OPINION OF ADVOCATE GENERAL MISCHO

delivered on 2 July 2002 [1]

1. By deciding, in the context of managing the health crisis unleashed by the outbreak of bovine spongiform encephalopathy ('BSE'), to apply in its territory precautionary measures going beyond what the Community authorities judged necessary, the French Government placed itself in the position of having to face simultaneously challenges in various forums.

2. Thus, the Commission brought an action for failure to fulfil obligations against the French Republic because of its refusal to end the ban on British beef as provided by Council Decision 98/256/EC of 16 March 1998 concerning emergency measures to protect against bovine spongiform encephalopathy, amending Decision 94/474/EC and repealing Decision 96/239/EC, [2] as amended by Commission Decision 98/692/EC of 25 November 1998, [3] and Commission Decision 1999/514/EC of 23 July 1999 setting the date on which dispatch from the United Kingdom of bovine products under the date-based export scheme may commence by virtue of Article 6(5) of Decision 98/256. [4]

3. Although the Court had not yet decided on that action for failure to fulfil obligations (Case C-1/00), on 25 June 2000 the National Farmers' Union, a professional body representing the farmers of England and Wales, brought before the Conseil d'État (Council of State) (France) an action for annulment of the French Government's implicit rejection of its applications for the ban to be lifted. That court found that the legality of the decisions which it was requested to annul was necessarily conditional on Decisions 98/692 and 1999/514 being valid and thus decided to use the procedure prescribed in Article 234 EC in order to refer questions to the Court on that subject. In consequence, by decision of 28 May 2001 registered under number C-241/01, it referred three questions to the Court in order to ascertain:

'(1) whether, having regard to the legislative nature of Commission Decision

1 — Original language: French.

2 — OJ 1998 L 113, p. 32.

3 — OJ 1998 L 328, p. 28.

4 — OJ 1999 L 195, p. 42.

98/692/EC of 25 November 1998 and Commission Decision 1999/514/EC of 23 July 1999, and notwithstanding the expiry of the time-limit for challenging them, a Member State may validly invoke significant changes in the factual or legal circumstances occurring after the expiry of that time-limit, where the changes in question are such as to cast doubt on the decisions' validity;

(2) whether, at the date of the decisions taken by the French authorities, the abovementioned Commission decisions were valid, having regard to the precautionary principle laid down in Article 174 of the Treaty establishing the European Community;

(3) whether a Member State may draw from the provisions of Article 36 of the EC Treaty (now, after amendment, Article 30 EC) the power to prohibit imports of agricultural products and live animals, inasmuch as Directives 89/662/EEC and 90/425/EEC cannot be regarded as harmonising the measures needed in order to attain the specific objective of protecting the health and life of humans provided for by that article.'

4. Meanwhile, on 13 December 2001, the Court delivered its judgment in Case C-1/00.[5] In the operative part of that judgment the Court:

'1. Declares that, by refusing to adopt the measures necessary in order to comply with:

— Council Decision 98/256/EC of 16 March 1998 concerning emergency measures to protect against bovine spongiform encephalopathy, amending Decision 94/474/EC and repealing Decision 96/239/EC, in the version resulting from Commission Decision 98/692/EC of 25 November 1998, in particular with Article 6 and Annex III, and

— Commission Decision 1999/514/EC of 23 July 1999 setting the date on which dispatch from the United Kingdom of bovine products under the date-based export scheme may commence by virtue of Article 6(5) of Decision 98/256, in particular with Article 1,

5 — Case C-1/00 *Commission* v *France* [2001] ECR I-9989.

in particular, by refusing to permit the marketing in its territory after 30 December 1999 of products subject to that scheme which are correctly marked or labelled, the French Republic has failed to fulfil its obligations under those two decisions, in particular their provisions referred to above;

2. Dismisses the remainder of the application;

...'.

5. The existence of that judgment, which had been preceded by my Opinion given on 20 September 2001, makes it unnecessary for me to retrace here the action taken by the Commission in response to the outbreak of BSE up until the adoption of Decisions 98/692 and 1999/514 or to recount in detail the events which took place between the date on which the second of those decisions entered into force and that on which the Commission brought its action for failure to fulfil obligations.

6. It will be sufficient for me to recall only the essentials, namely the content of the two Community decisions which, in the opinion of the Conseil d'État, are problematic from the point of view of their validity and the circumstances in which the French Government refused to apply them.

7. Decision 98/692, just like Decision 98/256, is based in particular on Article 9(4) of Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market,[6] last amended by Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A(I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC.[7]

8. Article 9 of Directive 89/662 states:

'1. Each Member State shall immediately notify the other Member States and the Commission of any outbreak in its territory, other than an outbreak of diseases referred to in Directive 82/894/EEC, of any zoonoses, diseases or other cause likely to

6 — OJ 1989 L 395, p. 13.
7 — OJ 1993 L 62, p. 49.

constitute a serious hazard to animals or to human health. The Member State of origin shall immediately implement the control or precautionary measures provided for in Community rules, in particular the determination of the buffer zones provided for in those rules, or adopt any other measure which it deems appropriate. The Member State of destination or transit which, in the course of a check referred to in Article 5, has established the existence of one of the diseases or causes referred to in the first subparagraph may, if necessary, take the precautionary measures provided for in Community rules. Pending the measures to be taken in accordance with paragraph 4, the Member State of destination may, on serious public or animal-health grounds, take interim protective measures with regard to the establishments concerned or, in the case of an epizootic disease, with regard to the area of protection provided for in Community rules. The measures taken by Member States shall be notified to the Commission and to the other Member States without delay.

2. At the request of the Member State referred to in the first subparagraph of paragraph 1 or on the initiative of the Commission, one or more Commission representatives may go at once to the place concerned to examine, in collaboration with the competent authorities, what measures have been taken, and shall issue an opinion on those measures.

3. If the Commission has not been informed of the measures taken, or if it considers the measures taken to be inadequate, it may, in collaboration with the Member State concerned and pending the meeting of the Standing Veterinary Committee, take interim protective measures with regard to products from the region affected by the epizootic disease or from a given establishment. These measures shall be submitted to the Standing Veterinary Committee as soon as possible to be confirmed, amended or cancelled in accordance with the procedure laid down in Article 17.

4. The Commission shall in all cases review the situation in the Standing Veterinary Committee at the earliest opportunity. It shall adopt the necessary measures for the products referred to in Article 1 and, if the situation so requires, for the originating products or products derived from those products in accordance with the procedure laid down in Article 17. The Commission shall monitor the situation and, by the same procedure, shall amend or repeal the decisions taken, depending on how the situation develops.

5. Detailed rules for the application of this article, and in particular the list of zoonoses or causes likely to constitute a serious hazard to human health, shall be adopted in accordance with the procedure laid down in Article 18.'

9. Decision 98/692 amended Decision 98/256, inserting in it an additional authorisation to export bovine products from the United Kingdom, namely those eligible

under the Date-Based Export Scheme ('the DBES') which is set out in detail in the new Annex III to Decision 98/256.

10. Point 3 of that annex defines the animals eligible as follows:

'A bovine animal is DBES-eligible if it has been born and reared in the United Kingdom and at the time of slaughter the following conditions are shown to have been met:

(a) the animal has been clearly identifiable throughout its life, enabling it to be traced back to the dam and herd of origin; its unique eartag number, date and holding of birth and all movements after birth are recorded either in the animal's official passport or on an official computerised identification and tracing system; the identity of its dam is known;

(b) the animal is more than six months but less than 30 months of age, determined by reference to an official computer record of its date of birth, and in the case of animals from Great Britain, the animal's official passport;

(c) the competent authority has obtained and verified positive official evidence that the dam of the animal has lived for at least six months after the birth of the eligible animal;

(d) the dam of the animal has not developed BSE and is not suspected of having contracted BSE.'

11. The traceability requirements are set out in point 7 of Annex III, according to which:

'Meat must be traceable back to the DBES-eligible animal or, after cutting, to the animals cut in the same batch, by means of an official tracing system until the time of slaughter. After slaughter, labels must be capable of tracing fresh meat and products referred to in Article 6(1)(b) and (c) back to the eligible animal to enable the consignment concerned to be recalled. Food for domestic carnivores must be traceable by means of accompanying documents and records.'

12. Furthermore, the United Kingdom is required, under point 9 of Annex III, to 'have detailed protocols in place covering:

(a) tracing and controls prior to slaughter;

(b) controls during slaughter;

(c) controls during processing of food for domestic carnivores;

(d) all labelling and certification requirements after slaughter to the point of sale.'

13. It was for the Commission, after having verified the application of all the provisions of Decision 98/256, as amended, on the basis of Community inspections and after having informed the Member States, to set the date on which dispatch of the products covered by the DBES could commence.

14. The Commission used that power in adopting Decision 1999/514, which sets the date for the resumption of dispatches under the DBES at 1 August 1999.

15. The French Government did not react to that decision, in the sense that it did not make an application to have it annulled, but nor did it adopt the measure of national law, that is the amendment of the ministerial order of 28 October 1998 establishing specific measures applicable to certain products of bovine origin dispatched from the United Kingdom, [8] which would have enabled the decision to be applied in French territory.

16. When the Commission, concerned by this lack of action, reminded it about its obligations, the French Government sent the Commission an opinion of the Agence française de sécurité sanitaire des aliments (French Food Safety Agency, 'the AFSSA'), according to which, having regard to current scientific knowledge and the epidemiological data then available, the risk of the United Kingdom exporting infected beef and veal could not be regarded as overcome. The French Government relied on that opinion to issue a firm refusal to lift the ban. Since that refusal was never subsequently withdrawn, in spite of the hopes of a settlement raised by the agreement between the French and United King-

8 — JORF of 2 December 1998, p. 18169.

dom Governments and the Commission of a draft protocol of understanding during the first two weeks of November, the Commission initiated and carried through the infringement procedure which culminated in the abovementioned judgment in *Commission* v *France*.

17. In those proceedings for failure to fulfil obligations, the French Government had put forward in its defence arguments not substantially different from those which it raised before the Conseil d'État against the National Farmers' Union and which it now puts forward in its observations.

18. In its submission, new factors arising after the expiry of the time-limit for bringing an action for annulment against either Decision 98/692 or Decision 1999/514, show that the lifting of the ban by those two decisions runs counter to the requirements of the precautionary principle, so that those decisions cannot be considered valid, which authorises it not to comply with them.

19. Furthermore, and still on the ground that the DBES is not able to ensure the protection, which is none the less essential, of consumers' health, in particular in that it contains gaps with regard to the traceability requirement, the French Government is entitled to invoke Article 36 of the Treaty in order to justify its refusal to import beef and veal from United Kingdom slaughterhouses.

20. The fact that the Court has, in the terms set out above, found that the French Republic failed to fulfil its obligations does not, however, make it possible to assert that all the arguments of the French Government have been held to be unfounded, so that it would be sufficient for the purposes of my Opinion in the present case for me to refer to the abovementioned judgment in *Commission* v *France*.

21. In reaching the conclusion that it was necessary to find that there had been a failure to fulfil obligations, the Court adopted an approach which relieved it of ruling on some of the French Government's grounds of defence. Thus, it did not need to take a view on whether Article 36 of the Treaty could be invoked, since it had considered that the Commission was not alleging an infringement by the French Republic of Article 30 of the EC Treaty (now, after amendment, Article 28 EC) which was separate from the infringement resulting from the failure to implement Decisions 98/692 and 1999/514. Nor did it measure the DBES against the precautionary principle, because it took the view, in application of settled case-law, that the French Government was not permitted to plead in its defence, in the context of infringement proceedings, the invalidity of the decisions which it was alleged not to have complied with and against which it had not, within the time-limit prescribed by Article 230 EC, brought an action for annulment.

22. That refusal to examine arguments calling in question the validity of decisions

not challenged by means of an action for annulment by the Member State to which they were addressed is, of itself, not of great assistance to us in the present case.

23. In fact, the refusal to the French Government arose in the context of infringement proceedings, whereas the issue facing the Conseil d'État, and on which it has referred a question to the Court, is raised in a completely different context.

The first question

24. It is in fact in purely national proceedings, before a French court, that the French Government denies that its failure to adopt the measures required by Community decisions addressed to it may be regarded as unlawful and it is to substantiate that denial that it pleads the unlawfulness of those decisions.

25. I readily accept that the Conseil d'État is not making a reference to the Court on the question of principle of whether such a challenge is permissible, but on a case which is very particular in two respects since, first, the decisions whose validity is called in question are, according to the national court's analysis, of a 'legislative nature' and, second, the grounds of invalidity put forward relate to 'significant changes in the factual or legal circumstances occurring after the expiry of [the] time-limit [for challenging them]'.

26. I am, however, of the opinion that the question of principle is unavoidable and that I must start by analysing it at the risk, of course, if I reach a negative answer, of afterwards considering whether exceptions may be envisaged in respect of particular cases, such as that identified by the Conseil d'État.

27. Let me therefore deal with this question head on. I will take as the starting point for my reasoning the judgment in Case 156/77 *Commission* v *Belgium*.[9] Admittedly, that judgment determined only whether a Member State may challenge before the Court, in the context of an action brought against it by the Commission pursuant to the second subparagraph of Article 93(2) of the EC Treaty (now the second subparagraph of Article 88(2) EC), the validity of a Commission decision which had been duly notified to it and which prohibited it from paying aid to an undertaking, but the grounds of the Court's refusal to accept such a ground of defence seem to me to have implications going well beyond the particular case.

9 — Case 156/77 *Commission* v *Belgium* [1978] ECR 1881.

28. On the basis of the fact that, under the fourth paragraph of Article 189 of the EC Treaty (now the fourth paragraph of Article 249 EC), a decision addressed by the Commission to a Member State is binding in its entirety upon that State, the Court stated that, '[i]n so far as the Member State to [which] it is addressed considers that it is unable to comply with that decision because it is legally unfounded, it may contest the legality thereof by having recourse to the legal remedies available to it under Article 173 of the Treaty on the conditions laid down by that provision'.

29. Those conditions include the time-limits within which applications must be lodged which 'are intended to safeguard legal certainty by preventing Community measures which involve legal effects from being called in question indefinitely'. If those time-limits expire without the Member State concerned bringing an action for annulment, that State is prohibited once and for all from challenging the validity of the decision by means of a plea of illegality, under Article 184 of the EC Treaty (now Article 241 EC), raised against the action for failure to fulfil obligations brought by the Commission.

30. Not to impose that prohibition would be, according to the Court, 'impossible to reconcile with the principles governing the legal remedies established by the Treaty and would jeopardise the stability of that system and the principle of legal certainty upon which it is based'. Intellectual honesty dictates that I make it clear that, in paragraph 24 of that judgment, the Court, concerned to counter an argument which might be raised against the coherence of the solution thus adopted in the light of the system of remedies overall, explained that:

'[a]lthough it is true that the validity of a Community measure may be called in question by means of the procedure for obtaining a preliminary ruling referred to in Article 177 of the Treaty, in spite of the expiry of the period laid down in the third paragraph of Article 173, such a procedure, which is laid down in respect of all measures adopted by the institutions and corresponds solely to the requirements of the national courts, is nevertheless subject to objectives and rules different from those which govern the applications referred to in Article 173 of the Treaty, and cannot justify a derogation from the principle of the time-barring of applications as a result of the expiry of the periods within which proceedings must be brought, without thereby depriving Article 173 of its legal significance.'

31. The ambiguity attaching to what seems more like an *obiter dictum* than a clearly imposed limit to the solution adopted by the Court in the particular case was dispelled when, in *TWD Textilwerke Deggendorf*,[10] the Court was directly faced with the issue of the validity of a decision, against which an action for annulment had not been brought in due time, being called in question in a reference for a preliminary ruling.

10 — Case C-188/92 *TWD Textilwerke Deggendorf* [1994] ECR I-833.

32. In that case, a German undertaking had received national aid which had been declared unlawful by a Commission decision ordering its repayment. That decision had been, as it must be, notified to the German Government which had sent a copy of it to the undertaking, informing it that it was entitled to contest the decision before the Community judicature by bringing an action pursuant to Article 173 of the EC Treaty (now, after amendment, Article 230 EC).

33. In fact, neither the German Government nor the undertaking concerned had taken that opportunity. When the German authorities had requested the undertaking to reimburse the amounts unlawfully received, that undertaking had brought an action before the national courts, claiming that the Commission decision was unlawful. The dispute came before the Court by means of a reference for a preliminary ruling, by which the national court, most judiciously, did not raise only the question of the validity of the decision in question, but also the question whether that validity was still open to discussion in the proceedings before it.

34. On that point, its question was worded as follows:

'Is a national court bound by a decision of the EEC Commission adopted pursuant to Article 93(2) of the [EC] Treaty when hearing an appeal regarding the implementation of that decision by the national authorities brought by the recipient of the aid and addressee of the implementation measures on the ground that the decision of the EEC Commission is unlawful in circumstances where the recipient of the aid did not institute proceedings under the second paragraph of Article 173 of the [EC] Treaty, or did not do so in good time, even though it was informed of the Commission's decision in writing by the Member State?'

35. The Court's answer was of exemplary clarity. Having recalled that a decision which has not been challenged by the addressee within the time-limit laid down by Article 173 of the Treaty becomes definitive as against him and that the undertaking in receipt of individual aid which is the subject-matter of a Commission decision has the right to bring an action for annulment under the second paragraph of Article 173 of the Treaty even if the decision is addressed to a Member State, the Court held that it was appropriate to apply to that undertaking the case-law arising out of the ruling in *Commission* v *Belgium*, cited above, in respect of a Member State's pleading the illegality of such a decision in the context of proceedings for non-compliance.

36. In that regard, it set out the following considerations:

'16 That case-law, according to which it is impossible for a Member State which is

the addressee of a decision taken under the first [sub]paragraph of Article 93(2) of the Treaty to call in question the validity of the decision in the proceedings for non-compliance provided for in the second paragraph of that provision, is based in particular on the consideration that the periods within which applications must be lodged are intended to safeguard legal certainty by preventing Community measures which involve legal effects from being called in question indefinitely.

17 It follows from the same requirements of legal certainty that it is not possible for a recipient of aid, forming the subject-matter of a Commission decision adopted on the basis of Article 93 of the Treaty, who could have challenged that decision and who allowed the mandatory time-limit laid down in this regard by the third paragraph of Article 173 of the Treaty to expire, to call in question the lawfulness of that decision before the national courts in an action brought against the measures taken by the national authorities for implementing that decision.

18 To accept that in such circumstances the person concerned could challenge the implementation of the decision in proceedings before the national court on the ground that the decision was unlawful would in effect enable the person concerned to overcome the definitive nature which the decision assumes as against that person once the time-limit for bringing an action has expired.'

37. It seems to me that, since the Court thus transposed to the challenge made by an individual to the validity of a Community decision of which it was not the addressee, but of which it was aware, the solution adopted, initially, in respect of the challenge made by a Member State, in the context of proceedings for non-compliance, to the validity of a decision of which it was the addressee, it is appropriate to transpose, as regards the challenge before the national court made by a Member State to the validity of a decision of which it was the addressee, the solution applied to the challenge from an individual.

38. It is difficult to imagine, if only in the light of the principle of equality of arms in judicial proceedings, that what, before a national court, may not be used as a ground of defence by an individual may be so used by a government.

39. The requirements of the principle of legal certainty and those flowing from the coherent organisation of the Community system of remedies cannot vary according to whether it is an individual or a Member State which, although it had the opportunity to bring an action for annulment pursuant to Article 173 of the Treaty, failed to do so.

40. On the contrary, the fact that the challenge is prohibited as against the indi-

vidual on the sole ground that he would have been permitted to bring an action for annulment against the decision brought to his attention, although it was not addressed to him, must necessarily result in the application of the same prohibition as against the Member State to which that decision was specifically addressed.

41. The maxim *vigilantibus non dormientibus subveniunt jura*, which Advocate General Jacobs recalled in his Opinion in *TWD Textilwerke Deggendorf*, is not applicable solely to individuals, but should clearly be applied to all persons subject to the Community legal order, just as Mr Jacobs' comment to the effect that the limitation period laid down in Article 173 of the Treaty 'would be deprived of all sense and purpose if a person who undoubtedly has *locus standi* to challenge a decision under Article 173 could simply ignore the decision and contest its validity in subsequent proceedings brought to enforce the decision' is not limited to challenges to validity from individuals.

42. That rule in *TWD Textilwerke Deggendorf*, subsequently confirmed by *Wiljo*,[11] is not disputed by the French Government. However, the Government does attempt to limit its scope or, at the very least, to convince the Court that it should not be applied in the present case.

43. The first argument which it puts forward to that effect is based on the fact that the grounds of the invalidity of Decisions 98/692 and 1999/514 became apparent only after the expiry of the time-limit for bringing an action for annulment, so that the Government cannot be reproached for having allowed that time-limit to pass without reacting and that it should therefore be accepted that, exceptionally, the Government cannot be time-barred as a result of having failed to bring an action for annulment.

44. According to its arguments, '...that exception must be restricted to new factors of which the Member State was not able to be aware in the context of its own legal and territorial competences, like those resulting from inquiries and checks which would not be revealed by other Member States or by the Commission in the context of its own competences. In order to be taken into account, those new factors must be such as to cast doubt, in law or in fact, on the purpose and effectiveness of the operative part of the act whose validity is at issue. They must therefore be of a significant nature.'

45. That is specifically true, unsurprisingly, of the factors casting doubt on the reliability of the DBES which came to the notice of the French Government.

11 — Case C-178/95 *Wiljo* [1997] ECR I-585.

46. However, even thus circumscribed, that exception runs counter to the principle that the validity of an act must be assessed by reference to the date on which it was adopted, a principle of which the French Government is well aware and which has certainly not been disproved by *Greenpeace France and Others*, [12] which the Government wrongly brings into the debate, because it allows recourse to provisional national measures [13] before the Commission re-examines its decision and not the calling in question of the validity of a Commission decision.

47. In order to discount that objection, the Government refers to the judgment in *Sam Schiffahrt and Stapf* [14] which indeed includes, in paragraph 47, the following somewhat obscure dictum:

'Even if the validity of a measure might, in certain cases, be assessed by reference to new factors which arose subsequently to its adoption, the documents before the Court do not permit the conclusion that any such factors exist in this case, as the Advocate General has pointed out...'.

48. Let me point out, first of all, that, in my view, although the Court used the expression 'even if', it was to indicate that it was going to countenance something which not only was highly hypothetical, but also seemed to it even, prima facie, incorrect.

49. I would observe, next, that that passage in the judgment is a reflection of paragraph 38 in the Opinion of Advocate General Jacobs, which cannot provide any argument in support of the submission that the appearance of new facts makes it possible to avoid being time-barred as the result of the expiry of the time-limits for bringing proceedings.

50. In fact, having noted that '[i]n general... the validity of a measure can be assessed only by reference to the situation when it was enacted', the Advocate General stated further that '[i]t seems to me that there might none the less be circumstances in which the Community legislature is under an obligation to repeal or amend a measure to take account of subsequent developments; that might be so where, for example, after its adoption a measure began to produce discriminatory effects, or had plainly achieved its purpose so that there was no longer any justification for the burden placed on individuals'.

51. What Mr Jacobs asserts, and with which I am in perfect agreement, is that, in the legal field, nothing is unchangeable and that, in particular, what is justified today will perhaps no longer be so tomor-

12 — Case C-6/99 *Greenpeace France and Others* [2000] ECR I-1651.

13 — On that subject, see below my arguments in respect of the third question.

14 — Joined Cases C-248/95 and C-249/95 *SAM Schiffahrt and Stapf* [1997] ECR I-4475.

row, with the result that the duty of every legislature is, first, to check, if not constantly at least periodically, that the rules which it has imposed still meet the needs of society and, second, to amend or even repeal the rules which have ceased to have any justification and are thus no longer appropriate in the new context in which they must produce their effects.

52. Between that statement and the revival of a right to bring an action which was not exercised when the rule was made, there is a gap, if not a chasm, which appears unbridgeable to anyone who is concerned about legal certainty.

53. On the other hand, and in my view this is what the Advocate General meant, where a rule has become unsuitable, the refusal of the rulemaker to repeal it may, in any judicial review, be deemed to be invalid.

54. However, and here I will end my examination of the French Government's first argument, the Community judicial system allows such a review by the Court. As I pointed out in my Opinion in *Commission* v *France*, cited above, to which I would refer, the French Government was perfectly entitled to request the Commission to reconsider Decisions 98/692 and 1999/514 in the light of the new factors which it believed it had discovered and either to challenge any refusal by means of an action for annulment or, if there were no reply to its request, to bring an action for failure to act against the Commission.

55. As we know, but as we find difficult to understand, the Government did not take that course, which would have enabled it to submit before the Court evidence which it believes is condemnatory of the DBES in the light of the requirements of the precautionary principle.

56. If the discovery of allegedly new factors does not enable the French Government to avoid the application of the rule in *TWD Textilwerke Deggendorf*, what is to be made of the argument to the effect that Decisions 98/692 and 1999/514 are not genuine decisions, but rather legislative measures, to which the rule in *TWD Textilwerke Deggendorf* does not apply?

57. Let me begin by saying that the argument of the French Government is not without finesse when, on the basis of case-law which is settled, but has been developed in respect of the right of natural or legal persons to bring an action for the annulment of a regulation if, upon inspection, that measure is shown to be a collection of individual decisions, and

according to which the nature of a Community act is not apparent from its form but from its scope, it analyses the decisions at issue, which were addressed to all the Member States, as putting in place actual legislation on the movement of certain bovine products from the United Kingdom, in order to reach the conclusion that, as legislative acts, those decisions fall within the scope of Article 184 of the Treaty and may therefore have the plea of illegality raised against them.

58. However, let me state immediately that that argument cannot succeed in the light of the most recent developments in the case-law of the Court. Although, as from *TWD Textilwerke Deggendorf*, it appeared that the element to be taken into account in determining whether the validity of a Community act could be challenged before the national courts was not the nature of the act but the presence or absence of an opportunity for the person concerned to challenge the validity of that act by means of an action for annulment, the subsequent case-law has not only sanctioned that access to the courts via an action for annulment as a sole criterion, but has drawn from it the strictest inferences.

59. In *Accrington Beef and Others*,[15] the Court held, in response to the doubts expressed by the United Kingdom Government as to whether, in the light of the rule in *TWD Textilwerke Deggendorf*, the applicant undertaking was able to challenge the validity of certain provisions of a regulation before the national courts, that:

'It is sufficient, on that point, to note that, since the contested provisions are contained in a Community regulation and are addressed in general terms to categories of persons defined in the abstract and to situations determined objectively, it is not obvious that an action by the applicants challenging that regulation under Article 173 of the Treaty would have been admissible.

The reference to *TWD* (*Textilwerke Deggendorf*), which concerned a company which was undoubtedly entitled, and which had been informed that it was entitled, to bring an action for annulment of the Community act whose validity it was indirectly challenging before a national court, is therefore irrelevant' (paragraphs 15 and 16).

60. In *Eurotunnel and Others*,[16] it took the view, in response to the national court which had referred a question on whether

15 — Case C-241/95 *Accrington Beef and Others* [1996] ECR I-6699.

16 — Case C-408/95 *Eurotunnel and Others* [1997] ECR I-6315.

an undertaking may raise before the national court the invalidity of provisions in a directive which it did not challenge by means of an action for annulment before the Community judicature, that '[i]t should be noted that the judgment in *TWD Textilwerke Deggendorf* concerned a company which, unquestionably, was entitled and had been informed that it was entitled to bring an action for annulment of the Community act whose validity it was challenging by a plea of illegality before a national court. On this point, in the case of Community directives whose contested provisions are addressed in general terms to Member States and not to natural or legal persons, it is not obvious that an action by Eurotunnel challenging Articles 28 and 28k under Article 173 of the Treaty would have been admissible (see, with respect to a regulation, Case C-241/95 *R* v *Intervention Board for Agricultural Produce, ex parte Accrington Beef and Others* [1996] I-6699, paragraph 15)' (paragraphs 28 and 29). By consequence, the Court agreed to examine the complaints raised before it, by means of a reference for a preliminary ruling, against the validity of provisions in a directive which were not of direct concern, within the meaning of Article 173 of the Treaty, to the undertaking which was challenging them.

61. Yet more recently, recourse to the same criterion led, in *Nachi Europe*,[17] to the opposite result, in the sense that it led to an undertaking being prohibited from pleading before the national court the invalidity of a Community act, and not just any act since it was a regulation.

17 — Case C-239/99 *Nachi Europe* [2001] ECR I-1197.

62. In that case, a question on the validity of an anti-dumping regulation was referred to the Court by a national court before which an importing undertaking was claiming the reimbursement of duties which it had had to pay, on the ground that that regulation had been annulled as the result of an action brought by other operators.

63. After having recalled that that annulment could affect only the duties payable on products imported by those operators and therefore did not apply to Nachi Europe, the Court refused to examine whether the regulation should also be held to be invalid *vis-à-vis* Nachi Europe, since that undertaking had not sought the annulment of the regulation although, as an importer associated with the exporter, whose resale prices for the products in question had formed the basis of the constructed export price applied by the regulation in order to establish the dumping margins operated by the exporter, it would undoubtedly have had standing to do so.

64. In order to arrive at that result, the Court, after discounting the application of Article 241 EC as such in proceedings for a preliminary ruling pursuant to Article 234 EC, held that:

'It is true, however, that Article 241 EC expresses a general principle of law under which an applicant must, in proceedings

brought under national law against the rejection of his application, be able to plead the illegality of a Community measure on which the national decision adopted in his regard is based, and the question of the validity of that Community measure may thus be referred to the Court in proceedings for a preliminary ruling (Case 216/82 *Universität Hamburg* [1983] ECR 2771, paragraphs 10 and 12).

The Court has also pointed out that this general principle confers on any party to proceedings the right to challenge, for the purpose of obtaining the annulment of a decision of direct and individual concern to that party, the validity of previous acts of the institutions which form the legal basis of the decision which is being attacked, if that party was not entitled under Article 230 EC to bring a direct action challenging those acts by which it was thus affected without having been in a position to ask that they be declared void (Case 92/78 *Simmenthal* v *Commission* [1979] ECR 777, paragraph 39, and *TWD Textilwerke Deggendorf*, paragraph 23).

However, this general principle, which has the effect of ensuring that every person has or will have had the opportunity to challenge a Community measure which forms the basis of a decision adversely affecting him, does not in any way preclude a regulation from becoming definitive as against an individual in regard to whom it must be considered to be an individual decision and who could undoubtedly have sought its annulment under Article 230 EC, a fact which prevents that individual from pleading the illegality of that regulation before the national court (see, in regard to a Commission decision, *TWD Textilwerke Deggendorf*, paragraphs 24 and 25). Such a conclusion applies to regulations imposing anti-dumping duties by virtue of their dual nature,... as acts of a legislative nature and acts liable to be of direct and individual concern to certain traders' (paragraphs 35 to 37).

65. It is thus indeed the impossibility of using the action for annulment to challenge the Community measure, and that alone, which determines the availability of the right to contest the validity of that act before a national court, the form and the nature of the measure being immaterial.

66. In the present case, the French Government clearly had standing to challenge Decisions 98/692 and 1999/514, so that it is prohibited on the ground that it is time-barred from contesting their validity before the Conseil d'État by the case-law developed as from *TWD Textilwerke Deggendorf*, irrespective of the legislative effect which those decisions might have.

The second question

67. Since I have thus established that the Conseil d'État's first question should

undoubtedly be answered in the negative, I have no need to examine the second question, relating to the validity of Decisions 98/692 and 1999/514, at the date of the French authorities' refusal to the National Farmers' Union to apply them, in the light of the precautionary principle laid down in Article 174 EC.

68. I should, however, like to make several brief comments on this question.

69. First, by requesting the Court to assess the validity of the Community decisions at issue 'at the date of the decisions taken by the French authorities' rejecting the applications from the National Farmers' Union, the Conseil d'État not only feigns ignorance of the fact that the validity of an act must be assessed by reference to the date on which it was adopted, but seems to adopt an approach according to which the person who refuses to comply with such an act could, through the choice of the date on which he expresses his refusal, choose the time, possibly far removed from that at which the act was adopted, at which he wishes the appropriateness of the measures taken to be assessed.

70. This, let us be clear, seems to me unacceptable from every point of view, since it shows total disdain for legal certainty and opens the way to a form of 'tempus shopping' lending itself to all sorts of manoeuvring.

71. Second, the fact that the precautionary principle has been enshrined in the Community legal order, both by primary law and case-law, as well as by the positions adopted by the Commission and the European Council, must not in any way mark the resurgence of unilateralism.

72. Since observance of that principle forms part of Community action, there can be no question of the Member States' relying on it in order to obstruct at will the application of measures adopted in the context of that action.

73. Third, judicial review of the observance of the precautionary principle must be exercised with caution.

74. Since that principle is to be applied in situations of great uncertainty, we cannot expect the courts to impose their own convictions, the possible basis of which is difficult to discern, moreover, in the realm of scientific problems.

75. It is obviously not a question of removing the application of the precautionary principle from the sphere of judicial review, but merely of recognising that the courts can, in this field, only exercise minimal review since the political authorities must be granted a broad discretion.

76. Fourth, the precautionary principle has a future only to the extent that, far from opening the door wide to irrationality, it establishes itself as an aspect of the rational management of risks, designed not to achieve a zero risk, which everything suggests does not exist, but to limit the risks to which citizens are exposed to the lowest level reasonably imaginable.

77. Fifth, the requirements of the DBES must not, in respect of the application of the precautionary principle, be considered in isolation, since the general preventive measures applicable throughout the Community, for example the removal of tissues presenting risks, must quite obviously be complied with in respect of DBES products. Accordingly, the presence, which can clearly not be ruled out entirely, of an infected bovine animal amongst the animals satisfying the requirements of that scheme does not mean that the consumption of its meat carries with it, *per se*, an unacceptable risk in the light of the requirements of the precautionary principle.

78. Lastly, however the precautionary principle is expressed, it is not disputed that the application of that principle does not have the effect of avoiding the application of other principles which are just as fundamental. That is particularly true of the principle of proportionality, which can be said to be inseparable from the precautionary principle, but also of the principle of non-discrimination.

79. In terms of this last principle, I would observe that the DBES, as the Commission has pointed out, seeks to ensure that beef and veal which come from the United Kingdom and are imported into other Member States do not present more risks than any other beef or veal produced in the Community, and that it really seems that this objective has been somewhat lost sight of by the French authorities which would like meat from the United Kingdom to be risk-free, even though it is agreed that the BSE epidemic has, unfortunately, not spared French cattle-farming.

The third question

80. I thus come to the third and final question referred by the national court

which seeks to ascertain whether 'a Member State may draw from the provisions of Article 36 of the EC Treaty (now, after amendment, Article 30 EC) the power to prohibit imports of agricultural products and live animals, inasmuch as Directives 89/662/EEC and 90/425/EEC cannot be regarded as harmonising the measures needed in order to attain the specific objective of protecting the health and life of humans provided for by that article'.

81. As the National Farmers' Union, the United Kingdom Government and the Commission propose to the Court, reference should first be made, in this respect, to the case-law of the Court on the possibility of applying Article 30 EC when harmonising measures have been adopted.

82. Rather than citing *Hedley Lomas*,[18] which related to a factual situation too different from that at issue in the main proceedings, I prefer to make reference to *Tedeschi*[19] and *Commission* v *Italy*,[20] in which it was held that:

'where Community directives provide for the harmonisation of the measures necessary to ensure the protection of animal and human health and establish Community procedures to check that they are observed, recourse to Article 36 is no longer justified and the appropriate checks must be carried out and the measures of protection adopted within the framework outlined by the harmonising directive'.

83. It is therefore necessary to determine whether, having regard to the legislation applicable to the fight against BSE, we are in that situation.

84. The French Government submits that Article 30 EC justifies the measures which it maintained or took following the Commission's adoption of Decisions 98/692 and 1999/514 for three principal reasons:

(1) Article 30 EC is applicable because Directive 89/662 and Council Directive

18 — Case C-5/94 *Hedley Lomas* [1996] ECR I-2553. The issue was the systematic refusal by a Member State to issue export licences for live animals on the ground that, in the slaughterhouses of the country of destination, those animals underwent treatment contrary to Council Directive 74/577/EEC of 18 November 1974 (OJ 1974 L 316, p. 10), which required that they be stunned before slaughter.

19 — Case 5/77 *Tedeschi* [1977] ECR 1555, paragraph 35.

20 — Case C-112/97 *Commission* v *Italy* [1999] ECR I-1821, paragraph 54.

90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market,[21] as well as Decision 98/256 and the abovementioned decisions, do not constitute full harmonisation.

The French Government points out that Directives 89/662 and 90/425 cannot, as such, be interpreted as pursuing an objective of combating BSE and its human variant, Creutzfeldt-Jakob disease ('CJD'). Moreover, the measures taken against the spread of BSE and CJD in the context of the protective clauses of those two directives did not constitute full harmonisation of preventive measures (Opinion of Advocate General Alber in *Eurostock*[22] and my Opinion in *Commission* v *France*[23]). Full harmonisation was achieved only by the adoption 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,[24] which did not enter into force until 1 January 2001;

21 — OJ 1990 L 224, p. 29.

22 — Case C-477/98 *Eurostock* [2000] ECR I-10695, points 58 to 61 of the Opinion.

23 — Cited above, points 168 to 170.

24 — OJ 2001 L 147, p. 1.

(2) the objective of those measures is health-related: BSE is a major risk to animal health and the possibility of the transmission of BSE to humans in the form of CJD constitutes a major risk for human health;

(3) the measures thus adopted are proportionate and necessary in relation to the objective pursued.

85. On that matter, I would point out, first of all, that it is beyond question that Directives 89/662 and 90/425, cited in the third question referred by the Conseil d'État, do not in any way achieve harmonisation of the laws and regulations of the Member States in respect of the protection of humans against BSE.

86. As the Court recalled in *Eurostock*, 'Directive 89/662, which was adopted with a view to the establishment of the internal market, is designed to eliminate veterinary checks at the Community's internal frontiers by concentrating on checks to be carried out at the place of dispatch and organising those that can be carried out at the place of destination. Thus, Article 1 of Directive 89/662 provides that Member States are to ensure that the veterinary checks to be carried out on products of

animal origin which are covered by certain directives... are no longer carried out at frontiers but in accordance with Directive 89/622'.

87. Similarly, Directive 90/425 also organises procedures according to which measures necessary for the protection of health are to be adopted. Just like Directive 89/662, it does not, of itself, prescribe those measures.

88. Furthermore, I am still of the view which I expressed in my Opinion in *Commission* v *France*, cited above, that full harmonisation in respect of the fight against BSE was achieved only through Regulation No 999/2001.

89. Having said that, I consider, however, that importance should be attached to the fact that, in *Tedeschi* and *Commission* v *Italy*, cited above, the Court used the expression 'harmonisation... *necessary* to ensure the protection of... health' and not 'full harmonisation'. [25]

25 — Emphasis added.

90. We must therefore examine whether the DBES, adopted before the entry into force of Regulation No 999/2001, is such as to ensure the protection of the health of the nationals of the other Member States, where products from bovine animals are dispatched from the United Kingdom.

91. It is certain that Decision 98/692, amending Decision 98/256 which defined that scheme, does not have the appearance of a 'harmonising directive' in the conventional sense, as did the directives at issue in *Tedeschi* and *Commission* v *Italy*, cited above.

92. Here we have the conditional lifting of an export ban. But the conditions attaching to the lifting of the ban are as detailed as, if not more than, the 'harmonising measures' which are included in many conventional directives. These latter directives often merely list the chemical substances which may or may not be incorporated into foodstuffs.

93. It is not necessary for me to describe here yet again the characteristics of the DBES. Suffice it to say that, as regards the actual problem at issue in the main proceedings, that is, exports of beef and veal from the United Kingdom to the other

Member States, the competent Community institution has laid down in detail the precautions and control measures to be applied to herds of cows, in slaughterhouses, in cutting plants and during transportation.

94. It is thus permissible to conclude that the Community legislature has 'occupied the terrain' and that there is no longer room for protective measures pursuant to Article 30 EC.

95. It seems to me that such was, moreover, the position implicitly adopted by the Court in *Eurostock*. In that case, a question had also been referred to the Court on whether, in the context of the fight against the spread of BSE, a Member State could take interim protective measures within the meaning of Article 9(1) of Directive 89/662 when the Commission had adopted a decision under Article 9(4) of that directive, but had postponed the entry into force of that decision, or whether, if the answer to that question were no, the Member State could rely on the provision on the protection of human health in Article 36 of the Treaty to justify a prohibition on the importation of certain material of bovine origin from another Member State. The Court replied in the affirmative in respect of the possibility of prohibiting the importation of those products by way of interim protective measures within the meaning of the fourth subparagraph of Article 9(1) of Directive 89/662 and it took the view that it was not necessary to answer the question on the applicability of Article 30 EC.

96. That said, the fact that Article 30 EC is no longer applicable in this area does not in any way deprive the other Member States of the power to take interim protective measures if there is a problem.

97. In that regard, different situations may arise. [26] Thus, in a certain number of cases, the Member State may use Article 9(4).

26 — It is interesting to note that Council Directive 90/396/EEC of 29 June 1990 on the approximation of the laws of the Member States relating to appliances burning gaseous fuels (OJ 1990 L 196, p. 15), which was at issue in *Commission v Italy*, cited above, itself makes a distinction between the different situations which may arise, since Article 7 thereof states:

'1. Where a Member State finds that normally used appliances bearing the EC mark might compromise the safety of persons, domestic animals or property, it shall take all appropriate measures to withdraw those appliances from the market and prohibit or restrict their being placed on the market.

The Member State concerned shall immediately inform the Commission of any such measure, indicating the reasons for its decision and, in particular, whether non-compliance is due to:

(a) failure to meet the essential requirements referred to in Article 3, where the appliance does not correspond to the standards referred to in Article 5(1);

(b) ncorrect application of the standards referred to in Article 5(1);

(c) shortcomings in the standards referred to in Article 5(1) themselves.

2. The Commission shall enter into consultation with the parties concerned as soon as possible. Where, after such consultation, the Commission finds that any measure as referred to in paragraph 1 is justified, it shall immediately so inform the Member State that took the measure and the other Member States.

...'

98. First, as the United Kingdom Government and the Commission have accepted in the course of the present proceedings, even where the Commission has taken measures pursuant to Article 9(4) of Directive 89/662, a Member State may take temporary protective measures, provided that those measures are justified by factors which the Commission had not been able to take into account previously.

99. In my opinion, that might be true, for example, if it were to turn out that BSE could be spread by means other than those so far accepted.

100. In that case, the Member State must, however, notify those measures to the Commission and to the other Member States without delay (fourth subparagraph of Article 9(1)).

101. If the Commission, in the context of the procedure of the Veterinary Committee, refuses to amend Community legislation, the Member State can challenge that decision before the Court and also make an application for interim relief in order to obtain the suspension of the Commission decision and the associated authorisation to maintain the national protective measure.

102. It is true that that procedure is different from that under Article 30 EC in the sense that, if a Member State took a protective measure on the basis of the latter provision, it would be for the Commission to bring before the Court any action for failure to fulfil obligations. However, in both cases, the protective measures may be introduced on the initiative of the Member State and it is, in the final analysis, for the Court to judge their merits.

103. Second, in *Eurostock*, the Court accepted that a Member State can prohibit the importation of material presenting risks as regards BSE, by way of an interim protective measure within the meaning of the fourth subparagraph of Article 9(1) of Directive 89/662, where the Commission has adopted a decision pursuant to Article 9(4) of that directive, but where the date on which the measures laid down by that decision are to become applicable has been postponed.

104. Furthermore, in other cases, without even having to act on the basis of Article 9(1), a Member State can prevent imports. That will be the case, in the first place, where all the elements of that scheme are not yet in place.

105. That is confirmed by *Commission* v *France*, cited above. In that judgment, the Court in fact noted that there were difficulties in interpreting and consequently in implementing Decision 98/256, as amended, as regards the traceability requirements imposed on all the Member States, which were neither clear nor precise. Those difficulties were clarified by the protocol of understanding in question in that case and the Court took the view that the French Republic had to have a reasonable period for implementing Decisions 98/256, as amended, and 1999/514, 'as interpreted and clarified by the protocol of understanding'.

106. The Court accordingly considered that the infringement consisting of a failure to implement those decisions was proved only from expiry of the period allowed to the French Republic for complying with the reasoned opinion, that is to say after 30 December 1999.

107. The Court therefore considered that the decision lifting the ban was not enforceable against the French Republic on the date prescribed by that decision, that is 1 August 1999. That means that, until 30 December 1999, it was the export ban imposed on the United Kingdom by Decision 98/256 in its original version and the associated right to refuse imports which flowed from it for the French Republic which remained applicable.

108. The same would be true, in the second place, if it turned out that the exporting Member State did not apply the DBES with sufficient rigour and that meat not complying with that scheme reached the border of the other Member States. In that case, those States could, similarly, consider that it is still the Community protective measure, that is the ban on dispatching products not complying with the DBES, which applies.

109. We may thus conclude, by paraphrasing the judgment in *Commission* v *Italy*, cited above, that, as regards the actual problem at issue in the main proceedings, that is direct exports of beef and veal from the United Kingdom to France, the Community legislation in force lays down the harmonising measures necessary for the protection of human and animal health, that it establishes sufficient Community procedures to check that they are observed, and that it also permits interim measures to be taken in the event of unforeseen problems, so that recourse to Article 30 EC is no longer justified.

Conclusion

110. Having completed my examination of the questions raised by the national court, I propose that the Court give the Conseil d'État the following answers:

— a Member State may not, in a dispute brought before a national court, call in question the validity of decisions adopted on the basis of the fourth paragraph of Article 189 of the EC Treaty (now the fourth paragraph of Article 249 EC) which were addressed to it and which it has not challenged by means of an action for annulment within the time-limit prescribed by Article 230 EC;

— the French Republic was not able to invoke Article 30 EC in order to ban imports of beef and veal or bovine products from the United Kingdom which satisfied the requirements imposed by Council Decision 98/256/EC of 16 March 1998 concerning emergency measures to protect against bovine spongiform encephalopathy, amending Decision 94/474/EC and repealing Decision 96/239/EC, as amended by Commission Decision 98/692/EC of 25 November 1998, and Commission Decision 1999/514/EC of 23 July 1999 setting the date on which dispatch from the United Kingdom of bovine products under the date-based export scheme may commence by virtue of Article 6(5) of Decision 98/256.