COMMISSION REGULATION (EC) No 553/2008

of 17 June 2008

amending Annex VII 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 monitoring of transmissible spongiform encephalopathies in bovine, ovine and caprine animals and for eradication measures to be carried out following confirmation of a transmissible spongiform encephalopathy (TSE) in ovine and caprine animals.

(2) Annex VII to Regulation (EC) No 999/2001 lays down the eradication measures to be carried out following confirmation of an outbreak of TSE in ovine and caprine animals.

(3) Although TSE has been known to be present in ovine and caprine animals for over two hundred years, there is no evidence of any relationship between outbreaks of TSE in those animals and outbreaks of TSE in humans. Nevertheless, in 2000 the Commission introduced a comprehensive set of measures for the monitoring, prevention, control and eradication of TSE in ovine and caprine animals, on the basis of the limited scientific knowledge available at that time, and in order to ensure that sourcing from ovine and caprine animals' materials is as safe as possible.

(4) Those measures are aimed at gathering as much data as possible on the prevalence of TSE other than bovine spongiform encephalopathy (BSE) in ovine and caprine animals, and on possible links with BSE and transmissibility to humans. The measures are also aimed at reducing as much as possible the occurrence of TSE. The measures include the removal of specified risk materials, an extensive active monitoring programme, measures applicable to flocks infected with TSE and voluntary breeding schemes to increase resistance to TSE in the ovine population. Since the introduction of such measures and with the information obtained from active surveillance programmes carried out in the Member States, no epidemiological link has ever been established between TSE, other than BSE, in ovine and caprine animals and TSE in humans.

(5) Article 7 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [2] provides that in specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure a high level of health protection may be adopted, pending further scientific information for a more comprehensive risk assessment. It also stipulates that such measures must be proportionate and no more restrictive of trade than is required to achieve the high level of health protection sought, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures are to be reviewed within a reasonable period of time.

(6) On 8 March 2007 the European Food Safety Authority (EFSA) adopted an opinion on certain aspects related to the risk of TSE in ovine and caprine animals [3]. In that opinion, EFSA concluded that 'there is no evidence for an epidemiological or molecular link between classical and/or atypical scrapie and TSEs in humans. The BSE agent is the only TSE agent identified as zoonotic. However, in view of their diversity it is currently not possible to exclude transmissibility to humans of other animal TSE agents'. It also concluded that 'current discriminatory tests as described in the Community legislation to be used for discrimination between scrapie and BSE appear, up to now, to be reliable for the differentiation of BSE from classical and atypical scrapie. However, at the current stage of scientific knowledge, neither their diagnostic sensitivity nor their specificity can be assumed to be perfect'.

[1] OJ L 147, 31.5.2001, p. 1. Regulation as last amended by Commission Regulation (EC) No 357/2008 (OJ L 111, 23.4.2008, p. 3).

[2] OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 202/2008 (OJ L 60, 5.3.2008, p. 17).

[3] The EFSA Journal (2007), 466, 1-10.

(7) Following that opinion and in the framework of the Communication from the Commission — TSE Road map of 15 July 2005 ([1]), and in line with the SANCO work programme 2006-07 on TSEs of 21 November 2006 ([2]), 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 ([3]) was adopted. The amendments made to Regulation (EC) No 999/2001 by Regulation (EC) No 727/2007 were aimed at adjusting the measures initially taken as regards TSE in ovine and caprine animals, to take account of updated scientific evidence. Regulation (EC) No 999/2001, as amended by Regulation (EC) No 727/2007, therefore discontinued the obligation to cull the entire flock and provided for certain alternative measures to culling in the event of confirmation of an outbreak of TSE in a holding of ovine or caprine animals and where the presence of bovine spongiform encephalopathy (BSE) had been excluded. In particular, taking into account the fact that the sector for ovine and caprine animals is different across the Community, Regulation (EC) No 999/2001, as amended by Regulation (EC) No 727/2007, introduced the possibility for Member States to apply alternative policies, as laid down in Regulation (EC) No 727/2007, depending on the specific characteristics of the sector in each Member State.

(8) On 17 July 2007, in Case T-257/07, France brought an action against the European Commission before the Court of First Instance of the European Communities, applying for the partial annulment of point 2.3(b)(iii), point 2.3(d) and point 4 of Chapter A of Annex VII to Regulation (EC) No 999/2001, as amended by Regulation (EC) No 727/2007, in particular regarding the measures to be applied to TSE-affected flocks, or alternatively the entire annulment of that Regulation. In its Order of 28 September 2007 ([4]), the Court suspended the application of those provisions pending delivery of a final judgment.

(9) In the Order of 28 September 2007, the Commission's assessment of the available scientific data on the possible risks was questioned. Accordingly, the Commission subsequently asked EFSA to assist it in clarifying the two main premises on which Regulation (EC) No 727/2007 was based. Firstly, the absence of any scientific evidence demonstrating that any TSE agent, other than BSE, may be considered to be a zoonotic agent. Secondly, the possibility to distinguish through molecular and biological tests between BSE and other animal TSE in ovine and caprine animals. On 24 January 2008, EFSA adopted the scientific and technical clarification ([5]), as regards the interpretation of some facets of the conclusions of its Opinion of 8 March 2007, which had been taken into account for the adoption of Regulation (EC) No 727/2007.

(10) As regards the transmissibility of TSE, EFSA confirmed that:

— in ovine animals, no TSE agents other than those causing Classical Scrapie and Atypical Scrapie have been identified,

— in caprine animals, no TSE agents other than those causing BSE, Classical Scrapie and Atypical Scrapie have been identified,

— the operational term 'BSE' covers a TSE of bovine animals that could be caused by at least three distinct TSE agents with heterogeneous biological properties,

— the operational term 'Classical Scrapie' covers a TSE of ovine and caprine animals caused by several TSE agents with heterogeneous biological properties,

— the operational term 'Atypical Scrapie' covers a TSE of ovine and caprine animals that differs from Classical Scrapie. Currently, it is a subject for debate whether it is caused by one or more TSE agents.

(11) However, EFSA cannot exclude transmissibility to humans of other TSE agents other than BSE as:

— experimental transmissions to primate and to transgenic mouse models expressing the human PrP gene are currently used to evaluate the potential capacity of a TSE agent to cross the human species barrier,

— TSE agents other than the Classical BSE agent from three field TSE cases (two Classical Scrapie cases and one L type BSE case) have been demonstrated to cross the modelled human species barrier,

— some limitations to these models have to be considered, including the uncertainty of how well they represent the human species barrier and the uncertainty of how well the experimental inoculation route employed represents exposure under natural conditions.

([1]) COM(2005) 322 final.
([2]) SEC(2006) 1527.
([3]) OJ L 165, 27.6.2007, p. 8.
([4]) OJ C 283, 24.11.2007, p. 28.
([5]) Scientific Report of the Panel on Biological Hazards on a request from the European Commission on 'Scientific and technical clarification in the interpretation and consideration of some facets of the conclusions of its Opinion of 8 March 2007 on certain aspects related to the risk of Transmissible Spongiform Encephalopathies (TSEs) in ovine and caprine animals'. The EFSA Journal (2008), 626, 1-11.

(12) It appears from EFSA's clarifications that the biodiversity of the disease agents in ovine and caprine animals is an important element which does not make it possible to exclude transmissibility to humans and that that diversity increases the likelihood of one of the TSE agents being transmissible. However, EFSA acknowledges that there is no scientific evidence of any direct link between TSE in ovine and caprine animals, other than BSE, and TSE in humans. The EFSA viewpoint that transmissibility to humans of TSE agents in ovine or caprine animals cannot be excluded is based on experimental studies on human species barrier and animal models (primates and mice). Those models, however, do not take into account genetic characteristics of humans which have a major influence on relative susceptibility to prion diseases. They also have limitations when extrapolating results to natural conditions, in particular regarding how well they represent the human species barrier and the uncertainty of how well the experimental inoculation route employed represents exposure under natural conditions. On that basis, it may be considered that although a risk of transmissibility to humans of TSE agents in ovine or caprine animals cannot be excluded, that risk would be extremely low, taking into account the fact that the evidence of transmissibility is based on experimental models which do not represent the natural conditions related to the real human species barrier and the real routes of infection.

(13) As regards the discriminatory tests, EFSA confirmed that:

— based on the limited data available, the discriminatory tests as implemented at European Union level are practicable tools for screening of field TSE cases, as referred to in point 3.2(c) of Chapter C of Annex X to Regulation (EC) No 999/2001, fulfilling the objective of rapid and reproducible identification of TSE cases that have a signature compatible with Classical BSE agent,

— those discriminatory tests cannot be considered to be perfect because of the current lack of understanding of both the true biodiversity of TSE agents in ovine and caprine animals and how the agents interact in case of co-infection.

(14) Following a request by the Commission for clarification as to whether the absence of statistically sufficient data on the performance of the tests is compensated by the procedure in place, which includes a ring trial with additional molecular testing methods in different laboratories and an evaluation by an expert panel chaired by the Community Reference Laboratory for TSEs, EFSA explained that:

— despite consistent performance in ring trials employing samples from experimental ovine BSE cases, there is uncertainty on about their performance in the field because of the lack of detection of natural BSE in ovine or caprine animals,

— TSE positive cases go through the full discriminatory process, including bioassay, only when biochemical discriminatory testing is compatible with BSE signature; therefore, data obtained through this process cannot be used for the evaluation of the sensitivity or the specificity of the discriminatory tests,

— increasing the number of negative results during TSE discriminatory testing of ovine or caprine animals cannot compensate for the absence of statistically sufficient data on the performance of the tests.

(15) EFSA acknowledged that the discriminatory tests established in Regulation (EC) No 999/2001 are practicable tools fulfilling the objective of rapid and reproducible identification of TSE cases that have a signature compatible with the classical BSE agent. Given the absence of scientific evidence of co-infection of BSE and other TSE agents in ovine or caprine animals in natural conditions, and given that the prevalence of BSE in ovine, if present, or caprine animals is very low and therefore the possibility of co-infection would be even lower, the number of BSE cases missed in ovine and caprine animals would be extremely low. Therefore, although the discriminatory tests cannot be considered to be perfect, it is appropriate to consider them as a suitable tool for the purposes of the TSE eradication objectives pursued by Regulation (EC) No 999/2001.

(16) In its Opinion of 25 January 2007 [1], EFSA gave an estimation of the likely prevalence of BSE in ovine animals. The Authority concluded that in high-risk countries there is a rate of less than 0,3 to 0,5 cases of BSE per 10 000 healthy slaughtered animals. EFSA also stated that in the European Union 'there is a 95 % confidence that the number of cases is equal to or below four cases per million sheep; at a 99 % confidence level, the number becomes equal to or below six cases per million. Since no BSE case has yet to be confirmed in sheep, the most likely prevalence is zero'. Since the introduction in 2005 of the discriminatory tests procedure, as set out in point 3.2(c) of Chapter C of Annex X to Regulation (EC) No 999/2001, 2 798 discriminatory tests have been carried out in TSE-affected ovine animals and 265 discriminatory tests have been carried out in TSE-affected caprine animals and none of them have been confirmed as BSE-like.

[1] Opinion of the Scientific Panel on Biological Hazards on a request from the European Commission on the quantitative risk assessment on the residual BSE risk in sheep meat and meat products, The EFSA Journal (2007) 442, 1-44.

(17) A high level of protection of human life and health is assured in the pursuit of Community policies. Community measures governing food and feed must be based on an appropriate assessment of the possible risks for human and animal health and must, taking into account existing scientific evidence, maintain or, if scientifically justified, increase the level of protection of human and animal health. It is impossible, however, to consider the complete elimination of risk as a realistic objective for any risk management decision in matters regarding food safety, where the cost and benefits of risk-reducing measures have to be carefully weighed in order to ensure the measure's proportionality. It is the role and responsibility of the risk manager to decide the acceptable level of risk, taking into account all the elements present in a scientific risk assessment.

(18) The Commission, in its role as risk manager on EU level, is responsible for establishing the acceptable level of risk and adopting measures that are the most appropriate for maintaining a high level of protection of public health. It has reviewed and assessed the most recent scientific information as regards the transmissibility of TSE to humans. It has assessed any risk that is present as being currently very low.

(19) The measures set out in Annex VII to Regulation (EC) No 999/2001 should therefore be reassessed in order to ensure that they do not impose a burden on the Member States and economic operators that is not appropriate to the level of risk involved and disproportionate to the objective pursued.

(20) The measures laid down in Annex VII to Regulation (EC) No 999/2001 should therefore be amended in order to make it possible for Member States to dispense with the requirement of total or partial herd culling if a TSE case is detected in ovine or caprine animals.

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

(22) 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

Annex VII to Regulation (EC) No 999/2001 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the 60th day following that of 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, 17 June 2008.

For the Commission
Androulla VASSILIOU
Member of the Commission

ANNEX

In Annex VII to Regulation (EC) No 999/2001, Chapter A is replaced by the following:

'CHAPTER A

Measures following confirmation of the presence of a TSE

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,

— insofar 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 TSE agent to or from the holding in question.

2. The measures laid down in Article 13(1)(c) shall comprise at least:

2.1. 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.

2.2. If a TSE is suspected in an ovine or caprine animal on 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 the TSE was suspected is not likely to be the holding where the animal could have been exposed to a TSE, 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.

2.3. In the case of confirmation of TSE in an ovine or caprine animal:

(a) if BSE cannot be excluded after the results of a ring trial carried out in accordance with the procedure set out in Annex X, Chapter C, point 3.2(c), the 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);

(b) if BSE is excluded in accordance with the procedure set out in Annex X, Chapter C, point 3.2(c), pursuant to the decision of the competent authority:

either

(i) 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). The conditions set out in point 3 shall apply to the holding;

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 three months old which are intended solely for slaughter.

The conditions set out in point 3 shall apply to the holding;

or

(iii) a Member State may decide not to kill and destroy the animals, identified by the inquiry referred to in the second and third indents of point 1(b) where it is difficult to obtain replacement ovine animals of a known genotype or 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, or based on a reasoned consideration of all the epidemiological factors. The conditions set out in point 4 shall apply to the holding;

(c) by way of derogation from the measures set out in point (b), and only where the TSE case confirmed on a holding is an atypical scrapie case, the Member State may decide to apply the measures laid down in point 5;

(d) Member States may decide:

(i) to replace the killing and complete destruction of all animals referred to in b(i) by slaughtering for human consumption;

(ii) to replace the killing and complete destruction of animals referred to in b(ii) by slaughtering for human consumption provided that:

— the animals are slaughtered within the territory of the concerned Member State,

— all animals which are over 18 months of age or have more than two permanent incisors erupted through the gum and are slaughtered for human consumption shall be tested for the presence of TSE in accordance with the laboratory methods set out in Annex X, Chapter C, point 3.2 (b);

(e) the prion protein genotype of ovine animals, up to a maximum of 50, killed and destroyed or slaughtered for human consumption in accordance with points (b)(i) and (iii) shall be determined;

(f) 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 delay the destruction of animals as referred to in point 2.3 (b)(i) and (ii) for up to five breeding years.

2.4. 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 the TSE 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.

3. Following the application on a holding of the measures referred to in point 2.3 (a) and (b)(i) and (ii):

3.1. Only the following animals may be introduced to the holding(s):

(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.

3.2. Only the following ovine germinal products may be used in the holding(s):

(a) semen from rams of the ARR/ARR genotype;

(b) embryos carrying at least one ARR allele and no VRQ allele.

3.3. Movement of the animals from the holding shall be subject to the following conditions:

(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 2.3 (b)(ii) or 4,

— if the competent authority so decides, lambs and kids may be moved to one other holding solely for the purposes of fattening prior to slaughter; the holding of destination 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 within the territory of the concerned Member State;

(c) caprine animals may be moved provided that the holding is subjected to intensified TSE monitoring, including the testing of all caprine animals which are over the age of 18 months and:

(i) are slaughtered for human consumption at the end of their productive lives; or

(ii) have died or been killed on the holding, and meet the conditions set out to in Annex III, Chapter A, Part II, point 3;

(d) if the Member State so decides, lambs and kids less than three months old may be moved from the holding to go directly for slaughter for human consumption.

3.4. The restrictions set out in points 3.1, 3.2 and 3.3 shall continue to apply to the holding for a period of two 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) the date when the intensified TSE monitoring set out in 3.3 (c) 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 two-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 referred to in the Table in Annex III, Chapter A, Part II, point 5, and

— all ovine animals referred to in Annex III, Chapter A, Part II, point 3 which have died or been killed on the holding.

4. Following the application on a holding of the measures set out in point 2.3 (b)(iii) and for a period of two breeding years following the detection of the last TSE case:

(a) all ovine and caprine animals on the holding shall be identified;

(b) all ovine and caprine animals on the holding, may be moved only within the territory of the concerned Member State for slaughter for human consumption or for the purposes of destruction; all animals over the age of 18 months slaughtered for human consumption shall be tested for the presence of TSE in accordance with the laboratory methods laid down in Annex X, Chapter C, point 3.2(b);

(c) the competent authority shall ensure that embryos and ova are not dispatched from the holding;

(d) only the semen from rams of the ARR/ARR genotype and embryos carrying at least one ARR allele and no VRQ allele may be used in the holding;

(e) all ovine and caprine animals which are over the age of 18 months which have died or been killed on the holding shall be subject to TSE testing;

(f) only male sheep of the ARR/ARR genotype and female ovine animals from holdings where no TSE cases have been detected or from flocks fulfilling the conditions set out in point 3.4 may be introduced in the holding;

(g) only caprine animals from holdings where no TSE cases have been detected or from flocks fulfilling the conditions of point 3.4 may be introduced in the holding;

(h) all ovine and caprine animals in the holding shall be subject to common grazing restrictions to be determined by the competent authority, based on a reasoned consideration of all the epidemiological factors;

(i) by way of derogation of point (b) if the competent authority so decides, lambs and kids may be moved to another holding within the same Member State solely for the purposes of fattening prior to slaughter; provided that the holding of destination 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 within the territory of the concerned Member State.

5. Following the application of the derogation provided for in point 2.3 (c) the following measures shall apply:

(a) 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). Member States may decide to determine the prion protein genotype of ovine animals which have been killed and destroyed;

(b) or, for a period of two breeding years following the detection of the last TSE case, at least the following measures:

(i) all ovine and caprine animals in the holding shall be identified;

(ii) the holding must be subject to intensified TSE monitoring for a period of two years, including the testing of all ovine and caprine animals which are over the age of 18 months and slaughtered for human consumption and all ovine and caprine animals over the age of 18 which have died or been killed on the holding;

(iii) the competent authority shall ensure that live ovine and caprine animals, embryos and ova from the holding are not dispatched to other Member States or third countries.

6. Member States applying the measures set out in point 2.3(b)(iii) or the derogations provided for in points 2.3(c) and (d) shall notify to the Commission an account of the conditions and criteria used for granting them. Where additional TSE cases are detected in flocks where derogations are applied, the conditions for granting such derogations shall be reassessed.'