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)

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)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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

Whereas:

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

(2) Article 5 of Regulation (EC) No 999/2001 provides that the bovine spongiform encephalopthy (BSE) status of Member States or third countries or regions thereof (countries or regions) is to be determined by classification into one of three categories. Annex II to that Regulation lays down rules for the determination of the BSE status of countries or regions. Article 5 of that Regulation also provides for a reassessment of the Community categorisation of countries following the establishment by the World Organisation for Animal health (OIE) of a procedure for the classification of countries by category.

(3) Annex V to Regulation (EC) No 999/2001 lays down the rules for the collection and disposal of specified risk materials and Annex IX to that Regulation lays down the rules for the importation into the Community of live animals, embryos, ova and products of animal origin.

(4) During the General Session of the World Organisation for Animal health (OIE) in May 2005, a new simplified procedure for the classification of countries according to their BSE risk based on three categories was adopted.

(5) Regulation (EC) No 999/2001 was amended by Regulation (EC) No 1923/2006 in order to transpose that new simplified categorisation system into Community legislation.

Following that amendment, Annexes II, V and IX to Regulation (EC) No 999/2001 should be amended to take account of the new categorisation system.

(6) In the absence of a decision on the classification of countries in accordance with Article 5(2) or (4) of Regulation (EC) No 999/2001, the provisions in Article 9 and Annex VI did not apply. In view of the fact that the new categorisation system is to apply from 1 July 2007 and in order to align this Annex with the rules applicable under the transitional measures based on scientific evidence and with the amendments made to the Articles, Annex VI should be amended.

(7) Annex VIII to Regulation (EC) No 999/2001 lays down the conditions for the placing on the market and export of live animals, their semen, embryos, ova and products of animal origin. Chapter C of that Annex lays down the conditions for intra-Community trade in certain products of animal origin. Those conditions should be amended to take into account of the new categorisation system.

(8) Point 5 of Part D of Annex XI to Regulation (EC) No 999/2001 lays down measures concerning intra-Community trade of bovine animals born or reared on the United Kingdom before 1 August 1996 and importation into the Community of meat products derived from cervid animals. For human and animal health protection reasons, these measures should continue to apply after 1 July 2007.

(9) For clarity and consistency reasons the provisions for intra-Community trade and export to third countries of bovine animals born or reared on the United Kingdom before 1 August 1996 should be laid down in Annex VIII and the provisions for importation of meat products derived from cervid animals should be laid down in Annex IX.

(10) The transitional measures concerning specified risk material contained in Annex XI to Regulation (EC) No 999/2001 should cease to apply with respect to each country or region immediately following the date of adoption of a decision on classification of that country or region. Annex XI should therefore be repealed.

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

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

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

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

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

Done at Brussels, 25 June 2007.

For the Commission

Markos KYPRIANOU

Member of the Commission

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EC) No 722/2007. (See end of Document for details)*

ANNEX

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

(1) Annex II to Regulation (EC) No 999/2001 is replaced by the following:

ANNEX II

DETERMINATION OF BSE STATUS

CHAPTER A

Criteria

The BSE status of Member States or third countries or regions thereof (hereinafter referred to as countries or regions), shall be determined on the basis of the criteria set out in points (a) to (e).

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

1. Structure of the risk analysis

The risk analyses shall comprise a release assessment and an exposure assessment.

2. Release assessment (external challenge)

2.1. The release 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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EC) No 722/2007. (See end of Document for details)*

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 account in carrying out the release 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;