ORDER OF THE JUDGE HEARING THE APPLICATION FOR INTERIM MEASURES

28 September 2007 *

In Case T-257/07 R,

French Republic, represented by E. Belliard, G. de Bergues, R. Loosli and A. During, acting as Agents,

applicant,

v

Commission of the European Communities, represented by M. Nolin, acting as Agent,

defendant,

APPLICATION for suspension of the operation of point (3) of the Annex to Commission Regulation (EC) No 727/2007 of 26 June 2007 amending Annexes I, III, VII and X to Regulation (EC) No 999/2001 of the European Parliament and of the

* Language of the case: French.

Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ 2007 L 165, p. 8), in so far as it introduces, into Chapter A of Annex VII to Regulation (EC) No 999/2001 of 22 May 2001 (OJ 2001 L 147, p. 1), point 2.3(b)(iii), point 2.3(d) and point 4,

THE JUDGE HEARING THE APPLICATION FOR INTERIM MEASURES,

replacing the President of the Court, in accordance with Article 106 of the Rules of Procedure, and with the decisions of the Court of First Instance in plenary session of 5 July 2006, 6 June 2007 and 19 September 2007,

makes the following

Order

Legal framework

1 On 22 May 2001, the Parliament and the Council adopted Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ 2001 L 147, p. 1).

2 Article 23 of Regulation No 999/2001 provides that, after consultation of the appropriate scientific committee on any question which could have an impact on public health, the annexes to the regulation, which lay down the measures for combating transmissible spongiform encephalopathies ('the TSEs') may be amended or supplemented.

3 On 12 February 2003, the Commission adopted Regulation (EC) No 260/2003 amending Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the eradication of transmissible spongiform encephalopathies in ovine and caprine animals and rules for the trade in live ovine and caprine animals and bovine embryos (OJ 2003 L 37, p. 7). In response to a recommendation by the Scientific Steering Committee, Regulation No 260/2003 introduced health measures for ovine and caprine herds infected with TSEs and, in particular, provided for the slaughter of entire herds with the exception of genetically resistant animals.

4 On 12 January 2005, the Commission adopted Regulation (EC) No 36/2005 amending Annexes III and X to Regulation (EC) No 999/2001 as regards epidemio-surveillance for transmissible spongiform encephalopathies in bovine, ovine and caprine animals (OJ 2005 L 10, p. 9). By Regulation No 36/2005, the Commission introduced the duty to apply a discriminatory test in each case of TSE detected, after an initial rapid test, in a herd of ovine or caprine animals, in order to determine whether the animal is suffering from scrapie or bovine spongiform encephalopathy ('BSE').

5 On 26 June 2007, the Commission adopted Regulation (EC) No 727/2007 amending Annexes I, III, VII and X to Regulation No 999/2001 (OJ 2007 L 165, p. 8).

6 Point (3) of the Annex to Regulation No 727/2007 reads as follows:

'Annex VII is replaced by the following:

"ANNEX VII

ERADICATION OF [TSE]

CHAPTER A

Measures following confirmation of the presence of a TSE

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:

...

2.2. If a TSE is suspected in an ovine or caprine animal on a holding in a Member State, all other ovine and caprine animals from that holding shall be placed under official movement restriction until the results of the examination are available. If there is evidence that the holding where the animal was present when the TSE was suspected is not likely to be the holding where the animal could have been exposed to a TSE, the competent authority may decide that other holdings or only the holding of exposure shall be placed under official control depending on the epidemiological information available.

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

(a) if BSE cannot be excluded after the results of a ring trial carried out in accordance with the procedure set out in Annex X, Chapter C, point 3.2(c), the killing and complete destruction of all animals, embryos and ova identified by the inquiry referred to in the second to fifth indents of point 1(b);

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

either

(i) the killing and complete destruction of all animals, embryos and ova identified by the inquiry referred to in the second and third indents of point 1(b). The conditions set out in point 3 shall apply to the holding;

or

(ii) the killing and complete destruction of all animals, embryos and ova identified by the inquiry referred to in the second and third indents of point 1(b), with the exception of:

— breeding rams of the ARR/ARR genotype,

— breeding ewes carrying at least one ARR allele and no VRQ allele and, where such breeding ewes are pregnant at the time of the inquiry, the lambs subsequently born, if their genotype meets the requirements of this subparagraph,

— sheep carrying at least one ARR allele which are intended solely for slaughter,

— if the competent authority so decides, sheep and goats less than three months old which are intended solely for slaughter.

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

or

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

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

(d) Member States may decide:

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

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

provided that:

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

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

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

...

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

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

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

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

..."

7 Under Article 3 of Regulation No 727/2007, the regulation entered into force on 17 July 2007.

Facts

8 TSEs are neurodegenerative diseases which affect both animals and humans and which include BSE and scrapie in sheep.

9 The rules introduced by Regulation No 999/2001, which apply to bovine and small ruminant animals (ovine and caprine) were laid down on the assumption that there was a link between BSE and the new variant of Creutzfeldt-Jakob Disease. Indeed, it is stated in the first recital in the preamble to that regulation that '[e]vidence continues to grow of the similarity between the BSE agent and that of the new variant of Creutzfeldt-Jakob Disease'.

10 Between 2003 and 2005, evolving scientific knowledge and the concerns expressed by the Member States prompted the Commission to restructure the legislation concerning action to combat TSEs. Accordingly, the Commission has on several occasions amended Regulation No 999/2001 and, on 15 July 2005, it adopted a 'TSE Road Map' [COM(2005) 322 — final], in which it stated its intention of proposing measures designed to review and relax the eradication measures in force at the time, taking into account the new diagnostic tools available but ensuring the current level of consumer protection.

11 In that document, the Commission pointed out that discriminatory testing in force since January 2005 might exclude the presence of BSE within a few weeks in most TSE cases detected following initial rapid testing. The Commission stated 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. Consequently, the Commission intended to propose that the carcasses of animals slaughtered in the infected herds should no longer have to be destroyed but could be made available for human consumption if the results of rapid screening tests were negative.

12 On 21 September 2005, the French authorities requested an opinion from the Agence française de sécurité sanitaire des aliments (French Food Safety Agency — AFSSA) concerning the developments in Community legislation proposed by the TSE Road Map; AFSSA expressed its views in an opinion delivered on 15 May 2006. That opinion found that the Commission's proposals significantly relaxed the current legislation. In view of the uncertainty regarding the reliability of the discriminatory tests and the transmissibility to humans of TSE strains other than BSE, AFSSA's response to the Commission's proposals was unfavourable.

13 On 22 June and 6 December 2006, the French authorities again consulted AFSSA, requesting it to carry out a detailed assessment of the measures proposed by the Commission. In response to those requests, AFSSA delivered a further opinion on 15 January 2007 concerning the changes in the health measures in herds of ovine and caprine animals in which a case of classic or atypical scrapie has been detected.

14 In that opinion, AFSSA stated that discriminatory testing did not make it possible to exclude the presence of BSE either in the tested animal or *a fortiori* in the herd to which it belonged. It added that the transmission to man of TSE strains other than BSE could not be excluded. AFSSA stated, finally, that products obtained from ovine and caprine animals from infected herds represented an additional risk to human health in relation to products obtained only from genetically resistant ovine animals. AFSSA therefore recommended that the current legislation on classic scrapie be retained.

15 Following the AFSSA opinion, the Commission asked the European Food Safety Authority (EFSA) to provide an assessment on (1) the existence of new available data which could provide evidence of any epidemiological or molecular link between classical and/or atypical scrapie and TSEs in humans and on (2) the performance of the current discriminatory analytical methods used for further examination of TSE positive cases in small ruminants and their ability to differentiate BSE from known atypical and/or classical scrapie strains.

16 On 8 March 2007, EFSA and its Scientific Panel on Biological Hazards delivered an opinion containing the following conclusions:

— there is no evidence of an epidemiological or molecular link between classical and/or atypical scrapie and TSEs in humans. The BSE agent is the only TSE agent identified as zoonotic; however, in view of their diversity, it is currently not possible to exclude transmissibility to humans of other animal TSE agents;

— the current discriminatory tests as described in the Community legislation to be used for discrimination between scrapie and BSE appear, up to now, to be reliable for the differentiation of BSE from classical and atypical scrapie; however, at the current stage of scientific knowledge, neither their diagnostic sensitivity nor their specificity can be assumed to be perfect.

17 By letter of 20 April 2007 addressed to the Director of EFSA, the Commission stated that a close examination of the AFSSA opinion of 15 January 2007 and the EFSA opinion of 8 March 2007 had revealed a certain disparity between the assessments of risk made by the two bodies in respect of the potentially zoonotic nature of scrapie. The institution considered that, in the light of that situation, it was necessary to

implement the procedure laid down in Article 30(4) 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) in order either to resolve the disparity or to prepare a joint document from the two bodies clarifying the statements contained in the conclusions. In view of the relevance of the matter in question to the adoption of a management risk decision on eradication measures in small ruminants, the Commission asked the Director of EFSA to reply within 10 working days of receipt of the letter.

18 On 24 April 2007, the Commission, against that background and on the basis of the EFSA opinion of 8 March 2007, submitted to the vote of the Standing Committee on the Food Chain and Animal Health (SCFCAH) a draft regulation amending Annexes I, III, VII and X to Regulation No 999/2001. The SCFCAH approved the proposal by a qualified majority.

19 By letter of 22 June 2007, the Director of EFSA informed the Commission that, following consultations with AFSSA, there was no divergence of opinion between the two bodies.

20 On 26 June 2007, the Commission adopted Regulation No 727/2007 which contains an annex, point (3) of which amends Annex VII to Regulation No 999/2001 ('Annex VII') which relates to the measures for eradicating TSE.

Procedure and forms of order sought by the parties

21 By application lodged at the Court Registry on 17 July 2007, the applicant brought an action pursuant to Article 230 EC for annulment of point (3) of the Annex to

Regulation No 727/2007, in so far as it introduces, in Chapter A of Annex VII, point 2.3(b)(iii), point 2.3(d) and point 4, and, in the alternative, annulment of Regulation No 727/2007 in its entirety.

22 By separate document lodged at the Court Registry on 17 July 2007, in accordance with Article 104 of the Rules of Procedure of the Court of First Instance and Article 242 EC, the applicant lodged this application for interim measures seeking suspension of the operation of point (3) of the Annex to Regulation No 727/2007 in so far as it introduces, in Chapter A of Annex VII, point 2.3(b)(iii), point 2.3(d) and point 4 ('the contested provisions').

23 On 8 August 2007, the Commission submitted its written observations on the application for interim measures, in which it contended that the application should be dismissed.

24 The parties presented oral argument at a hearing held on 5 September 2007.

Law

25 Under the combined provisions of Articles 242 EC and 243 EC, on the one hand, and Article 225(1) EC, on the other, the Court may, if it considers that the circumstances so require, order that application of the contested act be suspended or prescribe any necessary interim measures. For that purpose, it takes account of the conditions laid down in Article 104(2) of the Rules of Procedure, as defined by the case-law.

26 Accordingly, the judge hearing an application for interim relief may order suspension of operation of an act, or other interim measures, if it is established that such an order is justified, *prima facie*, in fact and in law (*fumus boni juris*) and that it is urgent in so far as, in order to avoid serious and irreparable harm to the applicant's interests, it must be made and produce its effects before a decision is reached in the main action. Where appropriate, the judge hearing such an application must also weigh up the interests involved (orders in Case C-377/98 R *Netherlands* v *Council* [2000] ECR I-6229, paragraph 41; Case C-445/00 R *Austria* v *Council* [2001] ECR I-1461, paragraph 73; and order of the President of the Court of First Instance in Case T-310/06 R *Hungary* v *Commission*, not published in the ECR, paragraph 19).

Prima facie case

Arguments of the parties

27 The applicant states that, in its main action, it seeks, principally, the annulment of the contested provisions on the ground that the Commission infringed the precautionary principle in both its assessment and management of the risk.

— Risk assessment

28 The applicant states that point (3) of the Annex to Regulation No 727/2007 amends Annex VII, which concerns measures for eradicating TSE and which provided, in the version in force until 17 July 2007, for outbreaks of scrapie to be controlled by the slaughter of all caprine animals, and by a slaughter possibly limited only to genetically susceptible ovine animals in the affected ovine herds; genetically resistant ovine animals could be retained.

29 The Annex VII currently in force distinguishes between the measures to be taken according to the results of discriminatory testing carried out following confirmation of the presence of TSE in an ovine or caprine animal.

30 In the case of confirmation of TSE in an ovine or caprine animal, if BSE cannot be excluded, the killing and complete destruction of the individual animals identified as being at risk are still mandatory. On the other hand, if BSE is excluded following the results of the discriminatory tests, point 2 of Chapter A of Annex VII to Regulation No 999/2001 significantly increases the circumstances in which Member States may decide not to kill and completely destroy the animals on the holding to which the ovine or caprine animal suffering from scrapie belonged.

31 The consequence of applying the contested provisions is that genetically susceptible ovine animals and caprine animals on a holding on which a case of classic scrapie has been confirmed may now be kept on that holding or slaughtered for human consumption.

32 It is apparent from recital 7 of Regulation No 727/2007 that that development is based on two assumptions: (a) the discriminatory tests render it possible definitely to exclude BSE on holdings contaminated by classic scrapie, and (b) scrapie is not transmissible to humans and presents no risk to human health.

33 On the basis of the AFSSA opinion of 15 January 2007 and the EFSA opinion of 8 March 2007, which is only partially reproduced in recital 9 of Regulation No 727/2007, the applicant considers that, in spite of scientific advances, uncertainties remain as to the possibility that, among the TSE responsible agents of animal origin, agents other than the BSE agent may be transmissible to humans, and as to the reliability of the discriminatory tests.

34 In those circumstances, the applicant considers that the advance of scientific knowledge concerning TSE does not alter the perception of the risk represented by classic scrapie and justify the adoption of less restrictive measures for monitoring and eradicating that disease and that the Commission has therefore infringed the precautionary principle by committing an error in the risk assessment.

35 The Commission maintains that, unlike BSE, which is nowadays considered to be the only TSE transmissible to humans, there is no evidence for an epidemiological or molecular link between the scrapie agent and TSEs in humans, as is apparent from numerous recent scientific opinions and documents issued by specialist international organisations. Therefore, scrapie cannot be regarded or identified as a zoonosis.

36 It is clear from the wording of the AFSSA Opinion of 15 January 2007 and the EFSA opinion of 8 March 2007, to which the applicant refers in its application for interim measures, that the risk of transmission to humans of TSE responsible agents of animal origin, other than the BSE agent, is a purely hypothetical risk to which the precautionary principle does not apply.

37 In that regard, the Commission points out that, under Article 7 of Regulation No 178/2002, the precautionary principle must be applied where scientific uncertainty persists and that the measures adopted in accordance with that principle must be proportionate.

38 In its judgment in Case T-13/99 *Pfizer Animal Health* v *Council* [2002] ECR II-3305, the Court specified the conditions for applying the precautionary principle in Community law, holding that a preventive measure cannot properly be based on a purely hypothetical approach to the risk, and may be taken only if the risk, although the reality and extent thereof have not been fully demonstrated, appears to be

adequately backed up by the scientific data available. It is clear from that judgment that there must be a certain degree of probability that the adverse effects it is sought to avoid by adopting the measure in question will actually occur, its being understood that it is not possible to have a 'zero risk' level.

39 As regards the applicant's doubts concerning the reliability of the discriminatory tests, the Commission points out that they are the result of the work of the TSE Community reference laboratory and of its panel of scientists and strain classification experts, work which has validated a rapid analysis procedure based on biochemical tests to differentiate BSE from scrapie.

40 The defendant points out that, in January 2005, it amended Regulation No 999/2001 by introducing the obligation to apply those discriminatory tests to each TSE 'index' case detected in an ovine or caprine herd, in order to confirm cases of BSE. It draws attention to the fact that the more flexible measures laid down by Regulation No 727/2007 were not adopted until two years after the introduction of those tests, two years in which their performance was monitored and their results analysed.

41 Accordingly, after noting that the AFSSA opinion of 15 January 2007 merely reproduces an opinion issued on 15 May 2006, the Commission claims that the fact that AFSSA considered, in 2006, that the tests did not enable the presence of BSE to be ruled out is not inconsistent with the fact that, in 2007, EFSA concluded, on the basis of the results of those tests, that the tests were reliable.

42 As regards the final sentence of EFSA's conclusions concerning discriminatory tests, it is explained by the fact that, by its very nature, no biological test can be regarded as 'perfect'. The Commission states, in that regard, that every result which is difficult to interpret is examined by the full panel of scientific experts referred to in

paragraph 39 above, and that, if necessary, additional examinations are carried out. The Commission adds that, if, at the end of those additional examinations, the results are still inconclusive, the dubious sample is tested using live mice so that the nature of the TSE strain may be determined with certainty.

43 Thus, the operation of this whole rigorous process serves to reduce significantly, if not eliminate completely, the initial uncertainty related to biological tests, and it is also pointed out that those tests do not in themselves constitute a public health measure but a technical tool for distinguishing quickly between BSE and scrapie.

44 Therefore, the approach taken by the French authorities, which seeks to impose a 'zero risk' level in the application of the precautionary principle, is not valid.

— Risk management

45 The applicant claims that the less restrictive measures for eradicating TSEs introduced by the contested provisions do not make it possible to contain the risk to human health represented by TSEs and are even likely to aggravate it.

46 The replacement of the pre-existing obligations to kill and destroy by the options of retaining the herds or killing the animals and subsequently releasing their meat for human consumption does not appear proportionate. According to the AFSSA

Opinion of 15 January 2007, there is at the moment no measure capable of replacing the slaughter and complete destruction of susceptible animals from infected herds.

47 Furthermore, the applicant claims that the rapid tests, carried out on the carcasses of animals slaughtered for human consumption in accordance with the provisions of point 2.3(d) and point 4 of Chapter A of Annex VII, are inadequate for identifying all the animals infected by TSEs, in so far as they are carried out on a sample taken from the central nervous system and only on animals which are over 18 months of age or have more than two permanent incisors.

48 Moreover, if animals from an infected herd are kept on the holding, the surveillance procedures introduced would be implemented for only two years. The applicant points out that, therefore, animals present on a holding when a TSE case has been detected may, at the end of a period of two years and if no other case has been identified, be slaughtered and released for human consumption without testing.

49 The applicant states that, under the system put in place by the contested provisions, it is foreseeable that animals will be released for human consumption even though they are infected with undetected TSEs. At the present stage of knowledge, it is not possible to rule out the possibility that the consumption of meat and products derived from animals with TSEs may constitute a danger to human health.

50 Finally, the increased health risk caused by the contested provisions cannot be justified by the profit they may generate. The cost of retaining the previous provisions is only a little higher than the total cost of implementing the conditions and procedures laid down in the contested provisions and is low in relation to the cost of all the measures for controlling TSEs. Consequently, that cost does not seem disproportionate in relation to the aim of protecting human health.

51 Accordingly, the Commission infringed the precautionary principle by committing an error in the management of the risk.

52 The Commission points out that the measures adopted until now pursuant to Regulation No 999/2001 are measures to combat BSE, not other TSEs such as scrapie, and that, having regard to the effectiveness of those measures and to the clear improvement in the situation, it took the initiative, in 2005, of introducing a global strategy for BSE. Within the framework of that strategy, a number of measures have already been adopted in order to relax the previous provisions, and the measures contested by the French authorities regarding the slaughter policy in the event of TSE in small ruminants also form part of that strategy.

53 As regards the age criteria (animals over 18 months of age) or dentition (the presence of two permanent incisors), imposed since 2002 by the Community legislation for subjection to screening tests, the Commission points out that the French authorities have never called them in question until now. It states that there is very little likelihood of detecting the 'prion' in the brain of an animal under 18 months of age or with fewer than two permanent incisors and that AFSSA clearly confirmed, in an opinion of 20 July 2006, that it was pointless to test younger animals.

54 The Commission points out that Regulation No 727/2007 amends the health measures applicable to herds infected with TSE which had been introduced by Regulation No 260/2003, when the discriminatory tests were not yet available. Since the entry into force, in January 2005, of the obligation to carry out discriminatory tests on all TSE cases detected, no discriminatory test has revealed cases of BSE among small ruminants in spite of the large number of tests carried out (2 377 on ovine animals and 339 on caprine animals).

55 As regards the intensive surveillance period limited to two years following the appearance of the last TSE case, it is very unlikely that infected animals would not be detected during that period. It means, according to the Commission, that during those two years, none of the animals slaughtered must be infected.

56 The defendant points out that the risk referred to by the French authorities, namely, the release of potentially dangerous meat and products, was also present before the adoption of Regulation No 727/2007 and is taken into account in the risk management.

57 The figure of 50% given by the applicant to define the percentage of animals infected and undetected by tests carried out at the time of slaughter refers to all TSEs, of which only BSE is zoonotic. As regards BSE, and on the assumption that it could be present in ovine animals, an assumption which is highly improbable but based on the precautionary principle, an EFSA report, adopted on 25 January 2007, quantifies the risk at 0.3/0.5 cases of BSE for every 10 000 animals slaughtered.

58 In conclusion, the Commission considers that, by implementing a strategy for combating TSEs and, more particularly, by requiring the removal of specified risk material, by imposing general surveillance of TSEs in the European Union and active surveillance of TSEs in all infected herds for two years, it managed the risk appropriately.

Findings of the Judge hearing the application for interim measures

— Preliminary observations

59 In order to determine whether the condition for establishing a *prima facie* case is satisfied in this case, it is necessary, first, to carry out a *prima facie* examination of the substance of the plea in law put forward by the applicant in support of the main action and therefore to ascertain whether the arguments concerning the alleged infringement, in the present case, of the precautionary principle by the Commission are so weighty that they cannot be ruled out in these proceedings for interim measures (see to that effect Case C-149/95 P(R) *Commission* v *Atlantic Container Line and Others* [1995] ECR I-2165, paragraph 26, and Case T-13/99 R *Pfizer Animal Health* v *Council* [1999] ECR II-1961, paragraph 132).

60 As the Court has already held, in accordance with Article 174 EC, the precautionary principle is one of the principles on which Community policy on the environment, which includes the policy relating to the protection of human health, is based, and the principle also applies where the Community institutions take, in the framework of the common agricultural policy, measures to protect human health (judgment in *Pfizer Animal Health* v *Council*, cited in paragraph 38 above, paragraph 114). Its existence has also been recognised by settled case-law (see the case-law cited in the judgment in *Pfizer Animal Health* v *Council*, cited in paragraph 38 above, paragraph 115).

61 Under the precautionary principle, it must be accepted that, where there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent (Case C-180/96 *United Kingdom* v *Commission* [1998] ECR I-2265, paragraph 99, and Case C-157/96 *National Farmers' Union and Others* [1998] ECR I-2211, paragraph 63). On the other hand, when new elements change the perception of a risk or show that that risk can be contained by less restrictive measures 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 (Case C-504/04 *Agrarproduktion Staebelow* [2006] ECR I-679, paragraph 40).

62 It should also be pointed out that Article 7 of Regulation No 178/2002 is entitled 'Precautionary principle' and is worded as follows:

'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.'

63 In the present case, it should be pointed out that, in view of the magnitude of the risk posed to human and animal health by certain TSEs, and after obtaining scientific opinions on measures to reduce the potential risk for humans and animals resulting from exposure to products derived from infected animals, the Parliament and the Council adopted Regulation No 999/2001 laying down rules for the prevention, control and eradication of TSEs in bovine, ovine and caprine animals. Regulation 999/2001, for which the legal basis is Article 152(4)(b) EC, 'directly concerns public health' (recitals 2, 3 and 4 in the preamble to Regulation No 999/2001).

64 Point (3) of the Annex to Regulation No 727/2007 amends Annex VII, which sets out the procedures for applying the rule, laid down in Article 13(1)(c) of Regulation No 999/2001, that animals identified as being at risk are to be slaughtered, and the derogations which may be applied.

65 The parties agree that the contested provisions constitute a relaxation of the health measures applicable to a herd of ovine or caprine animals in which a case of TSE has been detected. If it has been possible to exclude BSE by means of discriminatory testing, Member States now have the option of replacing the killing and complete destruction of the animals by keeping them on the holding, under surveillance, or by slaughtering them for human consumption carrying out rapid tests for the presence of TSEs, as provided by Regulation No 727/2007.

66 As stated in paragraph 61 above, the Community institutions may adopt less restrictive measures than the existing measures when such measures are capable of containing a risk the perception of which has been changed by new elements.

67 It should also be pointed out that, according to the case-law, the Community legislature is allowed a broad discretion in an area such as that involved in the present case, which entails political, economic and social choices on its part, and in which it is called upon to undertake complex assessments. In that regard, review by the Community judicature of the substance of the relevant act must be confined to examining whether the exercise of such discretion is vitiated by a manifest error or a misuse of powers or whether the Community institutions clearly exceeded the bounds of their discretion (*Agrarprodutkion Staebelow*, cited in paragraph 61 above, paragraph 36, and *Pfizer Animal Health* v *Council*, cited in paragraph 38 above, paragraph 166).

68 In the present case, the applicant claims that the Commission infringed the precautionary principle by committing an error in both its assessment and management of the risk.

— Risk assessment

69 The applicant maintains that the new elements mentioned by the Commission do not alter the perception of the risk taken into account in Regulation No 999/2001 and that the Commission therefore infringed the precautionary principle by committing an error in the risk assessment.

70 Apparently, the Commission does not deny that, in the context of the application of the precautionary principle, a risk assessment was a prerequisite for the adoption of the contested provisions. It even states, in its pleadings, that that assessment must include a scientific part, and also make it possible to determine the level of risk considered unacceptable, its being understood that a scientific assessment of the risks is a prerequisite for 'any measure'.

71 It is apparent from the documents in the case that the weight of the applicant's claims regarding the error committed by the Commission in the risk assessment must be evaluated principally in the light of the opinion of EFSA and its Scientific Panel on biological hazards dated 8 March 2007, on which Regulation No 727/2007, and more particularly the provisions at issue, are essentially based.

72 In that regard, it must be stated that recital 9 in the preamble to Regulation No 727/2007 expressly refers to the conclusions of the aforementioned opinion, but conceals a part of it which seems to call in question the Commission's dual premise on which the contested provisions are based, namely, that TSEs other than BSE cannot be transmitted to humans and that the discriminatory tests are reliable.

73 In the opinion in question, EFSA and its Scientific Panel on Biological Hazards stated that '[t]here is no evidence for an epidemiological or molecular link between classical and/or atypical scrapie and TSEs in humans' and that 'current discriminatory tests as described in the EC legislation to be used for discrimination between scrapie and BSE appear, up to now, to be reliable for the differentiation of BSE from classical and atypical scrapie', but those two considerations are accompanied and supplemented by two observations, in the form of reservations with which they seem to form an inseparable whole, and must therefore be assessed in their entirety in order to understand the full impact of the scientific answer given by the experts to the Commission's questions.

74 Thus, in addition to the aforementioned considerations, EFSA and its Scientific Panel clearly stated that 'in view of their diversity, it is currently not possible to exclude transmissibility to humans of other animal TSE agents' and that, with regard to discriminatory tests, 'at the current stage of scientific knowledge, neither their diagnostic sensitivity nor their specificity can be assumed to be perfect'.

75 It should be pointed out that the Commission, in Regulation No 727/2007, not only expurgated without justification part of EFSA's conclusions but also reproduced incorrectly that part of the conclusions which it retained. Whereas EFSA and its Scientific Panel on Biological Hazards stated that the discriminatory tests 'appear' currently, to be reliable for the differentiation of BSE from classical and atypical scrapie, the Commission states in recital 9 in the preamble to Regulation No 727/2007 that those tests 'are' reliable.

76 Moreover, although the EFSA opinion of 8 March 2007 is *prima facie* the only specific scientific assessment serving as a basis for adopting the contested provisions, the applicant produced to the Court a number of AFSSA opinions, one of which, dated 15 January 2007, expresses the same reservations and uncertainty with regard to the dual premise on which the Commission based the adoption of those provisions. The Director of EFSA, when asked by the Commission, by letter of 20 April 2007, whether there was any contradiction between the opinions concerned, clearly concluded that the views of the two organisations coincided completely; that conclusion was disregarded by the members of the SCHCAH, which must have taken a decision on the proposal for a regulation to amend the regulation on 24 April 2007, even before the time-limit for replying imposed by the Commission on EFSA's Director had expired.

77 Accordingly, the Commission does not appear to be justified in stating that there is a 'consensus' in the scientific community that TSEs of animal origin, other than BSE, are not transmissible to humans.

78 Its claim that the precautionary principle does not apply in this case, in view of the 'purely hypothetical' nature of the risk of transmission to humans of TSE responsible agents of animal origin, other than BSE, and of the reliability of the discriminatory tests, likewise does not seem *prima facie* justified.

79 It should be pointed out that, since a 'zero risk' cannot actually exist, the precautionary principle can therefore apply only in situations in which there is a risk, in particular to human health, which, although it is not founded on mere hypotheses that have not been scientifically confirmed, has not yet been fully demonstrated. Moreover, in a situation in which the precautionary principle is applied, which by definition must be in a situation in which there is scientific uncertainty, a risk assessment cannot be required to provide the Community 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 (judgment in *Pfizer Animal Health* v *Council*, cited in paragraph 38 above, paragraphs 142 and 146).

80 In the present case, the Commission does not appear to dispute the fact that the EFSA opinion of 8 March 2007 satisfies the criteria of excellence, transparency and independence required of scientific opinions (see, as regards that requirement, *Pfizer Animal Health* v *Council*, cited in paragraph 38 above, paragraph 159). The opinion in question contains not only the replies given to the two questions submitted by the Commission, but also a referenced scientific explanation underlying the conclusions expressed and enabling the institution to decide whether it was necessary to take measures. The AFSSA opinion of 15 January 2007 also seems to meet the aforementioned criteria.

81 In the EFSA opinion of 8 March 2007, it is clearly stated as follows:

'In conclusion, no scientific data currently enable us to consider any TSE agent other than BSE as a zoonotic agent. However, there are significant scientific uncertainties associated with the question whether TSE agents in their whole spectrum may cross the human transmission barrier under natural conditions.'

82 Furthermore, the Scientific Panel on Biological Hazards also referred to an EFSA opinion of 7 January 2007 worded as follows:

'Application [of the discriminatory tests] as part of small ruminant surveillance was continuing to improve the accuracy of these prevalence estimates. However, balanced against this optimistic scenario, the BIOHAZ panel accepted that the sensitivity and specificity of the discriminatory tests had, for logistical reasons, not been experimentally evaluated and potential confounding factors, such as concomitant infection of the same animal with scrapie and BSE, remained to be investigated.'

83 Also, it is quite inconceivable that EFSA's Scientific Panel on Biological Hazards, when formulating its conclusion on the reliability of the discriminatory tests, could have overlooked the observation made by the Commission in its pleadings on the ground that, by its very nature, no biological test may be regarded as perfect.

84 Furthermore, the Commission has not provided any cost assessment of the performance of the discriminatory test, and it conceded at the hearing that there was a problem relating to a lack of statistical data. The Commission's arguments regarding neutralisation of the risk linked to the existence of possible false negatives as a result of the implementation of additional tests in the event of results which are difficult to interpret requires an in-depth examination which cannot be carried out in the context of proceedings for interim measures.

85 It may therefore be considered, at least *prima facie*, that the two aforementioned opinions state the fact that, in spite of certain advances in scientific knowledge, genuine scientific uncertainties persist with regard, on the one hand, to the possibility that TSE responsible agents of animal origin, other than BSE agents, may be transmissible to humans and, on the other hand, to the reliability of the discriminatory tests.

86 Taking, in the present proceedings, the same approach as in the judgment in *Pfizer Animal Health* v *Council,* cited in paragraph 38 above, it appears, having regard to all documents in the case and to the evidence produced at the hearing, that the applicant's claim that the advance of scientific knowledge concerning TSE in small ruminants does not alter the perception of the risk represented by those diseases to public health is not without substance. In those circumstances, the claim that the Commission infringed the precautionary principle by committing an error in the risk management requires an in-depth examination which may be carried out only by the court adjudicating on the merits.

— Risk management

87 The applicant maintains that the less restrictive measures for eradicating TSEs introduced by the contested provisions do not made it possible to contain the risk presented by TSEs to human health and are even likely to aggravate it. By adopting those provisions, the Commission infringed the precautionary principle by committing an error in the risk management.

88 It should be pointed out that a scientific risk assessment must enable the competent authority to decide, in relation to risk management, which measures appear to it to be appropriate and necessary to prevent the risk from materialising (judgment in *Pfizer Animal Health* v *Council,* cited in paragraph 38 above, paragraph 163). It appears, therefore, that the relevance of the risk assessment is crucial to an appraisal of the management of that risk.

89 As has already been stated, the contested provisions constitute a relaxation of the health measures applicable to the herd of ovine or caprine animals in which a TSE case has been detected by means of an initial rapid test. If it has been possible to exclude BSE by means of discriminatory tests, the slaughter and complete

destruction of all the other ovine and caprine animals on the holding, and, in so far as they are identifiable, of the parents of the animal in which the disease was confirmed and of the last progeny of the female animal in which the disease was confirmed, is only an optional measure. Instead of implementing that measure, the competent authority may:

— slaughter immediately for human consumption all other ovine and caprine animals on the holding and, in so far as they are identifiable, of the parents of the animal in which the disease was confirmed and of the last progeny of the female animal in which the disease was confirmed; individuals which are over 18 months of age or have more than two permanent incisors erupted through the gum must undergo rapid testing to detect the presence of TSE (point 2.3(d) of Chapter A of Annex VII).

— where the conditions laid down in point 2.3(b)(iii) of Chapter A of Annex VII have been satisfied, keep all the ovine and caprine animals of the holding on the holding, those animals being prohibited from leaving the holding for a period of two years following the detection of the last TSE case: however, during that period, those animals may be sent for slaughter and their carcasses released for human consumption; individuals of over 18 months of age must first undergo rapid testing to detect the presence of TSE (point 4 of Chapter A of Annex VII).

90 It therefore appears that the new operative part introduced by the Commission is based, for both initial and later stages, on the carrying out of rapid tests for detecting the presence of a TSE.

91 At the initial stage, the tests form part of the surveillance programme for ovine and caprine animals imposed by Commission Regulation (EC) No 270/2002 of 14 February 2002 amending Regulation (EC) No 999/2001 of the European Parliament and of the Council 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).

92 It should be pointed out that that programme does not concern all animals intended for human consumption but is based on a sample. The rapid detection tests therefore relate only to a fraction of the animals slaughtered for consumption and, in the event of a positive reaction, give rise to the implementation of discriminatory tests which, the Commission maintains, make it possible to differentiate an animal with scrapie from an animal with BSE and which determine the options available to the competent authority as regards health measures.

93 The parties agree that the rapid tests for detecting the presence of a TSE are carried out exclusively on central nervous system tissue taken from the animal concerned. The applicant points out, without being contradicted by the Commission, that it has been scientifically demonstrated that, in the case of BSE and classic scrapie in small ruminants, the pathogenic prion accumulates only belatedly at rates which are detectable in the tissues of the central nervous system, although it may be present from a younger age in certain peripheral tissues which are not taken. In the AFSSA opinion of 15 January 2007, it is clearly stated that 'a negative result in a screening test carried out on the obex in no way guarantees the infectious status of a small ruminant in terms of BSE or scrapie', especially if the animal has a susceptible genotype.

94 In support of its claim, the applicant also produces an AFSSA opinion of 13 June 2007, in which it is stated that, on the basis of data collected in France regarding ovine animals, 'it has been established that tests on the obex detect only about 50% of

the infected animals in infected herds; the other 50% are animals in incubation carrying infection in their lymphoid organs'. In its pleadings, the Commission did not challenge this observation by AFSSA but merely stated that the figure given should be 'accepted with caution' and that it related to all TSEs of which BSE alone is zoonotic.

95 At the later stage, the rapid tests for detecting the presence of a TSE will determine the marketing of meat and products obtained from animals from a herd in which a TSE case has been detected and in which, according to the Commission, BSE may be excluded by means of the discriminatory test.

96 It is clear from the contested provisions that animals, including genetically susceptible ovine animals and caprine animals, from a holding in which a TSE case has been confirmed may now be slaughtered for human consumption whereas, under the wording prior to Regulation No 727/2007, they would have had to be killed and destroyed.

97 Of those animals, some may be slaughtered for human consumption without undergoing a rapid test to detect the presence of TSE, because they do not meet the criteria for subjection to that test, and may yet be carriers of infectious agents as has been stated above, in paragraphs 92 and 93.

98 In fact, the only animals subjected to the rapid test for detecting the presence of TSE are individuals which are over 18 months of age or which have more than two incisors; it is noted that this second criterion is mentioned only in the case of immediate slaughter provided for in point 2.3(d) of Chapter A of Annex VII and,

according to the explanations given by the Commission during the hearing, was omitted in the case of slaughter during the two-year surveillance period provided for in point 4 of Chapter A of Annex VII.

99 Those criteria, of age and dentition, are based on the degree of probability of detecting the pathogenic prion in the brain, which accumulates only belatedly at rates which are detectable in tissue taken from the central nervous system. Since the tests concerned enable the disease to be identified only at an advanced stage, it may be inferred *prima facie* that infected animals subjected to testing may not be detected if they do not have a sufficient accumulation of the pathogenic prion in the central nervous system.

100 It is important to point out that the Commission does not seriously dispute the AFSSA opinion of 13 June 2007, in which that body considers that 50% of the ovine animals infected by TSEs are not detected by the tests carried out at the time of slaughter.

101 Moreover, it is apparent from a reading of point 2.3(b)(iii) in conjunction with point 4 of Chapter A of Annex VII that ovine and caprine animals on a holding on which a TSE case has been detected may be kept on the holding and slaughtered for human consumption at the end of a period of two years without being tested for TSEs.

102 That finding must be evaluated in the light of the AFSSA opinion of 15 January 2007, according to which the risk of infection by TSEs from an animal from a herd infected with classic scrapie is between 20 to 600 times higher than the risk of infection by TSEs from an animal from the general population; this risk is increased again in the case of animals with a susceptible genotype. Although the Commission rightly pointed out at the hearing that AFSSA's committee of experts itself described the figure in question as a rough estimate, it did not in principle challenge the assertion that there is an increased risk of infection in the situation described above.

103 The Commission merely claims that the likelihood of infected animals not being detected during the two-year period is extremely low, since 'that means that, during those two years, none of the animals to be slaughtered must be infected'.

104 However, it is not disputed that not all the animals slaughtered for human consumption are subjected to a rapid test for detecting a TSE.

105 Moreover, it should be pointed out that the Commission concedes, in its pleadings, that scrapie has a variable incubation period the duration of which relates to several factors, among them the genetic patrimony of the host and the strain of the causal agent. It is apparent from discussions held during the hearing that the incubation period may be longer than two years; the Commission mentioned an 'average of two years', whereas the applicant assesses that duration at four or five years.

106 Therefore, the applicant's statement that it is foreseeable that, under the system introduced by the contested provisions, animals will be released for human consumption even though they are infected by undetected TSEs does not seem to be without substance.

107 As has already been stated, it may be considered, at least *prima facie*, that the AFSSA opinion of 15 January 2007 and the EFSA opinion of 8 March 2007 express genuine scientific uncertainties regarding the circumstances in which TSEs other than BSE may be transmissible to humans. At the current stage of scientific knowledge, it cannot be ruled out that the consumption of meat and products obtained from animals infected by TSEs other than BSE present a risk to human health.

108 Both opinions also appear to express genuine scientific uncertainties with regard to the reliability of the discriminatory tests, which means that meat and products obtained from animals carrying undetected BSE strains may be put on the market, which represents a real danger to human health.

109 In its pleadings, the Commission maintains that a situation in which BSE might be present in ovine animals is 'highly unlikely'.

110 It should be pointed out however, that recital 6 in the preamble to Regulation No 727/2007 refers to 'the detection of [BSE] in a goat in 2005 and three unusual TSE cases in sheep where BSE could not be excluded'. At the hearing, the Commission stated that the three cases in question were still being analysed and that no definitive conclusion was possible at this stage.

111 The Commission also produced an EFSA opinion of 25 January 2007, which quantified the risk at 0.3/0.5 BSE cases for every 10 000 animals slaughtered, with reference only to ovine animals. As the applicant rightly points out, that estimate, in order for its precise impact to be measured, must be applied to the whole ovine population of the Community, which the applicant estimates to be 67 million individuals.

112 In any event, it should be noted that the risk to human health represented by the presence of the ESB in small ruminants is clearly recognised in point 2.3(a) of Chapter A of Annex VII, which provides, in the case of confirmation of TSE in an ovine or caprine animal, and if BSE cannot be excluded, for the killing and complete destruction inter alia of all the ovine and caprine animals on the holding and, in so far as they are identifiable, the parents of the animal in which the disease was confirmed and the last progeny of the female animal in which the disease was confirmed.

113 The Commission points out, finally, that the risk of meat from animals infected by a TSE being made available for consumption is not a new risk, since it was already present before the adoption of Regulation No 727/2007, and that it was taken into account in connection with the risk management.

114 Apart from the fact that that observation contradicts the defendant's own statement that the approach taken by the French authorities seeks to impose a 'zero risk' level in the application of the precautionary principle, it appears that the situation prior to the adoption of Regulation No 727/2007 cannot be compared, in terms of risk to human health, with the situation which is the result of the application of the contested provisions.

115 Now, as well as the unsystematic nature of the surveillance programme for ovine and caprine animals established by Regulation No 727/2007 and the possibility that meat and products from genetically resistant animals may be released for human consumption, there is the fact that a whole range of meat and products obtained from animals from herds infected by a TSE and with a susceptible genotype which, under the system prior to the one introduced by Regulation No 727/2007, would have been killed and destroyed, will be put on the market.

116 In conclusion, the applicant's claim that the contested provisions do not make it possible to contain the risk which the TSEs represents for human health and are even likely to aggravate it does not seem, at least *prima facie*, irrelevant. Therefore, the claim that the Commission infringed the precautionary principle by committing an error in the risk management requires an in-depth examination which falls to be carried out only by the court adjudicating on the merits.

Urgency

Arguments of the parties

117 The applicant states that it seeks suspension of the operation of the contested provisions on account of the serious and irreparable harm to public health which might result if they were implemented. It states in that regard that, from 17 July 2007, meat and products obtained from the slaughter of herds infected by undetected TSEs may be put on the market, which represents a danger to human health.

118 It adds that, although it is not certain that the harm will be caused, the degree of probability that the damage will occur is sufficient to justify granting the interim measure requested.

119 The Commission maintains that the French authorities request suspension of the operation of the contested provisions on the basis of a so-called risk to public health which would materialise if they were implemented and, more particularly, because meat and products from animals which have contracted a TSE other than BSE might be put on the market for consumption.

120 It states that, apart from the fact that that situation already prevails today, it should be pointed out that there is as yet no evidence that scrapie is transmitted to humans, and that the discriminatory tests are not only reliable but are part of a whole series of measures.

121 That being so, the Commission considers that the risk of serious and irreparable harm described by the French authorities is hypothetical and therefore cannot justify the measures sought.

Findings of the Judge hearing the application for interim measures

122 It should be remembered that the purpose of proceedings for interim relief is to ensure the full effectiveness of the definitive future decision, in order to ensure that there is no lacuna in the legal protection provided by the Community Courts (order in Case C-399/95 R *Germany* v *Commission* [1996] ECR I-2441, paragraph 46). To attain that objective, the urgency of an application for the adoption of interim measures must therefore be assessed in the light of the extent to which an interlocutory order is necessary in order to avoid serious and irreparable damage to the party seeking the adoption of the interim measure (Case C-329/99 P(R) *Pfizer Animal Health* v *Council* [1999] ECR I-8343, paragraph 94).

123 It is for the party claiming serious and irreparable damage to establish its existence. While it is not necessary for it to be absolutely certain that the damage will occur, a sufficient degree of probability being enough, the applicant is none the less required to prove the facts which are considered to found the prospect of such damage (orders in Case C-280/93 R *Germany* v *Council* [1993] ECR I-3667, paragraph 34, and Case C-180/01 P-R *Commission* v *NALOO* [2001] ECR I-5737, paragraph 53).

124 In the present case, the French authorities, which are responsible for the public interest in connection with the protection of public health, request suspension of the operation of the contested provisions owing to the risk to human health resulting from their implementation.

125 As the applicant points out, without being contradicted by the Commission, the aforementioned situation must be assessed having regard to the size of the intra-Community flows of meat from small ruminants.

126 In that regard, it is common ground that, from 17 July 2007 and throughout European territory, ovine animals, including animals carrying a susceptible genotype, and caprine animals from a herd in which a TSE case has been detected, may be slaughtered for human consumption.

127 In the particular circumstances of the present case, it is necessary to take into consideration, when assessing urgency, the fact that, in the light of the information available to the judge hearing the application for interim measures, the factual and legal arguments presented by the applicant in support of the *fumus boni juris* appear serious.

128 It is therefore necessary to consider that, from 17 July 2007, it is possible that meat or meat products from animals infected by a TSE will be released for human consumption.

129 It should be pointed out that two specialist and independent bodies have recently concluded that, although there is no evidence of an epidemiological or molecular link between classic or atypical scrapie and TSEs in man and that the BSE agent is

the only TSE responsible agent identified as zoonotic, in view of their diversity it is currently not possible to exclude transmissibility to humans of other animal TSE agents. Therefore, the consumption of meat and products obtained from an animal infected by TSEs, other than BSE, represents a potential danger to human health.

130 The opinions given by those two bodies also express genuine scientific uncertainties regarding the reliability of the discriminatory test, designed to differentiate BSE from scrapie. The consumption of meat and products obtained from an animal infected by BSE represents a real danger for human beings.

131 Although, as the Commission points out, the risk to public health represented by the presence on the market of meat and products obtained from animals infected by a TSE was already present before the adoption of the contested provisions, that risk has objectively increased following the entry into force of those provisions, owing to the placing on the market of a whole range of meat and products from animals from herds infected by a TSE which, under the system prior to the one introduced by Regulation No 727/2007, would have been killed and destroyed.

132 It should be pointed out that, in an opinion of 13 June 2007, AFSSA states, in connection with an estimate only to determine scale, that the implementation of the contested provisions culminated, in 2006, in the release for human consumption of at least 1 000 French carcasses containing significant amounts of infection.

133 Therefore the condition for urgency is satisfied in this case.

Balancing of interests

Arguments of the parties

134 The applicant points out that, although keeping the current legislation involves a cost, it is not disproportionate in the light of public health issues, whereas the implementation of the contested provisions might cause serious and irreparable damage to human health.

135 It is apparent from the case-law that, when balancing the interests at issue, the Court cannot but recognise the paramount importance to be accorded to the protection of human health in the face of a serious risk, which can in no way be excluded at the current stage of scientific knowledge, as opposed to economic considerations (Case C-180/96 R *United Kingdom* v *Commission* [1996] ECR I-3903, paragraphs 90 to 93).

136 The applicant adds that if the contested provisions were annulled by the court adjudicating on the merits it would not be possible for the situation brought about by their immediate application to be reversed.

137 The applicant therefore considers that the balancing of interests justifies suspension of the operation of the provisions at issue.

138 The Commission disputes the applicant's claims regarding the release for human consumption of potentially dangerous meat and products and submits that continuing to slaughter and destroy the whole herd except for resistant animals is

no longer justified in the light of scientific developments and is contrary to the principle of proportionality.

139 It considers that the new provisions of Regulation No 999/2001 will create greater freedom for farmers, without compromising the current level of safety for consumer health and that, therefore, the balance the interests clearly leans in favour of applying the contested measures.

Findings of the Judge hearing the application for interim measures

140 In proceedings for interim measures, it is for the judge hearing the application, when weighing the various interests at stake, to examine whether the annulment of the contested measure by the Court giving judgment in the main action would make it possible to reverse the situation that would have been brought about by its immediate implementation and conversely whether suspension of the operation of that measure would be such as to prevent its being fully effective in the event of the main application being dismissed (orders in *Commission* v *Atlantic Container Line*, cited in paragraph 59 above, paragraph 50, and *United Kingdom* v *Commission*, cited in paragraph 135 above, paragraph 89).

141 It should be pointed out in that regard that, as a rule, there can be no question but that the requirements of the protection of public health must take precedence over economic considerations (Case T-70/99 R *Alpharma* v *Council* [1999] ECR II-2027, paragraph 152, and case-law cited). It follows that, where a serious risk to human health is invoked, the Judge hearing the application for interim relief, notwithstanding his formal discretion in balancing the interests, will almost inevitably lean in favour of protecting public health (see, to that effect, Case T-392/02 R *Solvay Pharmaceuticals* v *Council* [2003] ECR II-1825, paragraph 122).

142 In its pleadings, the Commission does not rely on economic considerations to countervail the application for suspension brought by the applicant, but again claims that it has demonstrated that the consequence of implementing the contested provisions would not be to release potentially dangerous meat and products for human consumption and that, at the current stage of scientific knowledge, it would be disproportionate to retain the killing and destruction of the whole herd.

143 It should be pointed out, however, that, in the light of the evidence before the Court, the factual and legal arguments presented by the applicant in support of the *fumus boni juris* appear to be sound and that it has been established above that there is a grave risk of serious and irreparable harm to human health.

144 As the applicant rightly points out, the suspension of the contested provisions would not be such as to prevent them being fully effective in the event of the main application being dismissed, because it would only mean a slight postponement of their effects. On the other hand, the consequence of the effective and immediate implementation of the contested provisions is the release for human consumption of potentially dangerous meat and products and the possible contamination of consumers, a situation which the annulment of the contested provisions by the court giving judgment in the main action could not remedy.

145 As regards the point concerning greater freedom for farmers, the Commission stated, during the hearing, that farmers were having great difficulty reconstituting their herds with resistant animals and that the relaxation, in the contested provisions, of the health measures would, in practice, ensure that breeders complied more fully with the obligation to report clinical cases, thus effectively preventing the 'risk of escape'.

146 It should be pointed out, however, that the Commission itself maintains that the option of keeping animals on a holding on which a TSE case has been detected is accompanied by intensive surveillance of that holding for two years, which most certainly restricts the activities of the farmer and which, *a priori*, cannot effectively prevent the 'risk of escape'.

147 This purely hypothetical advantage suggested by the Commission cannot prevail over the serious damage, in terms of public health of communities, which the immediate effective implementation of the contested provisions is likely to bring about and which could not be remedied in the event that the main action were subsequently successful.

148 The balancing of interests therefore cannot lean in favour of rejecting the measure of suspension of operation, as the Commission requests.

149 In conclusion, since the conditions for granting suspension of the operation of the contested provisions are satisfied, the application must be allowed.

150 The Commission considers that one of the measures challenged by the French authorities, namely the limitation of intensive surveillance to two years, will actually be applied only in two years' time and that therefore there is no reason to suspend it.

151 It should be pointed out, however, that the measure to keep animals on a holding on which a TSE case has been detected, with a ban on moving them to another holding during a period of two years following confirmation of the last TSE case, as provided in point 2.3(b)(iii) and point 4 of Chapter A of Annex VII, is fully applicable from 17 July 2007. In view of the fact that those animals may, during that two-year period, be sent for slaughter and their carcasses released for human consumption, and of the uncertainty as to the duration of the main action, the application of point (3) of the Annex to Regulation No 727/2007 must be suspended until judgment has been given in the main action, in so far as it introduces, into Chapter A of Annex VII, not only point 2.3(d) but also point 2.3(b)(iii) and point 4.

On those grounds,

THE JUDGE HEARING THE APPLICATION FOR INTERIM MEASURES

hereby orders:

1. **The application of point (3) of the Annex to Commission Regulation (EC) No 727/2007 of 26 June 2007 amending Annexes I, III, VII and X to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies is suspended until judgment has been given in the main action, in so far as it introduces, in Chapter A of Annex VII to Regulation (EC) No 999/2001 of 22 May 2001, point 2.3(b)(iii), point 2.3(d) and point 4.**

2. Costs are reserved.

Luxembourg, 28 September 2007.

E. Coulon — M. Vilaras

Registrar — Judge