COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 16.11.2001

Draft

COMMISSION REGULATION (EC) No .../..

of [...]

amending Annex XI to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards bovine vertebral column and amending Regulation (EC) No 1326/2001 as regards animal feeding

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amending Annex XI to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards bovine vertebral column and amending Regulation (EC) No 1326/2001 as regards animal feeding

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) 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) During the transitional period, detailed rules for the removal and the destruction of specified risk materials are laid down in Annex XI, Chapter A to Regulation (EC) No 999/2001. These rules also prohibits the use of bones of bovine, ovine and caprine animals for the production of mechanically recovered meat, as well as the use of certain slaughter techniques on bovine, ovine and caprine animals whose meat is destined to human and animal consumption. It also imposes restrictions on imports of specified risk materials and on certain products of animal origin containing or derived from these materials. Finally it proposes a review of its provisions, in particular with a view to adjust the age for the removal of bovine vertebral column in the light of the statistical probability of the occurrence of BSE in the relevant age groups of the Community's bovine population. This review should be based on the results of BSE monitoring.

(2) In its opinion of 9 December 1997 on Specified Risk Material (SRM), the Scientific Steering Committee (SSC) recommended that the vertebral column should be regarded as SRM because of the clause association and possible contamination with the spinal cord and the dorsal root ganglia.

(3) In its opinion of 20 February 1998 on BSE risk, the SSC stated that the brain, the spinal cord, the dorsal root ganglia and the vertebral column represent respectively 62.3, 25.1, 3.8 and 2.0 % of the total infective load in a BSE infected animal. It recognised in that opinion that based on the quantitative data, the brain, spinal cord, dorsal root ganglia and trigeminal ganglia constitute the major hazards for direct human consumption.

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[1] OJ L 147, 31.5.2001, p. 1.

(4) After experimental oral exposure of cattle to the BSE agent, detection of infectivity in brain and spinal cord occurs approximately after 88-90% of the incubation period. The minimum incubation period in oral BSE exposure pathogenesis studies was 35 months, but this early age of onset occurred in animals receiving very high doses of untreated BSE infective material. The central nervous system was only proven to be infective 3 months before the onset of clinical disease. At 9 months prior to clinical onset no infectivity was observed. In general, the dorsal root ganglia and the spinal cord are considered to pose a higher risk as from the second half of the incubation period.

(5) In its opinion of 12 January 2001 on the safety with regard to BSE of certain bovine tissues and certain animal-derived products, the SSC concludes that meat on the vertebrae of animals above 12 months of age should not be consumed whenever it cannot be demonstrated that the animal is unlikely to be incubating BSE. This probability of slaughtered cattle to be pre-clinically, sub-clinically and clinically infected depends on the probability of them having been exposed to the agent by weighting the effectiveness of risk reduction measures. Finally it agrees that the results of monitoring with rapid post-mortem tests should add information in this respect.

(6) In the monitoring carried out during the first 9 months of 2001, some 5.6 million rapid BSE tests were carried out on bovine animals in the Community. The testing was carried out on a random or systematic basis in all animals over 30 months, and in certain Member States, in all animals over 24 months.

(7) From these 5.6 millions tests, 504 turned out positive. In addition, 724 BSE cases were detected in clinically suspect animals. Positive cases have been detected in all Member States except Austria, Finland, Sweden and Luxembourg. Around 500,000 of the rapid tests were carried out on dead-on-farm and emergency slaughtered animals, 326 of which were positive. On average, 1 in 1500 was positive in this group. More than 5 million tests were carried out in healthy slaughtered animals, 170 of which were positive. On average, 1 in 30,000 was positive in this population.

(8) The youngest animal tested positive so far was 28 months old. These cases were found in emergency slaughtered animals. In the healthy slaughtered population, the youngest positive BSE cases have so far been detected at the age of 42 months.

(9) A preliminary analysis per age classes of positive test cases in the overall sample shows the following distribution: 2 in the 24-36 months class, 6 in the 36-48 months class, 87 in the 48-60 months class and 1203 in the over 60 months class.

(10) In the light of the age distribution of the cases detected up to end September 2001, evidence could be found to demonstrate that the BSE risk reduction measures taken since 1996 are having some effect. An increased age limit for the removal of the vertebral column in bovine animals could therefore be considered.

(11) In order to avoid any disruption of the internal market carcasses or parts of carcasses of bovine animals that still contain vertebral column should be accepted for trade between Member States and when imported from third countries. To control the removal, specific control measures should be laid down and the removal should take place at the level of the cutting plant.

(12) Member States should also have the possibility to allow removal of vertebral column in butcher shops specifically authorised and registered for this purpose. Such derogation should be limited to their territory under strict practical and control conditions.

(13) In its opinion of 9 December 1997 on SRM, the SSC concluded the dura mater should be regarded as SRM because of iatrogenic cases of CJD in humans associated with this tissue and its close association with spinal cord. Following the increased age limit for the removal of vertebral column, dura mater should be removed as SRM from bovine animals over 12 months.

(14) In its opinion of 29 June 2001 on adipose tissue associated with the digestive tract of cattle, sheep and goats, the SSC pointed out that potential infectivity could be found in the mesenteric nerves and the mesenteric lymph nodes situated near the arteria measenterica. It concluded that if slaughter practices cannot permit the removal of this specific area, the whole mesentery should therefore be regarded as SRM.

(15) It is necessary to clarify the measures following the removal of specified risk material and in particular those relating to their staining.

(16) The removal of specified risk material from products destined for food and feed is the single most important public health protection measure. Until classification decisions have been made for third countries, and as a precaution, it is appropriate to keep the minimal protection measures foreseen by Regulation (EC) 999/2001 for imports from all third countries which are not considered BSE free. Some third countries for which it was demonstrated by the SSC risk assessment that the risk of BSE being present in native cattle is highly unlikely, benefit from a derogation from the transitional measures. It is necessary to clarify the measures in which imports from these derogating countries are allowed, and in particular those relating to the additional attestation required in such case. In order to respect international obligations and to allow countries to adjust the certification procedures, a certain delay before the measures become applicable is necessary.

(17) In its opinion of 29 June 2001 on the Geographic BSE Risk of certain third countries, the Scientific Steering Committee (SSC) concluded that, in addition to previously evaluated countries, the occurrence of BSE in native cattle is highly unlikely in Panama and El Salvador. Panama and El Salvador should therefore be added to the list of third countries benefiting from a derogation for all imports of products of animal origin, live bovine animals, embryos and ova.

(18) It is necessary to clarify the measures applying to animal feeding.

(19) The measures provided for in this Regulation are in accordance with the opinion of the [...] Committee,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) 999/2001 is amended as follows:

1. The text in Annex XI, Part A is replaced by the text in Annex to this Regulation.

2. The text in Annex XI, Part D, point 4 is replaced by the following:

"4. Points 2 and 3 shall not apply to imports from:

Argentina

Australia

Botswana

Brazil

Chile

Costa Rica

El Salvador

Namibia

New-Zealand

Nicaragua

Panama

Paraguay

Uruguay

Singapore

Swaziland"

Article 2

[In Article 1 of Regulation (EC) 1326/2001, the second paragraph is replaced by the following:

"2. Article 7 shall not apply to a Member State until the coming into force of the decision determining the BSE status of that Member State, and until the Community provisions on animal feeding relevant to transmissible spongiform encephalopathies are effectively enforced there. Annex XI part C shall apply to that Member State until Article 7 become applicable there."]

Article 3

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

It shall apply from [31 March 2002] at the latest.

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

Done at Brussels, [...]

For the Commission
[...]
Member of the Commission

ANNEX

"ANNEX XI

A. *Concerning specified risk material,* ***mechanically recovered meat and slaughtering techniques***

1. The specified risk material designated below shall be removed and destroyed in accordance with points 5 to 8 and, as appropriate, point 11.

   a) The following tissues are designated as specified risk material:

      i) the skull including the brain and eyes, the tonsils, **the dura mater** and spinal cord of bovine animals aged over 12 months, and the vertebral column excluding the vertebrae of the tail and the transverse processes of the lumbar vertebrae but including dorsal root ganglia of **bovine animals aged over 30 months**, and the intestines from the duodenum to the rectum and **the mesentery** of bovine animals of all ages;

      ii) the skull including the brain and eyes, the tonsils and the spinal cord of ovine and caprine animals aged over 12 months or which have a permanent incisor erupted through the gum, and the spleen of ovine and caprine animals of all ages.

   [Second paragraph deleted]

   b) In addition to the specified risk material listed in (a), the following tissues must be designated as specified risk material in the United Kingdom of Great Britain and Northern Ireland and in Portugal, with the exception of the Autonomous Region of the Azores:

      – the entire head excluding the tongue, including the brain, eyes, trigeminal ganglia and tonsils; the thymus, the spleen and the spinal cord of bovine animals aged over 6 months.

2. a) By way of derogation from point 1 (a) (i), **Finland, Sweden and Austria may** allow the use of vertebral column and dorsal root ganglia from bovine animals born, continuously reared and slaughtered **on their territory, provided the conditions set out in (b) are fulfilled.**

   b) In addition to the requirements laid down in Annex III, Chapter A, Section I, the above Member States shall ensure that one of the approved rapid tests listed in Annex X, Chapter C, point 4 is applied to all bovine animals over 30 months of age which:

      i) have died on the farm or in transport, but which have not been slaughtered for human consumption, with the exception of those dead animals in remote areas with a low animal density situated in Member States where the occurrence of BSE is unlikely;

      ii) were subject to normal slaughter for human consumption.

3. Bones of bovine, ovine and caprine animals shall not be used for the production of mechanically recovered meat.

4. Laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity shall not be carried out on bovine, ovine or caprine animals whose meat is intended for human or animal consumption.

5. Specified risk material shall be removed at:

   a) slaughterhouses;

   b) cutting plants, high-risk processing plants or premises referred to in Articles 3 and 7 of Directive 90/667/EEC, under the supervision of a designated agent appointed by the competent authority. Those establishments shall be approved for that purpose by the competent authority.

[Second paragraph deleted = "points of sale to consumer"]

Where specified risk material is not removed from dead animals that have not been slaughtered for human consumption, the parts of the body containing specified risk material or the entire body must be treated as specified risk material.

6. By way of derogation from point 5, Member States may decide to allow removal of vertebral column from carcasses or parts of carcasses in butcher shops specifically authorised and registered for this purpose, provided that such carcasses or parts of carcasses come from an approved or registered slaughterhouse or cutting plant on their territory.

7. All specified risk material shall be stained with a dye and, as appropriate, marked immediately on removal, and completely destroyed:

   a) by incineration without pre-processing; or,

   b) after pre-processing, provided that **the pre-processed material is stained or marked unless** the dye or marking remains detectable:

      i) in accordance with the systems described in Chapters I to IV, VI and VII of the Annex to Decision 92/562/EEC:

         - by incineration;

         - by co-incineration;

      ii) in accordance at least with the standards set out in Annex I to Council Decision 1999/534/EC, by burial in an approved landfill site.

By way of derogation, entire bodies of dead animals may be destroyed without prior staining or marking.

8. Member States may derogate from the provisions of points 5 and 7 to allow the incineration or burial of specified risk material or entire bodies, without prior staining, or, as appropriate, without removal of the specified risk material, in the circumstances set out in Article 3(2) of Directive 90/667/EEC and by a method which precludes all risk of transmission of a TSE and is approved and verified by the competent authority, in particular where animals have died or have been killed in the context of disease control measures.

9. Member States may despatch specified risk material or the material processed therefrom to other Member States for incineration under the conditions laid down in Article 4(2) of Commission Decision 97/735/EC, where applicable or, where appropriate, in accordance with point 7(b).

This point may be amended at the request of a Member State to allow the despatch of specified risk material or the material processed therefrom to third countries for incineration, conditions governing such export having been adopted.

10. a) The specified risk material referred to in point 1(a) shall not be imported into the Community after 31 March 2001.

b) The products of animal origin listed below shall be subject to the conditions laid down in (c) on import into the Community:

- fresh meat: the meat defined by Directive 64/433/EEC,
- minced meat and meat preparations: the minced meat and meat preparations defined by Directive 94/65/EC[2];
- meat products: the meat products defined by Directive 77/99/EEC[3];
- other products of animal origin: other products of animal origin as defined by Directive 77/99/EEC;
- rendered fats as referred to by Directive 92/118/EEC;
- gelatin as referred to by Directive 92/118/EEC;
- petfood as referred to by Directive 92/118/EEC;
- the processed animal protein referred to in Directive 92/118/EEC;
- bones and bone products as referred to by Directive 92/118/EEC;
- raw material for the manufacture of animal feedingstuffs as referred to by Directive 92/118/EEC;

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2 Council Directive 94/65/EC of 14 December 1994 laying down the requirements for the production and placing on the market of minced meat and meat preparations (OJ L 368, 31.12.1994, p. 10).

3 Council Directive 77/99/EEC of 21 December 1976 on health problems affecting intra-Community trade in meat products (OJ L 26, 31.1.1977, p. 85). Directive as last amended by Council Directive 97/76/EC (OJ L 10, 16.1.1998, p. 25).

[Last indent deleted]

Any reference to "products of animal origin" designates products of animal origin listed in this point and does not concern other products of animal origin containing or derived from those products of animal origin.

c) When the above mentioned products of animal origin, containing material from bovine, ovine or caprine animals are imported into the Community from third countries or regions thereof, the health certificates shall be accompanied by a declaration signed by the competent authority of the country of production, worded as follows:

"**(*)Either**

This product does not contain and is not derived from specified risk material as defined in Annex XI, Section A to Regulation (EC) No 999/2001 produced after 31 March 2001, or mechanically recovered meat obtained from bones of bovine, ovine or caprine animals produced after 31 March 2001. After 31 March 2001 the **bovine, ovine and caprine** animals, **from which this product is derived**, have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity.

Carcasses, half carcasses and quarter carcasses may contain vertebral column on import;

(*)Or

This product does not contain and is not derived from bovine, ovine and caprine materials other than those derived from animals born, reared and slaughtered in the following countries:

Argentina
Australia
Botswana
Brazil
Chile
Costa Rica
El Salvador
Namibia
New-Zealand
Nicaragua
Panama
Paraguay
Uruguay
Singapore
Swaziland

(*) Delete one of these as appropriate"

11. Member States shall carry out frequent official inspections to verify the correct application of this Part and shall ensure that measures are taken to avoid any contamination, particularly in slaughterhouses, cutting plants, animal waste processing plants, high-risk processing plants or premises approved by the Member States in accordance with Article 7 of Directive 90/667/EEC, **butcher shops,** landfill sites and other facilities for storage or incineration.

Member States shall in particular set up a system to ensure and check that:

a) specified risk material used in the production of products referred to in Article 1(2) are used solely for authorised purposes;

b) specified risk material, especially where the removal takes place at establishments or premises other than slaughterhouses, is completely separated from other waste not intended for incineration, is collected separately and is disposed of in accordance with point l and points 5 to 9. Member States may decide to allow dispatch of heads or carcasses containing specified risk material to another Member State after that other Member State has agreed to receive the material and has approved the specific conditions applicable to such transport.

However, carcasses, half carcasses and quarter carcasses containing no specified risk material other than vertebral column, including dorsal root ganglia, may be imported into a Member State, or dispatched to another Member State without the latter's prior agreement.

12. In addition to point 11, Member States shall put in place a control system for the removal of vertebral column. The system shall include at least the following measures:

a) carcasses of bovine animals over 30 months shall be identified in the slaughterhouse by a red stripe on the label referred to in Regulation (EC) No 1760/2000[4];

b) a specific indication of the number of bovine carcasses or parts of carcasses, from which the vertebral column shall be removed, shall be added to the commercial document referred to in [Directive 64/433/EEC[5]].

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- même si l'étendue et la nature des obligations de service public restent encore ouvertes, ces obligations devront refléter les préoccupations liées à la protection de l'environnement.

- en tout état de cause il conviendra de rester attentif au bon développement des interconnexions entre les réseaux. La transmission prochaine d'une proposition de la Commission sur les réseaux énergétiques transeuropéens en fournira l'occasion.

5. De l'avis de la Présidence tel qu'il se reflète dans le présent rapport d'étape, le Conseil devrait désormais être en mesure de progresser rapidement sur les deux propositions [1], dans la perspective notamment du Conseil européen de Barcelone qui sera saisi d'un rapport d'évaluation que la Commission présentera sur la situation dans ces secteurs conformément au point 11 des conclusions du Conseil européen de Stockholm.

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[1] *Sous réserve de la disponibilité des avis du PE qui ne sont pas attendus avant le printemps 2002.*