JUDGMENT OF THE GENERAL COURT (Third Chamber, Extended Composition)

9 September 2011 *

In Case T-257/07,

French Republic, represented initially by E. Belliard, G. de Bergues, R. Loosli-Surrans and A.-L. During, and subsequently by E. Belliard, G. de Bergues, R. Loosli-Surrans and B. Cabouat, acting as Agents,

applicant,

v

European Commission, represented by M. Nolin, acting as Agent,

defendant,

* Language of the case: French.

supported by

United Kingdom of Great Britain and Northern Ireland, represented initially by I. Rao and C. Gibbs, subsequently by I. Rao and L. Seeboruth, and finally by L. Seeboruth and F. Penlington, acting as Agents, and by T. Ward, Barrister,

intervener,

APPLICATION for annulment of 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 (OJ 2008 L 202, p. 11), in that it authorises less restrictive measures of surveillance and eradication than those earlier prescribed for ovine and caprine flocks,

THE GENERAL COURT (Third Chamber, Extended Composition),

composed of J. Azizi (Rapporteur), President, E. Cremona, I. Labucka, S. Frimodt Nielsen and K. O'Higgins, Judges,

Registrar: C. Kristensen, Administrator,

having regard to the written procedure and further to the hearing on 6 July 2010,

gives the following

Judgment

Legal context

1. *Regulation (EC) No 178/2002*

1 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 (OJ 2002 L 31, p. 1) provides:

'1. 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 the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.

2. Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.'

2. *Regulation (EC) No 999/2001*

2 Article 13(1) of 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 (OJ 2001 L 147, p. 1) provides:

'When the presence of a TSE has been officially confirmed, the following measures shall be applied as soon as possible:

(a) all parts of the body of the animal shall be disposed of …;

(b) an inquiry shall be carried out to identify all animals at risk in accordance with Annex VII, point 1;

(c) all animals and products thereof at risk, as listed in Annex VII, point 2, [to] this Regulation, identified by the inquiry referred to in point (b) of this paragraph shall be killed and disposed of in accordance with Regulation (EC) No 1774/2002.'

3 Before the entry into force of Commission Regulation (EC) No 727/2007 of 26 June 2007 amending Annexes I, III, VII and X to Regulation (EC) No 999/2001 (OJ 2007 L 165, p. 8), Annex VII to Regulation No 999/2001, headed 'Eradication of transmissible spongiform encephalopathy', provided:

'1. The inquiry referred to in Article 13(1)(b) must identify:

…

(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 TSE agent to or from the holding in question.

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

…

(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) 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).'

4 Article 23 of Regulation No 999/2001 provides:

'After consultation of the appropriate scientific committee on any question which could have an impact on public health, the annexes shall be amended or supplemented and any appropriate transitional measures shall be adopted in accordance with the procedure referred to in Article 24(2) …'

5 Article 24a of Regulation No 999/2001 provides:

'Decisions to be adopted in accordance with one of the procedures referred to in Article 24 shall be based on an appropriate assessment of the possible risks for human and animal health and shall, taking into account existing scientific evidence, maintain, or if scientifically justified increase, the level of protection of human and animal health ensured in the Community.'

Contested measures

6 In order to take account of the most recent scientific data, Annexes I, III, VII and X to Regulation No 999/2001 governing certain measures to control transmissible spongiform encephalopathies (TSEs) in ovine and caprine animals were amended by Regulation No 727/2007.

7 Annex VII to Regulation No 999/2001, which lays down inter alia eradication measures to be applied following confirmation of the existence of a case of TSE within a flock of ovine or caprine animals, was then the subject of a further amendment by Commission Regulation (EC) No 746/2008 of 17 June 2008 amending Annex VII to Regulation (EC) No 999/2001 (OJ 2008 L 202, p. 11; 'the contested regulation').

8 The contested regulation amended Annex VII to Regulation No 999/2001 by inserting a Chapter A, headed 'Measures following confirmation of the presence of a TSE', and replacing point 2(b) of Annex VII to Regulation No 999/2001 with the following:

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

…

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.

…'

9 Point 4 of Chapter A of Annex VII to Regulation No 999/2001, inserted by the contested regulation, states:

'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);

…

(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;

…'

10 In addition, point 2.3(d) of Chapter A of Annex VII to Regulation No 999/2001, as amended by the contested regulation, provides:

'(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)'.

11 Finally, point 3.1 of Chapter A of Annex VII to Regulation No 999/2001, amended by the contested regulation, is identical to point 4 of the previous version of Annex VII to Regulation No 999/2001 and provides:

'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.'

Facts

1. *Transmissible spongiform encephalopathies*

12 TSEs are neurodegenerative diseases with a slow rate of development and fatal outcome. They are characterised by particular lesions of the central nervous system (the brain and spinal cord) and affect both animals and humans.

13 TSEs are all caused by a non-conventional transmissible agent called a 'prion'. This term refers to an infectious proteinaceous infectious particle, namely an abnormal form of the prion protein (PrP), which is a normal protein of the host.

14 Among the TSEs which can affect ovine, caprine or bovine animals, it is possible to distinguish the following pathologies: bovine spongiform encephalopathy (BSE), classical scrapie and atypical scrapie.

2. *Bovine spongiform encephalopathy*

15 BSE is a TSE which was identified for the first time in November 1986 in the United Kingdom. It affects bovine animals and is transmissible to humans, in whom it causes a new variant of Creutzfeldt-Jakob disease. It is also considered to be a disease capable of affecting ovine and caprine animals. On the basis of molecular and histopathological criteria, it is possible to distinguish classical BSE, L-type BSE and H-type BSE.

3. *Scrapie*

16 Scrapie is a TSE which affects ovine and caprine animals. It has been known in Europe since the early 18th century. It is transmitted mainly from the mother to her progeny immediately after birth or from the mother to other receptive newborns which are exposed to the foetal waters or to tissues from an infected animal. The frequency of transmission of scrapie to adult animals is much lower.

17 The term 'classical scrapie' refers to a group of varieties (strains) of TSE not classified to date but which have a number of characteristics considered representative. Those pathologies manifest themselves, from a molecular point of view, in wide dissemination of the prion within the organism, in contagion within flocks and between flocks and in genetic susceptibility or genetic resistance which varies according to the animal.

18 Sheep develop scrapie differently depending on the structure of the gene coding for PrP ('the PrP gene') and, more specifically, on the nature of the three amino-acids at positions 136, 145 and 171 in the PrP amino-acid sequence and which are designated by the upper-case letters 'A' for alanine, 'R' for arginine, 'Q' for glutamine and 'V' for valine, which serve to distinguish between the various forms of PrP. Four alleles of the PrP gene are known, namely the VRQ, ARQ, AHQ and ARR alleles. Sheep carrying the VRQ allele are hyper-susceptible to scrapie. They develop that disease rapidly and detectable traces of prion are found in many of the animal's organs throughout the disease incubation period. Sheep carrying ARQ or AHQ alleles are relatively susceptible to scrapie. Finally, sheep carrying the ARR allele have a virtually absolute resistance to scrapie. Animals carrying at least one ARR allele are semi-resistant to scrapie. In those animals, multiplication of the prion is very slow. It is confined to the nervous system and the prion is not detectable before the appearance of the clinical signs of the disease.

19 The term 'atypical scrapie' seems to correspond to a single variety of TSE. That pathology has characteristics considered atypical in small ruminants, such as a concentration of the prion in the central nervous system, limited or non-existent contagion and the absence of confirmed genetic resistance. Animals of the ARR/ARR genotype are therefore susceptible to infection with that pathology. However, the concentration of the prion in the central nervous system renders the screening measures and the removal of risk materials at the slaughterhouse very effective.

4. *Developments in Community policy for controlling TSEs in ovine and caprine animals*

20 Given that there was a theoretical possibility that BSE could also infect ovine and caprine animals under natural conditions, measures for the prevention and eradication of TSEs in the ovine and caprine population were introduced into Community legislation (see, inter alia, recital 3 in the preamble to Commission Regulation (EC) No 1139/2003 of 27 June 2003 amending Regulation (EC) No 999/2001 as regards monitoring programmes and specified risk material (OJ 2003 L 160, p. 22)).

21 On 22 May 2001, the Parliament and the Council adopted Regulation No 999/2001 which brings together within a single text all the provisions concerning control of TSEs which existed on that date. That regulation prohibits the feeding to ruminants of meal derived from animal protein, also known as meat and bone meal or 'MBM' (see Article 7(1) and Annex IV). It requires the disposal of the 'specified risk material', also known as 'SRM', that is to say, the tissues which are most susceptible to infection by a TSE (see Article 8 and Annex V). It lays down measures concerning animals

suspected of having been infected with a TSE and measures to be followed in the case of confirmation of the presence of a TSE in animals. Those measures include the destruction of animals at risk as defined in Annex VII to Regulation No 999/2001 in its original version (see Articles 12 and 13 and Annex VII). Moreover, it requires each Member State to introduce an annual programme for monitoring TSEs. For ovine and caprine animals, that monitoring is to be carried out inter alia on the basis of screening using 'rapid tests' on samples of the ovine and caprine population (see Article 6 and Annex III). Finally, in order to take account of developments in scientific knowledge, Article 23 of that regulation provides that its annexes may be amended and supplemented subject to compliance with a comitology procedure including consultation of the Scientific Steering Committee.

22 In accordance with the latter provision, Regulation No 99/2001 was amended on several occasions between 2001 and 2007. Those amendments related inter alia to measures to control TSEs in ovine and caprine animals in the light of developments in scientific knowledge concerning TSEs.

23 Thus, on 14 February 2002, the Commission adopted Regulation (EC) No 270/2002 amending Regulation (EC) No 999/2001 as regards specified risk material and epidemio-surveillance for TSEs and amending Regulation (EC) No 1326/2001 as regards animal feeding and the placing on the market of ovine and caprine animals and products thereof (OJ 2002 L 45, p. 4). The purpose of that regulation is, inter alia, to revise the rules for the monitoring of TSEs in ovine and caprine animals to take account of the opinion of 18 and 19 October 2001 of the Scientific Steering Committee, which recommended that a survey of the incidence of TSEs should urgently be carried out with the available 'rapid tests' using a statistically sound sample design and size (see recital 2 in the preamble to Regulation No 270/2002). That regulation thus provides for the monitoring of ovine and caprine animals on the basis of 'rapid tests' carried out by the Member State on a sample of a minimum size significantly larger than that laid down in the previous version of Regulation No 999/2001. In addition, it provides

that the prion genotype is to be determined for each positive TSE case in sheep (see Annex I to Regulation No 270/2002).

24 The 'rapid tests' referred to in Regulation No 999/2001 and its amended versions are tests which make it possible to detect TSEs in a short period of time on the basis of samples taken from the bodies of animals or from the carcasses of animals taken to slaughter. That screening by means of 'rapid tests' enables only the existence of a TSE to be identified, but not its type, that is BSE, classical scrapie or atypical scrapie. Where the results of those 'rapid tests' are positive, the brainstem is sent to a reference laboratory specified in Annex X to Regulation No 999/2001 ('the reference laboratory') to undergo confirmatory examinations. The confirmatory examinations consist of examinations by immunocytochemistry, examinations by immunoblotting, histopathological examinations of the cerebral tissues and/or the demonstration of characteristic fibrils by electron microscopy (taken together, 'the confirmatory examinations') (see Commission Regulation (EC) No 1248/2001 of 22 June 2001 amending Annexes III, X and XI to Regulation (EC) No 999/2001 (OJ 2001 L 173, p. 12)). Where, following those tests, BSE cannot be excluded, those tests are to be supplemented by biological tests, also known as 'bioassays' or 'strain typing'. Those tests consist in inoculating tissues contaminated with TSE into the brain of a live mouse in order to determine the nature of the TSE in question, namely BSE or scrapie. When the mouse dies, a microscopic examination of its brain is carried out and the results of that examination make it possible to determine the exact nature of the TSE. Those biological tests make it possible to determine with accuracy whether or not the TSE is BSE only after several years. Tests to distinguish BSE from other TSEs are commonly referred to as 'discriminatory tests'.

25 At the time of the adoption of Regulation No 270/2002, the only reliable discriminatory tests were biological tests. There were no reliable molecular discriminatory tests making it possible to distinguish between BSE and scrapie infection in ovine and caprine animals (see recital 3 in the preamble to Regulation No 1139/2003).

26 In June 2003, the Commission commissioned the reference laboratory to bring together a group of experts on strain typing of TSEs ('STEG') whose task was to develop and validate the use of tests to replace biological discriminatory tests for TSEs. STEG's work led to the validation of 'biochemical' or 'molecular' tests capable of differentiating BSE from scrapie. Those molecular discriminatory tests make it possible to exclude the presence of BSE in tissues in the space of a few days or even a few weeks.

27 On 12 January 2005, following the development of the molecular discriminatory tests, the Commission adopted Regulation (EC) No 36/2005 amending Annexes III and X to Regulation (EC) No 999/2001 as regards epidemio-surveillance for TSEs in bovine, ovine and caprine animals (OJ 2005 L 10, p. 9), in order, inter alia, to permit the use of those molecular discriminatory tests in the monitoring system introduced by Regulation No 999/2001.

28 Thus, Regulation No 36/2005 provides that, if, in the context of monitoring flocks of caprine and ovine animals, the result of 'rapid tests' on a sample taken proves inconclusive or positive and if that result is confirmed during the confirmatory examinations, the animal is to be regarded as a 'positive scrapie case', also known as an 'index case'. That case is to be subjected to primary molecular testing with discriminatory immunoblotting. Where the primary testing does not make it possible to exclude the presence of BSE, that case is then to be subjected to three further discriminatory molecular tests: a second test with immunoblotting, a test with immunocytochemistry and an enzyme-linked immunosorbent assay, also known as an ELISA. Only samples indicative for BSE and those inconclusive following those discriminatory molecular tests are to undergo mouse bioassays for final confirmation (see point 3.2 of Chapter C of Annex X to Regulation No 999/2001, as amended by Regulation No 36/2005). That regulation also requires TSE typing with discriminatory tests for all prion strains

detected in small ruminants following a rapid test. Finally, the regulation requires testing of a large sample of all flocks containing an infected animal.

29 Under the regulations cited above, Member States had only the choice, when an animal was infected with a TSE, which was not BSE, in a flock of ovine or caprine animals, either to destroy all the animals in the flock to which the infected animal belonged or, where the infected animal was an ovine animal, only to destroy the genetically susceptible animals in the flock after the genotype of all the animals in the flock had been determined in order to distinguish susceptible animals from resistant animals. In addition, the Member State was free not to kill sheep and goats less than two months old which were intended solely for slaughter (see paragraph 3 above). By contrast, where an animal was infected with BSE, Member States were required to ensure that all sheep and goats, embryos, ova and all animals were killed and completely destroyed, and that the material and other means of transmission were disposed of.

30 Following the confirmation, on 28 January 2005, of the presence of BSE in a goat born in 2000 and slaughtered in France in 2002, a programme of increased monitoring of caprine animals was introduced. It was the first case of BSE in a small ruminant under natural conditions (see recitals 2 to 4 in the preamble and annex to Commission Regulation (EC) No 214/2005 of 9 February 2005 amending Annex III to Regulation (EC) No 999/2001 as regards monitoring of TSEs in caprine animals (OJ 2005 L 37, p. 9)).

31 On 15 July 2005, the Commission adopted a communication entitled 'TSE Road Map' (COM(2005) 322 final; 'the TSE Road Map'), in which it announced its intention to propose measures designed to relax the eradication measures in force for small ruminants taking into account the new diagnostic tools available while ensuring the current level of consumer protection. In particular, it stated that the molecular discriminatory testing in force since January 2005 made it possible to exclude the presence of BSE within a few weeks in most TSE cases. Furthermore, it took the view that, when

BSE was excluded, a public health risk was no longer present and total herd culling might be considered disproportionate on public health grounds. It then presented a table showing, in percentages ranging from 0.3 to 3.5, the number of sheep and goats declared 'positive' within infected herds for the period from 2002 to 2004. It also stated that it wished to propose a relaxation of the policy of culling sheep and goats for all cases where BSE was excluded, with an increased testing regime within the infected herds and the slaughter for human consumption of all animals of all ages in infected herds if the results of 'rapid testing' were negative. Finally, it stated that conditions for herd certification should also be considered as an additional way of eradicating TSEs (see points 2.5.1 and 2.5.2 of the TSE Road Map).

32 On 21 September 2005, the French authorities referred the matter to the Agence française de sécurité sanitaire des aliments (French Food Safety Authority; 'AFSSA') so that it could examine, firstly, the health risks entailed by the measures proposed by the Commission in the TSE Road Map with regard to ovine and caprine animals and, secondly, the reliability of discriminatory tests.

33 On 26 October 2005, the European Food Safety Authority (EFSA) adopted an opinion on classification of atypical TSE cases in small ruminants. In that opinion, it concluded that an operational definition of atypical scrapie was possible. In addition, it recommended that monitoring programmes use appropriate combinations of tests and sampling to ensure that atypical scrapie cases continue to be identified.

34 Between December 2005 and February 2006, the monitoring programmes for TSEs implemented in the European Community made it possible to detect two sheep from France and one sheep from Cyprus suspected of being infected with BSE. In an

opinion of 8 March 2006, a panel of experts on TSEs chaired by the reference laboratory considered that, even though the samples from those three sheep were not consistent with the data contained in the database for 'experimental ovine BSE', there was not sufficient evidence to eliminate the presence of BSE categorically. Consequently, some biological tests were undertaken by inoculating mice with the three suspect samples. Following the detection of those three suspect cases, the Commission introduced increased monitoring of TSEs in ovine animals in all the Member States (see, inter alia, recitals 2 and 5 in the preamble and annex to Commission Regulation (EC) No 1041/2006 of 7 July 2006 amending Annex III to Regulation (EC) No 999/2001 as regards monitoring of TSEs in ovine animals (OJ 2006 L 187, p. 10)).

35 On 15 May 2006, AFSSA delivered an opinion on the developments in Community legislation proposed by the TSE Road Map. In that opinion, it opposed the Commission's proposal to relax the culling policy in order to allow the release for human consumption of meat from animals from herds of small ruminants infected with scrapie. It expressed the view that 'rapid tests' for prion strain typing, namely molecular discriminatory tests, did not make it possible to exclude the presence of BSE in a flock and that it was not possible to conclude that, with the exception of BSE, all TSE strains potentially present in small ruminants, including atypical forms, did not pose any health risk for humans.

36 The proposals contained in the TSE Road Map were submitted to the Standing Committee on the Food Chain and Animal Health, which is the competent committee referred to in Article 23 of Regulation No 999/2001.

37 On 22 June and 6 December 2006, the French authorities again referred the matter to AFSSA so that it could assess in detail the measures proposed by the Commission concerning classical scrapie and atypical scrapie.

38 On 15 January 2007, AFSSA gave an opinion relating to the developments in health measures in herds of ovine and caprine animals where a classical or atypical scrapie case was detected after the referrals by the French authorities on 22 June and 6 December 2006. In that opinion, it considered that discriminatory tests did not make it possible to exclude the presence of BSE either in the animal tested or, a fortiori, in the flock to which that animal belonged and that the transmission to humans of TSEs other than BSE could not be excluded. Moreover, it stated that products obtained from ovine and caprine animals from herds infected with classical scrapie, which had been slaughtered under the conditions described in the TSE Road Map, represented an additional risk to public health as compared with products from only genetically resistant ovine animals. Finally, according to AFSSA, a quantitative evaluation of those risks was impossible due to the inadequacy of the data concerning the real prevalence of scrapie in all affected flocks and due to the inadequacy of the data concerning the real genetic structure of the ovine population in general. However, it considered, on the basis of a rough estimate, that the relative risk represented by an animal from an affected flock as compared with an animal from the general population was 20 to 600 times greater. That additional risk would be still further increased if only animals of susceptible genotype from affected flocks were taken into account. Consequently, it recommended retention of the legislation in force concerning classical scrapie.

39 Following the AFSSA opinion of 15 January 2007, the Commission referred the matter to EFSA so that the latter could give an opinion on the two scientific assumptions on which its proposals were based, namely the reliability of discriminatory tests and the non-transmissibility to humans of TSE agents other than BSE.

40 On 25 January 2007, EFSA gave an opinion on the 'quantitative risk assessment on the residual BSE risk in sheep meat and meat products'. In that opinion, it estimated that, on the basis of the results of the increased monitoring of TSEs, that BSE in sheep concerned, at the most, a few cases, or even a few hundred cases, per million sheep taken to slaughter. It also considered that the most likely prevalence of BSE in sheep is zero. The position statement of 21 December 2006 by the Spongiform

Encephalopathy Advisory Committee (SEAC), which provides the Government of the United Kingdom of Great Britain and Northern Ireland with independent scientific advice on TSEs, had already indicated that the most likely scenario was that there was no sheep meat infected with BSE agents in the food chain in the United Kingdom.

41 On 8 March 2007, EFSA gave an opinion on certain aspects related to the risk of TSEs in ovine and caprine animals. In that opinion, it considered that there was no evidence for an epidemiological or molecular link between classical or atypical scrapie and TSEs in humans. It stated that the BSE agent was the only TSE agent which had been identified as zoonotic. However, in view of their diversity, it is not possible to exclude transmissibility to humans of animal TSE agents other than BSE. In addition, it considered that the discriminatory tests as described in the Community legislation appeared, up to then, to be reliable for the differentiation of BSE from classical and atypical scrapie, even though neither their diagnostic sensitivity nor their specificity could be considered to be perfect.

42 On 24 April 2007, following EFSA's opinion of 8 March 2007, the Commission submitted to the Standing Committee on the Food Chain and Animal Health for a vote a draft regulation amending Annexes I, III, VII and X to Regulation No 999/2001. The draft was adopted by a qualified majority. The Kingdom of Spain, the French Republic and the Italian Republic opposed it. The Republic of Slovenia abstained. The French Republic gave as the reason for its opposition its view that the regulation in question contravened the precautionary principle.

43 On 26 June 2007, the Commission adopted Regulation No 727/2007 against which the French Republic brought an action before the General Court as well as an application for interim measures.

44 On 24 January 2008, at the Commission's request, EFSA gave an opinion entitled '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 TSEs in ovine and caprine animals'. In that opinion, it clarified its position regarding questions of the transmission to humans of animal TSEs other than BSE and of the reliability of discriminatory tests.

45 On 30 April 2008, the reference laboratory published an updated opinion concerning the cases of TSE in small ruminants under examination. In that opinion, it stated that the two sheep from France and the one sheep from Cyprus (see paragraph 34 above) could not be classed as cases of BSE.

46 On 17 June 2008, the Commission adopted the contested regulation which amends Annex VII to Regulation No 999/2001 by conferring on the Member States a greater choice of measures to adopt when a flock of ovine or caprine animals is affected by a TSE where it has been possible to determine, following a discriminatory test, that it is not BSE. Where, within a herd of small ruminants, an animal is infected with scrapie, Member States may, in essence:

— destroy all the animals in the flock (point 2.3(b)(i) of Chapter A of Annex VII to the contested regulation), or

— in respect of ovine animals, determine the genotype of all the animals in the flock and destroy all genetically susceptible animals (point 2.3(b)(ii) of Chapter A of Annex VII to the contested regulation), or

— slaughter immediately for human consumption all the animals in the flock, although carcasses from animals over 18 months of age may be supplied for consumption only if they have previously been subjected to a rapid test to screen for TSEs which has given a negative result (point 2.3(d)(i) of Chapter A of Annex VII to the contested regulation and point 7.1 of Annex III to Regulation No 999/2001), or

— in respect of ovine animals, determine the genotype of all the animals in the flock, followed by immediate slaughter for human consumption of all susceptible animals, although carcasses from susceptible animals over 18 months of age may be supplied for human consumption only if they have previously been subjected to a rapid test to screen for TSEs which has given a negative result (point 2.3(d)(ii) of Chapter A of Annex VII to the contested regulation), or

— in the case of classical scrapie, keep the animals as they are on the holding with a prohibition on movements of animals to another holding for a period of two years following confirmation of the last case of TSE in the flock, on the understanding that, during that period, the animals may nevertheless be sent for slaughter and their carcasses may be supplied for human consumption if they have previously been subjected to a rapid test to screen for TSEs which has given a negative result (point 2.3(b)(iii) and point 4 of Chapter A of Annex VII to the contested regulation), or

— in the case of atypical scrapie, keep the animals as they are on the holding with a prohibition on exports to other Member States or third countries for a period of two years following confirmation of the last case of TSE in the flock, on the understanding that, during that period, the animals may nevertheless be sent for slaughter and their carcasses may be supplied for human consumption if they have previously been subjected to a rapid test to screen for TSEs which has given a negative result (point 2.3(c) and point 5 of Chapter A of Annex VII to the contested regulation).

Procedure

47 By application lodged at the Registry of the Court on 17 July 2007, the French Republic brought an action for the annulment of point 3 of the annex to Regulation No 727/2007 for breach of the precautionary principle, in so far as it inserts, in Annex VII to Regulation No 999/2001, points 2.3(b)(iii), 2.3(d) and 4 which relax the TSE eradication regime. In addition, it made an application for interim measures, seeking suspension of the operation of that regime.

48 By order of 28 September 2007 in Case T-257/07 R *France* v *Commission* [2007] ECR II-4153 (the first order in *France* v *Commission*), the judge of the General Court hearing applications for interim measures granted that application and suspended the application of those provisions until judgment has been given in the main action.

49 By separate document lodged at the Registry of the Court on 15 October 2007, the United Kingdom of Great Britain and Northern Ireland sought leave to intervene in support of the form of order sought by the Commission. By order of 30 November 2007, the President of the Third Chamber allowed that intervention.

50 On 17 June 2008, the Commission made an application for an order that there is no need to adjudicate in the main proceedings and waived its right to lodge a rejoinder. The reason for that application was the imminent adoption of the contested regulation.

51 On 28 July 2008, the French Republic lodged its observations on the Commission's application for an order that there is no need to adjudicate. It requested that the current judicial proceedings be extended to the provisions of the contested regulation on the ground that they replace in identical form the contested provisions of Regulation No 727/2007, but state more reasons for them.

52 On 31 July 2008, the contested regulation was published in the *Official Journal of the European Union*. It entered into force on 29 September 2008.

53 On 28 August 2008, the Commission lodged at the Registry of the Court its observations on the French Republic's request for extension of the current proceedings to the contested regulation. In those observations, the Commission submitted that that application was well founded.

54 By document lodged at the Registry of the Court on 19 September 2008, the French Republic made a new application for interim measures in which it claimed, in essence, that the President of the Court should order the suspension of operation of the contested regulation, in so far as it inserts, in Chapter A of Annex VII to Regulation No 999/2001, points 2.3(b)(iii), 2.3(d) and 4.

55 The United Kingdom did not lodge any observations on the request for extension of the current proceedings to the contested regulation by the time-limit of 25 September 2008 prescribed for that purpose.

56 By decision of 6 October 2008, the Court (Third Chamber) granted the French Republic's application for the current proceedings to be extended to the provisions in issue, and allowed the lodging of additional submissions and pleas in law.

57 By order of 30 October 2008 in Case T-257/07 R II *France* v *Commission*, not published in the ECR (the second order in *France* v *Commission*), the judge of the Court hearing applications for interim measures granted the French Republic's second application for suspension of operation in this case and suspended the application of the regime in question until judgment has been given in the main action.

58 On 19 November 2008, the French Republic lodged its additional submissions at the Registry of the Court.

59 On 23 December 2008 and 16 January 2009, the Commission and the United Kingdom respectively submitted their observations on those additional submissions. In addition, on 23 December 2008, the Commission made an application to the Court for the present case to be decided under an expedited procedure in accordance with Article 76a of the Court's Rules of Procedure.

60 On 21 January 2009, the French Republic submitted its observations on the Commission's application for the case to be decided under an expedited procedure. The United Kingdom did not submit observations on the Commission's application within the prescribed time.

61 By decision of 30 January 2009, the Court (Third Chamber) dismissed the Commission's application for an expedited procedure but decided, in the special circumstances of this case, to give it priority in accordance with Article 55(2) of the Rules of Procedure. Pursuant to Article 14 of the Rules of Procedure and on the proposal of the Third Chamber, the Court decided, in accordance with Article 51 of those rules, to assign the case to a Chamber sitting in extended composition.

Forms of order sought by the parties

62 The French Republic claims that the Court should:

— annul the contested regulation in so far as it inserts in Chapter A of Annex VII to Regulation No 999/2001 points 2.3(b)(iii), 2.3(d), and 4;

— order the Commission to pay the costs.

63 The Commission, supported by the United Kingdom, contends that the Court should:

— dismiss the action as unfounded;

— order the French Republic to bear the costs.

Substance

1. *Considerations of principle*

Protection of human health

64 Article 152(1) EC provides that a high level of human health protection is to be ensured in the definition and implementation of all Community policies and activities. That protection of public health takes precedence over economic considerations and may therefore justify adverse economic consequences, even those which are

substantial, for certain traders (see, to that effect, order in Case C-180/96 R *United Kingdom* v *Commission* [1996] ECR I-3903, paragraph 93, and Case T-158/03 *Industrias Químicas del Vallés* v *Commission* [2005] ECR II-2425, paragraph 134).

65 Article 24a of Regulation No 999/2001 reflects the obligation contained in Article 152(1) EC by requiring that, when decisions are adopted in the context of that regulation, the level of protection of human health ensured in the Community is to be maintained, or if scientifically justified, increased.

Precautionary principle

Definition

66 The precautionary principle is a general principle of European Union law arising from Article 3(p) EC, Article 6 EC, Article 152(1) EC, Article 153(1) and (2) EC and Article 174(1) and (2) EC, requiring the authorities in question, in the particular context of the exercise of the powers conferred on them by the relevant rules, to take appropriate measures to prevent specific potential risks to public health, safety and the environment, by giving precedence to the requirements related to the protection of those interests over economic interests (see Joined Cases T-74/00, T-76/00, T-83/00 to T-85/00, T-132/00, T-137/00 and T-141/00 *Artegodan and Others* v *Commission* [2002] ECR II-4945, paragraphs 183 and 184, and Case T-392/02 *Solvay Pharmaceuticals* v *Council* [2003] ECR II-4555, paragraph 121 and the case-law cited).

67 Moreover, as is made clear by Article 7(1) of Regulation No 178/2002, in the context of food law, the precautionary principle allows the adoption of provisional risk management measures necessary to ensure a high level of health protection when, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists.

68 Thus, where there is scientific uncertainty as to the existence or extent of risks to human health, the precautionary principle allows the institutions to take protective measures without having to wait until the reality and seriousness of those risks become fully apparent (see, to that effect, Case C-180/96 *United Kingdom* v *Commission* [1998] ECR I-2265, paragraph 99; Case C-236/01 *Monsanto Agricoltura Italia and Others* [2003] ECR I-8105, paragraph 111; Case C-504/04 *Agrarproduktion Staebelow* [2006] ECR I-679, paragraph 39; and Case T-177/02 *Malagutti-Vezinhet* v *Commission* [2004] ECR II-827, paragraph 54) or until the adverse health effects materialise (see, to that effect, Case T-13/99 *Pfizer Animal Health* v *Council* [2002] ECR II-3305, paragraphs 139 and 141, and Case T-70/99 *Alpharma* v *Council* [2002] ECR II-3495, paragraphs 152 and 154).

69 Within the process leading to the adoption by an institution of appropriate measures to prevent specific potential risks to public health, safety and the environment by reason of the precautionary principle, three successive stages can be identified: firstly, identification of the potentially adverse effects arising from a phenomenon; secondly, assessment of the risks to public health, safety and the environment which are related to that phenomenon; thirdly, when the potential risks identified exceed the threshold of what is acceptable for society, risk management by the adoption of appropriate protective measures. Although the first of those stages does not require further explanation, the two subsequent stages call for clarification.

Risk assessment

— Introduction

70 Assessment of the risks to public health, safety and the environment consists, for the institution required to cope with potentially adverse effects arising from a phenomenon, in scientifically assessing those risks and in determining whether they exceed the level of risk deemed acceptable for society. Thus, in order for the European Union institutions to be able to carry out a risk assessment, it is important for them, firstly, to have a scientific assessment of the risks and, secondly, to determine what level of risk is deemed unacceptable for society (see, to that effect, *Pfizer Animal Health* v *Council*, cited in paragraph 68 above, paragraph 149, and *Alpharma* v *Council*, cited in paragraph 68 above, paragraph 162).

— Scientific risk assessment

71 A scientific risk assessment is a scientific process consisting, in so far as possible, in the identification and characterisation of a hazard, the assessment of exposure to that hazard and the characterisation of the risk (*Pfizer Animal Health* v *Council*, cited in paragraph 68 above, paragraph 156, and *Alpharma* v *Council*, cited in paragraph 68 above, paragraph 169).

72 In its communication of 2 February 2000 on the precautionary principle (COM(2000) 1), the Commission defined those four components of a scientific risk assessment as follows (see Annex III):

'Hazard identification means identifying the biological, chemical or physical agents that may have adverse effects …

Hazard characterisation consists of determining, in quantitative and/or qualitative terms, the nature and severity of the adverse effects associated with the causal agents or activity …

Appraisal of exposure consists of quantitatively or qualitatively evaluating the probability of exposure to the agent under study …

Risk characterisation corresponds to the qualitative and/or quantitative estimation, taking account of inherent uncertainties, of the probability, of the frequency and of the severity of the known or potential adverse environmental or health effects liable to occur. It is established on the basis of the three preceding [components] and closely depends on the uncertainties, variations, working hypotheses and conjectures made at each stage of the process.'

73 As a scientific process, the scientific risk assessment must be entrusted by the institution to scientific experts (*Pfizer Animal Health* v *Council*, cited in paragraph 68 above, paragraph 157, and *Alpharma* v *Council*, cited in paragraph 68 above, paragraph 170).

74 Moreover, in accordance with Article 6(2) of Regulation No 178/2002, the scientific risk assessment is to be based on the available scientific evidence and undertaken in an independent, objective and transparent manner. It is important to point out in that regard that the duty imposed on the institutions to ensure a high level of protection of public health, safety and the environment means that they must ensure that their decisions are taken in the light of the best scientific information available and that they are based on the most recent results of international research (see, to that effect, *Pfizer Animal Health* v *Council*, cited in paragraph 68 above, paragraph 158, and *Alpharma* v *Council*, cited in paragraph 68 above, paragraph 171).

75 The scientific risk assessment is not required to provide the institutions with conclusive scientific evidence of the reality of the risk and the seriousness of the potential adverse effects were that risk to become a reality. A situation in which the precautionary principle is applied by definition coincides with a situation in which there is scientific uncertainty. However, a preventive measure cannot properly be based on a purely hypothetical approach to the risk, founded on mere conjecture which has not been scientifically verified (*Pfizer Animal Health* v *Council*, cited in paragraph 68 above, paragraphs 142 and 143; see also, to that effect, Case T-229/04 *Sweden* v *Commission* [2007] ECR II-2437, paragraph 161).

76 Furthermore, the adoption of a preventive measure, or, conversely, its withdrawal or relaxation, cannot be made subject to proof of the lack of any risk, in so far as such proof is generally impossible to give in scientific terms since zero risk does not exist in practice (see, to that effect, *Solvay Pharmaceuticals* v *Council*, cited in paragraph 66 above, paragraph 130). It follows that a preventive measure may be taken only if the risk, although the reality and extent thereof have not been 'fully' demonstrated by conclusive scientific evidence, appears nevertheless to be adequately backed up by the scientific data available at the time when the measure was taken (*Pfizer Animal Health* v *Council*, cited in paragraph 68 above, paragraphs 144 and 146). In such a situation, 'risk' thus corresponds to the degree of probability that the acceptance of certain measures or practices will adversely affect the interests safeguarded by the legal order (see, to that effect, *Pfizer Animal Health* v *Council*, cited in paragraph 68 above, paragraph 147).

77 Finally, it must be noted that it may prove impossible to carry out a full scientific risk assessment because of the inadequate nature of the available scientific data. However, that does not prevent the competent public authority from taking preventive measures in accordance with the precautionary principle. It is important, in such a situation, that scientific experts carry out a scientific risk assessment notwithstanding the existing scientific uncertainty, so that the competent public authority has available to it sufficiently reliable and cogent information to allow it to understand the ramifications of the scientific question raised and decide upon a policy in full knowledge of

the facts (see, to that effect, *Pfizer Animal Health* v *Council*, cited in paragraph 68 above, paragraphs 160 to 163, and *Alpharma* v *Council*, cited in paragraph 68 above, paragraphs 173 to 176).

— Determination of the level of risk

78 The responsibility for determining the level of risk which is deemed unacceptable for society lies, provided that the applicable rules are observed, with the institutions responsible for the political choice of determining an appropriate level of protection for society. It is for those institutions to determine the critical probability threshold for adverse effects on public health, safety and the environment and for the seriousness of those possible effects which, in their judgement, is no longer acceptable for society and above which it is necessary, in the interests of protecting public health, safety and the environment, to take preventive measures in spite of any existing scientific uncertainty (see, to that effect, Case C-473/98 *Toolex* [2000] ECR I-5681, paragraph 45, and *Pfizer Animal Health* v *Council*, cited in paragraph 68 above, paragraphs 150 and 151).

79 In determining the level of risk deemed unacceptable for society, the institutions are bound by their obligation to ensure a high level of protection of public health, safety and the environment. That high level of protection does not necessarily, in order to be compatible with that provision, have to be the highest that is technically possible (see, to that effect, Case C-284/95 *Safety Hi-Tech* [1998] ECR I-4301, paragraph 49). Moreover, those institutions may not take a purely hypothetical approach to risk and may not base their decisions on a 'zero risk' (*Pfizer Animal Health* v *Council*, cited in paragraph 68 above, paragraph 152).

80 The level of risk deemed unacceptable for society will depend on the assessment made by the competent public authority of the particular circumstances of each individual case. In that regard, the authority may take account, inter alia, of the severity of the impact on public health, safety and the environment were the risk to occur, including the extent of possible adverse effects, the persistency or reversibility of those effects and the possibility of delayed effects as well as of the more or less concrete perception of the risk based on available scientific knowledge (see, to that effect, *Pfizer Animal Health* v *Council*, cited in paragraph 68 above, paragraph 153).

Risk management

81 Risk management corresponds to the body of actions taken by an institution faced with a risk in order to reduce it to a level deemed acceptable for society having regard to its obligation to ensure a high level of protection of public health, safety and the environment. Where that risk exceeds the level of risk deemed acceptable for society, the institution is bound, by reason of the precautionary principle, to adopt provisional risk management measures necessary to ensure a high level of protection.

82 In accordance with Article 7(2) of Regulation No 178/2002, the provisional measures in question must be proportionate, non-discriminatory, transparent, and consistent with similar measures already taken (see, to that effect, Case C-286/02 *Bellio F.lli* [2004] ECR I-3465, paragraph 59).

83 Finally, it is for the competent authority to review the provisional measures in question within a reasonable period. It has been held that, when new elements change the perception of a risk or show that that risk can be contained by measures less

restrictive than the existing measures, it is for the institutions and in particular the Commission, which has the power of legislative initiative, to bring about an amendment to the rules in the light of the new information (*Agrarproduktion Staebelow*, cited in paragraph 68 above, paragraph 40).

Scope of judicial review

84 In matters concerning the common agricultural policy, the institutions enjoy a broad discretion regarding definition of the objectives to be pursued and choice of the appropriate means of action (see *Pfizer Animal Health* v *Council*, cited in paragraph 68 above, paragraph 166 and the case-law cited). In addition, in the context of their risk assessment, they must carry out complex assessments in order to determine, in the light of the technical and scientific information which is provided to them by experts in the context of the scientific risk assessment, whether the risks to public health, safety and the environment exceed the level of risk deemed acceptable for society.

85 That broad discretion and those complex assessments imply a limited power of review on the part of the Courts of the European Union. That discretion and those assessments have the effect that review by the Courts as to the substance is limited to verifying whether the exercise by the institutions of their powers is vitiated by a manifest error of appraisal, whether there has been a misuse of powers, or whether the institutions have manifestly exceeded the limits of their discretion (see *Monsanto Agricoltura Italia and Others*, cited in paragraph 68 above, paragraph 135; Case C-425/08 *Enviro Tech (Europe)* [2009] ECR I-10035, paragraph 47; and *Pfizer Animal Health* v *Council*, cited in paragraph 68 above, paragraph 166 and the case-law cited).

86 As regards the assessment by the Courts of the European Union as to whether an act of an institution is vitiated by a manifest error of assessment, it must be stated that, in order to establish that that institution committed a manifest error in assessing complex facts such as to justify the annulment of that act, the evidence adduced by the applicant must be sufficient to make the factual assessments used in the act implausible (see, to that effect, Case T-380/94 *AIUFFASS and AKT* v *Commission* [1996] ECR II-2169, paragraph 59, and Case T-308/00 *Salzgitter* v *Commission* [2004] ECR II-1933, paragraph 138). Subject to that review of plausibility, it is not the Court's role to substitute its assessment of complex facts for that made by the institution which adopted the decision (*Enviro Tech*, cited in paragraph 85 above, paragraph 47, and Case T-289/03 *BUPA and Others* v *Commission* [2008] ECR II-81, paragraph 221).

87 The abovementioned limits to the review by the Courts of the European Union do not, however, affect their duty to establish whether the evidence relied on is factually accurate, reliable and consistent, whether that evidence contains all the information which must be taken into account in order to assess a complex situation, and whether it is capable of substantiating the conclusions drawn from it (Case C-525/04 P *Spain* v *Lenzing* [2007] ECR I-9947, paragraph 57, and Case C-405/07 P *Netherlands* v *Commission* [2008] ECR I-8301, paragraph 55).

88 Moreover, it must be recalled that, where an institution has a wide discretion, the review of observance of guarantees conferred by the European Union legal order in administrative procedures is of fundamental importance. The Court of Justice has had occasion to specify that those guarantees include, in particular for the competent institution, the obligations to examine carefully and impartially all the relevant elements of the individual case and to give an adequate statement of the reasons for its decision (Case C-269/90 *Technische Universität München* [1991] ECR I-5469, paragraph 14; Joined Cases C-258/90 and C-259/90 *Pesquerias De Bermeo and Naviera Laida* v *Commission* [1992] ECR I-2901, paragraph 26; *Spain* v *Lenzing*, cited in paragraph 87 above, paragraph 58; and *Netherlands* v *Commission*, cited in paragraph 87 above, paragraph 56).

89 Thus, it has already been held that a scientific risk assessment carried out as thoroughly as possible on the basis of scientific advice founded on the principles of excellence, transparency and independence is an important procedural guarantee whose purpose is to ensure the scientific objectivity of the measures adopted and preclude any arbitrary measures (see *Pfizer Animal Health* v *Council*, cited in paragraph 68 above, paragraph 172).

2. *The sole plea in law, alleging breach of the precautionary principle*

90 The French Republic raises a single plea, alleging breach of the precautionary principle by the Commission on account of the adoption of points 2.3(b)(iii), 2.3(d) and 4 of Chapter A of Annex VII to Regulation No 999/2001, as contained in the contested regulation ('the contested measures').

91 In support of that plea, the French Republic puts forward, firstly, arguments seeking to challenge the Commission's risk assessment and, secondly, arguments seeking to challenge the Commission's risk management.

3. *Risk assessment*

Introduction

92 As regards the Commission's risk assessment, the French Republic claims, firstly, that the Commission did not take account of the scientific uncertainties surrounding the

risk of transmissibility to humans of TSEs other than BSE, secondly, that the Commission did not have the reliability of 'rapid tests' scientifically evaluated, thirdly, that the Commission disregarded the scientific uncertainties as to the reliability of discriminatory tests and, fourthly, that the Commission did not have the risks arising from the contested measures assessed in good time.

The complaints alleging failure to take into account and misinterpretation of the scientific uncertainties surrounding the transmissibility to humans of TSEs other than BSE

93 The French Republic submits that the Commission failed to have regard to the precautionary principle at the risk assessment stage by disregarding or interpreting in a biased way the scientific uncertainties persisting with regard to the risk of transmissibility to humans of TSEs other than BSE.

94 The Commission asserts that there is a consensus among the scientific community and the international institutions on the lack of evidence capable of demonstrating that scrapie is transmissible to humans. There is no proof of an epidemiological or molecular link between the scrapie agent and TSEs affecting humans. The only TSE which is zoonotic is BSE.

95 The United Kingdom maintains, in essence, that the French Republic's disagreement with the Commission's assessment as to the transmissibility to humans of TSEs in ovine and caprine animals is not sufficient to demonstrate an error in that regard and that the Commission was not obliged to wait and see whether the scientific models in question would be almost perfectly representative and would correspond in the more

or less near future. According to the United Kingdom, the EFSA opinions provided an entirely sufficient basis to act, as the Commission did.

96 In this case, in recitals 10 to 12 and 18 in the preamble to the contested regulation, the Commission set out its assessment regarding the risk of transmissibility to humans of TSEs affecting caprine or ovine animals other than BSE. In particular, taking as a basis EFSA's opinion of 24 January 2008, it considered as follows:

'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.' (See recital 12 in the preamble to the contested regulation.)

97 It is thus apparent from recital 12 in the preamble to the contested regulation that the Commission expressly acknowledged that it was impossible to exclude any

transmissibility to humans of TSEs affecting ovine and caprine animals, other than BSE, in the light of the biodiversity of the disease agents and of the results of experimental models. It follows that the French Republic is wrong in maintaining that the Commission overlooked the scientific uncertainties which persist as regards the risk of transmissibility to humans of those TSEs in the risk assessment which preceded the adoption of the contested measures.

98 However, the French Republic also maintains that the Commission interpreted the scientific opinions available to it in a biased way by considering that the risk of transmission to humans of an animal TSE other than BSE was extremely low.

99 In that regard, it is important to point out that, in the light of the Commission's broad discretion in matters concerning the common agricultural policy and of the complex assessments which it is required to carry out in the context of its risk assessment, the review by the Courts of the European Union is limited in this case. It consists in establishing whether the Commission made a manifest error in assessing the scientific opinions available to it. Such an error presupposes that the evidence which must be adduced by the party alleging it is sufficient to make the factual assessments used in the contested regulation implausible (see paragraph 86 above).

100 In this case, the Commission inferred from EFSA's opinions of 8 March 2007 and 24 January 2008 that the risk of transmissibility to humans of ovine or caprine TSEs other than BSE was extremely low.

101 In that regard, it must be pointed out that it is apparent from EFSA's opinion of 8 March 2007 and that it is not disputed by the parties that there was no proof of an epidemiological or molecular link between classical or atypical scrapie and TSEs in humans.

102 Moreover, in its opinion of 24 January 2008, EFSA stated that it was, however, not possible to exclude transmissibility to humans of an ovine or caprine TSE other than BSE. In that regard, it stated that the lack of evidence of an epidemiological link did not necessarily demonstrate a lack of correlation between TSEs in animals and TSEs in humans, since this was in part due to the lack of data and to the lack of understanding of the biodiversity of animal and human TSEs. Thus, according to EFSA, the assumed lack of association between TSEs in humans and those in animals might be biased by, firstly, the lack of data on the historical real prevalence and distribution of small ruminant TSEs, at a time when only passive surveillance was performed, secondly, the lack of understanding of the true biodiversity of TSEs in small ruminants in terms of both classical and atypical scrapie agents, thirdly, the lack of understanding of the diversity of TSEs in humans due to the limited molecular and bioassay characterisation of those TSEs and to the number and spectrum of neurodegenerative diseases affecting humans and, fourthly, the predicted phenotype of disease that might arise if an animal TSE were transmitted to humans (see EFSA opinion of 24 January 2008, p. 4).

103 Furthermore, it is apparent from EFSA's opinions of 8 March 2007 and 24 January 2008 that experimental studies did not make it possible to exclude transmissibility to humans of animal TSEs.

104 According to EFSA, *in vitro* transmissibility tests have demonstrated that the inherent ability of BSE and scrapie agents to affect humans following equivalent exposure is low (see EFSA opinion of 24 January 2008, p. 5). Moreover, laboratory tests with animal models have demonstrated the transmissibility of ovine and caprine TSEs other than classical BSE (see EFSA opinions of 8 March 2007, p. 6, and 24 January 2008, p. 4). EFSA referred inter alia to the transmission by the oral route of a classical scrapie agent in a hamster to a squirrel monkey, the transmission by the intracerebral route of classical scrapie from two distinct ovine sources to a macaque and

a marmoset and the transmission of a TSE agent other than classical BSE to a mouse used as a model for the human M129 PRP gene.

105 However, the Commission was entitled to consider, without committing any manifest error of assessment, that those experimental models were imperfect. In its opinion of 24 January 2008, EFSA stated that those models did not allow the human gene PRNP polymorphism to be taken into account. However, that gene plays a major role in assessing susceptibility towards TSEs and it is conceivable that other genes may be influential in determining overall susceptibility to TSEs. Moreover, in its opinion of 8 March 2007, EFSA had found that route of exposure, dose, and cumulative exposures were considered to influence the ability of TSE agents to cross the human species barrier. However, the influence of those factors on the representativeness of the experimental models is not expressly indicated in EFSA's opinions.

106 Thus, it is apparent from EFSA's opinions that the scientific knowledge regarding transmissibility to humans of animal TSEs other than BSE was limited, since, at the time of the adoption of the contested measures, the only data to corroborate the ability of TSE agents other than BSE to infect humans were experimental models. However, those models did not reliably represent the human species barrier and exposure under natural conditions of humans to animal TSEs other than BSE. Those ways in which the experimental models lacked representativeness significantly affected their suitability for demonstrating possible damage to human health from an animal TSE other than BSE. The interaction between an animal TSE and the human species barrier, on the one hand, and the routes of exposure of humans to animal TSEs other than BSE, on the other, are important factors in assessing the risk of transmission to humans of animal TSEs other than BSE.

107 Moreover, although, in its Statement on the Potential Human Health Risk from Changes to Classical Scrapie Controls of February 2008, SEAC confirmed that a link between classical scrapie and human TSEs could not be ruled out, it nevertheless considered that that risk must be very low. According to it, the very low and relatively constant incidence of human TSE cases worldwide showed that there must be at least a substantial, if not complete, barrier to transmission of classical scrapie to humans.

108 In view of the limited and unrepresentative nature of the scientific evidence to support transmissibility of an ovine or caprine TSE other than BSE to humans at the time of adoption of the contested measures, the Commission was entitled to consider, without committing a manifest error of assessment, that the likelihood of an ovine or caprine TSE other than BSE being transmissible to humans was extremely low. Consequently, the conclusion, contained in recital 12 in the preamble to the contested regulation, that the risk of transmission to humans of such a TSE was extremely low is not vitiated by a manifest error of assessment.

109 The French Republic does not put forward any argument or submit any evidence to render implausible the Commission's assessment that the risk of transmission to humans of animal TSEs other than BSE is extremely low. In particular, in so far as it considers that the limitations of the experimental models used for scrapie are the same as those of the models used for BSE, it must be observed that it stated at the hearing that the latter models were not sufficient on their own to establish transmissibility to humans of BSE. Without the molecular and epidemiological data for BSE, that transmissibility could therefore not have been established. Consequently, even though the experimental models used to assess the risk of transmissibility to humans of animal TSEs other than BSE were identical to those used to assess the risk of transmissibility to humans of BSE, that fact is not sufficient to characterise the extent of the risk. As the French Republic stated, that identity of the experimental models does not prove that the risk was low. On the other hand, the fact that, in this case, mere experimental

models indicate that transmissibility to humans of animal TSEs other than BSE could not be excluded can be regarded as an indicator, on the basis of the knowledge existing at the time of the adoption of the contested measures, of the low degree of likelihood of transmissibility to humans of animal TSEs other than BSE.

The complaint alleging failure to consult scientific experts on the reliability of 'rapid tests'

Preliminary considerations

110 The French Republic submits that the Commission breached the precautionary principle by failing to consult EFSA on the reliability of 'rapid tests'. The Commission and the United Kingdom submit, in essence, that the Commission was sufficiently informed concerning the reliability of 'rapid tests' thanks to EFSA's opinions of 17 May and 26 September 2005.

111 First of all, it must be recalled that the objective of 'rapid tests' is to detect the existence of a TSE, but not its type, namely BSE, classical scrapie or atypical scrapie, in small ruminants on the basis of tissue samples taken from dead animals.

112 Secondly, it must be observed that Regulation No 999/2001 provides that the prevention, control and eradication of TSEs are to take place, inter alia, within the framework of an annual programme for monitoring BSE and scrapie, which includes detection procedures using 'rapid tests'. That monitoring involves subjecting to those

tests a sample representative of dead animals for each region and season (see Annex I to Regulation No 270/2002). Those tests are listed in Annex X to Regulation No 999/2001 after being approved (see Article 6 of Regulation No 999/2001).

113 The purpose of EFSA's opinions of 17 May and 26 September 2005 is to evaluate the performance of nine post-mortem 'rapid tests' on tissues from ovine and caprine animals, taking into account the opinion of AFSSA, and to give recommendations on the approval of those tests.

114 In its opinions of 17 May and 26 September 2005, EFSA evaluated inter alia the various 'rapid tests' in question in terms of their 'diagnostic sensitivity' (that is to say, the ability correctly to identify infected tissues of positive samples), their 'diagnostic specificity' (that is to say, the ability correctly to identify non-infected tissues) and their 'analytical sensitivity' (that is to say, the ability to identify a low concentration of prion in a dilution series). Eight of the nine 'rapid tests' in question achieved a satisfactory result as regards their application to tissues from the brainstem, also known as the 'obex'. They achieved a percentage between 99.6 and 100 for 'diagnostic sensitivity' and 'diagnostic specificity'. EFSA therefore recommended those eight tests to assess the prevalence of classical scrapie and BSE in sheep on the basis of brainstem samples. Finally, on the basis of limited scientific knowledge, it recommended that, in terms of 'rapid tests', goats should be treated in the same way as sheep.

115 Following those opinions, the eight 'rapid tests' recommended were set out in point 4 of Chapter C of Annex X to Regulation No 999/2001.

Use of 'rapid tests' for purposes other than epidemiological purposes

116 The French Republic complains, in essence, that the Commission considered that the evaluation of the reliability of 'rapid tests', set out in EFSA's opinions of 17 May and 26 September 2005 and which had been carried out in the context of measures for the epidemiological monitoring of TSEs in small ruminants, was also valid in the context of the contested measures allowing the release for human consumption of meat from small ruminants in cases where the result of those tests was negative. At the hearing, it pointed out that the reliability requirement for a test to assess the prevalence of a disease within flocks of ovine and caprine animals could not be the same as that laid down for the purpose of deciding whether meat from ovine or caprine animals should be released for human consumption.

117 In that regard, it should be noted that EFSA had considered, in its opinion of 7 June 2007, that, although the sole objective of the 'rapid testing' programme at that time was epidemio-surveillance, it would have been possible to consider other uses for those tests in the future, such as certification of TSE-free flocks. Thus, EFSA expressly considered that 'rapid tests' could be used in contexts other than that of surveillance. Furthermore, if, as stated by EFSA, 'rapid tests' may be used to certify that the flock of small ruminants is not infected by a TSE, the Commission was entitled to infer from that, without committing a manifest error of assessment, that such certification would also be valid for meat originating from that flock intended for human consumption.

118 Moreover, it must be observed that effective epidemio-surveillance for TSEs in animals presupposes that TSE cases can be correctly identified. The effectiveness of that surveillance depends, inter alia, on the reliability of 'rapid tests'.

119 In the opinions of 17 May and 26 September 2005, EFSA considered, for each of the 'rapid tests' that it was recommending, that they obtained satisfactory results in terms of 'diagnostic sensitivity' and 'diagnostic specificity' when applied to brainstem tissues from clinical, confirmed cases of classical scrapie. Those results were between 99.6 and 100 %. Moreover, EFSA considered that all the 'rapid tests' recommended made it possible to detect the presence of the prion in three samples of BSE in sheep, which had been experimentally inoculated.

120 In the light of the nature and results of the evaluations of 'rapid tests' set out in the EFSA opinions of 17 May and 26 September 2005, the Commission was therefore entitled to consider, without committing a manifest error of assessment, that the 'rapid tests' carried out on brainstem samples satisfied the reliability requirements laid down for the purpose of controlling the release for human consumption of meat from small ruminants. Moreover, the French Republic does not put forward any evidence to support the inference that those EFSA evaluations did not make it possible to meet the standard required for tests used to control meat from sheep or goats which is intended for human consumption.

121 In any event, the evaluations of the reliability of 'rapid tests' contained in the EFSA opinions of 17 May and 26 September 2005 already justified, in the case of a negative result, the release for human consumption of sheep and goat meat. Even before the adoption of the contested measures, a negative result from the 'rapid tests' carried out for purposes of epidemio-surveillance allowed the release for human consumption of meat from the animal in question (see Annex III, Chapter A, point II, of Regulation No 999/2001 in the version applicable before the adoption of Regulation No 727/2007). However, the French Republic does not dispute the reliability of 'rapid tests' when they are used for epidemiological purposes notwithstanding the fact that the release or non-release for human consumption of meat from animals infected with a TSE also depends on their degree of reliability.

122 Consequently, the Commission was entitled, without committing a manifest error of assessment, to consider that the evaluation of the reliability of 'rapid tests', contained in EFSA's opinions of 17 May and 26 September 2005, was valid for the use of those tests in the context of the control of the release of sheep or goat meat for human consumption. The French Republic's complaint that it was necessary to consult EFSA specifically regarding the reliability of 'rapid tests' in the context of the control of release of sheep or goat meat for human consumption must therefore be rejected.

Absence of information in EFSA's opinions of 17 May and 26 September 2005 about the reliability of 'rapid tests' when small ruminants do not yet present a sufficient accumulation of prions in the brainstem

123 The French Republic submits, in essence, that the Commission adopted the contested measures without full knowledge of the facts, since it did not have available to it a scientific evaluation of the performance of 'rapid tests' taking account of the fact that, at an early stage of classical scrapie, the prions accumulate in the peripheral tissues before accumulating in the obex. According to it, EFSA's opinions of 17 May and 26 September 2005 give no information about the reliability of 'rapid tests' for the purpose of detecting infected small ruminants when they do not yet show a sufficient accumulation of the prion in the brainstem. Yet it is apparent from AFSSA's opinion of 13 June 2007 that that limitation of 'rapid tests' results in half the animals infected by a TSE not being detected.

124 In that regard, it should be observed that, in the opinions of 17 May and 26 September 2005, EFSA evaluated the various 'rapid tests', in particular in terms of their 'diagnostic sensitivity' and 'diagnostic specificity', on the basis of positive samples of tissues from the brainstem, the mesenteric lymph nodes, the spleen and the cerebellum

of animals in the age range 16 months to 6 years. Following that evaluation, EFSA recommended eight of the nine tests evaluated for the purpose of determining the prevalence of classical scrapie and BSE in sheep on the basis of brainstem samples. In addition, it recommended a test for detecting TSEs on the basis of samples of those lymph nodes and of the spleen.

125 Moreover, in its opinion of 15 May 2006, AFSSA took the view that 'the rapid screening tests as performed … [were] not capable of identifying the animals infected with a strain of TSE during a large part of the incubation period, because they [were] performed exclusively on samples of central nervous tissues even though certain tissues (lymphoid organs in particular) [might] contain large quantities of the infectious agent at an earlier stage'.

126 In its opinion of 15 January 2007, communicated to the Commission on 17 January 2007, AFSSA reiterated the assessment set out in paragraph 125 above, contained in its opinion of 15 May 2006.

127 In its opinion of 13 June 2007, AFSSA gave its view on the consequences of the limitations of 'rapid tests' carried out on the obex of small ruminants. It estimated that, 'on the basis of the data collected in France [from the active surveillance of sheep in 2006], it [was] established that tests on the obex detect[ed] only about 50 % of the infected animals in infected flocks; the other 50 % are animals in incubation carrying infectivity in their lymphoid organs'.

128 In its opinion of 5 December 2007, AFSSA stated that the 'diagnostic sensitivity' of tests on the obex could vary according to the genetic structures of the infected flocks, the prion strain and how the infection develops. However, it considered that,

although the estimated value of 50 % represented only an order of magnitude, such a value remained perfectly representative.

129 In addition, in its opinion of 25 January 2007, EFSA stated the following:

'In VRQ/VRQ sheep exposed to natural scrapie infection, PrPSc can be detected in ileal Peyer's patches (PP) from 21 days post-partum and in other PPs of the alimentary canal and in the tonsil of the lamb by 60 days of age. In similar conditions, PrPSc is detectable in the enteric nervous system (ENS) at 7 months old, almost three months prior to its first detection in the obex … Hence, during surveillance, screening the obex using rapid testing for PrPSc is a poor indicator [of] the absence of TSE infection in the digestive tract of the lamb.'

130 Finally, in its opinion of 5 June 2008, EFSA considered that TSE infection of small ruminants generally took place at or shortly after birth. According to it, placenta and foetal and maternal tissues were considered to be a source of infection. Moreover, it stated that, under natural conditions, the earliest evidence of scrapie infection is found in the first month of life in the alimentary canal and its associated lymphoid structures, that prions could be later detected in most secondary lymphoid formations and in the whole of the enteric nervous system and that prions are detected in the central nervous system from about the mid-incubation period. It inferred from this that screening the obex using 'rapid tests' for prions was a poor indicator of the absence of TSE infection in small ruminants' peripheral tissues.

131 Thus, the recommendations of 'rapid tests' in EFSA's opinions of 17 May and 26 September 2005 relate to their reliability only when carried out on certain tissues, including obex tissues. However, those recommendations do not take account of the spread of TSEs within the various tissues of the animal during the incubation period and, in particular, of the fact that TSEs generally spread first in the lymphoid tissues before spreading in the obex.

132 Nevertheless, the French Republic cannot complain that the Commission adopted the measures in question without having being aware of the limitations described by scientific experts concerning 'rapid tests' when carried out on the obex of young subjects. Those limitations were set out in AFSSA's opinions of 15 January, 13 June and 5 December 2007. As is clear from paragraph 126 above with regard to the opinion of 15 January 2007 and from the French Republic's reply to a written question put by the Court, those opinions were communicated to the Commission before the contested measures were adopted. Moreover, EFSA's opinions of 25 January 2007 and 5 June 2008, in which EFSA stated that screening the obex using 'rapid tests' for prions was a poor indicator of the absence of TSE infection in small ruminants' peripheral tissues, were adopted before the adoption by the Commission of the contested regulation.

133 However, the fact that the Commission was aware of those limitations of 'rapid tests' before the contested regulation was adopted does not prejudge the answer to the question whether the Commission drew the appropriate inferences from those limitations in the assessment of the risks to which the adoption of the contested measures would give rise. The French Republic also complains that the Commission did not draw the appropriate inferences from those limitations. That complaint and the complaint alleging failure to assess the increase in the risk and the risk management, which will both be assessed below in paragraphs 174 to 202 and under heading 4 'Risk management', overlap.

134 Finally, in so far as the French Republic claims that, in its opinion of 7 June 2007, EFSA recommended a re-evaluation of 'rapid tests', it must be observed that that

opinion was adopted following the Commission's request to EFSA to update the existing protocols for the evaluation of 'rapid tests' for TSEs with a view to launching, in mid-2007, a call for expressions of interest for 'rapid tests' to be used in the framework of TSE monitoring. That opinion states that the Scientific Panel on Biological Hazards (Biohaz panel) recommended that 'rapid tests' already approved should be required to undergo the new evaluation in order to confirm their robustness and their ability to fulfil the additional performance requirements with respect, for example, to atypical cases and 'analytical sensitivity'. That recommendation is based, firstly, on the fact that, in the previous test evaluation processes, differences had been observed between the tests in terms of 'analytical sensitivity', the significance of which in terms of 'diagnostic sensitivity' and biological relevance could not be scientifically assessed at the time of evaluation, and, secondly, on the fact that, following the surveillance programmes using validated tests, a new type of TSE, namely atypical scrapie/NOR 98, had been detected in Europe in small ruminants, and that the validated 'rapid tests' did not perform equally in respect of those atypical cases, which might result in non-recognition of various types of scrapie.

135 Consequently, contrary to what the French Republic maintains, in its opinion of 7 June 2007 EFSA did not recommend a re-evaluation of 'rapid tests' in the light of their ineffectiveness in detecting classical scrapie in young subjects. Furthermore, in that opinion, EFSA considered that, notwithstanding the variable prion distribution in the organism, carrying out the tests on the obex was the best compromise for detection of all the TSE agents which infect sheep.

136 In the light of all the foregoing, the French Republic's complaints that, on the one hand, the Commission was not aware, before the contested measures were adopted, of the limitations of the 'rapid tests' when carried out in young subjects and, on the other hand, the Commission made a manifest error of assessment by adopting the contested measures even though EFSA had recommended a re-evaluation of those tests in view of those limitations must therefore be rejected.

The complaints relating to discriminatory tests

Introduction

137 The French Republic claims that the Commission disregarded the scientific uncertainties persisting as regards the reliability of discriminatory tests. The contested measures were drawn up by the Commission before EFSA had been consulted and the Commission did not review the justification for those measures following EFSA's opinion of 24 January 2008. In addition, it submits that, in recital 15 in the preamble to the contested regulation, the Commission made biased use of EFSA's opinion of 24 January 2008. The Commission played down the doubts arising from the lack of understanding of the true biodiversity of TSE agents by relying on the absence of scientific evidence of the possibility of co-infection in natural conditions and on the low prevalence of BSE in small ruminants. By so doing, the Commission makes light of the very strong scientific uncertainties expressed by EFSA and distorts the latter's conclusions in its opinion.

138 The Commission and the United Kingdom dispute the argument that the Commission did not fully take into account EFSA's opinion of 24 January 2008.

139 As a preliminary point, it should be noted that the term 'discriminatory tests' refers to tests making it possible to identify the type of TSE in question, namely BSE, classical scrapie or atypical scrapie. Their application therefore presupposes prior identification of a TSE case which may in particular be done using 'rapid tests'.

140 Before 2005, the only approved discriminatory tests were 'biological' or '*in vivo*' discriminatory tests. They consisted in inoculating TSE-infected tissues into the brain of a live mouse in order to determine the exact nature of the TSE in question, namely BSE, classical scrapie or atypical scrapie. When the mouse died, a microscopic examination of its brain was performed and the results of that examination made it possible to determine the exact nature of the TSE after several years.

141 From 2002 onwards, molecular discriminatory tests, also known as 'biochemical' or '*in vitro*' discriminatory tests, were developed. The use of those tests in the context of Regulation No 999/2001 was authorised following the adoption of Regulation No 36/2005.

142 Finally, it should be pointed out that the term 'co-infection' refers, in the context of this case, to the possibility that a small ruminant may be concomitantly infected with BSE and with a TSE other than BSE.

The complaint alleging failure to take into account the scientific uncertainties surrounding the reliability of discriminatory tests

143 The French Republic complains that the Commission disregarded the scientific uncertainties persisting as regards the reliability of discriminatory tests.

144 In that regard, it must be observed that, +in recital 6 in the preamble to the contested regulation, the Commission quoted EFSA's opinion of 8 March 2007, according to

which, at the current stage of scientific knowledge, it is not possible to rely on the premiss that the 'diagnostic sensitivity' and 'diagnostic specificity' of the discriminatory tests were perfect. In addition, in recital 13 in the preamble to the contested regulation, the Commission stated that EFSA had confirmed, in its opinion of 24 January 2008, that the discriminatory tests could not be considered to be perfect because of the lack of understanding of both the true biodiversity of TSE agents in ovine and caprine animals and how those agents interacted in case of co-infection. Moreover, in recital 14 in the preamble to the contested regulation, the Commission drew attention to the absence of statistically sufficient data to evaluate the sensitivity or specificity of the discriminatory tests and stated that that absence of data could not be compensated for by the procedure in place, which included a ring trial with additional molecular testing methods in different laboratories and an evaluation by an expert panel. Finally, in recital 15 in the preamble to that regulation, the Commission noted that the discriminatory tests could not be considered to be perfect but considered them to be a suitable tool for the purpose of TSE eradication.

145 Consequently, the French Republic's complaint that, at the time of adopting the contested measures, the Commission disregarded the scientific uncertainties persisting as regards the reliability of discriminatory tests must be rejected.

146 The French Republic also complains that the Commission drew up the contested measures before it consulted EFSA. In that regard, it must be pointed out that, when a European Union institution decides to adopt measures necessitating observance of the precautionary principle, those measures must be adopted in the light of the best scientific information available and be based on the most recent results of international research (see paragraph 74 above). However, compliance with that obligation is assessed irrespective of whether the measures were drawn up before the adoption of an opinion by a particular scientific authority. The drawing-up of the contested measures constitutes a preparatory and internal stage of the decision-making process, during which the Commission may still modify its position in the light of new scientific data, whereas the adoption of the contested measures freezes the Commission's

position. Consequently, the complaint based on a drawing-up of the contested measures prior to consulting EFSA is ineffective.

147 In so far as the French Republic complains that the Commission did not review the contested measures following EFSA's opinion of 24 January 2008, it must be stated that, in the recitals in the preamble to the contested regulation, the Commission expressly referred to that opinion and that the French Republic does not demonstrate that there was no such review.

148 Finally, in so far as the French Republic maintains that the scientific uncertainties surrounding the reliability of discriminatory tests affirmed in the scientific opinions entail an unacceptable level of risk for society, when those tests are used in the system established by the contested measures, it must be observed that this complaint is very similar to the complaints alleging biased use of the abovementioned opinion and bad risk management, which will both be assessed below, in paragraphs 157 to 171 and under heading 4 'Risk management' respectively.

The complaint alleging biased use of EFSA's opinion of 24 January 2008

— Introduction

149 The French Republic complains that the Commission played down the doubts of the scientific experts surrounding the reliability of discriminatory tests due to the lack of understanding of the true biodiversity of TSE agents and how they interact in case

of co-infection by relying on the absence of scientific evidence of the possibility of co-infection in natural conditions and on the low prevalence of BSE.

150 In that regard, it must be observed that, in the contested regulation, the Commission did not call into question the imperfection of discriminatory tests due to the lack of understanding of the true biodiversity of TSE agents. On the other hand, it considered that the number of BSE cases not detected by discriminatory tests because of possible co-infection was extremely low due to the absence of scientific evidence of co-infection in natural conditions and to the very low prevalence of BSE in small ruminants.

151 In recitals 15 and 16 in the preamble to the contested regulation, the Commission stated the following:

'EFSA acknowledged that the discriminatory tests established in Regulation … 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 … No 999/2001.

… In its opinion of 25 January 2007, 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 … 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.'

— The risk of co-infection

152 In so far as the French Republic complains that the Commission played down the risk of non-detection by discriminatory tests of cases of co-infection because of the absence of scientific evidence of such infection in natural conditions, it must be observed that, in its opinion of 24 January 2008, EFSA considered, on the basis of the limited available data, that the discriminatory tests provided for by Regulation No 999/2001 were practicable tools for screening field TSE cases, fulfilling the objective of rapid and reproducible identification of TSE cases that have a signature compatible with classical BSE. Furthermore, EFSA considered that the discriminatory tests were not perfect because of the lack of understanding of the true biodiversity of TSE agents in ovine and caprine animals and how those agents interact in case of co-infection.

153 In particular, in its opinion of 24 January 2008, EFSA considered that, in case of co-infection of a single animal, the presence of one TSE agent can mask the presence of another and thus the manifestation of the disease. According to EFSA, that phenomenon of interference has been studied in experimental models using different TSE agents. It also took the view that, despite the fact that direct extrapolation of

the results of those observations to small ruminants was not possible, those results raised the possibility that the presence of BSE in sheep might remain undetected if it occurred as a co-infecting TSE agent in an established case of scrapie. Finally, it stated that, since the likelihood of such a situation was currently uncertain, experiments designed to answer specifically that question were ongoing.

154 Thus, the Commission was entitled, without committing a manifest error of assessment, to consider, in recital 15 in the preamble to the contested regulation, that the possibility of co-infection of small ruminants had not been demonstrated in natural conditions. Furthermore, it is plausible that an absence of evidence of co-infection of small ruminants in natural conditions reduces the degree of likelihood of the existence of such co-infections and, consequently, the risk that the discriminatory tests may not detect BSE because of a co-infection of a small ruminant. The risk of co-infection is indeed lower in the absence of evidence to establish the possibility of co-infection of small ruminants in natural conditions.

155 Moreover, in so far as the Commission inferred from the combination of the absence of evidence of possible co-infection of small ruminants in natural conditions and of the very low prevalence of BSE in small ruminants that there was an extremely low number of BSE cases which were missed because of co-infection, it is logical, and therefore plausible, that, if the prevalence of BSE cases is very low, the risk posed by the non-detection of cases is also very low. Furthermore, it is not manifestly erroneous for the Commission to infer from that circumstance, combined with the low risk of co-infection of small ruminants because of the absence of evidence of such infection in natural conditions, that the number of BSE cases missed in ovine and caprine animals due to possible co-infection is extremely low.

156 However, that finding depends on the assessment made by the Commission of the prevalence of BSE in small ruminants, which is also contested by the French Republic.

— The prevalence of BSE in small ruminants

157 As regards the prevalence of BSE in small ruminants, it is common ground between the parties that, at the time of the adoption of the contested measures, only one case of BSE had been formally identified in small ruminants. The animal in question was a goat born in 2000 and slaughtered in France in 2002. That goat was the first case of BSE in a small ruminant under natural conditions (see paragraph 30 above). No case of BSE has been identified in sheep.

158 In addition, the parties stated at the hearing that, at the time of the adoption of the contested measures, there were only three cases where any doubt remained as to their infection with BSE under natural conditions. Those cases were still being analysed to determine whether or not they should be regarded as BSE cases. The animals in question were two sheep from England and a goat from Scotland.

159 Moreover, both EFSA and AFSSA considered that the prevalence of BSE in ovine and caprine animals was very low, or even nil.

160 In its opinion of 20 July 2007, AFSSA stated that 'the epidemiological data available since 2002 (in France and in Europe) clearly indicate that the prevalence of BSE is very low (or even nil) in ovine and caprine animals'.

161 In its opinion of 25 January 2007, EFSA estimated that, since no case of BSE had been confirmed in sheep, the most likely prevalence of BSE in sheep was zero. In particular, in a table headed 'Cumulative uncertainty distribution of the BSE prevalence in the

EU sheep population', it concluded as follows: '… there is a 95 % confidence that the number of cases is equal to or below 4 BSE cases per million sheep; at a 99 % confidence level, the number becomes equal to or below 6 cases per million. Since no BSE case has yet to be confirmed in sheep, the most likely prevalence is zero.'

162 However, in its opinion of 25 January 2007, EFSA stated that the fact that, in the light of the data available up to 2006, no case of BSE had been identified on the basis of screening by means of discriminatory tests in the 25 Member States of the European Union of the time and in Norway could not be interpreted as implying that there had been no BSE-infected sheep in the European flock because, on the one hand, not all animals, including those slaughtered for human consumption, had been tested and, on the other, the screening tests had variable and largely undetermined sensitivities for detecting an infected animal at a preclinical stage. Depending on the statistical model and surveillance data used, it was calculated that there was 95 % confidence that in the United Kingdom there were fewer than two to four BSE cases in sheep per 10 000 healthy-slaughter animals and, combining data from other countries with a substantial BSE history, namely Ireland, France and Portugal, there was a 95 % confidence that in this subgroup of high-risk countries there was less than 0.3 to 0.5 cases of BSE in sheep per 10 000 healthy-slaughter animals. Finally, EFSA stated in that opinion that assuming lower sensitivities for the TSE screening and discriminatory tests would give higher prevalence estimates and that further experimental evaluation of those parameters should be considered.

163 In the light of all the foregoing considerations, the Commission was entitled to consider, without committing a manifest error of assessment, that the prevalence of BSE in ovine, if present, or caprine animals was very low. Moreover, the number of confirmed cases of BSE and inconclusive cases of TSE which might potentially prove to be a case of BSE at the time of the adoption of the contested regulation does not contradict the prevalence estimate for BSE in small ruminants.

164 The finding made in the previous paragraph is not called into question by the various arguments put forward by the French Republic in its written pleadings.

165 As regards the French Republic's argument that non-detection during active surveillance does not necessarily mean actual absence of BSE given the limitations of the 'rapid tests' and discriminatory tests carried out, it must be observed that the Commission has not at all claimed that AFSSA and EFSA stated the contrary in their opinions. The prevalence of BSE in small ruminants was only an estimate based on a probability model, as EFSA stated in its opinion of 25 January 2007 which was relied on by the Commission in recital 16 in the preamble to the contested regulation. Furthermore, that prevalence of BSE in small ruminants was established on the basis both of surveillance which was not systematic and of 'rapid tests' and discriminatory tests which were not perfect.

166 However, the fact that the prevalence of BSE in small ruminants was only an estimate is not sufficient to call into question the plausibility of the Commission's finding that the prevalence of BSE in small ruminants had to be considered very low.

167 As regards the French Republic's argument that, in order to determine the prevalence of BSE in sheep, it was necessary to relate the estimate of less than 0.3 to 0.5 cases of BSE in sheep per 10 000 healthy-slaughter animals in high-risk countries to the whole of the Community ovine population estimated at 67 million individuals, it must be observed that the French Republic does not put forward any scientific sources according to which the estimate for high-risk countries should be extended to the rest of Europe so that the prevalence of BSE in sheep should lead to an estimate of a number of cases of sheep infected with BSE in Europe of between fewer than 2 010 and 3 350 cases. The scientific opinions which were available to the Commission at the time of the adoption of the contested measures, namely AFSSA's opinion of 20 July 2007 and

EFSA's opinion of 25 January 2007, stated, on the contrary, that the most likely prevalence of BSE in small ruminants in Europe was very low or even zero.

168 As regards the French Republic's claim that the Commission has always shown the greatest caution on the subject of the prevalence of BSE, it must be held that that consideration has no bearing on the plausibility of the inferences which the Commission may make from the scientific estimates relating to the prevalence of BSE in small ruminants.

169 Finally, and in any event, it should be observed that the French Republic's representative stated at the hearing that the Commission had not made a manifest error of assessment by considering that the prevalence of classical BSE in small ruminants was very low. As the estimates for the prevalence of BSE relate only to classical BSE, that statement by the French Republic's representative confirms the validity of the finding set out in paragraph 163 above.

170 Accordingly, the Commission was entitled to consider, without committing a manifest error of assessment, that the estimated prevalence of BSE in small ruminants was very low.

171 Consequently, in the light of the considerations set out in paragraph 155 above, it was plausible that the risk of non-detection by discriminatory tests of cases of BSE in small ruminants because of possible co-infection was extremely low. The Commission therefore did not commit a manifest error in the assessment of the risk of co-infection of small ruminants.

— Taking into account of AFSSA's opinion of 8 October 2008 and of EFSA's opinion of 22 October 2008

172 So far as concerns AFSSA's opinion of 8 October 2008 and EFSA's opinion of 22 October 2008 on the risk of transmission of TSEs through milk, it must be recalled that the legality of a European Union measure is assessed on the basis of the elements of fact and of law existing at the time when the measure was adopted (Joined Cases 15/76 and 16/76 *France* v *Commission* [1979] ECR 321, paragraphs 7 and 8, and Joined Cases T-177/94 and T-377/94 *Altmann and Others* v *Commission* [1996] ECR II-2041, paragraph 119). It follows that elements post-dating the adoption of the European Union measure cannot be taken into account in assessing the legality of that measure (Case T-322/01 *Roquette Frères* v *Commission* [2006] ECR II-3137, paragraph 325).

173 Since AFSSA's opinion of 8 October 2008 and EFSA's opinion of 22 October 2008 were adopted after the adoption of the contested regulation, the Court cannot take account of them in assessing the legality of that regulation. It follows that the arguments put forward by the French Republic based on those opinions are ineffective.

The complaint alleging failure to assess the increase in the risk resulting from the adoption of the contested measures

174 As was stated in paragraph 84 et seq. above, the institutions enjoy a wide discretion as to the choice of the appropriate means of action in matters concerning the common agricultural policy. Moreover, although those institutions are obliged to ensure a high level of protection of human health, they also enjoy a wide discretion as to the choice of appropriate means of action in order to comply with that obligation. That wide discretion enjoyed by the institutions means that the review of observance of guarantees conferred by the European Union legal order in administrative procedures is

of fundamental importance (*Netherlands* v *Commission*, cited in paragraph 87 above, paragraph 56).

175 One of those guarantees consists in requiring the authorities to have available to them all the relevant information for that purpose when they adopt provisional measures pursuant to the precautionary principle in order to ensure a high level of protection of human health. It is therefore important for them to have available to them a scientific risk assessment founded on the principles of excellence, transparency and independence. That requirement constitutes an important guarantee designed to ensure the scientific objectivity of the measures adopted and preclude any arbitrary measures (see, to that effect, *Pfizer Animal Health* v *Council*, cited in paragraph 68 above, paragraph 172).

176 Another of those guarantees consists in requiring the authorities to have available to them a scientific assessment of the risks to human health to which the adoption of such provisions gives rise when they adopt provisions relaxing provisional measures adopted pursuant to the precautionary principle in order to ensure a high level of protection of human health.

177 Such a scientific assessment of the risks to human health includes, in principle, a comprehensive evaluation, by scientific experts, of the probability of exposure of humans to harmful effects of the measures for their health. Consequently, it includes, in principle, a quantitative evaluation of the risks in question (see paragraph 72 above).

178 However, it may prove impossible to carry out a full risk scientific assessment because of the inadequate nature of the available scientific data. However, that does not prevent the competent public authority from taking preventive measures in accordance with the precautionary principle. It is important, in such a situation, that experts carry out the fullest possible scientific risk assessment notwithstanding the existing

scientific uncertainty, so that the competent public authority has available to it sufficiently reliable and cogent information to allow it to understand the ramifications of the scientific question raised and decide upon a policy in full knowledge of the facts (see paragraph 77 above).

179 It follows that the necessity or otherwise of certain evaluations made by scientists participating in the scientific assessment of the risks to human health arising from the adoption of provisions relaxing the provisional measures adopted pursuant to the precautionary principle is assessed in the light, inter alia, of the available data.

180 In this case, the French Republic complains, in essence, that the Commission did not have available to it, at the time of the adoption of the contested measures, a scientific assessment of the risks to human health to which their adoption would give rise.

181 In that regard, it should be observed that, in its opinion of 5 June 2008, EFSA stated that the Commission had requested it to assess the additional risk to human health represented by the release for human consumption of meat from small ruminants less than six months old as compared with that from small ruminants less than three months old, originating from a flock infected by a TSE other than BSE, without being subjected to 'rapid tests' and irrespective of their genotype, but subject to the removal of SRM.

182 Following that request, however, EFSA and the Commission agreed that the requested assessment of the additional risk should relate only to the additional risk to humans of being exposed to TSEs and not to the additional risk to human health. That limitation of the requested assessment was justified by the fact that EFSA had already assessed the question of the risk of transmissibility to humans of TSEs in ovine and

caprine animals in its opinions of 8 March 2007 and 24 January 2008 and by the fact that no new scientific data justified a revision of those opinions.

183 However, in this case, it is not disputed that, in its opinions of 8 March 2007 and 24 January 2008, EFSA carried out an adequate scientific assessment of the risk of transmissibility to humans of TSEs in ovine and caprine animals which was available to the Commission before the adoption of the contested measures. Moreover, the French Republic founds its action, in part, on those opinions when it complains that the Commission made a biased interpretation of their content. Consequently, the French Republic's present complaint can relate only to the absence of any scientific risk assessment as regards the increase in the risk to humans of being exposed to TSEs following the adoption of the contested measures.

184 As regards the latter scientific assessment, it should be observed that the French Directorate-General for Food asked AFSSA to compare the additional risk to public health from products obtained from ovine and caprine animals from herds infected with classical scrapie, slaughtered under conditions corresponding to those set out in the contested measures, with that from a 'random' animal slaughtered under the conditions in force before the adoption of Regulation No 727/2007, given that the existing tools for monitoring in small ruminants made it possible to detect only, at best, a fraction of the herds infected with a TSE and that the ovine population was composed in part of genetically susceptible animals.

185 In reply to that request, AFSSA stated, in its opinion of 15 January 2007, that 'a relevant quantitative assessment of those risks [was then] impossible because of the inadequacy of the data concerning: [(i)] the real prevalence of scrapie in all infected flocks [and] [(ii)] the real genetic structure of the ovine population in general'.

186 In its opinion of 13 June 2007, AFSSA confirmed that reply by taking the view that 'the data enabling a precise quantitative assessment to be made [were] still not available' and that 'the data from the active surveillance of TSEs in small ruminants accumulated since 2002 were of insufficient quality to contemplate carrying out that quantitative study in the near future'.

187 Furthermore, in reply to the request of the French authorities to carry out a comparative analysis of the potential level of risk represented by the 'disinfection strategy', which corresponds, in essence, to the measures preceding those laid down by the contested regulation, as opposed to the 'alternative strategy', which corresponds, in essence, to the measures laid down by that regulation, AFSSA took the view that the strategies proposed as the replacement for the disinfection strategy posed a significantly increased risk both in terms of public health and in terms of animal health. However, in the light of the time-limits imposed and of the available data, it concluded that no quantified and relevant comparative analysis was possible.

188 However, in its opinions of 15 January 2007 and 13 June 2007, AFSSA also stated that an estimate or 'rough assessment' of that risk was possible.

189 In its opinion of 15 January 2007, AFSSA first stated the following:

'… studies carried out in flocks of ovine and caprine animals affected by scrapie have shown an incidence which may be as high as 10 to 45% of cohorts … Those figures make it possible to assess the order of magnitude of the additional risk of infection in a small ruminant born into a scrapie-infected flock'.

190 Secondly, AFSSA considered that the data on prevalence levels observed in certain flocks infected with classical scrapie 'ma[d]e it possible to make a rough assessment of that additional risk if it [was] borne in mind: [(i)] that the prevalence of classical scrapie in the general population of animals aged over 18 months, slaughtered, [was] of the order of 0.05 %; [(ii)] that the prevalence in flocks infected with classical scrapie [might] vary from about 1 to about 30 % (without taking account of the genotype of individuals)'. It inferred from this the following:

'[T]he relative risk represented by an animal from an infected flock by comparison with an animal from the general population would be 20 to 600. That additional risk would be further increased if account were taken only of animals of susceptible genotype from infected flocks.'

191 AFSSA's assessments regarding the estimated prevalence of TSEs within a flock of small ruminants infected with a TSE were shared by EFSA, which, in its opinion of 5 June 2008, stated that, although it was not possible to estimate prevalence in a given flock of small ruminants, it could be considered, on the basis of studies carried out on flocks naturally infected with the classical scrapie prion, that prevalence could range from 3 % to more than 40 %.

192 To supplement its analysis of the increased risk represented by the adoption of the contested measures, AFSSA tried, in its opinion of 13 June 2007, taking as its basis the data from the active surveillance carried out in 2006 in France, to determine the number of animals, with the exception of 'index cases', carriers of the susceptible genotype infected with classical scrapie, not detected by 'rapid tests' carried out on animals aged over 18 months and carriers of infectious material in their peripheral lymphoid organs, which could be released for human consumption following the adoption of the contested measures.

193 As regards ovine animals, AFSSA estimated that, for the 182 'index cases' infected with classical scrapie which were accounted for in France in 2006, the average number of secondary cases per 'index case' which were detected by 'rapid tests' was 5.34, which corresponded to the average estimated over the period from 2002 to 2006. Thus, 972 secondary cases were detectable in infected flocks. Moreover, AFSSA estimated that 'rapid tests' on the obex detected only around 50 % of infected animals, since they did not detect animals in incubation carrying infectivity in their lymphoid organs.

194 As regards caprine animals, AFSSA estimated that there were 8 outbreaks and 2.58 secondary cases per 'index case' in France and that 'rapid tests' were not more sensitive.

195 AFSSA pointed out that, as the active surveillance programmes did not detect all flocks infected with a TSE, some of the animals from those undetected infected flocks were also supplied for human consumption. However, AFSSA considered that it was impossible at the time to estimate usefully, for ovine as well as caprine animals, the number of infected animals from flocks wrongly considered to be healthy which were supplied each year for human consumption.

196 AFSSA also stressed that that estimate made it possible only to determine orders of magnitude and was dependent on the intensity of the active surveillance programme.

197 AFSSA concluded its opinion of 13 June 2007 by taking the view that the new animal-health proposals would have led, in France in 2006, to the supply for human consumption of at least 1 000 carcasses of small ruminants carrying significant amounts of infectivity in their lymphoid tissues. The release for human consumption of those carcasses is liable, according to AFSSA, to give rise to an increased risk of consumer exposure.

198 In the light of the scientific opinions referred to in paragraph 181 et seq. above, it cannot be complained that the Commission did not have available to it, at the time of the adoption of the contested measures, a quantitative scientific assessment of the additional risk to humans of being exposed to TSEs following the adoption of the contested measures.

199 Before the adoption of the contested measures, AFSSA had stated that, because of the lack of data regarding the real prevalence of scrapie in all infected flocks and regarding the true genetic structure of the ovine population in general, it was impossible to make a precise quantitative assessment of the increase in the risk due to the products obtained from ovine and caprine animals from herds infected with classical scrapie, slaughtered and tested under conditions corresponding to those set out in the contested measures and that that lack of data could not be overcome in the near future. In such circumstances, it cannot be complained that the Commission did not entrust such an assessment to EFSA or to any other scientific authority.

200 Furthermore, the lack of data regarding the real prevalence of scrapie in all infected flocks and regarding the real genetic structure of the ovine population in general preclude the inference that it was essential for the Commission to have available to it an estimate or 'order of magnitude' drawn up by a scientific authority of the increase in the risk to human health which the adoption of the contested measures would entail. Indeed, the lack of the data in question precludes the Commission from being required to ask a scientific authority for such an estimate of the risks in that regard. On the other hand, that lack of data does not by any means affect the obligation for the Commission to take account of all the available scientific assessments, including those made by AFSSA according to which the prevalence of scrapie in a flock infected with classical scrapie is significantly higher than that in a 'random' animal and according to which 'rapid tests' have limited effectiveness.

201 Consequently, the fact that the Commission did not have available to it, at the time of the adoption of the contested measures, a rough quantitative estimate, drawn up by EFSA or any other scientific authority, of the additional risk of exposure of humans to TSEs which their adoption would entail does not constitute a breach of the guarantees conferred by the European Union legal order.

202 Moreover, it must be pointed out that the quantitative estimate of that risk, expressed as a number of additional cases and made by the Commission itself following the commencement of the present action for annulment, has no bearing on the French Republic's complaint. Indeed, even assuming that the data on which the Commission's estimate is based were available at the time of the adoption of the contested regulation, that estimate does not seem to be issued by a scientific authority and, in any event, cannot be considered indispensable since it is only an estimate and not a quantitative assessment and AFSSA considered that a quantitative risk assessment was impossible because of the lack of relevant data (see paragraph 185 above).

4. *Risk management*

Overview of the parties' arguments

203 The French Republic maintains that, notwithstanding the broad discretion enjoyed by the European Union legislature in a field such as that concerned in this case and, consequently, the Court's limited power of review of the contested measures, by adopting such measures the European Union legislature breached both its obligation to ensure a high level of protection of human health and the precautionary principle. It submits that, in adopting the contested measures, the Commission relied on a twofold premiss relating, on the one hand, to the non-transmissibility to humans of animal

TSEs other than BSE, and, on the other, to the reliability of discriminatory tests for the purpose of distinguishing with certainty scrapie from BSE. However, the most recent scientific data, namely EFSA's conclusions in its opinions of 8 March 2007 and 24 January 2008, mention significant uncertainties concerning that twofold premiss. According to it, the most recent scientific data are not capable of changing the perception of the risk to human health posed by TSEs occurring in small ruminants and of justifying the adoption of less restrictive measures.

204 The Commission submits that, by taking into account all the available scientific opinions, it was entitled to conclude, in its capacity as risk manager, that a relaxation of the rules applicable to ovine and caprine animals would entail an acceptable level of risk for society. According to it, continuation of the slaughter and disposal of the whole flock of ovine or caprine animals whenever a TSE case was detected within that flock would be unjustified, since it would be disproportionate, in the light of the scientific advances enabling the development of biochemical discriminatory tests making it possible to distinguish rapidly BSE from scrapie. It further submits that the French Republic is attempting to assume the Commission's role in risk management and asking the Court to substitute its own risk assessment for that of the Commission on the question of the acceptable level of risk for society. However, the Court does not have any such power.

205 The United Kingdom submits that the French Republic's complaint regarding the question of risk management is no more than an expression of the French Republic's preference for a more cautious approach but that no manifest error of assessment is shown to have been made by the Commission. The French Republic erroneously bases its complaint on the premiss that the Commission is obliged to eliminate all risk to human health. However, the Commission managed the risk in question correctly by striking a balance, in the light of current, and evolving, scientific knowledge, between the assessed risk and measures appropriate for reducing that risk. The Commission

correctly concluded that the existing precautionary measures were no longer proportionate and that the existing control measures should be relaxed, but not removed.

Preliminary considerations

206 Under Article 13(1)(b) of Regulation No 999/2001, 'an inquiry shall be carried out to identify all animals at risk in accordance with Annex VII, point 1'. In addition, under Article 13(1)(c) of Regulation No 999/2001, 'all animals and products thereof at risk, as listed in Annex VII, point 2, [to] th[at] [r]egulation, identified by the inquiry referred to in point (b) of … paragraph [1 of Article 13] shall be killed and disposed of in accordance with Regulation (EC) No 1774/2002'. Thus, according to that provision, the animals which must be killed and disposed of are those which are identified by the inquiry to be carried out in accordance with point 1 of Annex VII to Regulation No 999/2001 and which, in addition, fulfil the criteria in point 2 of that annex.

207 According to Article 23 of Regulation No 999/2001, the Commission may amend the annexes to Regulation No 999/2001, in accordance with the comitology procedure referred to in Article 24(2) of that regulation, after consultation of the appropriate scientific committee on any question which could have an impact on public health. Thus, the legislature has delegated to the Commission the power to amend the annexes to Regulation No 999/2001.

208 In the light of the scope of Article 13(1)(c) and Article 23 of Regulation No 999/2001, the Commission must be recognised as having the power to limit, by regulation adopted in accordance with the comitology procedure referred to in Article 24(2) of Regulation No 999/2001, the animals identified by the inquiry which must be killed

and disposed of. Indeed, since Article 13(1)(c) of Regulation No 999/2001 defines the animals to be killed and disposed of by referring to the criteria in point 2 of Annex VII, the Commission had the power, under Article 23 of Regulation No 999/2001, to adopt provisions, such as those in issue in these proceedings, limiting the animals to be killed and disposed of which had been identified by the abovementioned inquiry.

209 The Commission's power to adopt the contested measures has not, however, been called into question by the French Republic, which, when questioned in that regard at the hearing, expressed the view, just like the Commission, that Article 13(1)(c) of Regulation No 999/2001 was to be interpreted as permitting the adoption of measures amending Annex VII to that regulation entailing the obligation to kill and dispose of certain animals and not all the animals in a flock in which a case of TSE has been detected.

210 It follows that, in the second citation in the preamble to the contested regulation, the Commission correctly stated that the latter had been adopted in accordance with Article 23 of Regulation No 999/2001.

211 Moreover, it must be recalled that the competent public authorities are obliged to maintain a high level of protection of human health even though that level does not have to be the highest possible (see paragraphs 64 and 79 above). Article 24a of Regulation No 999/2001 recalls that obligation in the context of the powers conferred on the Commission to amend the annexes to Regulation No 999/2001 by making the adoption of decisions taken in the context of that regulation subject to the condition that the level of protection of human health ensured in the Community is maintained or, if scientifically justified, increased. The precautionary principle is one of the instruments enabling those authorities to satisfy that obligation (see paragraph 67 above). That principle requires the public authority to manage a risk exceeding the level of risk deemed acceptable for society in such a way as to contain it at that level

(see paragraphs 67 to 81 above). Risk management through the adoption of appropriate measures to ensure a high level of protection of public health, safety and the environment therefore corresponds to all the actions undertaken by an institution in order to cope with a risk in such a way as to contain it at an acceptable level.

212 Furthermore, it is for the competent authorities to review the provisional measures which they have adopted in accordance with the precautionary principle within a reasonable period. It has been held that, when new elements change the perception of a risk or show that that risk can be contained by measures less restrictive than the existing measures, it is for the institutions, and in particular the Commission, to bring about an amendment to the rules in the light of the new information (see paragraph 83 above). Thus, the relaxation of preventive measures adopted previously must be justified by new elements changing the assessment of the risk in question.

213 When those new elements, such as new knowledge or new scientific discoveries, justify a relaxation of a preventive measure, they change the specific content of the obligation for the public authorities to maintain consistently a high level of protection of human health. Indeed, those new elements may change the perception of the risk and the level of risk which are deemed acceptable by society. The legality of the adoption of a less restrictive preventive measure is not assessed on the basis of the level of risk deemed acceptable which was taken into account for the adoption of the initial preventive measures. Indeed, the adoption of initial preventive measures in order to reduce the risk to a level deemed acceptable takes place on the basis of a risk assessment and, in particular, of the determination of the level of risk deemed acceptable for society. If new elements change that risk assessment, the legality of the adoption of less restrictive preventive measures must be assessed in the light of those new elements and not in the light of the elements which determined the risk assessment in the context of the adoption of the initial preventive measures. It is only when that new

level of risk exceeds the level of risk deemed acceptable for society that a breach of the precautionary principle must be found by the Court.

214 Finally, it must be recalled that the level of risk deemed unacceptable for society in a specific case results from a political choice which lies with the competent authority and not with the Court (see paragraph 78 above). The competent authority enjoys a broad discretion in that context and it is not for the Court to assume the authority's role. The Court's review of the substance is confined to examining whether the exercise by the authority of its powers is vitiated by a manifest error of assessment, whether there was a misuse of powers or whether the authority clearly exceeded the limits of its discretion (see paragraph 85 above). Finally, as regards the assessment by the Courts of the European Union as to whether an act of an institution is vitiated by a manifest error of assessment, it must be stated that, in order to establish that that institution committed a manifest error in assessing facts such as to justify the annulment of that act, the evidence adduced by the applicant must be sufficient to make the factual assessments used in the act implausible (see paragraph 86 above).

The new elements

215 In 2000, in the context of the BSE crisis, the Commission introduced some measures for the monitoring, prevention, control and eradication of TSEs in ovine and caprine animals, on the basis of the scientific knowledge available at that time, and in order to ensure that sourcing from ovine and caprine animals' materials is as safe as possible (see recitals 3, 4 and 6 in the preamble to the contested regulation). Those measures were adopted on the basis of poor scientific knowledge as regards the prevalence and transmissibility to humans of TSEs in ovine and caprine animals. Apart from prevention, those measures were aimed at gathering data on the prevalence of TSEs other

than BSE in ovine and caprine animals, and on possible links with BSE and transmissibility to humans.

216 As compared with the situation existing at the time of the adoption of the initial preventive measures, the Commission relied, in essence, on three new elements which, it claimed, justified the adoption of the contested measures.

217 Firstly, the Commission relied on the absence of any epidemiological link between, on the one hand, classical or atypical scrapie in small ruminants and, on the other, TSEs in humans since the implementation of the initial preventive measures including active surveillance of small ruminants. It referred, in that regard, to the EFSA opinions of 8 March 2007 and 24 January 2008 (see recitals 4 and 6 in the preamble to the contested regulation).

218 Secondly, the Commission relied on the development and validation of molecular discriminatory tests making it possible to distinguish reliably scrapie from BSE within a short period of time. It considered that the reliability of those tests had been confirmed by EFSA in its opinions of 8 March 2007 and 24 January 2008.

219 Thirdly, the Commission relied on the epidemiological data according to which the likely prevalence of BSE in ovine and caprine animals was very low (see recitals 15 and 16 in the preamble to the contested regulation).

220 The French Republic does not dispute the novelty of those elements, but disputes the assessment that they can justify the adoption of the contested measures.

221 It must therefore be determined whether, in the light of those new elements, the Commission had to adopt the contested measures, since they made it possible, while maintaining a high level of protection of human health, to reduce the cost for society in general of the preventive measures concerning TSEs in small ruminants, or, on the contrary, whether, by adopting the contested measures, the Commission breached the precautionary principle and infringed Article 24a of Regulation No 999/2001 and, consequently, breached the obligation contained in that principle and that provision to maintain a high level of protection of human health by exposing people to risks which exceed the level of risk deemed acceptable for society.

The complaint alleging a manifest error of assessment in the management of the risk

Introduction

222 By contrast with the regime pre-dating Regulation No 727/2007, which was replaced by the contested regulation, the contested measures allow, in essence, the release for human consumption, on the one hand, of meat from small ruminants over 18 months of age which form part of a herd within which a case of TSE, which is not BSE, has been detected and which, for those which are slaughtered immediately or within two years following the detection of the last case of TSE, have been subjected to a 'rapid test' the result of which is negative, and, on the other, of meat from small ruminants from 3 to 18 months of age and which form part of a herd within which a case of TSE, which is not BSE, has been detected, without being subjected to 'rapid tests'.

223 The French Republic maintains that the risks to human health posed by the contested measures manifestly exceed the level of risk which is acceptable for society, and that the Commission therefore made a manifest error of assessment by adopting the contested measures. According to it, the Commission thus breached the precautionary principle and its obligation to maintain the high level of protection of human health referred to in Article 24a of Regulation No 999/2001. The Commission submits, by contrast, that, in the light of the new elements, it was obliged to adopt the contested measures.

224 In that regard, it must be pointed out that detection of a TSE case in a herd, allowing the application of the contested measures, takes place, in particular, on the basis of a sampling of the general population of small ruminants and of 'rapid tests', which entails a risk of non-detection of TSE cases in the general population of small ruminants. However, that risk constitutes an acceptable risk for society, according to the French Republic. Indeed, the latter's complaint relates only to the risk of release for human consumption of meat from small ruminants which form part of a flock within which a TSE case has been detected, and not to the risk of non-detection of that case.

225 Furthermore, it is clear from EFSA's and AFSSA's opinions mentioned in paragraphs 190 and 191 above that prevalence in a flock containing an animal infected with classical scrapie could be estimated at a proportion ranging from 1% to over 40% whereas the prevalence of classical scrapie in the general population of animals over 18 months of age was of the order of 0.05% (see AFSSA's opinion of 15 January 2007, pp. 4 and 7, and EFSA's opinion of 5 June 2008, p. 8). The Commission was entitled to consider that small ruminants originating from a flock containing one case infected with a TSE, in the form of classical scrapie, have a greater likelihood of being infected than those originating from the general population of small ruminants.

226 Moreover, in its opinion of 5 June 2008, EFSA considered that infections of small ruminants with scrapie under natural conditions are generally contracted at or very soon after birth and the clinical signs appear within two to three years from the time

of infection in susceptible small ruminants. Furthermore, in that opinion, it stated, on the basis of a scientific study, that, in lambs of susceptible genotype which are exposed to an infection by a classical scrapie agent, the first signs of infection are detected in the first month of life in the alimentary canal and its associated lymphoid structures. On the other hand, the prions are detectable in the central nervous system only from the middle of the incubation period (see EFSA's opinion of 5 June 2008, pp. 8 and 9). In the annex to its opinion of 5 December 2007, AFSSA mentions a pattern of dissemination of the TSE agent in the organism which comprises three stages. The first stage, known as 'lympho-invasion', is characterised by early contamination of the lymphoid structures of the digestive tract then of the associated lymph nodes and leads progressively to the accumulation of PrPres in all secondary lymphoid formations. The second stage, known as 'neuro-invasion', is characterised by an accumulation of PrPres first in the neurones of the peripheral autonomous nervous system associated with the digestive tract then in those of the central nervous system. Finally, the third stage, known as 'centrifugal dissemination', is the stage in which the disease is disseminated from the central nervous system to peripheral structures such as muscle tissue.

The increase in the risk of exposure of humans to TSEs occurring in small ruminants

— The release for human consumption of meat from small ruminants over 18 months of age

227 A first relaxation of the rules in force provided for by the contested measures consists in allowing the release for human consumption of meat from small ruminants over 18 months of age which form part of a herd within which a TSE case has been detected, which is not BSE, provided, in the case of small ruminants slaughtered immediately

or within two years following the detection of the last TSE case detected in that herd, that they are subjected to a rapid test and that the result of that test is negative (see points 2.3(b)(iii) and 4 of Chapter A of Annex VII to Regulation No 999/2001, as amended by the contested regulation).

228 In that regard, it should be recalled that the infection of small ruminants with scrapie under conditions of natural exposure generally takes place at birth (see paragraph 226 above), that in genetically susceptible ovine animals the central nervous system is infected with prions from the age of 18 months (see paragraph 226 above) and that 'rapid tests' are almost 100 % effective when carried out on the obex (see paragraph 119 above). In the light of those considerations and subject to examination of the assessment of the reliability of discriminatory tests supporting the conclusion that the 'index case' was infected with a TSE which was not BSE, the Commission was entitled to consider, without committing a manifest error of assessment, that, in the case of genetically susceptible ovine animals, the first relaxation provided for by the contested measures does not entail a significant increase in the risk to humans of being exposed to meat from an animal infected with a TSE, provided that the carcass of the small ruminant from which the meat comes has been subjected to 'rapid tests' and that the result of those tests is negative. On the other hand, in the case of ovine animals with a lower susceptibility or of caprine animals, the same conclusion does not necessarily apply. It follows that that relaxation measure entails a certain increase in the exposure of humans to TSEs occurring in small ruminants.

229 The French Republic further submits that that relaxation measure entails an increase in the risk in so far as it limits to two years, following the last TSE case detected, the obligation to subject small ruminants over 18 months of age which have been slaughtered to 'rapid tests'. In reply to that argument, the Commission refers to the extremely low likelihood that infected animals would be detected during that period. According to the Commission, the measure in question means that, during those two years, no animal aged over 18 months which is slaughtered must present an infection.

Furthermore, in reply to some written questions put by the Court with regard to that relaxation measure, the Commission maintained that the information submitted by the Member States pursuant to Article 6(2) and (4) of Regulation No 999/2001 did not mention any resurgence of scrapie cases on holdings beyond the two years after the discovery of infected cases.

230 In that regard, it is plausible that the likelihood that animals over 18 months of age infected with a TSE which are released for consumption would not be detected during the period of two years following the last TSE case detected is extremely low. Indeed, as was stated in paragraph 226 above, since infection under natural conditions is generally contracted at birth, and that, in such a situation, from the age of 18 months the prions become detectable in the obex, 'rapid tests' on those animals over 18 months of age can be considered to be highly reliable.

231 However, the latter assessment does not give any precise indication as to the risk of exposure of humans to TSEs occurring in small ruminants posed by human consumption of meat from small ruminants over 18 months of age within the two years following the last TSE case detected within the flock. The latter assessment depends potentially on the frequency of slaughter of small ruminants over 18 months of age within that flock. However, the Commission has not put forward any evidence on the basis of which that factor can be assessed.

232 Moreover, in so far as the Commission takes the view that the information submitted by the Member States pursuant to Article 6(2) and (4) of Regulation No 999/2001 did not indicate any resurgence of scrapie cases beyond the two years after the discovery of TSE cases, it must be noted that the Commission has not provided those data. Furthermore, the French Republic's line of argument put forward at the hearing that those data do not give any indication of such a resurgence, since the relaxation measure in question was not yet in force, is plausible.

233 Consequently, in the light of the foregoing, it must be held that the first relaxation measure envisaged by the contested measures is liable to entail an increase in the risk of exposure of humans to TSEs occurring in small ruminants.

— The release for human consumption of meat from small ruminants from 3 to 18 months of age

234 The second relaxation of the rules in force provided for by the contested measures consists in allowing the release for human consumption of meat from small ruminants from 3 to 18 months of age originating from a flock within which a case of TSE, which is not BSE, has been detected, without those small ruminants being subjected to 'rapid tests'.

235 The absence of 'rapid tests' on slaughtered small ruminants from 3 to 18 months of age is not disputed. It is explained by the fact that, before small ruminants reach the age of 18 months, the prions have not yet reached the obex of sick small ruminants in sufficient quantity and therefore the results of 'rapid tests' carried out on the obex of those animals cannot be reliable (see EFSA's opinion of 5 June 2008, p. 9).

236 Moreover, the Commission concedes that those measures entail a 'mathematical increase' in the risk of exposure of humans to TSEs occurring in small ruminants.

237 Before assessing the extent of the increase in the risk of exposure of humans to TSEs occurring in small ruminants, it is important to observe that three factors may influence that assessment, namely, the effectiveness of the removal of SRM, the age of

the small ruminants released for human consumption and the genotype of the ovine animals released for human consumption.

238 As regards SRM, it must be observed that this includes, on the one hand, the skull including the brain and eyes, the tonsils and the spinal cord of small ruminants aged over 12 months or which have a permanent incisor erupted through the gum and, on the other, the spleen and ileum of small ruminants of all ages (see point 1 of Annex V to Regulation No 999/2001). Its disposal implies a limitation of the infected tissues which could potentially be released for human consumption following the adoption of the contested measures.

239 As regards the age of small ruminants slaughtered, since a TSE infection of a small ruminant under natural conditions is generally contracted at birth, but spreads only progressively within the organism, the younger the age at which the animal is slaughtered, the lower the risk. This was indirectly acknowledged by the French Republic at the hearing when it maintained that, up to the age of three months, it had to be considered that the small ruminant infected by the prion has not developed the TSE sufficiently to endanger human health. However, the parties have not provided any precise data on the number of small ruminants slaughtered by age bracket in Europe.

240 Finally, as regards the genotype of ovine animals slaughtered, it must be observed that, in the case of animals of resistant genotype, namely the ARR/ARR genotype, originating from a flock within which a case of TSE, which is not BSE, has been detected, it is not disputed that the risk of a classical scrapie infection is extremely low, although it cannot be completely excluded (see paragraph 18 above). By contrast, in the case of animals of susceptible genotype, namely the VRQ/VRQ genotype, originating from a flock within which a case of TSE, which is not BSE, has been detected, the risk of a classical scrapie infection of a small ruminant originating from that flock is high. Thus, the release for human consumption of meat from small ruminants of susceptible genotype originating from a flock within which a case of TSE has been detected entails an increase in the risk of exposure of humans to TSEs occurring in small ruminants.

— Extent of the increase in the risk of exposure of humans to TSEs occurring in small ruminants

241 As was set out in paragraph 184 et seq. above, AFSSA stated on two occasions that a quantitative assessment of the increase in the risk of exposure of humans to TSEs occurring in small ruminants entailed by the adoption of the contested measures was not possible in view of the inadequacy of the data concerning the real prevalence of scrapie in all infected flocks and the real genetic structure of the ovine population in general.

242 However, in its opinion of 13 June 2007, AFSSA gave an 'order of magnitude' of the increase in the risk in question. It considered, on the basis of the data collected in France, that tests on the obex detect only about 50 % of the infected animals in infected flocks, the remaining approximately 50 % corresponding to animals in incubation carrying infectivity in their lymphoid organs. In its opinion of 5 December 2007, AFSSA confirmed that the value of 50 % contained in its opinion of 13 June 2007 was representative.

243 Consequently, despite the imperfection of AFSSA's estimates, the adoption of the contested measures entails a not insignificant increase in the risk of exposure of humans to TSEs occurring in small ruminants as a result of the release for human consumption of meat from animals infected with a TSE.

244 The Commission's arguments do not make it possible to call into question that not insignificant increase in the risk of exposure of humans to TSEs occurring in small ruminants.

245 In so far as the Commission submits that 'rapid tests' detect the great majority of animals of susceptible genotype because such animals represent more or less 50 % of the ovine population and 'rapid tests' detect susceptible animals much more quickly, it must be observed that, while it may be inferred from EFSA's opinion of 5 June 2008 that susceptible animals infected with a TSE can be detected by 'rapid tests' carried out on the obex effectively from an age between 12 and 18 months, AFSSA stated that the 50 % of animals undetected corresponded to animals in incubation carrying infectivity in their lymphoid organs. Consequently, the more rapid detection of animals of susceptible genotype does not affect AFSSA's assessment that tests on the obex detect only about 50 % of infected animals (see paragraph 242 above).

246 In so far as the Commission relies on the removal of SRM, it must be observed that AFSSA considered, in its opinion of 15 January 2007, that 'in individuals of susceptible genotype (not carrying an ARR allele), the removal of SRM, even when extended to the head and intestines, [did] not make it possible to dispose of all tissues carrying significant levels of infection'. Thus, even though the removal of SRM helps to limit the risk of exposure of humans to TSEs occurring in small ruminants, that measure does not make it possible to call into question the assessment that the increase in that risk is not insignificant.

247 Moreover, it must be observed that, regardless of the question of its scientific rigour, the estimate made by the Commission during the proceedings does not invalidate AFSSA's rough estimate from which it is possible to infer a not insignificant increase in the exposure of humans to ovine and caprine TSEs following the adoption of the contested measures.

248 Notwithstanding the foregoing, it must however be observed that the French Republic has not adduced any evidence making it possible to call into question the Commission's assessment that the increase in the risk of exposure of humans to TSEs occurring in small ruminants entailed by the adoption of the contested measures is considerably smaller than that entailed by the reduction in the monitoring programme provided for by Regulation No 727/2007.

The increase in the risk to human health

— Introduction

249 The fact that the contested measures entail an increase in the risk of exposure of humans to TSEs occurring in small ruminants is not sufficient to establish a breach of the precautionary principle or of the obligation for the Commission to maintain a high level of protection of human health enshrined in Article 152(1) EC and Article 24a of Regulation No 999/2001. Indeed, such a breach may be established only to the extent that the adoption of the contested measures and, therefore, the increase in the risk of exposure of humans to TSEs occurring in small ruminants entail risks to human health which exceed the level deemed acceptable for society.

250 In order to determine whether the Commission made a manifest error of assessment in its risk management, it must be determined whether the Commission was entitled to consider, without making a manifest error of assessment, that the contested measures were appropriate to ensure a high level of protection of human health. In that regard, a distinction must be drawn between, on the one hand, the question of the risk to human health of being exposed to meat from small ruminants which is contaminated with BSE following the adoption of the contested measures and, on the other, the question of the risk to human health of being exposed to meat from small ruminants which is contaminated with scrapie following the adoption of the contested measures.

— The risk to human health in the context of human consumption of meat from ovine or caprine animals infected with TSEs other than BSE

251 For the reasons set out in paragraph 93 et seq. above, it must be held that the Commission did not commit a manifest error of assessment by considering, on the basis of the available scientific opinions, that the risk of transmissibility to humans of TSE agents other than BSE which are present in ovine and caprine animals was extremely low.

252 An extremely low risk of transmissibility to humans of TSEs other than BSE occurring in small ruminants reduces considerably the impact on human health of the increase in the risk of exposure of humans to TSEs other than BSE occurring in small ruminants entailed by the adoption of the contested measures.

253 Consequently, as regards TSEs other than BSE occurring in small ruminants, the Commission was entitled to consider, without making a manifest error of assessment, that the contested measures do not entail an increase in the risk to human health exceeding the level of risk deemed acceptable for society.

— The risk to human health in the context of human consumption of meat from ovine or caprine animals infected with BSE

254 In order to review the assessment made by the Commission of the risk to human health entailed by the contested measures in the light of the transmissibility to humans of BSE, it is first necessary to reiterate the importance of molecular discriminatory tests in the regime provided for by the contested measures.

255 The contested measures provide that, when a case of TSE is detected within the general population of small ruminants, the infected animal is to be slaughtered, samples taken from its body are to be subjected to a molecular discriminatory test and its body is to be destroyed. If the result of that test is positive, the flock to which the individual belongs is to be completely destroyed. On the other hand, if the result of that test is negative, the flock to which the individual belongs may be released for human consumption provided that slaughtered animals which are over 18 months of age are subjected to a rapid test within a period of two years following the last TSE case detected and that the result of that test is negative.

256 The molecular discriminatory tests provided for by the contested measures thus help to reduce the risk of exposure of humans to BSE occurring in small ruminants by making it possible to exclude the release for human consumption of meat originating from a flock within which there has been a case of BSE. The consequence of a failure in such a test is, in particular, that the flock within which a case of BSE becomes apparent may be released for human consumption without the animals which are less than 18 months of age being subjected to any test.

257 However, molecular discriminatory tests were not introduced into Regulation No 999/2001 by the contested measures. Those tests have formed part of Regulation No 999/2001 since 2005 in order to identify BSE cases among TSE cases identified following active surveillance or suspect cases (see paragraph 27 above). The French Republic has not, however, called into question the reliability of those tests in that context.

258 In its opinions of 8 March 2007 and 24 January 2008, EFSA considered that, on the basis of the available data, molecular discriminatory tests were to be regarded as practicable tools for screening field TSE cases in accordance with point 3.2(c) of Chapter C of Annex X to Regulation No 999/2001, and that they fulfilled the objective of rapid

and reproducible identification of TSE cases that have a signature compatible with classical BSE.

259 However, AFSSA and EFSA also took the view that molecular discriminatory tests could not be considered perfect. That imperfection results from the lack of understanding of the true biodiversity of TSE agents in ovine and caprine animals and how those agents interact in case of co-infection (see EFSA's opinions of 8 March 2007, p. 7, and 24 January 2008, p. 7). Although no scientific data evidences such a co-infection under natural conditions (see paragraph 154 above), it cannot be excluded. The imperfection of molecular discriminatory tests also arises from the imperfect evaluation of their sensitivity and specificity. In its opinion of 20 July 2006, AFSSA thus stated that, although the sensitivity of the discriminatory tests was estimated at 100 %, the lower limit of the confidence scale relating to that sensitivity was 82.35 %, since the estimate of sensitivity had been established only on the basis of 19 small ruminants experimentally infected with BSE. In its opinion of 25 January 2007, EFSA stated that the limits of that evaluation of the molecular discriminatory tests arise in part from the absence of detection of natural BSE cases in caprine and ovine animals. It also stated that the molecular discriminatory tests had been designed to distinguish classical BSE from other TSEs. They were therefore not evaluated in terms of their ability to distinguish L-type or H-type BSE from other TSEs.

260 Consequently, the contested measures do not make it possible to exclude the possibility that meat originating from a flock within which an animal has been infected with BSE may be released for human consumption.

261 However, as regards classical BSE, it must be reiterated that, for the reasons given in paragraph 157 et seq. above, the Commission was entitled to consider, without making a manifest error of assessment, that the prevalence of classical BSE in small ruminants was very low. Furthermore, it must be reiterated that, at the time of the adoption of the contested measures, only one case of BSE had been confirmed in small

ruminants and concerned a goat which had been fed meat and bone meal, which is now banned.

262 Given that molecular discriminatory tests have been recognised by EFSA as fulfilling the objective of rapid and reproducible identification of TSE cases that have a signature compatible with classical BSE, that the estimated prevalence of classical BSE in small ruminants is very low, that only one case of BSE in small ruminants has been identified and that a very small number of TSE cases is still under analysis in order to determine definitively whether they are a TSE or BSE, the Commission was entitled to consider, without making a manifest error of assessment, that the additional risk of exposure of humans to classical BSE occurring in small ruminants entailed by the adoption of the contested measures did not give rise to risks to human health which exceeded the level of risk deemed acceptable for society.

263 As regards the risk of exposure of humans to strains of BSE other than classical BSE, it must be observed that, in its opinion of 25 January 2007, EFSA considered that the significance, origin and transmissibility of L- or H-type BSE were, at that time, speculative. The authors of the scientific article referred to by the French Republic did not cast doubt on that assessment even though they did mention a possible transmissibility to humans of L-type BSE.

264 However, in the absence of additional evidence, the Commission was entitled to consider, without making a manifest error of assessment, that the additional risk of exposure of humans to types of BSE other than classical BSE occurring in small ruminants entailed by the adoption of the contested measures did not give rise to risks to human health which exceeded the level of risk deemed acceptable for society.

Conclusion

265 In the light of all the foregoing considerations, the Commission was entitled to consider, without making a manifest error of assessment, on the basis of the scientific data available to it, that the increase in the risk of exposure of humans to TSEs occurring in small ruminants entailed by the adoption of the contested measures did not give rise to risks to human health which exceeded the level of risk deemed acceptable for society.

266 Consequently, the Commission did not breach the precautionary principle and the obligation to maintain a high level of protection of health enshrined in Article 152(1) EC and Article 24a of Regulation No 999/2001 by adopting the contested measures. The action must therefore be dismissed.

Costs

267 Under Article 87(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since the French Republic has been unsuccessful, it must be ordered to bear its own costs and to pay those of the Commission in respect of the main proceedings and the interlocutory proceedings, in accordance with the form of order sought by the Commission.

268 In addition, in accordance with Article 87(4) of the Rules of Procedure, which provides that the Member States which intervened in the proceedings are to bear their own costs, the United Kingdom must be ordered to bear its own costs.

On those grounds,

THE GENERAL COURT (Third Chamber, Extended Composition)

hereby:

1. **Dismisses the action;**

2. **Orders the French Republic to bear its own costs and to pay those of the European Commission in respect of the main proceedings and the interlocutory proceedings;**

3. **Orders the United Kingdom of Great Britain and Northern Ireland to bear its own costs.**

Azizi Cremona Labucka

Frimodt Nielsen O'Higgins

Delivered in open court in Luxembourg on 9 September 2011.

[Signatures]

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