Commission Regulation (EC) No 746/2008 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)

COMMISSION REGULATION (EC) No 746/2008

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'.

(7) Following that opinion and in the framework of the Communication from the Commission — TSE Road map of 15 July 2005[(4)], and in line with the SANCO work programme 2006-07 on TSEs of 21 November 2006[(5)], 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[(6)] 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[7], 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[8], 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.

(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[9], 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.

(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