclusive or positive, and at least one of the confirmatory examinations referred to in points (i) to (v) of the second subparagraph is positive.

(c) *Further examination of positive BSE cases*

Samples from all positive BSE cases shall be forwarded to a laboratory, appointed by the competent authority, **[**[F223]where they must be further tested by a two-blot method for the provisional classification of bovine TSE isolates**]**.

Textual Amendments

F223 Words in Annex 10 Ch. C point 3.1(c) omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(71)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

3.2. *Laboratory testing for the presence of TSE in ovine and caprine animals*

(a) *Suspect cases*

Samples from ovine and caprine animals sent for laboratory testing pursuant to the provisions of Article 12(2) shall immediately be subjected to confirmatory examinations using at least one of the following methods and protocols laid down in the latest edition of the Manual:

(i) the immunohistochemical (IHC) method;

(ii) Western blot;

(iii) the demonstration of characteristic fibrils by electron microscopy;

(iv) histopathological examination.

In case the histopathological examination is inconclusive or negative, the tissues shall be submitted to a further examination by one of the other confirmatory methods and protocols.

Rapid tests may be used for primary screening of suspect cases. Such tests may not be used for subsequent confirmation.

Where the result of the rapid test used for primary screening of suspect cases is positive or inconclusive, the sample shall be subjected to an examination by one of the confirmatory examinations referred to in points (i) to (iv) of the first subparagraph. Where the histopathological examination is used for that purpose, but proves to be inconclusive or negative, the tissues shall be submitted to a further examination by one of the other confirmatory methods and protocols.

[[F224]If the result of one of the confirmatory examinations referred to in points (i) to (iv) of the first subparagraph is positive, the animal shall be regarded as a positive TSE case.**]**

Textual Amendments

F224 Substituted by Commission Regulation (EU) 2020/1593 of 29 October 2020 amending Annex X to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards further examination of positive cases of transmissible spongiform encephalopathies in ovine and caprine animals (Text with EEA relevance).

(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, 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 **[**[F225]the relevant**]** official laboratory for confirmatory examinations by histopathology, immunohistochemistry, Western blotting or demonstration of characteristic fibrils by electron microscopy, as referred to in point (a). If the result of the confirmatory examination is negative or inconclusive, the tissues shall be submitted to a further examination by immunohistochemistry or Western blotting.

Textual Amendments

F225 Words in Annex 10 Ch. C point 3.2(b) substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(72)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

[[F224]If the result of one of the confirmatory examinations is positive, the animal shall be regarded as a positive TSE case.**]**

(c) *Further examination of positive TSE cases*

[[F226]Samples that, following the examinations referred to in points (a) or (b), are regarded as positive TSE cases, but which are not considered atypical cases, shall be examined to exclude the presence of BSE only when they come from an index case. Other cases, which display characteristics that, according to the testing laboratory, merit investigation, shall also be examined to exclude the presence of BSE.**]**

Textual Amendments

F226 Inserted by Commission Regulation (EU) 2020/1593 of 29 October 2020 amending Annex X to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards further examination of positive cases of transmissible spongiform encephalopathies in ovine and caprine animals (Text with EEA relevance).

[[F224](i) Primary molecular testing with a discriminatory Western blotting method

For the exclusion of the presence of BSE, samples shall be examined by a discriminatory Western blotting method **[**[F227]approved by the national reference laboratory**].]**

Textual Amendments

F227 Words in Annex 10 Ch. C point 3.2(c)(i) substituted (31.12.2020) by S.I. 2019/170, **reg. 2(72)(b)(i)** (as substituted by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(a), **20(2)(w)**)

[[F228](ii) Secondary molecular testing with additional molecular testing methods

In TSE cases in which the presence of BSE cannot be excluded by the primary molecular testing referred to in point (i), the samples must be submitted to further investigation and confirmation by at least one alternative method, differing immunochemically from the original primary molecular method, depending on the volume and nature of the referred material. These additional tests will be carried out by the national reference laboratory.**]**

Textual Amendments

F228 Annex 10 Ch. C point 3.2(c)(ii) substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(72)(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

(iii) Mouse bioassay

Samples indicative of BSE or inconclusive for BSE, following secondary molecular testing, shall be further analysed by mouse bioassay for final confirmation. The nature or quantity of available material may influence the bioassay design[F229]....

Textual Amendments

F229 Words in Annex 10 Ch. C point 3.2(c)(iii) omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(72)(b)(iii)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F230 …

Textual Amendments

F230 Words in Annex 10 Ch. C point 3.2(c)(iii) omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(72)(b)(iii)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

3.3. *Laboratory testing for the presence of TSEs in species other than those referred to in points 3.1 and 3.2*

Where methods and protocols are established for tests carried out to confirm the suspected presence of a TSE in a species other than bovine, ovine and caprine, they shall include at least a histopathological examination of brain tissue. The competent authority may also require laboratory tests such as immunohistochemistry, Western blotting, demonstration of characteristic fibrils by electron microscopy or other methods designed to detect the disease associated form of the prion protein. In any case at least one other laboratory examination shall be carried out if the initial histopathological examination is negative or inconclusive. At least three different examinations with positive results shall be carried out in the event of the first appearance of the disease.

F231 …

Textual Amendments

F231 Words in Annex 10 Ch. C point 3.3 omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(73)**; 2020 c. 1, Sch. 5 para. 1(1)

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

— 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 PrPSc capture and a monoclonal detection antibody directed against conserved regions of the PrP molecule

(IDEXX HerdChek BSE Antigen Test Kit, EIA & HerdChek BSE-Scrapie Antigen (IDEXX Laboratories)),

— 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 PrPSc (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 PrPSc capture and a monoclonal detection antibody directed against conserved regions of the PrP molecule (HerdChek BSE-Scrapie Antigen (IDEXX Laboratories)),

— F232...

Textual Amendments

F232 Deleted by Commission Regulation (EU) 2017/110 of 23 January 2017 amending Annexes IV 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).

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 F233... ensures that the test performance does not change. F234...

Textual Amendments

F233 Words in Annex 10 Ch. C point 4 omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(74)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F234 Words in Annex 10 Ch. C point 4 omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(74)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

Changes to rapid tests and to test protocols may only be made **[**F235if**]** the change does not alter the sensitivity, specificity or reliability of the rapid test. F236...

Textual Amendments

F235 Word in Annex 10 Ch. C point 4 substituted (31.12.2020) by The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(74)(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F236 Words in Annex 10 Ch. C point 4 omitted (31.12.2020) by virtue of The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/170), regs. 1, **2(74)(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

5. **Alternative tests**

(To be defined)**]**

[F237]ANNEX XI

. . . . . .

Textual Amendments

F237 Deleted by Commission Regulation (EC) No 722/2007 of 25 June 2007 amending Annexes II, V, VI, VIII, IX and XI to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

F238 Substituted by Commission Regulation (EC) No 1139/2003 of 27 June 2003 amending Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards monitoring programmes and specified risk material.

(1) **[**F1**[**F2**[**F3**]**Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).**]]]**

(2) **[**F1**[**F2**[**F3**]**Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (OJ L 54, 26.2.2011, p. 1).**]]]**

(3) **[**F1**[**F2**[**F3**]**Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).**]]]**

(4) **[**F1**[**F2**[**F3**]**Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC (OJ L 229, 1.9.2009, p. 1).**]]]**

(5) **[**F1**[**F2**[**F3**]**Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals (OJ L 328, 24.11.2006, p. 14).**]]]**

(6) **[**F1**[**F2**[**F3**]**Regulation (EU) 2016/1012 of the European Parliament and of the Council of 8 June 2016 on zootechnical and genealogical conditions for the breeding, trade in and entry into the Union of purebred breeding animals, hybrid breeding pigs and the germinal products thereof and amending Regulation (EU) No 652/2014, Council Directives 89/608/EEC and 90/425/EEC and repealing certain acts in the area of animal breeding ('Animal Breeding Regulation') (OJ L 171, 29.6.2016, p. 66).**]]]**

(7) **[**F1**[**F6**]**http://vla.defra.gov.uk/science/docs/sci_tse_rl_handbookv4jan10.pdf**]]**

(8) **[**F1**[**F6**]**OJ L 349, 24.12.2002, p. 105.**]]**

(9) **[**F1**[**F6**]**http://vla.defra.gov.uk/science/docs/sci_tse_rl_2blot.pdf**]]**

(10) **[**F1**[**F6**]**OJ L 5, 9.1.2004, p. 8.**]]**

(11) **[**F15**]**Design prevalence is used to determine the size of a testing survey expressed in terms of target points. If the actual prevalence is greater than the selected design prevalence, the survey is highly likely to detect disease.**]**

(12) **[**F19**[**F6**]**OJ L 139, 30.4.2004, p. 55.**]]**

(13) **[**F19**[**F6**]**OJ L 139, 30.4.2004, p. 206.**]]**

(14) **[**F19**]**OJ L 99, 20.4.1996, p. 14.**]**

(15) **[**F2**]**OJ L 54, 26.2.2009, p. 1.**]**

(16) **[**F15**[**F16**]**Commission Regulation (EC) No 136/2004 of 22 January 2004 laying down procedures for veterinary checks at Community border inspection posts on products imported from third countries (OJ L 21, 28.1.2004, p. 11).**]]**

(17) **[**F6**]**OJ L 300, 14.11.2009, p. 1.**]**

Textual Amendments

F1 Substituted by Commission Regulation (EC) No 1234/2003 of 10 July 2003 amending Annexes I, IV and XI to Regulation (EC) No 999/2001 of the European Parliament and of the Council and Regulation (EC) No 1326/2001 as regards transmissible spongiform encephalopathies and animal feeding (Text with EEA relevance).

F2 Substituted by Commission Regulation (EU) No 56/2013 of 16 January 2013 amending Annexes I and IV 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).

F3 Substituted by Commission Regulation (EU) 2020/772 of 11 June 2020 amending Annexes I, VII and VIII to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards eradication measures for transmissible spongiform encephalopathies in goats and endangered breeds (Text with EEA relevance).

F6 Substituted by Commission Regulation (EU) No 630/2013 of 28 June 2013 amending the Annexes to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

F15 Substituted by Commission Regulation (EC) No 722/2007 of 25 June 2007 amending Annexes II, V, VI, VIII, IX and XI to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

F16 Substituted by Commission Regulation (EU) 2016/1396 of 18 August 2016 amending certain Annexes to Regulation (No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

F19 Substituted by Commission Regulation (EC) No 2245/2003 of 19 December 2003 amending Annex III to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards monitoring of transmissible spongiform encephalopathies in ovine and caprine animals.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council.