ANNEX VIII

PLACING ON THE MARKET AND EXPORT

[F1CHAPTER A

[F2Conditions for intra-Community trade in live animals, semen and embryos]

I. CONDITIONS WHICH APPLY IRRESPECTIVE OF THE CATEGORY OF THE MEMBER STATE OR THIRD COUNTRY OF ORIGIN OR RESIDENCE OF THE ANIMAL

The following conditions shall apply to trade in ovine and caprine animals:

(a) [F3ovine and caprine animals for breeding shall either be sheep of the ARR/ARR prion protein genotype, as defined in Annex I of Commission Decision 2002/1003/EC(1), or they shall have been kept continuously since birth or for the last three years on a holding or holdings which have satisfied the following requirements for at least three years:

(i) until 30 June 2007:

— it is subject to regular official veterinary checks,

— the animals are marked,

— no case of scrapie has been confirmed,

— checking by sampling of old female animals intended for slaughter is carried out,

— females, with the exception of sheep of the ARR/ARR prion protein genotype, are introduced into the holding only if they come from a holding which complies with the same requirements.

From 1 July 2004 at the latest, the holding or holdings shall begin to satisfy the following additional requirements:

— all animals referred to in Annex III, Chapter A, Part II, point 3 over the age of 18 months which have died or been killed on the holding shall be examined for scrapie in accordance with the laboratory methods laid down in Annex X, Chapter C, point 3.2(b), and

— ovine and caprine animals, with the exception of sheep of the ARR/ARR prion protein genotype, shall be introduced into the holding only if they come from a holding which complies with the same requirements.

(ii) from 1 July 2007:

— it is subject to regular official veterinary checks,

— the animals are identified in conformity with Community legislation,

— no case of scrapie has been confirmed,

— all animals referred to in Annex III, Chapter A, Part II, point 3 over the age of 18 months which have died or been killed on the holding have been examined for scrapie in accordance with the laboratory methods laid down in Annex X, Chapter C, point 3.2(b),

— ovine and caprine animals, with the exception of sheep of the ARR/ARR prion protein genotype, are introduced into the holding only if they come from a holding which complies with the same requirements.

If they are destined for a Member State which benefits, for all or part of its territory, from the provisions laid down in point (b) or (c), ovine and caprine animals for breeding shall comply with the additional guarantees, general or specific, which have been defined in accordance with the procedure referred to in Article 24(2).**]**

(b) a Member State which has a compulsory or voluntary national scrapie control program for all or part of its territory:

(i) may submit the said program to the Commission, outlining in particular:
— the distribution of the disease in the Member State,
— the reasons for the program, taking into consideration the importance of the disease and the cost/benefit ratio,
— the geographical area in which the program will be implemented,
— the status categories defined for holdings and the standards which must be attained in each such category,
— the test procedures to be used,
— the program 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 provisions of the program are positive,

(ii) the program referred to in point (i) may be approved if it complies with the criteria laid down in that point, in accordance with the procedure referred to in Article 24(2). The additional guarantees, general or specific, which may be required in intra-Community trade, shall be defined at the same time or at the latest three months after approval of the program in accordance with the procedure referred to in Article 24(2). Such guarantees must not exceed those which the Member State implements nationally,

(iii) amendments or additions to the programmes submitted by Member States may be approved in accordance with the procedure referred to in Article 24(2). Amendments to the guarantees which have been defined in accordance with point (ii) may be approved in accordance with that procedure,

(c) where a Member State considers that its territory or part of its territory is free from scrapie:

(i) it is to submit to the Commission appropriate supporting documentation, setting out in particular:
— the history of the occurrence of the disease in its territory,
— the results of surveillance testing based on serological, microbiological, pathological or epidemiological investigation,
— the period over which the surveillance was carried out,
— the arrangements for verifying the absence of the disease,

(ii) the additional guarantees, general or specific, which may be required in intra-Community trade are to be defined in accordance with the procedure

referred to in Article 24(2). Such guarantees must not exceed those which the Member State implements nationally,

(iii) the Member State concerned is to notify the Commission of any change in the details specified in point (i) which relate to the disease. The guarantees defined in accordance with point (ii) may, in the light of such notification, be amended or withdrawn in accordance with the procedure referred to in Article 24(2)**[**[F2]**,]**

(d) **[**[F4]from 1 January 2005 semen and embryos of ovine and caprine animals shall:

(i) be collected from animals which have been kept continuously since birth or for the last three years of their life on a holding or holdings which have satisfied the requirements of subparagraph (a)(i) or, as appropriate, (a)(ii) for three years or

(ii) in the case of ovine semen, be collected from male animals of the ARR/ARR prion protein genotype as defined in Annex I to Commission Decision 2002/1003/EC[(2)]or

(iii) in the case of ovine embryos, be of the ARR/ARR prion protein genotype as defined in Annex I to Decision 2002/1003/EC.**]]**

Textual Amendments

F3 Substituted by Commission Regulation (EC) No 876/2004 of 29 April 2004 amending Annex VIII to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards trade in ovine and caprine animals for breeding (Text with EEA relevance).

F4 Inserted by Commission Regulation (EC) No 1492/2004 of 23 August 2004 amending Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards eradication measures for transmissible spongiform encephalopathies in bovine, ovine and caprine animals, the trade and importation of semen and embryos of ovine and caprine animals and specified risk material (Text with EEA relevance).

II. CONDITIONS WHICH APPLY DEPENDING ON THE CATEGORY OF THE MEMBER STATE OF ORIGIN OR RESIDENCE OF THE ANIMAL DETERMINED IN ACCORDANCE WITH ANNEX II, CHAPTER C

1. Dispatch to other Member States is to follow the rules of Article 15(1).

2. The BSE category of the Member State of origin of bovine, ovine and caprine animals are to be communicated to the Member State of destination.

3. The following conditions are to apply to movements as referred to in point 1 of bovine animals coming from or having resided in the Member States or one of the regions thereof placed in:

CATEGORIES 3 AND 4

The animals must have:

(a) been born, raised and have remained in herds in which no case of BSE has been confirmed for at least seven years; or

(b) been born after the date from which the ban on the feeding of ruminants with proteins derived from mammals has been effectively enforced.

CATEGORY 5

The animals must have:

(a) been born after the date from which the ban on the feeding of farmed animals with proteins derived from mammals has been effectively enforced; and

(b) been born, raised and have remained in herds in which no case of BSE has been confirmed for at least seven years, and which contain only bovine animals born on the farm or coming from a herd of equivalent status.

Textual Amendments

F1 Substituted by Commission Regulation (EC) No 260/2003 of 12 February 2003 amending Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the eradication of transmissible spongiform encephalopathies in ovine and caprine animals and rules for the trade in live ovine and caprine animals and bovine embryos (Text with EEA relevance).

F2 Substituted by Commission Regulation (EC) No 1492/2004 of 23 August 2004 amending Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards eradication measures for transmissible spongiform encephalopathies in bovine, ovine and caprine animals, the trade and importation of semen and embryos of ovine and caprine animals and specified risk material (Text with EEA relevance).

CHAPTER B

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

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

CHAPTER C

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

I. The following products of animal origin are exempt from the prohibition referred to in Article 16(3), provided that they are derived from bovine animals that satisfy the requirements of Parts II or III below:

— fresh meat;
— minced meat;
— meat preparations;
— meat products;
— petfood which is destined for domestic carnivores.

Date-based Scheme

II. Deboned fresh meat from which all adherent tissues, including obvious nervous and lymphatic tissue, has been removed, and products of animal origin referred to in Part I deriving therefrom obtained from eligible animals from countries or regions in category 5 may be marketed in accordance with the second subparagraph of Article 16(3) when they are obtained from animals born after the date from which the animal feeding standards laid down in Article 7(2) were effectively enforced and certified as meeting the conditions laid down in point 1 and they are produced in establishments which meet the condition laid down in point 9. The competent authority shall ensure

that the conditions with respect to controls laid down in points 2 to 8 and point 10 are complied with.

1. A bovine animal shall be eligible for the Date-based Scheme if it was born and raised in the Member State concerned and if at the time of slaughter it is shown that the following conditions are fulfilled:

(a) the animal has been clearly identifiable throughout its life, enabling it to be traced back to its dam and herd of origin; its unique eartag number, date and holding of birth and all movements after birth are recorded either in the animal's official passport or in an official computerised identification and tracing system; the identity of its dam is known;

(b) the animal is more than six months but less than 30 months of age, determined by reference to an official computer record of its date of birth, or to the animal's official passport;

(c) the competent authority has obtained and verified positive evidence that the dam of the animal has lived for at least six months after the birth of the eligible animal;

(d) the dam of the animal has not developed BSE and is not suspected of having contracted BSE.

Controls

2. If any animal presented for slaughter or any circumstance surrounding its slaughter does not meet all of the requirements of this Regulation, the animal must be automatically rejected and its passport confiscated. If that information becomes available after slaughter, the competent authority must immediately cease issuing certificates and cancel certificates issued. If dispatch has already taken place, the competent authority must notify the competent authority of the place of destination. The competent authority of the place of destination must take the appropriate measures.

3. Slaughter of eligible animals must take place in slaughterhouses which are not used for the slaughter of bovine animals other than those slaughtered under a Date-based Scheme or under a Certified Herd Scheme.

4. The competent authority must satisfy itself that procedures used in the cutting plants ensure that the following lymph nodes have been removed:

popliteal, ischiatic, superficial inguinal, deep inguinal, medial and lateral iliac, renal, prefemoral, lumbar, costocervical, sternal, prescapular, axilliary, caudal and deep cervical.

5. Meat must be traceable back to the eligible animal, or after cutting, to the animals cut in the same batch, by means of an official tracing system until the time of slaughter. After slaughter, labels must be capable of tracing fresh meat and products referred to in Part I back to the eligible animal to enable the consignment concerned to be recalled. In the case of petfood, accompanying documents and records must allow tracing.

6. All approved eligible carcasses must have individual numbers correlated with the eartag number.

7. The Member State must have detailed protocols in place covering:

(a) tracing and controls prior to slaughter;

(b) controls during slaughter;

(c) controls during processing of petfood;

(d) all labelling and certification requirements after slaughter to the point of sale.

8. The competent authority must set up a system for recording checks on compliance so that control can be demonstrated.

The establishment

9. To obtain approval, the establishment must devise and implement a system whereby the eligible meat and/or eligible product is identifiable and all meat can be traced back to the eligible animal, or after cutting, to the animals cut in the same batch. The system must allow full traceability of the meat or products of animal origin at all stages and records must be retained for at least two years. Details of the system employed must be given, in writing, by the management of the establishment to the competent authority.

10. The competent authority must assess, approve and monitor the system provided by the establishment in order to ensure that it provides full segregation and traceability both backwards and forwards.

Certified herd Scheme

III. Deboned fresh meat from which all adherent tissues, including obvious lymphatic and nervous tissue, has been removed, and products of animal origin referred to in Part I, deriving therefrom which are obtained from eligible animals from countries or regions in category 5, may be marketed in accordance with the second subparagraph of Article 16(3) when obtained from animals which are certified as meeting the conditions laid down in point 2 and coming from herds in which no case of BSE has occurred in the last seven years and which are certified as meeting the conditions laid down in point 1 and produced in establishments which meet the condition laid down in point 11. The competent authority shall ensure that the conditions laid down in points 3 to 10 and 12 with respect to the computerised tracing system and the controls are complied with.

Conditions relating to herds

1.

(a) A herd is a group of animals forming a separate and distinct unit, that is a group of animals which is managed, housed and kept separately from any other group of animals and which is identified with unique herd and animal identification numbers.

(b) A herd is eligible when for at least seven years there has been no confirmed case of BSE, nor a suspect case for which the diagnosis of BSE has not been ruled out, in any animal which was still in or had moved through or from the herd.

(c) As an exception to the provisions in point (b), a herd that has been in existence for less than seven years may be considered eligible, after a thorough investigation by the competent veterinary authority, on condition that:

  (i) all animals born or moved into the newly established herd complied with the conditions set out in point (2)(a), (d) and (e); and,

  (ii) the herd has complied with the conditions set out in point (b) during its entire existence.

(d) If a herd is newly established on a holding which experienced a confirmed case of BSE in any animal which was still in or had moved through or from a herd on that holding, the newly established herd can only be eligible after a thorough investigation by the competent veterinary authority, certifying compliance with each of the following conditions to the satisfaction of that authority:

(i) all animals of the affected herd previously held on the same holding have been removed or killed;

(ii) all feed has been removed and destroyed and all feed containers thoroughly cleansed;

(iii) all buildings have been emptied and thoroughly cleansed before the new animals were admitted;

(iv) all conditions set out in point (c) have been complied with.

Conditions relating to the animal

2.

(a) all records of the animal's birth, identity and movements are recorded on an official computerised tracing system;

(b) the animal is more than six months but less than 30 months of age, determined by reference to an official computer record of its date of birth;

(c) its dam has lived for at least six months after its birth;

(d) its dam has not developed BSE and is not suspected of having contracted BSE;

(e) the herd of birth of the animal and all herds through which it has moved are eligible.

Computerised tracing system

3. The official computerised tracing system referred to in point 2(a) will be approved only where it has been in operation for sufficient time to contain all the information, relating to the lifetime and movements of the animals, needed to check compliance with the requirements of this Regulation, and concerns only animals born after the system came into operation. Historical data loaded into a computer for any period before the system was operational will not be accepted for this purpose.

Controls

4. If any animal presented for slaughter or any circumstance surrounding its slaughter does not meet all of the requirements of this Regulation, the animal must be automatically rejected and its passport confiscated. If that information becomes available after slaughter, the competent authority must immediately cease issuing certificates, and cancel certificates issued. If dispatch has already taken place, the competent authority must notify the competent authority of the place of destination. The competent authority of the place of destination must take the appropriate measures.

5. Slaughter of eligible animals must take place in slaughterhouses used exclusively for the slaughter of animals under a Date-based Scheme or under a Certified Herd Scheme.

6. The competent authority must satisfy itself that procedures used in the cutting plants ensure that the following lymph nodes have been removed:

popliteal, ischiatic, superficial inguinal, deep inguinal, medial and lateral iliac, renal, prefemoral, lumbar, costocervical, sternal, prescapular, axilliary, caudal and deep cervical.

7. Meat must be traceable back to the herd of the eligible animal, or after cutting, to the animals cut in the same batch, by means of the computerised tracing system until the time of slaughter. After slaughter, labels must be capable of tracing fresh meat and products referred to in Part I back to the herd to enable the consignment concerned to

be recalled. In the case of petfood, accompanying documents and records must allow tracing.

8. All approved eligible carcasses must have individual numbers correlated with the eartag number.

9. The Member State must have detailed protocols in place covering:

(a) tracing and controls prior to slaughter;

(b) controls during slaughter;

(c) controls during processing of petfood;

(d) all labelling and certification requirements after slaughter to the point of sale.

10. The competent authority must set up a system for recording checks on compliance so that control can be demonstrated.

The establishment

11. To obtain approval, the establishment must devise and implement a system whereby the eligible meat and/or eligible product is identifiable and all meat can be traced back to its herds of origin, or after cutting, to the animals cut in the same batch. The system must facilitate full traceability of the meat or products of animal origin at all stages and records must be retained for at least two years. Details of the system employed must be given, in writing, by the management of the establishment to the competent authority.

12. The competent authority must assess, approve and monitor the system provided by the establishment in order to ensure that it provides full segregation and traceability both backwards and forwards.

CHAPTER D

Conditions applicable to exports

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

(1) **[**F1**[**F3OJ L 349, 24.12.2002, p. 105.**]]**

(2) **[**F1**[**F4OJ L 349, 24.12.2002, p. 105.**]]**

Textual Amendments

F1 Substituted by Commission Regulation (EC) No 260/2003 of 12 February 2003 amending Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the eradication of transmissible spongiform encephalopathies in ovine and caprine animals and rules for the trade in live ovine and caprine animals and bovine embryos (Text with EEA relevance).

F3 Substituted by Commission Regulation (EC) No 876/2004 of 29 April 2004 amending Annex VIII to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards trade in ovine and caprine animals for breeding (Text with EEA relevance).

F4 Inserted by Commission Regulation (EC) No 1492/2004 of 23 August 2004 amending Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards eradication measures for transmissible spongiform encephalopathies in bovine, ovine and caprine animals, the trade and importation of semen and embryos of ovine and caprine animals and specified risk material (Text with EEA relevance).

Status:
Point in time view as at 01/01/2005.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council, ANNEX VIII.