

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)

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 the first paragraph of Article 23 thereof,

Whereas:

- (1) Regulation (EC) No 999/2001 lays down rules for eradication measures to be carried out following the confirmation of transmissible spongiform encephalopathy (TSE) in bovine, ovine and caprine animals.
- (2) On 14 September 2000, in its opinion on bovine spongiform encephalopathy (BSE)-related culling in cattle, the Scientific Steering Committee (SSC) concluded that largely the same effect can be reached by birth cohort culling as by herd culling. On 21 April 2004, the Biological Hazards panel of the European Food Safety Authority adopted an opinion in which it concludes that insufficient additional argument exists to modify the SSC opinion. The provisions relating to culling in Regulation (EC) No 999/2001 should be brought into line with those opinions.
- (3) In the interest of certainty of Community legislation, it is also necessary to clarify the definition of the cohort of a BSE case and the action to be taken regarding cohort animals in order to avoid different interpretations.
- (4) In addition, it is necessary to clarify the application of TSE eradication measures as they apply to pregnant ewes and to holdings containing multiple flocks. To address practical problems, the rules should be amended regarding holdings producing lambs for further fattening, the introduction of ewes of unknown genotype to infected holdings, and the time period during which derogations are to apply for the destruction of animals in holdings or breeds in which the frequency of the ARR allele is low.

- (5) Scrapie eradication measures, as advised in the opinion of the SSC of 4 April 2002, were inserted in Regulation (EC) No 999/2001, as amended by Commission Regulation (EC) No 260/2003⁽²⁾. Those measures were introduced on a gradual basis, in order to take account of management issues. According to currently available evidence, it is highly unlikely that the carcasses of animals of less than two months of age contain significant amounts of infectivity, provided that the offal including the head is removed. Further amendments to the eradication measures should be made to resolve problems encountered in some Member States in relation to those young animals.
- (6) It is appropriate to introduce restrictions on holdings following the suspicion of scrapie in an ovine or caprine animal in order to avoid movement of other possibly infected animals prior to confirmation of the suspicion.
- (7) Testing requirements to permit the lifting of restrictions on infected holdings have proven to be excessively onerous for large flocks of sheep and should be amended. It is also appropriate to clarify the definition of the target groups for such testing.
- (8) General rules regarding the trade and importation of semen and embryos of ovine and caprine animals are laid down in Council Directive 92/65/EEC⁽³⁾. Specific TSE rules for the placing on the market of semen and embryos of those species should be laid down in this Regulation.
- (9) In line with the current provisions provided for in Regulation (EC) No 999/2001 on specified risk material to exclude the transverse processes of the lumbar and thoracic vertebrae from the list of specified risk material, the spinous processes of these vertebrae, the spinous and transverse processes of the cervical vertebrae and the median sacral crest should also not be considered as specified risk material.
- (10) Regulation (EC) No 999/2001 should therefore be amended accordingly.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

⁽¹⁾ OJ L 147, 31.5.2001, p. 1. Regulation as last amended by Commission Regulation (EC) No 876/2004 (OJ L 162, 30.4.2004, p. 52).

⁽²⁾ OJ L 37, 13.2.2003, p. 7.

⁽³⁾ OJ L 268, 14.9.1992, p. 54. Directive as last amended by Directive 2004/68/EC, (OJ L 139, 30.4.2004, p. 320).

HAS ADOPTED THIS REGULATION:

Article 2

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

Article 1

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

Points 3 and 4 of the Annex to the present Regulation shall apply from 1 January 2005.

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

Done at Brussels, 23 August 2004.

For the Commission

David BYRNE

Member of the Commission

ANNEX

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

1. In Annex I, point 2 is replaced by the following:

'2. For the purpose of this Regulation, the following

- (a) "indigenous case of BSE" means a case of bovine spongiform encephalopathy which has not been clearly demonstrated to be due to infection prior to importation as a live animal;
- (b) "discrete adipose tissue" means internal and external body fat removed during the slaughter and cutting process, in particular fresh fat from the heart, caul and kidney of bovine animals, and fat from cutting rooms;
- (c) "cohort" means a group of bovine animals which includes both:
 - (i) animals born in the same herd as the affected bovine animal, and within 12 months preceding or following the date of birth of the affected bovine animal; and
 - (ii) animals which at any time during the first year of their lives were reared together with the affected bovine animal during the first year of its life;
- (d) "index case" means the first animal on a holding, or in an epidemiologically defined group, in which a TSE infection is confirmed.'

2. Annex VII is replaced by the following:

'ANNEX VII

ERADICATION OF TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY

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 two years prior to, or after, clinical onset of the disease,
- all animals of the cohort of the animal in which the disease was confirmed,
- the possible origin of the disease,
- other animals on the holding of the animal in which the disease was confirmed or on other holdings which may have become infected by the TSE agent or been exposed to the same feed or contamination source,
- the movement of potentially contaminated feedingstuffs, of other material or any other means of transmission, which may have transmitted the TSE agent to or from the holding in question;

(b) in the case of ovine and caprine animals:

- all ruminants other than ovine and caprine animals on the holding of the animal in which the disease was confirmed,
- in so far as they are identifiable, the parents, and in the case of females all embryos, ova and the last progeny of the female animal in which the disease was confirmed,
- all other ovine and caprine animals on the holding of the animal in which the disease was confirmed in addition to those referred to in the second indent,
- the possible origin of the disease and the identification of other holdings on which there are animals, embryos or ova which may have become infected by the TSE agent or been exposed to the same feed or contamination source,
- the movement of potentially contaminated feedingstuffs, other material or any other means of transmission, which may have transmitted the BSE agent to or from the holding in question.

2. The measures laid down in Article 13(1)(c) shall comprise at least:
 - (a) in the case of confirmation of BSE in a bovine animal, the killing and complete destruction of bovine animals identified by the inquiry referred to in the second and third indents of point 1(a); however, the Member State may decide:
 - not to kill and destroy animals of the cohort referred to in the third indent of point 1(a) if evidence has been provided that such animals did not have access to the same feed as the affected animal,
 - to defer the killing and destruction of animals in the cohort referred to in the third indent of point 1(a) until the end of their productive life, provided that they are bulls continuously kept at a semen collection centre and it can be ensured that they are completely destroyed following death;
 - (b) in the case of confirmation of TSE in an ovine or caprine animal, from 1 October 2003, according to the decision of the competent authority:
 - (i) either the killing and complete destruction of all animals, embryos and ova identified by the inquiry referred to in the second and third indents of point 1(b) or
 - (ii) the killing and complete destruction of all animals, embryos and ova identified by the inquiry referred to in the second and third indents of point 1(b), with the exception of:
 - breeding rams of the ARR/ARR genotype,
 - breeding ewes carrying at least one ARR allele and no VRQ allele and, where such breeding ewes are pregnant at the time of the inquiry, the lambs subsequently born, if their genotype meets the requirements of this subparagraph,
 - sheep carrying at least one ARR allele which are intended solely for slaughter,
 - if the competent authority so decides, sheep and goats less than two months old which are intended solely for slaughter;
 - (iii) if the infected animal has been introduced from another holding, a Member State may decide, based on the history of the case, to apply eradication measures in the holding of origin in addition to, or instead of, the holding in which the infection was confirmed; in the case of land used for common grazing by more than one flock, Member States may decide to limit the application of those measures to a single flock, based on a reasoned consideration of all the epidemiological factors; where more than one flock is kept on a single holding, Member States may decide to limit the application of the measures to the flock in which scrapie has been confirmed, provided it has been verified that the flocks have been kept isolated from each other and that the spread of infection between the flocks through either direct or indirect contact is unlikely;
 - (c) in the case of confirmation of BSE in an ovine or caprine animal, killing and complete destruction of all animals, embryos and ova identified by the inquiry referred to in the second to fifth indents of point 1(b).
3. If scrapie is suspected in an ovine or caprine animal at a holding in a Member State, all other ovine and caprine animals from that holding shall be placed under official movement restriction until the results of the examination are available. If there is evidence that the holding where the animal was present when scrapie was suspected is not likely to be the holding where the animal could have been exposed to scrapie, the competent authority may decide that other holdings or only the holding of exposure shall be placed under official control depending on the epidemiological information available.
4. Only the following animals may be introduced to the holding(s) where destruction has been undertaken in accordance with point 2(b)(i) or (ii):
 - (a) male sheep of the ARR/ARR genotype;
 - (b) female sheep carrying at least one ARR allele and no VRQ allele;

- (c) caprine animals, provided that:
- (i) no ovine animals for breeding other than those of the genotypes referred to in points (a) and (b) are present on the holding,
 - (ii) thorough cleaning and disinfection of all animal housing on the premises has been carried out following destocking,
 - (iii) the holding shall be subjected to intensified TSE monitoring, including the testing of all caprine animals which are over the age of 18 months and:
 - either are slaughtered for human consumption at the end of their productive lives, or
 - which have died or been killed on the holding, and which meet the criteria referred to in Annex III, Chapter A, Part II, point 3.
5. Only the following ovine germinal products may be used in the holding(s) where destruction has been undertaken in accordance with point 2(b)(i) or (ii):
- (a) semen from rams of the ARR/ARR genotype;
 - (b) embryos carrying at least one ARR allele and no VRQ allele.
6. During a transitional period until 1 January 2006 at the latest, and by way of derogation from the restriction set out in point 4(b), where it is difficult to obtain replacement ovine animals of a known genotype, Member States may decide to allow non-pregnant ewes of an unknown genotype to be introduced to the holdings referred to in point 2(b)(i) and (ii).
7. Following the application on a holding of the measures referred to in point 2(b)(i) and (ii):
- (a) movement of ARR/ARR sheep from the holding shall not be subject to any restriction;
 - (b) sheep carrying only one ARR allele may be moved from the holding only to go directly for slaughter for human consumption or for the purposes of destruction; however,
 - ewes carrying one ARR allele and no VRQ allele may be moved to other holdings which are restricted following the application of measures in accordance with point 2(b)(ii),
 - if the competent authority so decides, lambs carrying one ARR allele and no VRQ allele may be moved to one other holding solely for the purposes of fattening prior to slaughter; the destination holding shall not contain any ovine or caprine animals other than those being fattened prior to slaughter, and shall not dispatch live ovine or caprine animals to other holdings, except for direct slaughter;
 - (c) if the Member State so decides, sheep and goats less than two months old may be moved from the holding to go directly for slaughter for human consumption; the head and organs of the abdominal cavity of such animals shall however be disposed of in accordance with Article 4(2)(a), (b) or (c) of Regulation (EC) No 1774/2002 of the European Parliament and of the Council (*),
 - (d) without prejudice to subparagraph (c), sheep of genotypes not referred to in subparagraphs (a) and (b) may only be moved from the holding for the purposes of destruction.
8. The restrictions referred to in points 4, 5 and 7 shall continue to apply to the holding for a period of three years from:
- (a) the date of attainment of ARR/ARR status by all ovine animals on the holding or
 - (b) the last date when any ovine or caprine animal was kept on the premises or
 - (c) in the case of point 4(c), the date when the intensified TSE monitoring commenced or
 - (d) the date when all breeding rams on the holding are of ARR/ARR genotype and all breeding ewes carry at least one ARR allele and no VRQ allele, provided that during the three-year period, negative results are obtained from TSE testing of the following animals over the age of 18 months:
 - an annual sample of ovine animals slaughtered for human consumption at the end of their productive lives in accordance with the sample size indicated in the table in Annex III, Chapter A, Part II, point 4; and
 - all ovine animals referred to in Annex III, Chapter A, Part II, point 3 which have died or been killed on the holding.

(*) OJ L 273, 10.10.2002, p. 1.

9. Where the frequency of the ARR allele within the breed or holding is low, or where it is deemed necessary in order to avoid inbreeding, a Member State may decide to:
- (a) delay the destruction of animals as referred to in point 2(b)(i) and (ii) for up to five breeding years;
 - (b) allow ovine animals other than those referred to in point 4 to be introduced to the holdings referred to in point 2(b)(i) and (ii), provided that they do not carry a VRQ allele.
10. Member States applying the derogations provided for in points 6 and 9 shall notify to the Commission an account of the conditions and criteria used for granting them.'
3. In Annex VIII, Chapter A is amended as follows:
- (a) The title of the Chapter is replaced by the following:
- 'Conditions for intra-Community trade in live animals, semen and embryos'**
- (b) In Part I, the following point (d) is added:
- '(d) 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 (*) 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.

(*) OJ L 349, 24.12.2002, p. 105.'

4. Annex IX is amended as follows:
- The following Chapter H is added:

'CHAPTER H

Import of ovine and caprine semen and embryos

Semen and embryos of ovine and caprine animals imported into the Community from 1 January 2005 shall satisfy the requirements of Annex VIII, Chapter A(I)(d).'

5. In Annex XI, Part A, point 1(a)(i) is replaced by the following:
- '(i) The skull excluding the mandible and including the brain and eyes, the 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, and the spinal cord of bovine animals aged over 12 months, and the tonsils, the intestines from the duodenum to the rectum and the mesentery of bovine animals of all ages;'