Reports of Cases

JUDGMENT OF THE COURT (Fourth Chamber)

11 July 2013 *

(Appeal — Action for annulment — Protection against transmissible spongiform encephalopathies — Regulation (EC) No 746/2008 — Regulation authorising less restrictive measures of surveillance and eradication than those previously laid down — Precautionary principle — Level of protection of human health — New elements capable of altering the perception of the risk — Failure to state reasons — Distortion of the facts — Error of law)

In Case C-601/11 P,

APPEAL under Article 56 of the Statute of the Court of Justice of the European Union, brought on 28 November 2011,

French Republic, represented by E. Belliard, C. Candat, R. Loosli-Surrans, G. de Bergues and S. Menez, acting as Agents,

appellant,

the other parties to the proceedings being:

European Commission, represented by F. Jimeno Fernández and D. Bianchi, acting as Agents, with an address for service in Luxembourg,

defendant at first instance,

United Kingdom of Great Britain and Northern Ireland,

intervener at first instance,

THE COURT (Fourth Chamber),

composed of L. Bay Larsen, President of the Chamber, J. Malenovský, U. Lõhmus (Rapporteur), M. Safjan and A. Prechal, Judges,

Advocate General: M. Wathelet,

Registrar: A. Calot Escobar,

having regard to the written procedure,

having decided, after hearing the Advocate General, to proceed to judgment without an Opinion,

gives the following

* Language of the case: French.

Judgment

1 By its appeal, the French Republic seeks to have set aside the judgment of the General Court of the European Union of 9 September 2011 in Case T-257/07 *France* v *Commission* [2011] ECR II-4153 ('the judgment under appeal'), by which that court rejected its action for partial 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; 'the contested regulation').

Legal context

Regulation (EC) No 178/2002

2 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 [European Union] 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 [European Union], 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.'

Regulation (EC) No 999/2001

3 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), as amended by Commission Regulation (EC) No 727/2007 of 26 June 2007 (OJ 2007 L 165, p. 8) ('Regulation No 999/2001), provides:

'When the presence of a [transmissible spongiform encephalopathy ("TSE")] has been officially confirmed, the following measures shall be applied as soon as possible:

…

(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 [of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption (OJ 2002 L 273, p. 1)].

…'

4 Article 23 of Regulation (EC) 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 [European Union].’

6 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 feeding stuffs, other material or any other means of transmission, which may have transmitted the [bovine spongiform encephalopathy (‘BSE’)] 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 animals which are genetically non-sensitive or 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).

…'

The contested regulation

7 The contested regulation amended Annex VII to Regulation No 999/2001, reproducing almost word for word the text of that annex, in the version resulting from Regulation No 727/2007.

8 The provisions contested by the French Republic in the present appeal are point 2.3(b)(iii) and (d) and point 4 of Chapter A of Annex VII of Regulation No 999/2001 (collectively the 'contested measures').

9 Point 2.3(b)(iii) of Chapter A of Annex VII lays down the conditions under which Member States can decide, in the case of confirmation of TSE in an ovine or caprine animal and provided that BSE is excluded in accordance with the test procedures set out in Regulation No 999/2001 not to kill and destroy all the animals identified where the proportion of genetically resistant ovine animals is low in the holding, where it is difficult to obtain resistant replacement ovine animals, in order to preserve the genetic richness of a herd or of a race, or based on a reasoned consideration of all the epidemiological factors.

10 Under point 2.3(d) of Chapter A of Annex VII of Regulation No 999/2001, Member States may decide, in certain conditions, to replace the killing and complete destruction of individual animals by slaughtering them for human consumption, provided that the animals are slaughtered within the territory of the Member State concerned and all animals which are over 18 months of age or which have more than two permanent incisors erupted are tested for TSE.

11 Point 4 of the same chapter fixes the conditions for maintaining the holding of animals from a flock infected with TSE and their slaughter for human consumption within two years following the detection of the last case of TSE. It provides that all animals over the age of 18 months which are dead or slaughtered for human consumption are to be tested for TSE.

Background to the dispute and the contested regulation

12 The background to the dispute was set out at paragraphs 12 to 46 of the judgment under appeal and may be summarised as follows.

13 TSEs are neurodegenerative diseases which affect both animals and humans and have a slow rate of development and fatal outcome. Among the TSEs which can affect ovine, caprine or bovine animals, it is possible to distinguish the following pathologies: BSE, classical scrapie and atypical scrapie.

14 Given that BSE, a disease which can be transmitted to humans, could theoretically also infect ovine and caprine animals under natural conditions, different measures for the prevention and eradication of TSEs in the ovine and caprine population were introduced into European Union legislation.

15 On 22 May 2001, Regulation No 999/2001 was adopted, which brings together within a single text all the existing provisions concerning the control of TSEs. That regulation 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 including the destruction of animals at risk. That regulation, in addition, requires each Member State to introduce an annual programme for monitoring TSEs to be carried out on, inter alia, the basis of screening using so-called 'rapid tests' on samples of the ovine and caprine population.

16 The rapid tests enable the existence of a TSE to be identified in a short period of time, but not its type, namely, BSE, classical scrapie or atypical scrapie. Where the results of those rapid tests are positive, the brainstem undergoes confirmatory examinations in a reference laboratory. Where, following those tests, BSE cannot be excluded, those tests are to be supplemented by biological tests on live mice.

17 Regulation No 999/2001 has been amended on a number of occasions between 2001 and 2007. Those amendments related to, inter alia, measures to control TSEs in ovine and caprine animals in the light of developments in scientific knowledge concerning TSEs, such as the development of the molecular discriminatory tests capable of differentiating BSE from classical scrapie or from atypical scrapie ('discriminatory tests'). The application of those tests presupposes prior identification of a TSE case which may in particular be done using rapid tests.

18 Under the legislation in force in 2005, Member States had only the choice, when an animal, in a flock of ovine or caprine animals, was infected with a TSE which was not BSE either to destroy all the animals in the flock to which the infected animal belonged or, where the infected animal was an ovine animal, to destroy only 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. 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.

19 Following the confirmation, on 28 January 2005, of the presence of BSE in a goat born during 2000 and slaughtered in France during 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.

20 On 15 July 2005, the European Commission adopted the communication entitled 'TSE Road Map' (COM(2005) 322 final), in which it announced its intention to propose new measures designed to relax the eradication measures in force for small ruminants taking into account the new diagnostic tools available while maintaining the current level of consumer protection. It took the view in particular that, when BSE was excluded, a public health risk was no longer present and total herd culling could be considered disproportionate on public health grounds.

21 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, first, the health risks entailed by the measures proposed by the Commission in the TSE Road Map with regard to ovine and caprine animals and, second, the reliability of discriminatory tests.

22 On 26 October 2005, the European Food Safety Authority (EFSA) adopted an opinion on the classification of atypical TSE cases in small ruminants, recommending that monitoring programmes use appropriate combinations of tests and sampling to ensure that atypical scrapie cases continued to be identified.

23 Between December 2005 and February 2006, the monitoring programmes for TSEs implemented in the European Union made it possible to detect two sheep from France and one sheep from Cyprus suspected of being infected with BSE. Following those detections, the Commission introduced increased monitoring of TSEs in ovine animals in all the Member States.

24 On 15 May 2006, AFSSA issued an opinion in which 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 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.

25 In response to new requests brought by the French authorities, AFSSA issued an opinion, on 15 January 2007, relating to the developments in health measures in which 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. Consequently, AFSSA recommended the retention of the legislation in force concerning classical scrapie.

26 EFSA, following a reference from the Commission, on 25 January and 8 March 2007, issued two opinions on the quantitative risk assessment on the residual BSE risk in sheep meat and meat products and on certain aspects related to the risk of TSEs in ovine and caprine animals, respectively.

27 As regards that first opinion on BSE, EFSA considered that the most likely prevalence of BSE in sheep was zero. As regards TSE, it considered that even though there was no evidence for an epidemiological or molecular link between classical or atypical scrapie and TSEs in humans, transmissibility to humans of animal TSE agents other than BSE could not be excluded. In addition, it considered that the discriminatory tests as described in European Union law appeared, up to then, to be reliable for the purpose of differentiating BSE from classical and atypical scrapie, even though neither the diagnostic sensitivity nor the specificity of those tests could be considered to be perfect.

28 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.

29 On 26 June 2007, the Commission adopted Regulation No 727/2007 against which the French Republic brought an action before the General Court.

30 On 24 January 2008, at the Commission's request, EFSA issued 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, EFSA clarified its position regarding questions of the transmission to humans of animal TSEs other than BSE and of the reliability of discriminatory tests.

31 On 30 April 2008, the reference laboratory published an opinion in which it stated that the two sheep from France and the one sheep from Cyprus (see paragraph 23 above) could not be classed as cases of BSE.

32 On 17 June 2008, the Commission adopted the contested regulation amending Annex VII to Regulation No 999/2001 granting the Member States a greater choice of measures to be adopted 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. That regulation reproduces almost word for word the provisions of Regulation No 727/2007 relating to Annex VII to Regulation No 999/2001, while supplementing that regulation's statement of reasons.

33 Accordingly, the contested regulation allows, 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 which are 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.

The procedure before the General Court and the judgment under appeal

34 By application lodged at the Registry of the General Court on 17 July 2007, the French Republic brought an action requesting the General Court to annul point 3 of the Annex to Regulation No 727/2007 for breach of the precautionary principle, in that it relaxes the TSE eradication regime. The French Republic also made an application for interim measures, seeking suspension of the operation of that regime until the delivery of the General Court's judgment. The General Court granted that latter application by order of 28 September 2007 (Case T-257/07 R, ECR II-4153).

35 Following the adoption of the contested regulation, the General Court, by decision of 6 October 2008, granted the French Republic's application for the current proceedings to be extended to the provisions of that regulation and allowed the lodging of additional submissions and pleas in law. By order of 30 October 2008 (Case T-257/07 R II), the General Court also granted the French Republic's second application for suspension of the operation [of that new regime] and, by decision of 30 January 2009, it rejected the Commission's application for the case to be adjudicated under an expedited procedure.

36 In support of its application, the French Republic put forward a single plea, alleging breach of the precautionary principle by the Commission for introducing, by the contested regulation, the contested measures.

37 The Commission, supported by the United Kingdom, requested that the action be dismissed.

38 In the judgment under appeal, the General Court dismissed the action in its entirety.

39 The General Court at the outset, at paragraphs 66 to 89 of the judgment under appeal, set out the considerations of principle relating to protection of human health, the precautionary principle and the scope of judicial review as regards the acts of the institutions of the European Union in matters concerning the common agricultural policy.

40 The General Court went on to consider the French Republic's arguments in support of its single plea challenging, first of all, the Commission's risk assessment and, second, the Commission's risk management.

41 In the first place, as regards the Commission's risk assessment, the French Republic claimed, first, that the Commission had not taken account of the scientific uncertainties surrounding the risk of transmissibility to humans of TSEs other than BSE, secondly, that the Commission had not had the reliability of rapid tests scientifically evaluated, thirdly, that the Commission had disregarded the scientific uncertainties as to the reliability of discriminatory tests and, fourthly, that the Commission had not had the risks arising from the contested measures assessed in good time.

42 At paragraphs 93 to 202 of the judgment under appeal, the General Court rejected those complaints in their entirety.

43 As regards the complaint alleging failure to take into account and misinterpretation of the scientific uncertainties surrounding the transmissibility to humans of TSEs other than BSE, the General Court rejected that complaint at paragraphs 93 to 109 of the judgment under appeal, stating that the French Republic was wrong in maintaining that the Commission had overlooked, in the risk assessment preceding the adoption of the contested measures, the scientific uncertainties about that transmissibility, given that it was apparent from recital 12 in the preamble to the contested regulation that the Commission had expressly acknowledged that it was impossible to exclude any transmissibility to humans of TSEs affecting ovine and caprine animals, other than BSE.

44 In addition, the General Court held that, 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 regulation, the Commission had been entitled to consider, under recital 12, 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. Moreover the French Republic had not put forward, according to the General Court, any argument or submitted any evidence to render the Commission's assessment implausible.

45 At paragraphs 110 to 136 of the judgment under appeal, the General Court dismissed the French Republic's complaint alleging failure to consult scientific experts on the reliability of rapid tests. The General Court considered, in particular, that the Commission had been 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 relevant in the context of the use of those tests for the purpose of controlling the release of sheep or goat meat for human consumption. It was therefore not necessary to consult EFSA specifically to that end.

46 The General Court also rejected 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 had 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.

47 At paragraphs 137 to 173 of the judgment under appeal, the General Court considered and rejected the complaint relating to the reliability of the discriminatory tests.

48 First of all, at paragraphs 143 to 148 of the judgment under appeal, the General Court, first of all, rejected the French Republic's argument alleging failure to take into account the scientific uncertainties still remaining regarding the reliability of discriminatory tests, by finding that the Commission had acknowledged those uncertainties in the recital to the preamble to the contested regulation. Second, the General Court rejected as ineffective the complaint alleging failure to consult EFSA when the contested measures were drawn up. Third, the General Court found that the French Republic had not demonstrated that the Commission had not reviewed the contested measures following EFSA's opinion of 24 January 2008, given that the contested regulation contained references to that opinion.

49 Next, at paragraphs 149 to 171 of the judgment under appeal, the General Court dismissed the complaint alleging that the Commission had 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. The General Court decided, in particular, that the Commission, without committing a manifest error of assessment, could infer from EFSA's opinion of 24 January 2008 that the possibility of co-infection of small ruminants had not been demonstrated in natural conditions and conclude from it that the risk of the existence of such co-infection and, *a fortiori*, the risk of non-detection of that co-infection were reduced. The General Court also held that the Commission had not committed a manifest error of assessment in finding that the prevalence of BSE in small ruminants could be considered very low.

50 Finally, concerning AFSSA's opinion of 8 October 2008 and EFSA's opinion of 22 October 2008, the General Court found, at paragraphs 172 and 173 of the judgment under appeal, that since those opinions had been issued after the adoption of the contested regulation, the arguments put forward by the French Republic based on those opinions were ineffective.

51 At paragraphs 174 to 202 of the judgment under appeal, the General Court dismissed the complaint alleging failure to assess the increase in the risk resulting from the adoption of the contested regulation. Specifically, it found that in the light of the scientific opinions of EFSA and AFFSA and given the lack of data necessary to make a precise quantitative assessment, it could not be complained that the Commission did not have available to it, at the time of the adoption of the contested regulation, a quantitative scientific assessment of the additional risk to humans being exposed to TSEs following the adoption of the contested regulation. The General Court therefore held that the Commission had not breached the guarantees conferred by the European Union legal order.

52 In the second place, as regards the arguments relating to risk management, the French Republic complained that the Commission had breached both its obligation to ensure a high level of protection of human health and the precautionary principle in that the Commission had 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, even though the most recent scientific data had shown significant uncertainties concerning that twofold premiss.

53 The General Court dismissed those complaints at paragraphs 206 to 264 of the judgment under appeal.

54 In this respect, the General Court found, in its preliminary considerations at paragraphs 206 to 214 of the judgment under appeal, that the Commission's power to adopt the contested provisions had not been called into question by the French Republic. It recalled that the competent public authorities are obliged to maintain or, as the case may be, improve the level of protection of human health even though that level does not have to be the highest possible. To satisfy that obligation, it would be for the competent authorities, applying the precautionary principle, to manage the risk exceeding the level deemed acceptable for society through measures designed to contain it at that level. The General Court therefore concluded that the relaxation of preventive measures adopted previously had to be justified by new elements changing the assessment of the risk in question. The General Court considered that such new elements, such as new knowledge or new discoveries, might change both the perception of the risk and the level of risk deemed acceptable by society.

55 In addition, the General Court held that 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. It recalled, however, that the review by the court of the competent authority's determination of the level of risk deemed unacceptable for society is confined to examining, first, whether there was a manifest error of assessment, secondly, whether there was a misuse of powers or, thirdly, whether the

authority clearly exceeded the limits of its discretion. As regards the manifest error of assessment, the General Court stated that the party pleading it must adduce sufficient evidence showing that the factual assessments made by the competent authority were implausible.

56 As regards the three elements relied on by the Commission – namely, first, 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, secondly, the development and validation of discriminatory tests making it possible to distinguish reliably scrapie from BSE within a short period of time and, thirdly, the very low probability of BSE in ovine and caprine animals – the General Court considered that French Republic did not contest the novelty of those elements, but disputed the assessment that they could justify the adoption of the contested measures. Consequently, the General Court found that it was necessary to assess whether, in the light of those new elements, the Commission was correct to adopt the contested regulation, since they made it possible to maintain a high level of protection of human health while reducing the cost of the preventive measures for society or whether, on the contrary, by adopting the contested regulation, the Commission had breached the precautionary principle and, consequently, had breached the obligation contained in that principle to maintain a high level of protection of human health by exposing people to risks exceeding the level of risk deemed acceptable for society.

57 In that regard, the General Court assessed, in the first place, at paragraphs 227 to 248 of the judgment under appeal, whether the contested regulation entailed an 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 small ruminants which formed part of a flock within which a TSE case has been detected. Having found that there was a not insignificant increase in that risk, the General Court held however that that finding was not sufficient to establish a breach of the precautionary principle or of the obligation to maintain a high level of protection of human health. According to the General Court, it was also necessary to verify whether that increase had raised the risks to human health to a level deemed unacceptable for society.

58 The General Court, in the second place, therefore, at paragraphs 249 to 264 of the judgment under appeal, examined whether the adoption of the contested regulation had entailed risks to human health exceeding the level deemed acceptable for society.

59 As regards the risk resulting from human consumption of meat from small ruminants infected by TSEs other than BSE, the General Court found that, given the extremely low risk of transmissibility to humans of those TSEs affecting small ruminants, the Commission had not committed a manifest error of assessment by considering that the contested measures did not entail an increase in the risk to human health exceeding the level of risk deemed acceptable for society.

60 As regards the risk arising from human consumption of meat from ovine or caprine animals infected with BSE, the General Court observed that, even if the contested measures did not allow it to be excluded that meat originating from a flock within which an animal has been infected with BSE might possibly be released for human consumption, the prevalence of classical BSE in small ruminants was very low and only one case of BSE had been confirmed in small ruminants and concerned a goat which had been fed meat and bone meal, which had since been banned.

61 The General Court concluded that the Commission had not committed a manifest error of law by considering that the additional risk of exposure of humans to classical BSE occurring in small ruminants, entailed by the adoption of the contested provisions, did not give rise to risks to human health which exceeded the level of risk deemed acceptable for society.

62 Moreover, the General Court considered that it was clear from different scientific opinions that the significance, origin and transmissibility of L- or H-type BSE were, at the time of the adoption of the contested regulation, speculative. Accordingly, the Commission had not committed an error of assessment by considering that the additional risk of exposure of humans to types of BSE other than classical BSE was acceptable.

63 Consequently, the General Court held that, by adopting the contested regulation, the Commission had not breached the precautionary principle or the obligation to maintain a high level of protection of human health laid down in Article 152(1) EC and in Article 24a of Regulation No 999/2001.

Procedure before the Court

64 The French Republic contends that the Court of Justice should:

— set aside the judgment under appeal;

— give final judgment and annul the contested regulation or, in the alternative, refer the case back to the General Court for judgment; and

— order the Commission to pay the costs.

65 The Commission contends that the Court of Justice should:

— dismiss the appeal; and

— order the appellant to pay the costs.

The appeal

66 In support of its appeal, the French Republic puts forward four pleas in law, alleging, first, breach of the obligation to state the reasons for the decision, secondly, distortion of the facts, thirdly, incorrect legal classification of the facts and, fourthly, an error of law relating to the breach of Article 24a of Regulation No 999/2001 and breach of the precautionary principle.

67 The Commission considers that the pleas put forward in support of the appeal must be rejected as manifestly inadmissible or, in any event, unfounded.

68 It is necessary, first of all, to examine the general plea of inadmissibility put forward by the Commission.

The general plea of inadmissibility

69 The Commission pleads, as a preliminary point, that the appeal is inadmissible in that it constitutes an attempt to re-examine the application submitted to the General Court which the Court of Justice would not have jurisdiction to undertake. According to the Commission, the pleas put forward by the French Republic either simply repeat the plea and the arguments that it had submitted before the General Court or seek a re-examination of the evidence considered by the General Court.

70 In this regard, it is clear from Article 256 TFEU and Article 58 of the Statute of the Court of Justice of the European Union that an appeal lies on points of law only.

71 Moreover, it is settled case-law that, where the appellant challenges the interpretation or application of EU law by the General Court, the points of law examined at first instance may be discussed again in the course of an appeal. Indeed, if an appellant could not thus base his appeal on pleas in law and arguments already relied on before the General Court, an appeal would be deprived of part of its purpose (see, inter alia, Joined Cases C-514/07 P, C-528/07 P and C-532/07 P *Sweden and Others* v *API and Commission* [2010] ECR I-8533, paragraph 116, and Case C-335/09 P *Poland* v *Commission* [2012] ECR, paragraph 27).

72 As regards the present appeal, it is sufficient to note that, as is apparent in particular from paragraph 66 of the present judgment, and contrary to what the Commission argues, the French Republic does not seek to challenge, in a general way, the General Court's factual assessments by repeating the plea and arguments put forward before that court. On the contrary, the appellant raises for the most part questions of law which can form a valid basis for the appeal. At a result, the general plea of inadmissibility raised by the Commission must be dismissed.

73 However, to the extent that the Commission puts forward more detailed objections of inadmissibility in relation to a number of specific pleas or complaints of the appeal, those objections fall to be addressed in the context of the examination of the pleas concerned.

The first plea, alleging breach of the obligation to state reasons

Arguments of the parties

74 The plea is, in essence, divided into two parts. By the first part of its first plea, the French Republic claims that the General Court, in the judgment under appeal, did not answer to a sufficient legal standard its complaints alleging that the Commission had failed to take account of the scientific data available.

75 The French Republic points out that, while it is true that the General Court stated that the Commission was aware of the scientific data available when it adopted the contested regulation, the fact nevertheless remains, according to its argument, that the French Republic sought to establish that the Commission had not taken those data fully into consideration, even though they called into question the twofold premiss on which the Commission relied when adopting the provisions of Regulation No 727/2007, namely, first, the non-transmissibility to humans of TSEs other than BSE and, second, the reliability of the discriminatory tests. That the Commission cited, in the preamble to the contested regulation, the findings of EFSA's opinion of 24 January 2008 does not mean that those conclusions had actually been taken into consideration by the Commission.

76 In addition, it claims that the General Court failed to consider whether the Commission was entitled to reproduce word for word, in the contested regulation, the provisions of Regulation No 727/2007, despite the fact that EFSA's opinion had called into question the twofold premiss on which the Commission relied when adopting those provisions.

77 By its second part of the first plea, the French Republic claims that the General Court did not answer to a sufficient legal standard its complaints alleging breach of Article 24a of Regulation No 999/2001, in so far as the General Court considered that those complaints amounted to a request to ascertain whether the contested measures were appropriate to ensure a high level of protection of human health.

78 In that regard, it maintains that the General Court erred in finding that Article 24a of Regulation No 999/2001 merely reflected the obligation contained in Article 152(1) EC, that the competent public authorities must ensure a high level of human health protection in the European Union. In the French Republic's opinion, Article 24a of Regulation No 999/2001 imposes an additional requirement

to that contained in Article 152(1) EC, namely, that decisions taken on the basis of Article 24a of that regulation should not reduce the level of protection afforded by the measures in force, and even that those decisions should raise the level of protection. Accordingly, the General Court should have checked that the contested measures maintained or raised the level of protection which was guaranteed by the earlier preventive measures.

79 The Commission considers that the first plea must be rejected as manifestly inadmissible or, in any event, unfounded, since the reasoning followed by the General Court at paragraphs 97, 144, 145, 201 and 221 of the judgment under appeal shows that the Commission had adopted the contested regulation after a thorough examination of the best scientific data and the most recent results of international research.

80 As regards, in particular, the argument that the Commission was not entitled to reproduce word for word, in the contested regulation, the provisions of Regulation 727/2007, the Commission points out that the appeal does not identify precisely the parts of the judgment under appeal which it criticises. In any event, the appellant does not state why the Commission would not be permitted to reproduce, in the contested regulation, the measures of the preceding regulation, since those were justified, but requests the Court to review the facts, since it confines itself to criticising the General Court for having interpreted EFSA's opinion in the same manner as the Commission.

81 As regards Article 24a of Regulation No 999/2001, the French Republic has not indicated which elements provide a basis for a different interpretation of that provision than that given by the General Court. In any case, the Commission submits that the General Court satisfied itself that not only Article 152(1) EC but also Article 24a of Regulation No 999/2001 had been respected since it checked, at paragraphs 211, 221, 249 and 266 of the judgment under appeal, whether the new measures increased the risk to human health and concluded that they did not.

Findings of the Court

82 It should be recalled at the outset that the extent of the obligation to state reasons is a question of law reviewable by the Court on appeal (Case C-413/06 P *Bertelsmann and Sony Corporation of America* v *Impala* [2008] ECR I-4951, paragraph 30 and the case-law cited).

83 The Court has also held that the obligation for the General Court, under Article 36 of the Statute of the Court of Justice, applicable to the General Court by virtue of the first paragraph of Article 53 thereof, and Article 81 of the Rules of Procedure of the General Court, to state reasons does not require the General Court to provide an account which follows exhaustively and one by one all the arguments put forward by the parties to the case. The reasoning of the General Court may therefore be implicit on condition that it enables the persons concerned to know the reason for the General Court's decision and provides the Court of Justice with sufficient material for it to exercise its power of review (see, inter alia, Case C-260/09 P *Activision Blizzard Germany* v *Commission* [2011] ECR I-419, paragraph 84 and Case C-403/10 P *Mediaset* v *Commission* [2011] ECR I-117, paragraph 88).

84 As regards the first part of the plea alleging breach of the obligation to state the reasons relating to the argument concerning the failure to take into account the scientific data available, it is clear from paragraphs 96 to 109 of the judgment under appeal that the General Court did check whether the contested regulation referred to the available scientific opinions and the uncertainties which are expressed therein. The General Court concluded that the Commission had not overlooked the scientific uncertainties in the risk assessment which preceded the adoption of the contested measures and that, therefore, the Commission's findings were not vitiated by a manifest error of assessment. In addition, the General Court considered that the French Republic had not put forward any argument or submitted any evidence to render the Commission's assessment implausible.

85 In those circumstances, it cannot be considered that the General Court has not provided sufficient reasons for rejecting the argument, put before it by the French Republic, relating to not taking into account the scientific data available.

86 As regards the complaint alleging that the General Court failed to consider whether the Commission was entitled to reproduce word for word, in the contested regulation, the provisions of Regulation No 727/2007, it must be observed that an examination of the French Republic's pleadings before the General Court, and in particular its additional submissions lodged following the adoption of the contested regulation, shows that the assertion regarding the identical nature of the measures adopted by the contested regulation compared with Regulation No 727/2007 was raised before the General Court not as an independent submission, but merely as an observation made when comparing those two regulations.

87 While the French Republic did, admittedly, mention in its arguments before the General Court that it did not understand how a full consideration of EFSA's opinion of 24 January 2008 could have led the Commission to adopt, in the contested regulation, provisions identical to the contested measures, it is clear that that observation is not expanded upon or accompanied by a specific line of argument intended to underpin it.

88 It follows from the foregoing that, since the French Republic has not set out, with the clarity and precision required, the reasons why the Commission was not entitled to reproduce word for word, in the contested regulation, the provisions of Regulation No 727/2007, its observation regarding the identical nature of the two regulations at issue cannot be regarded as a distinct plea which would have warranted a specific response in the judgment under appeal. Consequently, the General Court has not breached its obligation to state reasons by not responding specifically to that observation.

89 As regards the second part of the first plea, in which the French Republic alleges failure to comply with the obligation to state reasons as regards the alleged breach of Article 24a of Regulation No 999/2001, it must be pointed out that the appellant, according to its arguments, does not claim that the statement of reasons is inadequate but seeks to challenge the substance of the General Court's reasoning.

90 It is apparent that, at paragraphs 79, 211 to 213, 249 and 266 of the judgment under appeal, the General Court has provided an adequate statement of reasons inasmuch as it allows, on the one hand, the French Republic to know why the General Court has not upheld its arguments alleging breach of Article 24a of Regulation No 999/2001 and, on the other, the Court to exercise its power of review.

91 Consequently, the argument alleging breach of the obligation to state reasons as regards the application of Article 24a of Regulation No 999/2001 must be rejected as unfounded. To the extent that the question of the substance of that statement of reasons is indistinguishable from the alleged violation of Article 24a thereof, which is the subject of the first part of the fourth plea of the appeal, that question will be examined in the context of the fourth plea.

92 It follows from all the above considerations that the first plea is, in part, inadmissible and, in part, unfounded.

The second plea in law, alleging distortion of the facts

Arguments of the parties

93 The second plea is divided into three parts. By the first part of its second plea, the French Republic claims that the General Court has, at paragraphs 101 to 108 of the judgment under appeal, distorted the meaning of EFSA's opinions of 8 March 2007 and 24 January 2008 in that it considered that the Commission could have inferred from those opinions, without committing a manifest error of

assessment, that the risk of transmissibility to humans of TSEs other than BSE was extremely low. In those opinions, EFSA reached the conclusion, in reality, not that the risk was extremely low, but that it was not possible to exclude such transmissibility.

94 Specifically, the French Republic contends that paragraphs 101 to 106 of the judgment under appeal do not refer to any assessment by EFSA of the degree of the probability of the risk of transmissibility to humans of TSEs other than BSE. In addition, by considering that, at paragraph 107 of the judgment under appeal, the experimental models at issue were unrepresentative, the General Court distorted the meaning of EFSA's opinions. According to the French Republic, the General Court confused the uncertainty of the existence of a risk with the low probability of that risk.

95 In the second part of that plea, the French Republic alleges that the General Court distorted, at paragraphs 116 to 122 of the judgment under appeal, the meaning of EFSA's opinions of 17 May 2005, 26 September 2005 and 7 June 2007, in holding that the Commission had not committed a manifest error of assessment by considering that, first of all, the rapid tests were reliable and, second, the evaluation of the reliability of those tests contained in those opinions was also valid in the context of allowing the release for human consumption of meat from ovine or caprine animals.

96 In that regard, the French Republic points out that, while it is true that EFSA, in its opinions, considered that the rapid tests could be recommended for evaluating the prevalence of classical scrapie and BSE, nevertheless it could not be inferred that those tests were reliable in the context of allowing the release for human consumption of meat from ovine or caprine animals. The required degree of reliability of the rapid tests could not be the same for, on the one hand, following the epidemiological evolution of classical scrapie and BSE and, on the other hand, checking the carcasses systematically with a view to allowing them to be consumed.

97 By the third part of its second plea, the French Republic alleges that the General Court distorted the facts, at paragraphs 215 to 221 of the judgment under appeal, when it considered that the scientific elements relied on by the Commission to justify the adoption of the contested regulation consisted of new elements when compared to the earlier preventive measures.

98 According to the French Republic, it was not apparent from either the Commission's pleadings or its intervention at the hearing before the General Court that it asserted that the scientific elements on which it relied were new in nature, with the exception of the development and validation of discriminatory tests. Accordingly, the Commission never demonstrated, as a new scientific fact, either that there was no epidemiological link between classical or atypical scrapie in small ruminants and TSEs in humans, or the low prevalence of BSE in small ruminants.

99 That distortion of the facts had a bearing on the assessment of the legality of the contested regulation, as is apparent from paragraphs 83 and 212 of the judgment under appeal, inasmuch as the precautionary principle requires, in order to justify a relaxation of the preventive measures in force, the competent institutions to present new elements capable of changing the perception of a risk or showing that that risk can be contained by measures less restrictive than the existing ones.

100 The Commission argues that the first two parts of the second plea are inadmissible, since, first, the French Republic's arguments are based on the General Court's assessment and interpretation of the facts, which come within the exclusive jurisdiction of the General Court and, second, the French Republic does not indicate precisely either the parts of the judgment under appeal that it criticises or the legal arguments specifically advanced in support of the application, in particular the documents in the file from which it might be inferred that those findings were materially inaccurate.

101 The third part of the second plea is also inadmissible or is, in any event, unfounded. The French Republic seeks merely to have its interpretation of the facts prevail over the different approach followed by the Commission.

102 In that regard, the Commission indicates that the assessment of the need to amend certain measures in force follows not from new elements coming to light, but, in essence, from the evolution of data and scientific evidence being taken into account. The requirement of new elements to which the French Republic refers is not to be found either in Article 24a of Regulation No 999/2001 or Article 7 of Regulation No 178/2002, since these provisions refer to the assessment of available information and to existing scientific evidence.

Findings of the Court

103 As regards the first and second part of the second plea, concerning the alleged distortion, by the General Court, of the meaning of certain opinions of EFSA, at paragraphs 101 to 108 and 116 to 122, respectively, of the judgment under appeal, it should be pointed out that, in those paragraphs, the General Court examined the complaints of the French Republic seeking a declaration that the Commission made a manifest error in the assessment of the scientific opinions available to it, in so far as it had considered, first of all, that the risk of transmission to humans of an animal TSE other than BSE was extremely low and, second, that the evaluation of the reliability of rapid tests which had been carried out in relation to measures for the epidemiological monitoring of TSEs in small ruminants, was also valid for the contested measures authorising the release for human consumption of meat from small ruminants in cases where the result of those tests was negative.

104 In present appeal, the French Republic, relying on, in essence, the same arguments which it had already submitted to the General Court, contests the same findings of the Commission, which the General Court had found not to be manifestly erroneous, by pleading a distortion of EFSA's opinions of 17 May 2005, 26 September 2005, 8 March 2007, 7 June 2007 and 24 January 2008.

105 In that regard, it is clear that, first of all, the appellant's arguments are based on an incomplete reading of the judgment under appeal. As regards the risk of transmission to humans of an animal TSE other than BSE, it is apparent from paragraph 107 of the judgment under appeal that the General Court also took into consideration the statement of SEAC (Spongiform Encephalopathy Advisory Committee) on the Potential Human Health Risk from Changes to Classical Scrapie Controls of February 2008. According to the General Court, in that statement, even if it confirmed that a link between classical scrapie and human TSEs could not be ruled out, SEAC nevertheless considered that that risk must be very low. According to SEAC, the very low and relatively constant incidence of human TSE cases worldwide demonstrated that there must be at least a substantial, if not complete, barrier to transmission of classical scrapie to humans. The appellant does not contest the relevance or the validity of that statement.

106 Second, the French Republic has not shown to the requisite legal standard that the General Court adopted an interpretation of those scientific opinions which is manifestly at odds with their content.

107 Consequently, the first and second parts of the second plea must be rejected as unfounded.

108 As regards the third part of the second plea, directed against paragraphs 215 to 221 of the judgment under appeal, it should be ascertained whether the French Republic has not established a distortion of the Commission's arguments as regards the novelty of the scientific elements justifying the adoption of the contested measures.

109 It should be observed in that regard that while it is certainly true that, at the paragraphs from the judgment under appeal cited above, the General Court presented the three elements mentioned at paragraph 56 of the present judgment as novel with respect to the situation existing when the initial preventive measures were adopted, it is clear that that characterisation was not based on the arguments of the Commission before the General Court but resulted from the application of the case-law set out at paragraphs 83 and 212 of the judgment under appeal.

110 In those last paragraphs of the judgment under appeal, the General Court recalled the case-law of the Court of Justice according to which, 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 (see Case C-504/04 *Agrarproduktion Staebelow* [2006] ECR I-679, paragraph 40). The General Court inferred from this that the relaxation of preventive measures previously adopted had to be warranted by new elements, such as new knowledge or new scientific discoveries, changing the assessment of the risk in question.

111 It follows that the complaint based on an alleged distortion of the Commission's arguments must be rejected, without its being necessary to examine the Commission's arguments contesting the merits of the requirement that the scientific data be novel to justify the adoption of the contested measures.

112 In the light of the foregoing, the third part of the second plea and, consequently, the second plea in its entirety must be rejected as unfounded.

The third plea, alleging incorrect legal classification of the facts

Arguments of the parties

113 By its third plea, the French Government complains that the General Court erred in the legal classification of the facts when it considered that the scientific elements relied on by the Commission constituted new elements capable of altering the perception of the risk.

114 Accordingly, in the French Republic's view, the General Court, at paragraphs 215 to 221 of the judgment under appeal, was incorrect in presuming not only that the three scientific elements relied on by the Commission were new but also that those elements were capable of altering the perception of the risk.

115 The French Republic submits that even if the discriminatory tests constituted a new scientific element, that element was not capable of altering the perception of the risk, for the reliability of those tests was limited. As regards the absence of any epidemiological link between classical scrapie and TSEs in humans as well as the low prevalence of BSE in small ruminants, the French Republic is of opinion that since that scientific element had already been identified when the earlier preventive measures were adopted, they could not entail an alteration of the perception of the risk.

116 The Commission argues that the third plea must be rejected as manifestly inadmissible on the ground that the General Court's finding, that the Commission did not commit any manifest error of assessment on the basis of the evolution of the science, is a finding of fact.

117 In any event, that plea must be rejected as unfounded since the scientific assessment of the risks from which the contested measures derive are based on scientific evidence, available when those measures were adopted, which show that there was a change of circumstances.

Findings of the Court

118 The French Republic's third plea is directed, like the third part of the second plea, against paragraphs 215 to 221 of the judgment under appeal. By the arguments it puts forward in support of the present plea, the appellant contests the fact that the elements identified by the General Court, the novelty of which is denied by the appellant, could have the effect of altering the perception of risk in society.

119 In that regard it is settled case-law that, when the General Court has found or assessed the facts, the Court of Justice has jurisdiction under Article 256 TFEU to review the legal characterisation of those facts by the General Court and the legal conclusions it has drawn from them (see, inter alia, Case C-551/03 P *General Motors* v *Commission* [2006] ECR I-3173, paragraph 51; Case C-397/03 P *Archer Daniels Midland and Archer Daniels Midland Ingredients* v *Commission* [2006] ECR I-4429, paragraph 105; and *Bertelsmann and Sony Corporation of America* v *Impala*, paragraph 29).

120 However, it is not apparent from paragraphs 215 to 221 of the judgment under appeal, referred to by the French Republic in the context of its third plea, that the General Court made any legal assessment therein as regards the perception of the risk by society. Indeed, it confined itself therein to examining the novelty of the scientific elements relied on by the Commission, which is a finding of fact.

121 Therefore, since the General Court, at paragraphs 215 to 221 of the judgment under appeal, had made a legal characterisation of the facts, the French Republic has misread the judgment.

122 The third plea must therefore be rejected as unfounded.

The fourth plea, alleging error of law

Arguments of the parties

123 The fourth plea is divided into three parts.

124 By the first part of this plea, which is linked to the second part of the first plea, the French Republic submits that, by considering, at paragraphs 249 and 250 of the judgment under appeal, that the Commission had not breached the provisions of Article 24a of Regulation No 999/2001 since it had respected the obligation contained in Article 152(1) EC, the General Court has erred in law. In that regard, the French Republic argues that Article 24a lays down an additional requirement compared to Article 152(1) EC, meaning that the General Court was incorrect in confining itself to considering that the measures that the Commission had adopted pursuant to Article 152(1) EC ensured a high level of protection of human health. To reach that conclusion, the General Court should have checked that those measures maintained or increased the level of protection of human health which was guaranteed by the earlier preventive measures.

125 By the second part of its fourth plea, the French Republic claims that the General Court erred in law in assuming, at paragraph 213 of the judgment under appeal, that the scientific elements relied on by the Commission to justify the adoption of contested regulation could entail a change in the level of risk deemed acceptable. In the alternative, the French Republic submits that the General Court erred in law in failing to ascertain whether, when determining the level of risk deemed acceptable, the Commission had taken into account the gravity and irreversibility of the adverse effects of TSEs on human health. Lastly, the French Republic submits that there was bound to be an increase in the risk to human health exceeding the level of risk acceptable for society.

126 As regards the third part of the fourth plea, the French Republic claims that the General Court erred in law by failing to take into account the fact that the contested measures do not replace the earlier preventive measures but supplement them with alternative, more flexible measures. The coexistence of the initial measures and the new measures raises questions about the coherence of the legislation that the General Court should have examined. That error of law resulted in an erroneous assessment of the French Republic's complaint alleging breach of the precautionary principle in the risk management.

127 The Commission considers that the fourth plea must be rejected as manifestly inadmissible or, in any event, unfounded.

128 Concerning the first part of this plea, the Commission considers that the General Court has carried out its examination correctly. Even if, by adopting relaxation measures based on scientific elements, the Commission has contributed to the increase in the risk of exposure of humans to the scrapie agent, that would still not weaken the level of protection of human health given that the risk of transmission of scrapie to humans is extremely low. Therefore, the level of protection has not been lowered and Article 24a of Regulation No 999/2001 has been complied with.

129 As regards the second part of the fourth plea, the Commission submits that the French Republic has not put forward any evidence in support of its argument that the risk to human health had exceeded the level deemed acceptable for society due to the contested measures. Neither before the General Court nor in the context of the present appeal has the French Republic presented any evidence contradicting the assessment of the Commission and the General Court in this regard.

130 Lastly, as regards the third part of the fourth plea, the Commission argues that the French Republic is attempting to substitute its own analysis for that of the General Court.

Findings of the Court

131 As regards the first part of the fourth plea, alleging infringement of Article 24a of Regulation No 999/2001, it must be recalled that, according to the wording of that provision, decisions to be adopted in accordance with one of the procedures referred to in Article 24 of that regulation, including amendments of the annexes, '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 [European Union]'.

132 Article 24a was inserted into Regulation No 999/2001 by Regulation (EC) No 1923/2006 of the European Parliament and of the Council, of 18 December 2006 (OJ 2006 L 404, p. 1). It is apparent from the travaux préparatoires of that latter regulation that Article 24a did not appear in the proposal for a Regulation of the European Parliament and of the Council amending Regulation No 999/2001 (COM(2004) 775 final) of 6 December 2004, presented by the Commission, but originated in the opinion of the Committee on Agriculture and Rural Development of 29 March 2006 and its inclusion in the text of the regulation was proposed by the European Parliament in its draft legislative resolution of 27 April 2006.

133 Even though the recitals of the preamble to Regulation No 1923/2006 do not contain any explanation as to the purpose of the proposal concerned, it follows, inter alia, from the justifications offered by the Parliament in its draft legislative resolution that '[t]his amendment shall ensure that crucial aspects of this Regulation can only be changed by the Commission and Member States in the comitology procedure if a justification is given that a reduction of the level of human and animal health is excluded'. Furthermore, in the accompanying explanatory statement to the draft, the Parliament referred to the difficulty of being in a position to pay due attention where the Commission, together with the Member States, adopts a complex list of modifications step by step.

134 It is therefore clear from those travaux préparatoires that Article 24a of Regulation No 999/2001 was envisaged as a guarantee aimed at preventing measures, which lower the level of protection of human and animal health in the European Union, from being adopted under the comitology procedure.

135 It does not, however, follow, contrary to the appellant's submission, that Article 24a excludes any relaxation of the earlier preventive measures. First of all, Article 24a of Regulation No 999/2001 does not lay down as a yardstick the fact that the comparison must be carried out with respect to the level of protection resulting from the earlier preventive measures adopted in the same field, but refers in general to the level of health 'assured in the [European Union]'. Second, it follows from both

Article 7(2) of Regulation No 178/2002 and the case-law cited at paragraph 110 of the present judgment that the provisional risk management measures, which are adopted in the context of scientific uncertainty, must be re-examined within a reasonable amount of time in order to ensure that they are proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen by the Union.

136 Therefore, the level of protection of human health is tightly correlated to the level of risk deemed acceptable for society, which depends, in turn, on the scientific knowledge available at a given moment. It cannot be ruled out that, in the light of scientific progress, the same level of protection may be ensured by less restrictive measures.

137 As regards whether the General Court erred in law by considering, at paragraphs 65 and 250 of the judgment under appeal, that Article 24a of Regulation No 999/2001 merely reflected the obligation contained in the first subparagraph of Article 168(1) TFEU, in order to carry out such an assessment, those points should be examined in the light of all the grounds of the judgment under appeal.

138 In that regard it should be observed that the General Court admittedly refers, at paragraphs 74, 79, 81, 174 to 176 and 250 of the judgment under appeal, to the duty imposed on the institutions to ensure a high level of protection of public health, safety and the environment, which can give the impression, as the French Republic argues, that the General Court limits its review to checking whether the contested measures respect the obligation contained in the first subparagraph of Article 168(1) TFEU. However, it is clear from paragraphs 211 to 213, 221, 249 and 266 of the judgment under appeal that the General Court interprets Article 24a of Regulation No 999/2001 with due regard to the obligation to maintain the level of protection of human health ensured in the European Union.

139 At paragraphs 211 to 213 of the judgment under appeal the General Court made the following observations, in particular:

> ‘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 … . 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. 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 … . 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 … . 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.'

140 It follows from those grounds that the General Court accords, in essence, the same scope to Article 24a of Regulation No 999/2001 as that which results from paragraphs 134 to 136 of the present judgment. In so far as the French Republic has not contested the substance of that interpretation, but confines itself to referring to the paragraphs of the judgment under appeal mentioning the obligation to maintain the high level of protection of human health, the first part of the fourth plea must be rejected as unfounded.

141 As concerns the second part of its fourth plea, alleging error of law in that the General Court assumed, at paragraph 213 of the judgment under appeal, that the scientific elements relied on by the Commission in order to justify the adoption of the contested regulation could entail a change in the level of risk deemed acceptable, it must be stated that, notwithstanding the manner in which that argument is formulated, the French Republic, in fact, is simply contesting a finding of fact, the review of which falls outside the jurisdiction of the Court in the context of the appeal, under the first subparagraph of Article 256(1) TFEU and the case-law referred to at paragraph 70 of the present judgment.

142 As regards the appellant's argument, pleaded in the alternative, that the General Court erred in law in failing to ascertain whether, in determining the level of risk deemed acceptable, the Commission had taken into account the gravity of the risk of transmission to humans of TSEs actually occurring and the irreversible nature of TSEs as diseases, it must be recalled that in a sphere in which the European Union legislature is called on to undertake complex assessments, judicial review of the exercise of its powers must be limited to examining whether it is vitiated by a manifest error of assessment or a misuse of powers or whether the legislature has manifestly exceeded the limits of its discretion (Case C-236/01 *Monsanto Agricoltura Italia and Others* [2003] ECR I-8105, paragraph 135).

143 Given the Commission's broad discretion for the purposes of determining the level of risk deemed unacceptable for society, the General Court was right to confine its review to manifest errors of assessment.

144 Moreover, it follows from the written pleadings before the General Court that the French Republic expressly stated in its additional submissions that it was not contesting the fact that it was for the institutions of the European Union to determine the level of risk deemed unacceptable for society.

145 It is sufficient to state that the argument presented by the French Republic contains nothing capable of showing that a manifest error was committed by the Commission and was not detected by the General Court.

146 In those circumstances, the complaint alleging error of law in the assessment of the evolution of the level of risk deemed acceptable must be rejected as, in part, inadmissible and, in part, unfounded.

147 As regards the third part of the fourth plea of the French Republic, alleging that the contested regulation is inconsistent, it must be stated that that complaint is new in character, inasmuch as it was not raised by the appellant before the General Court.

148 Before that court, the appellant did not argue that the fact that the contested measures did not replace the earlier preventive measures but supplemented them with different measures would have an effect on the assessment of the legality of the contested regulation.

149 In an appeal the jurisdiction of the Court of Justice is in principle confined to a review of the findings of law on the pleas argued before the General Court (see, inter alia, Case C-266/05 P *Sison* v *Council*, paragraph 95 and the case-law cited). Therefore, a party cannot, in principle, put forward for the first time before the Court of Justice a plea in law which it has not raised before the General Court, because that would amount to allowing the Court of Justice to review the legality of the findings of the General Court, in the light of pleas of which the latter did not take cognisance (Case C-544/09 P *Germany* v *Commission* [2011] ECR, paragraph 63).

150 Accordingly, the third part of the fourth plea must be rejected as inadmissible.

151 In the light of the foregoing, the fourth plea must be rejected as, in part, inadmissible and, in part, unfounded.

152 Since none of the four pleas relied on by the appellant can be upheld, the appeal must be dismissed in its entirety.

Costs

153 Under Article 138(1) of the Rules of Procedure of the Court of Justice, which applies to appeal proceedings by virtue of Article 184(1) thereof, 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 Commission has applied for costs and the French Republic has been unsuccessful, the latter must be ordered to pay the costs.

On those grounds, the Court (Fourth Chamber) hereby:

1. Dismisses the appeal;

2. Orders the French Republic to pay the costs.

[Signatures]