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)

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)

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 6a(2) and Article 23 thereof,

Whereas:

(1) Regulation (EC) No 999/2001 lays down rules for the monitoring of transmissible spongiform encephalopathies in bovine, ovine and caprine animals and for eradication measures to be carried out following the confirmation of a transmissible spongiform encephalopathy (TSE) in ovine and caprine animals.

(2) In October 2005 the European Food Safety Authority (EFSA) adopted an opinion on the classification of atypical TSE cases in small ruminants. In its opinion EFSA concludes that an operational definition of atypical scrapie is possible and provides the elements for a classification of scrapie cases. EFSA also recommends that surveillance programmes, including tests and sampling arrangements, be used so as to enable detection of all forms of TSE in small ruminants.

(3) It appears appropriate, therefore, to introduce definitions for TSE in small ruminants, scrapie cases, classical scrapie cases and atypical scrapie cases.

(4) Where an animal slaughtered for human consumption is found positive to a rapid test under the current rules, namely Annex III to Regulation (EC) No 999/2001, at least the carcase immediately preceding the test-positive carcase and two carcases immediately following the test-positive carcase on the same slaughter line have to be destroyed, in addition to the test-positive carcase.

(5) The complete destruction, on the same slaughter line, of the three carcases adjacent to a rapid test-positive one is disproportionate with regard to the risk. These carcases should

only be destroyed if the result of a rapid test is confirmed positive or inconclusive after examination by the reference methods.

(6) Regulation (EC) No 999/2001, as amended by Commission Regulations (EC) No 214/2005[(2)] and (EC) No 1041/2006[(3)] provide for increased monitoring programmes in caprine and ovine animals, following the detection of bovine spongiform encephalopathies (BSE) in a goat in 2005 and three unusual TSE cases in sheep where BSE could not be excluded. Those monitoring programmes should be reviewed in the light of the results of two years of intensified testing which have not led to the detection of any additional BSE case in ovine or caprine animals. In order to ensure an efficient implementation of the programmes the reviewed monitoring requirements should apply from 1 July 2007.

(7) The monitoring programmes in ovine and caprine animals should be assessed and reviewed in the light of new scientific data.

(8) In view of the results of the increased monitoring in ovine and caprine animals, the current strict culling and repopulation policy in TSE affected flocks appears to be disproportionate. In addition, several difficulties, in particular regarding repopulation of infected flocks, hamper the effective implementation of measures following the detection of a TSE in a flock.

(9) On 8 March 2007 EFSA adopted an opinion on certain aspects related to the risk of TSEs in ovine and caprine animals. In its opinion, the Authority considers that there is no evidence for an epidemiological or molecular link between classical and/or atypical scrapie and TSEs in humans and that the BSE agent is the only TSE agent identified as zoonotic. In addition, the Authority considers that Current discriminatory tests as described in the EC legislation to be used for discrimination between scrapie and BSE are reliable for the differentiation of BSE from classical and atypical scrapie.

(10) Additional factors which confirm the need to reappraise TSE eradication measures in small ruminants include the absence of scientific evidence to indicate that scrapie is transmissible to humans, the ruling out of BSE in cases of TSE in small ruminants and the detection of atypical TSE cases having a limited spread of infection within a flock but also emerging in sheep with genotypes considered resistant to BSE and classical scrapie.

(11) The structure of the sheep and goat sector is notoriously different across the Community, Member States should therefore have the possibility to apply alternative policies, provided that harmonised rules are established.

(12) The Commission's TSE roadmap, adopted on 15 July 2005, establishes as one of the strategic goals the review of the eradication measures for small ruminants taking into account the new diagnostic tools available but ensuring the current level of consumer protection.

(13) On 13 July 2006 EFSA adopted an opinion on the Breeding Programmes for TSE resistance in sheep. In its opinion EFSA concludes that the breeding programmes increase the robustness of sheep populations against the currently known TSEs and

therefore contributes to both improved animal health and consumer protection. EFSA also made recommendations on the determination of the prion protein genotype.

(14) Article 6a of Regulation (EC) No 999/2001 provides that Member States may introduce breeding programmes to select for resistance to TSEs in their ovine populations. It is necessary to introduce harmonised minimum requirements for those breeding programmes.

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

(16) Commission Decision 2003/100/EC of 13 February 2003 laying down minimum requirements for the establishment of breeding programmes for resistance to transmissible spongiform encephalopathies in sheep[(4)] is obsolete as the provisions provided for therein are now to be replaced by provisions laid down in this Regulation. In the interests of clarity and legal certainty that Decision should be repealed.

(17) 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 I, III, VII and X to Regulation (EC) No 999/2001 are amended in accordance with the Annex to this Regulation.

Article 2

Decision 2003/100/EC is repealed.

Article 3

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

Point (2)(b) of the Annex to this Regulation shall apply from 1 July 2007.

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

Done at Brussels, 26 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 727/2007. (See end of Document for details)*

ANNEX

Annexes I, III, VII and X 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 definitions shall also apply:

(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;

(e) "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;

(f) "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 Community reference laboratory's technical handbook on TSE strain characterisation in small ruminants[(5)];

(g) "classical scrapie case" means a scrapie confirmed case classified as classical in accordance with the criteria laid down in the Community reference laboratory's technical handbook on TSE strain characterisation in small ruminants;

(h) "atypical scrapie case" means a scrapie confirmed case which is distinguishable from classical Scrapie in accordance with the criteria laid down in the Community reference laboratory's technical handbook on TSE strain characterisation in small ruminants.

(2) In Annex III, Chapter A is amended as follows:

(a) In part I, points 6.4 and 6.5 are replaced by the following:

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 4(2)(a) and (b) of Regulation (EC) No 1774/2002, apart from material to be retained in conjunction with the records provided for in Chapter B(III).

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 tested positive or inconclusive animal on the same slaughter line shall be destroyed in accordance with point 6.4. By way of derogation, Member States may decide to destroy the aforementioned carcases only if 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).

(b) Part II is replaced by the following:

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).

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

(a) Member States in which the population of ewes and ewe lambs put to the ram exceeds 750 000 animals shall test in accordance with the sampling rules set out in point 4 a minimum annual sample of 10 000 ovine animals slaughtered for human consumption;

(b) Member States in which the population of goats which have already kidded and goats mated exceeds 750 000 animals shall test in accordance with the sampling rules set out in point 4 a minimum annual sample of 10 000 caprine animals slaughtered for human consumption;

(c) Where a Member State experiences difficulty in collecting sufficient numbers of healthy slaughtered ovine or caprine animals to reach its allotted minimum sample size established in points (a) and (b), it may choose to replace a maximum of 50 % of its minimum sample size 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. In addition a Member State may choose to replace a maximum of 10 % of its minimum sample size 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.

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

Member States 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:

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

— slaughtered for human consumption.